Development and Validation of a Hybrid Surgical Simulator for Ultrasound Guided Laparoscopic Common Bile Duct Exploration

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Abstract

This thesis investigates using 3D printing for developing a low-cost, quick, and simple fabrication method for the surgical simulation of the basic skills needed in a laparoscopic common bile duct exploration using ultrasound. This is achieved through a human-centred design methodology where each step of the development is guided by interactions or evaluations with the end users. The specifications are defined by using interviews to understand the needs of surgeons in a simulation practice and to characterise the experience of performing surgery, including the embodied knowledge of surgeons when they manipulate soft tissues. Using an action research methodology combining qualitative and quantitative evaluations in an iterative process, commonly used materials in simulation are thoroughly investigated to identify the most suitable synthetic materials for each type of soft tissue. The synthetic materials identified are silicones because of their tactile properties; moreover, two augmented reality techniques are implemented in addition to the physical model. The first one is style transfer, which aims to improve the appearance of the physical simulator when it is viewed through the laparoscopic camera. The style transfer algorithm used during this research can successfully modify the appearance of the simulator to replicate the diversity of real life. The second technique is marker tracking, which is used to simulate the laparoscopic ultrasound step by overlaying pre-recorded ultrasound images onto the physical model. This technique allows surgeons to practice reading laparoscopic ultrasound images and identifying key anatomical features during the surgery. Through consultations with the surgeons, the outcomes of this research are evaluated using face, content, and construct validations. Throughout this thesis, the research methods and results are explained and discussed to provide a basis for further research. These findings can be used as a framework for future development of surgical simulators.

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Chapter 1: Introduction

*Gallstones** are a common medical condition; they occur in about 15% of the US population and 5.9% to 21.9% of Europeans at some point in their adult life (Winder and Pauli, 2016). Gallstones are also a significant reason for emergency hospital admission and procedures (Beckingham *et al.*, 2015).

Gallstones originate in the gallbladder. One of the complications they can cause is when they migrate from the gallbladder to the bile duct (Hazey *et al.*, 2016). The bile duct is the liver's main drainage pipe and, if stones are located within it, they can block it and prevent drainage from the liver, resulting in further complications. Moreover, if the gallstones go into the cystic duct, they can block the release of bile, which can then upset the digestive process (Hazey *et al.*, 2016).

One of the options for treating gallstones is to conduct a *laparoscopic** common bile duct exploration. Traditionally, surgeons have used X-rays during this procedure. Laparoscopic ultrasound scanning is a faster and radiation-free alternative. With this option, the surgeon has to undertake a series of complex steps including laparoscopic *ultrasound** imaging and laparoscopic suturing (Beckingham *et al.*, 2015).

Surgical simulators are synthetic models designed to train surgeons (O'Brien *et al.*, 2016). They are beneficial as they can provide an alternative to the gold standard of surgical training, that is, practicing on animals or cadavers. This type of training raises issues related to cost, access, and ethics (Forte *et al.*, 2016). It is also proven that surgical simulators can improve the performance of surgeons through practice (Bernier and Sanchez, 2016); however, they are not currently generalised in surgical education partly because of their expenses.

A surgical simulator would be particularly beneficial for a complex procedure such as *laparoscopic common bile duct exploration (LCBDE)** where there is an identified need for training systems (Santos *et al.*, 2012a; Ponsky, 2010). Such a simulator would enable both surgeons in training and those who seldom perform these procedures to gain experience and knowledge of the steps and skills required for

* All terms italicised and with an asterisk are defined in Appendix A, the Glossary.

the surgery and to improve their confidence in undertaking the procedure on their patients.

1.1 Research aims and objectives

This research aimed to design, prototype, and test a surgical simulator for surgeons to acquire the basic skills of LCBDE, by developing a set of methods to create realistic models that simulate the look and feel of human organs.

The aim of this research was connected to the following Null Hypothesis: "developing a method to create an easily replicable, validated, realistic simulator to enable surgeons to gain the basic skills of ultrasound guided LCBDE is not possible".

The research initiated from a collaboration with a paediatric surgeon from the University Hospitals Bristol NHS Foundation Trust who was interested in developing low cost models to train junior surgeons. The literature also revealed an interest surrounding the development of less expensive methods (Bernier and Sanchez, 2016). This is why, despite the benefits of using advances in new technologies, I decided to focus on researching low cost approaches to surgical simulation.

The following objectives were identified to address the research aim:

1) To investigate the state-of-the-art and interview surgeons to identify their expectations and the specification of a surgical simulator.

To develop a useful training tool, it is important to understand what has previously been developed and how previous simulators succeeded and failed in answering the end users' needs. Surgical training is complex because it must train surgeons for a great variety of skills and scenarios in a realistic way. As the surgeons I interviewed explained, failing to train in a realistic setting could result in them learning a task erroneously. Therefore, it is crucial to fully understand what the end users require and look for in the simulator. To identify the specification, this research used investigation with surgeons who have performed LCBDE.

2) To characterise soft tissues' properties and mimic them using synthetic materials.

* All terms italicised and with an asterisk are defined in Appendix A, the Glossary.

There are multiple examples of articles on surgical simulation where the authors have selected their synthetic materials using properties assessed via quantitative tests (Tejo-Otero *et al.*, 2020; Cheung *et al.*, 2014; Condino *et al.*, 2011). However, in this research, quantitative tests were combined with perceptual studies. This aimed to achieve a more complete and complex understanding of surgeons' *embodied knowledge** when they are touching and handling the tissues. The characterisation of the soft tissues enabled a specification of the synthetic materials to be defined.

A literature review identified the materials commonly used for surgical simulation. During this research, this list of materials was used as a basis for the investigation, aiming to identify the most suitable synthetic material for each type of soft tissue.

3) To design a quick, simple, and low-cost method to build physical simulators using *3D printing** and *augmented-reality (AR)** techniques.

This research aimed to develop a surgical simulator using a combination of fabrication techniques such as 3D printing and moulding, and engineering approaches such as 3D modelling and AR. 3D printing allows the quick development of complex shapes but fails to provide suitable materials to mimic the soft tissues. This research investigated the combination of 3D printing and moulding to develop anatomically accurate and realistic synthetic tissues.

Because synthetic materials have limitations in terms of visual realism and physical properties, one of the objectives of this research was to develop a set of techniques based on AR that would improve the training system by providing new features that can address these limitations.

4) To evaluate the different prototypes on a quantitative and qualitative basis. This evaluation would illustrate the strengths and weaknesses of the models, giving the possibility to improve the outcome through an *action research** workflow approach.

Findings from interviews with surgeons revealed that surgeons are reluctant to integrate into their training routine methods that have not been validated with

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proven benefit. Consequently, the simulators developed are often not generalised in surgeons' training. The purpose of this last objective was to develop an evaluation method to assess the potential of surgical simulators for LCBDE and to implement it to prove the benefit of the prototypes developed.

1.2 Research methodology

This section describes the underlying methodological approach used to conduct this research, and the different methods undertaken to complete the research objectives.

This research aimed to create a product that meets the needs of a specific group of end users. In many industries, product design has traditionally followed a linear top-down methodology where designers define the entire product before testing it with users. This methodology has significant limitations as it requires the implementation of a long and complex process before doing any user testing; this can result in a significant loss of time and reluctance to modify an already rigid and advanced design because of the money invested in this solution (Hall *et al.*, 2013). More recent methodologies have focused on quicker cycles of design, prototyping, user testing, and reflection. These methodologies, known as design thinking or *Human Centred Design* (HCD), have significant benefits in their flexibility and ability to move towards the best solution according to the end users (Hall *et al.*, 2013). Thus, I decided to implement HCD as the overall research methodology of this research.

Furthermore, because I was working towards developing prototypes, I emphasised practice greatly. As such, I conducted the study as a *practice-based research** project, as described by Candy (2006). Practice-based research is a process that is "*an original investigation undertaken to gain new knowledge partly by means of practice and the outcomes of that practice*". Indeed, research objectives 2 and 3 are deeply based on traditional practice in materials testing and digital practice, including computer-based techniques. The research aimed to combine digital and traditional practice to develop prototypes and identify a repeatable fabrication method.

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In the context of the practice, the research followed an iterative process with phases of action, for example, creation of a new prototype, followed by phases of analysis, such as testing of the prototype. This iterative process was especially pertinent while investigating materials for synthetic tissues and fabrication methods using 3D printing, and the development of the style transfer algorithm. This iterative process is also a part of HCD methodology. Figure 1 shows the overall methodology used within the research with the different HCD phases which are detailed in the next section, and action research iterative cycles.

Another possibility would have been to implement a methodology based on data modelling to direct the outcome. This methodology was also tested in the research as it offered the advantage of avoiding iterative cycles and saving materials through extensive planning and limited testing. This methodology was implemented when defining the prototype evaluation method through a literature review, as it allowed the definition of an effective evaluation method without requiring a cycle of multiple interactions with the end users. I had also planned to use this method to design the liver mould by modelling the flow of casting material using simulation software; however, using this approach would have required learning how to use new software. The iterative approach allowed me to identify a functional design after four trials, which was less time-consuming. Furthermore, iterative methods allowed me to understand the materials' properties and techniques, which is not possible with data modelling.

** All terms italicised and with an asterisk are defined in Appendix A, the Glossary.*

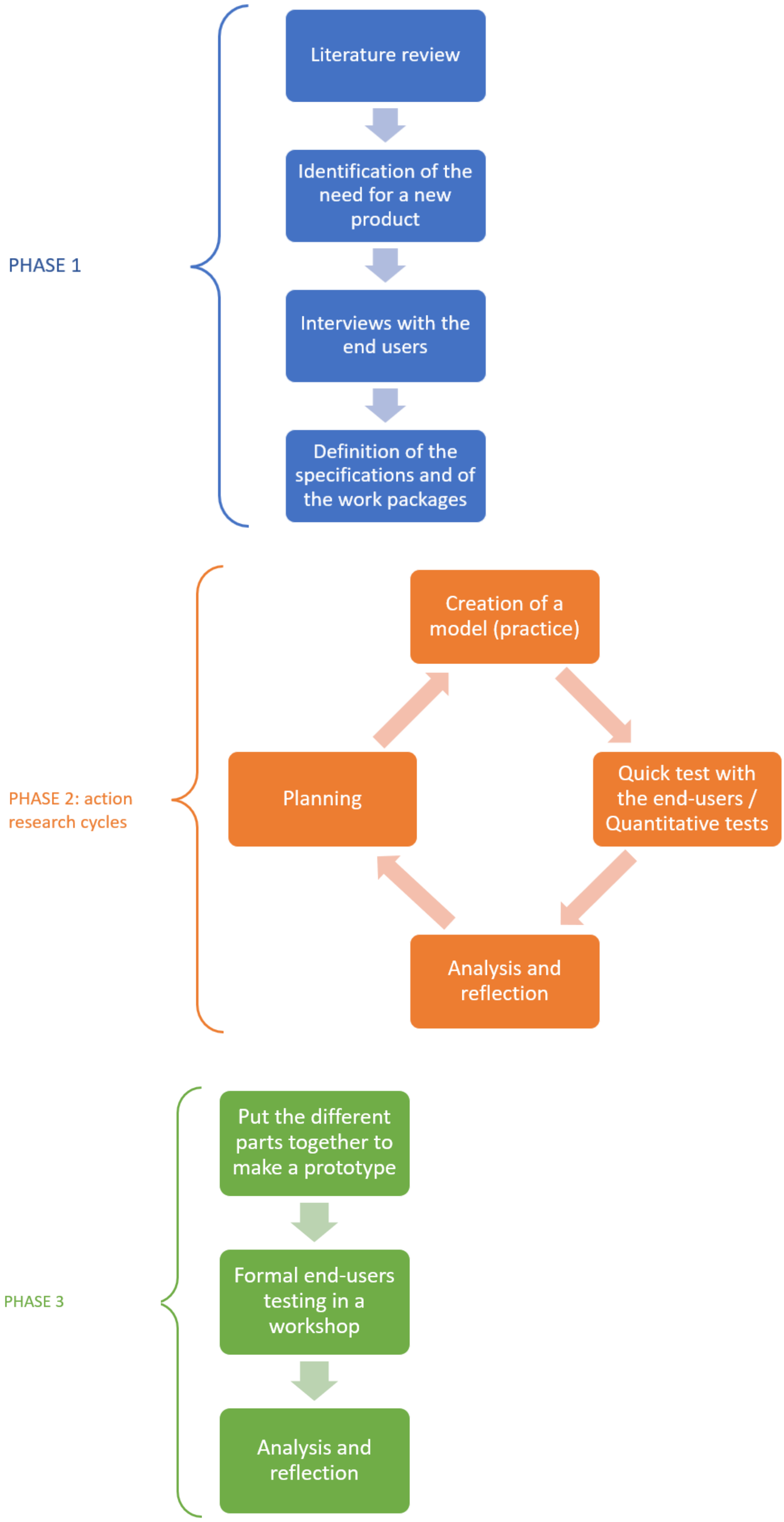

Figure 1: Research process undertaken during this project

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1.2.1 Human centred design (HCD)

HCD defines a methodology which aims to develop a product by working directly with its end users. This methodology has previously been used in the development of mobile health technologies (Polhemus *et al.*, 2020), medical equipment (Vincent, Li and Blandford, 2014) and the design of aircraft cabins (Hall *et al.*, 2013) because of its ability to integrate the end users' needs and requirements into the design. It is especially useful in health-related devices where the end users are very diverse (Vincent and Blandford, 2014). The HCD methodology is usually implemented at each step of the product design. To do so, the design is divided into three phases: Phase 1 entails establishing the context of use and the user requirements, Phase 2 consists of expert inspections and walkthroughs, and finally, Phase 3 is usability testing with end users (Harte *et al.*, 2017).

1.2.1.1 Phase 1: Context of use and user requirements

The first phase aims to establish the context of use and identify the end users' requirements. Previous research shows that past designs have commonly focused on the technical side instead of the end users' experience, which has been detrimental to the final simulators as they are not adapted to the users' needs and learning objectives (Persson, 2017). This phase typically includes interviews and surveys. During this research, interviews were conducted with surgeons. The findings were combined with a literature review which attempted to gain more knowledge on the state-of-the-art and surgical experience.

This association with surgeons who would be the simulator's end users was significant, as the surgeons provided the expertise necessary to develop the research iteration (Li *et al.*, 2021; Melles, Albayrak and Goossens, 2021). As highlighted by Persson (2017), there are not many examples of designs developed using a HCD methodology; however, Li *et al.* (2021) underlined the usefulness of involving surgeons to understand their surgical experience. The intention was to understand the surgical experience as well as possible to be able to recreate it. During this phase, the context of use was identified by asking the surgeons to

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provide a step-by-step description of what they do in the *operating theatre** and explain what they feel when touching soft tissues.

The simulator’s requirements were determined through these surgeons’ descriptions of their surgery experience. The descriptions provided a thesaurus of words and sensations during surgery that helped to define the simulator’s specifications and develop an accurate and realistic simulation practice. This was especially useful for defining tactile sensations. In my literature review, I did not find any example of this method being used in the context of defining the sensations of surgery; however, it has been used in other sectors, such as the textile industry (Xue *et al.*, 2014). Furthermore, surgeons could also help to identify the requirements by describing their experiences of using prior surgical simulation and how it had succeeded or failed to provide realistic training.

1.2.1.2 Expert inspections and walkthroughs

This second phase aimed to rapidly evaluate the initial prototypes and improve them through iterative circles. This phase also relied on the action-research methodology, which involved multiple trials with end users or experts, but also quantitative tests (Section 4.2.2). The experts were other researchers advising on the research who provided feedback on the research's technical aspects, such as the development of a fabrication technique (Chapter 3). They offered another perspective and contributed towards developing a solution.

There are many benefits in conducting usability inspections with end users regularly during development, as it allows the prototypes’ assets and limitations to be identified and guides the research direction. These inspections are less formal than end user testing and seek quick and concise feedback; consequently, they are more easily implemented. Having the possibility to frequently test low-fidelity mock-ups or prototypes is beneficial for gaining input and assessments early on and being able to revise the design accordingly. This is visible in the study of Harte *et al*. (2017), where they developed a connected health system and benefited from frequent testing to identify usability problems and rectify them. Because of the high frequency of these tests, they are conducted online when possible to reach the end

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users more rapidly. In the research described in this dissertation, inspections were implemented in evaluating ultrasound images of the investigated materials and the style transfer algorithm, by sending pictures regularly to surgeons. It was also helpful for adjusting the simulator's design, by showing the surgeons different prototypes and getting their opinions on their suitability.

1.2.1.3 Phase 3: Usability testing with end users

Formal tests with end users are the best way to evaluate prototyping research outcomes, since they can determine a product's strengths and limitations and indicate the aspects that require more research and development. In contrast to the ongoing evaluation, these tests are more formal and extended as they seek to evaluate the product globally rather than scrutinise small aspects of the prototypes. The tests can also serve as the baseline of another research cycle where Phase 2 would be repeated.

To evaluate the outcome of my research, I conducted a workshop (workshop 2, detailed in Section 7.1.2) with the surgeons to evaluate its potential as a training tool. Different types of scales are available in the literature to grade perceptions and the usability of a prototypes; they are described in section 2.3.1.2 of this manuscript. Some examples are the System Usability Scale (SUS) (Lewis, 2018), the Visual Analogue Scale (Johnson, 2001), and 5-point Likert scale questionnaires (Joshi *et al.*, 2015). In this work, I chose the Likert scale, as it provides quantitative results easily analysed using statistical tests.

1.2.1.4 Limitations of HCD

Previous studies on using HCD to develop medical devices have revealed many challenges, such as the complexity of communicating in multidisciplinary teams (Vincent and Blandford, 2014). During my research, I had to communicate with engineers, surgeons, and other art and design specialists, which led to difficulties in both communication and divergent perspectives. A potential solution I employed to address this was the use of *scenarios**.

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Scenarios describe what the end users will do with a product through discussions and descriptions; picturing the product in use is beneficial in designing the solution and gaining understanding from all the actors in a project (Vincent and Blandford, 2014). This was incorporated into the interviews with surgeons by asking them about the surgical experience that needed to be recreated and the various scenarios that could happen within this experience.

1.2.2 Action research

The second phase of HCD includes quick evaluations of prototypes and iterative circles. In the scope of practice-based research this naturally leads to action research as described by Bryman and Bell, as "*an approach in which the action researcher and a client collaborate in the diagnosis of the problem and in the development of a solution based on the diagnosis*" (Bryman and Bell, 2011). This methodology includes observational and reflective cycles to improve the result of the practice; more precisely, this methodology includes four steps, as shown in Figure 2: design of the experiment, practice, analysis of the outcome of the practice and the practice itself, and modification of the initial experiment design regarding this analysis. Each cycle brings new knowledge and contributes towards creating a better solution.

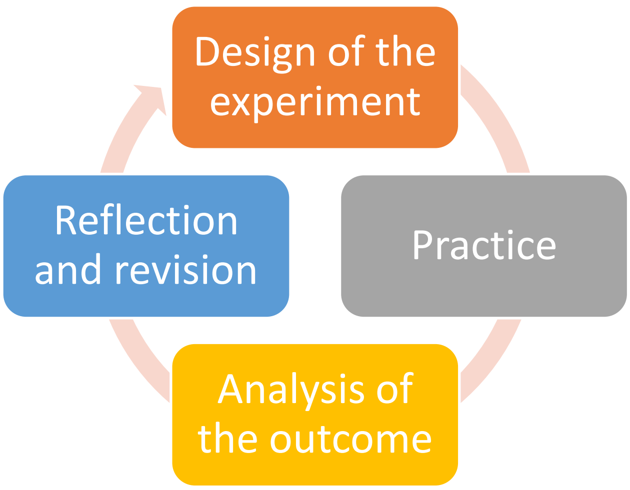

Figure 2: Action research iterative process

This methodology has been used in product design to understand the needs of the end-users (Henfridsson and Lindgren, 2007). In this research, it was implemented in

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my investigation of the fabrication methods, such as designing the moulds and optimising the rotomoulding technique, investigating the materials, and optimising the style transfer algorithm. The research on these techniques was a collaborative journey, the feedback from the stakeholder - in this case the surgeons, allowed me to undertake the next iterative experiment to solve the problem.

The analysis evaluates the practice itself as well as the outcome of the practice. The aim of examining the practice is to be able to determine the most effective way to achieve a positive outcome; indeed, if the outcome is outstanding, but the practice developed to achieve this outcome is long and complex, then, despite the potential of the outcome, it will not be reproduced in future surgical training. This is connected to the research objective 3, which aims to develop a low-cost fabrication method of surgical simulators.

Action research has been criticised for lacking the repeatability and rigour of other methods, such as the quantitative ones (Bryman and Bell, 2011). However, action research can generate rich information which cannot be gathered in other ways.

In the scope of these reflective iterations, I kept a research diary of successive trials including observations of both the practice and the outcome, and photographic evidence. This research diary was useful for ensuring a constructive evolution at each cycle as it allowed me to reflect on the previous experience. It was also useful for keeping a trace of past experiments, to go back to previous trials when the last direction of the research did not result in favourable outcomes. The research diary is detailed in Table 1.

One important aspect of conducting research is triangulation. The aim is to increase the reliability of the findings through diversification. There are many types of diversification, such as diversification of the data by using different data sources, diversification of the method by using both quantitative and qualitative approaches, or diversification of the researchers or theoretical positions (Mayer, 2015). To get a holistic view and analysis, the analysis phase included both qualitative and quantitative methods when possible. The qualitative studies were

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user-based as defined by the HCD methodology; the quantitative studies included *physical testing** of the materials or evaluation using precise *evaluation metrics** for the style transfer algorithm.

Table 1: Contents of the research diary

Research activity	Research span	Tests
Investigation of the materials: ultrasound	Sep 2020 - Aug 2022	Qualitative assessment (around 20 reviews and tests cycles)
		Quantitative tests (1 test/sample; 58 samples)
Investigation of the materials: tactile properties	March 2020 - Jan 2022	Qualitative assessment (around 30 tests)
		Quantitative tests (1 test/sample; 58 samples)
		End user evaluation (12 participants)
Development of a style transfer algorithm	Apr 2020 – Nov 2021	Qualitative assessment (around 30 tests (3 different style images, 10 tests with different parameters per images).
		Quantitative tests (5 tests / pre-trained model; 5 pre-trained models tested)
		End user evaluation (8 participants)
Fabrication technique: clamping system	Jan 2020 – Aug 2021	Qualitative assessment (20 tests)
Fabrication technique: opening in the moulds	Sep 2021 – Dec 2021	Qualitative assessment (5 tests)
Fabrication technique: smoothing the moulds	Apr 2022 – June 2022	Qualitative assessment (1 test/technique; 6 tested techniques)
Fabrication technique: rotomoulding process	Aug 2021 – Jan 2022	Qualitative assessment (tests of rotation speed and fluidity of material; around 10 tests)

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1.2.3 Qualitative research

Qualitative research aims not only to understand how something operates but also why it operates this way (Thorne, 2000). One of the distinctions between quantitative and qualitative research is the role each takes. Qualitative research is well suited for inductive research and generating hypotheses while quantitative research is more suitable for deductive research and testing hypotheses (Mayer, 2015). Qualitative research was a significant part of this research, notably during Phase 1 of the HCD methodology, which included consultations with surgeons and more specifically interviews.

An interview is a data collection method where the researcher gathers information from the interviewee's experience and knowledge (Rashidi *et al*., 2014). Several types of interviews can be conducted to retrieve information: structured, semi-structured or unstructured interviews. The type depends on what kind of data the interviewer wants to obtain. If the aim is to verify hypotheses, structured interviews are the most common option; however, to explore a new field and gain a better understanding, qualitative interviews are more suitable (DiCicco-Bloom and Crabtree, 2006). Qualitative research is more appropriate when seeking to understand specific experiences and perceptions (Rashidi *et al*., 2014). Such interviews are often semi-structured or unstructured (DiCicco-Bloom and Crabtree, 2006). Furthermore, it is also possible to combine both types of study: semi-structured interviews to understand the main issues surrounding a topic followed by a questionnaire, for instance (Mashuri *et al*., 2022).

Unstructured interviews can be compared to a guided conversation taking place during the interviewee's normal activity. They are based on participant observations which trigger the basis of the discussion. The questions emerge from these observations or from the discussion instead of being predetermined prior to the interview (DiCicco-Bloom and Crabtree, 2006).

Semi-structured interviews do not rely on any observation of the participant's activities and are closer to a scheduled discussion which includes several open

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questions. New questions can emerge naturally during the discussion; there is an iterative nature to semi-structured interviews, as the questions might evolve between participants to generate more useful insights, (DiCicco-Bloom and Crabtree, 2006). This flexibility is one of the characteristics of qualitative research where the theory follows the data (Mayer, 2015). As for conducting an interview, Adhabi and Anozie (2017) list the following guidelines: the participant needs to be interested in the research topic, the questions should be open, and the interviews should start with 'easy' questions before moving on to more complex topics. Thus, there is still a need for some degree of preparation for semi-structured interviews. (Mashuri *et al.*, 2022) suggest that an interviewer should prepare an interview guide that lists the topics to be brought up during the interview. This guide should not be a rigid constraint, but more a basis for the discussion.

In contrast, in a structured interview the questions are predetermined prior to the interview and follow the same pattern and the same formulation for all participants. Structured interviews consist of a list of precise questions designed to gather specific responses. The questions generally allow only a limited number of answers, which are relatively short. The questions are straightforward and the interview process is rigidly defined, as such the interviewer does not deviate from the predefined series of questions and always maintains the same wording (Adhabi and Anozie, 2017). This approach is useful to ensure uniformity of answers across participants and repeatability between participants, and it facilitates comparison of the responses through data processing and analysis (Rashidi *et al.*, 2014).

In the process of any interview, it is important to pay attention to question formulation. Sometimes a question's phrasing may favour one type of answer, leading to misleading results (DiCicco-Bloom and Crabtree, 2006). Moreover, there can be bias from the interviewer that impacts on how they ask and express questions, which can then modify the answers participants feel comfortable providing (Adhabi and Anozie, 2017).

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Analysing data from qualitative interviews should be carried out in conjunction with the process of interviewing participants so that new questions can emerge and new fields can be identified. It also allows researchers to identify the point where no new topics emerge or data saturation (DiCicco-Bloom and Crabtree, 2006). This is connected to the grounded theory approach (Mayer, 2015) in which findings evolve in an iterative process. It is based on an initial theory, followed by data collection and comparison of the data to refine the initial theory, followed by new cycles of data collection until saturation is reached.

After conducting a round of interviews, there are three phases of data analysis: the first one is data preparation, to clean the raw data gathered during the interview. This is often a transcription step. The second step is data analysis, which entails regrouping the answers by searching for patterns or categorising the data. This is an organisation step which can be coupled with data display through the utilisation of graphs (Maye, 2015). The final step consists of summarising the results of the study and analysing them further to draw new conclusions from the data. This step can be followed by new rounds of interviews until data saturation is reached (Mashuri *et al*., 2022).

For the data analysis step, DiCicco-Bloom and Crabtree (2006) identified the following approaches: the "editing approach" where a researcher reviews and identifies text segments while making interpretative statements during the process of identifying patterns for organising text. This type of analysis can include evaluating the frequency of occurrence of certain words, as a way to determine their importance (Mayer, 2015). There is also the "template approach", which is commonly used and relies on using codes from a code-book to firstly tag segments of text and then sort text segments with similar content into separate categories for a final distillation into major themes. This is a comparative approach where the researcher takes one piece of data and compares it to the remaining data to find correspondences and identify relations between them. The process is repeated until all the data have been compared (Thorne, 2000). Lastly, in the "crystallisation approach" the researcher uses a much less structured approach, repeatedly

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immersing themselves into the text in reflective cycles until interpretations intuitively crystallise. This approach aims to dig deeper into the data to discover its underlying structure or essence (Thorne, 2000).

1.2.4 Ethics requirements

Because the research followed HCD guidelines, it involved recruiting participants. Thus, I needed ethical approval for the interviews and the workshops. I received ethics approval from the University Research Ethics Committee (Approval reference number: ACE.20.07.043).

1.3 Published papers resulting from this research

During this research project, several research papers were published in conference proceedings and academic journals. A list of these publications and their connections to the research is provided below.

Conference proceedings:

1. M. Shao, C. Parraman and D. Huson (2020): Physical Patient Simulators for Surgical Training: A Review. Society for Imaging Science and Technology, 2020, London Imaging Meeting 2020 p. 124-128.
2. M. Shao, D. Huson, and J. Clark (2022): Simulation of laparoscopic ultrasound imaging and suturing of the bile duct using silicone. Proceedings Volume 12034, Medical Imaging 2022: Image-Guided Procedures, Robotic Interventions, and Modeling; 1203423 https://doi.org/10.1117/12.2611340
3. M. Shao, J. Clark, D. Huson and J. Hardeberg; *Real-time Style Transfer for Videos to Enhance the Realism of Simulation of Laparoscopic Surgeries* at EUVIP 2022. DOI: 10.1109/EUVIP53989.2022.9922706 *© 2022, IEEE*

Journal paper:

4. M. Shao, T. Vagg, M. Seibold, M. Doughty. Towards a Low-Cost Monitor-Based Augmented Reality Training Platform for At-Home Ultrasound Skill Development. *Journal of Imaging* **2022**, *8*, 305. https://doi.org/10.3390/jimaging8110305

* All terms italicised and with an asterisk are defined in Appendix A, the Glossary.

5. M. Shao, M. Aburrous, D. Huson, C. Parraman, J.Hardeberg, J. Clark. Development and validation of a hybrid simulator for ultrasound-guided laparoscopic common bile duct exploration. *Surgical Endoscopy* **2023** https://doi.org/10.1007/s00464-023-10168-w

Publication 1 was a review paper on physical surgical simulators and 3D printing, which was published in the proceedings of the LIM 2020. The content of this paper is included in the literature review in Chapter 2:

The material investigation conducted to determine the most suitable materials to simulate soft tissues was described in a conference paper at SPIE 2022 (publication 2). This investigation and the results are described in Chapter 4.

Publication 3 describes the style transfer technique and was published in the conference proceeding of EUVIP 2022. This work is also described Chapter 5.

The context-aware simulation of ultrasound was described in publication 4, published in the Journal of Imaging. This publication describes the specific case of ultrasound training for scanning an arm through a combination of body tracking and marker tracking. Some of the techniques described in this publication are also used in this work for the training of scanning a bile duct and are described in the Chapter 6 of this thesis.

The evaluation of the simulator was described in publication 5. The content of this publication is also described in Chapter 7.

1.4 Overview of the chapters

This account of my research project is presented in the following order: description of the scope of the research and the methodology, clinical background and overview of the state-of-the-art, followed by chapters describing each different aspect of the research, that is, fabrication of a physical simulator, investigation of the tactile feedback during surgery, enhancement of realism through style transfer, marker-tracking for simulating an ultrasound examination, and evaluation of the simulator. The last chapter comprises my conclusion and suggestions for future work.

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Chapter 1 provides the clinical background to this research and explains why it is important to develop a surgical simulator for LCBDE. It also introduces the research methodologies followed during this PhD. The user-based methodology applied in this research is not common in the context of surgical simulation (Persson, 2017) and one of the contributions of this research is the proof of its potential.

Chapter 2 follows with a literature review on surgical education and surgical simulation. It presents the baseline which guided the choice of the methods used in the following chapter.

The fabrication techniques used to create a physical simulator are described in **Chapter 3.** These techniques were based on a combination of 3D printing of flexible moulds and rotomoulding.

Chapter 4 presents my work on the characterisation of soft tissues and my investigation into which materials could mimic them, using quantitative and qualitative approaches. Two contributions of this research are the characterisation of the subtlety of the tactile feedback of soft tissues using perceptual studies and the identification of suitable materials to mimic each organ.

Chapter 5 describes style transfer, which was used in this research to improve the visual realism of the simulator. The research shows its ability to mimic the variability of real life and reproduce the differences that can be found between patients.

Chapter 6 explains the marker tracking technique for context-aware ultrasound simulation. This technique has shown its potential to train surgeons to identify stones in the bile duct by reading ultrasound images.

Chapter 7 concludes the account of my research developing prototypes, including investigating the simulator requirements and subsequently evaluating the prototypes. This research enabled me to identify the important training points for LCBDE, so one of the contributions of my study is the identification of a new training step, the laparoscopic ultrasound examination. This step was included in the final simulator which was validated during its evaluation by surgeons.

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Chapter 8 summarises the outcome of this research and concludes by outlining the future research that could improve this field of study.

* All terms italicised and with an asterisk are defined in Appendix A, the Glossary.

Chapter 2: Literature review

This chapter is a literature review which aims to provide more information on the targeted procedure and to highlight the state-of-the-art in medical education and surgical simulation. As such, it describes the different methods and approaches used in surgical simulation.

2.1 Laparoscopic treatment of gallstones

One of the common pathologies that can affect the upper abdomen is gallstones. Gallstones are a serious condition which can lead to several complications. There are two types of gallstones – cholesterol-based stones and stones from the breakdown products of blood. The first type of stones are yellow and crumbly; while the second type are black and hard (Hazey *et al.*, 2016).

When identified before surgery, surgeons can use the *endoscopic** method to retrieve these stones. With this method, a camera is pushed down the patient's throat and into the stomach to find and retrieve the stones. But stones cannot always be recovered this way. This can be due to the lack of resources, or because the procedure has failed so the patient requires surgery (Hazey *et al.*, 2016).

Some of the surgical units which undertake the procedure still choose to carry out open surgery, which consists of performing a large cut under the ribs. The other option is the laparoscopic approach, although this is challenging and complex to perform. However, the laparoscopic approach is significantly superior on multiple criteria such as length of stay of the patient in hospital, complication rate, and return to normal activities (Vagholkar, Nachane and Vagholkar, 2021; Helmy and Ahmed, 2018; Redwan and Omar, 2017).

The laparoscopic approach is described in the literature (Helton and Ayloo, 2019; Zerey *et al.*, 2018) and the process is summarised in Figure 3. The steps of the surgery are: patient positioning and port placement, gallbladder exposure, *dissection** of Calot's triangle, ultrasound examination, bile duct exploration, dissection of the gallbladder, suturing of bile duct, gallbladder removal, and closure. Each step is detailed in the following section.

* All terms italicised and with an asterisk are defined in Appendix A, the Glossary.

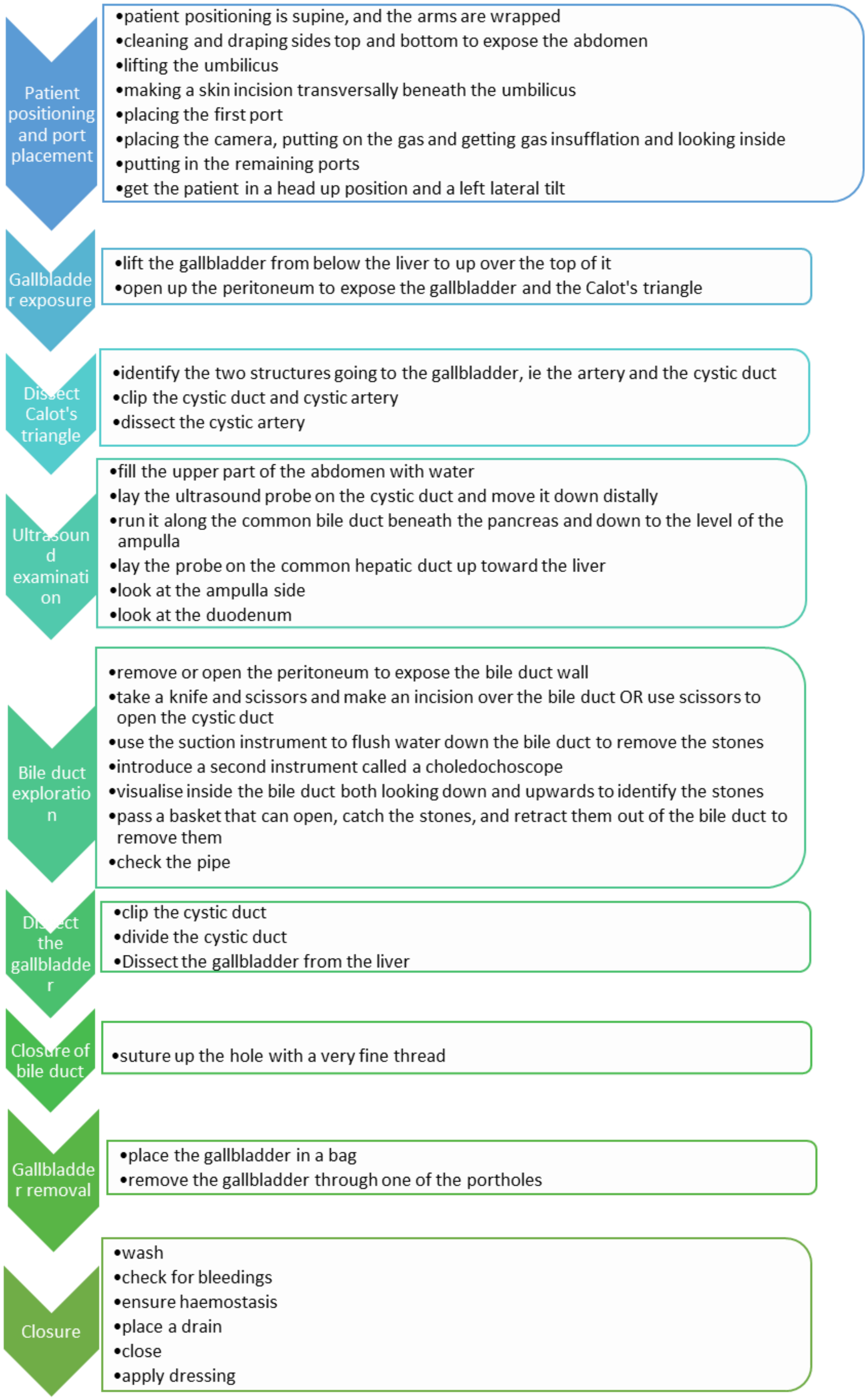

Figure 3: Steps of a ultrasound guided LCBDE

* All terms italicised and with an asterisk are defined in Appendix A, the Glossary.

2.1.1 Patient positioning and port placement

The patient is placed in a *supine position** with their arms wrapped. Then the surgeon *drapes** the patient and exposes the abdomen.

The surgeon enters the abdomen by lifting the *umbilicus**, making an incision beneath the umbilicus, and placing the first *port**. A camera is inserted inside the abdomen through that port, and the surgeon *insufflates** the abdomen with gas to get visibility. Then the surgeon puts in the remaining ports: one in the epigastrium and two in the right upper quadrant.

After port placement, the patient is positioned with their head up and a left lateral tilt.

2.1.2 Gallbladder exposure

The first part of the procedure is to expose the area of the gallbladder as shown in Figure 4. Anatomically the gallbladder sits below the liver, so retracting it consists of lifting the gallbladder up over the top of the liver. As the gallbladder is lifted over, it exposes the bile duct and the cystic duct. Then, the overlying tissue over the gallbladder called the peritoneum is opened, to expose the gallbladder itself.

Figures 4 to 14 were obtained from screenshots of a video of the surgery uploaded to the Touch Surgery website *(Clark, 2020)*; anonymisation was performed prior to upload on the website and permission for use was granted by the video's content owner.

* All terms italicised and with an asterisk are defined in Appendix A, the Glossary.

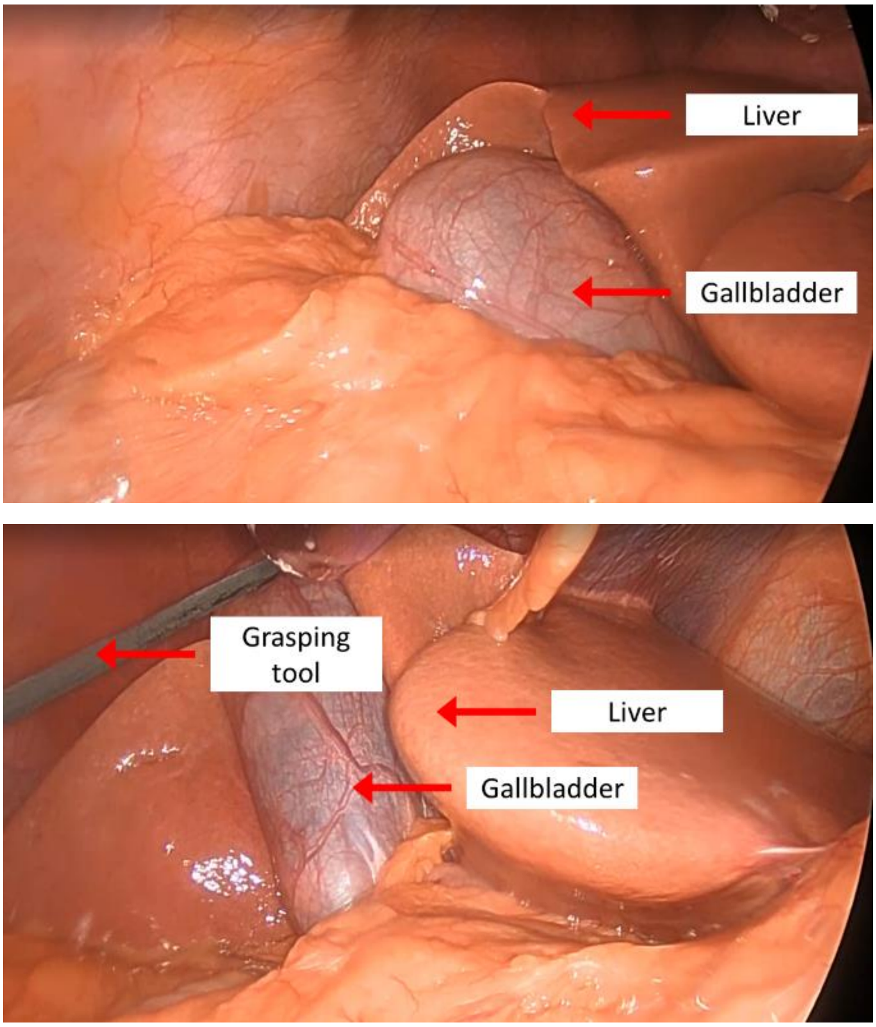

Figure 4: Exposing the gallbladder by lifting it from below the liver to over the top of it; initial position (top); final position (bottom) (Clark, 2020)

2.1.3 Dissection of Calot's triangle

The next step, shown in Figure 5, is for the surgeon to dissect the gallbladder along a defined anatomical area called *Calot's triangle**. Calot's triangle is formed by the cystic duct, the common hepatic duct, and the edge of the liver. This step allows the exposition of the cystic duct and the cystic artery, which the surgeon will then clip, as shown in Figure 6. The surgeon will finally divide the cystic artery.

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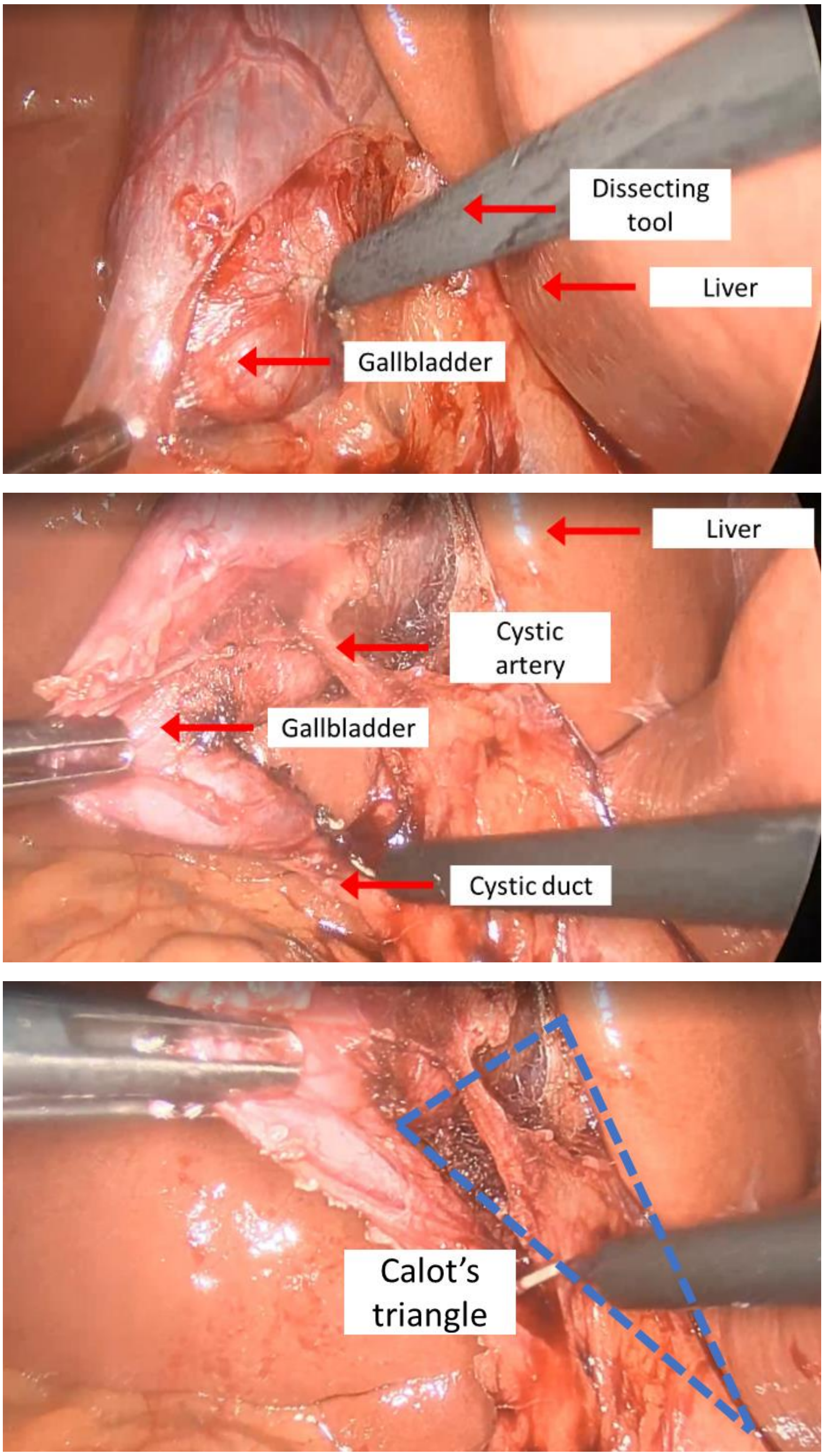

Figure 5: Dissecting the gallbladder by opening the peritoneum using electro-cautery (top); exposing the cystic duct and cystic artery (middle); identifying Calot's triangle (bottom) (Clark, 2020)

* All terms italicised and with an asterisk are defined in Appendix A, the Glossary.

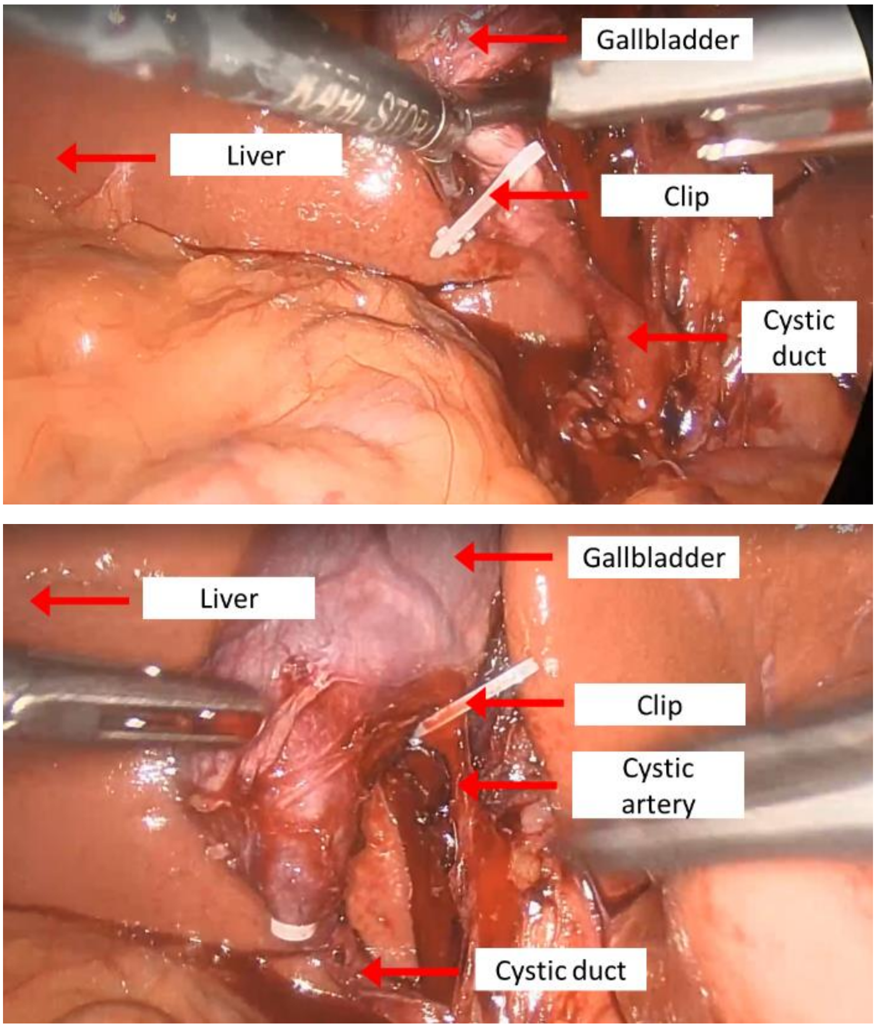

Figure 6: Clipping the cystic duct (top); clipping the cystic artery (bottom) before dissecting the artery (Clark, 2020)

2.1.4 Ultrasound examination

To perform the ultrasound examination, the surgeon will first fill the upper part of the abdomen with water. The ultrasound examination is performed using a laparoscopic *ultrasound probe**, which the surgeon runs along the side of the bile duct to ascertain if there are any stones within it. The examination also aims to measure the size of the bile duct and the size of the stones. This process is shown in Figure 7.

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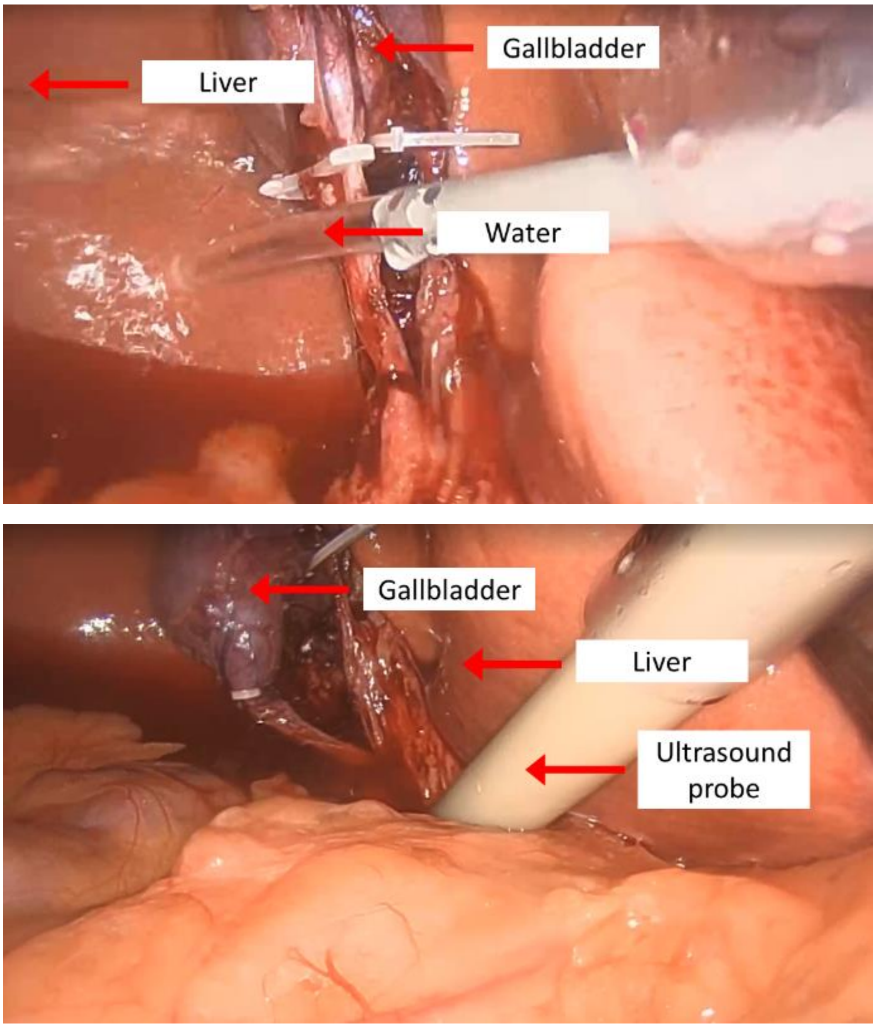

Figure 7: Ultrasound examination: filling the abdomen with water (top); running the probe along the bile duct (bottom) to identify the stones and take measurements (Clark, 2020)

2.1.5 Bile duct exploration

If stones are identified during the ultrasound examination, then the three following options will be considered:

1) The first option would be, if the diameter of the bile duct is very small, the surgeon would divide the cystic duct by putting a second clip on it and dividing it into two parts. Then they would remove the gallbladder through a dissection process and send the patient for a second procedure.
2) The second option is, if the bile duct is of a size greater than eight millimetres in diameter, then the surgeon could perform a bile duct exploration, as shown in Figures 8 and 9. They would first remove the peritoneum to expose the bile duct

* All terms italicised and with an asterisk are defined in Appendix A, the Glossary.

wall, then take a knife to make an incision over the bile duct and use scissors to increase the size of the incision. Then the small stones are removed from the inside of the bile duct using suction-irrigation. If they do not all come out, the surgeon would then introduce a second instrument called a *choledochoscope** into the bile duct. This is a flexible camera of five millimetres or three millimetres in diameter, which is controlled externally. With this camera, the surgeon can visualise the inside of the bile duct and identify the stones. There is a small channel in that choledochoscope through which the surgeon can pass a *basket** to catch the stones and retract them out of the bile duct.

3) The third option is to do a trans-cystic approach, when the cystic duct is large enough to pass the stones. The surgeon would open the cystic duct with scissors and put a three-millimetre scope inside it. The surgeon would then remove the stones in the same way as in option two, but through the cystic duct *stump**.

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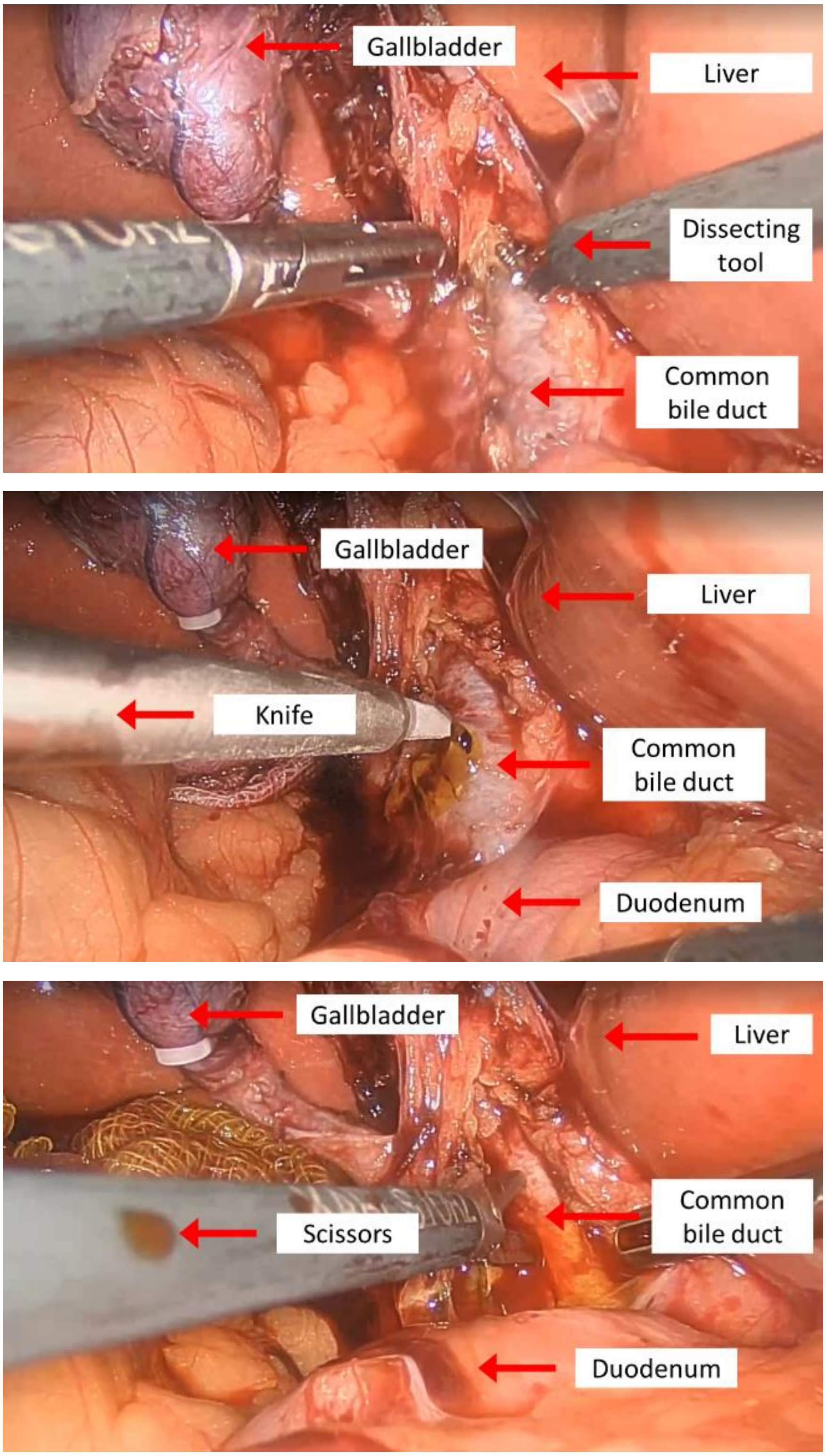

Figure 8: Exposing the bile duct by removing the peritoneum (top) and opening it with a knife (middle) and scissors (bottom) (Clark, 2020)

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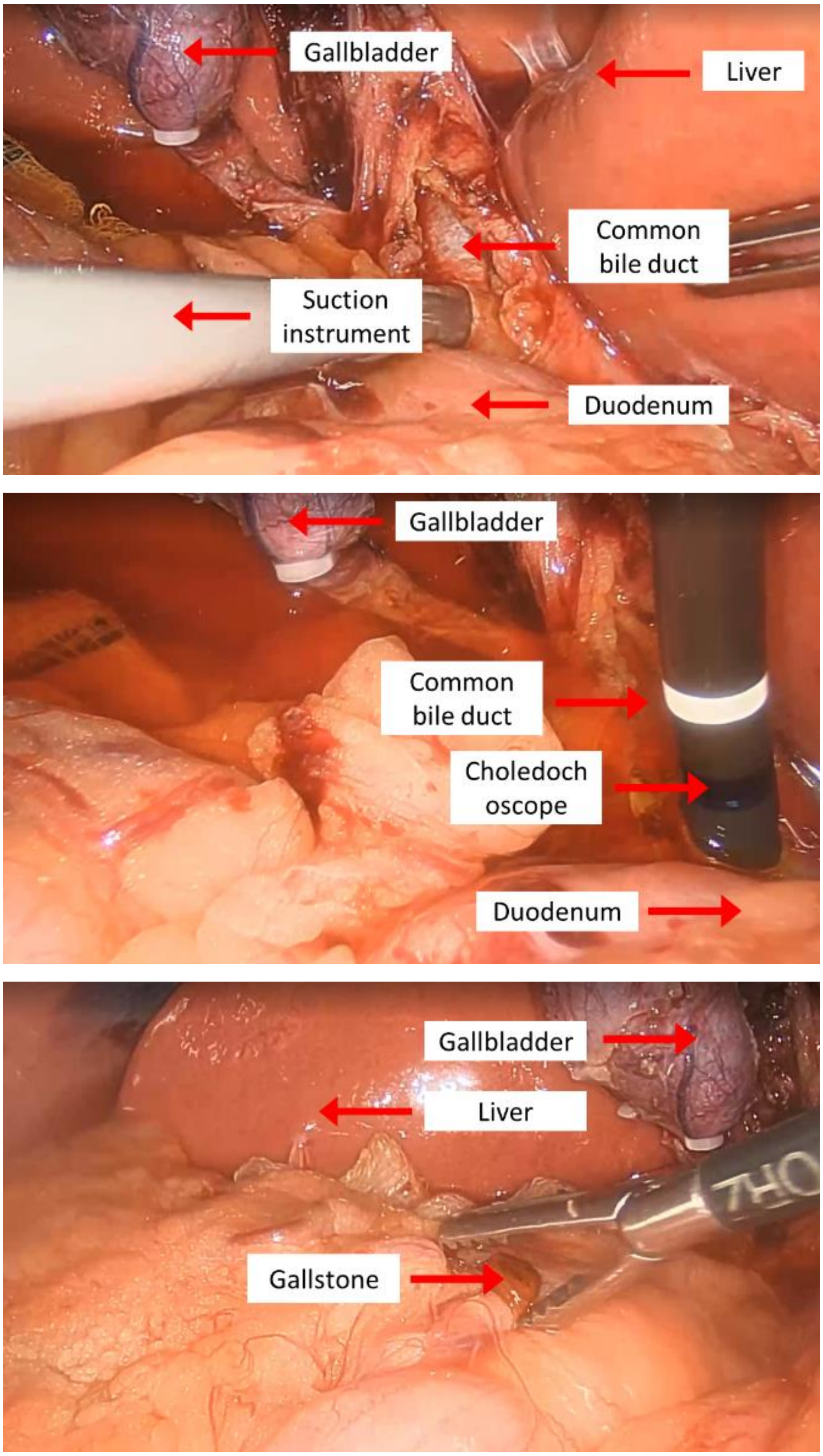

Figure 9: Flushing the stones out of the bile duct with a suction instrument (top); inserting the choledochoscope (middle) to remove the remaining stones from the bile duct; removing a stone from the patient (bottom) (Clark, 2020)

2.1.6 Dissection of the gallbladder

After removing the stones, the surgeon would place another clip on the cystic duct and artery and divide it, as shown in Figure 10. After this step, the gallbladder would be free from the duct and from the blood vessels. At that point, the surgeon would dissect the gallbladder away from the liver on which it is attached, as shown in Figure 11.

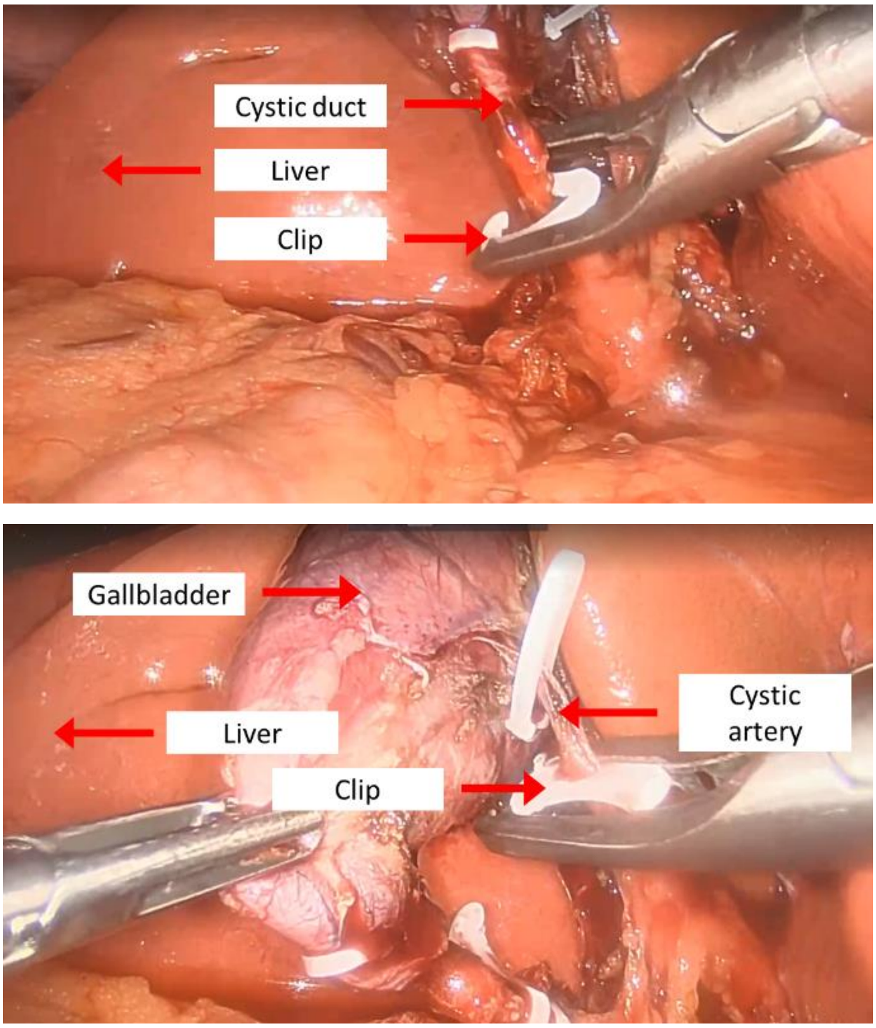

Figure 10: Clipping the cystic duct (top) and the cystic artery (bottom) (Clark, 2020)

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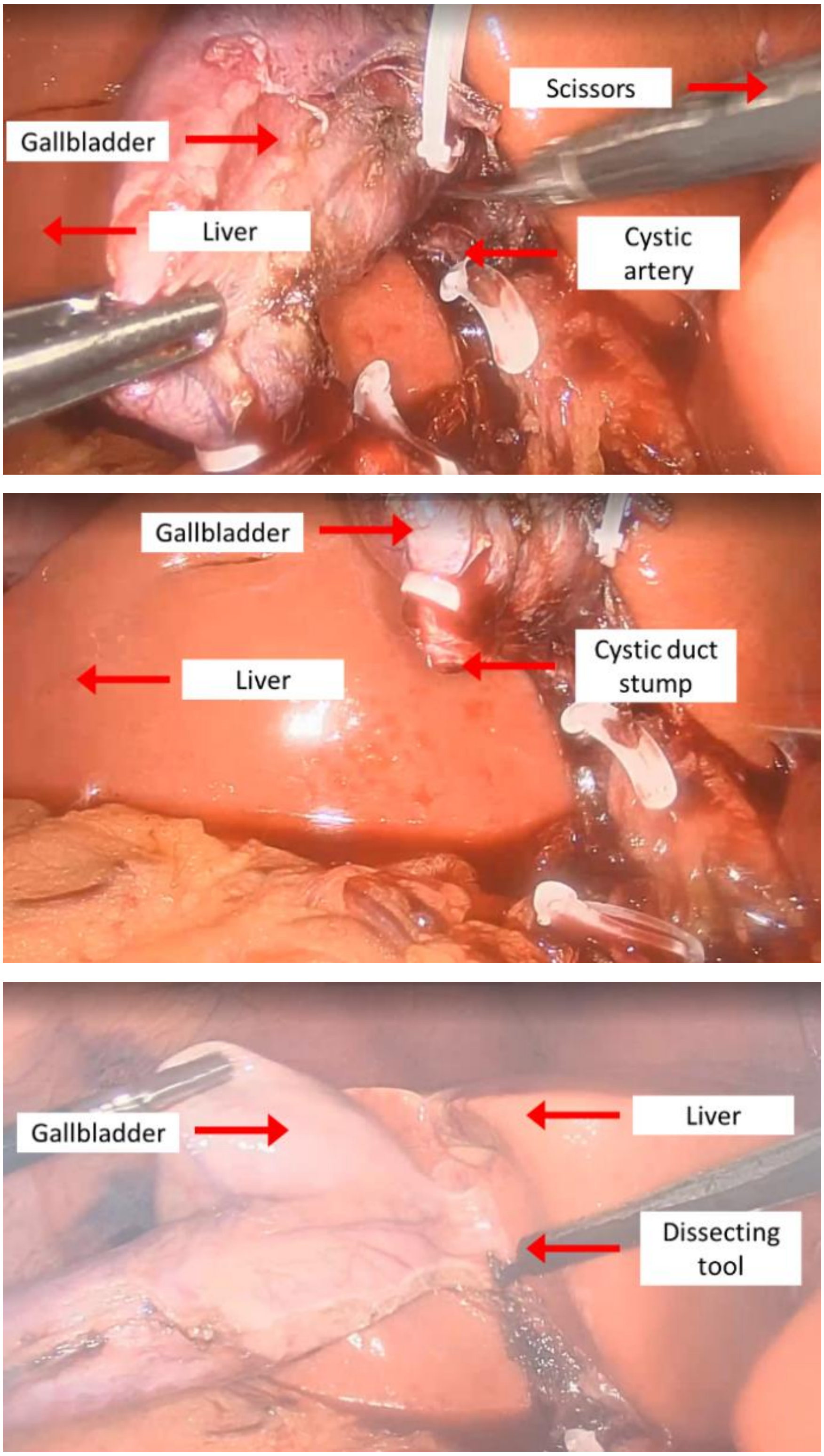

Figure 11: Dissecting the cystic artery (top) and the cystic duct (middle) to separate the gallbladder; dissecting the gallbladder from the liver (bottom) using electro-cautery (Clark, 2020)

* All terms italicised and with an asterisk are defined in Appendix A, the Glossary.

2.1.7 Suturing the bile duct

In a case where the surgeon chooses the second option and makes a hole in the common bile duct, it would be necessary to close the bile duct afterwards using a suture. This is visible in Figure 12. According to the surgeons, this step is difficult because the bile duct is thin and they need to stitch very close to the edges of the hole to avoid narrowing the bile duct, which could cause a blockage in the long term.

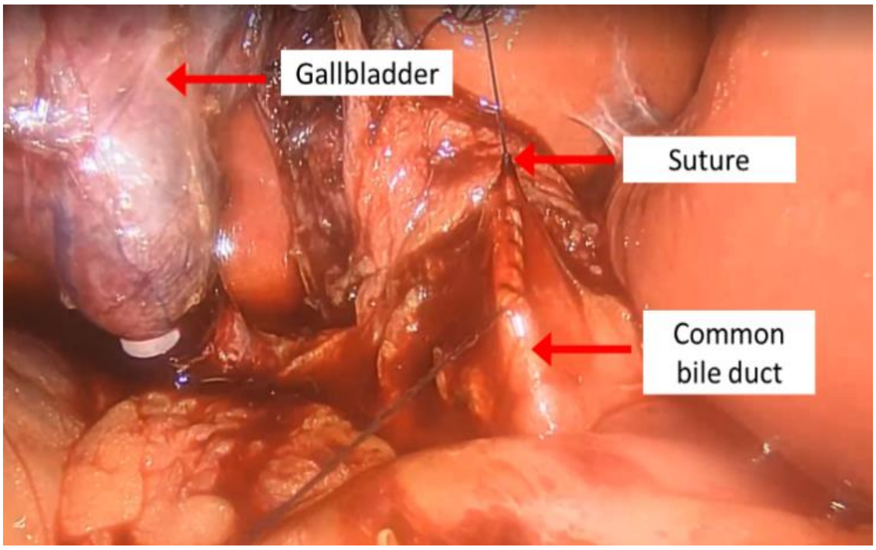

Figure 12: Suturing the bile duct (Clark, 2020)

2.1.8 Gallbladder removal

As shown in Figure 13, a bag is inserted in the abdomen through one of the ports. The gallbladder is then placed inside this bag and removed through one of the portholes near the umbilicus.

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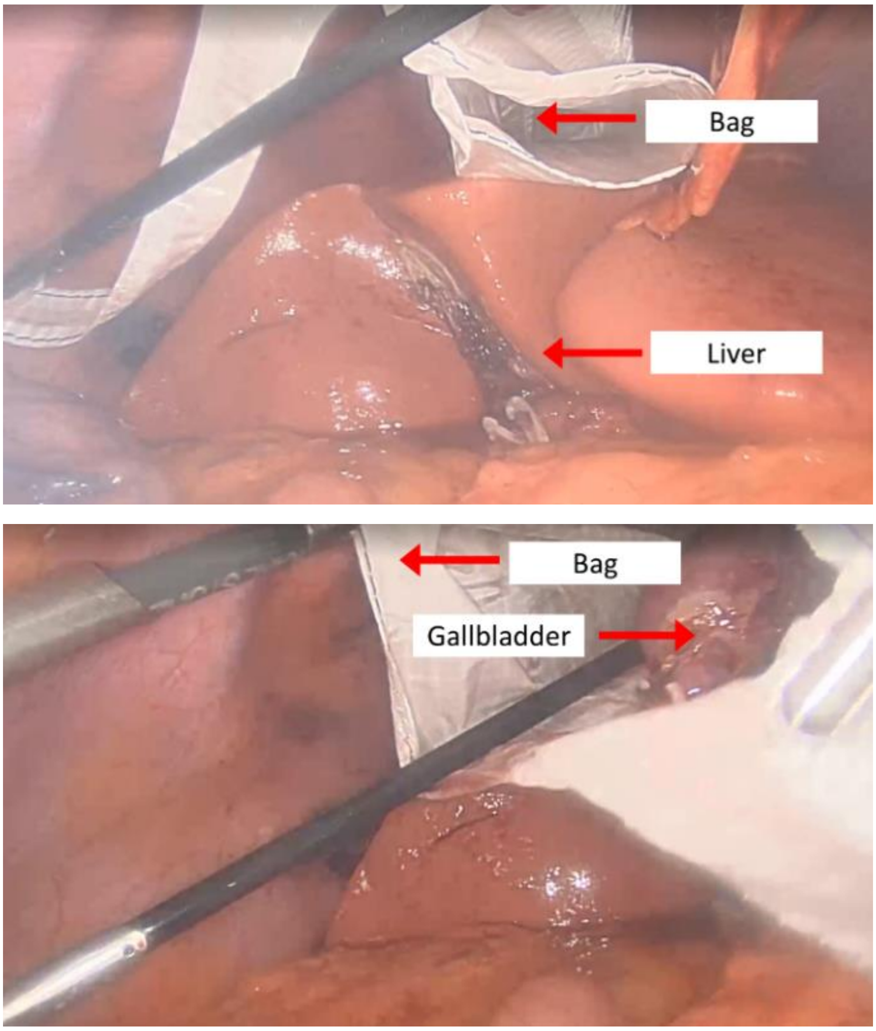

Figure 13: Inserting a bag inside the abdomen (up); placing the gallbladder inside the bag to remove it from the abdomen(bottom) (Clark, 2020)

2.1.9 Closure

In the final step shown in Figure 14, the surgeon would perform washing, and *haemostasis**. They would also place a *drain**, which is a silicon plastic tube. This drain is useful in case the bile leaks. Lastly, the surgeon would close the port sites and apply dressings to complete the procedure.

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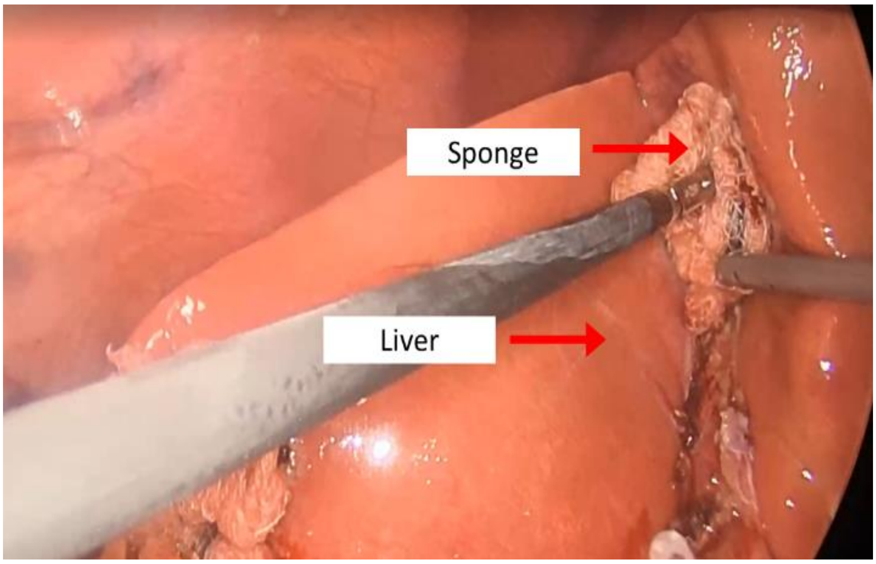

Figure 14: Haemostasis of the liver using a sponge to stop the bleeding (Clark, 2020)

2.2 The place of simulation in medical education

As highlighted in the previous section, LCBDE is a long procedure which involves multiple steps requiring complex technical skills. As such, surgeons would benefit from being able to practice these technical skills.

Trainee surgeons usually practice new technical skills on animal subjects or on human cadavers (Forte *et al.*, 2016). This method, while gold standard, has significant drawbacks including ethical issues and the costs of obtaining subjects and in theatre time. Animal anatomy is different from human anatomy, and training on cadavers has limitations related to tactile feedback because all the tissues have been treated with *formalin** (Phillips, 2017).

Medical simulation aims to provide an alternative way to practice technical skills before performing surgeries on patients. Using a synthetic model ensures ethical training and provides the possibility to train anytime and anywhere.

2.2.1 The place of simulation in practicing surgical skills

Diverse types of simulations have emerged during the last years and simulators are proving to be a promising tool for the surgical training of future generations of surgeons; although it is quite a recent technology, several studies describe the potential of simulators (Meling and Meling, 2020).

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The use of surgical simulators in education is starting to increase. In the United States, surgical education has changed over the last decade, offering more opportunities to train on surgical simulators. In the United Kingdom, Health Education England has produced the Improving Surgical Training project; one of the aspects of which is improving surgical training by including simulation (McIlhenny *et al.*, 2018). However, there is still too little simulation-based skills training, resulting in a lack of experience and manual dexterity in residents (Yaow *et al.*, 2020).

Surgical simulators can benefit surgical training. Previous studies demonstrate that they can achieve the acquisition of new skills faster than using traditional methods. For instance, a study on ultrasound simulators showed that students learning with simulators were faster and could successfully identify *lymph nodes** better than students who learned without simulators (Stather *et al.*, 2011).

Surgical simulators can also have a benefit on *preoperative planning** (Marro, Bandukwala and Mak, 2016). In this case, a simulator is *patient-specific** and mimics a patient's anatomy. A study on their utility for preoperative planning shows that they can improve the *surgical scores** (Morgan *et al.*, 2020). Furthermore, they can have an impact on surgeons' medical decision making. A study reports that using 3D printed cardiac models for preoperative planning had an impact on the surgical approach taken in 47.5% of the cases (Sun *et al.*, 2019).

One of the limitations to their generalisation however is that, despite their potential, their availability depends on the medical specialty. In orthopaedics, surgical simulation is common and has an impact on preoperative planning (Morgan *et al.*, 2020). Even though they are less common in other specialties, many surgeons acknowledge their potential and are interested in using them in the future (Birbara, Otton and Pather, 2019). Nonetheless, commercially available simulators mainly focus on some broadly used surgical skills, and there is a lack of solutions for less common pathologies or anatomies (Cheung *et al.*, 2014).

The price of the available simulators is high, ranging from around a thousand US dollars for a basic physical simulator, to several hundred thousand dollars for a

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*virtual reality (VR)** simulator (Bernier and Sanchez, 2016), and this might be the reason why they are not systematically used in surgeon training.

2.2.2 The place of simulation in practicing sonography*

Ultrasound is an *imaging technique** which can be used for diagnostic purposes (Soni, Arntfield and Kory, 2015). It is one of the steps of LCBDE.

There are two main steps in ultrasound education. The first one includes theoretical knowledge focusing on physics and image acquisition, and the second one includes practices which aim toward the development *psychomotor skills** (Cantisani *et al.*, 2016). These practices can be conducted on a simulator under *supervision** or be *clerkship experiences** with patients (Fox *et al.*, 2007).

Pessin and Tang-Simmons (2018) conducted a survey with those involved in teaching accredited sonography programmes within the United States. Their results showed that 75% of respondents are using simulation during their education curriculum. The respondents also confirmed that simulation as part of sonography education was a good teaching tool (89%) that provided a very positive student experience (81%).

2.2.3 Challenges in the utilisation of simulation in education

One of the difficulties of surgical education is that trainees often require the supervision of an expert to get real-time feedback on their performances. This is a limitation to the generalisation of the training because experts are not always available to supervise training sessions (Gaete *et al.*, 2023). Previous research highlights the potential of using methods other than supervision to assess trainees' skills during their practice sessions, more specifically, computer-based skills assessments. Chan *et al.* (2022) studied the feasibility of using video-based skills assessment in a needle insertion task. They provided examples of performance metrics such as path length, motion smoothness, and elapsed times. In their study, data collection was done using only a camera, which has many benefits because it is cheap, non-obstructive, and accessible.

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2.3 Types of simulators

Because of the need for simulation to practice medicine in a safe environment, different solutions have emerged during recent years. There are three main types of surgical simulators – VR simulators, physical simulators, and *hybrid** simulators:

- VR simulators provide training in a virtual environment; they are like videogames. They provide step-by-step training for complex surgeries. Their main limitations are their price (Alvarez-Lopez *et al*., 2020) and their limited tactile feedback (Dyulicheva *et al*., 2021; Korzeniowski *et al*., 2021). Furthermore, for advanced training, the surgeons require high level of visual realism, but virtual simulator often provides a plastic-like appearance that is not very convincing (Elhelw *et al*., 2006).
- Physical simulators cannot provide as many *surgical scenarios** as the VR simulators and are not able to teach the steps of an entire complex procedure. As such, they are simpler and tend to be aimed at novices. Contrary to the VR simulators, they provide tactile feedback; however, their appearances are often not very realistic. Moreover, they can often be used only one time (Cheung *et al.*, 2014).
- Hybrid simulators aim to combine the benefits of the two methods (Viglialoro *et al.*, 2019). Those simulators usually provide a physical model onto which they add more complexity through virtual techniques. The VR and the physical models can be connected using several methods such as embedding sensors into the physical model or using tracking techniques.

Similarly, ultrasound simulators can also be divided into the same categories (Meuwly *et al.*, 2021; Pessin and Tang-Simmons, 2018).

In the following sections, I provide more details on the different types of simulators, that is physical, virtual, and hybrid simulators, as well as on the state-of-the-art on LCBDE simulators.

* All terms italicised and with an asterisk are defined in Appendix A, the Glossary.

2.3.1 Physical simulators

Physical simulators provide a physical model for surgeons to practice on. When they target the training of surgical skills, they are generally single use only because they get damaged when surgeons practice their surgeries (Cheung *et al.*, 2014). Therefore, it is important to be able to recreate a model multiple times using an established fabrication method.

2.3.1.1 Fabrication method of a physical simulator

The fabrication method of a physical simulator is divided into several steps. First, it requires a 3D model. This model can be created on a computer using *computer assisted design (CAD)** (Nisar *et al.*, 2020), however, this is quite unusual and is limited to simple anatomies. For more complex anatomies, the 3D model is created using the *segmentation** of medical images (Cantinotti, Valverde and Kutty, 2017).

Medical imaging consists of data acquisition of the anatomy of a patient. Using medical images to create a simulator allows for the development of a patient-specific model. Patient-specificity has many benefits, such as better surgical training, preoperative planning, and patient understanding (Hong *et al.*, 2019).

One medical imaging method commonly used to acquire 3D models is magnetic resonance imaging (MRI) (Ryan *et al.*, 2015). Alternatively, previous research has also used multi-detector computerised tomography (Ryan *et al.*, 2015) and ultrasounds (Farooqi and Sengupta, 2015). The medical imaging step is usually followed by image segmentation to determine the geometries of the different soft tissues and generate a 3D model (Ryan *et al.*, 2015).

From the 3D model, a physical simulator is created through 3D printing. The most commonly used 3D printing techniques are Fused Filament Fabrication (*FFF)**, Selective Laser Sintering *(SLS)**, *binder jetting**, *material jetting** and Stereolithography *(SLA)**.

FFF consists of extruding a fused thermoplastic filament onto a heated bed. The melted filament cools and solidifies during the extrusion. This technique is simple and there are a wide range of materials available. Its accuracy is not as good as with

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other 3D printing techniques, and there is a need for post-processing the part to enable a good finish (Garcia *et al.*, 2018).

SLS consists of the fusion of polymer powder to create a solid object. First, a laser selectively heats a thin layer of powder to solidify the first cross-section of the solid, then the bed is slightly lowered, and the machine adds another layer of powder on the top of the last layer. The process repeats itself until the print is completed. This technique is more expensive than FFF; however, it does not require support, which makes post-processing easier. It is also possible to use more flexible materials, which can be useful to mimic the properties of soft tissues (Tejo-Otero, Buj-Corral and Fenollosa-Artés, 2020).

Another technique is binder jetting. This consists of dispersing a binder onto a bed of polymer powder to solidify it locally; the process then follows the same principle as SLS to make multiple layers (Hong *et al.*, 2019). Alternatively, *material jetting** deposits drops of a liquid, and a UV light then solidifies the drops. (Pietrabissa *et al.*, 2020). The Polyjet 3D printer (Stratasys, Eden Prairie, USA) uses this technology to develop models able to mimic the properties of soft tissues (Severseike *et al.*, 2019).

Finally, with the *vat photopolymerisation** technique SLA (Pietrabissa *et al.*, 2020), a laser beam selectively solidifies a liquid resin through photopolymerisation. Vat photopolymerisation and material jetting have the highest resolution (Garcia *et al.*, 2018); however, this technique uses a more limited number of types of materials than FFF, and the materials are generally more expensive than 3D printing filaments. Furthermore, it requires multiple post-processing steps to obtain the final print (Tejo-Otero, Buj-Corral and Fenollosa-Artés, 2020).

There are two main fabrication methods commonly used to build simulation models from 3D models (Smith and Dasgupta, 2019). The first one is to directly 3D print materials that can mimic human tissues. The second option is to create moulds and use these moulds to cast synthetic organs.

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- 3D printing of soft materials

Direct 3D printing can reproduce a large range of soft tissues, from the hardest tissues such as bones (Waran *et al.*, 2014a) to softer tissues (Anderson *et al.*, 2016; Maddox *et al.*, 2018). Direct 3D printing of a phantom can be challenging because the properties of soft tissues vary a lot and some tissues have a very low hardness.

There is a range of flexible materials that can be used to create soft tissue replicas, such as the Tango^{TM} family (Stratasys Ltd, Rehovot, Israel) of photopolymers for PolyJet printing, or thermoplastic elastomer (TPE) filaments for FDM printing (Qiu *et al*., 2018). These are softer than the rigid materials traditionally used in 3D printing and have been previously used in surgical simulation for cardiology, urology, neurology, and pulmonology. In a study by Park and Kim (2022), the authors compared the properties of two direct 3D printing materials for soft tissue simulation to the properties of pig hearts. The investigated materials were Agilus and Tango, which were printed using a PolyJet 3D printer and have been used in previous research to mimic soft tissues. Agilus and Tango were found to be more elastic than the pig heart (10 times and 5 times higher respectively), and to have higher tear resistance (2 times and 4 times), and higher shore hardness (2 times as much for both materials).

In a review by Yu *et al.* (2023), they described the techniques for 3D printing of gels for surgical training. One of the techniques used to directly print very soft gels such as hydrogel is suspension printing, also known as fresh printing. This is based on material extrusion into a support bath and can be used to create complex and very soft tissues such as the brain and blood vessels.

It is also possible to use powder based methods such as starch infiltrated with 3D printing ink (Qiu *et al*., 2018). In the context of surgical simulation, this method was used by Schmauss *et al.* (2015) to create cardiac models from a starch/cellulose powder infiltrated with a polymer binder and an elastomeric resin. This method was also used to fabricate a soft tissue prosthesis in a previous study by Xiao *et al.* (2012), in which the authors used a Zcorp Z510 3D colour printer to print a 3D

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prosthesis with starch powder, a binder, and coloured inks; the print was later infiltrated with medical grade silicone. Their method allows the reproduction of skin colour. Similarly, in another study by Lee *et al.* (2022), the authors used a binder jetting 3D printing process with silicone powder and silicone infiltration to create maxillofacial prostheses. Their process generated silicone prostheses with appealing appearance and good mechanical properties, notably elongation at break and elastic modulus.

3D printing of silicone is very interesting for developing surgical simulators; however, the properties of silicone such as its curing time, viscosity and low elastic modulus make it challenging to print with (Wu *et al*., 2023).

One of the challenges of SLA silicone 3D printing is the viscosity of the silicone, which prevents easy flow of the resin during the printing process (Wu *et al*., 2023). Kim and Tai (2017) have developed modified SLA printers with complex optics systems to create a printing process with a hydrostatic condition that enables the structures to maintain their positions and shapes without any support structures. Other researchers have modified silicone resins to adapt SLA to silicone 3D printing (Bhattacharjee *et al*., 2018; Wallin *et al*., 2020). More precisely, Wallin *et al.* (2020) produced a double network silicone resin that can be directly 3D printed using SLA technology. This resin achieved mechanical properties not yet attainable by commercially available SLA resins in terms of low elastic moduli with a simultaneous high elongation, toughness, and strength. They proved the potential of their formulation by printing hollow synthetic hearts for surgical simulation.

Another approach is to 3D print silicone using material jetting. With this process, an inkjet head deposits droplets of silicone onto a work platform, which then fuse together to form a homogeneous silicone layer. After each layer, a UV light is used to cure the silicone layer (Wu *et al*., 2023). This technique was used by Unkovskiy *et al.* (2018) to 3D print aesthetically pleasing nose prostheses using ACEO printers by Wacker Chemie AG (Munich, Germany) and Riedle *et al*. (2018) to print aortic valves.

* All terms italicised and with an asterisk are defined in Appendix A, the Glossary.

The last option is to 3D print silicone via extrusion, using one of the three following processes: direct ink writing, complete support-embedded 3D printing, or removable support-embedded 3D printing (Wu *et al*., 2023).

Haghiashtiani *et al*. (2020) used the first process and a custom-built Aerotech AGS1000 3D multi-materials printer to fabricate aortic root models. They used four types of inks to mimic the properties of the different soft tissues. They prepared the inks themselves to replicate different values of Young modulus. Yet, one of the limitations of this first process is that the silicone has a low viscosity which can affect the shaping. Both the rheology and the viscosity of the silicone can have an impact on the printing process (Jaksa *et al*., 2021). The process can be improved by adding materials with stronger rheological properties to increase the solidification of the silicone; however, that modifies the properties of the printed silicone. Zhou *et al*. (2019) proposed a solution by altering the nozzle squeezing method. They also added nanosilica to modify the rheology and improve the printability of the silicone; this technique improved the mechanical properties of the outcome.

The second process relies on a complete solidified supporting matrix. First, this matrix is cured into the desired shape, then the printing ink is extruded into the supporting structure to generate a model (Wu *et al*., 2023).

The last process also relies on a supporting structure, but one which is not cured. This allows the printing of very low viscosity and extra-soft materials. Duraivel *et al.* (2023) used this process with a support material made of silicone oil emulsion and managed to successfully print a silicone heart valve model. The silicone oil emulsion had low interfacial tension against silicone-based inks, which allowed the creation of high quality prints even for complex shapes such as a brain aneurysm.

There are commercially available silicone 3D printers. Jaksa *et al*. (2021) listed the following: Wacker Chemie AG (Munich, Germany), which has developed a droplet jetting silicone printer called ACEO where each layer is cured with UV light; Dow Inc. (Midland, USA), German RepRap GmbH (Feldkirchen, Germany) and Fripp Design Ltd (Rotherham, UK) have all developed silicone 3D printers based on an extrusion process. The first process uses a heat source to cure the silicone while the second is based on extruding a catalyst in a bath of base component. Finally, Spectroplast AG (Zürich, Switzerland) uses a vat photopolymerisation process for silicone 3D printing from a liquid silicone bath. The authors listed the following limitations: 1) except for the printers from Dow and GermanRepRap, these printers cannot print empty cavities because of the need for support; 2) these printers are also only suitable for single material printing. In their study, Riedle *et al*. (2019) used a commercially available silicone 3D printer to create a ventricular system in transparent pure silicone with a Shore A hardness of 10. Even though the properties of the model were not completely satisfying, this study shows that a direct silicone 3D printing process can be used to print very soft material for complex geometrical anatomies. Moreover, the Spectroplast SLA silicone 3D printer is commercially available and has been used to print heart valve models (Wu *et al*., 2023). In another study by Wang *et al*. (2023), the commercially available S300 silicone 3D printer (San Draw, Taiwan, China) was used to print cartilage models in silicone through a liquid extrusion moulding process. The authors managed to replicate the mechanical properties of the cartilage, showing the benefit of their method to develop cartilage phantoms.

Using direct 3D printing has the benefit of being a simpler and quicker fabrication method than other approaches. This is particularly beneficial for preoperative planning, where the model needs to be modified in between each patient to remain patient-specific.

- 3D printing of moulds

3D printing of moulds allows for the use of a broader range of materials. The moulds are created by digitally subtracting the organ model's volume from a larger rectangular volume using CAD software (Cheung *et al.*, 2014). This method can reproduce a wide variety of tissues. Especially it can replicate the softest tissues such as abdominal organs (Condino *et al.*, 2011) and the brain (Forte *et al.*, 2016).

* All terms italicised and with an asterisk are defined in Appendix A, the Glossary.

However, moulding techniques have a limitation related to the type of geometry that can be created. For hollow structures, the moulds need to be more sophisticated to be able to remove the model after casting. It is possible to create dissolvable moulds (Mix *et al.*, 2018) or an organ replica by *rotomoulding** (Park, 2016). Another option for some of the organs is to design a mould consisting of multiple parts, usually two outer shells and one inner core (Choi *et al.*, 2020).

2.3.1.2 Characterisation of soft tissues

Physical simulators not only aim to replicate the anatomy using a suitable fabrication method, but they also aim to replicate the properties of soft tissues. Thus, creating a good physical simulator requires the selection of suitable synthetic materials (Pacioni *et al.*, 2015).

The synthetic materials used for physical simulators aim to recreate the characteristics of soft tissues, such as their tactile feedback with their physical properties or their ultrasound images with their *acoustic properties** (Pacioni *et al.*, 2015).

To be able to mimic the characteristics of soft tissues, it is important to describe them accurately. There are different ways to describe soft tissues, using both quantitative and qualitative methods. Quantitative methods include measures such as their physical and acoustic properties (Herman, 2010), while qualitative methods include descriptions of their feedback.

- Physical characterisation

Quantitative methods focus on investigating physical properties though physical tests. There are two main methods employed to perform these tests on soft tissues, which are *in vivo** tests on a living subject and *in vitro** tests on extracted tissue.

The main *in vivo* technique used to evaluate soft tissues' properties is an *indentation test**. Indentation tests study how the tissue reacts under a controlled compression (Frauziols *et al.*, 2016). They can evaluate superficial tissues (Abdouni *et al.*, 2017) or deep tissues such as abdominal organs (Hollenstein and Bajka,

* All terms italicised and with an asterisk are defined in Appendix A, the Glossary.

2012); however, evaluating deep tissues results in an invasive procedure because it requires applying pressure to the tissues inside the abdomen cavity.

Another method is to carry out *in vitro* tests on soft tissues. These can evaluate a greater variety of parameters because there are no constraints related to performing tests on living subjects. They are often used to test animal (Andrikakou, Vickraman and Arora, 2016) or human tissues (Forte, Gentleman and Dini, 2017).

The characterisation of soft tissue often consists of *in vivo* animal tissues, or *in vitro* animal or human tissues. Animal tissues from different species do not have the same properties; consequently, the properties of human tissues cannot be determined from tests made on animals. Studies also show that *in vivo* and *in vitro* responses of soft tissues differ (Rosen *et al.*, 2008; Tay, Kim and Srinivasan, 2006). For these two reasons, the properties of human internal tissues *in vivo* cannot precisely be determined. There are only a limited number of measures available to evaluate human abdominal tissues *in vivo*, which are not enough to accurately characterise the complexity of the tactile feedback.

My literature review obtained the information shown in Table 2 about the soft tissues involved in a gallstone surgery – that is, the common bile duct, the gallbladder, the artery and vein, the liver, the skin, the fat, the muscle, and the peritoneum. Because the authors usually mention when the properties they report are those of diseased tissues (Mancia *et al.*, 2019), I hypothesised that otherwise the tissue was healthy.

Table 2: Physical properties of the soft tissues

Physical Parameter	Common bile duct	Gallbladder	Blood vessels	Liver	Skin	Fat	Muscle	Peritoneum
Young modulus (kPa)	500 [2]	50 [1] - 500 [2]	160 [4]	6.5 [6] – 20 [1]	200 [8] – 300 [1]	0.5 [8] – 100 [10]	20 [1] – 50 [6]	932 [10]
Ultimate strain (%)	NF	43 [3] – 53 [1]	63 [3]	32.6 [7] – 46 [1]	58 [1]	NF	61 [1]	26 [11]
Ultimate stress (MPa)	NF	2.1 [1] – 2.5 [3]	1.4 [3]	0.024 [1] – 1.85 [7]	3.8 [1] – 20 [8]	NF	0.11 [1]	0.37 [11]
Hardness (shore)	NF	NF	00-41 [5]	OOO - 52 to OO -25 [6]	OO - 10 [9]	NF	O-35 to A – 25 [6]	NF

[1] (Herman, 2010): healthy human and rabbit tissue (rabbit gallbladder and liver, human skin and muscle)

[2] (Li, 2020): healthy human tissue

[3] (Mancia *et al.*, 2019): healthy human tissue

[4] (Ma *et al*., 2020): healthy human tissue

[5] (Maclean, Brodie and Nash, 2010): healthy bovine tissue

[6] (Fenollosa *et a*l., 2019): healthy human tissue

[7] (Umale *et al.,* 2013): healthy porcine tissue

[8] (Gefen and Dilmoney, 2007): healthy human tissue

[9] (Jorgensen, Sheets and Zhu, 2015): healthy human tissue

[10] (Kuzin, Khakimov and Yukhin, 2001): healthy human tissue

[11] (Kao *et al.*, 2019): healthy rat tissue

- Acoustic characterisation

Quantitative methods can also focus on investigating the tissues' acoustic properties, to mimic the ultrasound images obtained with sonography. Sonography is a medical imaging technique based on the propagation of ultrasound waves into the body (Alkins and Hynynen, 2014).

A sonographic examination is performed by putting an ultrasound probe in contact with the patient. The ultrasonic wave generated by the ultrasound probe is transmitted into the body and interacts with the soft tissues in a predictable way. There are four types of interactions: *scattering** of the wave when it hits a small

* All terms italicised and with an asterisk are defined in Appendix A, the Glossary.

object, absorption of the wave from the tissue, and reflection and *refraction** at an interface between two types of tissues. Some of the wave is reflected back to the probe, and that is what generates the image (Paredes, 2018).

Different tissues do not return the same types of images during an examination. Some tissues are *echoic** or *hyperechoic**, they appear white or bright because they reflect most of the wave back to the probe. Other tissues are *anechoic** or *hypoechoic**, they absorb most of the wave and appear black or dark on the screen (Paredes, 2018). These differences are due to the *acoustic impedance** of the tissues, *Z*, which characterises a material's resistance to sound wave propagation. The following formula can calculate this acoustic impedance:

$$Z = \rho\vartheta \tag{1}$$

Where ρ is the density of the material in kg/m^3 and ϑ is the speed of sound in the material in m/s. The impedance Z determines the reflection and transmission of the wave at an interface and influences the generated image (Alkins and Hynynen, 2014).

The image also depends on the soft tissues' attenuation coefficient and scattering coefficient; these parameters influence the portion of energy of the wave which is absorbed by the tissue and the scattering from the wave. Nevertheless, the scattering contribution is relatively small compared to the absorption (Alkins and Hynynen, 2014).

My literature review obtained the information shown in Table 3 on the soft tissues involved during an ultrasound examination performed to evaluate gallstones in the context of a LCBDE – that is, the typical soft tissue, the gallbladder, the artery and vein, the liver, the muscle, the skin, and the fat. Similarly, I hypothesised that the tissue was healthy unless specified otherwise.

* All terms italicised and with an asterisk are defined in Appendix A, the Glossary.

Table 3: Acoustic properties of the soft tissues

Ultrasound parameter	Soft tissues	Common bile duct	Gallbladder	Blood vessels	Liver	Muscle	Skin	Fat
Speed of sound (m/s)	1540 [1]	1600 [3]	1584 [3]	Blood: 1580 [4] Vessels: 1560 [4] – 1626 [3]	1540 [6] – 1595 [7]	1547 [7] – 1595 [9]	1631 [9]	1435 [9] – 1478 [7]
Attenuation (dB/cm/MHz)	0.75 [1]	NF	Bile: 0.013 [4] – 0.031 [4]	Blood: 0.21 [4]	0.5 [7] – 0.7 [6]	1.09 [7] - 1.47 [9]	0.22 [9]	0.48 [7] – 0.97 [9]
Density (kg/m3)	1060 [2]	1060 [3]	Bile: 995 [4] – 1015 [4] Gallbladder: 1010 [4] – 1032 [4]	Blood: 1050 [5] -1075 [4] Vessels: 1050 [3] -1063 [2]	1050 [8] -1060 [6]	1041 [9]	1100 [9]	916 [2]
N (scattering)	*NF*	NF	NF	Blood: 0.034 [4]	0.1 [4] – 1.5 [4]	1.15 [9]	1.15 [9]	1.09 [9]

[1] (Soni, Arntfield and Kory, 2015): healthy human tissue

[2] (Vlaisavljevich *et al.*, 2013): healthy porcine tissue

[3] (Mancia et al., 2019): healthy human tissue

[4] (Duck, 1990): healthy human tissue

[5] (Ma et al., 2020): healthy human tissue

[6] (Pacioni *et al*., 2015): healthy human tissue

[7] (Ceh, Peters and Chen, 2015): healthy human tissue

[8] (Tejo-Otero, Buj-Corral and Fenollosa-Artés, 2020): healthy human tissue

[9] (Maggi *et al.*, 2009): healthy human tissue

- Perceptual studies

It is also possible to use qualitative studies to describe the tactile feedback from the soft tissues, by conducting *perceptual studies**. Perceptual studies are used to evaluate perceptions; more precisely, they study the feedback we get from our five senses.

In studies focusing on the sense of touch, perceptual studies are used to assess how human get feedback from an object (static touch and dynamic touch) and what kind of feedback we gain from the object. These types of studies can gather a wide

* All terms italicised and with an asterisk are defined in Appendix A, the Glossary.

range of information (Bergmann Tiest, 2010) and have the potential to determine tactile feedback during surgeries. To my knowledge, this method has never been used in the context of choosing materials for a surgical simulator; however, it is commonly used in the textile industry to evaluate how buyers perceive clothes (Ding, Pan and Zhao, 2018; Xue *et al.*, 2014).

Participants can either provide a free description (Xue *et al.*, 2014) or evaluate their sensations according to a list of predefined characteristics (Ding, Pan and Zhao, 2018). In cases where participants provide a free description, they take part in a brainstorming session to describe their sensations. However, in using their own words to describe a complex concept such as texture, participants use different synonyms to describe the same sensation, leading to a complex interpretation of the results. An analysis can avoid this confusion; to this end, Xue *et al.* (2014) asked textile specialists to describe the sensations of touching different pieces of clothing, creating a thesaurus of sensations. This study only included five participants but garnered more than 200 qualificatives; the authors conducted an analysis of which showing that many of the words are correlated, and they could decrease the size of their list to 22 pairs of opposite sensations. It is also possible to select the most important terms using their frequency (Mirjalili and Hardeberg, 2019).

Having a small list of predefined qualificatives is another method commonly used to conduct perceptual studies; in that case, the participants know that they must evaluate the samples according to the factors on the list. This type of study gathers less general information, but it allows more emphasis to be placed on the identified qualificatives. It also enables researchers to make a quantitative analysis by using scales to evaluate each predefined qualificative (Ding, Pan and Zhao, 2018; Rakhin and Onkar, 2018; Xue *et al.*, 2014).

Many different scaling methods have been used to quantify sensations. In her review, Lim (2011) compared the advantages and disadvantages of different rating scales. There are different classifications among these scales which can be used for categorisation, ranking, measuring degrees of difference, or approximating magnitudes. The types of evaluation can also be divided into categories: active vs

* All terms italicised and with an asterisk are defined in Appendix A, the Glossary.

passive – whether the participant has access to a sample or not; absolute vs relative – where the participant grades one sample on a scale or compares different samples against each other (Royer *et al*., 2022).

The 9-point hedonic scale is a balanced bipolar scale around neutral at the centre with four positive and four negative categories on each side. This scale has many advantages as it is easy for the researcher to use and for the participant to understand. The results can be analysed using parametric tests. The disadvantages are the limited options to answers, making this scale more appropriate for identifying preferences and ranking rather than fine comparisons. As such, it is difficult to use this scale to discriminate between ranges of liking. Furthermore, previous studies show that there is a need for at least 75 responses before parametric tests can be used, in order to meet the hypothesis of normality (Lim, 2011).

Another type of scale is used for magnitude estimation (ME). This aims to enable more fine discrimination between sensations. In this case, participants have to assign numbers to sensations without semantic aids, and the numbers should reflect the ratios of the perceived intensity of sensations. For example, a sensation twice as intense as another should be assigned a number twice as large. Usually, it is also divided between positive and negative numbers to reflect like/dislike. However, this rating scale has been widely discussed in terms of its validity, its ability to compare between participants, and for participants' capacity to accurately estimate sensation ratios (Lim, 2011).

Another type is the category-ratio scale. This includes a line scale that has verbal descriptors of magnitude placed at different positions in a quasi-logarithmic manner. These descriptors should provide some degree of ratio. The aim is to enable evaluation of intensities of perception whilst still getting a more "absolute" value than with the magnitude estimation scale. This scale has been adapted multiple times and comes in several forms. This type of scale has shown potential in distinguishing between very intense sensations and is also valuable since it is easy

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for participants to understand, and it generates normal distributions. One limitation of this scale is that it tends to compress the data because it gives more space for extreme sensations which are less frequent (Lim, 2011).

Another type of scale is the relative scaling method. One such example is to use a rank rating method to measure relative intensity between two stimuli. Another example is to define the scale's maximum and minimum by selecting the samples with the most and least intensity, then grading the other samples intermediately. This second method requires the least training time for participants and makes them use the full range of the scale, however it results in not normally distributed data and its power of discrimination is not as strong as for the 9 point hedonic scale (Lim, 2011).

Previous studies have compared these scales. Ribe (2022) described a comparative study between three rating scales for psychophysical experiments in the context of aesthetic perception. The aim was to compare how robust these different rating scales were to block out noise from different participants and to reflect the underlying perception felt by the majority of people. The three types of rating scale were: first, a numerical rating scale from 1 to 10 with the following instruction: "The rating scale goes from 1, for very low scenic beauty, up to 10, for very high scenic beauty"; second, a bipolar scale evaluating beauty from -5 to +5 with a zero to allow for a neutral response and the direction: "Please circle one number for each picture, according to how much scenic beauty or ugliness you think it shows. Circle positive numbers for beautiful scenes and negative numbers for ugly scenes"; and third, a bipolar scale evaluating the beauty from -5 to +5 without a zero, giving the same instructions. The ratings were averaged before analysis, then the study compared the rating scales by evaluating several responses for each rating scale, the mean square error (MSE) of measurement for each photo, and the average and variance of these MSEs across all the photos. A lower MSE showed a higher reliability of the results and the rating scale, with the lowest MSE being the evaluation from 1 to 10.

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In another study by Aveline, Thomas-Danguin and Sinding (2023), the authors compared Visual Analog Scales (VAS) and ranking methods to evaluate perceptions. VAS scales are commonly used but have been criticised as they are subject to several biases. Notably, using this scale, participants usually avoid using the scale extremities. Ranking evaluations are based on a comparison between samples and have been praised for their easy implementation and analysis. In the study, participants had to grade sensations on visual analogue scales (VAS) which were labelled from left, “not intense” to right, “very intense”, and to rank order samples from lowest to highest according to the intensity of the sensation. The results show that rank ordering is more suitable for highlighting subtle differences. However, the authors also noted that ranking should be limited to a few items, with no more than 6 to 8 items being assessed at the same time.

In their review, Royer *et al.* (2022) stated the importance of paying attention to the validity of a scale, i.e. ensuring that the scale actually captures the intended investigated variable and does not overlap with other parasite factors. It should also be reliable and ensure consistency and repeatability. There are many types of biases that can affect the validity of responses, such as contraction bias where participants tend to overestimate small intensities and underestimate large values, or centring bias where most participants choose the central values of the scale. Furthermore, there are discussions surrounding the number of points on a scale, the order of the labels, and the availability of a neutral response to ensure the effectiveness of any rating scale. In this study, the authors recommended using a rating scale made of intervals with at least 5 values and without assigning words to intermediate points of the scale.

The data analysis of these psychophysical experiments consists of statistical analysis; however, before conducting this statistical analysis, researchers must pay attention to the hypothesis of the models. The analysis will differ depending on whether the data are interval or ordinal and whether it is possible to use parametric tests or not (Royer *et al*., 2022).

* All terms italicised and with an asterisk are defined in Appendix A, the Glossary.

2.3.1.3 Commonly used materials

The materials commonly used for surgical simulation are different from the ones used for ultrasound simulation. Indeed, in each case, the synthetic materials aim to replicate different properties of the soft tissues, which are their physical or acoustic properties.

- Synthetic materials for surgical simulation

A review of the literature reveals the materials most commonly used for physical surgical simulators. The choice of material depends on the type of fabrication method, mainly moulding or 3D printing, and on the targeted organ or soft tissue. This is due to the great diversity between different tissues, which vary considerably from the softest tissues such as the brain and the lungs, to the hardest tissues such as the bones.

For direct 3D printing, previous research illustrates the use of different types of material, including flexible filaments (Birbara, Otton and Pather, 2019; Hong *et al.*, 2019; Anderson *et al.*, 2016) and photopolymers (Birbara, Otton and Pather, 2019; Hong *et al.*, 2019; Maddox *et al.*, 2018). These two types of materials are commonly used to mimic muscular structures such as the heart, thyroid or fibrous capsule. For rigid structures such as the bones, prior research has shown the possibility of working with SLA and Durable resin (Kokko *et al.*, 2022).

For the casted materials, a common option is to use silicone, because its physical properties can reproduce those of human tissues (Riedle *et al.*, 2019; Pacioni *et al.*, 2015; Cheung *et al.*, 2014; ondino *et al.*, 2011). Silicone is a versatile material for casting surgical simulation models; indeed, the transparent types can be useful for allowing observation of internal components; otherwise, it is possible to add colourant into the silicone to reproduce the appearance and colours of real organs (Condino *et al.*, 2011). Polyurethane is an alternative material used to mimic the same types of soft tissue (Rethy *et al.*, 2018).

Another casting material that is widely used is hydrogel, because of its softness and its properties which are similar to the softest organs. Brain and lung tissues are the

* All terms italicised and with an asterisk are defined in Appendix A, the Glossary.

softest tissues in the human body (Tan *et al.*, 2017), and previous researchers have used hydrogel to make brain and lung tissue simulators (Forte *et al.*, 2016; Ryan *et al.*, 2015). Earlier research has also focused on other types of gels, such as Polyvinyl acetate (PVA) (Melnyk *et al.*, 2019; Park, 2016; Ceh, Peters and Chen, 2015), poymethyl methacrylate (PMMA) (Rethy *et al.*, 2018), Polydimethylsiloxane (PDMS) (Zhou *et al.*, 2016), or Polyvinyl chloride (PVC) (Ceh, Peters and Chen, 2015).

The properties of all these materials can be adjusted to mimic the properties of human tissues. For instance, when using silicone, mixing the silicone with another agent modifies the stiffness of the outcome (Kokko *et al.*, 2022; Cheung *et al.*, 2014). Similarly, the properties of a hydrogel can be adjusted by varying the *agarose** concentration to give the correct feel of an organ such as a liver (Condino *et al.*, 2011). It is also feasible to modify the properties of other polymers using the same method (Tejo-Otero, Buj-Corral and Fenollosa-Artés, 2020).

Similarly, when the simulation model is directly 3D printed, a PolyJet 3D printer can blend hard and soft materials during the build process to simulate the tactile feel of a human organ (Severseike *et al.*, 2019). Achieving varying properties is also an important aspect of silicone 3D printing. Qiu *et al*. (2018) adjusted their silicone ink to replicate the properties of prostatic tissues. They developed customised inks for soft tissue phantoms which can mimic the physical properties of soft tissue. Jaksa *et al*. (2021) developed a silicone 3D printer with tuneable mechanical properties. To do so, they attached a print head enabled for silicone onto a FFF 3D printer. Doing this, they made a bi-material print with silicone and PLA. Using this process, they successfully managed to print a rib cage and surrounding soft tissues. In another study, Young *et al*. (2022) explored how to 3D print silicone with variable stiffness. To do this, they used a FFF process which extruded into a gel support matrix using two heads containing different types of silicone. They varied the extrusion rate of the print heads to modify the ratio of the two materials and managed to 3D print silicone with differing gradients of stiffness.

Some of the soft tissues are more complex to simulate because of their heterogenous properties, and this is the case for muscle, which is fibrous. In a

* All terms italicised and with an asterisk are defined in Appendix A, the Glossary.

previous study, Kokko *et al.* (2022) used polystyrene coated with foam to mimic muscle.

- Comparison between moulded and 3D printed silicone

Silicone is a commonly used material for surgical simulation. Previous work shows that it can be either moulded or directly 3D printed. There are studies comparing the results of silicone 3D printing with traditional moulding processes. In one such study by Yirmibesoglu *et al*. (2018), a silicone 3D printer with an extrusion process was used to create DragonSkin samples for soft robotics. The results of the 3D printing were compared to samples made though traditional moulding processes and indicated that 3D printing allowed samples to be developed which had a similar or better performance than traditional fabrication methods. Jaksa *et al.* (2021) also noted that using traditional modelling techniques such as casting results in fully dense parts, but it could be useful to have more control in order to mimic the mechanical properties correctly. In a more recent study, Jaksa *et al.* (2023) showed that directly 3D printing silicone with an extrusion process can successfully be used to 3D print a liver. It also proved that, by using a lower infill of silicone and filling with silicone oil by using two print heads, it is possible to create a phantom with better mechanical and radiological properties than a phantom made fully of silicone. This shows that 3D printing has the potential to create samples with more interesting properties than traditional silicone fabrication techniques such as casting. However, this process is also time consuming, and printing a full size liver would require several days.

Riedle *et al.* (2018) stated that traditional silicone fabrication methods have limitations in the geometries they can produce because of the casting process. For example, cavities and undercuts are complex to create through moulding. In their research, they compared direct 3D silicone printing to moulding in the context of creating models for surgical simulation. For the direct 3D printing in their study, the authors used the commercially available ACEO 3D printer. They notably compared the direct 3D printing to the moulding of an aortic valve and of a lip cleft model. To cast the lip model, they used two different silicones with various shore hardness to

* All terms italicised and with an asterisk are defined in Appendix A, the Glossary.

mimic the different types of soft tissues. Because the anatomy is complex, they had to use six-part moulds. For the direct 3D printing, it was not possible to use multiple materials with the ACEO 3D printer, so they made two separate prints that they later assembled together. They found that there was no difference in behaviour between the models made through the two fabrication processes. The direct 3D printing allowed the creation of cavities and undercuts as well as thin-walled structures. As these types of geometries are complex to create through moulding, direct 3D printing seems more suitable for producing complex models in limited numbers. However, for simple geometries such as the liver, moulding is more appropriate, especially for producing large volumes.

With direct 3D printing, there was the issue that the print layers were visible on the silicone print. Because silicone is soft, it is complex to remove these lines with mechanical smoothing (Riedle *et al.,* 2018). In the study on facial prostheses, removing print lines was especially important and was conducted using two methods: the first was silicone coating and the second was finishing with a fine milling cutter and subsequently sealing in the same manner (Unkovskiy *et al.*, 2018).

- Synthetic materials for ultrasound simulation

To be visible with ultrasounds, a simulator should have the same acoustic properties as soft tissues. Contrary to surgical simulators which are sometimes 3D printed, most examples of ultrasound simulators in the literature are directly cast into moulds. The materials are often made of a *bulk agent**, usually gel based, and a *scattering agent**, which must be incorporated into the bulking agent (Rodriguez, 2017).

The commonly used materials for the bulk agent are gel based, such as agar gel (Chazot *et al.*, 2022; Trumpour *et al.*, 2022; Ahmad *et al.*, 2020), polyurethane gel (Ahmad *et al.*, 2020; Rethy *et al.*, 2018), PVA (Park *et al.*, 2021; Ahmad *et al.*, 2020; Choi *et al.*, 2020; Jayarathne, 2018; Mix *et al.*, 2018), gelatine-alginate (Ahmad *et al.*, 2020), agarose (Diab *et al.*, 2019), PVC (Young *et al.*, 2022; Chiu *et al.*, 2020;

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Jayarathne, 2018), synthetic gel (Morrow, Cupp and Broder, 2016), or gelatine (Rodriguez, 2017). Less frequently, silicone is also mentioned as an option for the bulk agent (Ahmad *et al.*, 2020; Pacioni *et al.*, 2015), but silicone is limited because its sonographic properties differ from the properties of soft tissues, notably on the speed of sound.

The scattering agents are powders such as Sephadex G2580 (Rethy *et al.*, 2018), glass powder or glass beads (Choi *et al.*, 2020; Diab *et al.*, 2019), calcium carbonate powder (Mix *et al.*, 2018), graphite (Pacioni *et al.*, 2015), methylene blue (Diab *et al.*, 2019), flour (Rodriguez, 2017), or Metamucil (Rodriguez, 2017). They are usually mixed into the bulk agent with a percentage of between 0.1%w/w and 5%w/w.

Previous research shows that silicone offers poor image quality in contrast to gels such as PVA, PVC, and agar. Furthermore, silicone cannot replicate the characteristics of soft tissues such as the speed of sound, contrary to gels like PVC. However, gels have a lower *shelf life**, which can be a challenge when using them for multiple training sessions. Some of the materials such as PVA are more complex to handle, because they require freezing cycles (Ahmad *et al.*, 2020).

For ultrasound imaging, a literature review by Filippou and Tsoumpas (2018) demonstrates that printed ultrasound simulators can either combine direct and indirect 3D printing techniques using moulding, or use specific printing materials such as agar-based mixtures or silicone gel. When using commercially available printing materials, it is difficult to mimic the acoustic properties of soft tissues because the information regarding speed of sound, acoustic impedance, and attenuation coefficient are lacking (Filippou and Tsoumpas, 2018).

Still, direct 3D printing can also be used to create medical imaging simulators. In their study, Hatamikia *et al.* (2022) used an extrusion process to create a silicone phantom for CT; by varying the type of silicone and the infill, they managed to replicate the properties of multiple types of soft tissues. Previous studies have investigated direct 3D printing of imaging phantoms, but have usually focused on CT (Wang *et al*., 2020). The materials used for ultrasound phantoms are usually gels

* All terms italicised and with an asterisk are defined in Appendix A, the Glossary.

that cannot be directly 3D printed. Wang *et al.* (2020) investigated using direct 3D printing to develop an ultrasound imaging cardiac phantom. They tested both a high-end PolyJet printer with TangoPlus material and an FFF printer (WASP Delta 2040, Italy) using Poro-Lay material (Kai Parthy, Germany). The results indicate that the properties of the Poro-Lay filaments, especially Lay-fomm 40, are suitable for mimicking cardiac muscles and could produce ultrasound images with less artefacts and boundary reflection than the TangoPlus materials.

2.3.2 Virtual reality simulator

It is also possible to employ VR simulators as virtual models for surgeons to practice on. They provide some level of visual realism but fail to provide tactile feedback (Dyulicheva *et al.*, 2021; Korzeniowski *et al.*, 2021). Thus, they are not the most appropriate tool for teaching surgical skills; however, they have been used in the context of creating synthetic ultrasound images.

2.3.2.1 Virtual reality-based ultrasound image synthesis

Virtual simulators are valuable as they can provide a great variety of anatomies and pathologies (Blum *et al*., 2013). Several methods are commonly used to simulate ultrasound images with computers.

- Interpolative method

The interpolative method is also the most common (Blum *et al*., 2013); with this method the ultrasound image is interpolated from an 3D ultrasound volume that has been pre-recorded from patients (Heer *et al*., 2004). The 3D ultrasound volume can either be directly recorded (Persoon *et al*., 2010) or 2D ultrasound images can be recorded and then processed off-line to create a 3D ultrasound volume. The data acquisition protocol for this method is the most complex (Kutter, Shams and Navab, 2009).

During the simulation, the ultrasound plane can be deduced from the position of the probe. The ultrasound image is then produced by re-slicing the 3D data and extracting a 2D plane, followed by post-processing to add motion or artefacts. This

* All terms italicised and with an asterisk are defined in Appendix A, the Glossary.

method is fast and can generate images in real-time. However, the image is often only realistic if the person using the simulator remains close in position and orientation in comparison to the data acquisition. If the difference increases, the simulation fails to reproduce realistically view-dependent artefacts (Kutter, Shams and Navab, 2009). To address this limitation, it is possible to record 3D volumes from multiple viewpoints, remove view-dependent artefacts from the recorded images such as speckles using Gaussian filters, shadow using masks, and finally add view-dependent artefacts back onto the simulated image, such as shadows, using a ray-tracing algorithm (Ni *et al*., 2011).

- Generative image-based methods

The generative image-based simulates wave propagation into the 3D volumes or 3D mesh. The 3D volumes are usually CT or MRI (Qin *et al*., 2012). This method provides easier data acquisition for view-independent models in comparison to the interpolation method and is particularly useful for patient specificity where easy data acquisition is more important (Magee *et al*., 2007). There are two types of ultrasound interactions in soft tissues: when the wave interacts with structures smaller than the wavelength, this causes scattering and speckles in the image; when the wave reaches an interface between different tissues, the wave is reflected, refracted and transmitted.

The quality of the simulated ultrasound image depends on the physical model used to mimic wave propagation and on the tissue properties in the volumes. The volume first needs to be segmented, then the wave propagation can be simulated using one of the three following techniques (Burger *et al*., 2013).

The most complex and precise technique is to solve the wave equation as in FIELD II, by calculating the spatial impulse response (Jensen, 1996). In another example, Karamalis, Wein and Navab (2010) used the Westervelt equation which can be solved using the Finite Difference Scheme. They accelerated calculation with GPU because these techniques are too slow for real-time synthesis. One limitation of FIELD II is that it can only mimic linear ultrasounds. Varray *et al*. (2011) developed a

* All terms italicised and with an asterisk are defined in Appendix A, the Glossary.

new nonlinear ultrasound simulator by generalising the angular spectrum method to simulate wave propagation in homogeneous nonlinear media.

The second technique is to simulate the ultrasound image by generating speckles. The speckles can be simulated using scatterers' distribution of varying amplitudes and a convolution model. The linear convolution model was first described by Bamber and Dickinson (1980); this method is based on the convolution between tissue scatterers and the point spread function (PSF). 3D convolution is also time consuming and previous researchers have made hypotheses and simplifications to decrease computation time, such as using 2D convolution models, using a 1D marked regularity model followed by a fast Hilbert filling curves algorithm to extend the line to the 2D or 3D space (Dillenseger, Laguitton and Delabrousse, 2009), or reducing 3D convolution into multiple 1D convolutions (Gao *et al*., 2009). The convolution can also be computed using either a direct approach or a grid approximation; the direct approach makes a loop over each scatterer and is very time consuming, while the grid approximation approach is less precise but significantly faster. It is also possible to accelerate computation time using GPU and parallelisation by calculating the position and amplitude of scatterers separately (Gjerald *et al*., 2012).

The last technique is to use ray-tracing, but this technique can only be used to simulate structures larger than 1mm. It mimics reflection, refraction and transmission at interfaces between tissues (Mattausch and Goksel, 2016), usually using Snell's law and Fresnel's law to determine the intensity of the reflected and transmitted rays (Bürger, Abkai and Hesser, 2008). In their study, Mattausch and Goksel (2016) argued that most research considers tissue interfaces as perfect mirrors, resulting in unrealistic behaviours. In their work, they simulated the reflection from rough imperfect surfaces by computing multiple reflections. They used Monte-Carlo methods to generate many random rays that were perturbed according to a probability distribution. With the ray-tracing technique, the wave absorption is also mimicked using Beer-Lambert's law (Law *et al*., 2011). These two latter approaches can be combined to simulate both speckles and large-scale

* All terms italicised and with an asterisk are defined in Appendix A, the Glossary.

behaviours of the wave (Satheesh and Thittai, 2018; Bürger, Abkai and Hesser, 2008).

- Texture-based methods

Another possibility is to use texture obtained from ultrasound images or artificial textures (Bo and McKenzie, 2011). Zhu *et al*. (2007) and Magee *et al*. (2007) reconstructed ultrasound images by assigning a texture to each tissue type in a plane extracted from a segmented 3D CT scan. This texture was derived from a 2D ultrasound dataset. In another example, speckles were simulated using pre-computed texture (Vidal *et al*., 2008). With texture-based techniques, ultrasound-specific artefacts are not mimicked well. To make the appearance of the simulated image more realistic, Zhu *et al*. (2007) added Gaussian distributed artificial noise to simulate the speckle effect, a 2D ray casting approach to simulate shadows, and radial blur effect to simulate the radial scanning motion.

- Artificial Intelligence (AI)-based methods

In AI-based methods, there are two main approaches to generating ultrasound images (Mendez *et al*., 2023). The first approach aims to learn the mapping from a random distribution to the distribution of the ultrasound dataset, for instance using deep convolutional Generative Adversarial Networks (GANs) (Singh, Mehta and Chatterjee, 2021). The other approach aims to learn how to transform images from domain A to domain B so as to perform image to image translation. For example, Liang *et al*. (2020) used GANs to generate ultrasound images from sketches, and Grimwood *et al*. (2021) performed CT-to-endoscopic ultrasound translation. These methods have also been used to improve the realism of computer generated ultrasound images (Peng *et al*., 2019; Tom and Sheet, 2018; Zhang, Portenier and Goksel, 2021). In a study by Hu *et al*. (2017), GANs were trained on a dataset of calibrated ultrasound images to learn how to generate images at given 3D spatial locations during training.

* All terms italicised and with an asterisk are defined in Appendix A, the Glossary.

- Moving models methods

There are also methods which can simulate moving anatomy (Blum *et al*., 2013). These methods often use 3D mesh as their input; it is also possible to calculate deformation of volumes but it is more computationally heavy and it is challenging to simulate complex deformations because of the risk of discretisation errors. The size of the mesh is adapted to the geometry, for instance it is finer for thin structures (Law *et al*., 2011).The deformations of the mesh are usually based on freeform deformations (FFDs), mass spring systems (MSSs), and finite element methods (FEMs). The first method is suitable for generating known movements such as breathing. Both MSSs and FEMs are suitable for simulating user induced deformations, the FEMs are more accurate but slower (Burger *et al*., 2013). Then, the methods map the ultrasound image pixels, which are created using one of the previously-described methods such as the texture-based methods or the generative image-based methods to the deformed mesh using a point location operation to obtain pixel intensity through interpolation (Goksel and Salcudean, 2009), or add motion onto the 3D scatterers' distribution (Alessandrini *et al*., 2015).

2.3.2.2 Visual appearance reproduction or enhancement methods

Visual feedback is very important during surgery, notably because the organs' surfaces have characteristics that provide important information to surgeons, such as depth cues or indicators of pathologies. This is why it is important to represent the organs' textures correctly (Elhelw, 2020). Computer graphics techniques can be used to generate photorealistic rendering; however, photorealistic rendering of surgical simulation is complex because of the diversity of textures and colours, the deformation of the tissues during the simulation, and the mucous layer (Lim, Jin and De, 2007).

- Texture

To mimic the appearance of the soft tissues, it is possible to use textures to reproduce organ skin colour and texture. One option is to directly create a 3D texture. This offers a high level of realism; however it is too computationally heavy

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for real-time application in surgical simulation. Berndt, Torchelsen and Maciel (2017) recently used the Visible Human dataset to create 3D textures able to mimic any type of tissue. Using 3D texture is useful for avoiding the texture mapping step.

The other option consists of synthesising a 2D texture and then mapping it onto the 3D organ mesh (Liu *et al*., 2012). Szekely *et al.* (2000) have created a texture database for different organs, including pathological cases.

There can be difficulties when using mapped textures because of mapping distortion, but this can be fixed by using undistorted pattern mapping with triangular tiles for isotropic and homogeneous textures. Neyret, Heiss and Sénégas (2002) used pre-computed textures made of cells as described by Worley (1996), and a triangular patterns mapping method.

Liu, Hao and Zhao (2009) also developed a method to generate organ textures for virtual simulation. Their method is fast and can produce multiple types of texture. It is based on the Ashikhmin algorithm (Ashikhmin, 2001) and uses images from surgery as inputs. Similarly, Liu *et al*. (2012) described two methods to synthesise texture. The first one is also based on an Ashikhmin algorithm. The second texture synthesis method is based on Perlin noise (Perlin, 1985), which can create texture with characteristics of randomness. The results showed that Perlin noise is suitable for mimicking the texture of simple organs; otherwise the Ashikhmin algorithm generated better results.

Alternatively, Paget, Harders and Székely (2005) took images from surgery to create new tileable textures using a fast non-parametric texture synthesis (FNTS) approach. Their method is more computationally heavy than that from the Ashikhmin algorithm, but produces better outcomes.

Texture mapping consists of applying the 2D texture onto the organ geometry. It can be tricky because projecting the texture can result in distortions onto the surface of the organ, causing an unrealistic effect. To map the textures onto the 3D mesh, Paget, Harders and Székely (2005) parametrised the mesh. More precisely, they cut the mesh and mapped it to a 2D plane; then they applied a texture to the flattened mesh before projecting it back onto the 3D surface. They used alpha blending to reduce artefacts and discontinuities and another blending process to handle the interface between different types of textures. Their method can map textures onto complex surfaces and manage changes of textures between different types of tissues. Liu *et al*. (2012) described a similar technique based on iso-charts to create texture atlases for parameterisation.

- Mucous layer

One of the important aspects for the realistic rendering of soft tissues is mimicking the mucous layer which gives a wet appearance with specular highlights to the soft tissues. These specular highlights are crucial in laparoscopic surgery as they provide indications to the surgeons about the depth and deformation of the soft tissues (Elhelw *et al*., 2004). The incoming light can be divided into two behaviours – the specular reflectance and subsurface scattering. To render the appearance of the surface, these two phenomena have to be mimicked correctly (Hao *et al*., 2009).

In computer graphics, the main technique typically used to mimic this light reflectance is the Bidirectional Reflectance Distribution Function (BRDF) (Elhelw *et al*., 2006). Previous work has demonstrated the benefits of using BRDF are that it allows the soft tissues to be rendered under any illumination or view point (Chung *et al*., 2006). Guo *et al*. (2021) simulated the mucus layer using a two-layer surface reflection model with BRDF-based highlight rendering. To do this, they calculated the transmittance of light entering the mucous layer using the Fresnel reflection formula as well as simulating the highlight component using the specular BRDF defined by Ashikhmin and Shirley (2000).

However, measuring the BRDF of soft tissues is challenging as it typically requires goniospectro-reflectometers which cannot be used *in vivo*. Indeed, one of the limitations for the photorealistic rendering of soft tissues in virtual simulation is the lack of *in vivo* data. Nunes *et al*. (2017) described taking a laparoscopic approach to measure the BRDF of real organs. The data measured with their approach can be used for rendering under a global illumination algorithm; it allows realism and patient specificity. Another example of measuring BRDF of real tissues was given by ap Cenydd *et al*. (2012). They made BRDF measurements of animal tissues and managed to mimic subsurface scattering this way.

Alternatively, it is possible to use analytical models to simulate BRDF, for example the micro surface models which consider a rough surface topology with perfect micro-reflectors that can be used to simulate the specular highlights. Tai *et al.* (2018) and Qian *et al*. (2015) have used a microfacet model to simulate diffuse reflection and specular reflection.

Previous authors have argued that it is not possible to use BRDF to simulate subsurface scattering because light exits a surface at a different point from its entry. Instead, it is possible to use the Bidirectional Scattering Surface Reflectance Distribution Function (BSSRDF) that simulates reflectance in translucent materials. Jensen *et al*. (2001) simplified multiple scattering in the BSSRDF model by describing a fast algorithm based on dipole source approximation. Their method was later used to simulate the subsurface scattering of tissues (Hao *et al*., 2009; Liu *et al*., 2012).

Another approach is to use empirical models such as the Phong reflection model (Phong, 1975), which can calculate some of the light-surface interactions. This model has been used to simulate specular reflections in previous research (Kerwin, Shen and Stredney, 2009); however, it results in a plastic-like appearance. Neyret, Heiss and Senegas (2002) developed a method that can take into account surface roughness and the light's distance to generate more realistic highlights, a method that is based on environment texture to represent specular spots. Similarly, Hao *et al*. (2009) and Liu *et al*. (2012) simulated specular highlights through bump mapping; they used a height map created from 2D noise, which was then converted into a normal map that was used to disturb the normal map of the 3D model. The specular highlights were then simulated through the Blinn-Phong model (Blinn, 1982).

* All terms italicised and with an asterisk are defined in Appendix A, the Glossary.

Elhelw *et al*. (2004; 2006) developed a noise-based model for reflectance modelling used to simulate the specular highlights. This is based on refractance and reflectance maps created using Perlin noise in the simulation pre-processing stage which defines the surface-light interactions. During the simulation, the specular highlights were calculated in real time by texture mapping the per-triangle reflectance information. The method creates realistic highlights, avoiding the plastic-like effects that can be noticed in some virtual simulators. It can produce patient-specificity through a combination with patient data, and generate valuable surgical training systems.

Alternatively, Lim, Jin and De (2007) created realistic glistening effects using image mosaicing (Szeliski, 1994) and view-dependent texture-mapping (Debevec *et al*., 1998). They used images from laparoscopic cameras to create background textures through image mosaicing. To replicate specular highlights, they used view-dependent texture-mapping and registered images from various viewpoints. They then used weighted blending to eliminate seams.

Finally, some works have used ray casting approaches in their rendering (Chan *et al*., 2016); more precisely, Kerwin, Shen and Stredney (2009) have used ray casting to simulate the refraction of light.

- Handling deformations

Another challenge is reproducing realistic textures onto deformed soft tissues. Elhelw *et al*. (2003) described how to render realistically deformed soft tissues in virtual simulation. In pre-processing, the model is divided into macro and micro-surface structures. The macro structures are used to model deformations due to the instruments with a mass-spring model. The microstructure captures the surface details and is added onto the deformed macro-structure through 3D image wrapping. This method allows deformed models to be rendered, while preserving rich surface details. Another example is Ruthenbeck *et al.*'s (2013) method, which is based on a triangle-based 3D mesh model extracted from a CT scan. Each node of the mesh has predefined mechanical properties which allows it to be deformed to

* All terms italicised and with an asterisk are defined in Appendix A, the Glossary.

simulate user interaction through a spring damper model. Then, the appearance is rendered by applying these textures as well as lighting effects onto this mesh.

- Handling artefacts

The visual rendering of virtual simulation also includes rendering surgical effects such as smoke and bleeding. Although these effects are usually not well mimicked for computational cost reasons, Halic, Sankaranarayanan and De (2010) have described how to mimic these effects realistically on GPU. Smoke is mimicked by overlaying sample smoke videos and modifying its transparency value using Perlin noise; bleeding is mimicked through an animation variable stored at each vertex and is propagated through vertex neighbours. If the value of the animation variable exceeds a determined threshold, bleeding is rendered at the vertex.

2.3.3 **Hybrid simulator**

Hybrid simulators aim to combine the assets of both physical and VR simulators by providing realistic tactile feedback along with more complexity and realism than either approach alone (Viglialoro *et al.*, 2019). They are based on AR techniques which generate models situated in between reality and the virtual space.

There are different ways to incorporate AR into a simulator, one of which is to introduce virtual elements into the real space, for instance through the use of AR glasses (Bernardo, 2017). Another possibility is to include elements from reality into the virtual space, for instance through sensors or tracking (Condino *et al.*, 2011).

2.3.3.1 Augmented reality with style transfer

A laparoscopic procedure is a surgical technique where a surgeon is guided by an endoscope to control instrument inserted into the abdomen through access ports. One possibility of using AR with this approach is to image-process the video from the endoscopic camera, with the aim of enhancing its realism.

Image *style transfer** is an image processing technique which mixes two images, a content image (*C*) and a style image (*S*), to generate a new image (*G*) with the content of *C* and the style of *S* (Gatys, Ecker and Bethge, 2016). The algorithm

* All terms italicised and with an asterisk are defined in Appendix A, the Glossary.

creates the image *G* through an optimisation process which aims to minimises the difference of content and style between *G* and the images *C* and *S*.

With this technique, the algorithm is based on an optimisation loop to create *G* from a *white-noise image**. It takes several minutes to create *G*, so the algorithm is too long for real-time application. Previous researchers from other research centres have managed to make quicker style transfer algorithms. Johnson, Alahi and Fei-Fei (2016) advocated training a *feed-forward Convolutional Neural Network** which would be able to stylise any images after training. The training is conducted on a large database of content images and using one single style image. During the training, the minimisation of both content loss and style loss are backpropagated on the parameters of the neural network. This technique enables real-time style transfer for any content images.

It is possible to stylise a video using the previous technique by modifying each frame with the pre-trained stylisation network. However, because the algorithm was designed to stylise one image at a time, it does not generate smooth videos because it does not include *temporal consistency**. Huang *et al.* (2017) developed a technique which can stylise videos in real time. Their technique removes temporal inconsistencies by adding a temporal loss term. They also proposed the inclusion of a *Total Variation** (*tv*) loss which compares neighbouring pixels to limit spatial inconsistencies.

Style transfer is already being used to improve the realism of a VR simulator of eye surgery (Luengo *et al.*, 2019). With this technique, the machine learning algorithm is trained on a database of images of eyes during surgery.

Engelhardt *et al.* (2018) made an implementation of *image-to-image translation**, which could improve the appearance of physical simulators. This technique has also shown its ability to improve the appearance of simulated laparoscopic images (Pfeiffer *et al.*, 2019), and to generate surgical datasets for segmentation tasks (Marzullo *et al.*, 2021).

* All terms italicised and with an asterisk are defined in Appendix A, the Glossary.

One of the limitations of these techniques is that their results rely on *weights** which are defined before training the algorithm. To compare the outcomes with another set of weights, the time-consuming process of training another neural network must be repeated each time. One solution to that issue was proposed by Babaeizadeh and Ghiasi (2018) – an adjustable style transfer technique. Their technique makes changing the weights after training and in real-time possible by training two networks at the same time. The two neural networks include a stylisation network and a conditioner network. During the algorithm training, the networks are trained considering that the weights are no longer fixed parameters but variable inputs instead. After the algorithm training, the weights can be modified in real-time to find the optimum output image.

2.3.3.2 Augmented reality ultrasound simulator

The ultrasound image synthesis methods discussed above have been used in hybrid environments by tracking a mock ultrasound probe and sometimes instruments such as needles (Magee *et al*., 2007). This tracking can be done using sensors (Zhu *et al*., 2007), optical tracking (Markov-Vetter *et al*., 2009), or dedicated devices such as the Omni system (Ni *et al*., 2008). As a student moves their probe on a mannequin, the ultrasound image synthesis will calculate the correct ultrasound plane from the position of the probe. As such, the ultrasound volume is already matched to the mannequin. In their research Markov-Vetter et al. (2009) let an experienced radiologist match the 3D ultrasound to the mannequin, but it is also possible to perform computer-based registrations (Magee *et al*., 2007).

Palmer *et al.* (2015) have developed SmartScan – an application for tablet devices which allows a patient’s heart to be visualised at the same time as the ultrasound images. The aim of their system is to make the learning process quicker by facilitating access to ultrasound education. With this mobile system, the user can visualise a heart within a patient’s body and ultrasound images.

Mahmood *et al.* (2018) suggest that hybrid simulation for ultrasound education allows educators to teach sonography with a focus on enhanced spatial orientation.

* All terms italicised and with an asterisk are defined in Appendix A, the Glossary.

In their study, Mahmood *et al.* used a Microsoft Hololens *head-mounted display** with a physical simulator. In this work, the authors have conducted an initial experience of implementing their ultrasound education system into their current programme, and they have received an overwhelmingly positive response from both faculty and residents (Mahmood *et al.*, 2018).

2.3.3.3 Context-aware augmented reality

*Context-aware** simulation generates an experience that is aware of the user's environment and allows interactions between the real world and the virtual world (Penza *et al.*, 2018). One of its aspects is that it tracks elements in the user's environment as well as the user. When used for medical education, the tracking of elements can be surgical instruments, or tracking the surgical simulator (Palmer *et al.*, 2015). As explained in section 2.3.3.2, there are multiple solutions for the tracking such as sensors or tracking systems. A common approach is the tracking *fiducial markers*,* for example an *ArUco marker** (Garrido-Jurado *et al.*, 2014).

2.4 Evaluating simulators

The previous section discussed the main types of simulators used in medical education; however, these simulators often fail to be implemented generally, and the surgeons mentioned during their interviews that this might be because they were not being correctly evaluated. A formal evaluation can prove simulators' potential and encourage surgeons to use them more systematically in their training.

The gold standard used to evaluate simulators is *face, content and construct validity** (McDougall, 2007). Evaluating a surgical simulator can include both quantitative and qualitative methods. Quantitative tests include measures of the materials' properties (Severseike *et al.*, 2019) or measures of the content validity's benefit in training students. Qualitative tests are evaluations of prototypes by surgeons or other medical specialists on their resemblance to the human anatomy (face validity) and on their usefulness as a teaching tool or during preoperative planning (content validity).

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2.4.1 Face validity

Simulator and training technologies can be evaluated by students and medical specialists on their realism; more precisely, on whether a simulator represents correctly or not what it is supposed to represent. For physical simulators, this means that the simulator must look like real tissue (Cheung *et al.*, 2014), and also be able to reproduce the same tactile response, which is essential for teaching students (Ryan *et al.*, 2015).

2.4.2 Content validity

Medical specialists can also evaluate the usefulness of the simulators, this is also known as content validation. There are different ways to evaluate the usefulness of the simulation.

One way is to evaluate students' learning outcomes after training on a simulator (Ryan *et al.*, 2015). More precisely, it is possible to assess a student's performance on different criteria at the beginning and end of a training session. Criteria used to evaluate the students' performance can be the time needed to perform a procedure or the number of tries needed before succeeding at it (Waran *et al.*, 2014b).

A second possibility is to compare surgical scores before and after training, such as the complication rate, length of the surgery, recovery time, and quantity of blood loss during surgery (Maddox *et al.*, 2018).

Another option is to compare groups who have used simulation with groups who have not used simulation to learn new skills. For instance, Banerjee *et al.* (2022) tested their VR simulator with medical students. They divided the students into two groups: a control group and an experimental group. The two groups of students both reviewed head CTA exams, then the experimental group practiced on the simulator, and finally the two groups evaluated head CTA exams again. During the CTA exam review, the students had to find aneurisms and assess on a scale from 1 to 5 their confidence in their localisation. At the end, the students answered a questionnaire in which they evaluated the simulator's usefulness for learning new skills and improving their confidence. The results show that the simulation was useful for improving the students' accuracy and confidence.

2.4.3 Construct validation

It is also possible to demonstrate the functionality of a surgical simulator by proving that it can differentiate between novices and experts. This is called construct validation. For instance, a simulator can be tested by both novice and experienced surgeons and should demonstrate a difference in success rate between the two groups (Santos *et al.*, 2012b).

In a study on the simulation of medical images, radiologists were asked to assess on a scale from 1 to 6 their confidence level that the images were realistic and their confidence level that there was a pathology in the image. The study included experienced and non-experienced radiologists and the difference in results between the two groups was evaluated as part of the construct evaluation (Camp *et al.*, 2022).

2.5 Simulation of bile duct exploration

There are multiple descriptions of simulators aiming at LCBDE; however, few of them are commercially available, resulting in a lack of training. The training systems are made of either animal or synthetic tissues. They all use the same tools as in real surgery, allowing for better immersion and training.

One barrier to the generalisation of training is the cost of the simulator. Commercially available models are often expensive (from hundreds or thousands of dollars) and generally require replacing parts between training sessions, resulting in additional costs.

Santos *et al.* (2012b) created a low-fidelity, low-cost physical model using commercially available materials such as plastic tubing, cotton, and balloon. The model could be opened to put new stones and prepare a new simulation practice. The simulator created a realistic simulation for both trans-choledochal and trans-cystic approaches and also included a simulated fluoroscopy examination. This

* All terms italicised and with an asterisk are defined in Appendix A, the Glossary.

study demonstrates the potential of their model through construct validation. This simulator is commercialised by 3-DMed (3-DMed, Franklin, USA).

A more recent study by Campagna *et al.* (2021) evaluated this simulator in more detail, and their results show that surgeons who practiced using this simulator were more knowledgeable on the procedure and retained long-term confidence in their ability to perform it. Similarly, Sánchez *et al.* (2010) developed another low-fidelity simulator using plastic tubing and sutures. Their model allows the reproduction of the main steps performed during the procedure and has been formally evaluated. Yet, it has not been commercialised. More recently Sbrocchi *et al*. (2020) have produced a simulator from commercially available materials such as balloon and retention suture tubing; their simulator was evaluated as realistic and useful for teaching the steps of the surgery.

Limbs&Things (Limbs&Things, Bristol, UK) also commercialises a training model for LCBDE. Their simulator can offer training for many of the skills of the surgery such as ligation of cystic artery and cystic duct, and cholangiogram catheter insertion and stone retrieval.

Simulab (Simulab Corporation, Seattle, USA) commercialises a model that can train for both trans-cystic and trans-choledochal approaches.

One example of VR simulation was described by Basdogan, Ho and Srinivasan (2001). Their simulator can train users how to grasp and insert a flexible catheter into the cystic duct; however, it does not teach any other steps of the surgery. To provide tactile feedback, their system was coupled with a box and laparoscopic tools with an incorporated force feedback system. Kim *et al.* (2015) developed a virtual model which aims to realistically mimic tissue deformation during the VR training of gallbladder removal surgery. This model is not aimed at LCBDE, so it does not offer training for this procedure, however, it mimics the same tissues as those in bile duct exploration.

Previous research evaluated a commercially available simulator with trainees (Kemp Bohan *et al.*, 2017) who took part in a training course on the simulator. The

* All terms italicised and with an asterisk are defined in Appendix A, the Glossary.

results show that the participants improved their performance, which demonstrates the usefulness of training on a simulator. Similarly, another study showed that implementing a simulation-based curriculum for LCBDE could improve the knowledge and the technique of trainees for this complex procedure (Teitelbaum *et al.*, 2014).

Because of the limited high-fidelity simulation training options for LCBDE, previous work also shows that surgeons have used live animals and animal tissues (Brewer *et al.*, 2021; Watson, Treacy and Williams, 1995; Cameron, O'Regan and Anderson, 1994) or cadavers (Sharma *et al.*, 2016) in the course of their training. Using animal tissues ensures high-fidelity training; an evaluation of a simulator based on porcine aorta to simulate the common bile duct achieved high scores on the model's reliability, face validity and content validity. Training on cadavers also demonstrates potential in improving the trainee surgeons' confidence and improving their oral examination scores.

The simulators described above do not include training for the ultrasound part of LCBDE surgery, however, there are many examples of simulators which contain the same soft tissues as those required in this surgery, and which are ultrasound visible. Chazot *et al.* (2022) developed a liver simulator which is especially interesting because it is ultrasound visible and includes blood vessels with blood flow created through a pump, allowing for *doppler imaging**. This feature is usually absent in commercially available simulators.

2.6 Simulation of laparoscopic surgery

During laparoscopic surgery, the surgeons access the anatomical region on which they operate through access ports inserted in the abdomen. They do not have a direct view of the organs and only manipulate them through laparoscopic tools inserted though these ports. Thus, when developing a surgical simulator for laparoscopic surgery, it is important to include a box in which to store the simulated organs and which simulates the restricted access encountered in this type of surgical setting (Yoon *et al.*, 2017).

* All terms italicised and with an asterisk are defined in Appendix A, the Glossary.

Some previous researchers have used a commercially available *lap-trainer** for this box (Sbrocchi *et al.*, 2020; Santos *et al.*, 2012a). Another option is to build a box specifically for each patient. In a recent study, Kokko *et al.* (2022) made their simulator housing from laser cut acrylic plates. The dimensions of the housing were calculated from CT scan data to reproduce the abdominal cavity of a specific patient.

2.7 Conclusion

This review has described the state-of-the-art in surgical simulation, discussing the key aspects of existing simulators. These simulators play an important role in surgical education as they have proven their capacity to improve surgeons' performance. The three types of simulators are physical, virtual, and hybrid. Physical simulators are useful for providing tactile feedback but fail to mimic complex procedures well; virtual simulators can mimic complex aspects of procedures such as ultrasound scanning but usually fail to provide realistic tactile feedback. There is extensive work on the visual realism of virtual simulators, notably on mimicking the texture of soft tissues and the reflection of the light. Hybrid simulation aims to combine the advantages of both physical and virtual simulators by providing a physical model and virtual features at the same time.

Following this literature review, and informed by my findings, I decided to develop a hybrid simulator for LCBDE. The idea was to create a physical model with emphasis on tactile feedback through a careful analysis of the sense of touch during surgery and through my selection of materials. The literature review highlighted that physical simulators often lack visual realism. The methods already developed to enhance realism in virtual simulations are interesting but require prior knowledge of the 3D geometry and deformation of the soft tissues; alternatively, style transfer has been used to modify videos' appearance and improve the realism of surgical simulators without necessitating as much information. In my research, I chose to use the style transfer method in my endeavour to improve simulation realism.

* All terms italicised and with an asterisk are defined in Appendix A, the Glossary.

This literature review has outlined the current training options for simulating LCBDE. It has highlighted how they are important for training students, but also that there is still a lack of good training options for LCBDE using ultrasound. This is an important aspect of this research, and the literature review revealed that there are two methods to simulate ultrasounds – either through a physical simulator or through virtual methods. In my research, I explored developing a physical ultrasound simulator but, as explained in Chapter 4, the results were not compelling because it was not possible to use the same materials to mimic both the ultrasounds and the tactile feedback well. Thus, I chose the interpolative method based on pre-recorded images in this research to apply images from a physical ultrasound simulator onto the final physical model, aiming to mimic tactile feedback using context-aware simulations and marker tracking.

Finally, the literature review has highlighted the importance of validation in simulation and therefore, the last part of my research consisted of validating the developed hybrid simulator.

* All terms italicised and with an asterisk are defined in Appendix A, the Glossary.

Chapter 3: Development of a physical simulator

This research investigated the development of a low-cost fabrication method based on 3D printing. Because the literature shows that the properties of the softest tissues cannot be accurately mimicked by 3D printing materials used with commercially available low cost 3D printers (Section 2.3.1), the synthetic soft tissues were moulded. However, the moulding techniques needed to be able to replicate the complex shapes of the anatomical structures. In this research, the moulding techniques were multiple-part moulds used to create the tube-like shapes such as the intestine and the vessels, and rotomoulding for the complex hollow shapes, such as the liver capsule or the gallbladder.

There were several reasons for deciding to use these fabrication methods. The first one was the cost of the materials and of equipment; indeed, one of the aims of this research was to develop a low-cost fabrication method for basic skills training (Section 1.1). This excluded the possibility of directly 3D printing organ replicas because low-cost 3D printers cannot create replicas with satisfactory properties (Garcia *et al.*, 2018); however, 3D printing with FFF or with SLA allowed for the production of moulds at an affordable price. Furthermore, because the aim was for trainee surgeons to practice how to perform basic skills, there was no need for highly complex methods.

Another reason was the necessity to create replacement parts quickly and easily, because the organ replicas get damaged during the training sessions (Kwon *et al.*, 2020). Using moulding enabled replacements to be produced within a few hours. Finally, one of the requirements of the simulator, due to the targeted procedure, was the possibility of having ultrasound visible samples. Moulding techniques can generate ultrasound visible samples, which is not possible with direct 3D printing (Section 2.3.1).

* All terms italicised and with an asterisk are defined in Appendix A, the Glossary.

3.1 Methods

3.1.1 Design of the moulds

The moulds were designed on the CAD software Rhino 7 for Windows (Robert McNeel & Associates, Seattle, USA). The design of the moulds was based on an organ library including 3D models of the stomach, duodenum, liver, gallbladder, etc. The organ library was the Human Male Digestive System Anatomy 3D Model V04 (Plasticboy Pictures CC, Cape Town, South Africa). Permission to use this dataset was obtained from the supplier. The organ models were only used to design the moulds for 3D printing and I did not do any FEM simulation on these models.

If the targeted soft tissue was part of the organ library, then the procedure to create the mould, summarised in Figure 15, was the following:

1) The targeted organ was isolated from the rest of 3D model by performing cuts on the model.
2) The targeted organ was resized to the desired dimensions. There was no further processing of the mesh.
3) A rectangular block big enough to enclose the organ was generated. The positioning of the organ within the block had to be carefully determined so that the mould was cut in a way that would allow the organ to easily be demoulded.
4) A *Boolean difference** between the organ and the block generated a negative mould of the organ.
5) The block was then cut into two parts, to allow demoulding.
6) Post-processing steps were performed on the mould, including creating a *gasket**, making openings to allow casting material to be poured into the mould, and adding a position referencing system including a male part on one half of the mould and a female part on the other half. The referencing system consisted of three small spheres on the surface of one of the outer parts and their negative on the other part, which allowed precise positioning when clamping the mould.

* All terms italicised and with an asterisk are defined in Appendix A, the Glossary.

7) If the targeted organ was a tube-like structure, such as the duodenum, then an interior mould was also created from the original organ, by shrinking its surface by several millimetres (to achieve the desired thickness in the final model).

This procedure, notably the post-processing step, was determined using an action-research iterative process to identify the right design for the moulds.

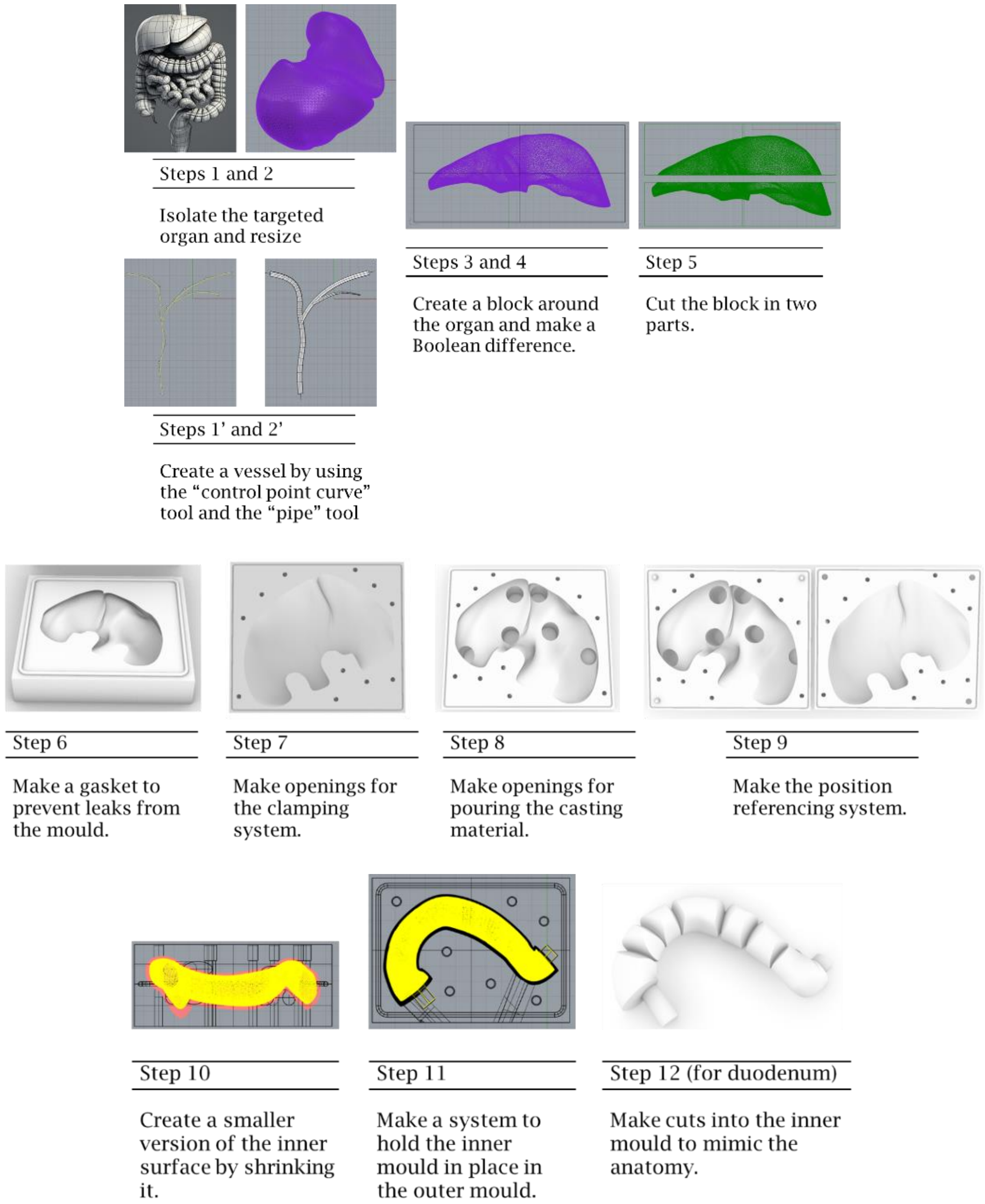


Figure 15: Steps to make a soft tissue mould

* All terms italicised and with an asterisk are defined in Appendix A, the Glossary.

When a targeted soft tissue was not part of the organ library, it was necessary to design it from scratch. This was only the case for the vein, the artery and the bile duct. To design these models, I used the “control point curve” tool from Rhino to design a curve and then the “pipe” tool to create a tube of the desired thickness from this curve. Then, I used the same procedure as previously explained, starting from Step 3 to make a mould from the generated tubes.

3.1.2 3D printing of moulds

The moulds were 3D printed. I have selected the following printing technologies: FFF and SLA because of the costs of the printers and printing materials (Garcia *et al.*, 2018). During the development of the simulator, I have used the SLA printer Form 3+ (Formlabs Ohio Inc., Millbury, USA), and the FFF printers Creator Pro (Flashforge, Zhejiang, China), LulzBot TAZ Workhorse (LulzBot®, Fargo, USA), and Ender-5 S1 3D Printer (Creality, Shenzhen, China).

The outer parts of the moulds were printed on FFF 3D printers using the flexible filament Cheetah (Ninjatek, Lititz, USA), with the aim of obtaining a tight fit between the two parts of the mould and preventing any leak from the casting material. For the same reason, the mould included a gasket which was also 3D printed with the same flexible filament. Using flexible material and a gasket were the results of an action research cycle that explored the best way to prevent leaks from the moulds.

The mould also needed a clamping system during the moulding phase to prevent leaks and close it tightly. The external clamping system consisted of nuts, screws and washers.

The inner parts of the moulds were printed using SLA. SLA is a more precise technology than FFF and using it produced a better quality inner mould (Garcia *et al.*, 2018). The inner moulds required better quality than the outer moulds because they were made of multiple small parts which needed to be assembled. This technology was not used with the outer moulds because it is more expensive (Garcia *et al.*, 2018).

* All terms italicised and with an asterisk are defined in Appendix A, the Glossary.

Because the mould was 3D printed with FFF, the surface was unclear, with visible print lines (Hong et al., 2019). Leaving the print lines would give an unrealistic aspect to the printed organ replica. To remove them and preserve the geometry of the mould, the inner surface of the outer moulds was manually coated with sulphur-free Chavant NSP clay (Chavant Clay, Macungie, USA). Sulphur-free clay is commonly used in car prototyping. It was necessary to use sulphur-free clay to prevent issues around the silicone curing (Techsil, 2019). Other methods than sulphur-free clay were tested to remove the print lines, such as using filler primer and sanding. These methods are described in Appendix D: Tests performed to find how to make the moulds smooth.

Because of the targeted organ's dimensions, the two parts of the liver moulds were both large. Thus, it was possible to divide each outer mould into two parts to create a *jacket mould**. The principle of a jacket mould is to print an outer shell in a cheaper non-flexible filament and then print the mould's working part in a flexible filament. This method allowed me to use less of the expensive material by saving it for just the most important part of the mould.

3.1.2.1 Liver mould

Because the mould included an opening to allow the casting materials to be poured in, it was necessary to develop a system to close this opening and prevent leaks from the casting material during the rotomoulding step. In this research, I used 3D printed plugs to close the opening while maintaining the anatomy. These plugs were designed by making a Boolean difference between the outer mould and cylinders. The Boolean difference resulted in an outer mould with openings and the core of the plugs separately. The liver mould is shown Figures 16 and 17.

* All terms italicised and with an asterisk are defined in Appendix A, the Glossary.

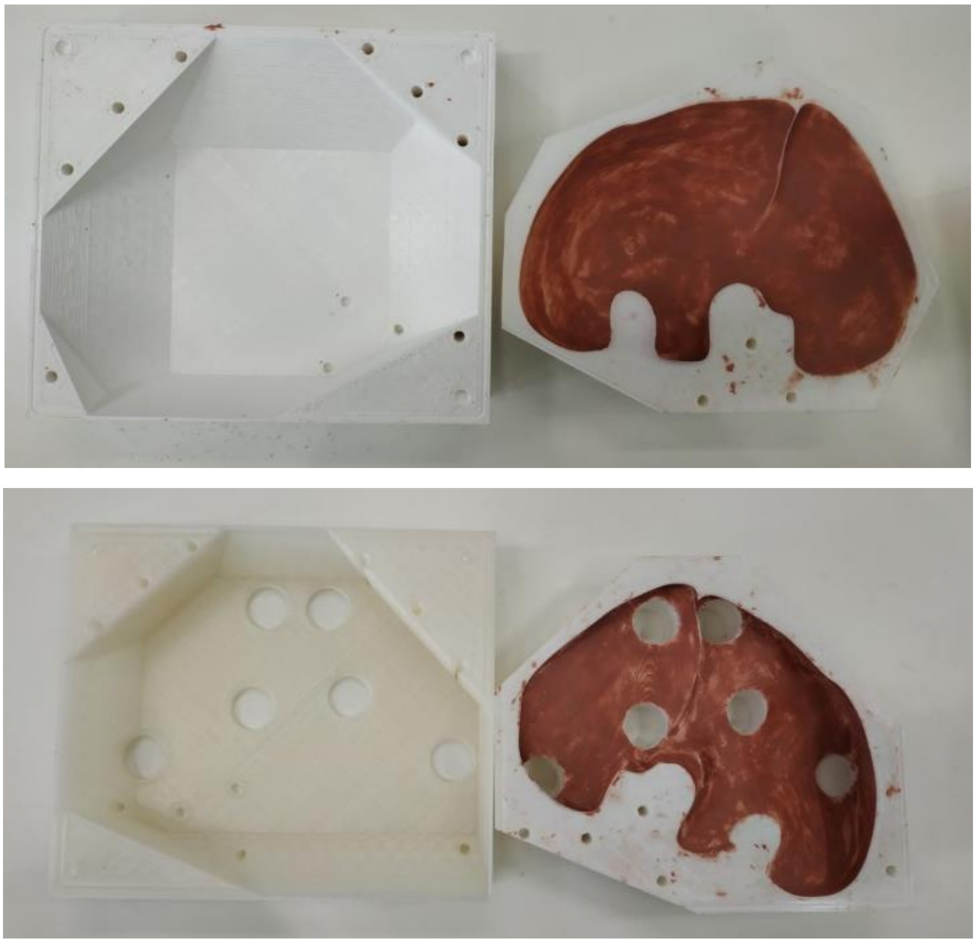


Figure 16: Division of the liver mould's outer parts in jacket moulds

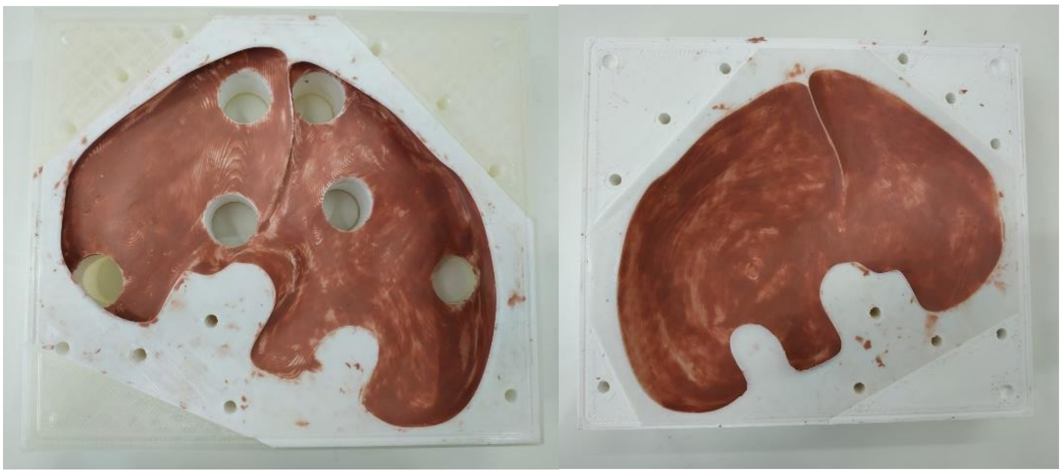


Figure 17: Jacket moulds assembled to make the two halves of the liver mould

3.1.2.2 Gallbladder mould

The gallbladder mould, shown in Figure 18, did not include an inner mould as it was made with a rotomoulding process.

Figure 18: Gallbladder mould and mould clamping system

3.1.2.3 Bile duct and cystic duct mould

The bile duct was deliberately made larger than in most patients, with an inner diameter of 1cm. The cystic duct has a diameter of 5mm and a thickness of 0.5mm. The design is shown in Figure 19. The aim was to help training practice by providing a duct large enough to introduce the scoping instruments. This decision was made by the surgeon advising on this research.

* All terms italicised and with an asterisk are defined in Appendix A, the Glossary.

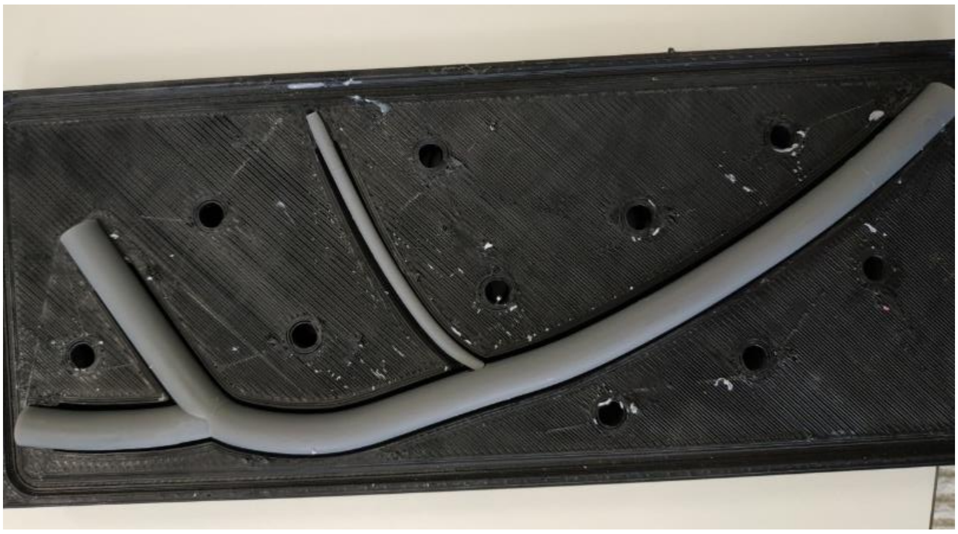


Figure 19: Bile duct and cystic duct mould

3.1.2.4 Artery mould

Figure 20 shows the artery mould. The cystic artery is a very small, thick vessel. It has an outer diameter of 6mm and a wall thickness of 1.5mm.

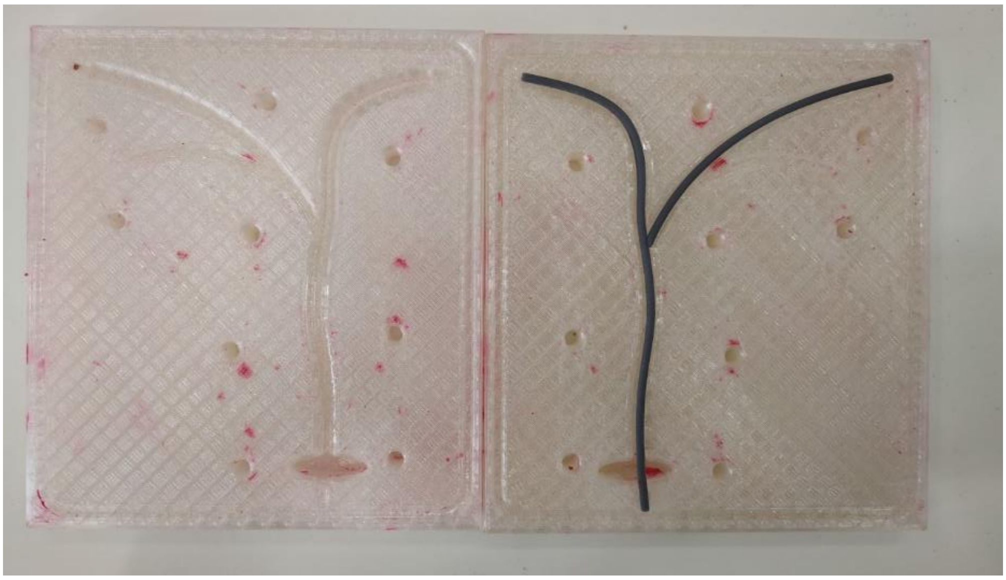


Figure 20: Cystic artery mould

3.1.2.5 Vein mould

The vein's design, shown in Figure 21, was based on the average dimensions of patients' cystic veins. The inner diameter is 1cm and the thickness is 1mm.

* All terms italicised and with an asterisk are defined in Appendix A, the Glossary.

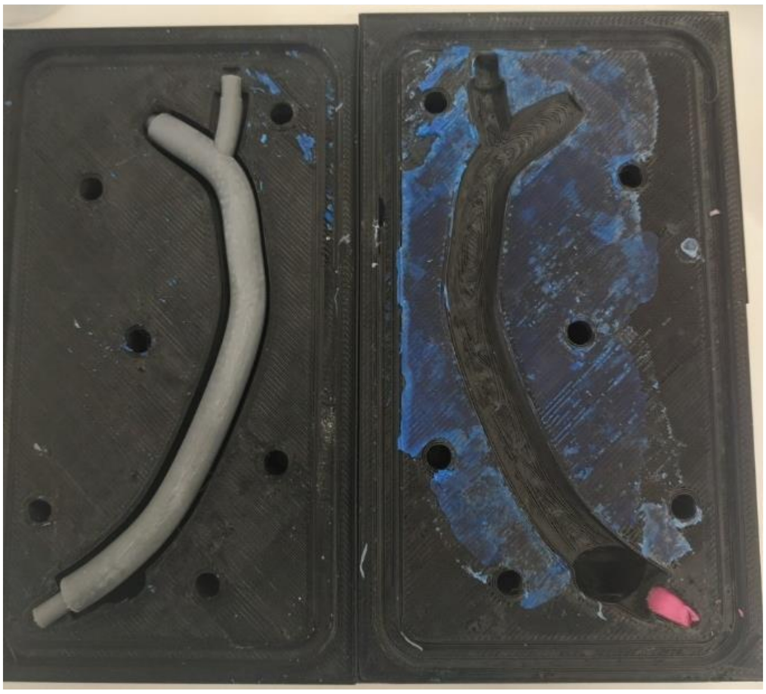


Figure 21: Portal vein mould

3.1.2.6 Duodenum mould

The design of the inner mould of the duodenum created an outer thickness of 2.5mm, which is the average thickness of the duodenum in patients. This is shown in Figure 22.

Figure 22: Duodenum mould

* All terms italicised and with an asterisk are defined in Appendix A, the Glossary.

3.1.3 Rotomoulding technique

The fabrication methods used in this research were multiple-parts moulding and rotomoulding; consequently, a rotomoulder was developed during the research and is shown in Figure 23. The design was based on a design from an online guide (JorgeD78, 2017), and was adapted to make it more robust by avoiding drilling the wood.

The wooden inner frame was replaced by a new one cut from aluminium slot. Aluminium slot was chosen to easily integrate a clamping system for the mould that could be adjusted to the size of each mould. The clamping system consisted of two parallel pieces of wood mounted on an aluminium threaded rod; the distance between the two pieces could be varied by using nuts.

The initial design used 3D printed gears, but when they were tested in the research they got damaged quickly under use. Therefore, instead of using 3D printed gears, metallic gears were purchased to make the parts more robust. The threaded rod was also replaced by an aluminium rod, because it allowed for a tighter junction and better positioning. Similarly, all the 3D printed parts were redesigned. The new parts included a system to hold grub screws, which could tighten the position of the metallic parts.

The rotomoulding technique consisted of inducing a rotation of the mould to spread the casting material on its inner surface (PriorityPrototypes, 2021). The steps taken, shown in Figure 24, were as follows:

1. pouring liquid silicone into the mould,
2. closing the mould,
3. rotating the mould at a regular speed using the rotomoulder,
4. once the casting material was cured, the mould was opened, and the technique had created a uniform hollow structure.

* All terms italicised and with an asterisk are defined in Appendix A, the Glossary.

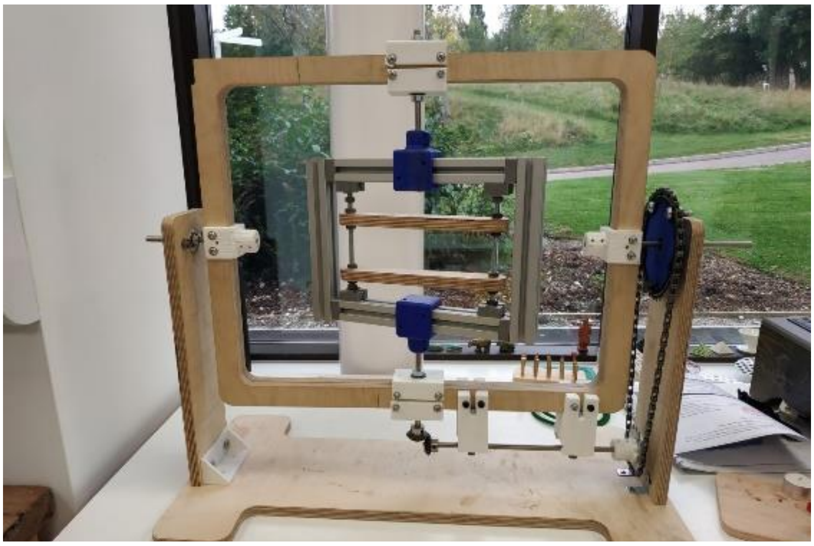


Figure 23: Rotomoulder developed in the research

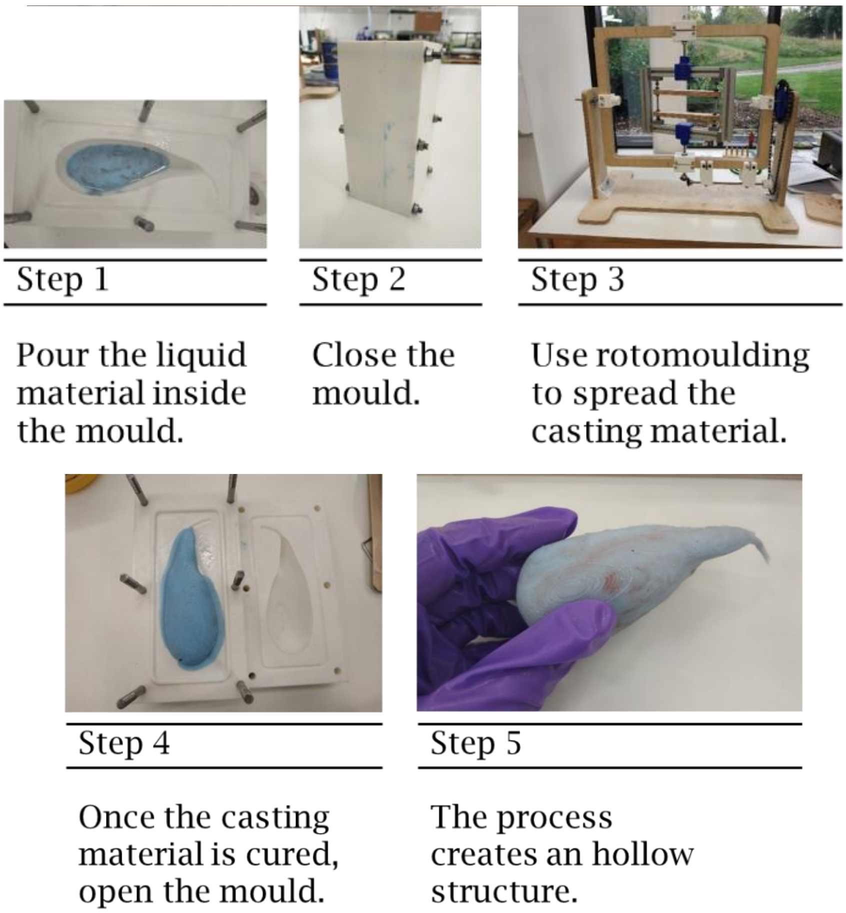


Figure 24: Steps to perform the rotomoulding technique

The rotomoulding technique required tuning to adapt the rotational speed to the *viscosity** of the material (Shaker and Rodrigue, 2019). This aimed to ensure that

* All terms italicised and with an asterisk are defined in Appendix A, the Glossary.

the casting material covered the whole mould evenly. The action research cycles demonstrated that it was best to use a slow rotation speed of below 20rpm. At this speed the material spread because of the gravity force and stayed on the mould because of its stickiness. If the rotation speed was too high, then the material stuck in the corners of the mould because of the centrifugal force.

The quantity of the casting material also required tuning to adjust the final thickness of the hollow structure. The targeted thickness was 1mm for the gallbladder and 1mm for the liver outer capsule.

3.1.4 Developing the prototypes

These different organs replicas were combined by using junctions, and by including a box and instruments.

The synthetic soft tissues were joined by sewing them together with an elastic yarn (Gütermann GmbH, Gutach-Breisgau, Germany) and gluing them with silicone glue (Smooth-On, Macungie, USA). The sewing step allowed me to precisely locate the junction, while the glue made the junction waterproof.

Because the targeted procedure was a laparoscopic surgery, the organs needed to be in a box to increase the realism of the simulation (Section 2.6). In this research, I placed the simulated organs inside a commercially available LapTrainer box (Erler-Zimmer, Lauf, Germany) shown in Figure 25.

* All terms italicised and with an asterisk are defined in Appendix A, the Glossary.

Figure 25: Laparoscopic training box

The box also included surgical instruments such as an endoscopic camera and a laparoscopic set purchased from Gerati (Gerati Healthcare Ltd, Sialkot, Pakistan).

3.2 Results

The sample were prepared by pouring silicone into the moulds. To recreate visually realistic synthetic tissues, I mixed the liquid silicone with the pigments Silc Pig (Smooth-On, Macungie, USA) during the preparation.

The benefit of using 3D printed moulds was that it gave the ability to create as many models as necessary, this is shown in Figure 26. The models also had the same anatomy. Using this method also made it convenient to prepare the replacement parts for the next simulation practice.

* All terms italicised and with an asterisk are defined in Appendix A, the Glossary.

Figure 26: "Development of multiple identical models for the training (left); Creation of replacement parts (right)" by Marine Shao, used under CC BY 4.0

Each model was fixed inside a box trainer (Erler-Zimmer, Lauf, Germany) using Velcro tape. I placed a USB camera inside the box trainer to record the practice, as visible in Figure 27. The surgeons also had access to the following instruments: graspers, clip applier, Berci knife, scissors, choledochoscope, Dormia basket, needle holders, and sutures.

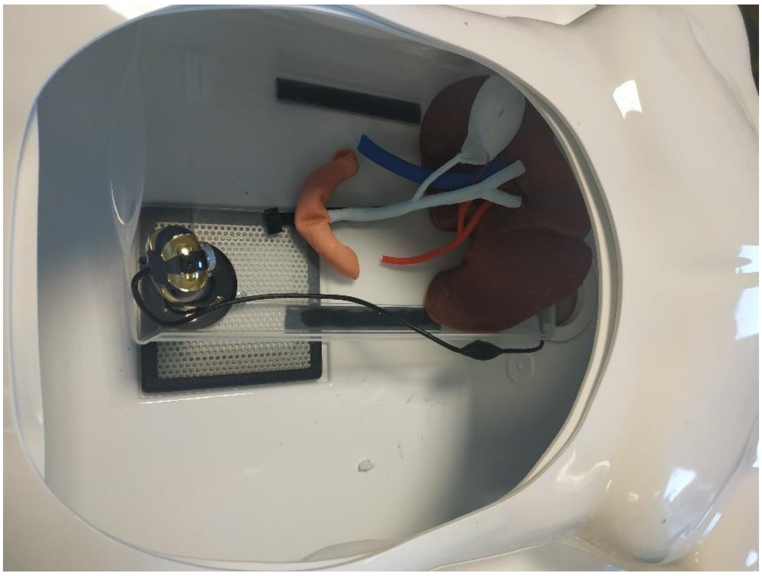


Figure 27: "Setup of the synthetic soft tissues into the lap-trainer" by Marine Shao, used under CC BY 4.0 / cropped from original

* All terms italicised and with an asterisk are defined in Appendix A, the Glossary.

3.3 Discussions

One aspect of the research was defining the best fabrication method to mimic the anatomy of the soft tissues and organs involved in LCBDE surgery. This aspect focused on the choice of the fabrication method, which included the method as well as the technology.

3.3.1 Using indirect 3D printing

In this research, I used a combination of 3D printing and silicone moulding. Previous studies have demonstrated the feasibility of 3D printing the same types of silicone used in this PhD research, such as DragonSkin (Miron *et al.,* 2021) and Ecoflex 0030 (Luis *et al*., 2020) using an extrusion process. This would be a valuable alternative to the lengthy process of 3D printing of moulds followed by casting. Furthermore, the 3D printing process allows creators to reduce the percentage of infill and thereby reduce the hardness of the material, which can also be useful for mimicking soft tissues. Luis *et al.* (2020) compared the properties of 3D printed silicone to those of moulded silicone, finding that there were no differences and indicating the potential of this new fabrication method as an alternative to moulding.

However, the 3D printing process remains complex as the silicone needs to be fluid enough to be extruded but also viscous enough to keep its shape until curing. Morrow *et al*. (2017) used thickening agents to increase the viscosity of Ecoflex 0030 and a heat gun to decrease the curing time, but this was a complex process as the print was stopped in between each layer for hot air treatment and the lifespan of the extrusion syringe of silicone was only 15 minutes before curing. Furthermore, the quality of the outcome was not satisfying as there was still a large percentage error in wall thickness. Another difficult aspect of the process is mixing the two parts of the silicone, which can be challenging because of their viscosities. Previous research describes how using mixers can overcome this problem. In their study, Gharaie *et al*. (2023) used a static mixer before 3D printing Ecoflex 0050 in a gel bath and successfully managed to 3D print complex silicone structures with overhangs such as a heart.

* All terms italicised and with an asterisk are defined in Appendix A, the Glossary.

3.3.2 The influence of 3D printer technology

Several 3D printing technologies have been used in the field of surgical simulation; such as material extrusion with polymeric filament or FFF, powder bed fusion, material jetting, binder jetting, and vat photopolymerisation (Pietrabissa *et al.*, 2020; Tejo-Otero, Buj-Corral and Fenollosa-Artés, 2020).

A study by Hong *et al*. (2019) compared three 3D printing technologies: a material extrusion technique (FFF), a colour jet printing (binder jetting), and a PolyJet technique (material jetting). The relative difference between the 3D printed model and the STL file were respectively 4.0%, 2.4% and 1.5% for the FFF, the colour jet printing, and the material jetting. These results were confirmed by another study by Chen *et al*. (2022) who also found that the cost was highest for the PolyJet, medium for the colour jet printing, and lowest for the FFF. The printing time for the FFF was 65 hours, against 7 hours for the colour jet printing and 18.5 hours for the PolyJet.

Moreover, other technology-related artefacts can also affect the outcome of a 3D printed model. FFF products are subject to wrapping and shrinkage, which makes them unsuitable for mimicking hollow models and small vessels. SLA and material jetting outputs are also subject to shrinkage and can have limitations if the first layers get partially detached during the printing because of lateral stress.

This research aimed to develop a low-cost fabrication method (Section 1.1). My literature analysis revealed that two 3D printing technologies were most suited to fulfilling this requirement: FFF and SLA. For surgical training, there is no need for the simulator's geometry to be extremely precise, because there are inter-patients' differences. Thus, choosing a printer because of its price over its accuracy is a reasonable option for surgical training.

For patient-specific preoperative planning, the precision of the technique is most important; indeed, the model needs to be very precise because the surgeons can use it to fit an implant or to decide the trajectory of an instrument from a specific patient's anatomy. Because these models are generally used only one time, it is also more efficient to be able to 3D print them directly instead of using moulding

* All terms italicised and with an asterisk are defined in Appendix A, the Glossary.

techniques which make the fabrication method more time-consuming. Therefore, Polyjet printers have the potential to achieve better performances for this type of application (Hong *et al.*, 2019).

3.3.3 Fabrication methods

Because this research combined the use of various printing technologies, the printers did not have the same accuracy (Cantinotti, Valverde and Kutty, 2017). There were some printer-specific differences between the 3D model and the printed model, which meant having to post-process the 3D printed models to adjust them to these inaccuracies. More precisely, the different parts of the moulds which fitted well into the digital 3D model did not fit once 3D printed, resulting in the need to sand the different parts to rectify them. In future studies, it would be interesting to quantitatively evaluate the impact of the different printed technologies on the 3D printed model geometry to gain a guide to the right tolerances to apply between the different parts, depending on the type of printers.

Because the organ library used in this research did not include all the types of soft tissues required in the simulation, the geometry of some of the soft tissues was designed using CAD. Consequently, the anatomy might not be completely accurate and too simplified. More precisely, the cystic duct was created as a straight pipe, when in real life it usually has a more complex anatomy. A simplified model was appropriate for novices learning the basic skills of the surgery but might not be adequate for more expert surgeons' training.

3.3.4 Research methodology

Action research was also very useful throughout the research as it allowed me to gain feedback after testing the fabrication method. From this feedback, I adjusted the materials and methods, before creating the next iterative prototype.

More precisely, when developing the liver mould, I encountered an issue with air bubbles getting trapped within the mould. The action research iterative cycle enabled a solution to be identified, by redesigning the mould several times.

Similarly, the iterative cycles allowed a functional rotomoulding process to be identified, by adjusting the fluidity of the casting material and the rotational speed.

The HCD methodology also guided the research through the user-testing phases, where valuable feedback was gathered which helped to identify new research directions. For instance, during workshop 1 (described in section 4.2.3), several comments were made about the samples' smoothness. Because the moulds were 3D printed, the print lines were visible on the casted samples. These comments led to investigating how to smooth the moulds' surface, resulting in the subsequent creation of smooth samples using sulphur-free clay.

3.4 Conclusion

This chapter has described the methods employed during my research to develop a physical simulator for LCBDE. The methods were a combination of 3D printing and moulding. The rationale behind my utilisation of these methods was to develop a low-cost and easy to use fabrication process, which would allow it to be adopted widely.

* All terms italicised and with an asterisk are defined in Appendix A, the Glossary.

Chapter 4: Investigation on the tactile feedback during surgery and on how to mimic it

Another aspect of creating a physical simulator is selecting the materials. This is of primary importance to provide the appropriate tactile feedback during training sessions, as well as realistic ultrasound images. The importance of the tactile feedback and of the ultrasounds were stressed by surgeons in interview 1 described in Section 7.2.1.4 More precisely, the surgeons said that having realistic tactile feedback during training would enable surgeons to be engaged in a challenging training practice.

4.1 Methods

In my research, the material selection was divided into three phases: first was defining the specifications using qualitative and quantitative approaches, second was investigating commonly-used materials through an action research approach, and, last, identifying the best synthetic materials through quantitative tests and user-based selection. The first phase included a review of the literature to identify the physical and acoustic properties of the soft tissues, and a two-step user study to describe the soft tissues in a more qualitative way. The second phase was focused on exploring materials by testing commonly-used materials for their tactile properties and their appearance during ultrasound examinations. The last phase included quantitative tests of the synthetic materials to compare them to the soft tissues, then a user-based selection of which materials had the best properties for each type of soft tissue.

4.1.1 Investigating the properties of the soft tissues

The research approach used to investigate this tactile feedback focused on gathering information on the properties of soft tissues using quantitative and qualitative methods. The quantitative method obtained the numerical measures of the properties of the soft tissues described in Section 4.2.2.2.

As an engineer, I initially intended to fully characterise the soft tissues using quantitative measures; however, during my research training, I learned about

* All terms italicised and with an asterisk are defined in Appendix A, the Glossary.

perceptual studies through the study by Mirjalili and Hardeberg (2019). Their study showed the diversity of perceptual cues that can be gathered using qualitative research. This is why I decided to apply this approach as well, for the characterisations of the soft tissues.

The qualitative method followed the HCD methodology (Section 1.2.1) by involving users in interviews and other participant-based studies. Participant-based studies are explained in more detail in Sections 1.2.3 and 2.3.1.2. In this research, it entailed a preliminary interview followed by a survey. The preliminary interview was a semi-structured interview which aimed to gather data on tactile sensations during surgery. From the results of this interview, the survey further investigated the properties of each soft tissue involved in the surgery and how they are interconnected.

4.1.1.1 Preliminary study

The first part of the study aimed to identify the main characteristics of tactile feedback during surgery by interviewing surgeons to understand their embodied knowledge of manipulating soft tissues.

- Interview with specialists: interview 2

To obtain a description of the tactile sensations during surgery, the first step consisted of interviewing surgeons who practice LCBDE. The selected participants were only surgeons who could precisely describe the sensations during this specific surgery.

During the interview, hereafter referred to as interview 2, I asked the surgeons to describe in their own words the texture of the different organs and soft tissues. I asked them about their sensations during open surgery and laparoscopic surgery. Because the aim was to explore surgeons’ sensations, the interviews were semi-structured, where the questions could evolve depending on the surgeons' responses.

* All terms italicised and with an asterisk are defined in Appendix A, the Glossary.

This list of soft tissues was deduced from previous interview (interview 1) in which the surgeons listed the steps of the surgery and defined the specifications of the simulator; this is detailed in Section 7.1.1. The surgeons were asked to evaluate the following soft tissues: the abdominal wall including the skin, fat, muscle, the liver, the gallbladder, the bile duct, the blood vessels, and the stones.

The surgeons were asked about their sensations using direct touch through their gloves, and indirect touch via tools. The instruments involved in this surgery are grasping tools, dissecting tools, cutting tools, clamping tools, scoping tools such as the laparoscope and the choledochoscope, and suturing tools. This list of tools was also deduced from the previous interview 1 with the surgeons (Section 7.1.1).

To describe the soft tissues, the surgeons could use descriptors such as “soft”, “smooth” or “coarse”; or comparisons such as “like squid” or “like jelly”. The outcome was a list of descriptors when using direct touch and when using tools. The aim of the interview was to gather extensive qualitative feedback on the soft tissues, but this list of descriptors also led to the definition of quantitative tests. For instance, for the previous descriptors I imagined using the following complementary quantitative tests:

- For the softness, I could use indentation tests
- For the elasticity, I could use tensile tests
- For the smoothness, I could study surface properties such as the angle of the cone of friction

However, the aim of this study was to identify tissues’ properties, not to obtain the precise measurements.

Participant recruitment centred on the network of James Clark, one of the supervisors of this PhD. I sent them an email to explain the aim of the study, why they were being contacted, and what they could do to help the study. All the people interviewed volunteered to take part, and their participation was anonymised.

* All terms italicised and with an asterisk are defined in Appendix A, the Glossary.

Nine surgeons were recruited in this way to participate in interview 2. Interviews were conducted online, and the surgeons were asked to answer using their memory of the experience of touching soft tissues, they were not directly touching soft tissues during interview 2. They had all either performed or assisted on a LCBDE. Interviews were conducted individually to avoid any interviewees influencing one another.

- Analysis of interview 2 findings

Interview 2 aimed to obtain a list of descriptors of the soft tissues when using direct or indirect touch; however, as shown by Xue *et al*. (2014) and mentioned in Section 2.3.1.2, the participants used different terms and different types of words to describe the same properties. Consequently, an analysis of the results was undertaken, to keep only the main properties.

At first, because it was more convenient to work with the same type of words during the study, some of the surgeons' descriptions were reformulated, to replace verbs by adjectives. Then the descriptors were grouped according to their meanings, for example, synonyms and antonyms. This step generated groups of words and the most frequently used descriptor in each group was selected to describe it. Finally, the main characteristics of the tactile feedback were determined using a frequency-based selection, where only the characteristics cited most by the surgeons were selected for further analysis.

At the end of the analysis, the remaining words were kept to describe the main characteristics of surgeons' tactile feedback from soft tissues during surgery.

4.1.1.2 Survey

The second part of the study had two aims. The first was to identify the specificities of each soft tissue. The second aim was to understand the connections between the touch parameters, especially the connections between indirect and direct touch.

To fulfil these two aims, a survey was conducted to quantitatively rate the soft tissues according to the list of characteristics determined in the preliminary study.

Gathering quantitative data allowed me to conduct statistical analysis by which to compare the soft tissues.

- Survey conduction

During the survey, I asked participants to perform two separate tasks for each tactile parameter. First, the participants were invited to rank the list of soft tissues in order, from the most to the least sensitive to the studied parameter, for example, from the smoothest to the least smooth.

The second task was to grade each tissue between 0 and 10 to describe the intensity of the evaluated parameter; this grade captured more information than the *rank order** alone. The aim was to understand nuances that were not captured by the rank ordering alone, such as degree of magnitude between the sensations of the different tissues; for instance, if the artery and the vein were ranked in 3rd and 4th positions for their softness, the intention was to assess if they had a similar level of softness or if one was multiple times softer than the other. Rank ordering the soft tissues first made the grading task easier.

This part of the study was conducted through an online survey on Qualtrics (Qualtrics, Seattle, USA). Eight surgeons with experience in LCBDE participated in this second study. The surgeons also replied to this survey using their memory of touching soft tissues.

- Analysis of the results

A statistical analysis of the results was conducted using SPSS IBM Statistics software (SPSS, Chicago, USA). This was intended to determine the relationships between the tactile feedback parameters and this analysis is described in Section 4.1.1. The steps of the analysis were the following:

1. Normalisation of the data.
2. Importation of the data into the SPSS software.
3. Exploration of the data, especially the distributions of the data using *Kruskall Wallis tests** and boxplots (pages 139 to 144).

* All terms italicised and with an asterisk are defined in Appendix A, the Glossary.

4. Determination of the data normality using the *Shapiro-Wilk test**.
5. Statistical analysis using the *Spearman non-parametric test** (page 144).
6. Analysis of the results.

The data were normalised at the beginning of the study because all the surgeons had not graded the soft tissues at between 0 and 10. Some of the surgeons gave grades between 5 and 7 for instance, which complicated the interpretation of the results. The following formula was used to normalise the results:

$$\bar{X} = \frac{X - m}{M - m} \qquad (2)$$

Where $\bar{X}$ is the normalised data, X is the original data, m is the minimum of the dataset, and M the maximum.

4.1.2 Exploration of the materials

Characterising the soft tissues allows the specifications of the synthetic materials to be identified and used to replicate their tactile feedback. This list of specifications was an addition to the quantitative acoustic and physical properties of soft tissues identified in the literature review.

Because the targeted procedure includes laparoscopic ultrasound, the synthetic soft tissues also needed to be able to provide realistic ultrasound images. As discussed in Section 2.3.1.3, synthetic materials used for ultrasound practice are generally made of a bulk material and a scattering agent. The next section outlines how various commonly used materials were investigated using successive action research cycles (Section 1.2.2).

4.1.2.1 Bulk materials

The exploration undertaken into suitable materials for the bulk agent did not include materials used in 3D printing; indeed, direct 3D printing is not a good option to create simulators for ultrasound training (Section 2.3.1.3). The exploration focused on materials commonly used for surgical simulation.

* All terms italicised and with an asterisk are defined in Appendix A, the Glossary.

The most commonly used bulk materials are silicones, gels, PVA, and polyurethane. PVA and polyurethane are more complex to use (Ahmad *et al.*, 2020), therefore the research focused initially on silicone and agar gel.

I tested a range of silicones (Ecoflex gel, Ecoflex 0010, Ecoflex 0030, DragonSkin) (Smooth-On, Macungie, USA) and agar gel (Special Ingredients ®, Chesterfield, UK). The different silicones tested have diverse hardness. Taking inspiration from a study by Chanda (2018), I created samples with a wider range of properties by mixing together several products in varying ratios. These products were either other types of silicones, or other Smooth-On additives such as Slacker and Thinner.

More precisely, I tried to mix different types of silicones to get samples with properties “in between”: I created one sample with 50% Ecoflex gel and 50 % Ecoflex 0010, and another one with 50% Ecoflex 0030 and 50 % DragonSkin. I also tried mixing each silicone with different stoichiometric ratios: the silicones that I used were addition cured silicones, which included two liquid materials that had to be mixed in an equal amount. During the research, I experimented with changing the ratio between these two liquids.

To evaluate the materials, I have kept a journal including a photographic record, comments on the tactile feedback, on the fabrication method, and on the ultrasound examination of the different samples (Section 1.2.2). This was to identify the best bulk agents for the different soft tissues.

Comments on tactile feedback of the materials consisted of quantitative tests which evaluated on a scale from 1 to 10 tactile properties such as softness, tackiness, elasticity, and ability to deform.

The record also included ultrasound images recorded with a Healcerion Sonon 300L (Orca Medical, Bristol, UK). The parameters of the ultrasound transducer used to record the images were set as shown in Table 4 before testing the materials. The aim was to use the same settings as during surgery so that the images would be comparable to those achieved during real surgery.

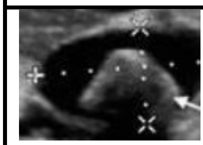
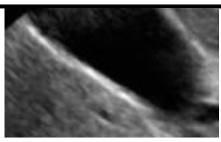
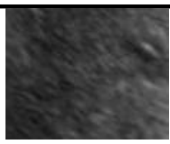
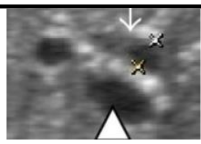
Table 4: "Parameters for ultrasound testing" by Marine Shao, used under CC BY 3.0 / modified the table formatting

Mode	Carotid/Thyroid (4cm depth recommended)
Frequency	7.5MHz
SRI	Off
Graymap	D or E
Gain	Medium, to be adjusted
DR	Medium, to be adjusted
TGC	Medium, to be adjusted

In the ultrasound images, each type of soft tissues appeared differently:

- Common bile duct: in black, no visible outer layer or white outer layer.
- Stones: light grey with a shadow.
- Gall bladder: black, clear outer layer.
- Artery/vein: black interior, white layers.
- Liver: uniform dark grey (darker than conjunctive tissue).
- Conjunctive tissue: light grey.

Table 5: Ultrasound images of the different soft tissues. Bile duct with stones, gallbladder, liver and conjunctive tissues by Rossi Kleinübing, Alves Rodrigues and Luiz Brum used under CC BY 3.0. Artery, vein and bile duct by Lin et al.*, used under ©2014.*

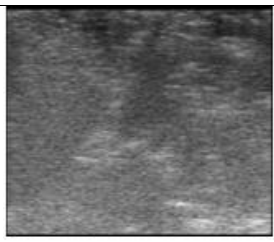
Bile duct with stones	Gallbladder	Liver	Conjunctive tissues	Artery, vein and bile duct
Images parameter: depth 15cm, gain 61%, DR 55				Images parameter: depth 8cm, gain 77%, DR 60
				

The differences of appearance within one image were due to the variation of the acoustic properties that influence how sound waves propagated into the material, such as density or the speed of sound (Section 2.3.1.2).

The materials were compared to the images in Table 5 to qualitatively evaluate them. The comparison was conducted by myself and one of my supervisors who was a surgeon with experience in using ultrasound.

An example of a journal entry is given in Table 6.

Table 6: Evaluation of the samples for bulk material

Sample type	Comments	Tactile properties	Ultrasound image
Ecoflex gel not degassed	Very sticky, soft, and elastic, return to its initial shape after deformation, tear easily, does not change after aging. Fabrication: needs to be cast directly into its final shape, needs to be degassed to remove the air bubbles. Potential use: liver infill	Tackiness: 9/10 Indentation: 9/10 Elasticity: 10/10 Ability to deform: 500% Ability to tear: 1/10	

4.1.2.2 Scattering agents

Scattering agents are powders that were incorporated into the bulk material. They were used to reflect the ultrasound wave, thereby making the synthetic material visible using ultrasound (Section 2.3.1.3).

To investigate the scattering agents, I conducted an analysis of the influence of the particle size and percentage of particles inside the bulk agent on the ultrasound images. To do so, particles of various size were tested as detailed in Table 7: silica (Investment casting supplies LTD, Kegworth, UK), alumina (Simba Materials Limited t/a CMT Potters Supplier, Edlington, UK), polestar CCC (Imerys, Paris, France), flour

* All terms italicised and with an asterisk are defined in Appendix A, the Glossary.

(Asda, Leeds, UK), glass spheres (Merck KGaA, Darmstadt, Germany), graphene (Merck KGaA, Darmstadt, Germany), and sugar (Asda, Leeds, UK).

Table 7: Size of the scattering particles tested

Particle type	Particle size
Silica	<10 µm
Alumina	60 m
Polestar CCC	2 m
Flour	10-41 m
Glass sphere	9-13 m
Graphene	<20 m
Sugar	200-400 m

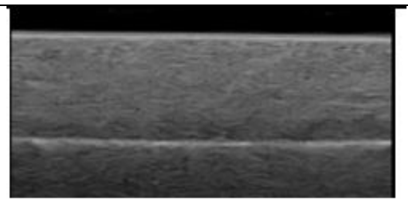
The particles were tested with the following percentages: 0.1*%w/w**, 0.2%w/w, 0.5%w/w, 1%w/w, 2%w/w, and 5%w/w. The choice of these percentages resulted from an analysis of the literature (Section 2.3.1.3). In this study, the particles were mixed with DragonSkin and Ecoflex gel, two of the investigated silicones. DragonSkin is the most viscous silicone and Ecoflex gel the least viscous. Figure 28 shows how the samples were made.

* All terms italicised and with an asterisk are defined in Appendix A, the Glossary.

Figure 28: Fabrication of samples using a glass sphere scattering agent and a bulk matrix of DragonSkin

The samples were evaluated in terms of their ultrasound images, on how the introduction of a scattering agent influenced the samples' tactile feedback (for example, the texture of the materials changed when there was a high percentage of scattering agent in them), and through free comments describing the samples and the problems encountered during the fabrication process. The aim was to firstly evaluate the samples qualitatively to gather initial feedback; the materials were also evaluated quantitatively later on, as discussed in the next section of this thesis. Table 8 provides an example of how the samples were assessed.

Table 8: Evaluation of the samples made with scattering agents

Sample type	Comments	Tactile properties	Ultrasound image
Silica in DragonSkin	Silica has very fine particles resulting in a very smooth appearance	Tackiness: 0/10 Indentation: 1/10 Elasticity: 3/10 Ability to deform: 150% Ability to tear: 1/10	

4.1.2.3 Heterogenous materials

One of the challenges of mimicking the tactile feedback of soft tissues was their complexity and, notably, their heterogeneity. Interview 2 on the characterisation of the tactile feedback highlighted that some soft tissues have fibres, notably the muscle, the skin, and the peritoneum.

I investigated several methods of adding fibres into the materials:

- For unidirectional fibres, the tests focused on incorporating cotton fibres (Bluedot, Cheshire, UK) into the bulk agent.
- For bidirectional fibres the tests focused on incorporating stretchy fabrics such as tights (Manzi, Yiwu, China) and Power mesh (The Fabric Centre, Walsall, UK) into the bulk agent. This was inspired by a comment from a surgeon, which compared the peritoneum to women's tights.

The evaluation of the heterogenous samples included tests on the fibres' properties and on incorporating them into the bulk agent, as depicted in Table 9:

* All terms italicised and with an asterisk are defined in Appendix A, the Glossary.

Table 9: Evaluation of the heterogenous materials

Sample type	Tactile properties	Fibres incorporation
Ecoflex 0030 with stretchy fabric	Tackiness: 0/10 Indentation: 1/10 Elasticity: 2/10 Ability to deform: 120% Ability to tear: 0/10	

4.1.3 Evaluation of the materials

As indicated by the action research methodology used (Section 1.2.2), the materials were regularly evaluated and results kept in the research journal. Furthermore, a quantitative evaluation and then a qualitative evaluation from participants were conducted to select the best materials.

4.1.3.1 Quantitative evaluation

The quantitative evaluation focused on the physical and acoustic properties of the synthetic materials; the aim was to replicate the properties of the soft tissues.

To quantitatively test the acoustic properties of the synthetic materials in this study, I compared them to those of the soft tissues. My literature review obtained the information shown in Table 3 on the soft tissues involved during an ultrasound examination performed to evaluate gallstones in the context of a LCBDE (Soni, Arntfield and Kory, 2015; Duck, 1990; Tejo-Otero, Buj-Corral and Fenollosa-Artés, 2020; Ceh, Peters and Chen, 2015; Pacioni *et al.*, 2015; Maggi *et al.*, 2009).

The properties of the bile duct were not found in the literature. Because the appearance of the ultrasound images from the bile duct are very similar to those of blood vessels, I hypothesised that they both have the same properties.

- Measure of the density

The protocol to measure the density d of a sample was to first measure the weight *w* using a precision balance. Then, the volume *V* of the sample was measured by immersing it in water and calculating how the volume varied.

* All terms italicised and with an asterisk are defined in Appendix A, the Glossary.

Then I deduced the density d using this formula:

$$d = \frac{w}{V} \qquad (3)$$

- Sound celerity or speed of sound

Ultrasound imaging systems are calibrated with the assumption that the speed of the ultrasound wave in the materials is 1540m/s. For this reason, the following process can be used to determine the sound celerity, also known as the speed of the sound in a sample:

1. Using an ultrasound machine, scan the material (of known thickness) using the highest frequency possible.
2. Optimise the machine control setting to get the largest image on screen, then freeze the image.
3. Using the on-screen callipers, measure the depth of the material on the image.

The speed of sound in the sample was then calculated as follow:

$$\textit{Speed of sound in material} = 1540 \frac{\textit{actual depth of material}}{\textit{on screen measured depth}} \, m/s \qquad (4)$$

To quantitatively test the physical properties of the synthetic materials in this study, I compared them to those of the soft tissues. My literature review obtained the information shown in Table 2 on the soft tissues (Li, 2020; Mancia *et al.*, 2019; Herman, 2010; Ma *et al.*, 2020; Maclean, Brodie and Nash, 2010; Fenollosa *et al.*, 2019; Umale *et al.*, 2013; Jorgensen, Sheets and Zhu, 2015; Gefen and Dilmoney, 2007; Vlaisavljevich *et al.*, 2013; Kuzin, Khakimov and Yukhin, 2001; Kao *et al.*, 2019).

The physical properties of the materials could be evaluated using physical tests. Since Young's modulus is proportional to hardness, regardless of the material (Sun, Kothari and Sun, 2018), it was only necessary to measure one of the two parameters. Because the literature offers more values of Young's moduli than

* All terms italicised and with an asterisk are defined in Appendix A, the Glossary.

hardness, I decided to measure the Young's moduli of the samples and compare them to the soft tissues.

The Young's modulus was tested on a tensile testing machine X350-20 (Testometric, Rochdale, UK). This machine was used to evaluate the mechanical properties of samples by stretching them until they ruptured and recording the strength applied to generate a given elongation. This testing machine could record the materials' stress/strain behaviour, from which I could deduce the Young's modulus, the ultimate stress, and the ultimate strain.

The tensile tests were performed on *dog-bone samples**, which were created using a 3D printed mould. The geometry of the samples was determined using the ASTM D412 standard specimen used for elastomers and vulcanised rubber as seen in Figure 29. The dimensions of the samples were: length=25mm, width=6mm, and thickness=2.5mm. Clamps were used to constrain the samples during tensile testing.

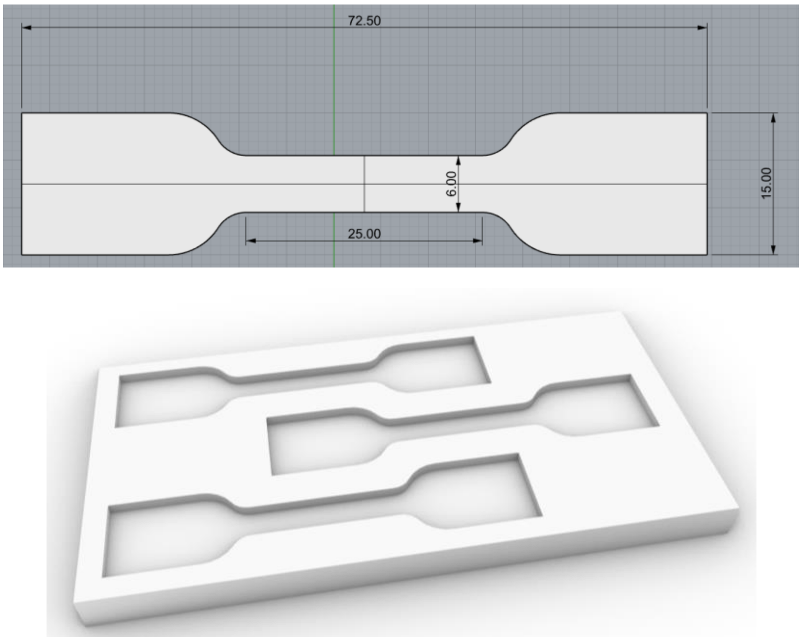


Figure 29: "Dog-bone shaped samples (a); Mould designed on the Computer Assisted Design Software Rhino (b)" by Marine Shao is licensed under [CC BY 3.0]

The physical tests were conducted at a rate of 50 mm/min with a maximum displacement of 1050 mm and a load cell of 100kgf. The WinTest Analysis software

* All terms italicised and with an asterisk are defined in Appendix A, the Glossary.

(Testometric, Rochdale, UK) was used to control the strain and stress in the material. The software recorded the stress, strain, ultimate stress and strain, and calculated the Young's modulus of the material. Average values were taken from three or more samples.

During the tests, the stress-strain curve was recorded. Stress and strain have a linear relationship in the elastic range, known as Hooke's law:

$$\sigma = \varepsilon E, \tag{5}$$

where σ is the stress in the sample, ε the strain, and E the Young modulus.

4.1.3.2 Qualitative evaluation: workshop 1 on the materials selection

As indicated by the HCD methodology (Section 1.2.1), the synthetic materials were finally selected through a participant-based study, thereafter referred to as workshop 1. This study focused on their tactile aspect and not the ultrasound images, which were only assessed during my ongoing material evaluation and through the quantitative tests. The qualitative evaluation aimed to select the materials which best mimicked the soft tissues, by asking surgeons to test them during workshop 1. Their evaluation focused on the following soft tissues: gallbladder, cystic duct and bile duct, skin, fat, muscle, the liver, the peritoneum, and the cystic artery.

During workshop 1, I presented samples of synthetic materials to the surgeons so that they could test and evaluate them. The tests were not blind tests as the surgeons knew what type of synthetic materials they were evaluating. I did not make any comparison between my materials and real samples, as that would have brought further ethical implications. The synthetic materials were those evaluated in the material exploration. They were divided into three groups, based on the results of the quantitative physical tests.

The samples selected for each type of soft tissue are summarised in Table 10. For each soft tissue, the surgeons evaluated one of the selected group of materials. I used the results of interview 2 and survey to select which one of the group of materials to test for each type of tissue. More precisely, during the participant-based characterisation of the soft tissues, the surgeons described and graded the tissues. The results of this enabled me to identify which group of synthetic materials best matched each soft tissue.

For each soft tissue, I provided 5 different types of materials for participants to evaluate. I presented one to five samples of each of these materials. More precisely, for the homogenous and smooth soft tissues (liver, gallbladder, bile duct, cystic duct, artery, and fat), I asked the surgeons to only evaluate one sample for each type of material. For the muscle, I showed four samples of each type of material with and without cotton fibres: material without fibres, material with a low density of fibres, material with a medium density of fibres, and material with a high density of fibres. Similarly, for the skin I prepared the same types of samples with stretchy fabric as bidirectional fibres and I additionally showed samples with texture to obtain their evaluation of a material without a smooth surface.

The samples were made using the same protocol for each type of tissue, which meant that they all had the same geometry (same moulds for the liver, gallbladder, artery, and bile duct) and the same thickness for the fat, muscle and skin. The aim was to ensure the consistency of the study.

The survey and interview 2 illustrated similarities in the properties of the bile duct, the cystic duct, and the arteries. Thus, it was possible to use the same materials for the samples of those three types of soft tissues.

* All terms italicised and with an asterisk are defined in Appendix A, the Glossary.

Table 10: Samples for workshop 1

Liver	Homogenous Smooth	1. Ecoflex gel,
		2. Ecoflex 0010,
		3. 50% Ecoflex gel/50%Ecoflex 0010,
		4. Ecoflex gel 25% part A (yellow),
		5. Ecoflex gel 75% part A (yellow),
Gallbladder	Homogenous Smooth	1. Ecoflex 0030
		2. DragonSkin Fast
		3. DragonSkin 25% part A (yellow),
		4. DragonSkin 75% part A (yellow),
		5. DragonSkin + 20% slacker
Bile duct, Cystic duct, Artery	Homogenous Smooth	1. Ecoflex 0030
		2. DragonSkin
		3. DragonSkin 25% part A (yellow),
		4. DragonSkin 75% part A (yellow),
		5. DragonSkin + 20% slacker
Fat	Homogenous Smooth	1. Ecoflex gel,
		2. Ecoflex 0010
		3. 50% Ecoflex gel/50%Ecoflex 0010
		4. Ecoflex gel 25% part A (yellow)
		5. Ecoflex gel 75% part A (yellow)
Muscle-Skin	Homogenous Smooth	1. Ecoflex 0030
		2. DragonSkin
		3. DragonSkin 25% part A (yellow),
		4. DragonSkin 75% part A (yellow),
		5. DragonSkin + 20% slacker
Muscle-Skin	Homogenous Not smooth	1. Ecoflex 0030
		2. DragonSkin
		3. DragonSkin 25% part A (yellow),
		4. DragonSkin 75% part A (yellow),
		5. DragonSkin + 20% slacker
Muscle	Heterogenous (unidirectional fibres) Not smooth (with the fibres)	1. Ecoflex 0030
		2. DragonSkin
		3. DragonSkin 25% part A (yellow),
		4. DragonSkin 75% part A (yellow),
		5. DragonSkin + 20% slacker
Skin	Heterogenous (with bidirectional fibres) Not smooth (with the fibres)	1. Ecoflex 0010
		2. Ecoflex 0030
		3. DragonSkin
		4. DragonSkin 25% part A (yellow),
		5. DragonSkin 75% part A (yellow),

During workshop 1, I provided different samples for each type of soft tissue and asked the surgeons to evaluate the tactile properties of the samples. More precisely, I asked the surgeons to:

- Give a free description of the samples.
- State the most important characteristics of each sample, using the list of descriptives defined at the end of the survey.
- Select the best sample for the organ overall.

Figure 30 shows the liver samples, Figure 31 the gallbladder samples and Figure 32 the vessel samples prepared for this workshop.

Figure 30: Presentation of the liver samples

* All terms italicised and with an asterisk are defined in Appendix A, the Glossary.

Figure 31: Presentation of the gallbladder samples

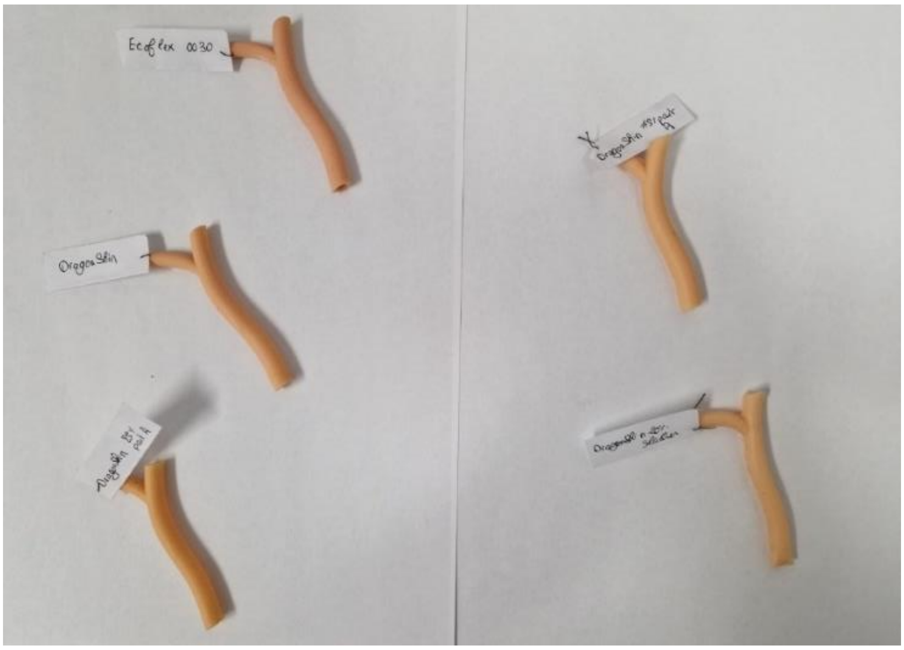


Figure 32: Presentation of the vessel samples

4.2 Results

Selecting the material was a multiple-step process which included characterising the properties of the soft tissues to be simulated, investigating and evaluating

* All terms italicised and with an asterisk are defined in Appendix A, the Glossary.

various materials with the properties of the soft tissues deduced from the first part of the study.

4.2.1 Properties of soft tissues

I implemented both quantitative and qualitative methods to choose the right materials. The first step was to characterise the soft tissues using these two methods. The literature review ascertained the physical and acoustic properties of the tissues (Section 2.3.1.2); then a two-step participant-based study allowed me to obtain a description of the tactile feedback from the tissues and to identify the main characteristics of the feedback using both direct touch and touch through the tools, through interview 2 followed by a survey.

4.2.1.1 Interview 2 on characterising the tactile feedback

During interview 2, each surgeon was asked about the tactile feedback from touching the soft tissues that needed to be included in the simulator. The soft tissues evaluated comprised the abdominal wall (skin, fat, and muscle), the liver, the gallbladder, the bile duct, the blood vessels, and the stones.

The surgeons were asked to describe their sensations when using direct touch, and when touching the tissues through the tools involved in the surgery, that is grasping tools, dissecting tools, cutting tools, clamping tools, scoping tools, and suturing tools.

Nine surgeons participated in interview 2; they are referred to as surgeon A to surgeon I. Among them, two were novice surgeons (surgeon B and surgeon C) and seven are experienced surgeons.

Interview 2 illustrated the need to correctly mimic tactile feedback using different types of materials for the different tissues. Indeed, the surgeons explained that they get validation of what they are touching using their tactile sense. Surgeon E stated that, during surgery, "Y*ou bounce the tissue in your hands and you feel what it feels like. When you've got that feedback and you're in, it's a very natural movement for me now, but I'm sure I've learned it over the years, what's easy to*

* All terms italicised and with an asterisk are defined in Appendix A, the Glossary.

cut, what will cut. And it's the springiness and sort of like elasticities of it as well, which tells you a lot about the tissues". This feedback from a surgeon depicted the diversity of information included in the tactile feedback. It also showed that this is something that needs to be learned over time, which emphasised the need to select the right materials to mimic the soft tissues.

When using direct touch, the soft tissues were described using a list of 53 descriptive and 32 comparatives. Using surgical tools also had an influence on the tactile feedback, interview 2 gathered a list of 35 descriptives of the tactile feedback though the different tools.

The list of descriptives is analysed according to the procedure described in Section 4.1.1. A first analysis of the results is based on grouping words with similar meanings, by using a dictionary and paying attention to the participants' statements to understand whether they were referring to the same property of the soft tissue when using different words. The word grouping was done by analysing which words are synonyms or opposites. Figure 33 shows which words were grouped together.

* All terms italicised and with an asterisk are defined in Appendix A, the Glossary.

Figure 33: (a) Grouping words with similar meanings; (b) selecting the main word per group of words

Then a frequency-based selection was done to keep only the most relevant parameters to describe tactile feedback from the soft tissues; the most frequent terms are shown in Figure 34. After this analysis, there was only a list of 10 parameters left to be analysed in the second part of the study, which covered both using direct touch and touch through the tools. This list includes softness, smoothness, thickness, elasticity, attachment to other tissues, resistance to gripping, resistance to cutting, resistance to suture, resistance to pulling, and

* All terms italicised and with an asterisk are defined in Appendix A, the Glossary.

resistance to tearing. These parameters should describe most of the tactile feedback during LCBDE surgery.

Other commonly mentioned characteristics were how tense or pliable the soft tissues are. These characteristics are not a part of the main adjective list because they are less frequently mentioned and because they are very close in meaning to softness and elasticity.

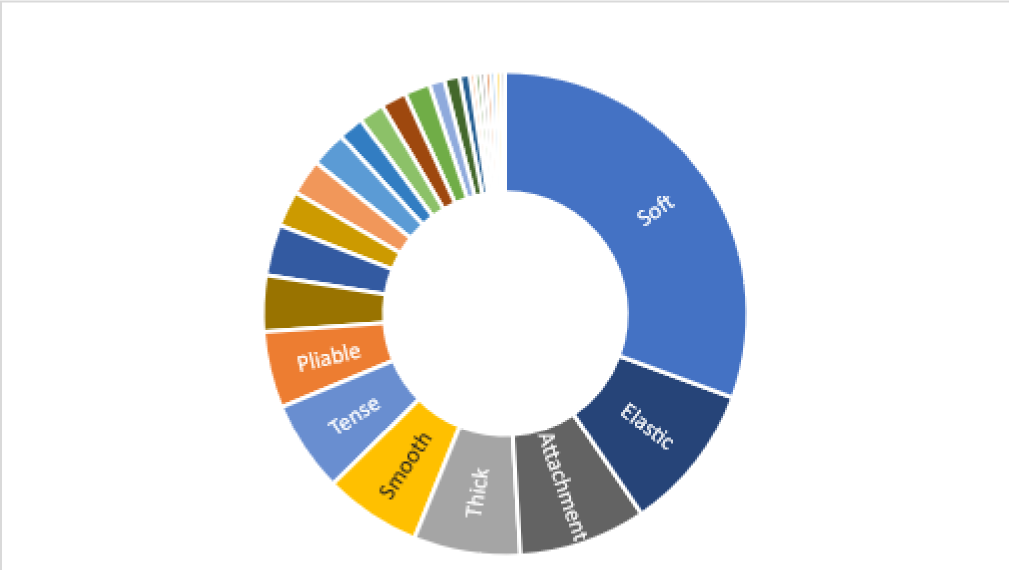


Figure 34: Characteristics of the soft tissues displayed proportionally to how frequently they were mentioned by the participants

During interview 2, several surgeons said that there are fibres in some of the soft tissues. They were referring to the skin, muscle, and peritoneum. The word "fibres" was not mentioned as much as other descriptives because it does not concern all the soft tissues, but it is an important characteristic for the soft tissues that it does concern. For instance, surgeon A said the following about muscle: "*Because they are in fibres, the fibres will tend to split easily, but the fibres themselves are difficult to tear, so they're easily splayed, but not torn".* This statement provides a valuable insight about the characteristics of muscle and its behaviour during surgery. Thus, it was important to investigate both homogenous and heterogenous materials to be able to mimic correctly the specificities of the soft tissues.

* All terms italicised and with an asterisk are defined in Appendix A, the Glossary.

Similarly, the terms “in a capsule”, “fragile”, and “friable” were not mentioned frequently because they only concern the liver and fat; however, they are important features of the liver and fat, especially the liver capsule. Another comment was the fact that soft tissues can bleed, which is an important feature but is difficult to include in the context of simulation. The other adjectives were mentioned less than three times and are not crucial characteristics of the soft tissues.

During interview 2, the surgeons made additional comments on the tactile feedback and more specifically the feel of touching through tools, which was also important to consider to mimic the soft tissues correctly. These findings are summarised in the following table.

* All terms italicised and with an asterisk are defined in Appendix A, the Glossary.

Table 11: Important tactile characteristics mentioned by the surgeons during the interviews

Tactile parameter or characteristic	Comments
Complexity and subtlety of resistance to suture	For instance, the surgeons mentioned the difficulty of penetrating a tissue with a needle, and the wear between the yarn and the tissue during a suture.
Tactile feedback is influenced both by the type of tool	There would be more feedback when using a more precise and sharply pointed instrument.
Tactile feedback is less precise and complete when using tools comparing to direct touch, but there is still feedback in laparoscopic surgery.	The surgeons stated that they gained a sense of tactile feedback from the tissues and how they respond to the instrument, because it is reverberated up the shaft of the instrument.
The feedback also differs from one tissue to another, and the surgeons can recognise the soft tissues because of that.	For instance, because the liver has an external capsule, there is a small resistance at the beginning of a suture which then disappears. Because of these differences between tissues, some surgeons said that they can use tactile feedback to identify which tissue they are in contact with during the surgery, however, some of the surgeons argued that they use the tissues' location and appearance more to identify them. Indeed, interview 2 showed that the tissues' appearance and location is also very important for identification.
The tissues' colours and textures can be very variable between patients.	Surgeon D said that "*I'm not sure whether necessarily the colour always is so important, because the colours can be so variable. Sometimes you can be fooled by the colour. And the texture again*

* All terms italicised and with an asterisk are defined in Appendix A, the Glossary.

	can vary so much, but again, you can be a little bit fooled". Notably, the liver and the gallbladder vary a lot between patients, depending on if they are inflamed or not. In the context of simulation, this shows that it is important to pay attention to colour and texture, but it is not necessarily very precise.

* All terms italicised and with an asterisk are defined in Appendix A, the Glossary.

4.2.1.2 Conducting the survey

The survey was conducted on Qualtrics. The survey made a quantitative analysis of the parameters identified in the first part of the study. To do this, participants were asked to rank order the soft tissues, and then grade them. For instance, in terms of smoothness, participants were asked to rank order the soft tissues from the smoothest to the least smooth and then to grade them on a scale from 0 to 10.

The data were statistically analysed on SPSS software. The data were first analysed using the boxplots shown in Figures 35 and 36, then the correlation relationships were assessed with the Spearman test.

- Inter-user variability

Kruskall Wallis and boxplots were used to assess inter-user variability. The Kruskall Wallis test showed that all the parameters had the same distribution across the participants, which indicates that the surgeons agreed in their responses.

Boxplots were used to evaluate the distribution of the surgeons' responses of on a tactile property according to the type of soft tissue, to assess inter-user variability and to identify the outliers. In the cases where the data range was narrow on the boxplot, most surgeons had evaluated the specific property of a specific tissue similarly. However, a large distribution of the surgeons' answers showed that they disagreed. Table 12 shows where the surgeons agreed and where there was contrast in their answers.

For the bile duct, cystic duct, cystic artery, gallbladder, muscle and skin, the boxplots were the narrowest. This showed that there was less variability for these soft tissues and that the results were more reliable for them.

* All terms italicised and with an asterisk are defined in Appendix A, the Glossary.

Table 12: Dispersion of the surgeons' responses: items where the surgeons tended to agree are shown in green (data range inferior to 3), items where there was no consensus are in orange (data range of 3 to 6); items where there was a lot of contrast are shown in red (data range superior to 6)

Parameter	Bile duct	Cystic artery	Cystic duct	Fat	Gallbladder	Liver	Muscle	Peritoneum	Skin
Attachment									
Elasticity									
Resistance to gripping									
Resistance to pulling									
Smoothness									
Softness									
Resistance to suture									
Resistance to cutting									
Resistance to tearing									
Thickness									

For some of the soft tissues, the results were more widespread. The dispersion of the results for fat might be because there are two types of fat during LCBDE surgery: subcutaneous fat and abdominal fat; these can have different properties, which could explain these differences. The softest tissues such as the liver and gallbladder can also have more variability between patients, which could explain their wide distribution. During interview 2, surgeon A said that "*Liver, it's soft. Well it can be soft, it can be pliable with variable sort of... actually it has variable concessions in textures depending upon how much fat infiltration it's had. You can have a coarse outline, but generally it's smooth and it's soft*". The large distribution for the peritoneum could be because its tactile characteristics depends on the tissues it is attached to, so it is also very variable.

There was no clear agreement amongst the surgeons on their evaluation of the tissues' softness and smoothness. This might be due to the variability between patients or possibly a lack of clarity in the question.

The results were quite widespread regarding the resistance to pulling and resistance to suture, which might be due to the clarity of the question. For instance, there could be different interpretations of resistance to suture: either resistance to getting the needle in or to driving the thread through the tissue. Surgeon H described tactile feedback during a suture as follows: “*And suturing, you’ve just got to be able to feel that during the suture the point of the needle is going through different tissues. So you’ve got to have that initial resistance. And it depends on whether you're using a monofilament or braided filament. Depends on what the resistance feels like as you pull the suture through. Braided obviously gives you a bit more resistance as you're pulling through; monofilament, it just comes very quickly through*”.

Furthermore, scrutinising these plots revealed that some soft tissues have similar properties. They can be divided into three categories: firstly, the gallbladder, bile duct, cystic duct, and cystic artery have similar properties. Secondly, the liver and fat are very similar. Finally, the muscle and skin are also comparable.

* All terms italicised and with an asterisk are defined in Appendix A, the Glossary.

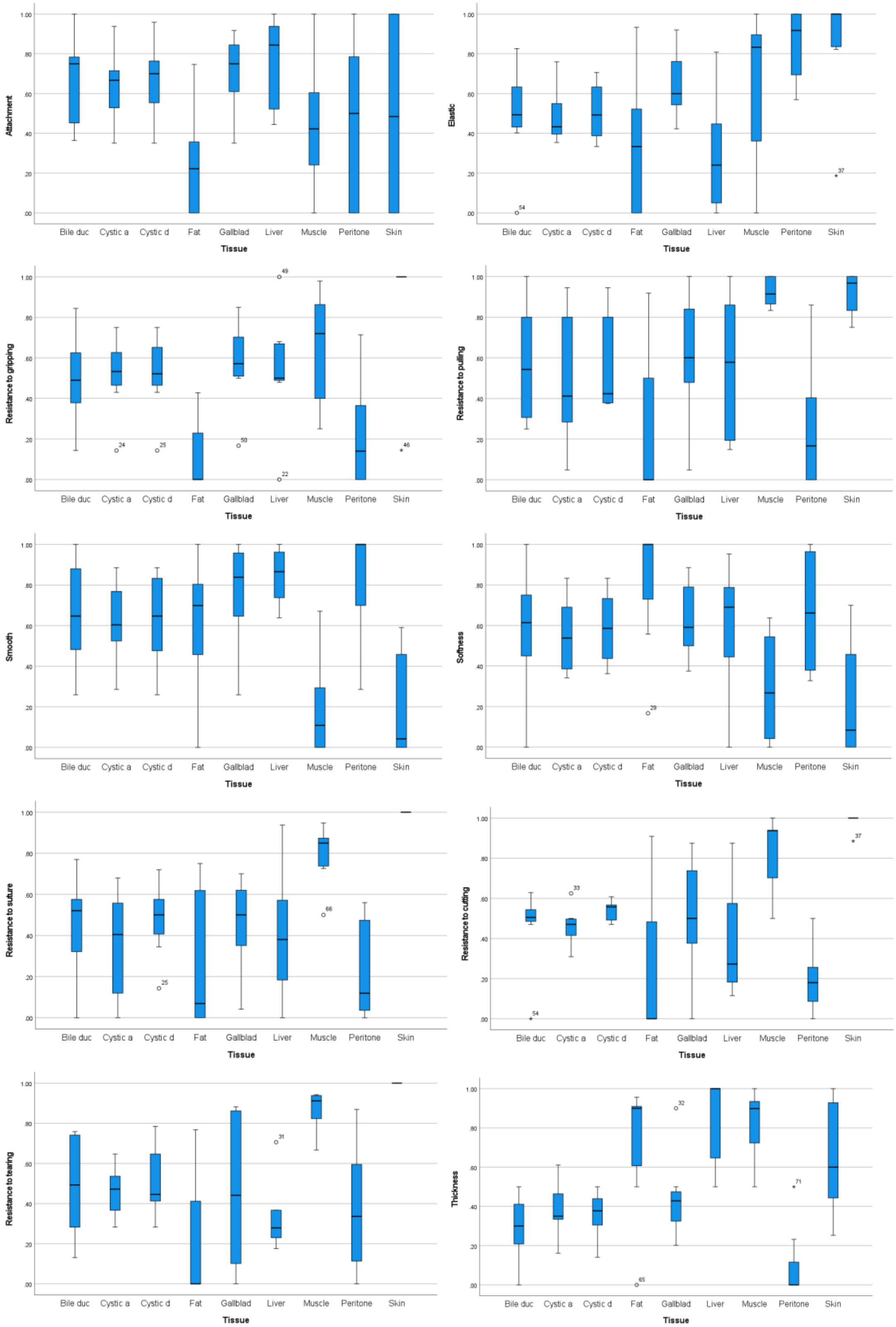


Figure 35: Boxplots showing the distribution of data over types of soft tissues

* All terms italicised and with an asterisk are defined in Appendix A, the Glossary.

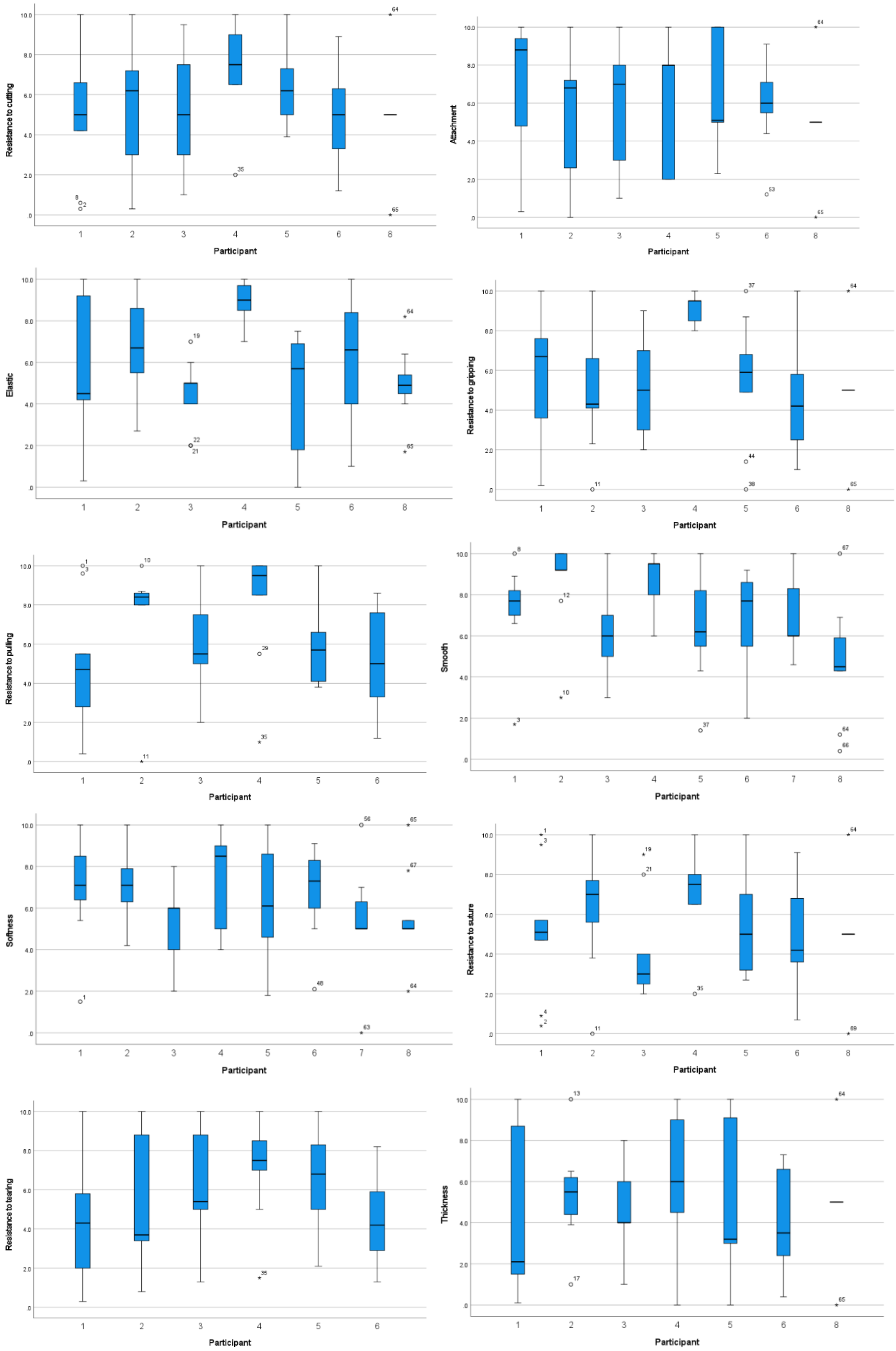


Figure 36: Boxplots showing the distribution of data over participant number before normalisation. Participants 7 and 8 did not reply to all the questions in the survey

* All terms italicised and with an asterisk are defined in Appendix A, the Glossary.

- Inter-tissues variability

The boxplots used to ascertain the distribution of a tactile property according to participant numbers were analysed to evaluate inter-tissue variability.

Outliers and data dispersion patterns showed the dispersion of certain properties among the tissues: where the data range is narrow with outliers, it shows that most tissues have similar properties but a few of them have very different properties from the main group. For instance, the data range for smoothness was narrow with many outliers for participants 1, 2 and 8; this shows that many tissues have similar properties except one or two with very different properties – generally the muscle and fat. Alternatively, very dispersed data illustrates diversity between tissues.

- Outcome of the statistical analysis

The Shapiro-Wilk test showed that not all the datasets were normally distributed. Thus, the data was analysed with the Spearman non-parametric test, to evaluate the correlation relationship between quantitative parameters.

Table 13 shows the correlation coefficient between pairs of parameters; this coefficient is between -1 and 1. Where the absolute value of the correlation coefficient was close to 1, there was a strong correlation between the two evaluated parameters. Where the value was close to 0, there was a weak correlation. Where the correlation parameter was negative, the correlation was negative, which means that when one of the parameters increases, the other decreases.

Tissue elasticity and attachment were independent parameters as they were not correlated to any other type of touch parameters. These two parameters did not seem to impact on indirect touch, which is the most essential type of touch during laparoscopy. However, as surgeon F mentioned, attachment is an important factor in how the tissue will behave: "*For example, attachment is important: if the bile duct was a piece of tubing strung between two fixed points, then that would be quite different to how it is in life because in life the bile duct is embedded in tissue*

* All terms italicised and with an asterisk are defined in Appendix A, the Glossary.

throughout its length ". This showed the importance of properly attaching the synthetic soft tissues during the simulation, to accurately replicate the feedback by avoiding unrealistic behaviour.

Some of the direct touch parameters were correlated, but not strongly. There was a correlation of -0.342 between thickness and softness and a correlation of -0.364 between thickness and smoothness, which indicated that the largest tissues were also the softest and smoothest. This could be due to the sample of soft tissues being evaluated in this study; indeed, the thickest soft tissues in the study were fat and the liver, which tend to be very smooth and soft. There was also a correlation of 0.596 between softness and smoothness, showing that the smoothest tissues tend to also be soft.

Because the correlation between the direct touch parameters were weak, they can be considered as primarily independent, and each described different aspects of the tactile feedback during surgery. They were all necessary to describe the surgeons' sensations when touching the tissues directly.

The direct touch parameters mainly explained sensations felt through the tools. More precisely, the results showed that smoothness, thickness, and especially softness were important parameters for identifying tissues when using indirect touch. Consequently, if these properties are mimicked well, then the sensation through the tools should also be mimicked well.

There was a negative correlation between touch through the tools and softness, between touch through the tools and smoothness, and a weak positive correlation between thickness and touch through the tools. This showed that thicker tissues provided more resistance when using tools. The impact of smoothness can be explained by the difficulty of making an incision or grasping a very smooth surface.

* All terms italicised and with an asterisk are defined in Appendix A, the Glossary.

Table 13: Statistical analysis of the data using Spearman's test

		Softness	Thickness	Smooth	Elastic	Attachment	Resistance to gripping	Resistance to suture	Resistance to cutting	Resistance to pulling	Resistance to tearing
Spearman's rho	Softness	1	-.342**	.596**	-0.072	-0.087	-.418**	-.682**	-.694**	-.552**	-.654**
	Thickness	-.342**	1	-.364**	-0.066	0.036	0.139	.330**	.458**	.339*	0.197
	Smooth	.596**	-.364**	1	-0.164	0.147	-.289*	-.426**	-.536**	-0.242	-.508**
	Elastic	-0.072	-0.066	-0.164	1	-0.186	0.073	0.141	0.226	0.028	0.250
	Attachment	-0.087	0.036	0.147	-0.186	1	0.205	0.061	0.159	0.261	0.089
	Resistance to gripping	-.418**	0.139	-.289*	0.073	0.205	1	.520**	.517**	.464**	.522**
	Resistance to suture	-.682**	.330**	-.426**	0.141	0.061	.520**	1	.809**	.765**	.731**
	Resistance to cutting	-.694**	.458**	-.536**	0.226	0.159	.517**	.809**	1	.770**	.826**
	Resistance to pulling	-.552**	.339*	-0.242	0.028	0.261	.464**	.765**	.770**	1	.730**
	Resistance to tearing	-.654**	0.197	-.508**	0.250	0.089	.522**	.731**	.826**	.730**	1

*. Correlation is significant at the 0.5 level

**. Correlation is significant at the 0.01 level

Represents a strong correlation with a coefficient superior to 0.8

Represents a correlation with a coefficient between 0.7 and 0.8

Represents a correlation with a coefficient between 0.6 and 0.7

Represents a correlation with a coefficient between 0.5 and 0.6

Represents a correlation with a coefficient between 0.4 and 0.5

Represents a correlation with a coefficient between 0.3 and 0.4

Represents a weak correlation with a coefficient inferior to 0.3

Represents a non-significant correlation

Furthermore, there was a strong positive correlation between different sensations felt through the tools. This showed that the main sensations experienced through the tools were similar in the way that, when it is more difficult to perform one task,

* All terms italicised and with an asterisk are defined in Appendix A, the Glossary.

it was also more challenging to perform the other tasks. In the context of surgical simulation, it was therefore not necessary to evaluate the synthetic materials on each sensation through the tools, and evaluating them on their resistance to suture was enough for the indirect touch.

4.2.2 Results of the materials investigation

The second step of the materials selection was to investigate commonly used materials in the literature to define which ones would be suitable to mimic the soft tissues' tactile properties and ultrasound properties in a simulation practice. The investigated materials included bulk agents such as silicone and gels, and scattering particles of various sizes.

4.2.2.1 Qualitative evaluation

The material investigation aimed to determine which materials best mimicked the soft tissues. It was done following an action research methodology (Section 1.2.2) and was divided into quantitative and qualitative evaluations. The qualitative evaluation focused on evaluating the ultrasound images, the tactile properties, and the fabrication method.

- Bulk material

The materials investigation first consisted of testing several bulk materials. As discussed in Section 4.1.2, the tested materials were silicone and gels. The tests, recorded in the research diary, allowed me to make several observations. Firstly, the tactile properties of the samples varied greatly, from the softest material (gels and silicone Ecoflex gel) to the hardest (silicone DragonSkin). Thus, they had the capacity to mimic a wide range of soft tissues. However, agar gel is soft but not elastic and is not very suitable for mimicking the tactile feedback of soft tissues.

During my investigation, I experimented with modifying the stoichiometric ratio of the silicone. Having a higher percentage of part A resulted in a harder sample compared to the stoichiometric ratio; having a higher percentage of part B resulted in a softer sample. When the percentage of one of the two parts was further increased, it caused curing problems. This is why, in the final samples, I only kept samples with a ratio of 25% part A/75% part B for Ecoflex gel and with a ratio of 25% part A/75% part B or 75% part A/25% part B for DragonSkin, which increased the range of the materials' properties.

Addition cure silicones usually have a long shelf life (Ahmad *et al.*, 2020); however, in my study, I investigating the impact of not using the stoichiometric ratio recommended by the supplier (50% part A and 50% part B). This allowed me to obtain more variability in the materials' properties, but previous studies have shown that this can result in instability over time because it leads to post-reactions, which can cause a degradation of the properties (Mazurek, Vudayagiri and Skov, 2019). In my research, I did not perform comparative quantitative tests over a long period so it was not possible to predict if the material selected by the surgeons would still have the right properties over long periods of time. In this study, the materials were tested within one month after their fabrication, and I recommend to use them within this timespan to replicate the results.

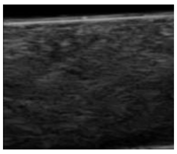
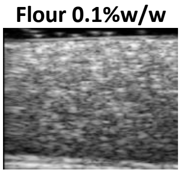
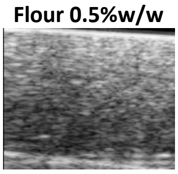
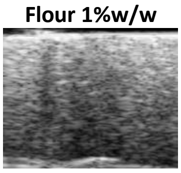
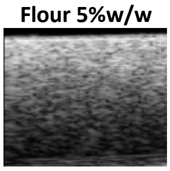
Another observation was that the air bubbles within the silicone samples had an influence on the tactile feedback and on the ultrasound. Vacuuming them removed air bubbles trapped inside the samples. The air bubbles acted the same way as a scattering agent for the ultrasounds and made the sample appear clearer during the ultrasound examination. From this study, it also became apparent that there were more air bubbles in the softest silicones comparing to the hardest ones, which made them appear clearer with the ultrasounds.

- Scattering materials

In the ultrasound images, the agar gel appeared grey and looked realistic without having any scattering material added to it; however, the silicone took on differing shades of grey. The hardest silicones were anechoic and appeared black in the image, which might be due to the low level of air bubbles trapped inside them. Incorporating a scattering material into the material made the sample more visible by increasing the reflection of the ultrasound waves; the scanned material then appeared in grey in the ultrasound image.

Studying the influence of the percentage and particle size on the images demonstrated that raising the percentage of scattering materials resulted in brighter ultrasound images because the particle caused more reflection, as visible in Table 14. When there was too much scattering material (more than 1%w/w), the ultrasound wave was reflected so much on the particles that it limited its penetration into the sample, causing the ultrasound images to become dark at the bottom. The best percentage seemed to be 0.5%w/w, which created a clear sample without too much reflection.

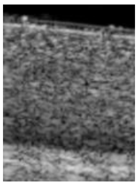
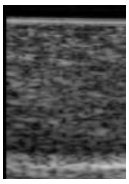
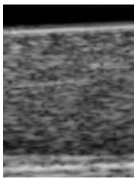
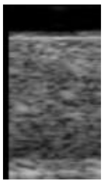
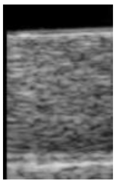
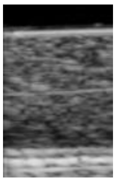
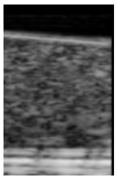
Table 14: "Effect of increasing the percentage of scattering agent" by Marine Shao, used under CC BY 3.0

Flour 0.05%	Flour 0.1%w/w	Flour 0.5%w/w	Flour 1%w/w	Flour 5%w/w
				

The impact of the size of the scattering material, where the different powders were mixed using the same ratio in samples of the silicone DragonSkin, is shown in Table 15. However, there was not much visible difference between the images in terms of echogenicity, homogeneity and texture. This was because the particles of the scattering agent did not spread evenly into the silicone matrices, as their surface chemistry made them tend to agglomerate rather than to disperse into the bulk agent. Because of the silicone's high viscosity, it was difficult to force a homogenous dispersion of the particles into the samples (Krauter *et al.*, 2015). Thus, the particles regrouped and appeared bigger in the ultrasound image, resulting in very similar images for particles of different sizes.

* All terms italicised and with an asterisk are defined in Appendix A, the Glossary.

Table 15: "Effect of the different types of scattering particles" by Marine Shao, used under CC BY 3.0

Polestar 450	Graphite	Glass sphere	Flour	Silica	Alumina	Sugar
						

Adding the scattering agent also resulted in a modification of the tactile feedback; indeed, adding a high percentage of powder into the material modified the material's tactile feedback, making it more friable and less elastic.

- Heterogenous materials

The heterogenous materials were made of silicone and fibres. The agar samples were not considered among the heterogenous materials because the heterogenous soft tissues are the skin and the muscle, which are among the hardest soft tissues. The fibres tested were unidirectional with the inclusion of cotton gauze and bidirectional with the inclusion of a flexible fabric.

When using bidirectional fibres, the final samples' properties of elasticity and ability to deform were the same as those of the stretchy fabric alone. This was because the fabric was less elastic than the polymer.

With the inclusion of fibres, the sample was less tacky and less smooth than the polymer alone. Indeed, the fibres added a texture onto the surface.

4.2.2.2 Results of quantitative test on the materials

The quantitative evaluation aimed to measure the physical properties of the investigated materials and compare them to the properties of the soft tissues. Physical tests were only carried out on the silicone samples as the gel-based materials could not be placed in the tensile testing machine.

The full results are provided in the appendices. Measuring their density revealed that the samples' density varied between $9.6x10^{2}kg/m^{3}$ and $1.1x10^{3}kg/m^{3}$. The density of soft tissues usually varies between 950 to 1060 kg/m^3 (Soni, Arntfield and Kory, 2015), so the tests showed that the samples' density was in the correct range.

The tests also showed that the density of the silicone sample seemed to be correlated to the silicone's hardness; the softest silicones had a low density, while the hardest silicones had the highest density.

From the results on the materials' density, it was evident that DragonSkin-based materials, which are more rubber-like, were suitable for the liver capsule, blood vessels, and the ducts; and that softer materials such as Ecoflex gel or Ecoflex 0010 were more suitable for the gallbladder, which is less rigid, and for softer tissues such as the peritoneum.

The evaluation found that the speed of sound varied between 9.0x10^{2}m/s and 1.0x10^{3}m/s in the silicone samples. The speed of sound in soft tissues is typically from 1450 to 1590m/s (Section 2.3.1.2), which is significantly higher than the speed of sound in the samples. The speed of sound in the agar gel samples was 1.40x10^{3}m/s, which fits the range of the speed of sound in soft tissues.

Vacuuming the samples or the addition of a scattering agent did not seem to have any effect on the speed of sound into the sample or the density of the samples.

The low speed of sound in the silicone resulted in a distortion of the ultrasound image. This has been documented in previous research (Pacioni *et al*., 2015), and results in a deformation of the sample's dimensions in the image. The speed of sound in the silicone was about 2/3rd of the speed of sound in the soft tissues, which led to the sample appearing deformed with a factor of 1.5. Thus, silicone is not suitable for ultrasound simulation.

Agar gel is commonly used in ultrasound simulation because of its suitable acoustic properties (Ahmad *et al.*, 2020); however, because of its gel-like consistency, it cannot be used to mimic the tactile feedback of soft tissues. Therefore, it was not possible to use the same physical model to mimic both tactile feedback and

* All terms italicised and with an asterisk are defined in Appendix A, the Glossary.

ultrasound. A second physical model made of agar gel was developed for the ultrasound.

The WinTest Analysis software recorded the stress-strain curve, such as the curve depicted in Figure 37. The curve was linear before rupture, which demonstrated the suitability of using Hooke's law to calculate the Young's modulus. At the beginning, the curve was flat, due to the deformation of the sample when it was placed in the testing machine, which resulted in an offset.

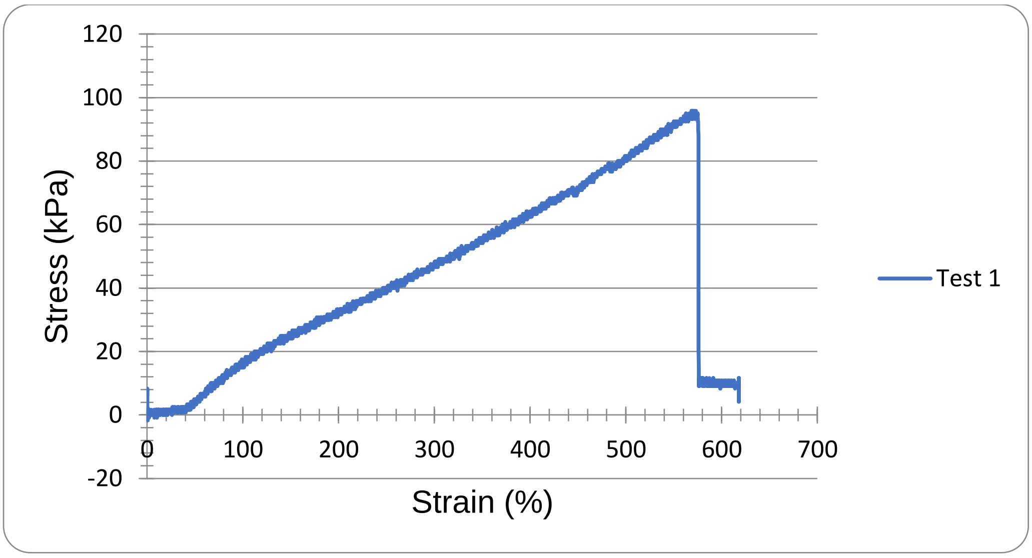


Figure 37: Stress-strain curve from a sample

The software also recorded the following parameters: stress and force at peak, strain and deformation at peak, and the Young's modulus.

The suppliers stated the shore hardness of some of the materials in their data sheets. It was also possible to compare the materials' shore hardness to the information about soft tissues' shore hardness found in the literature.

The physical tests showed that it was possible to divide the materials into categories depending on their properties, including their softness and stress at break. This allowed me to identify which synthetic samples to use for each type of soft tissue, by referring to the properties of the soft tissues described in Section 2.3.1.2. The materials were divided into three categories, as shown in Table 16:

* All terms italicised and with an asterisk are defined in Appendix A, the Glossary.

Table 16: Categories of synthetic materials

Category	Materials	Properties	Similar soft tissues
Extremely soft materials	Ecoflex gel, Ecoflex gel 25% part A, Ecoflex gel 75% part A, and Ecoflex gel 10% thinner	- Young modulus below 10kPa - Low ultimate strain (around 100%) - Low ultimate stress (around 10^{-2}N/mm^2)	Liver, fat
Very soft materials	Ecoflex 0010, Ecoflex 0030, 50% Ecoflex gel and 50% Ecoflex 0010, DragonSkin 20% Slacker	- Young modulus ranging from 10 to 100kPa - ultimate strain of around 1000% - ultimate stress of around $5x10^{-1}$N/mm^2	Liver, fat, peritoneum, muscle
Soft materials	50% Ecoflex 0030 and 50% DragonSkin, DragonSkin, DragonSkin 25% part A, DragonSkin 75% part A, DragonSkin and sugar	- Young modulus ranging from 100 to 200kPa - ultimate strain of around 1000% - ultimate stress ranging from 1 to 2N/mm^2	Gallbladder, artery, vein, liver capsule

Introducing a scattering agent – except for sugar because of its larger size – did not impact on the samples' physical and acoustic quantitative properties. Similarly, vacuuming did not impact on the properties. The results helped to define the materials for the samples used in workshop 1.

4.2.3 Workshop 1 on the materials selection

The quantitative evaluation and tests on the synthetic materials enabled me to divide them into groups for workshop 1. This grouping allowed me to select the most suitable samples to show the surgeons for each type of soft tissue. The surgeons were then asked to decide which sample from the selection was the most suitable to mimic the tactile feedback of each soft tissue. Full details of the results are provided in the appendices.

4.2.3.1 Liver

The material which best mimicked the liver was found to be Ecoflex gel 25% part A. Figure 38 shows the suturing tests made on the liver samples. As mentioned previously, this silicone was not mixed in a stoichiometric ratio which could impact its properties over time (Mazurek, Vudayagiri and Skov, 2019). To replicate the results, the sample has to be used within one month after fabrication. This is also the case for the bile duct, cystic duct, cystic artery, and peritoneum.

The surface of the liver needed to be smooth and feel wet and slippery, with a colour that is closer to red than brown. The most important tactile properties were elasticity and pliability. More precisely, for the liver, the surgeons needed to have a similar sensation when they moved it. The liver has a specific response when a surgeon presses it because it does not go back to its initial shape immediately, but only after some time.

* All terms italicised and with an asterisk are defined in Appendix A, the Glossary.

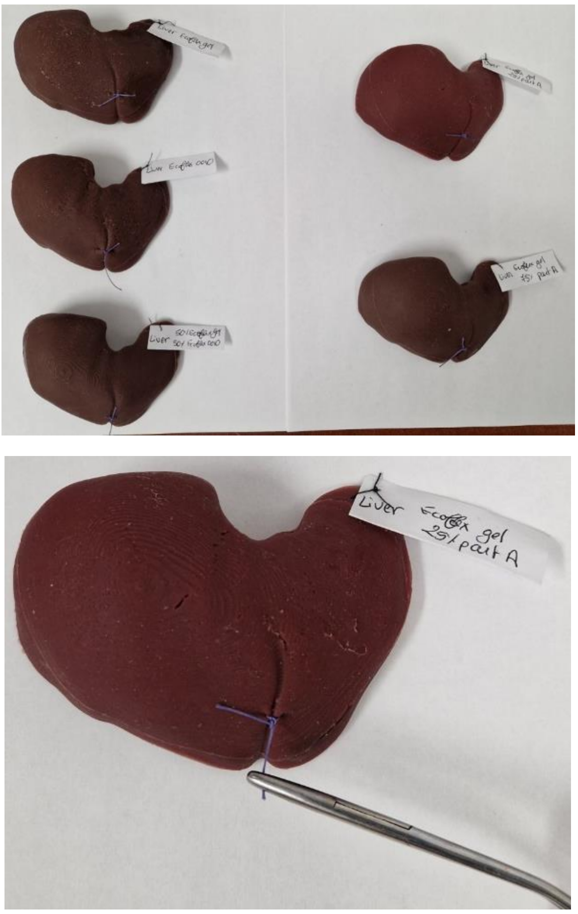


Figure 38: Evaluating cuts and sutures on the liver samples

4.2.3.2 Gallbladder

The material that best mimicked the gallbladder was DragonSkin for direct touch, DragonSkin 25% for cutting, and DragonSkin 75% for suturing, as shown in Figure 39. During their training, surgeons do not cut or suture the gallbladder, so it was easier to use DragonSkin than the other two options. Therefore, I decided to mimic the gallbladder with DragonSkin.

The gallbladder is thin-walled and its surface is wet and slippery and not sticky. It has some consistency because it is possible to squeeze and move around without it tearing. It feels soft but slightly tense. If there are any impacted stones, the surgeons can feel them too. It is very variable between patients.

* All terms italicised and with an asterisk are defined in Appendix A, the Glossary.

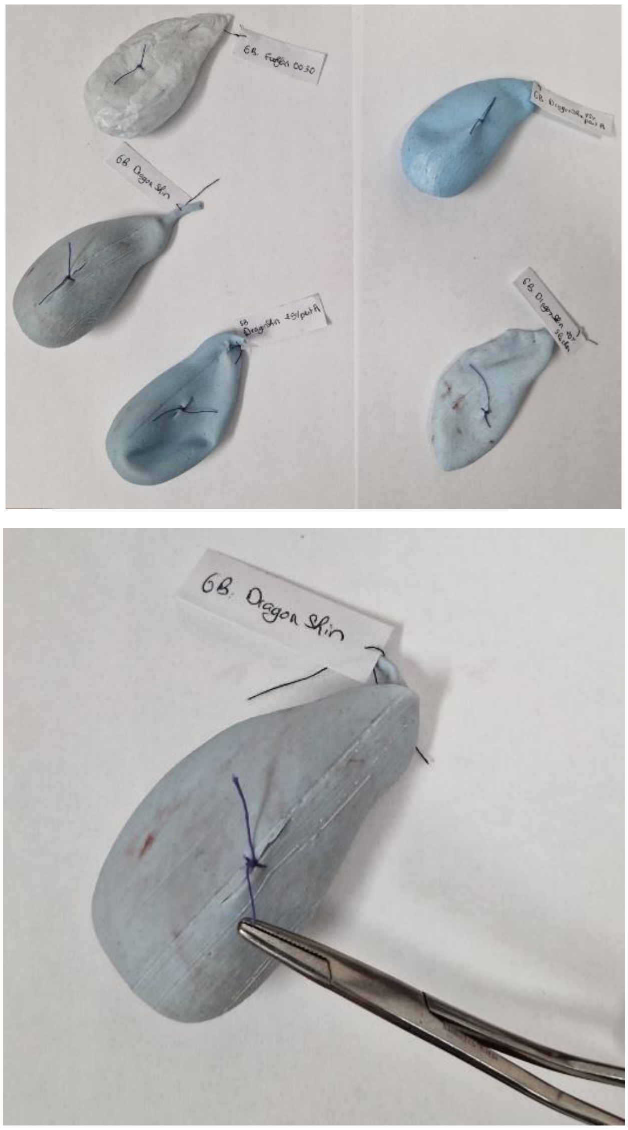


Figure 39: Evaluating cuts and sutures on the gallbladder samples

4.2.3.3 Bile duct and cystic duct

The material that best mimicked the bile duct was DragonSkin 75% A, which was evaluated as best for cutting and suturing, as shown in Figure 40, but bad for direct touch. Because LCBDE is laparoscopic surgery, cutting and suturing are more important than direct touch.

The colour of the bile duct is like the colour of the gallbladder, which is somewhere between blue and green, surrounded with a white structure which gives an overall grey appearance. The tube is wider than the hepatic artery but has thin walls. The texture is not sticky. It is soft and elastic but has some strength.

* All terms italicised and with an asterisk are defined in Appendix A, the Glossary.

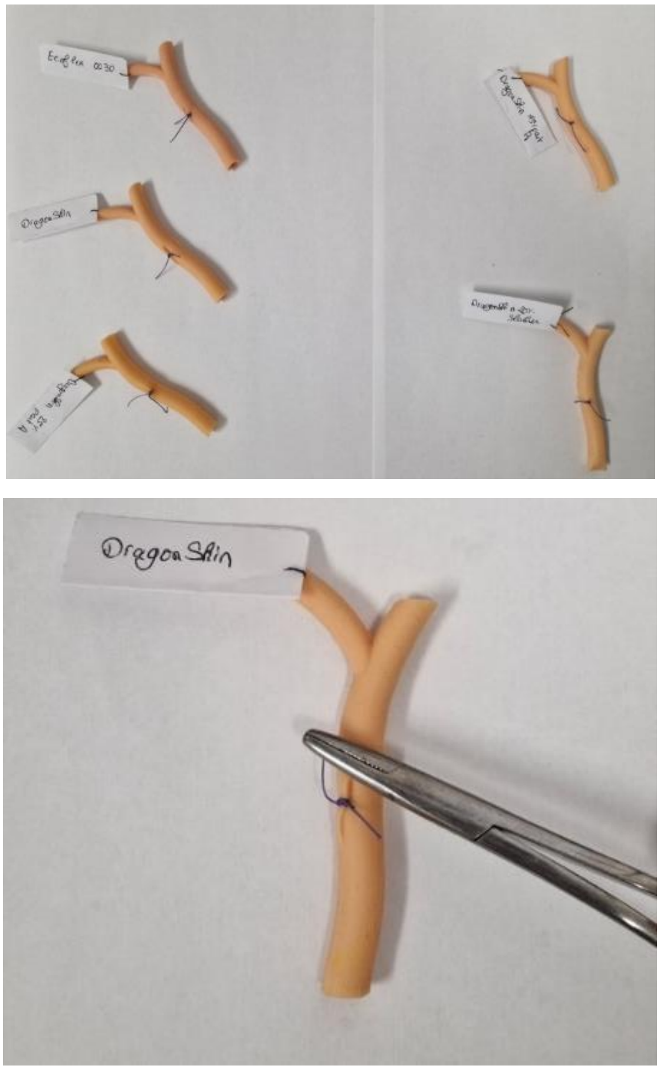


Figure 40: Evaluating cuts and sutures on the bile duct samples

4.2.3.4 Cystic artery

The best material to mimic the cystic artery was DragonSkin 25% part A. The cystic artery's tube is thick with a small calibre. It is solid, stiff, and elastic. It is springier than the ducts because it is thicker. It is also pulsatile.

For this research, I decided to use the same material as for the vein. As surgeons do not touch it during the surgery, it is not as important as the other parts.

4.2.3.5 Skin

The best materials to mimic skin were Ecoflex 0030 or DragonSkin 20% slacker. It felt better with four layers of bidirectional fibres in it; it also felt better with a texture.

* All terms italicised and with an asterisk are defined in Appendix A, the Glossary.

However, real skin is thinner than the samples. Consequently, I had to reduce its size in the final model and include less fabric layers. The size of the sample was 1cm whereas the size of skin is around 5mm; thus, I only included one layer of fabric.2

Skin is both soft and firm, and surgeons can feel that it is harder than the other subcutaneous layers. It has some elasticity and does not tear or rip when surgeons cut or stitch it. It is not sticky. It also varies between patients.

4.2.3.6 Muscle

The best materials to mimic muscle were found to be Ecoflex 0030 or DragonSkin 20% slacker. It felt better with low density unidirectional cotton fibres in it.

In term of consistency, muscle has tension, elasticity and softness, and is less compressible than skin because it is thicker. It is smooth, slippery, and not sticky. It does not rip; when surgeons move and dissect it, it does not tear. It also bleeds a lot.

4.2.3.7 Fat

The best materials to mimic the fat was Ecoflex gel. Fat is yellow in colour. It is very soft and springy and does not indent. It is thinner than the samples. The surface is not sticky but slippery and oily.

4.2.3.8 Peritoneum

The best materials to mimic the peritoneum were DragonSkin or DragonSkin 25% part A. It felt better without any fibres in it. The peritoneum is smooth and slippery rather than sticky. It is very thin. It rips easily when stretched to twice its original size and it dissect easily. It has some elasticity and strength.

4.2.3.9 Other soft tissues

The best material for the duodenum was selected as Ecoflex 0030. Surgeons do not touch it directly during LCBDE surgery, consequently, it was not as important in this study.

* All terms italicised and with an asterisk are defined in Appendix A, the Glossary.

4.3 Discussions

One of the main aspects of the research was finding the best materials to mimic the soft tissues. This aspect was divided into characterising the soft tissues, exploring the materials, and then evaluating and selecting them.

4.3.1 Characterising the soft tissues using perceptual studies

As described in my literature review, when they are moulded, physical surgical simulators are usually made of silicone or hydrogel. Otherwise, if they are 3D printed, they are made of a 3D printing compatible material. These materials are used due to their ability to reproduce the strain-stress response of some soft tissues. Nevertheless, using only the stress-strain response to choose the material was not enough for this research, as soft tissues have multiple complex tactile characteristics. For instance, my study has highlighted several additional characteristics which are important for an accurate reproduction of the tactile feedback, such as the type of surface of the soft tissues and their heterogeneity.

This study illustrates the complexity of the soft tissues' tactility that any simulator should intend to replicate. While it has provided a more complete description of the characteristics of touch, one of the limitations of this study is the variability of responses from participants. It demonstrated the subjectivity of their sensations. Even though physical tests can only measure a limited number of characteristics, using these types of tests does allow for precise measurements and defined goals for the synthetic materials.

4.3.2 Exploration and evaluation of the materials

Exploring the materials aimed to investigate the properties of synthetic materials commonly used in surgical simulation, to determine which one was the most adequate for each type of soft tissue. However, one of the limitations of this study is that this exploration only focused on a few materials, namely silicone and agar. The reason for this choice was to limit the number of materials tested to be able to make a thorough evaluation of each of them; however, it is possible that I overlooked other materials with better characteristics which would have been

* All terms italicised and with an asterisk are defined in Appendix A, the Glossary.

more suitable. However, this research aimed to mimic basic skills; for this reason, a simplified tactile feedback was not as problematic as for an expert's training.

In my study, the physical tests were limited to the tensile test; the literature describes multiple supplementary tests that could have been conducted to evaluate the synthetic soft tissues (Severseike *et al.*, 2019). Similarly, the quantitative sonographic parameters tested in this study were limited to the speed of sound in the tissue and the density; however, there are other parameters that influence the visual appearance of ultrasound images, such as the attenuation coefficient (Maggi *et al.*, 2009).

An important limitation of this study is that, while exploring the materials, I did not take into account the conductivity of the synthetic tissues. In real surgery, surgeons dissect tissues using electro-cautery, which relies on the conductivity of human soft tissues. With the materials chosen for this research, it was not possible to use this dissection technique, which was a limitation for training some of the steps of the surgery, such as the dissection of the gallbladder. A review by Yu *et al.* (2023) also described this as a limitation of most physical surgical simulators. Electro-cautery is not well mimicked because most models are made of polymers which are not conductive. As electro-cautery is now commonly used in surgery, though, it is important to also mimic it. Amiri *et al.* (2022) proposed a model that can be used to mimic electro-cautery using a combination of fat, water, and agar/gelatin. It would be interesting to explore this limitation further in future work.

This research relied on rotomoulding to create some of the organ replicas. Because this fabrication method is based on the material flowing along the surface of the inner mould, it required the material to be fluid enough to cover the entire mould before curing. Thus, additive materials were added into the silicone to make it more fluid. According to the supplier (Smooth-On, Macungie, USA), these additives are not supposed to modify the overall properties of the silicone, and the quantitative tests undertaken during this study confirmed that they did not have a visible impact; however, they might have had an impact on some tactile properties that

* All terms italicised and with an asterisk are defined in Appendix A, the Glossary.

were not recorded with the quantitative tests. To reproduce the results from the study, it is important to use the same additives in the same amounts.

4.3.3 User studies

This research relied on user studies with surgeons, which consisted of interviews, surveys, and workshops with participants to gather information on the surgical simulator produced during this research.

One of the limitations in conducting the interviews was the clarity of the questions. Previous research has highlighted that formulating questions during participant-based studies can be a bottleneck (DiCicco-Bloom and Crabtree, 2006). This was an issue in my own research, as the surgeons did not all interpret and understand the questions in the same way. When I asked them about the strengths and weaknesses of using surgical simulators, some surgeons focused on their previous experience of developing simulators and replied about fabricating and evaluating, rather than using a simulator. This question was interpreted in multiple ways depending on the surgeon's experience, which was good because it garnered more diverse answers, but was also a limitation because some surgeons did not give an answer to the question intended.

The clarity of questions was also a problem in the survey where the surgeons were asked to rank order and then grade the soft tissues according to different parameters. The main issue with this question was that it was too long and not clearly formulated, resulting in the surgeons misunderstanding what they were supposed to do. Moreover, the survey was also too long and repetitive, causing the surgeons to lose patience when answering the last questions.

Conversely, during the workshops, most participants stressed the same usability issues, such as the model's stickiness and thickness, confirming the results' reliability. In the literature, Kessner *et al.* (2001) have suggested that more specific and focused requests should lead to more overlap in problem discovery; in the workshops, the questions' focus was clearly defined as being the tactile feedback when touching the model, which could explain the repeatability in the results.

Another limitation was the vocabulary, because the words that I used, and the ones used by the surgeons were not always understood by both parties in the same way. For instance, during the surveys, I assumed that the surgeons clearly understood the terms "resistance to gripping" and "attachment of the tissue", which was not always the case, resulting in less clear results. It would have been important to clarify what I meant, but that would have generated a longer and more compact question, which would also have been detrimental to the experience.

Finally, the user study mostly comprised participants who work in the same surgical unit in one hospital. This could mean that the results are not generalisable to all surgeons. Previous studies have questioned the reliability, validity, and usefulness of usability testing, showing that different groups of users can provide radically divergent outcomes (Nielsen, Lewis and Turner, 2006).

4.3.4 Quantitative and qualitative methods

As part of the action research methodology, I combined quantitative and qualitative methods. The quantitative methods were very useful for drawing statistical analyses and conclusions on the research results, for instance, on the survey of the soft tissues' tactile properties. They were also helpful for evaluating the physical properties of the synthetic materials and classing them according to their characteristics.

The qualitative methods were even more valuable, as they provided indications on research directions and the research's limitations as well as ascertaining how far the research succeeded in its objectives. Participants gave qualitative feedback freely and provided extremely useful and specific recommendations. For example, during workshop 1, one of the surgeons said that "*the bile duct is stiffer on the model than in real life*", which helped improving the model.

4.4 Conclusion

This chapter has described the investigation conducted during my research to analyse surgeons' feedback from soft tissues during surgery and replicate it with synthetic materials. The findings suggested that the synthetic materials suitable for

* All terms italicised and with an asterisk are defined in Appendix A, the Glossary.

mimicking acoustic properties and those suitable for mimicking tactile properties were not the same. As such, the materials used to mimic the tactile feedback of soft tissues were a range of silicones, as they have similar tactile properties, and the material used to mimic the ultrasound was agar gel.

* All terms italicised and with an asterisk are defined in Appendix A, the Glossary.

Chapter 5: Style transfer for enhancing realism

The simulator developed in this research is a hybrid simulator. As such, it includes AR features, one of which aims to enhance its realism. The literature review revealed that surgeons gather important information on soft tissues from their appearance, for instance depth cues or indications of whether the tissue is healthy or not. Furthermore, according to the surgeons during interview 1 (Section 7.2.1), one of the most important aspects of surgical simulation is visual realism.

Physical simulators often lack authenticity because they are made of plastic. To improve their visual appearance, there are two possibilities:

- Working directly on the physical model through an artistic method or 2.5D printing. 2.5 D printing is a relief printing technique where a thin layer of solidified ink is printed onto a flat surface. The printer can add multiple layers of ink to create variations of surface height and modify its appearance (Liu *et al.*, 2014). The artistic method requires skills that cannot be generalised easily, and the 2.5D printing modifies appearance by adding something on the surface which alters the texture and results in a modification of the samples' tactile feedback.
- Improving the visual realism of the laparoscopic video through image processing techniques, such as style transfer.

The second option offers a systematic method that does not require any skills from the end user, making it more suitable for generalised utilisation of the simulator.

5.1 Methods

5.1.1 Adjustable style transfer for surgical simulation

Because the targeted surgery is a laparoscopic procedure, it was possible to enhance the simulation's realism by using style transfer (Section 2.3.3.1). This technique has been implemented to improve the realism of virtual simulators in past research (Luengo *et al.*, 2019).

* All terms italicised and with an asterisk are defined in Appendix A, the Glossary.

In contrast to Luengo *et al*. (2019), who did not take into account the temporal loss, the technique adopted was style transfer for videos. More precisely, the style of a picture taken from surgery was implemented on the simulator's recorded video to improve its appearance. This method was only used to improve the visual appearance of the soft tissues recorded through the laparoscope, but not to improve the appearance of the ultrasound images.

To avoid any issues around the choice of hyper-parameters, as highlighted by Babaeizadeh and Ghiasi (2019) and described in section 2.3.3.1, the technique was also intended to provide an adjustable solution which could modify stylisation in real-time to the end user's preferences, to generate the most realistic stylisation of the surgical simulator.

5.1.1.1 Definition of the losses

The stylisation of images is achieved through the minimisation of losses. The losses include content loss, style loss, and temporal loss. Content loss and style loss are the same as those defined by Gatys, Ecker and Bethge (2016), while temporal loss is the same as that defined by Huang *et al*. (2017) in their technique to stylise videos.

To calculate the different losses, the proposed technique used a machine learning recognition algorithm which applied different filters to the images. In this work, I used the VGG19 network, which includes 1 content layer with 512 filters "conv4_2" and the 4 style layers "conv1_2", "conv2_2", "conv3_4", "conv4_4" with 64, 128, 256, and 512 filters respectively; this represents 512 content filters $\boldsymbol{F_{content}}$ and 960 style filters $\boldsymbol{F_{style}}$. Each layer included a series of convolution operations on the image which performed weighted dot products of the values of the neighbouring pixels, followed by an activation with the ReLU function. In between some of the layers, maxpooling operations were performed to reduce the size of the input.

Each filter looked inside the image for a special feature, at different scales and levels of precision. The following function was used to calculate the difference, or loss, of content between the generated image (***G***) and the content image (***C***), in

* All terms italicised and with an asterisk are defined in Appendix A, the Glossary.

which $F_{content_{ij}}$ is the contribution of the *i*[th] content filter on position *j* of an image:

$$L_{content}(\boldsymbol{C},\boldsymbol{G}) = \frac{1}{2}\sum_j (F_{content_{ij}}(\boldsymbol{C}) - F_{content_{ij}}(\boldsymbol{G}))^2 \qquad (6)$$

The Gram matrix can be used to capture the style of an image (Gatys, Ecker and Bethge, 2016); it gives the covariance of the contribution of the different filters $\boldsymbol{F_{style}}$:

$$G_{ij} = \sum_k F_{style_{ik}} F_{style_{jk}} \qquad (7)$$

The following function was used to measure the difference of style between the generated image and the style image (***S***):

$$L_{style}(\boldsymbol{S},\boldsymbol{G}) = \sum_{ij} \alpha_l (G_{ij}(\boldsymbol{S}) - G_{ij}(\boldsymbol{G}))^2 \quad , \qquad (8)$$

where *l* indicates the number of the style layer from 1 to 4 and **α** is a weight that allows stylisation to be modified by influencing which style layers had more or less impact. This parameter **α** also allowed me to determine the importance of the content in comparison to the style in the final stylisation, by reducing or increasing the style loss.

Temporal loss was defined as:

$$L_t(\boldsymbol{G}^t, \boldsymbol{G}^{t-1}) = \frac{1}{D}\sum_{i=1}^{D} c_i \left(G_i^t - f\left(G_i^{t-1}\right)\right)^2 \qquad (9)$$

where *t* is the time of the processed frame, *D* is the dimension of the output image, and *f* is a function that modifies the output frame at the time *t-1* to *t* using an optical flow. The optical flow calculated the RGB 2D displacement vectors of objects between the two following frames and was calculated using the Gunnar Farnebäck algorithm (Farnebäck, 2003). *c* is a parameter that defines the per-pixel confidence of the optical flow and has a value between 0 and 1. In the algorithm, *c* is defined as a mask representing the grayscale image of the RGB optical flow. Finally, my algorithm minimised the following loss:

$$L = \alpha_{content} L_{content} + \alpha_{style} L_{style} + \alpha_{temporal} L_{temporal,} \qquad (10)$$

* All terms italicised and with an asterisk are defined in Appendix A, the Glossary.

where $\alpha_{content}$, α_{style}, and $\alpha_{temporal}$ are weight set empirically to make sure each loss term is in the same order of magnitude.

5.1.1.2 Adjustable style transfer

I have implemented a conditioner network into my style transfer algorithm using the same model as the one by Babaeizadeh and Ghiasi (2019). My aim was to have the possibility of changing the stylisation weight $\boldsymbol{\alpha}$ = [α_1, α_2, α_3, α_4] defined in equation (8) after the training of the algorithm and in real-time. Thanks to this technique, the weight $\boldsymbol{\alpha}$ became inputs that could be changed after the training of the algorithm. As a result, there were three inputs – the content image, the style image, and the weight.

To explore how the weight impacted on the stylisation, I used the conditional instance normalisation technique described by Ulyanov, Vedaldi, and Lempitsky (2016) and Dumoulin, Jonathon, and Manjunath (2017). In their work, Dumoulin, Jonathon, and Manjunath observed that the convolutional weights of the stylisation network can be shared across multiple styles, and it is possible to retrieve the specificities of each stylisation using an affine transformation. The core of the technique was to replace the standard activation of a layer *x* in the stylisation network by a normalised activation *z* using this affine transformation. The new activation was conditioned by the weight $\boldsymbol{\alpha}$, which was an additional input parameter:

$$z = \gamma_{\boldsymbol{\alpha}} \frac{x - \mu}{\sigma} + \beta_{\boldsymbol{\alpha}} \qquad (11)$$

where μ and σ are the mean and standard deviations of the activation at the layer *x* across spatial axes. $\gamma_{\boldsymbol{\alpha}}$ and $\beta_{\boldsymbol{\alpha}}$ are the learned mean and standard deviations for one specific style; they are calculated with the conditioner network which was trained at the same time as the stylisation network by sampling random values for $\boldsymbol{\alpha}$ from U(0,1) (Babaeizadeh and Ghiasi, 2019).

5.1.1.3 Real-time style transfer with adjustable loss

The architecture of the network is shown in Figure 41. It includes the following parts: a stylising network, a conditioner network, and the losses. The weight vector $\boldsymbol{\alpha}$ is fed to the conditioner network to calculate γ_α and β_α, the parameters that normalise the activation of the stylising network. The image classifier VGG19 analyses the two stylised frames and calculates the style loss L_{style} and content loss $L_{content}$. The temporal loss $L_{temporal}$ is calculated by comparing two stylised frames at time *t* and *t-1.* Then the different losses are multiplied by a corresponding input adjustment parameter. The stylisation network and the conditioner network are trained at the same time through the minimisation of the weighted sum. At generation time, values for $\boldsymbol{\alpha}$ can be adjusted manually or chosen randomly to generate varied stylisations.

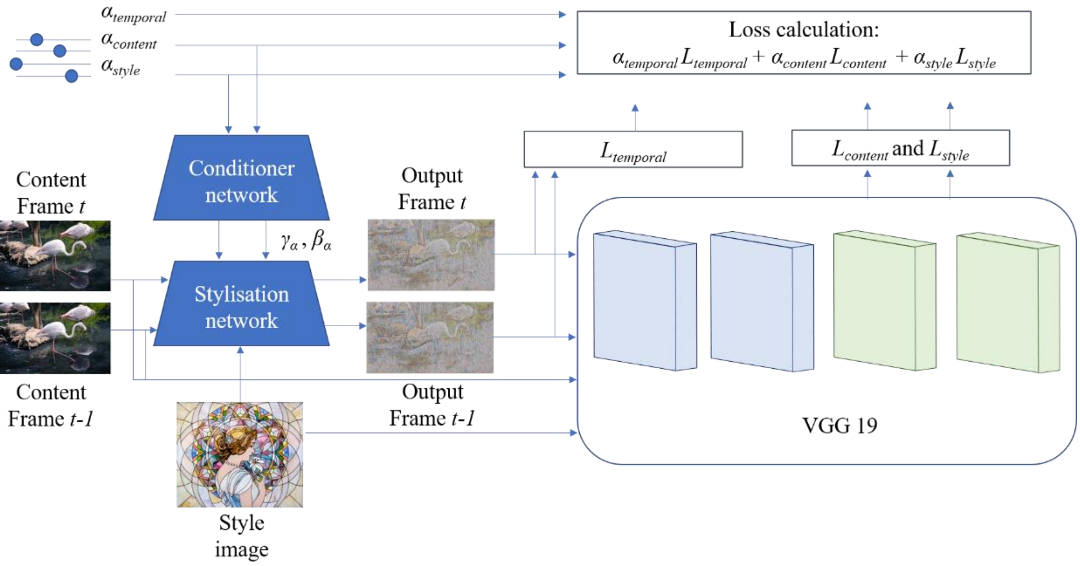


Figure 41: Architecture of the network © 2022, IEEE

5.1.2 **Experiments**

The two networks were implemented as fully *convolutional networks**. My implementation consisted of mixing two existing software packages: the one from Babaeizadeh and Ghiasi (2019) and the one from Huang *et al*. (2017). I used the same architecture as Babaeizadeh and Ghiasi (2019) and added the temporal loss term defined by Huang *et al*. (2017). The technique was tested by transferring the

* All terms italicised and with an asterisk are defined in Appendix A, the Glossary.

style of a frame from a video of a real surgery onto my physical simulator. The frames were found in articles describing the procedure (Sherwinter *et al.*, 2020; Koshitani *et al.*, 2012). The two networks were trained using the style frame as the stylisation image and with the DAVIS video dataset for the content videos (Caelles *et al.*, 2019). This database includes 150 videos. During the training, a randomised vector was generated to feed the conditioner network into the style network. The training of the algorithm was done on Anaconda Python 3.7 using a Pytorch (Linux Foundation, San Francisco, USA) implementation on a NVIDIA RTX 3090 GPU.

The algorithm was trained using the *Adam stochastic gradient descent method**, with a learning rate of 10^{-3} (Kingma and Ba, 2014). Additional hyperparameters during the training were empirically set to each loss term. The loss terms varied at different orders of magnitude but adding those hyperparameters prevented one loss term from dominating. The batch size was 30 and there were 20 *epochs**. The action research cycles showed that adding more epochs did not result in much more reduction of the overall loss. It also showed that reducing the batch size led to a less smooth output image.

5.1.3 Evaluation of the outcome

The technique was tested on a video of the commercially available simulator LapSim (Surgical Science, Gothenburg, Sweden) and on pictures and videos of the physical model.

The quantitative evaluation included comparing the scores of the algorithm with other state-of-the-art techniques. These scores were training time, processing time, optimisation of the different losses, and temporal consistency. Temporal consistency was measured on two following frames and was calculated with two evaluation metrics.

The first one assessed the percentage of difference Δ between two images; it is based on a difference score calculated to compare two images I_1 and I_2, and which is defined as follows:

* All terms italicised and with an asterisk are defined in Appendix A, the Glossary.

1. First, the difference map between the two images was calculated. It is defined as the absolute value of the pixel-by-pixel difference.
2. Then, a difference score was derived from the histogram *h* of this difference map. The histogram is a tool which highlights the distribution of intensity in an image; *h(i)* defines the number of pixels in the image with intensity *i*. The difference score was calculated as

$$difference(I_1, I_2) = \sum_i h(i) \times i, \qquad (12)$$

where *h* is the histogram of the difference map calculated between I_1 and I_2. *Δ* was then calculated as follows:

$$\Delta = \frac{difference(two\ following\ frames)}{difference(black\ image,\ \ white\ image)} \times 100, \qquad (13)$$

The second metric was the temporal stability as defined by (Lai *et al.*, 2018). It was calculated with the temporal loss function shown in equation 9.

The qualitative evaluation included an assessment of the outcomes' realism by me and surgeons. The surgeons were asked to use the "realness score" proposed Yi *et al.* (2017) to grade the outputs; this score ranged the realism from 0 (totally missing), 1 (bad), 2 (acceptable), 3 (good), to 4 (compelling). The surgeons were asked to concentrate on three aspects which are the realism of the colours, the quality of the images, and the fluidity of the videos. The fluidity of the video described the consistency of stylisation between frames; because style transfer modified each frame individually, there might be elements which were not coherent in between subsequent frames, so the aim of this metric was to evaluate that. The evaluation also focused on the influence of the stylisation vector by analysing images where all the weights are set to zero except one which varies from 0 to 1.

5.2 Results

Adjustable style transfer was implemented in this research to improve the video realism of the laparoscopic surgical training. This technique is compared to the state-of-the-art techniques discussed in Section 2.3.3.1, and more precisely to the

* All terms italicised and with an asterisk are defined in Appendix A, the Glossary.

techniques advocated by Babaeizadeh and Ghiasi (2019), Huang *et al*. (2017), and Johnson, Alahi and Fei-Fei (2016).

The evaluation was conducted online through a survey made on Qualtrics. The choice to conduct this evaluation online was made due to a hardware limitation; because the algorithm could not be implemented in real-time on a laptop. As such, it was not integrated with the real-time training simulation.

During the training, the style images were two images from surgery, one view of the gallbladder (Sherwinter *et al.*, 2020) and one view from inside the bile duct (Koshitani *et al.*, 2012). Permission to use the first image was obtained from Medscape Drugs & Diseases (https://emedicine.medscape.com/) and the second image was published under a CC BY 4.0 Creative Commons licence. The content images and videos were from the DAVIS and COCO datasets, both made available under CC BY 4.0. DAVIS is a video dataset of 150 videos of 4.14 GB and COCO is an image dataset of 330K images (Lin *et al.*, 2015).

5.2.1 Adjusting the parameters in real-time

The influence of each parameter was tested by setting all the weights but one to zero and making the targeted weight vary between zero and one. The influence was tested and compared on one frame, as shown in Figure 42.

* All terms italicised and with an asterisk are defined in Appendix A, the Glossary.

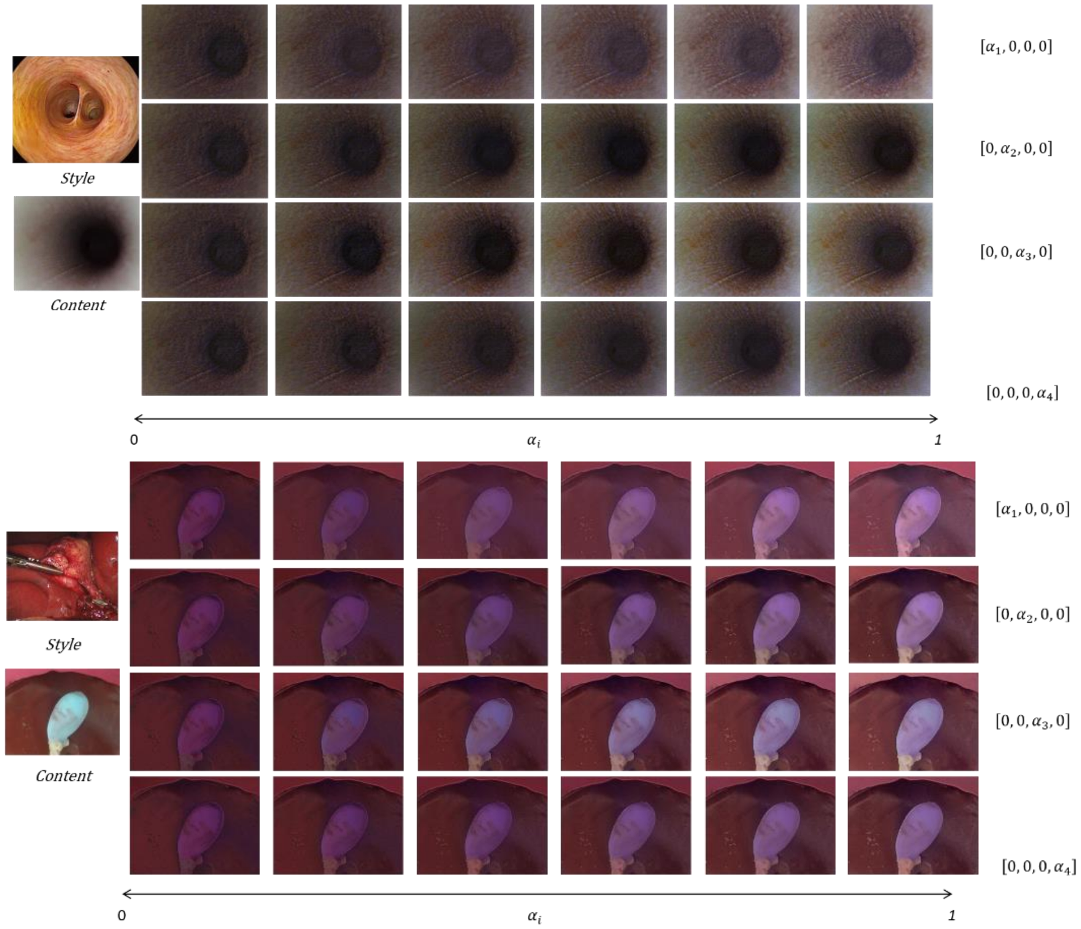


Figure 42: This figure shows how the modification of the input vector ***α*** *after training impacted the outcome.* α_i *was tested from 0 to 1 for each parameter of* ***α****, while maintaining the others at 0; the results for each parameter are shown on each row of the figure. Second style image reproduced with permission from Medscape Drugs & Diseases (https://emedicine.medscape.com/), Laparoscopic Cholecystectomy, 2022, available at: https://emedicine.medscape.com/article/1582292-overview.*

When the parameter got closer to 1, the stylisation became more pronounced. Each layer modified different components of the image – the first layer modified small details while the deepest layer modified bigger features, resulting in a smoother texture.

5.2.2 Quantitative evaluation

Table 17 shows the results of the quantitative evaluation; the generating time was evaluated on each frame of a sequence of 209 frames of 480x640 pixels, for the temporal consistencies the algorithm compared two consecutive frames. The training time and generating time were significantly longer by using Huang *et al.*'s

* All terms italicised and with an asterisk are defined in Appendix A, the Glossary.

technique (2017), however, the implementation was not on Pytorch and GPU but on Tensorflow and CPU, which could explain this difference.

The training time using either the proposed technique or that of Babaeizadeh and Ghiasi (2019) was significantly longer than that of Johnson, Alahi and Fei-Fei (2016), which could be explained by the optimisation of two networks instead of one; however, the main benefit of my approach is that it can provide multiple stylisations, in contrast to Johnson, Alahi and Fei-Fei's (2016) technique, which only generates one stylisation at a time. Generating multiple stylisations is an interesting feature to allow a surgeon to adapt the stylisation to their preferences and to be able to replicate the diversity of multiple patients in different simulation sessions.

All the generating times were below 40ms, which is the minimum required to ensure the generation of a fluid video. With the first temporal metric, the results showed that the proposed technique created videos with a significantly smoother fluidity compared to the techniques without temporal loss; however, the results are not statistically significant with the second temporal metric.

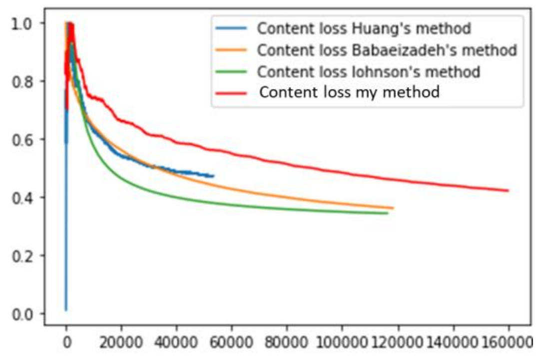
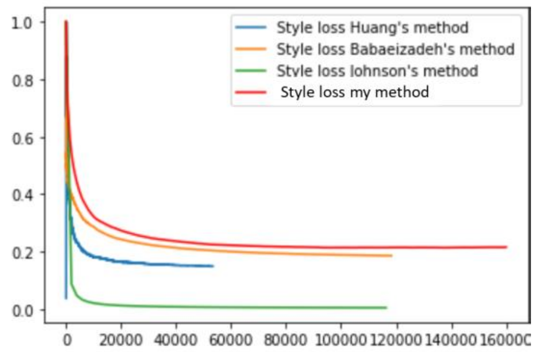
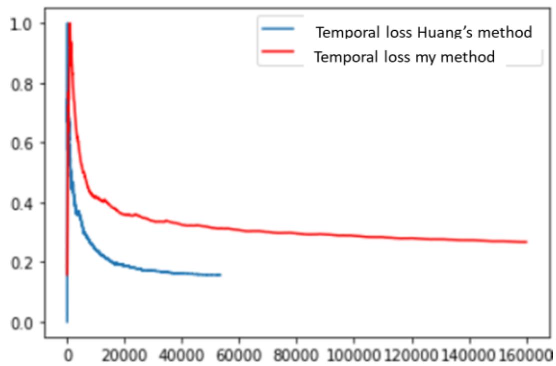
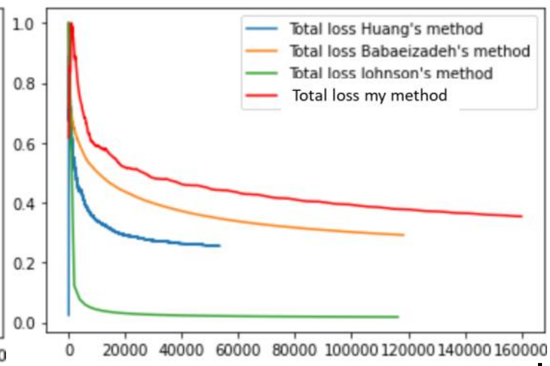
Table 17: Comparison of the scores between the proposed technique and state-of-the-art technique © 2022, IEEE

Technique	Babaeizadeh and Ghiasi	Huang *et al.*	Johnson *et al.*	My method
Training time	3h47	8h09	1h11	3h43
Generating time (ms)	27.1 ± 0.2	328.2 ± 0.4	21.3 ± 0.1	27.9 ± 0.1
Number of stylisations	∞	1	1	∞
Temporal metric 1	1.7 ± 0.1	1.2 ± 0.1	1.9 ± 0.1	1.5 ± 0.1
Temporal metric 2	54.4 ± 15.7	43.6 ± 25.8	40.1 ± 28.0	42.9 ± 23.8

* All terms italicised and with an asterisk are defined in Appendix A, the Glossary.

As shown in Table 18, the proposed technique required more iterations to minimise the different losses, especially content loss. This can be explained by the necessity to optimise two networks instead of one, and according to three different loss terms instead of two.

Table 18: Comparison of the loss optimisation between the proposed technique and state-of-the-art techniques. The losses are normalised for better visualisation © 2022, IEEE

<table>
<tr><td>Content Loss</td><td>Style Loss</td></tr>
<tr><td>
</td><td>
</td></tr>
<tr><td>Temporal loss</td><td>Total loss</td></tr>
<tr><td>
</td><td>
</td></tr>
</table>

5.2.3 **Qualitative evaluation**

Eight surgeons evaluated the "realness score" of five image sets and two video sets, including initial data and processed output. These datasets included pictures and videos from both the physical model and the virtual simulator LapSIM.

Table 19 shows the results of this evaluation. The average "realness score" was higher with the proposed technique comparing to the other techniques, except from that of Johnson, Alahi and Fei-Fei (2016). Their high score could be the results of their stronger stylisation.

* All terms italicised and with an asterisk are defined in Appendix A, the Glossary.

There seemed to be a correlation between surgeons' evaluation of the simulator's realism and the second temporal evaluation metric. This indicated how crucial the smoothness of the videos is to the overall realism.

One surgeon commented that "*The colours are all acceptable – they represent the variation one sees* in vivo". This illustrated the benefit of adjustable style transfer, which allowed me to recreate the variability of real life. This was also evident by the similar scores surgeons gave to videos that were stylised by my algorithm but with different stylisation vectors, which resulted in different stylisations.

Moreover, the surgeons commented that two of the stylised images were good, but it would have been even better to have something in between them. Using this new technique, I can adjust the stylisation to these remarks by modifying the weights accordingly.

Table 19: Comparison of the "realness score" © 2022, IEEE

Technique	Initial	Babaeizadeh and Ghiasi	Huang *et al.*	Johnson *et al.*	My method
"Realness score"	1.6 ± 0.8	1.8 ± 0.9	1.6 ± 0.7	2.2 ± 0.8	1.9 ± 0.7

The qualitative evaluation showed that the proposed technique was successful in implementing different stylisations onto the simulator video in real-time while maintaining both temporal consistency and overall image smoothness.

Figure 43 illustrates that each component of the stylisation vector or layer modified different features of an image – the last layer created more contrast and made the small details such as blood vessels more apparent. The first layer focused on bigger features which resulted in a smoother texture. Each layer generated a different stylisation; however, there is no one better than the other. The results showed that the surgeons did not agree on which stylisation was the best.

The pronounced texture of the tissues was not very realistic. A possible explanation is the selected style image, as this image did not include any significant neat and

* All terms italicised and with an asterisk are defined in Appendix A, the Glossary.

smooth area, meaning that the algorithm was unable to learn how to stylise smooth surfaces. Moreover, in this style image, multiple small areas reflected the light which generated a lot of contrast; the algorithm interpreted that as a part of the style and tried to recreate this, resulting in less convincing stylisation.

Figure 44 shows the diversity of possible stylisations. Huang *et al.*'s (2017) technique created very smooth outcomes, which could be a result of the tv-loss term, while that of Johnson, Alahi and Fei-Fei (2016) created a stronger stylisation, which could be useful for recreating realistically the specificities of real tissues; however, these results could be very different if the hyper-parameters defined before training were modified. The techniques of Babaeizadeh and Ghiasi (2019) and the proposed technique could create multiple stylisations, but the appearance was less realistic.

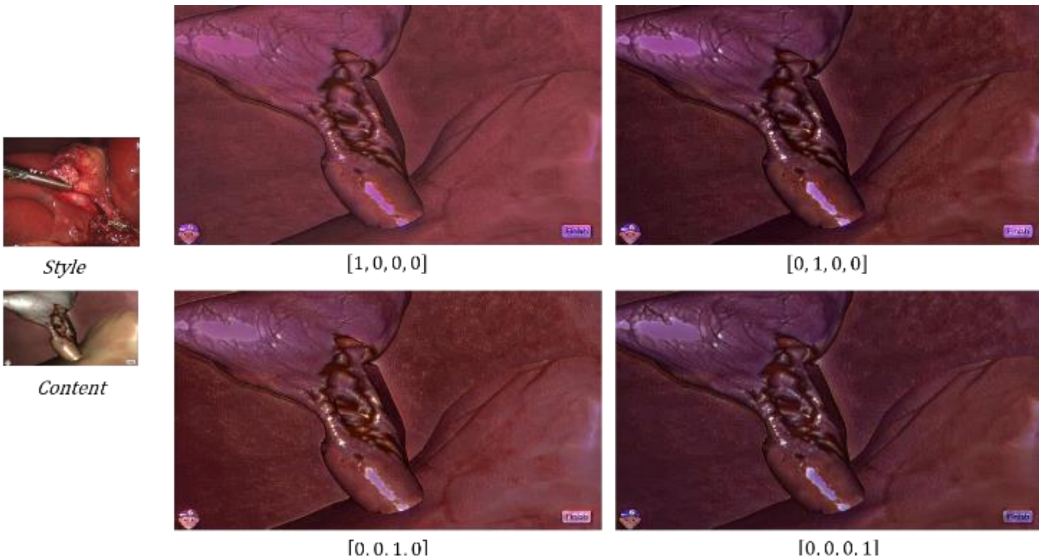


*Figure 43: Results from modifying the input vector **α** in real time © 2022, IEEE. Style image reproduced with permission from Medscape Drugs & Diseases (https://emedicine.medscape.com/), Laparoscopic Cholecystectomy, 2022, available at: https://emedicine.medscape.com/article/1582292-overview.*

* All terms italicised and with an asterisk are defined in Appendix A, the Glossary.

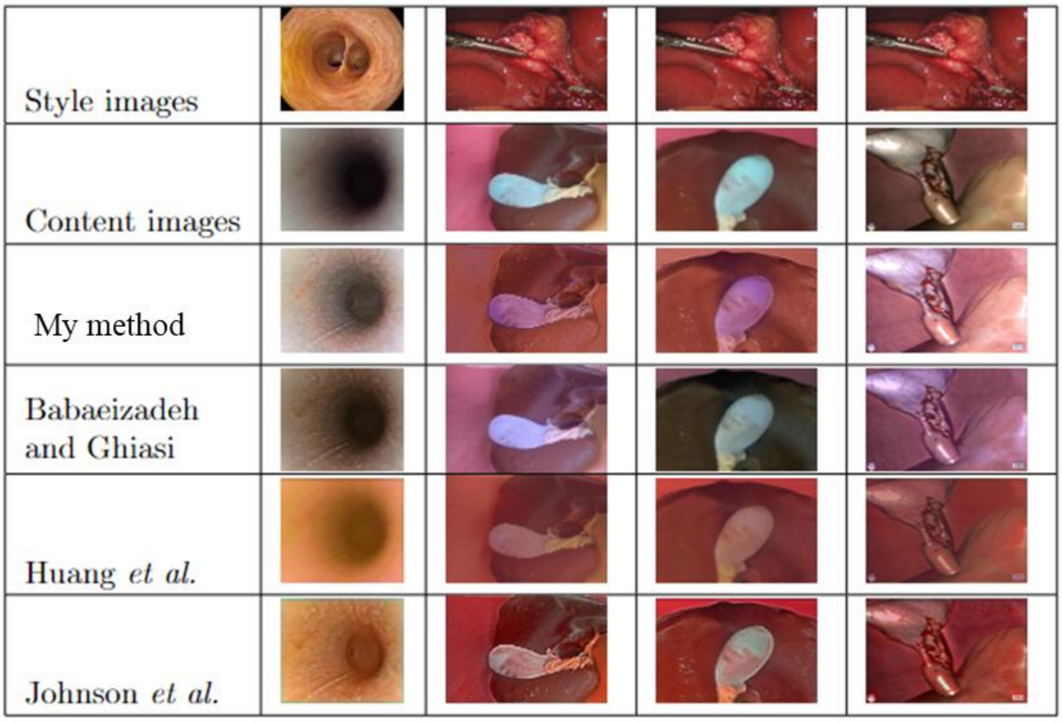


Figure 44: Comparison of outputs using the different techniques © 2022, IEEE. Second style image reproduced with permission from Medscape Drugs & Diseases (https://emedicine.medscape.com/), Laparoscopic Cholecystectomy, 2022, available at: https://emedicine.medscape.com/article/1582292-overview.

Compared to the other image-processing techniques used in the context of surgical simulation and described in Section 2.3.3.1, the proposed technique has multiple advantages. It is quick, easy to implement, and can offer diversified stylisations. In a previous study, Engelhardt *et al.*'s (2018) technique was found to stylise videos more realistically. During an evaluation by surgeons using the same realism scale as mine, they received an average realness score of 3.3. However, that method requires training with datasets of images from the simulator and images of surgery, while the proposed technique requires training on the generic database DAVIS.

Luengo *et al.*'s (2019) stylisation technique is too complex for real-time application and does not take into account the temporal loss, resulting in temporal fluctuations. However, the strength of their technique is that it can implement multiple stylisations within one frame, with a style selection adjusted to the elements included in the frame. This feature is very useful because the instruments and the soft tissues require different stylisation. The proposed technique modifies the instruments using the same stylisation as the tissues, as a results, they no longer look realistic.

5.3 Discussions

5.3.1 Hardware limitations

This style transfer technique was useful for making the simulation more realistic; however, it required an endoscopic camera to be connected to a computer to be able to launch the style transfer algorithm. Moreover, the computer had to be sophisticated enough to be able to process the images in real-time. The hardware used for this research was good enough to allow real-time stylisation, but this technique might not be easy to generalise because of this requirement. For instance, a gaming desktop would have the necessary specifications to run the stylisation in real-time, but most laptops could not provide this feature.

Because of this limitation, style transfer was only evaluated using an online survey; it could not be evaluated in workshop 2 as the stylisation could not be run in real-time on a laptop. Thus, the final evaluation did not include all the features of the developed simulator

5.3.2 Comparison to other visual appearance reproduction methods

There has been extensive work conducted on the visual rendering of virtual simulators, which were summarised in section 2.3.2.2 of this thesis. In comparison to this previous research, the appearance of the soft tissues rendered using my method is not very convincing, for the following reasons:

1. The training of my style transfer algorithm was based on a single image from surgery, as such it learned the style from one view which was either the interior of the bile duct or a view of the gallbladder in front of the liver. For this reason, it did not create tissue-specific stylisations, causing several artefacts and unrealistic effects. It would have been better to use stylisation images including one single type of soft tissue to allow the algorithm to generate different stylisations by learning the texture of each organ during the training time. Through such a method, each organ would have been rendered more

* All terms italicised and with an asterisk are defined in Appendix A, the Glossary.

realistically; however, this would have required being able to determine what type of soft tissue was in the frame during the simulation's run-time in order to apply the correct stylisation. This would also have been possible using masks, such as in the work by Luengo *et al.* (2019).

2. As highlighted in the literature review chapter, light's effects on the organs during laparoscopic surgery gives important information to surgeons, so it is important to mimic this during simulation. With my method, these effects are not mimicked which is a significant limitation. A physics-based method such as those described in the state-of-the-art section 2.3.2.2 would have allowed a better representation of view-dependant artefacts such as these, but would require camera tracking to know the view, and tracking of the deformations of the soft tissues. There are different methods to do so, such as using embedded sensors (Condino *et al.*, 2011) or image analysis techniques like biomechanical models, deformation models or deep-learning based methods (Liu et *al*., 2023); however, they greatly increase the complexity of the simulation.
3. Finally, the style transfer method developed in this research cannot simulate artefacts such as smoke and bleeding during the surgery training.

One of the benefits of my method is that it does not require knowledge of the mesh information such as the deformations of the soft tissues. The stylisation only takes the image from the laparoscope as input. While this is still computationally heavy, not requiring knowledge about the tissue deformations makes the method easier to implement.

Even if the visual realism of my method is not very convincing, there are still interesting features. Because the method is an adjustable style transfer algorithm, it can create multiple stylisations. By using a style image of one single type of soft tissue during the algorithm training, it would be possible to create variations of textures for this specific soft tissue. That would replicate the diversity of real life and would allow to have differences between patients during the simulation.

5.3.3 Evaluation of the outcome

The algorithm evaluation was based on quantitative metrics and an appraisal by surgeons using a 5-point Likert scale. Previous work has also highlighted that other types of metrics can be used to assess how realistic a simulation is; more precisely, some researchers have used blind tests or visual Turing tests (Chuquicusma, Sarfaraz Hussein and Ulas, 2017) to evaluate the realism of generated images, for instance, asking experts to identify which of two images was computer-generated and which one was real (Alessandrini *et al*., 2015). Such methods are very interesting as they clearly illustrate when a simulation is realistic enough to fool the user.

5.4 Conclusion

This chapter has described the simulator's realism enhancement using a style transfer approach. Although this method did not provide very realistic results, it allowed me to modify the simulation's appearance and adjust it in real-time to replicate the diversity of real life.

* All terms italicised and with an asterisk are defined in Appendix A, the Glossary.

Chapter 6: Context-aware simulation of laparoscopic ultrasounds

Another aspect of AR in my hybrid simulator was developing a solution for ultrasound training. The AR solution is context-aware simulation through marker tracking. The choice of using context-aware ultrasound simulation was based on two reasons.

The first reason came from the exploration of materials, which highlighted the difficulties of finding a material which could mimic both the physical and acoustic properties of the soft tissues. Silicone can mimic the tactile feedback but fails to mimic the ultrasound (Section 4.2.2), while agar gel can mimic the ultrasound but not the tactile feedback. Context-aware simulation allowed me to develop separate models for both the tactile aspect and the ultrasound aspect and then combine them (Section 2.3.3.3).

The second reason was to be able to develop a training solution which did not require the surgical trainees to have access to a laparoscopic ultrasound probe. Because of the price of ultrasound probes, not all medical students can use the required equipment. One of this research's aims was to develop a low-cost training solution, and context-aware simulation can provide a suitable solution.

6.1 Methods

The idea behind using context-aware simulation was to track elements of the simulator and display ultrasound images depending on the positions of these elements. The tracking was conducted with ArUco markers (Garrido-Jurado *et al.*, 2014) and was used to track a laparoscopic instrument and the simulated soft tissues. The ultrasound images are based on a database of pre-recorded images created especially for this application.

Using this solution, a student can train for an ultrasound examination using just two printed ArUco markers, one USB endoscopic camera, and one computer. With this technique the laparoscopic ultrasound probe can be replaced by a simulated probe.

* All terms italicised and with an asterisk are defined in Appendix A, the Glossary.

The simulated probe can be any laparoscopic instrument with a similar shape as a laparoscopic ultrasound probe.

6.1.1 Process overview

To conduct an ultrasound scan, the trainee must follow the following steps:

1. Ensure that the endoscopic camera is connected to the computer.
2. The student places one of the ArUco markers on the simulated soft tissues and one on the simulated probe.
3. The student starts the Unity program on the computer: the live video from the simulated soft tissues recorded by the endoscopic camera appears.
4. On the computer screen, the student can see the live video from the camera and a simulated space where there is the 3D model of the soft tissues and the ultrasound probe. The soft tissues on the screen follow the simulated soft tissues thanks to the ArUco marker; similarly, the virtual ultrasound probe follows the simulated probe.
5. The student performs a calibration step to indicate to the algorithm where the duodenum is in the 3D space.
6. The student clicks on one of the ultrasound buttons on the screen which represents the training modes. This generates the appearance of the ultrasound display screen.
7. The student starts their examination by running the simulated probe along the soft tissues: the ultrasound images will appear on the ultrasound display screen. These images are pre-recorded on the simulated soft tissues made of agar gel. The student can learn how to read the ultrasound while moving the simulated probe. The process is shown in Figure 45.

* All terms italicised and with an asterisk are defined in Appendix A, the Glossary.

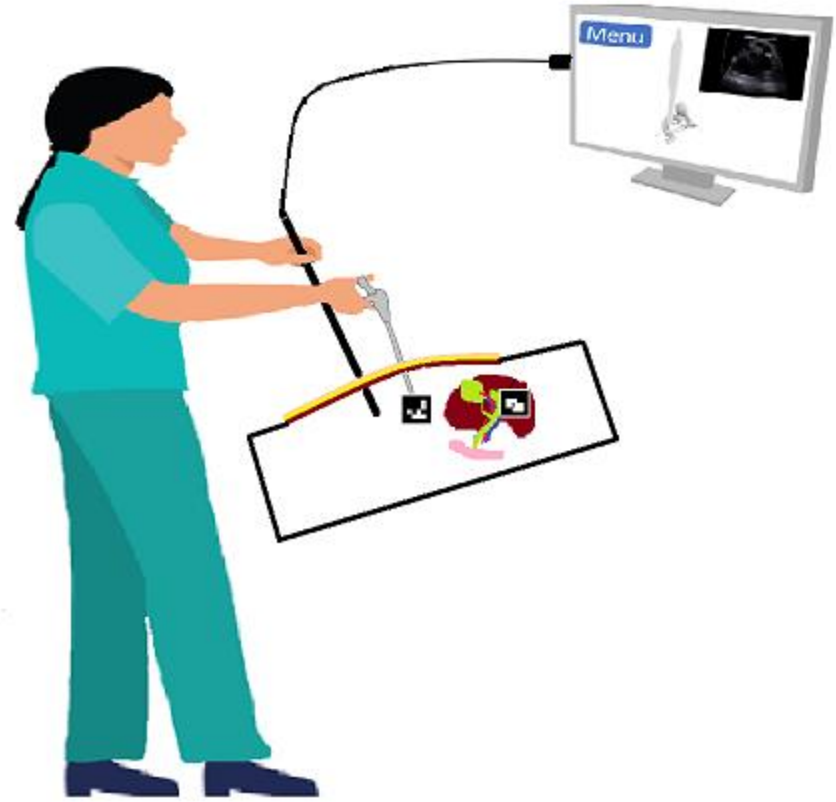


Figure 45: Setup for the context-aware simulation of ultrasounds

6.1.2 Creation of the ultrasound images database

To create this training session, ultrasound images were pre-recorded on a second simulator made of agar gel. The parts of this simulator were casted in the same 3D printed moulds (Section 3.1) as the silicone model to create two models with the same anatomy. Because agar gel is not flexible, some modifications were made to the 3D printed moulds. More precisely, the internal moulds were printed in soluble filament instead of rigid material. This was PolyDissolve filament from Polymaker (Polymaker, Shanghai, China). After casting, the simulator was immersed in water until dissolution of the inner mould.

The agar-based simulator included the main structures that surgeons visualise during an ultrasound examination, which are the duodenum, the bile duct, and the gallbladder. Figure 46 shows the different parts of the simulator and the assembly of the different parts.

* All terms italicised and with an asterisk are defined in Appendix A, the Glossary.

Figure 46: "Fabrication of synthetic soft tissues made of agar gel" by Marine Shao, used under [CC BY 4.0](CC BY 4.0)

As visible in Figure 47, a surgeon was asked to use a laparoscopic ultrasound probe to pre-record ultrasound videos under different conditions (different training scenarios). The videos are recorded on the agar based simulator by sweeping the probe along the bile duct. A database of 2D ultrasound images was created by extracting frames from these videos; the images were also post-processed on Paint software (Microsoft Windows, Redmond, USA) to get rid of the echo caused by the Tupperware glass which was recorded in the original images.

Doppler ultrasounds images are typically used in LCBDE surgery to identify the bile duct among the different structures recorded by the ultrasound and distinguish it from the vein and the artery. During the creation of the ultrasounds database, it was not possible to directly record images in Doppler mode or the measurements. The images in Doppler mode could not be recorded because there was no flow in the model as it was not connected to a pump. As for the measurements, the laparoscopic ultrasound probe software does not offer the facility to export these kinds of images. Thus, the images were created artificially in Paint by using examples from real images.

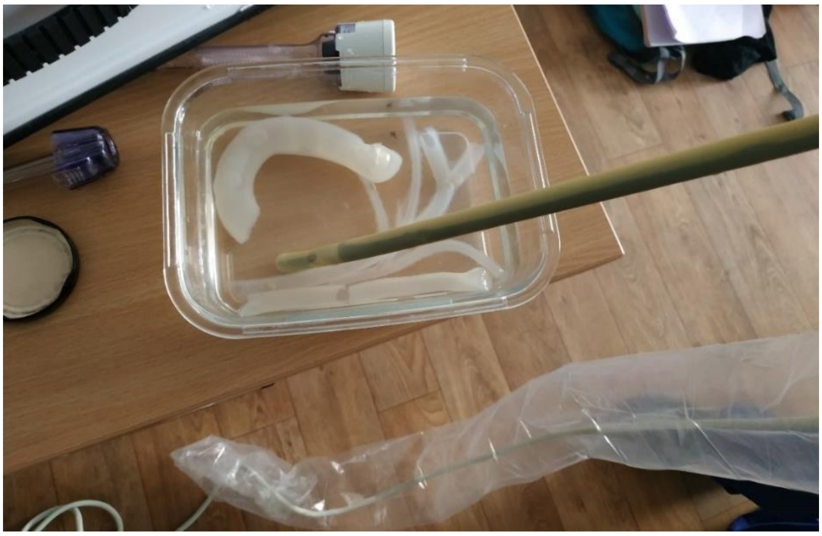


Figure 47: "Recording of the ultrasound images on the agar model using a laparoscopic ultrasound probe" by Marine Shao, used under [CC BY 4.0](CC BY 4.0)

6.1.3 Tracking of the markers and display of the ultrasound images

The marker tracking was conducted on Unity 2020 (Unity Software Inc., San Francisco, USA), Visual Studio (Microsoft, Redmond, USA), and Python 3.9 (Python Software Foundation, Delaware, USA) for Windows. The endoscopic camera connected to the computer recorded the live scene of the surgical practice and detected the ArUco markers stuck on the simulated liver and on the laparoscopic instrument; then the code updated the localisations of the soft tissues and the probe in the simulated space.

During the training session, the code displayed ultrasound images on the screen; the selection of the ultrasound image was linked to the distance between the two markers. If we define *L* as the distance between the end of the bile duct and the duodenum in the simulated place (defined during the calibration step), *n* as the number of ultrasound images [i_1, i_2,..., i_n] in the dataset, and *l* as the distance between the two ArUco markers, then the algorithm displayed the image with the following number *i*:

$$i = \left|\frac{l}{L} \times n\right| \qquad (14)$$

The surgeon had to first select a training scenario, which impacted on where the stone would be located within the model, as is visible in Figure 48. Once a training

* All terms italicised and with an asterisk are defined in Appendix A, the Glossary.

mode was selected, the surgeon could perform the scan in B-mode, as in Figure 49. For scenarios 1 and 2, the stone was situated in the common bile duct; in these two cases, the surgeon could also perform a Doppler scan and take measurements of the diameter of the stones and the common bile duct. These different modes are shown in Figure 50.

Figure 48: Selecting the training mode in the menu on the upper right corner

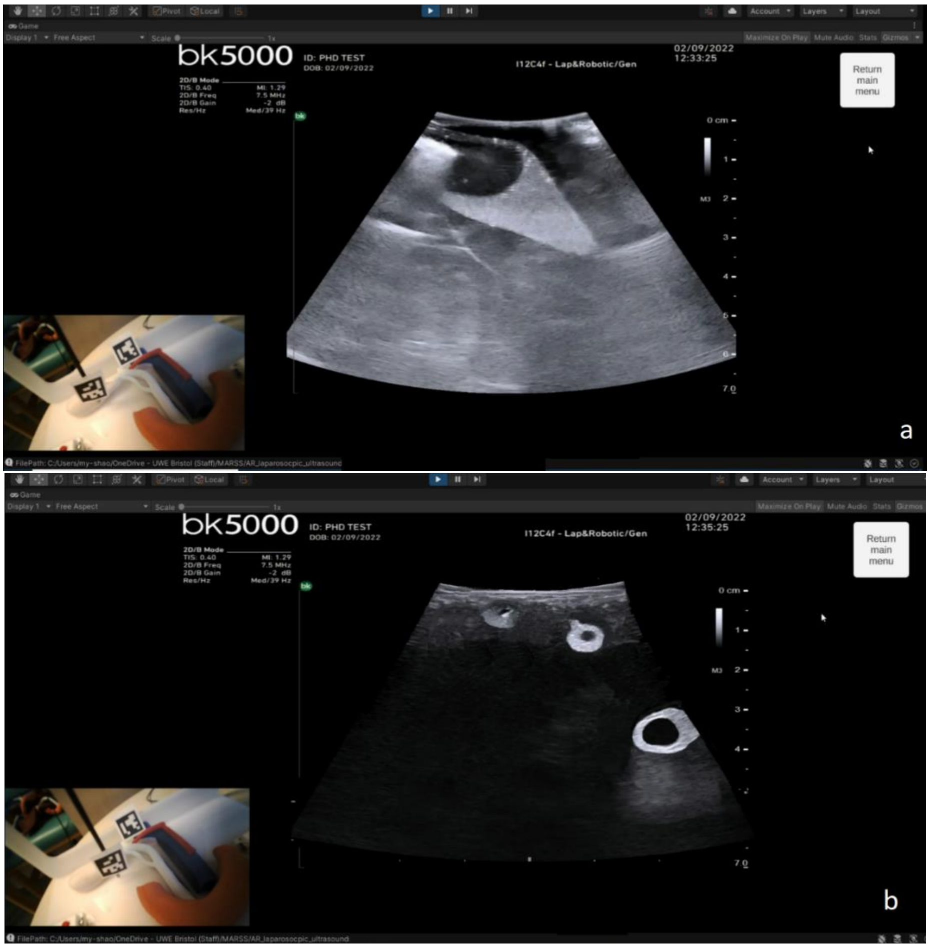


Figure 49: Ultrasound images in B-mode of the scenario 3 (a) and of the scenario 4 (b)

* All terms italicised and with an asterisk are defined in Appendix A, the Glossary.

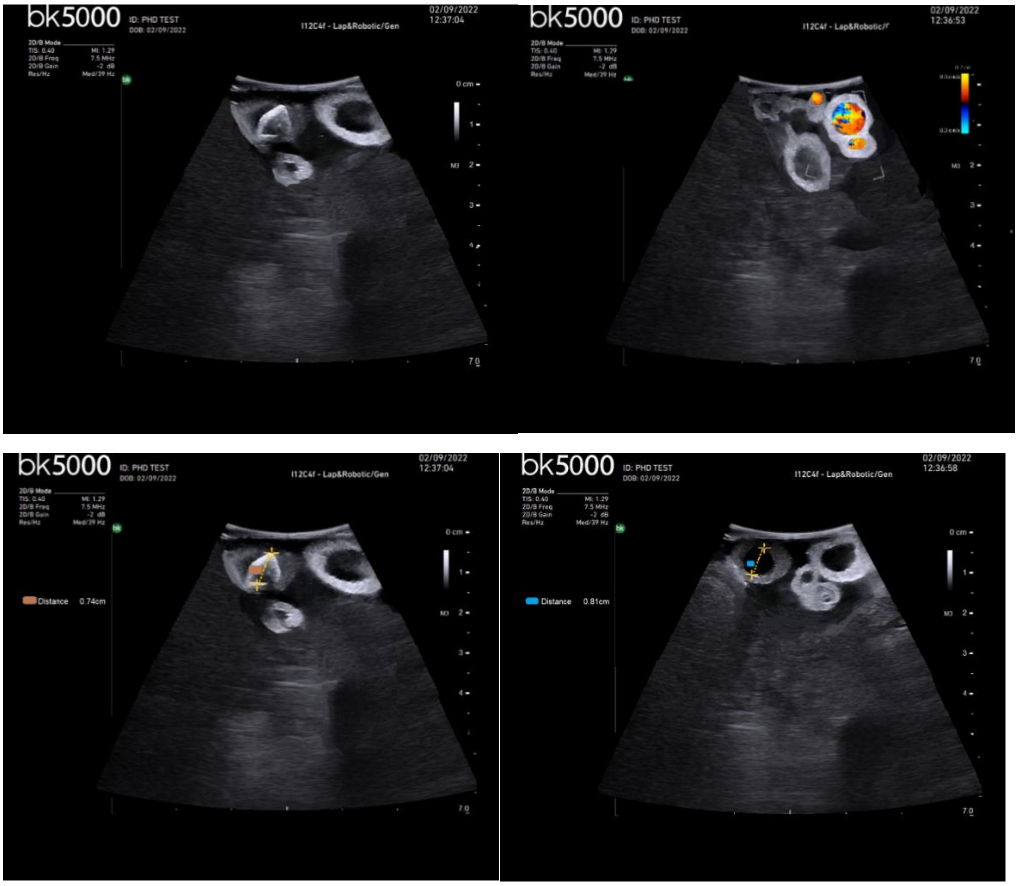


Figure 50: "Creation of a dataset of ultrasound images in B-mode (upper left), Doppler mode (upper right), and with measures of the anatomical features (lower left and right)" by Marine Shao, used under CC BY 4.0.

The image on the upper left side shows the bile duct with a stone as well as the portal vein and the cystic artery. The image on the upper right shows the blood flow within the vein and the artery, which is used to distinguish between the bile duct and the blood vessels. The two bottom images show the measurements of the size of the stone and of the diameter of the bile duct.

6.2 Results

The context-aware simulation of ultrasounds was evaluated at the same time as the final prototype, and the results of both are discussed in section 7.2.1 of this thesis.

6.3 Discussions

6.3.1 Limitations of the method

During the evaluation of this method, the error between reality and the markers' detected positions was not assessed. Because of this error, the image that a

* All terms italicised and with an asterisk are defined in Appendix A, the Glossary.

surgeon was visualising could not match the position of the probe on the model. This was a problem for its realism and for learning the gesture of performing an ultrasound examination. Future work could investigate the precision and accuracy of this technique, referring to literature which describes methods to assess errors in detecting the position of fiducial markers (Park *et al.*, 2021).

Moreover, this training technique was also limited by the available hardware, because it required real-time processing to smoothly display the ultrasound images. This issue is linked to digital exclusion (Khalid and Pedersen, 2016), where those who do not have equal access to equipment are disadvantaged in their learning.

6.3.2 Comparison to ultrasound image synthesis methods

The training system used in this research was based on pre-recorded ultrasound images. The images were 2D ultrasound images captured by running the probe along the gel-based model. This resulted in the following complications:

1) There were only a limited number of recorded images, so during the training it was not possible to recreate ultrasound images from all angles and positions. This was a limitation because one of the aspects of ultrasound training is to gain the ability to optimise images by moving the ultrasound probe around an anatomical area. Because of this limitation, there was a risk that the surgeons using the simulator would learn the task incorrectly.

2) Another limitation of using pre-recorded ultrasound images was the creation of Doppler images. During the recording, the gel-based model was not connected to a pump, and as a result it was not possible to record Doppler images. In this research, the images were recorded in B-mode only and the Doppler training mode was created by post-processing the images. This step is time-consuming and cannot provide results as realistic as if real Doppler images had been recorded. Nonetheless, the aim of the Doppler during the surgery is only to distinguish between the bile duct and the blood vessels and not to take measurements, so I hypothesised that this does not need to be extremely realistic.

* All terms italicised and with an asterisk are defined in Appendix A, the Glossary.

3) Using this method limits the number of training scenarios in the simulation. Indeed, with this method, adding new scenarios is time-consuming as it necessitates creating a new ultrasound model and recording more images.

4) Because I used pre-recorded images, there were no deformations or movement in the images during the simulation practice; this is a limitation because there is a lot of deformation during a real ultrasound examination.

Using computer-based simulation models such as the generative image-based methods described in section 2.3.2.1 would have avoided these limitations. Indeed, they can produce images from all positions and orientations, making them suitable to practice manipulating an ultrasound probe; they can be used to simulate deformations using mesh and techniques such as FEMs as well as blood flow. Furthermore, the methods can be based on 3D meshes, so it is possible to add elements into the mesh or modify the mesh to create new cases and scenarios. The aim of using pre-recorded images was to improve the quality and realism of the ultrasound images; however, because of the limitations noted above, my simulator is only suitable for training on how to read ultrasound images, not for practicing manipulating a laparoscopic ultrasound probe. As such it is limited to basic skills.

6.3.3 Means for improving the method

In my research, I used two ArUco markers to track the relative position between the simulated soft tissues and the simulated laparoscopic ultrasound probe. Using one single marker per tracked object limited the quality of the tracking, especially relative to the orientation. Wu *et al*. (2017) used a set of 11 markers rigidly attached onto a dodecahedron to allow a precise 6 degrees of freedom tracking; using a similar technique with more than one marker would have made my method more robust in terms of changes of orientation.

The method could have been improved by post-processing the recorded 2D ultrasound images to generate a 3D volume. This would have enabled the generation of images at every position and angle; however, the literature shows that images created in this way are not realistic if the viewing angle during the simulation is very different to the recording angle (Kutter, Shams and Navab, 2009).

Finally, during the simulation practice, a calibration step was performed to define the distance *L* between the duodenum and the liver in the 3D space. Then an ultrasound image was displayed, depending on the distance between the instrument and the liver. An assumption was made that the instrument was always on the bile duct and that if the surgeon moved the simulated probe in another direction, then an image would still have been displayed showing the bile duct. It would have been better to avoid this behaviour, for example by going further during the calibration by identifying the position of the bile duct in the 3D space and showing images only if the simulated probe was sufficiently close to it. Alternatively, if I had created a 3D volume, I could have registered the volume of the phantom to the 3D ultrasound volume using techniques such as the Iterative Closest Point algorithm and the RanSaC algorithm (Magee et al., 2007).

6.4 Conclusion

This chapter has described the development of an ultrasound training system using a context-aware technique. The method can be used by surgeons to practice reading laparoscopic ultrasound images and performing the ultrasound task of LCBDE, which is locating and measuring stones within the bile duct.

* All terms italicised and with an asterisk are defined in Appendix A, the Glossary.

Chapter 7: Development and evaluation of an LCBDE simulator

The previous chapters have detailed how the hybrid simulator was developed, including the fabrication of a physical model and the inclusion of context-aware simulation of ultrasounds. This section describes the development of prototypes. It gives an account of identifying the simulator requirements and its evaluation.

7.1 Methods

7.1.1 Investigating the requirements

As recommended by the HCD methodology (Section 1.2.1), the simulator requirements were investigated with end users – surgeons who perform LCBDE.

To identify their requirements, interviews were carried out with surgeons, thereafter referred to as interview 1. Interview 1 were carried out to understand the surgical experience of performing a LCBDE with ultrasound to be able to recreate it. More specifically, interview 1 aimed to assess which soft tissues to include and which instruments surgeons use during the surgery. The questions were precise, as this was a structured interview. This was useful for identifying which parts should be included in the model, and it also helped to define the questions asked in interview 2. Interviews were also conducted to gain an understanding of all the steps of the surgery.

In relation to surgical training, interview 1 helped in assessing the features the surgeons need in a training session and the important characteristics of surgical simulators. More precisely, it was important to know what surgeons require to train students in this specific surgery.

7.1.2 Evaluating the prototypes: workshop 2

As described in the HCD methodology (Section 1.2.1), the outcome of the research was evaluated through usability testing with end users. This step consisted of organising a workshop, thereafter referred to as workshop 2, where the surgeons were firstly asked to test the simulator and then to grade it according to a

* All terms italicised and with an asterisk are defined in Appendix A, the Glossary.

questionnaire. When they were testing the simulator, the setup was as shown in Figure 51, which depict the simulated soft tissues placed inside a laparoscopic box and the instruments held by a surgeon which allowed them to visualise the inside of the box on a screen.

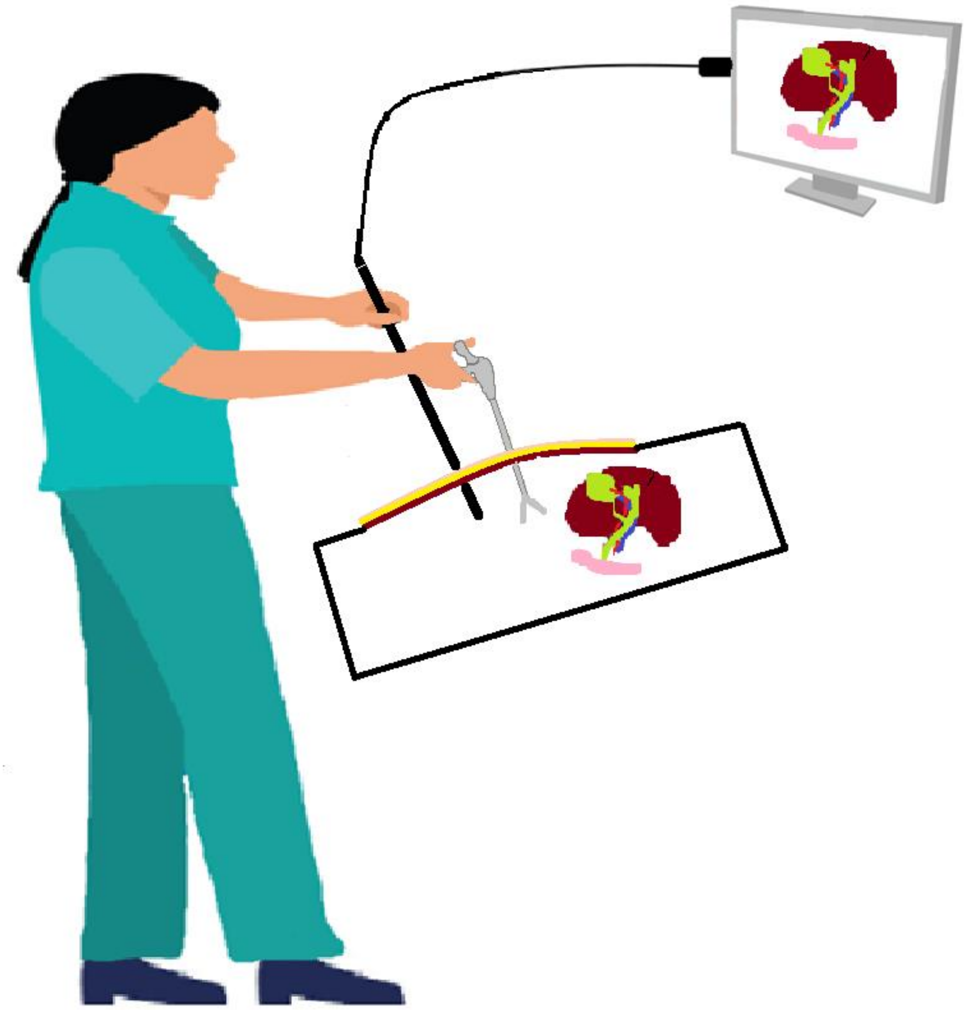


Figure 51: Training on the synthetic soft tissues put inside the box to simulate the setup of laparoscopic surgery

7.1.2.1 Training on the simulator

Interview 1 with surgeons allowed me to identify that the main training steps are: laparoscopic ultrasound imaging, opening the bile duct, clearing the bile duct, and the laparoscopic suturing. The other challenging steps such as dissecting the Calot's triangle and removing the bile duct already have available training solutions with

* All terms italicised and with an asterisk are defined in Appendix A, the Glossary.

simulators for cholecystectomy; consequently, they were not the focus of this new simulator.

I implemented different surgical scenarios into the practice; to do so, I have placed the simulated gallstone at different locations within the model. Figure 52 shows the different training scenarios effected during this research. The different locations of the gallstones were:

1. Next to the ampulla: the most common scenario in patients.
2. In the hepatic duct.
3. In the cystic duct.
4. In the gallbladder.

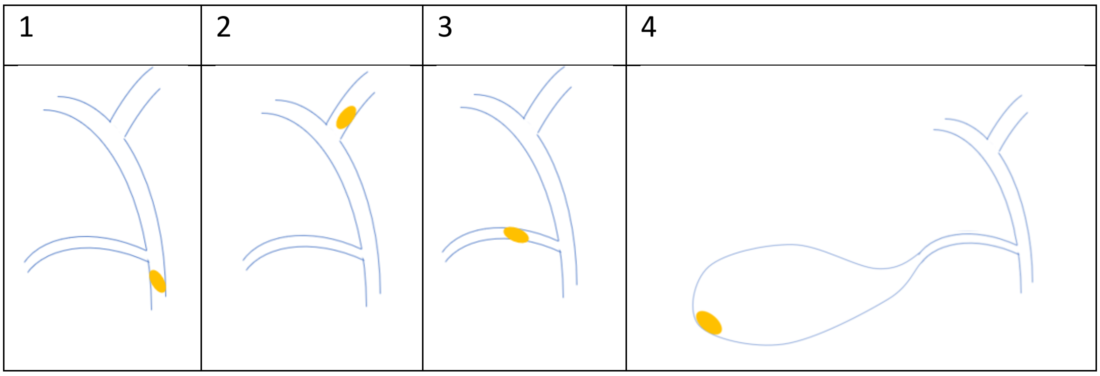


Figure 52: Positions of the stones for the different training scenarios

Even though scenarios 2 to 4 are less common, all these scenarios present variations of what can be found in real life. The different scenarios were validated by the surgeon advising on this research.

In the course of a training session, I asked the surgeons to perform the following steps of the simulated procedure:

1. Port insertion.
2. Clipping and dividing the cystic artery.
3. Milking, clipping and partial dissection of the cystic duct.
4. Ultrasound evaluation using the context-aware training system; during this step, the surgeon had to assess the number of stones and locate them.

5. From the ultrasound scan, the surgeon then decided their approach to the surgery: trans-cystic or trans-choledochal.
6. Choledochotomy.
7. Choledochoscopy and stone extraction.
8. Suturing the bile duct.

The different scenarios were all provided in the ultrasound training task, but the other tasks were all simulated using scenario 1.

7.1.2.2 Evaluation

The evaluation consisted of asking the surgeons who had tested the simulator to fill a questionnaire. This first part of the questionnaire regrouped preliminary questions focusing on each surgeon's background, such as the number of times they had performed laparoscopic procedures before, the number of times they had performed an LCBDE, and the number of times they had used laparoscopic suturing. The aim was to ascertain their experience of LCBDE surgery. This was in order to split the participants into three groups of various level of expertise.

- Face validation

The evaluation conducted during the face validation consisted of the surgeons' assessment of the simulator's realism and its ability to represent correctly what it was supposed to represent (Section 2.4.1). Similarly to the algorithm evaluation, I have asked the surgeons to grade the realism using the Likert scale from 1 (poor performance of the model) to 5 (excellent performance of the model) (Joshi *et al.*, 2015). The evaluation focused on the following aspects (for each soft tissue):

1) Realism:
   a) Soft tissues: how realistic are the soft tissues with direct vision?
   b) Tactile feedback: how realistic is the tactile feedback? How realistic are:
      i) The choledochotomy,

ii) The choledochoscopy,

iii) The suturing of the bile duct?

c) Anatomy: does the trainer include all the relevant soft tissues?

d) Ultrasound: how realistic are the ultrasound images?

2) Perceived utility:

a) How useful would this simulator be to teach the steps of the procedure?

b) How useful is it to have different training scenarios?

c) How useful is the simulator for teaching each of the training tasks?

d) Was the simulation challenging enough?

e) Would you like to incorporate more simulations like this one in your training/surgeons' training?

- Content validity

The evaluation of the content validity aims to assess the usefulness of the simulator as a training tool (Section 2.4.2). In my evaluation, content evaluation was used to assess the following aspects using the Likert scale:

1) Procedural confidence (knowing the steps of the procedure): before and after training on the simulator.
2) Confidence level in performing each task: before and after training.
3) Validation of the selection of the training tasks. Participants rated the usefulness/suitability of each training task, to select the most important tasks for future use and evaluation of this simulator.

- Construct validity

Construct validity was used to prove whether the simulator could differentiate between experts, intermediates, and novices (Section 2.4.3). In this research, the comparison between surgeons focused on the following scores: completion time of

* All terms italicised and with an asterisk are defined in Appendix A, the Glossary.

each training tasks, the level of assistance needed to complete the tasks evaluated on the Likert scale by an assistant surgeon, success or failure in completing the tasks, number of instrument changes during the practice, and a global score (S) defined as follows:

$$S = \frac{time}{max(time)} + \frac{AL}{max(AL)} + \frac{Number\ of\ failed\ tasks}{Number\ of\ tasks} + \frac{IE}{max(IE)}, \quad (15)$$

where max indicated the maximum for a given score from all the participants, time indicated the time taken to complete the procedure on the simulator, AL indicated the level of assistance required, and IE the number of instrument exchanges. This score aimed to give an overall grade to the surgeon which included all aspects of their evaluation.

I also imposed a time limit to complete each task; the participants could not exceed a maximum of 10 minutes. This was enforced to avoid spending too much time on a single task.

The tasks included in the simulation were the ones listed in the following table. This list was defined using the description of the surgery given by the surgeons. The evaluation of the scores listed previously was carried out by a surgeon who agreed to help organising this study and who had previous experience of performing LCBDE. This surgeon assisted the other participants during the simulation sessions and observed them to assess their performance. This surgeon was also there to give guidance to the participants if they had difficulty in completing the tasks.

Table 20: Tasks evaluated during the training session

1. Clip and divide the cystic artery.
2. Milk and clip the cystic duct
3. Choledochotomy
4. Choledochoscopy
5. Stone retrieval
6. Suture close defect

The surgeons were divided into three groups depending on their level of expertise. I used Kruskal-Wallis tests to investigate if there were statistically significant

* All terms italicised and with an asterisk are defined in Appendix A, the Glossary.

differences between the performances of these groups. The evaluation was conducted on the SPSS software. The difference between confidence levels before and after training were evaluated using the Wilcoxon test

7.2 Results

7.2.1 The simulator specifications

Firstly, to get a better understanding of the requirements of a surgical simulator for LCBDE using ultrasounds, HCD methodology recommended investigating this with the end users (Section 1.2.1.1). Therefore, I conducted interview 1 with a total of eight surgeons who regularly perform this surgery. They are referred to as surgeon A to surgeon H; of whom surgeons B and C were novice surgeons.

7.2.1.1 Soft tissues to include

During interview 1, the surgeons were asked about the soft tissues they come into contact with during the procedure. They listed the tissues shown in Figure 53:

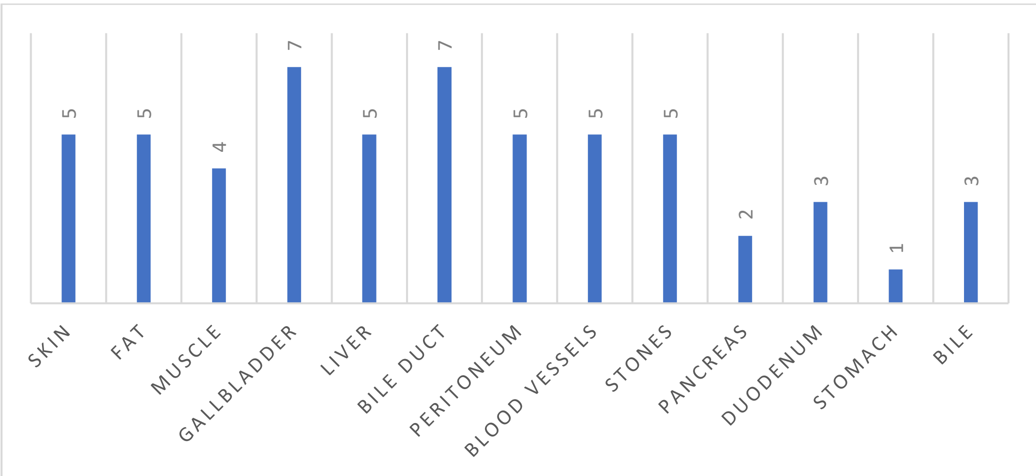


Figure 53: Soft tissues mentioned by surgeons during interview 1

Considering that the soft tissues mentioned by less than half of the surgeons were not as likely to be involved during the procedure, I hypothesised that it was not as important to include them in a simulation practice. Indeed, if only a limited number of surgeons mentioned the soft tissues, then it showed that either the surgeons did not always come into contact with those tissues or that their contact with these tissues was very limited within the procedure. Thus, the organs and soft tissues that

* All terms italicised and with an asterisk are defined in Appendix A, the Glossary.

were included in the simulator are the ones that were the most cited during interview 1 – the gallbladder, the bile duct, the abdominal wall (skin, fat, and muscle), the liver, the peritoneum, the blood vessels, and the stones.

Surgeons D and E mentioned the duodenum and the pancreas because they are part of the ultrasound examination and because they are also a remarkable anatomical feature that can be used to locate the position of the organs. However, the surgeons said they did not have direct contact with these two soft tissues during LCBDE surgery.

The bile was only mentioned by surgeons A, D, and F, which might be because it is a liquid. However, it is part of the gallbladder, so it was included in the simulator.

Surgeon D mentioned the stomach, but not in their description of the steps of the surgery. Surgeon D also mentioned the pancreas, the duodenum, and the bile, which most surgeons did not. An explanation for this could be that this surgeon was describing the soft tissues that are around the tissues involved in the surgery as well, even if there is no direct contact with them.

When the procedure is described in the literature (Helton and Ayloo, 2019; Zerey *et al.*, 2018), the following soft tissues are mentioned: hepatic duct, liver, common bile duct, duodenum, gallbladder, visceral fat, stones, blood vessels, cystic duct, skin, and falciform. It is notable that the literature does not mention the abdominal wall, because the authors are describing the surgery after the access ports have been inserted.

The hepatic duct is the part of the bile duct that connects the liver, which is why the surgeons did not mention it explicitly.

The falciform is a ligament which does not have a great impact on the surgery as described in the literature, as shown by the fact that none of the surgeons interviewed mentioned it. It was not deemed necessary to include it in the model.

The duodenum was mentioned multiple times both in the literature and by the surgeons. Consequently, it was considered an important aspect of the surgery that

* All terms italicised and with an asterisk are defined in Appendix A, the Glossary.

was added to the original list of organs. The reason why not all the surgeons interviewed mentioned it was that, during the surgery, they do not act on the duodenum but only push stones into it and use it as an anatomical marker. They do not perform any cut on it or directly touch the duodenum, which is also confirmed by the literature.

The final list of soft tissues included in the simulator was therefore: gallbladder, bile duct, abdominal wall (skin, fat, and muscle), liver, peritoneum, blood vessels, stones, and duodenum.

7.2.1.2 Important steps to include

During interview 1, the surgeons identified the most important steps to include in a surgical simulator. Figure 54 summarises their answers.

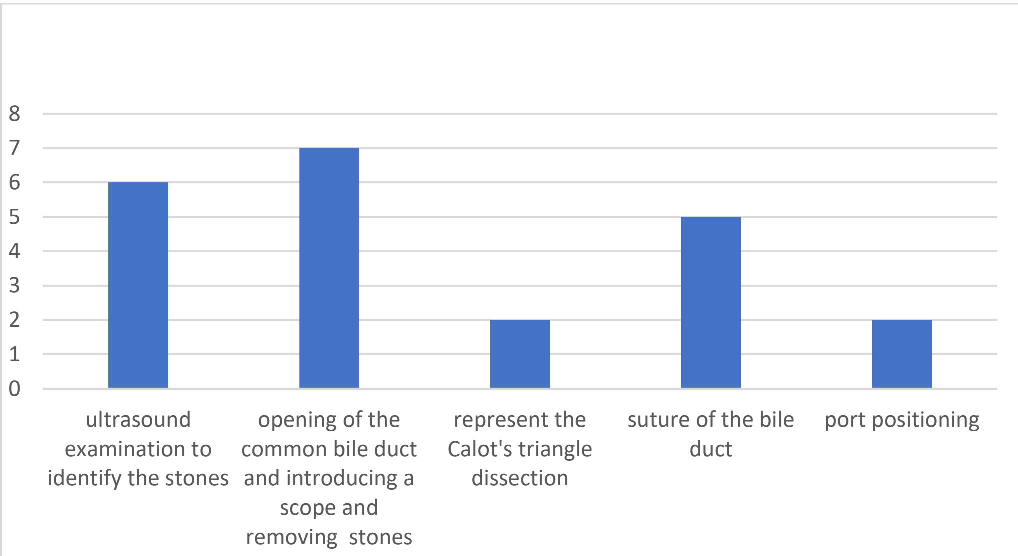


Figure 54: Important steps of the surgery that needed to be included in the simulator

Thus, the most important steps included in the simulator were:

- The ultrasound examination.
- Gaining access to and opening the common bile duct.
- Introducing the scope and removing the stones.
- Suturing the bile duct.

Surgeons A and E noted the importance of the port positioning; indeed, this step is important for the setup of the surgery because it allows a surgeon to make sure

* All terms italicised and with an asterisk are defined in Appendix A, the Glossary.

that their instruments are set at the right position. Surgeons B and E mentioned the Calot's triangle dissection; this step is also challenging because of the complexity in finding the anatomical features. However, these two steps are not specific to bile duct exploration, and gallbladder simulation models can offer training for these two steps; consequently, there was less need to replicate them in this simulator. This step allowed the training tasks for the workshop 2 to be identified (Section 7.1.2).

7.2.1.3 Decision points to include

LCBDE surgery includes several steps where surgeons need to take a decision depending on what they find in the body. These decisions result in different scenarios, which are summarised below.

The first decision point is during port placement and patient preparation; if the patient has already had abdominal surgery or is overweight, then the port placement might need to be changed from a standard patient to be able to find a good access.

The second decision point is during the gallbladder exposure. The surgeon might not be able to clearly identify the Calot's triangle, in which case they might need to either dissect the entire gallbladder, perform a subtotal colectomy, convert to an open procedure, or even abandon the procedure.

Then during the ultrasound examination, the surgeon needs to identify the stones and the anatomy of the bile duct. If the bile duct measures less than 8mm, the surgeon must stop the procedure and send the patient to another endoscopic surgery. If the bile duct measures more than 8mm, the surgeon can go on with the procedure, but depending on what the ultrasound examination reveals, the surgeon needs to determine which approach to take to enter the bile duct, which can be trans-cystic or trans-choledochal.

Finally, the last decision point is on the stone removal technique. The surgeon has many options for this – flushing, basket removal, lithotripsy, and through the ampulla – and needs to determine which technique is the most suitable for a specific patient.

* All terms italicised and with an asterisk are defined in Appendix A, the Glossary.

According to the surgeons interviewed, the important scenarios to include in the simulation were:

- The ultrasound examination (to measure the size of the bile duct, location, size, and number of stones) to determine which approach to take to remove the stones, as shown in Figure 55.
- The bile duct exploration, to choose how to remove the stones, as shown Figure 56.

It was not considered to necessary to include decisions about port placement and identifying the Calot's triangle in the simulation. Diagrams of the decision points which were included are provided below:

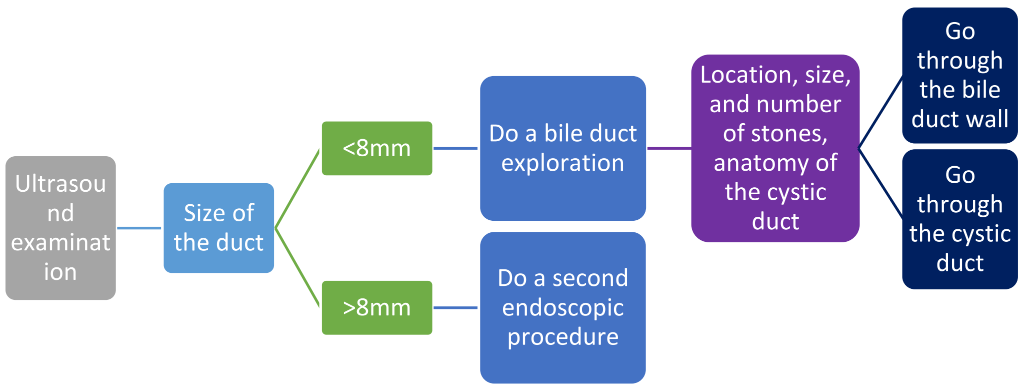


Figure 55: First scenario during surgery to include in the simulation

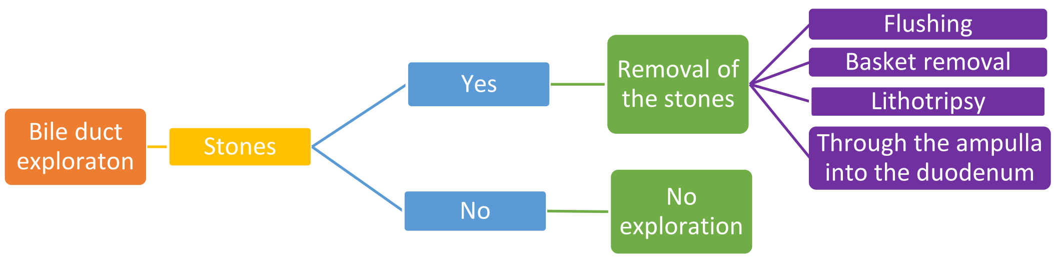


Figure 56: Second scenario during surgery to include in the simulation

According to the literature (Helton and Ayloo, 2019; Zerey *et al.*, 2018), the aspects that might impact on LCBDE surgery are:

* All terms italicised and with an asterisk are defined in Appendix A, the Glossary.

- The patient's medical history, such as a history of choledocholithiasis or prior biliary operations. This could make the access more complex and relates to what the surgeons said in interview 1 about the first decision point.
- The size, number, and location of stones, as well as the size and anatomic course of the cystic duct and the size of the common bile duct. These factors relate to the decision point at the time of the ultrasound examination identified by the surgeons during interview 1.
- The biliary drainage procedure and closure of the bile duct; this aspect was not mentioned by most of the surgeons in interview 1.
- The patient's body habitus and ability to safely expose their CBD. This relates to the ability to safely expose the anatomy, as described by the surgeons.
- The literature also describes the different possibilities for stone removal.

Draining the bile duct at the end of the procedure was also mentioned by some surgeons in their descriptions of the surgery; however, for a simulation practice, most of them thought that suturing the bile duct was a more important skill (surgeons A, C, D, G, and H). Therefore, the simulation did not include this decision point, so that the surgeons could focus on suturing the bile duct.

In the literature (Helton and Ayloo, 2019; Zerey *et al.*, 2018), the main decision point is cited as whether to take a trans-cystic or trans-choledochal approach, depending on the number of stones, the size of the stones, and the anatomy of the bile duct and cystic duct. The literature also illustrates the variety of possibilities for clearing the bile duct. This confirms the importance of these two decision points in the simulation.

7.2.1.4 Important aspects of the simulation

The interviewed surgeons had previously used the types of training devices shown in Figure 57:

* All terms italicised and with an asterisk are defined in Appendix A, the Glossary.

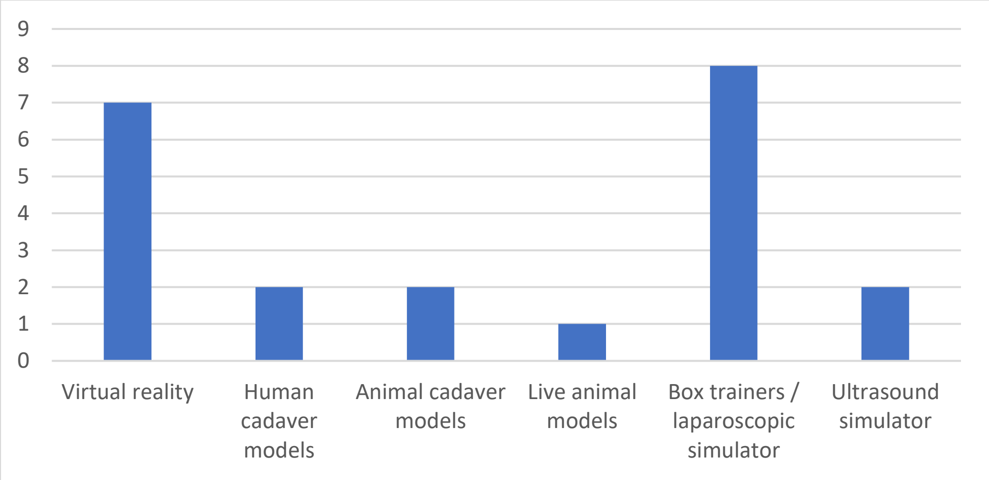


Figure 57: Types of training devices used previously by the surgeons

Most surgeons had experienced using surgical simulators that were VR-based or box trainers. However, only surgeons C and E had used ultrasound simulators; this might be because they are less common and often home-made. Only surgeons A and D mentioned using cadaver or animal models, but this is surely because the other surgeons were only talking about their experience of simulations and did not count those models as simulations.

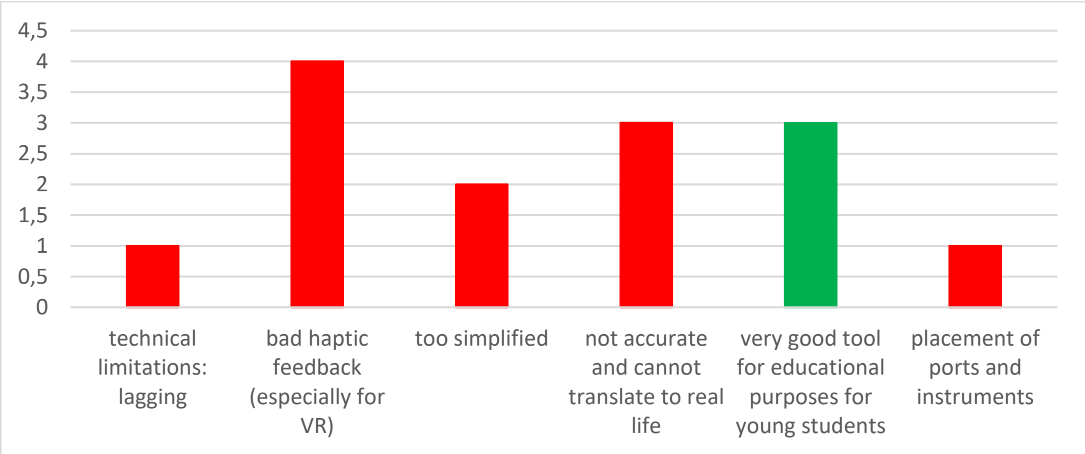


Figure 58: Benefits (green) and drawbacks (red) of commercially available simulators

As shown in Figure 58, according to the interviewees, available simulators can teach young students the use of tools and the steps of surgery, but they have several limitations including unrealistic tactile feedback, being too simplified and not able to translate into real life.

* All terms italicised and with an asterisk are defined in Appendix A, the Glossary.

It is notable that only surgeon H mentioned port placement, which could be linked to the fact that only two surgeons interviewed considered port placements to be an important step for simulators to replicate.

As shown in Figure 59, the aspects interviewees deemed most important for the simulator were tactile feedback and realism. They stated that, during the evaluation phase, it would also be good to prove that the simulator could:

- differentiate between novices and experts,
- improve performance in theatre (transferrable),
- teach the steps of the procedure.

Surgeon E also commented that it would be useful if the simulator could eventually include complications. Surgeon E had mentioned the widest variety of soft tissues in the first part of interview 1. According to this participant, every aspect of the simulation must be as realistic as possible. It is worth noting that surgeon E is an experienced surgeon who regularly performs the LCBDE procedure and therefore is interested in more complex cases.

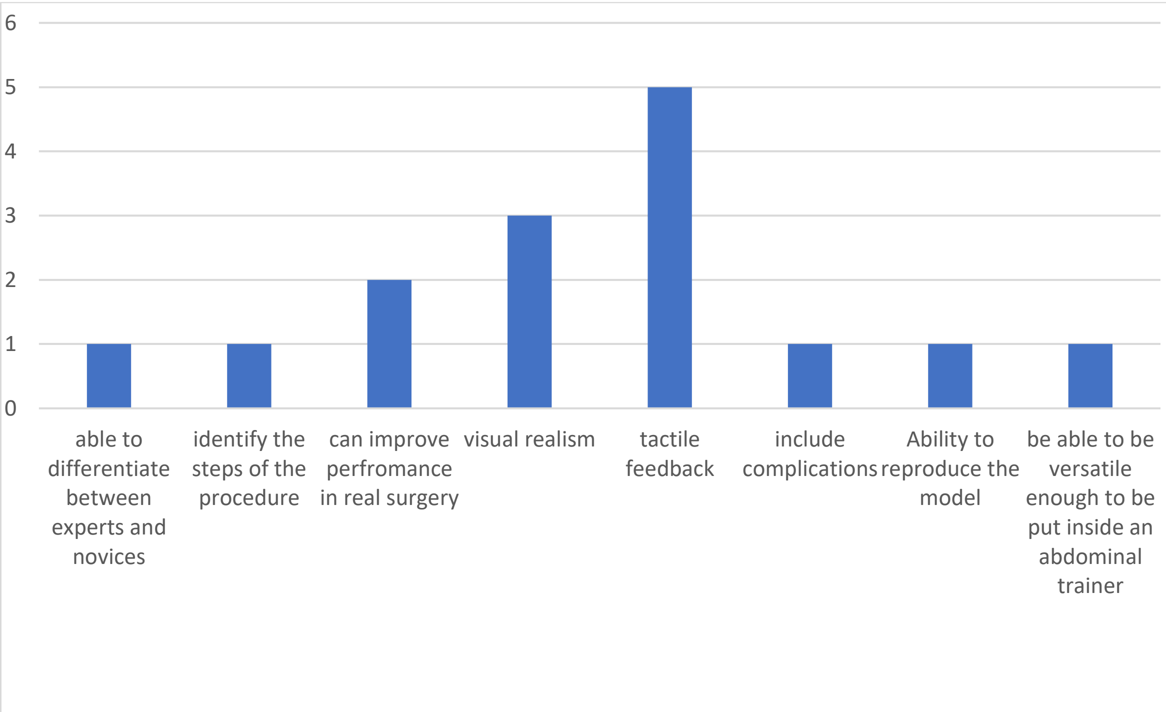


Figure 59: Key aspects of simulators according to surgeons

* All terms italicised and with an asterisk are defined in Appendix A, the Glossary.

Surgeon A suggested that the simulator should be able to "differentiate between experts and novices", "identify the steps of the procedure", "improve the performance in real surgery", "reproduce the model", and "be versatile enough to be put inside an abdominal trainer". Surgeon A has experience of developing and evaluating simulators; therefore, stated these requirements because they are parts of these two processes.

7.2.1.5 Length of the simulation

As shown in Figure 60, the interviewees asserted that the simulation should last between 20 and 40 minutes, to have enough time to teach the different steps but not be too long to keep the trainee surgeons engaged. More precisely, they said that the ultrasound examination should last around five minutes, opening the common bile duct should also last five minutes, scoping with the choledochoscope and the stone removal should last around twenty minutes, and lastly, the suturing should last ten minutes.

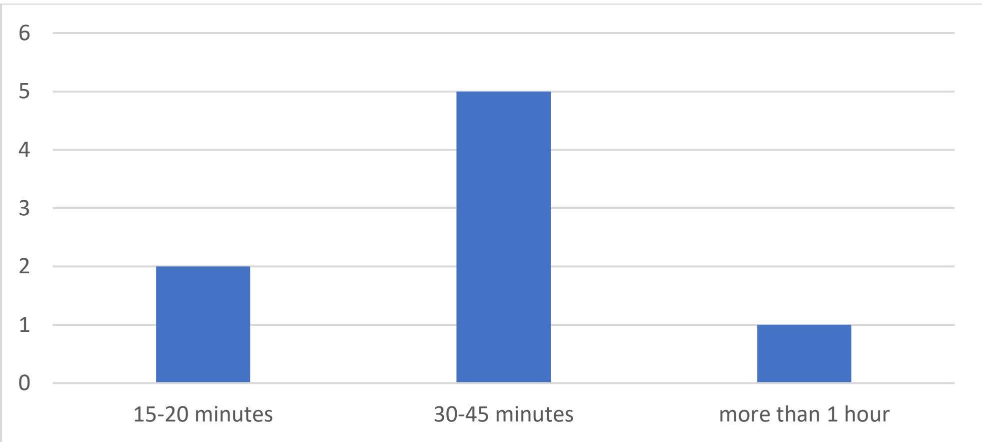


Figure 60: best total length of simulation according to the participants

Surgeon E expressed that the simulation should last more than one hour. This might be because this was one of the most experienced surgeons, so would require a more challenging simulation to have a useful training tool. Conversely, the surgeons who suggested a shorter simulation time were more novice surgeons who were mostly interested in learning the steps of the surgery.

* All terms italicised and with an asterisk are defined in Appendix A, the Glossary.

7.2.1.6 Analysis of interview 1

In interview 1, it was evident that the novice group tended to give more importance the visual cues and less to tactile feedback. One of the novice surgeons said that "*you can feel, of course limited tactile feedback, but mainly it depends on your visual senses rather than the motor senses, which in comparison, if you compare it to open surgery, it depends more on your motor or the feeling that you have in the inside and the tissue while you're gripping and pulling*". This could be because, in laparoscopic surgery, tactile feedback is very nuanced, and the novice surgeons did not have enough experience to be able to distinguish between these nuances very well. Thus, they were not using their tactile sense as much as the expert surgeons and relied more on their visual sense.

7.2.1.7 Conclusion on the specifications

In interview 1, the surgeons described their needs, which produced the specifications for the surgical simulator. Their responses determined that the simulator should include the following soft tissues: gallbladder, bile duct, abdominal wall (skin, fat, and muscle), liver, peritoneum, cystic artery, vein, stones, duodenum, and visceral fat.

The simulator should aim to train surgeons in the following steps: ultrasound examination, access to and opening the common bile duct, introducing the scope, removing the stones, and suturing the bile duct. It should also include the two decision points during the ultrasound examination and the exploration.

Respondents asserted that important aspects of a surgical simulator are to provide good tactile feedback and realism. They also stated that it should be able to: differentiate between experts and novices, improve performance in theatre (transferrable), teach the steps of the procedure, and eventually include complications.

The consensus was that a simulation practice should last around 30 minutes.

From this first list of requirements, I deduced the following supplementary requirements:

* All terms italicised and with an asterisk are defined in Appendix A, the Glossary.

- The materials must be ultrasound visible for the bile duct examination.
- The bile duct and stones inside the bile duct would need to be changed after each simulation practice because cuts would be made in them. The other parts (abdominal wall, liver, part of the peritoneum, gallbladder, cystic artery, hepatic artery, and portal vein) would not be damaged during the practice, so could stay the same at each practice. The gallbladder, the bile duct including the cystic duct, common bile duct, left and right hepatic duct, and stones would comprise just one block that would be made multiple times, to have spare parts available to change in between each surgeon.
- Because the parts needed to be changed several times, it was important for the fabrication method to be quick, inexpensive, and easy to make. It was also important to be able to add the new parts quickly by joining them to the initial model to make a new complete model.
- It was important to provide multiple training scenarios by changing the location and number of stones.

7.2.2 Evaluation of the simulator

Seven models and seven replacement parts were prepared, and these were shown to the surgeons for their evaluation.

Figures 61 and 62 show the setup for the ultrasound training task, and Figure 63 shows the port insertion training task.

* All terms italicised and with an asterisk are defined in Appendix A, the Glossary.

Figure 61: Evaluation of the context-aware simulation of the laparoscopic ultrasound examination of the bile duct.

Figure 62: "Setup for the augmented reality ultrasounds training" by Marine Shao, used under [*CC BY 4.0*]

* All terms italicised and with an asterisk are defined in Appendix A, the Glossary.

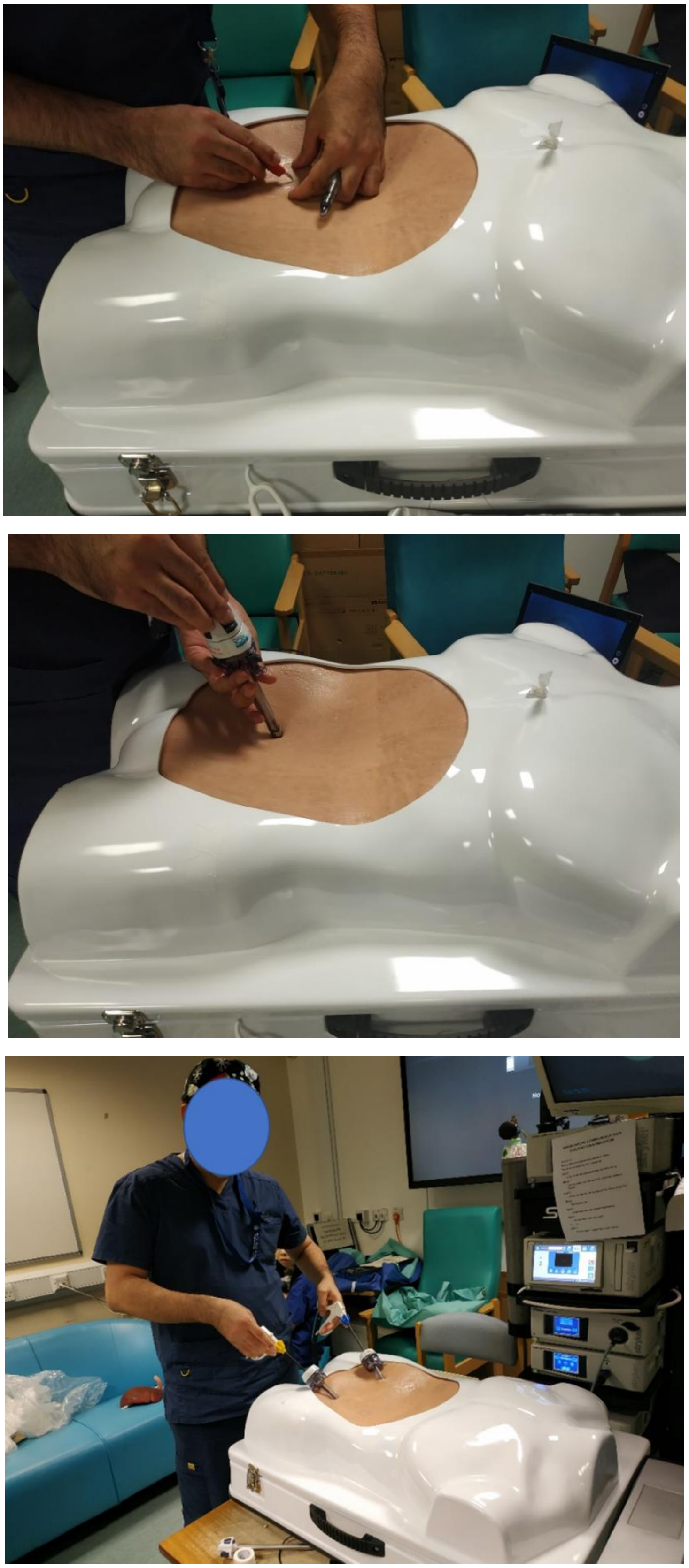


Figure 63: Adapted from "Training for port insertion" by Marine Shao, used under [CC BY 4.0](CC BY 4.0)

For the port insertion task, the cover supplied with the box trainer was replaced with my simulated abdominal wall. Then, as seen in Figure 64, the cover was put back into place for the other steps.

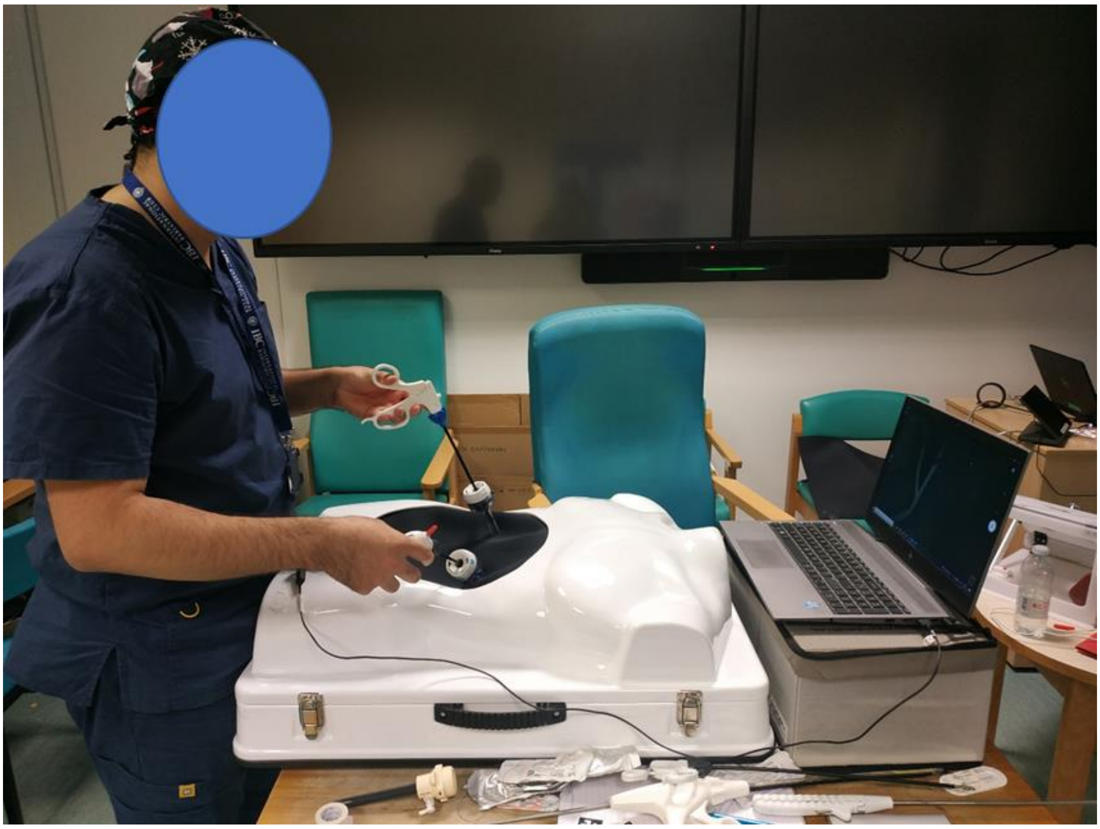


Figure 64: Setup for the laparoscopic training

The next training tasks were clipping and dividing the cystic artery, opening of the cystic duct and the bile duct, insertion of the choledochoscope, choledochoscopy and stones removal, and suturing of the bile duct. These are visible in Figures 65 to 69.

* All terms italicised and with an asterisk are defined in Appendix A, the Glossary.

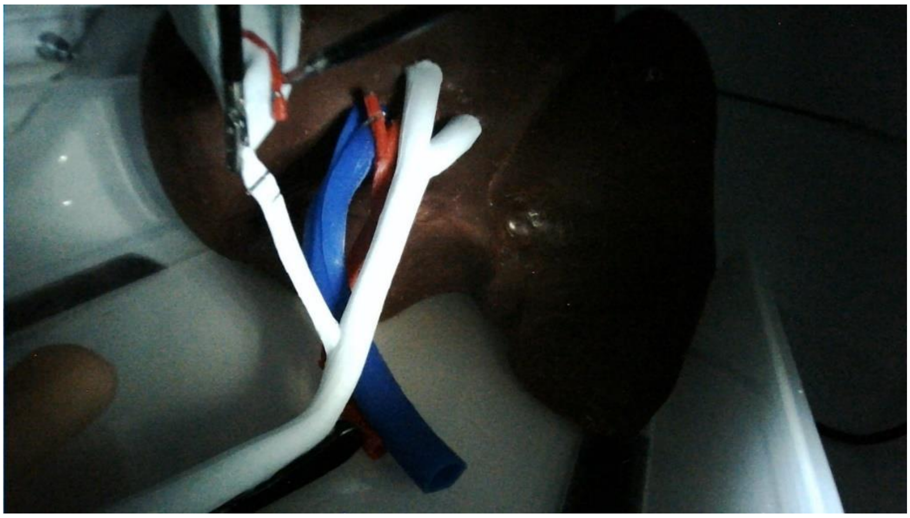


Figure 65: "Clipping and dividing the cystic artery" by Marine Shao, used under [CC BY 4.0](CC BY 4.0)

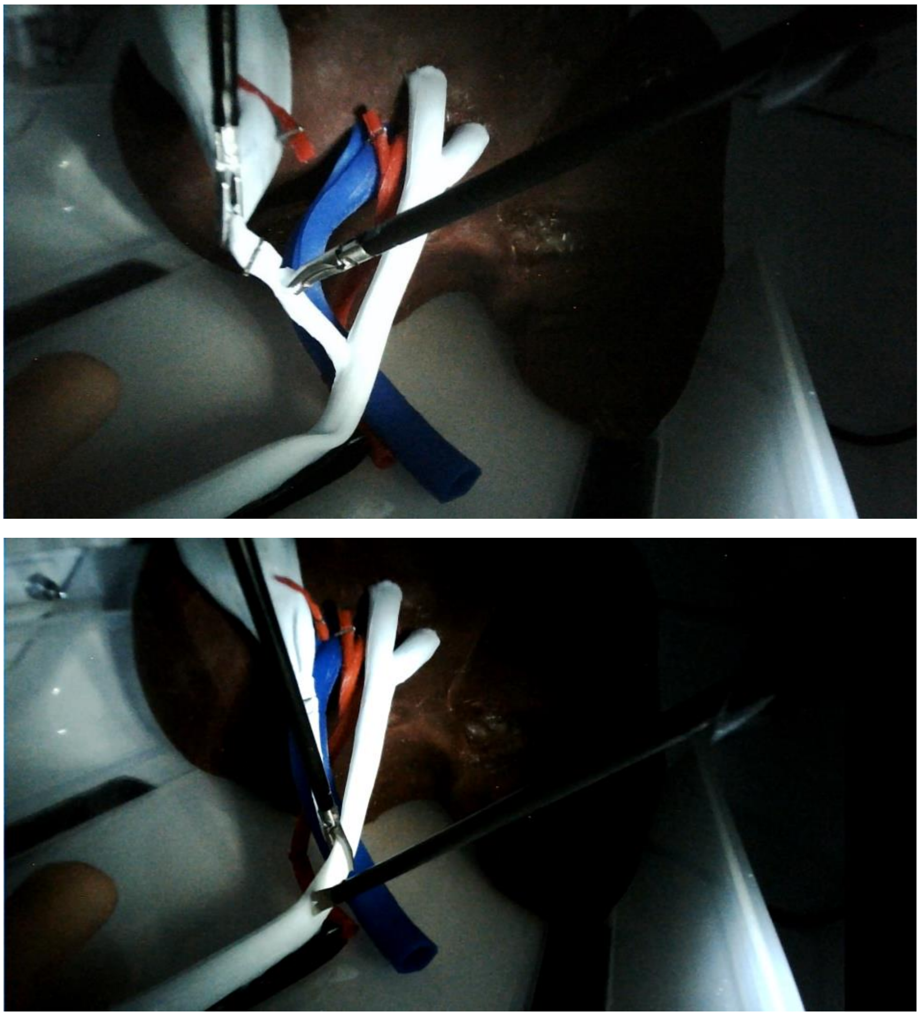


Figure 66: Opening the cystic duct (top) and the bile duct (bottom)

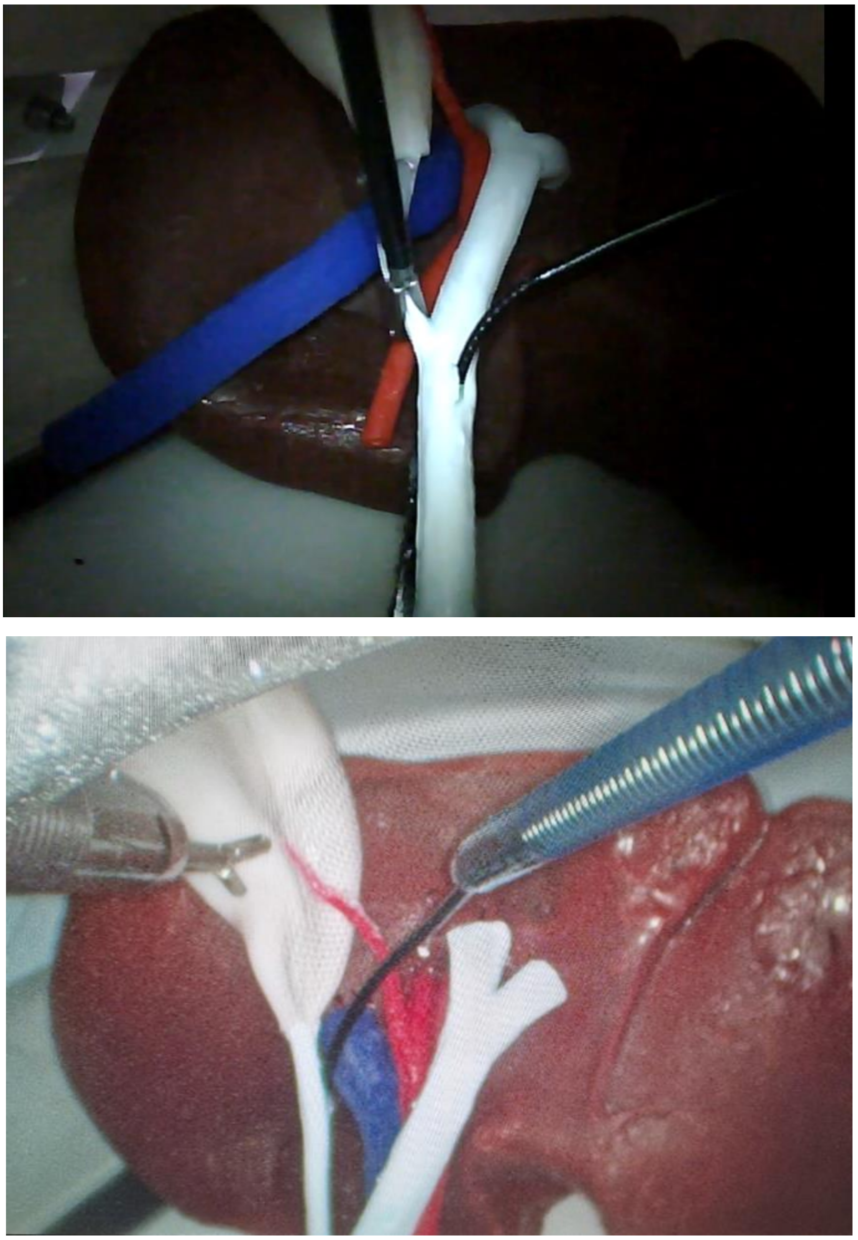


Figure 67: "Insertion of the choledochoscope with a trans-choledochal approach (top) or a trans-cystic approach (bottom)" by Marine Shao, used under CC BY 4.0 / changed formatting

* All terms italicised and with an asterisk are defined in Appendix A, the Glossary.

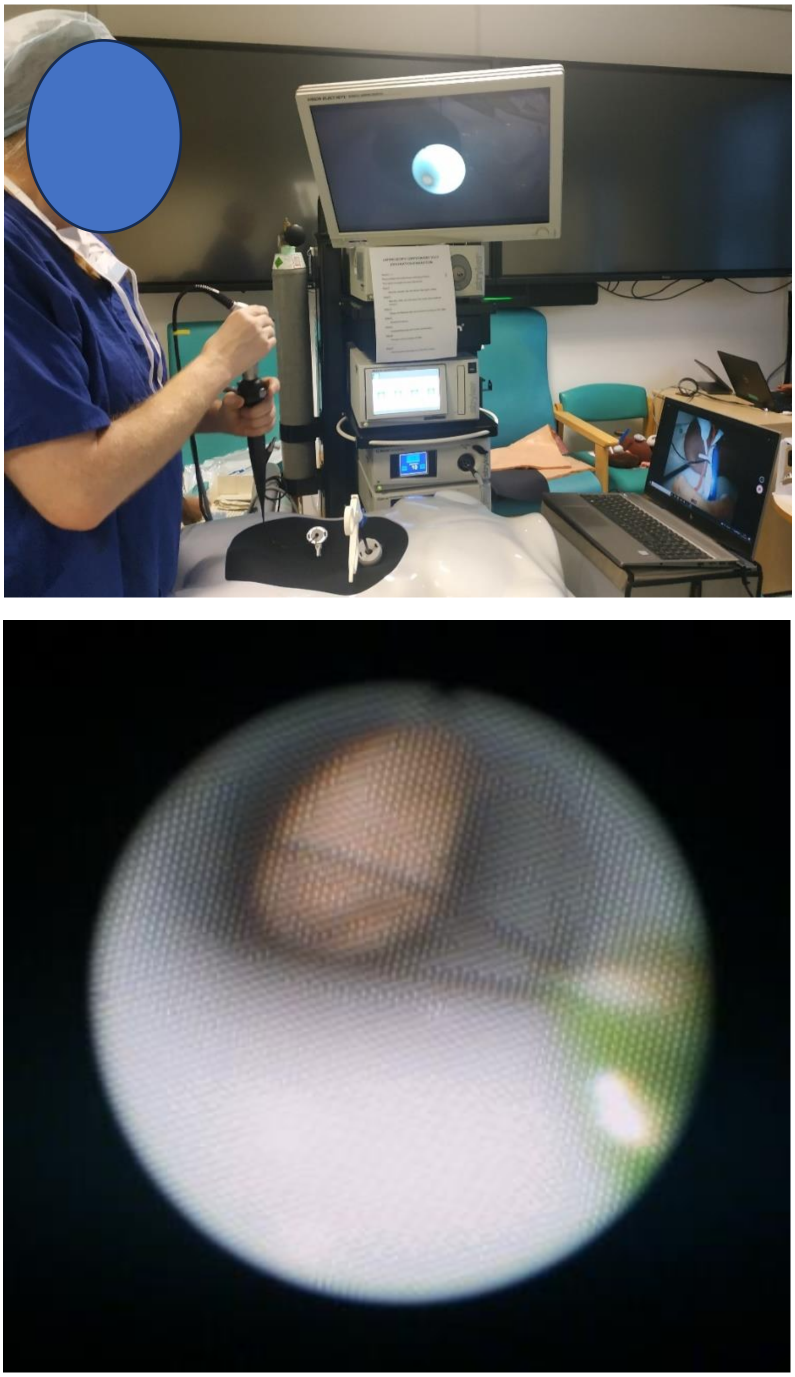


Figure 68: "Choledochoscopy and capture of the stone" by Marine Shao, used under CC BY 4.0 / changed formatting

Figure 69: "Suturing the bile duct" by Marine Shao, used under [CC BY 4.0](CC BY 4.0) / changed formatting

The full results of workshop 2 are available in the appendices.

7.2.2.1 Participant types

Two novices, eight intermediate, and three experts participated to this study. Having different levels of expertise allowed me to analyse their performance relative to their experience for construct validation.

Before beginning each practice, I presented the model to the participant and explained the aim of the simulator. I also detailed the steps of the procedure; the steps could be repeated during the practice when needed.

There was an assistant surgeon during the practice; this surgeon's roles were to help the participant by giving instructions or explanations of the steps and to evaluate the level of assistance required by the participant.

7.2.2.2 Face validity

Face validation evaluation was used to evaluate the simulation's realism using the Likert scale (Joshi *et al.*, 2015).

When using direct vision, all the participants rated the visual realism of the abdominal wall and the liver as between 4 and 5. The realism of the synthetic soft

* All terms italicised and with an asterisk are defined in Appendix A, the Glossary.

tissues was graded as 4.5, 3.4, 3.7, 3.5, 4.1, 4.0, and 4.3 for the liver, artery, vein, bile duct, gallbladder, duodenum, and abdominal wall respectively.

For the tactile feedback, the realism of the synthetic soft tissues was graded as 4.2, 3.5, 3.2, 3.7, 4.0, 4.0, and 4.1 for the liver, artery, vein, bile duct, gallbladder, duodenum, and abdominal wall respectively.

Most of the surgeons thought that all the relevant soft tissues were included in the simulator; however, one participant suggested that it would have been better to add more soft tissues, more specifically the omemtum. This surgeon had a lot of experience in performing laparoscopic surgery and might prefer more complex simulation practice.

The participants evaluated the usefulness of having multiple training scenarios as 3.9; which highlighted their interest in this option.

When performing the different tasks, the surgeons evaluated the realism of:

- the port insertion as 3.5, stating that to be realistic, it needed to be tougher, especially the muscle layer. Two surgeons added that they would have also included a fascia layer,
- the ultrasound image as 3.7,
- the choledochotomy as 3.6,
- the choledochoscopy as 4.4,
- the retrieval of the stone as 4.5,
- the suturing of the bile duct as 4.1.

The choledochotomy and the suturing tasks got the lowest scores, but one of the surgeons said that it was because the poor lighting and low camera's visual quality made it very difficult to visualise the cut and thread of the suture. During a real surgery, the camera has a very good resolution and an assistant adjusts it in real-time for the surgeon.

The perceived utility of the simulator was rated as:

- 4.0 for the port insertion,

- 4.0 for the ultrasound training,
- 4.0 for the decision on the approach,
- 4.5 for the choledochotomy,
- 4.7 for the choledochoscopy,
- 4.3 for suturing the bile duct.

The participants evaluated including the simulator in their training with a grade of 4.5. This is encouraging as it showed they would value the simulation as a useful way to train surgeons.

The participants evaluated the level of challenge of the simulation at 4.4. Some of them said that it was more difficult than real-life because of the visualisation issues.

7.2.2.3 Content validity

Content validation was used to evaluate the different criteria using the Likert scale (Joshi *et al.*, 2015).

The results showed that the surgeons' confidence level when performing:

- the port insertion stayed at 4.8 before and after training, indicating that this is a very simple task which does not require practice,
- ultrasound evaluation: the surgeons' confidence level rose from 3.1 to 3.5,
- the approach decision: their mean confidence on deciding which approach to take was 2.8 before training and 3.8 after training,
- choledochotomy: their mean confidence was 3.5 before training and 3.7 after training,
- choledochoscopy: their mean confidence level increased from 3.2 to 3.8 after training,
- suturing the bile duct: their mean confidence level decreased from 3.2 to 3.1, but this could be because, as the surgeons said, it was more difficult to perform the suture than in real life because of the poorer visualisation.

* All terms italicised and with an asterisk are defined in Appendix A, the Glossary.

The results were statistically analysed using the Wilcoxon test to check for differences in confidence before and after training, but no statistically significant difference was found.

There were four participants who had a low confidence in knowing the steps of the surgery. The same participants also said that this simulator had the ability to teach them the steps (giving it a score of 4 to 5), which indicated that my model could be used as a teaching tool for less confident surgeons and teach them the steps of the surgery.

Overall, the participants graded the model as 4.3 for its ability to teach the steps of the procedure.

The results showed that the surgeons rated the usefulness of being trained on the simulator for the following tasks as:

- 4 for the port insertion,
- 3.9 for the ultrasound training,
- 4.2 for the decision of the approach,
- 4.5 for the choledochotomy,
- 4.6 for the choledochoscopy and the stone retrieval,
- 4.3 for the suturing task.

This showed that the most important training tasks for the surgeons are the choledochotomy, choledochoscopy and stone retrieval, and the suturing.

7.2.2.4 Construct validity

Participant 3 was withdrawn from the results for the construct validation as they had tested the simulator before their participation. The analysis included three experts, seven intermediate, and two novices. In this study, a better performance resulted in a lower score.

During the workshop, the three experts successfully completed all their assigned tasks. The intermediates managed to successfully complete most of the tasks, except the most complex which were the suturing or the stone retrieval for five of them. The two novices also completed most of the tasks, but they needed more assistance to do so. They also both failed the suturing task.

The Kruskal-Wallis test was applied and showed a statistically significant difference in assistance level for the tasks of choledochotomy (p=0.004) between the experts, intermediate, and novices. The total assistance for the entire procedure also showed differences, with an average of 17.5 for the novices, 9.3 for the intermediate, and 8 for the experts, but this was not statistically significant.

The Kruskal-Wallis tests also showed a statistically significant difference of time to completion for the laparoscopic suturing task (p=0.022) and of total time to complete the procedure (p=0.018). On average, the total time of the procedure was 1681 seconds for the novices, 1193 seconds for the intermediate, and 642 seconds for the experts.

The number of instruments exchanges also depended on the surgeons' level of expertise: on average, the novices made 26.5 exchanges, the intermediate made 22.1 exchanges, and the experts made 17.7 exchanges; this was also statistically significant (p=0.041).

Finally, a total score taking into account the normalised total time, normalised total assistance, normalised number of failed tasks, and normalised number of instrument exchange also showed statistical differences between the three groups (p=0.019). On average, the novices achieved a score of 2.9, the intermediate a score of 2.0, and the experts a score of 1.4.

It is also notable that the surgeons did not consider the utility of being trained for each task similarly in relation to how frequently they perform the surgery. Surgeons who seldom performed LCBDE said it would be more beneficial to be trained for the choledochotomy (average score of 4.8 instead of 3.75 for others) (p=0.012).

* All terms italicised and with an asterisk are defined in Appendix A, the Glossary.

Similarly, surgeons who rarely performed LCBDE said it would be more useful to be trained for laparoscopic ultrasounds (4.4 instead of 3) (p=0.017).

7.3 Discussions

7.3.1 Prototypes development

The physical models developed in this study can train surgeons at a low price. The 3D printers used in this research are FFF and SLA 3D printers, which are the most affordable type of printers (Hong *et al.*, 2019; Tejo-Otero, Buj-Corral and Fenollosa-Artés, 2020). It costs £60 to make all the internal synthetic tissues and £110 to make the abdominal wall. The fabrication of replacement parts is both quick (a few hours) and inexpensive. Indeed, it is only necessary to replace the bile duct and the artery after a practice as they are the only parts that receive cuts. With the fabrication process developed in this research, such new parts can be moulded and replaced easily. The price of the new parts is the price of the materials and is only 50p for each artery and £1 for each bile duct.

However, while the physical model was intended to be affordable, by using relatively low-cost 3D printers and materials, its development still required access to a 3D printer and silicone, as well as having the skills sets necessary to use the 3D printers and make the models. This aspect could limit the generalisation of these types of simulators, especially since the aim is to ultimately develop more models which would then require skills in CAD to generate more anatomies. At this stage, there is only one anatomical model available, but it would be interesting for the surgeons to provide multiple types of anatomy, especially multiple types of bile duct.

Similarly, the box trainer selected for this study was quite expensive (£2,000); there are less expensive solutions on the market, but they do not always correctly mimic the position of the ports and laparoscopic instruments, which could have led to a less realistic simulation.

There are a few limitations to the prototypes which were simplifications made because the aim of this research was to provide training for basic skills. One of the

* All terms italicised and with an asterisk are defined in Appendix A, the Glossary.

limitations is that the gallstones were simulated using gravel, which does not have the same properties as the real thing, resulting in less realism of the simulation. During workshop 2, one of the surgeons mentioned that in real life they could just crush a stone for easier removal, which was not possible with my model.

The model developed does not include blood flow and complications. During the interviews, expert surgeons stated that they would find it useful to have a more complex training system which includes complications and abnormal cases. As such, the developed simulator is more suitable for novice and basic skills training. Several research projects have previously demonstrated that it is possible to connect simulated models to a pump (Mix *et al.*, 2018; O'Reilly *et al.*, 2016; Ryan *et al.*, 2015). Using a pump would have allowed me to record the images in Doppler mode directly.

The study used a simple way to develop models of just the abdominal soft tissues. Even though these models are currently limited to the upper abdomen, the developed method, including description of the soft tissues and the fabrication method, could be generalised to other anatomical areas.

7.3.2 Evaluation of the prototypes

Because of the limited time of the research, there was no evaluation of how beneficial the simulation was in terms of improving surgical scores before and after training on the simulator. This type of evaluation is very important to prove the usefulness of a simulator and should be included in future work.

One of the metrics employed to evaluate the effectiveness of the simulation was the time taken to complete a given task, however, this metric has been criticised in previous studies. Indeed, using this evaluation metric favours the idea that surgeons should be working fast. Previous studies have shown that this assumption can lead trainees to try to perform a task quickly, which can result to them learning the task inaccurately (Overtoom *et al.*, 2019). Furthermore, one participant stressed that doing a task while being timed generated more stress, which is not an ideal learning environment.

* All terms italicised and with an asterisk are defined in Appendix A, the Glossary.

The evaluation scale used in this research required the participants to be watched and assessed while they were using the simulator. This could have induced stress and modified the outcome of their practice, however, traditional training is also based on a trainee practicing under supervision, so it should not have had a great impact. Moreover, this evaluation scale required having access to an expert who was competent to give relevant feedback. Previous studies have shown that surgical simulators fail to be generalised because of the need for an expert to supervise the learning and the imbalance in numbers between trainees and teachers (Waran *et al.*, 2014a). Consequently, quantitative evaluation metrics could be developed to analyse a trainee's movement as recorded by the camera. In addition, several quantitative metrics have already been proposed, such as time to complete a task or the path length (Cardoso *et al.*, 2017).

In my research, evaluation of the surgeons' performance was limited to their time, level of assistance needed and number of instrument exchanges, when conducting the steps of the surgery. It might be more interesting to develop a new evaluation metric by directly asking surgeons which aspects of a surgery they would evaluate. For instance, one surgeon mentioned during the workshop that it would be useful to assess if the suture each participant made on the bile duct was waterproof or not. Future work could focus on using participant-based studies to define relevant metrics to evaluate surgical performances.

During workshop 2, there were limitations related to the visualisation of the soft tissues because of the camera's quality. This made the simulation more complex than real life for some of the tasks, such as the suturing, which limited the utilisation of the simulator. Thus, the evaluation sometimes resulted in lower scores because of the conditions of use of the simulation, rather than the simulator itself. Having designed workshop 2 conditions more effectively could have resulted in better evaluation.

One of the surgeons also noted some difficulties in using the simulator that were more due to workshop 2's design than the model itself. The participant could not adjust the patient positioning and did not have an assistant to move the camera position, which made it more difficult to perform the tasks. Taking these comments into account contributes to improving research after the completion of this research and defining future research directions to include a model in which the surgeon could adjust patient positioning.

7.3.3 Comparison to the state-of-the-art surgical simulators for LCBDE

LCBDE is a challenging procedure that requires multiple skills. A previous study by Teitelbaum *et al*. (2014) showed that a curriculum that uses surgical simulators can improve the knowledge and technical competences of senior surgeons relative to this procedure; demonstrating the benefits of developing such simulators.

There are multiple examples of LCBDE simulators, notably porcine models (Brewer *et al.*, 2021; Watson, Treacy and Williams, 1995; Cameron, O'Regan and Anderson, 1994), physical simulators (Sánchez *et al*., 2010; Santos et al., 2012b), and the cadaver model (Sharma *et al.*, 2016); however, the commercially available options are limited to the models of Limbs&Things (Limbs&Things, Bristol, UK), 3-DMed (3-DMed, Franklin, USA), and Simulab (Simulab Corporation, Seattle, USA). Animal and cadaver-based models offer great realism but are more expensive and have ethical implications. One of the benefits of using physical models such as those is that it is possible to use the same equipment as during real surgery, allowing the surgeons to familiarise themselves better with the procedure.

VR-based simulators would be very valuable for this procedure because they could offer unlimited training sessions without being limited by replacement parts; however, I could not identify a virtual reality-based simulator offering training for LCBDE except that in the study by Basdogan, Ho and Srinivasan (2001). The commercially available products closest to the LCBDE procedure might be the ones from Surgical Science (Surgical Science, Göteborg, Sweden), who have developed VR simulators for cholecystectomy and cholangiography, and the one from VirtaMed (VirtaMed, Zurich, Switzerland), who have developed a VR simulator for cholecystectomy.

The interviews among surgeons and literature review highlighted that ideally a LCBDE simulator should have the following characteristics:

- Be realistic.
- Contains all the key steps of the surgery, including laparoscopic ultrasound scanning.
- Can train on both approaches.
- Has face, content, and construct validation.
- Can be commercialised.
- Is affordable.
- Is reproducible.

The following table shows how the simulator developed in this thesis compares to the solutions from the state-of-the-art.

* All terms italicised and with an asterisk are defined in Appendix A, the Glossary.

Table 21: Comparison between my simulator and state-of-the-art solutions

Simulator	Santos *et al.*	Sanchez *et al.*	Simulator from 3-DMED	Simulator from Limbs&Things	Sbrocchi *et al.*	Simulator from Simulab	Porcine live biliary system	Porcine Aorto-Renal arteries	My simulator
Ultrasound scanning	No	No	No	No	No	No	Yes	No	Yes
Both approaches	Yes	No	Yes	No	No	Yes	Yes	Yes	Yes
Stone retrieval	Yes	Yes	Yes	Yes	No	No	Yes	Yes	Yes
CBD suture closure	Yes	Yes	Yes	Yes	No	Yes	Yes	Yes	Yes
Reproducible for mass production	No	No	Yes	Yes	No	Yes	No	No	Yes
Realism	Low	Low	Intermediate	Intermediate	Low	Intermediate	High	High	Intermediate
Ethics approval required	No	No	No	No	No	No	Yes	Yes	No
Complexity in preparation	Low	Low	Low	Low	Low	Low	High	Intermediate	Intermediate
Construct validation	Yes	Yes	No	No	Yes	Yes	No	No	Yes
Cost	Low	Low	Intermediate	Intermediate	Low	High	High	Intermediate	Low

* All terms italicised and with an asterisk are defined in Appendix A, the Glossary.

The advantages of the simulator developed in this research are that:

- The simulator includes all the key steps of the surgery but is not based on animal tissues; as such, it can provide complete training without requiring ethics approval nor the complex handling of real tissues.
- My simulator has construct validation; validation is important to demonstrate the usefulness of a surgical simulator and construct validation provides clinically meaningful assessment for simulators (Gallagher and O'Sullivan, 2011).

My proposed fabrication method for developing the physical model is low cost because it is based on basic 3D printers and moulding; furthermore, it provides realistic anatomical structures and tactile feedback in comparison to the balloon and plastic tubes used in (Sánchez *et al*., 2010; Santos *et al*., 2012b).

One of the unique advantages of my fabrication method is that it employs a visual enhancement technique that does not require prior knowledge of the viewing angle or deformation of the soft tissues. Its realism is not very accurate but the technique could be improved using masks, and it is promising for generating the diversity of textures that can be found in real life. Such a technique is particularly useful in hybrid simulations, which allow for better tactile feedback than virtual simulators such as the ones from VirtaMed and Surgical Science.

Another unique advantage of this simulator is that the technique uses the laparoscopic aspect of the procedure to simulate ultrasounds through the visual tracking of fiducial markers. The approach is simple and can identify the localisation of soft tissues and an ultrasound probe during training sessions without requiring additional materials except the printed markers. Previous ultrasound simulation systems have used tracking as well as sensors (Zhu *et al*., 2007; Bo and McKenzie, 2011) or optical tracking with additional cameras (Markov-Vetter *et al*., 2009; Hu *et al*., 2017), making the implementation of the tracking system more complex.

* All terms italicised and with an asterisk are defined in Appendix A, the Glossary.

7.4 Conclusion

This chapter has described the development and evaluation of a simulator for LCBDE. The simulator was developed through a HCD methodology where the end users guided the whole process. The simulator was validated through face, content, and construct validations, demonstrating its potential for training surgeons for this complex procedure.

* All terms italicised and with an asterisk are defined in Appendix A, the Glossary.

Chapter 8: Conclusion

Laparoscopic treatment of gallstones has significant advantages for patients, but its adoption fails to be generalised because of its challenging steps. One of these is conducting an ultrasound examination laparoscopically; to my knowledge, there is no available simulator able to teach it. Because of the lack of training options, surgeons often use animal models to practice on, which leads to several issues around price, access, conservation, and ethics. The model developed in this research could provide an alternative training method that overcomes all these difficulties.

This thesis has detailed the development of a hybrid simulator for practicing the basic skills of ultrasound-guided LCBDE. The model can be used to simulate trans-cystic or trans-choledochal LCBDE and was made from silicone, a relatively inexpensive material. The physical model's fabrication was based on 3D printing using FFF and SLA and on silicone casting. This was combined with AR techniques to provide both better realism with style transfer, and ultrasound training using a tracking system. The model's evaluation demonstrated its usefulness for training surgeons for this procedure.

This research was arranged around four research objectives. The first objective was to identify the specifications of the surgical simulator. The PhD research first entailed a literature review, which identified surgical simulators currently used by surgeons in their training, as well as their fabrication methods, their benefits, and their limitations. The methodology guiding this research was based on HCD, which advocates developing a product by working with the end users at every stage of its development. Using this methodology in the context of surgical simulation was quite unusual, even though previous research has shown that failing to use this type of user-centred methodology can result in developing a simulator which fails to provide appropriate training (Persson, 2017). In this research, HCD was implemented during interview 1, which aimed to ascertain the needs of surgeons when they use surgical simulation, and more specifically, their needs for training for this specific surgery. The prototypes evaluation highlighted how successful the HCD methodology was in identifying what training tasks were useful for the surgeons.

The second objective focused on identifying suitable synthetic materials. This research objective was based on the need to correctly mimic tactile feedback during surgery to provide a training simulator that was realistic enough to engage the surgeons. To meet this objective, this research combined HCD and action research methodologies. HCD was implemented through interview 2 where surgeons defined the soft tissues' properties using descriptives and comparisons. To my knowledge, this is the first time this methodology has been used to describe soft tissues and, this research shows its potential for highlighting the complexity of soft tissues. Then an action research cycle was implemented to create, evaluate, and reflect on the commonly used materials in surgical simulation. Finally, the end users selected which synthetic material option best mimicked each soft tissue.

The third objective focused on the techniques used to create a simulator. The development of a surgical simulator is often based on 3D printing technologies, which range from a very simple 3D printer costing around £100 to extremely high-end technologies costing several hundreds of thousands of pounds. In this research, I used the most readily available 3D printers, such as FFF and SLA printers. The cost of the printers and the materials was reasonable enough to allow for the generalisation of the method, especially the quick creation of replacement parts, at a low price. Moreover, style transfer and the context-aware technique designed in this research were based on open-source software (Python and Unity), which did not incur any additional expenditure.

Finally, the last objective of this PhD research was to evaluate the prototypes designed and created. During the action research cycles, the research team qualitatively evaluated the materials produced. All the prototypes, including the materials and the software, as well as the final simulator, were qualitatively evaluated by surgeons.

* All terms italicised and with an asterisk are defined in Appendix A, the Glossary.

8.1 Contributions to knowledge

This PhD research has successfully developed a method to design a surgical simulator to provide training in the basic skills of ultrasound-guided LCBDE. The research was divided into multiple aspects, namely the materials selection, fabrication methods, style transfer, context-aware simulation of ultrasounds, prototypes development and evaluation. Because of the research's wide-ranging nature, it has contributed to the knowledge in various aspects, each of which are covered below.

8.1.1 Characterising the soft tissues

The first part of this study has demonstrated the need to correctly mimic tactile feedback by using different types of synthetic materials for different types of soft tissues. This is important because the surgeons indicated during interview 2 that they obtain validation about what they are touching from tactile feedback.

This study evaluated tactile feedback during a LCBDE and discovered that the main sensations of surgery can be limited to 10 parameters – softness, smoothness, thickness, attachment, elasticity, and resistance to gripping, pulling, suturing, cutting, and tearing. These 10 parameters are interconnected. Moreover, their feel through tools is mainly determined by the softness, smoothness, and thickness of the soft tissues. The methods used to identify the main sensations of surgery are novel, as they have never been used in this context before to my knowledge. These parameters defined the specifications for the synthetic soft tissues and informed the set of tests made on these materials to ensure their accuracy in mimicking the properties of the tissues.

This study has also highlighted the similarities between some of the soft tissues encountered during LCBDE surgery. In the context of surgical simulation, this suggests that the same material can be used to mimic them.

* All terms italicised and with an asterisk are defined in Appendix A, the Glossary.

8.1.2 Identifying the materials

A subsequent finding of this study is identifying suitable materials to mimic the soft tissues involved in a LCBDE simulation practice. These materials were identified through quantitative and qualitative assessments.

For the tactile aspect, the best materials were found to be Ecoflex gel 25%-part A for the liver, DragonSkin for the gallbladder and the peritoneum, DragonSkin 75%-part A for the bile duct, DragonSkin 25%-part A for the blood vessels, Ecoflex 0030 with bidirectional and unidirectional fibres for the skin and muscle respectively, Ecoflex 0030 for the duodenum, and Ecoflex gel for the fat.

For the ultrasound examination, the best material was established to be agar gel, as it is inexpensive, easy to use, and realistic when using sonography.

8.1.3 Defining the specifications for a surgical simulator for LCBDE

This study has defined the specifications for an effective LCBDE training system with ultrasound. To my knowledge, this is the first study which has included laparoscopic ultrasound into a LCBDE simulator and the first to define the important aspects and implications of this ultrasound task, such as identifying and measuring the anatomical features which will then allow a trainee to determine the best surgical approach for the rest of the surgery. Workshop 2 highlighted the surgeons' enthusiasm for this feature and how useful they found it to receive training for this challenging task.

8.1.4 Developing a quick, easy, and low-cost fabrication method to produce simulated organs

While the use of 3D printed moulds to replicate soft tissues is not a novel method, the research used original methods to create the organs' replicas. To my knowledge, the use of jacket moulds for the fabrication of larger organs has never been described before, but it enabled the creation of a functional mould using a limited amount of the most expensive and functional filament. This was a valuable cost-saving development.

Similarly, there has been little development of a gel-based model using 3D printed soluble inner moulds, in fact, I only found one article that mentioned a similar technique (Dong, Zhang and Lee, 2017). The innovation made in this PhD study was that using soluble filaments allowed gel-based blood vessels of limited thickness (below 2mm) to be produced, contrary to the other study, where researchers surrounded the vessel with a medium before dissolving the inner core. Keeping the blood vessels free of their medium enabled more versatility for their positioning and assembly.

8.1.5 Developing a simulator for LCBDE

This research is the first to describe a LCBDE simulator and produce prototypes which included both an ultrasound examination step and the possibility to perform the surgery with either a trans-choledochal or a trans-cystic approach. The participant surgeons stated that this is very useful for learning and practicing the steps of this challenging procedure, and that it would be helpful to generalise the use of such a simulator in their training routine.

From these findings, the null hypothesis identified in the research aim and objectives section has been rejected.

8.2 Future work

As explained in the previous Discussions sections, there are several areas in which the work could be improved. Nonetheless, the most important aspects to focus on in future research are evaluating the simulator and generalising it to other training modules. The evaluation should include a study to ascertain the benefit of using this simulator on surgeons' scores during surgery on real patients. Such a study would involve evaluating several surgical scores during surgery on patients from a cohort of surgeons, then undertaking a training session on the simulator, followed by a new session of surgeries on real patients including recording of the same surgical score criteria as in the first phase of the evaluation. This would allow researchers to compare the performance of the surgeons before and after training, so would reveal whether training on the simulator is beneficial in real-life surgery.

* All terms italicised and with an asterisk are defined in Appendix A, the Glossary.

The other primary aspect that future work should focus on is how to generalise this training. This would include adding more scenarios into the surgery, such as different position and number of stones, as well as different patients' anatomies. Providing diversified training is important to keep surgeons challenged and engaged in it. Furthermore, the methodology used to develop a simulator in this research could be extended to other pathologies and offer training for different surgical specialities.

* All terms italicised and with an asterisk are defined in Appendix A, the Glossary.

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Appendix A: Glossary

%w/w: percentage of mass of a solute within the overall mass of the solution (for example, 0.1%w/w of scattering material into the bulk agent means that for every 100g of final material, there are 0.1g of scattering agent).

3D printing: this is the process of creating a 3D object layer by layer from a digital 3D model.

Action Research: action research is a research methodology which is based on successive cycles of planning, acting, observing, and reflecting to improve the next cycle.

Acoustic impedance: the acoustic impedance is an acoustic property which measures the ease with which a sound wave propagates through a particular medium.

Acoustic properties: the acoustic properties are a set of properties of a particular medium which will affect the propagation of a sound wave within this medium.

Adam stochastic gradient descent method: this is an optimisation method for the training of deep learning models.

Agarose: agarose is a natural polymer that is commonly used in surgical simulation. It comes as a powder and is usually prepared by mixing it with water, heating the solution, and pouring it into moulds. It becomes a gel after cooling.

Anechoic: an anechoic material does not generate an echo. In the context of ultrasound examination, this means that the ultrasound wave is not reflected by the material which cause it to appear black on the screen.

Aruco marker: ArUco markers are a type of fiducial marker, it is a synthetic square marker composed by a wide black border and an inner binary matrix which determines its identifier (id). It is used for pose estimation in context-aware augmented reality.

Augmented Reality: augmented reality is an interactive experience which combines elements of the real environment and elements generated digitally. It is based on sensors which allow the integration of elements of the real world.

Basket: the basket or Dormia basket is a surgical instrument designed to retrieve stones during a LCBDE. It is made of four wires able to trap stones within the bile duct.

Boolean difference: in Rhino, when there is an intersection between two solids, the Boolean Difference command can trim the portion of the first solid that is inside the second solid away while the rest of the first solid is preserved.

Bulk agent: the bulk agent is the main material of an ultrasound simulator. It is used to provide texture and volume to the model. It is used in combination with a powder (the scattering agent) which aims to simulate the scatter that the ultrasound wave would make within a real soft tissue.

CAD: computer assisted design is a technique to create 3D models or designs using a software such as Rhino, Solidworks, or Blender.

Calots triangle: it is an anatomical region delimited superiorly by the liver, laterally by the cystic duct and the gallbladder, and medially by the common hepatic duct.

Capsule: the liver is covered by thin fibrous capsule called Glisson capsule; if the capsule is broken, there will be a lot of bleeding from it and from the liver itself.

Choledochoscope: surgical instrument which consists of a flexible camera of five millimetres or three millimetres in diameter. It is controlled externally with the tube passed down through a port and into the hole made in the bile duct. The surgeon uses it to visualise inside the bile duct. There is a small channel in that choledochoscope that allows to pass an instrument to catch the stones.

Clerkship experience: clerkship experience designates a clinical experience in the education of a student of the health professions in which he or she is introduced to the practical care of patients with particular illnesses or characteristics.

Cognitive activity: cognitive activity refers to a mental process through which we analyse and make sense of information. In the context of ultrasound education, it refers to the ability to process new information obtain through the scan.

Binder jetting: 3D printing technology which consists of dispersing a binder onto a bed of polymer powder to solidify it locally.

Content validation: in the context of surgical simulation, content validation refers to the evaluation by medical specialists of the usefulness of surgical simulators.

Construct validation: in the context of surgical simulation, construct validation refers to the demonstration of the functionality of a surgical simulator by proving that it is able to differentiate between novices and experts.

Context-awareness: context-awareness is the ability of a system to gather information about its environment and to adapt behaviours accordingly.

Convolutional network: convolutional network is a type of neural network used commonly in machine learning for the analysis of images.

Cross sectional imaging: cross-sectional imaging refers to imaging technique that produces an image in the form of a plane through the body of the patient with the structures cut across.

Discovery Likelihood: the discovery likelihood is a statistical tool which, in the context of usability testing by participants, defines the percentage of the overall usability problems that have been discovered by the participants.

Dissection: dissection refers to the process of cutting apart or separating soft tissues.

Distally: away from the centre of the body or from the point where a bone or muscle is attached. It is the opposite of proximally.

Dog-bone samples: type of samples used in mechanical tests and more precisely in tensile tests. The sample has a shoulder at each end and a gauge section in between. The shoulders are wider than the gauge section which causes a stress concentration to occur in the middle when the sample is loaded with a tensile force.

Doppler imaging: type of ultrasound imaging which shows the blood moving in the blood vessels and estimate the blood flow speed.

Drain: a drain or T-tube is a silicon plastic tube. It is useful in case the bile leaks.

Draping: draping is the procedure of covering a patient and surrounding areas with a sterile barrier to create and maintain a sterile field during a surgical procedure.

Echoic: an echoic material generates an echo. In the context of ultrasound examination, this means that the ultrasound wave is reflected by the material which cause it to appear grey on the screen.

Embodied knowledge: the embodied knowledge is a type of knowledge where the body knows how to act; in the context of surgery, it refers to the capacity of the surgeons to know how to perform a surgery (for example, know how much pressure to apply on the soft tissues).

Endoscopic: an endoscopic procedure is a surgical procedure where a long, thin tube with a small camera inside, called an endoscope, is passed into your body through a natural opening such as your mouth.

Epoch: an epoch indicates the number of passes of the entire training dataset the machine learning algorithm has completed.

Evaluation metric: an evaluation metric is a quantitative measure of the performances of a system.

Face validation: the face validation evaluation consists of the assessment of the realism of the simulator and on its ability to represent correctly what it is supposed to represent.

Feed-forward neural network: the feed forward neural network is the simplest form of neural network as information is only processed in one direction. While the data may pass through multiple hidden nodes, it always moves in one direction and never backwards.

Fiducial markers: a fiducial marker is an object placed in the field of view of an imaging system such as a camera and that appears in the image produced, for use as a point of reference or a measure.

Formalin: formalin is a colourless solution of formaldehyde in water; it is used mainly as a preservative for biological specimens.

Fused Filament Fabrication (FFF): 3D printing technique which consists of extruding a fused thermoplastic filament onto a heated bed. The melted filament cools and solidifies during the extrusion.

Gasket: in mould making, a gasket is thin structure made of rubber or another flexible material which is used to seal the junction between the two surfaces of the mould.

Image-to-image translation: image-to-image translation is an image processing technique which aims to transform an image from one domain to another.

Imaging technique: an imaging technique is a technique used by doctors to visualise the inside of the body of a patient such as CT, MRI, or ultrasound.

In vivo: in the living body.

In vitro: outside of the body.

Indentation tests: an indentation test is a mechanical test which consists of applying pressure on a sample to study its hardness by evaluating its deformation.

Insufflation: in a laparoscopic surgery, insufflation is the act of blowing gas into the abdomen to get visualisation of the organs.

Ionising: Ionising medical imaging systems are high energy medical imaging systems such as X-ray. They have more energy than non-ionising radiation such as the ones from ultrasounds. The high energy is enough to cause damage to living tissue.

Jacket mould: a jacket mould is a two-part mould made of a functional part and an outer shell.

Gallstones: gallstones are small stones, usually made of cholesterol, that form in the gallbladder.

Haemostasis: it is the process to stop the bleeding.

Head-mounted display: head-mounted displays are small displays or projection technology integrated into eyeglasses or mounted on a helmet or hat.

Human Centred Design: methodology used in product design and which consists of working together with the end users of the product within each phase of the product development.

Hybrid: in the context of surgical simulation, a hybrid simulator designates a simulator which combines a physical model and augmented-reality techniques.

Hyperechoic: a hyperechoic material generates a lot of echoes. In the context of ultrasound examination, this means that most of the ultrasound wave is reflected by the material which cause it to appear white on the screen.

Hypoechoic: a hypoechoic material does not generate many echoes. In the context of ultrasound examination, this means that most of the ultrasound wave is not reflected by the material which cause it to appear dark grey or black on the screen.

Knobology: knobology is a terminology that describes the manipulation of ultrasound knobs and system controls to obtain the best image possible from diagnostic ultrasound.

Kruskall Wallis tests: type of statistical tests which aims to determine if there are statistically significant differences between two or more groups of an independent variable on a continuous or ordinal dependent variable.

Laparoscopic or Keyhole: laparoscopic surgery is a type of surgical procedure that allows a surgeon to access the inside of the abdomen without having to make large incisions in the skin (like in open surgery). During a laparoscopic surgery, the surgeon makes a few small incisions in the skin and inserts the surgical instruments through surgical ports.

Lap-trainer: a lap-trainer is a type of simulator used to practice laparoscopic surgery.

LCBDE: LCBDE or laparoscopic common bile duct exploration is the laparoscopic procedure for the treatment of gallstones.

Lobulated: made up of or having lobules.

Longitudinal waves: a longitudinal wave is a type of wave where all the particles of the medium vibrate in the same direction as the direction of propagation of the wave.

Lymph nodes: Lymph nodes are small structures that work as filters for foreign substances within the body.

Material jetting: 3D printing technique which consists of depositing drops of a liquid onto a bed of powder then using a UV light to solidify the drops.

Operating theatre: operating room where the surgeons perform surgery.

Patient specific: a patient specific simulator mimics the anatomy of a specific patient by using the medical images of the patient as a baseline. They are mostly used for preoperative planning.

Perceptual studies: in this work, perceptual studies designate studies or research which studies the perceptions of participants in a given context.

Physical testing: Set of tests to evaluate the physical properties of a material such as the harness, the Young modulus, or the stress and strain at break.

Port: or access port is a hollow tube with a valve at the end that allows surgeons to put instruments in and out without losing any gas within the abdomen.

Practice based research: Practice-based Research is an original investigation undertaken to gain new knowledge partly by means of practice and the outcomes of that practice.

Preoperative planning: preoperative planning is the preparation made by surgeons before performing a specific surgery. It is usually based on the medical images of the patient but can also be made on a patient-specific model.

Psychomotor skills: the psychomotor skills relate to the relationship between cognitive functions and physical movement. In the context of ultrasound education, it relates to learning how to manipulate the ultrasound probe.

Rank order: during a survey, a rank order question refers to a question which asks the participant to arrange a set of propositions according to a defined order.

Right upper quadrant: the right upper quadrant is an anatomical area which includes the pancreas, right kidney, gallbladder, liver, and intestines.

Rotomoulding: rotomoulding or rotocasting is a modelling technique where a mould is put under a slow rotation which causes the casting material to disperse and stick to the walls of the mould forming a hollow part.

Refraction: refraction refers to the modification of the direction of a wave as it passes from one medium to another.

Sample size: the sample size refers to the number of participants which took part into the study.

Scattering: in the context of ultrasound, the scattering refers to a physical process where the ultrasound wave is forced to deviate from a straight trajectory by localised non-uniformities in the medium.

Scattering agent: in an ultrasound simulator, the scattering agent is a powder which aims to simulate the scatter that the ultrasound wave would make within a real soft tissue. It is used in combination with a bulk agent which provide texture and volume to the simulation model.

Scenarios: scenarios describe what the end users will do with the product; it helps picturing the product in use which benefits the design of the solution and the understanding from all the actors of the project.

Segmentation: image segmentation is the process of identifying what are the different features or objects inside an image and to locate their boundaries.

Shapiro-Wilk test: Shapiro-Wilk test are statistical tests which aims to assess if the data is normally distributed or not.

Shelf-life: the shelf-life refers to the length of time a product can be kept before being used without losing its properties.

SLA (Stereolithography): 3D printing techniques where a laser beam selectively solidifies a liquid resin through photopolymerisation.

SLS (Selective Laser Sintering): 3D printing technique which consists of the fusion of polymer powder to create a solid object. At first, a laser selectively heats a thin layer of powder to solidify the first cross-section of the solid, then the bed is slightly lowered, and the machine adds another layer of powder on the top of the last layer. The process repeats itself until the completion of the print.

Sonography: sonography refers to the use of ultrasounds for diagnostic purposes.

Spearman non-parametric test: this is a non-parametric statistical test which measures the correlation between a set of parameters.

Stump: the part of an anatomical structure remaining after the rest has been cut off.

Style transfer: image processing technique which aims to blend a content image and a style image to generate an image with the features of the content image and the style of the style image.

Supine position: the supine position is a position the patient can take for a surgical procedure; in the supine position, the patient is lying horizontally with the face and torso facing up.

Surgical scores: quantitative measures used to evaluate the success of a surgery; it can refer to the quantity of blood loss, or to the complication rate.

Surgical scenarios: the surgical scenarios refer to the different possibilities a surgeon might encounter during a surgical procedure and which might impact the remaining steps of the surgery.

Supervision: supervised simulator use refers to the utilisation of a simulator by a novice surgeon while being watch and guided by an expert surgeon.

Temporal consistency: in the context of video processing, temporal consistency refers to the smoothness of the processed video and the limitation of the fluctuations between frames.

Total variation: the total variation is a mathematical operator used to assess the homogeneity of a function over an interval; in image processing it is used to evaluate the homogeneity in neighbouring pixels.

Ultrasounds: ultrasounds are high-frequency sound waves that can be used in medical examination to get an image of what is inside the body.

Ultrasound probe or transducer: the ultrasound probe also called ultrasound transducer is the instrument used during an ultrasound examination to transmit the ultrasound wave into the body and to get an image.

Umbilicus: the umbilicus is the scar on the abdomen caused by the removal of the umbilical cord on the baby.

Usability problem: a usability problem is anything in a new product that can lead to an undesirable outcome.

Vat photopolymerisation: Vat photopolymerisation is an additive manufacturing process based on photopolymerisation. Photopolymerisation is a technique that uses light to initiate and propagate a polymerisation reaction to form a linear or crosslinked polymer structure. In 3D printing, it is used to solidify locally a polymer resin.

Viscosity: the viscosity is a physical property which relates to the resistance of a fluid to flow.

Virtual reality: virtual reality is a computer-generated environment; in the context of surgical simulation, it refers to the conduction of a surgery on a computer in an environment similar to a video game.

Weights: the weights are the parameters within a neural network that transforms the input data within the network; in the context of style transfer, the weights are used to favour some characteristics of the networks over other.

White-noise image: a white noise image is a black and white image where each pixel is an independent random variable with uniform probability distribution over some interval.

Appendix B: Publications and presentations

Journal papers:

1. M. Shao, T. Vagg, M. Seibold, M. Doughty. Towards a Low-Cost Monitor-Based Augmented Reality Training Platform for At-Home Ultrasound Skill Development. *J. Imaging* **2022**, *8*, 305. https://doi.org/10.3390/jimaging8110305
2. M. Shao, M. Aburrous, D. Huson, C. Parraman, J.Hardeberg, J. Clark. Development and validation of a hybrid simulator for ultrasound-guided laparoscopic common bile duct exploration. *Surgical Endoscopy* **2023** https://doi.org/10.1007/s00464-023-10168-w

Conference proceedings:

3. M. Shao, C. Parraman and D. Huson; (2020): Physical Patient Simulators for Surgical Training: A Review. Society for Imaging Science and Technology, 2020, London Imaging Meeting 2020 p. 124-128.
4. M. Shao, D. Huson, and J. Clark; (2022): Simulation of laparoscopic ultrasound imaging and suturing of the bile duct using silicone. Proceedings Volume 12034, Medical Imaging 2022: Image-Guided Procedures, Robotic Interventions, and Modeling; 1203423 https://doi.org/10.1117/12.2611340
5. M. Shao, J. Clark, D. Huson and Jon Hardeberg; *Real-time Style Transfer for Videos to Enhance the Realism of Simulation of Laparoscopic Surgeries* at EUVIP 2022.

Conference presentations:

- M. Shao, C. Parraman and D. Huson; (2020): *Physical Patient Simulators for Surgical Training: A Review* at the London Imaging Meeting 2020 (poster)
- M. Shao and D. Huson; (2021): *Can style transfer improve the realism of simulation of laparoscopic common bile duct exploration using ultrasound?* at the London Imaging Meeting 2021 (poster)
- M. Shao, D. Huson, and J. Clark; (2022): *Simulation of laparoscopic ultrasound imaging and suturing of the bile duct using silicone* at SPIE Medical Imaging 2020 (poster)

- M. Shao, T. Vagg, M. Doughty; (2022): *Towards a low-cost monitor-based augmented reality training platform for at-home ultrasound skill development* at International Surgical Week 2022 (poster)
- M. Shao, D. Huson, C. Parraman, J. Clark; (2022): *Extracting the tactile information of surgery with a participant-based study* at International Surgical Week 2022 (oral presentation)
- M. Shao, J. Clark, D. Huson and Jon Hardeberg; *Real-time Style Transfer for Videos to Enhance the Realism of Simulation of Laparoscopic Surgeries* at EUVIP 2022 (oral presentation).

Appendix C: Anatomical reminders

The following section summarises the anatomy of the upper abdomen and describes the soft tissues surrounding the gallbladder and their functions (Seeley, Stephens and Tate, 2001). More precisely, the soft tissues situated in the upper abdomen include the liver, pancreas, duodenum, gallbladder, bile duct, peritoneum, abdominal wall, blood vessels, and stomach.

Liver

The liver is the largest of the organs. Positioned in the *right upper quadrant** of the abdomen, it is made of two major lobes and two smaller lobes. The hepatic artery and the hepatic portal vein are its two sources of blood; the hepatic veins and the inferior vena cava are the exit vessels from the liver. The role of the liver is to process the nutrients and detoxify the blood from harmful substances; more precisely, it acts as a blood filter. The liver is covered by a *capsule** made of thin connective tissue.

Pancreas

The pancreas is a soft organ with an elongated shape. It measures between 12 and 20 cm. It is *lobulated** and contain in a thin capsule.

The pancreas includes an exocrine part and an endocrine part. The functions of the pancreas are the production of digestive enzymes in the exocrine part, and the production of insulin and glucagon in the endocrine part. The exocrine part release digestive enzymes into the bile duct through the duodenum. The insulin and glucagon control the level of nutrients in the blood, for instance, if the there is a high level of blood glucose, the pancreas will generate insulin, whereas if there is a low level of glucose, the pancreas will release glucagon.

* All terms italicised and with an asterisk are defined in Appendix A, the Glossary.

Duodenum

The duodenum is the first part of the small intestine, which connects the stomach and the jejunum, the second part of the upper small intestine. It is approximately 25cm long. The duodenum forms a 180-degree arc making a C-shape in the abdominal cavity, the head of the pancreas is situated within this arc. The common bile duct empties in the duodenum at the duodenal papilla.

The peritoneum

The peritoneum is a membrane that covers the abdominal wall and the organs in the abdominal cavity. It connects and supports the internal organs. For instance, the liver is mostly enclosed in peritoneum, except on a small posterior area.

Gallbladder and bile duct

The gallbladder is a small sac that stores the bile and usually contains around 50mL of bile. It is situated on the inferior surface of the liver. The Hartmann's pouch is the part of the gallbladder which connects the bile duct through the cystic duct. It is also where the stone in the gallbladder usually get stuck.

The bile duct is the main drainage pipe from the liver to the duodenum. It is divided into several parts: the common bile duct, which is the main part of the pipe, the pancreatic duct which connects the pancreas, the cystic duct which connects the gallbladder, and, at the end, the common hepatic duct which divides into the right and left hepatic ducts to connect the liver.

The right and left hepatic ducts join into the common hepatic duct which typically measure around 4cm and is then combined with the cystic duct which also measures around 4cm to form the common bile duct which measures 10cm. The hepatics ducts transport the bile out of the liver.

The abdominal wall

The abdominal wall is made of three layers: the skin, the fat, and the abdominal muscle. The three layers of the abdominal wall measure about 3 to 4cm. The skin is the narrowest portion, the fat the largest, and the muscle measures between 1-

* All terms italicised and with an asterisk are defined in Appendix A, the Glossary.

1.5cm. Muscles tend to be surrounded by a dense and fibrous material; their role is to hold and protect the abdominal organs.

Blood vessels

The main blood vessels are the hepatic artery, which supplies the liver with oxygen-rich blood, and the portal vein which supplies the liver with oxygen-poor blood but rich of materials from the digestive tract.

The cystic artery supplies the gallbladder and is connected to the hepatic artery. The hepatic artery is a small calibre blood vessel; previous studies on cadaver show that the mean diameter of the common hepatic artery in male is 5.4 mm, and in female 5.2 mm. (Singh *et al.*, 2014)

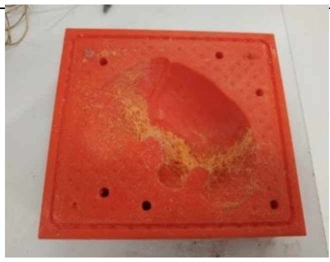
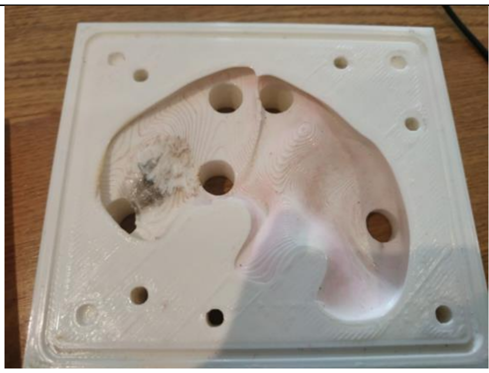
The stomach

The stomach is in the upper abdomen, on the left side of the body. The role of the stomach is to digest food and to pass it to the intestines through the duodenum. To do so, it contracts and produces acids and enzymes which will break down the food.

* All terms italicised and with an asterisk are defined in Appendix A, the Glossary.

Appendix D: Tests performed to find how to make the moulds smooth

Table 22: Tests conducted to make the moulds soft and removing the print lines

Tested method	Results
Sanding: electric sanding with Dremel; (requires gloves and face protection)	  The technique is quite long and unprecise. It requires to change the Dremel bits often because they get damaged quickly.
Heating: with a match held close enough to make it melt	 Difficult to control when it starts to melt and difficult to give it a nice shape. Quite dangerous too.
Filler-primer: move the can for 3 min then apply one coat, then apply 2 other coats (wait for 15 min between coats). 24h later, sand with wet sandpaper. Then apply 3 new coats. 24h later, sand again	 There are cracks on the surface when it dries that can be removed with wet sanding. The process is long and quite dangerous but results in a nice finish which is

with wet sandpaper. Requires wearing EPP.	precise even for complex surfaces. However, even with sanding, it is difficult to remove all the little cracks.
Plasti-dip: apply 3 to 4 coats with 30 minutes wait in between each. Requires wearing EPP.	  Quite dangerous to use and not a nice finish (especially on the overhangs).
Plasticine: heat with the hands and apply a coat on the mould	 

	Quite long and requires some sculpting skills for coating the complex surface. But not dangerous, can make a nice finish (depending on the skill level).

Appendix E: Ultrasound probe settings

In this project, I used the ultrasound probe SONON 300L from Orca medical. The probe has different options and parameters that can be modified:

1) Different modes:

- Carotid: 3cm depth
- Thyroid: 4cm
- Breast: 5cm
- MSK: 5cm

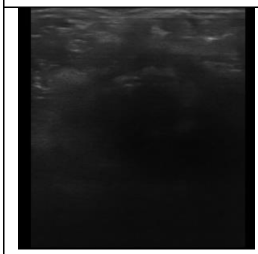
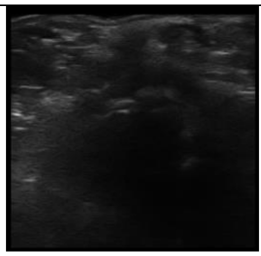
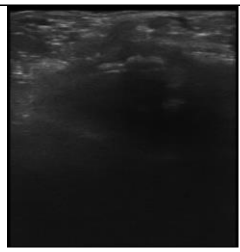
Thyroid	Carotid	Breast	MSK
			

Figure 70: Influence of the ultrasound examination mode

2) ETC: Frequencies

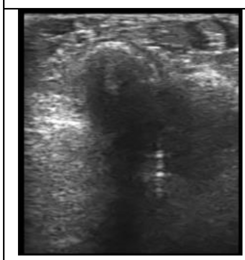
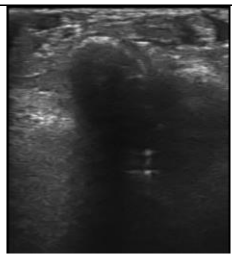
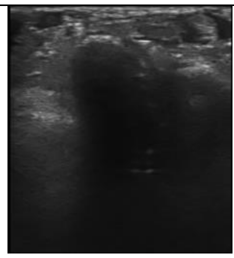
F=5MHz	F=7.5MHz	F=10MHz
		

Figure 71: Influence of the frequency

3) Filter: I can modify the SRI and the Gray map to change the image

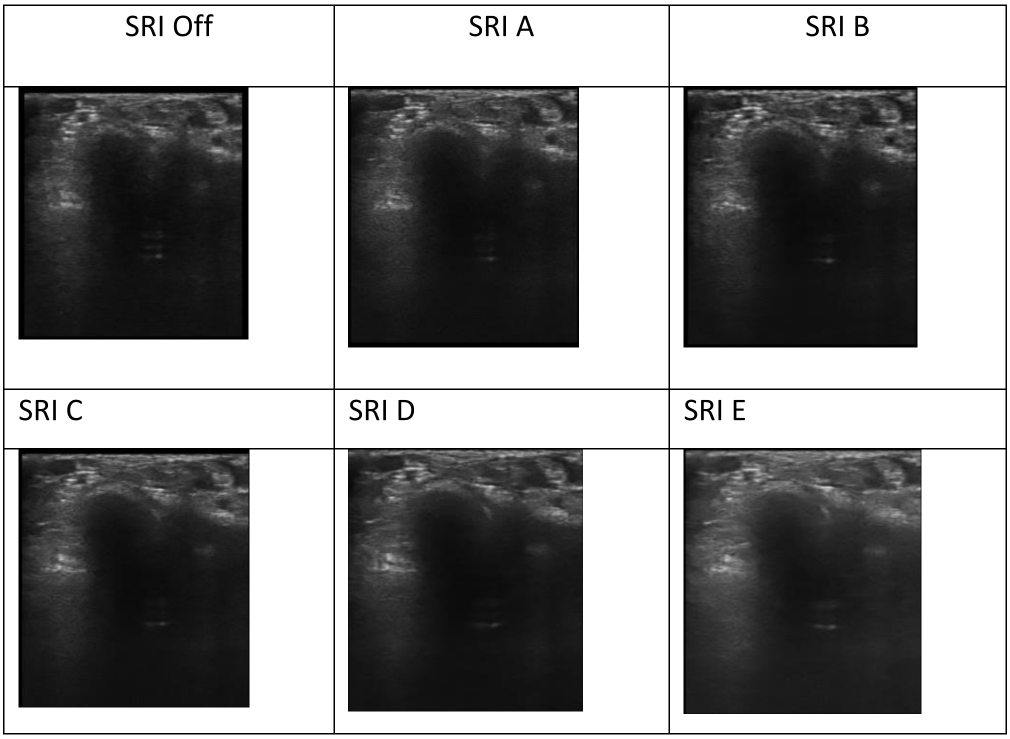


Figure 72: Influence of the SRI

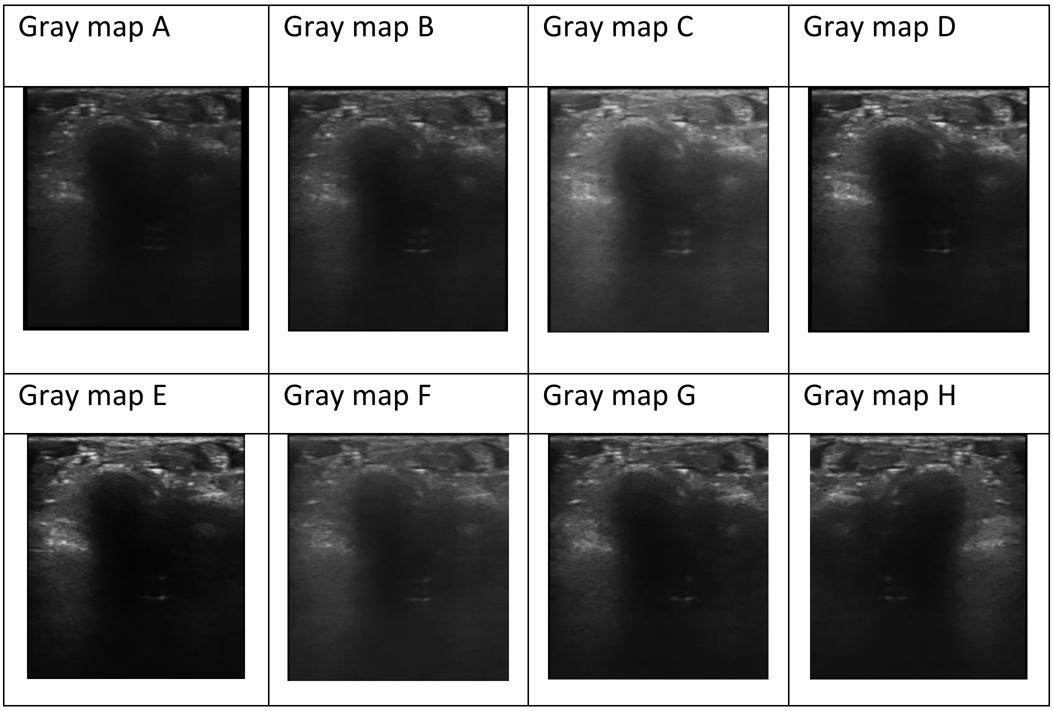


Figure 73: Influence of the Graymap

4) B-mode: I can also change the gain and increase the DR for more contrast.

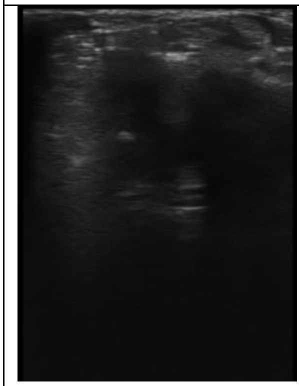
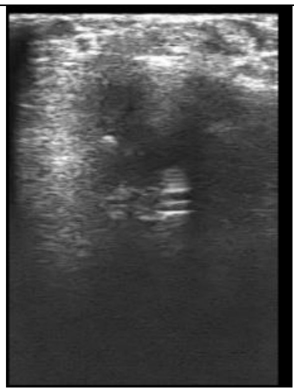
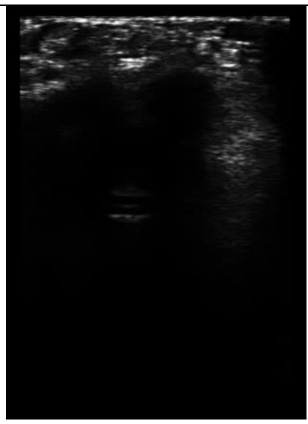
Gain min	Gain Max
	
DR min	DR Max
	

Figure 74: Influence of the gain and the DR

5) TGC: I can locally increase the gain at different depth.

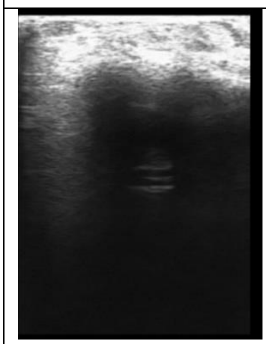
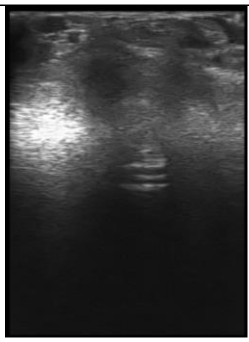
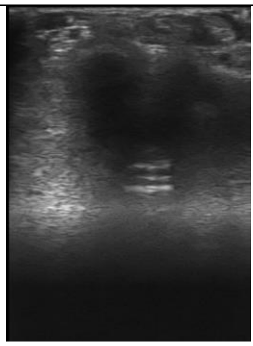
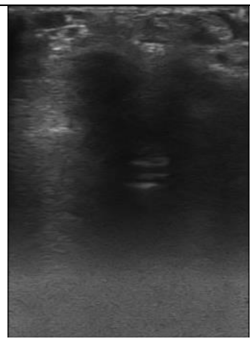
1st ligne TGC au max	2nd ligne TGC au max	3rd ligne TGC au max	4th ligne TGC au max
			

Figure 75: Influence of the TGC

6) Colour Flow

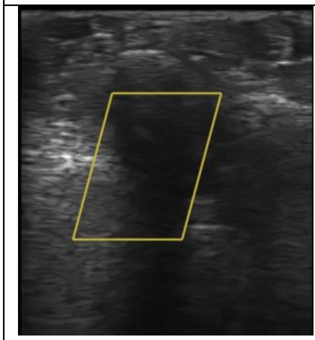
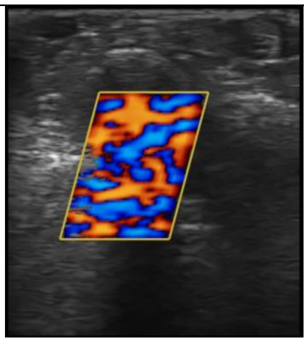
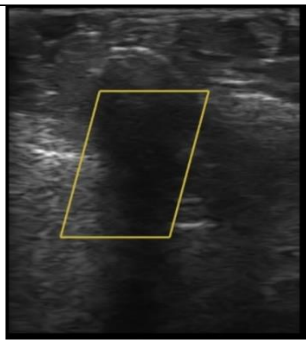
Gain C minimum	Gain C max	Rejection and C gain max
		

Figure 76: Influence of the colourflow

Appendix F: Structure of the algorithm (style transfer)

Table 23: Architecture of the stylisation network

Operation	Kernel size	Stride	Feature maps	Padding	Non linearity
Network					
Convolution 1	9	1	32	SAME	ReLU
Convolution 2	3	2	64	SAME	ReLU
Convolution 3	3	2	128	SAME	ReLU
Residual block 1			128		
Residual block 2			128		
Residual block 3			128		
Residual block 4			128		
Residual block 5			128		
Residual block 6			128		
Residual block 7			128		
Upsampling 1			64		
Upsampling 2			32		
Convolution	9	1	3	SAME	Sigmoid
Residual block					
Convolution	3	1	N	SAME	ReLU
Convolution	3	1	N	SAME	Linear
	Add the input and the output				
Upsampling					
	Nearest neighbour interpolation, factor 2				
Convolution	3	1	N	SAME	ReLU
Normalisation	Conditional instance normalisation after every convolution				
Optimiser	Adam (α = 0.001, β1=0.9, β2=0.999)				
Training iterations	160K				
Batch size	30				
Weight initialisation	Isotropic gaussian (μ = 0, σ=0.01)				

Table 24: Architecture of the conditioner network

Operation	Input dimensions	Output dimensions
Conv2D	4 (α)	1000
ReLU	1000	1000
4x Dense	1000	1000
Conv2D	1000	4224 (γ and β)
Optimiser	Adam (α = 0.001, β1=0.9, β2=0.999)	
Training iterations	160K	
Batch size	30	
Weight initialisations	Isotropic gaussian (μ = 0, σ=0.01)	

Appendix G: Evaluation of the style transfer: workshop

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Consent Form

I have read the information sheet for participants.
I understand that I may withdraw from this project and that the information used will be made anonymous.
You can stop answering this survey at any time and return back later to complete your answer.

- ◯ I consent to participating in this survey
- ◯ I do not consent to participating in this survey

→

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The aim of this survey is to evaluate the realism of the colours of the images of the surgical simulator. The images are processed using different algorithms to look more realistic in terms of colour differentiation. In this survey, you will be asked to rank the level of realism of the images and videos on a scale ranging from 0 (totally missing), 1 (bad), 2 (acceptable), 3 (good), 4 (compelling).

→

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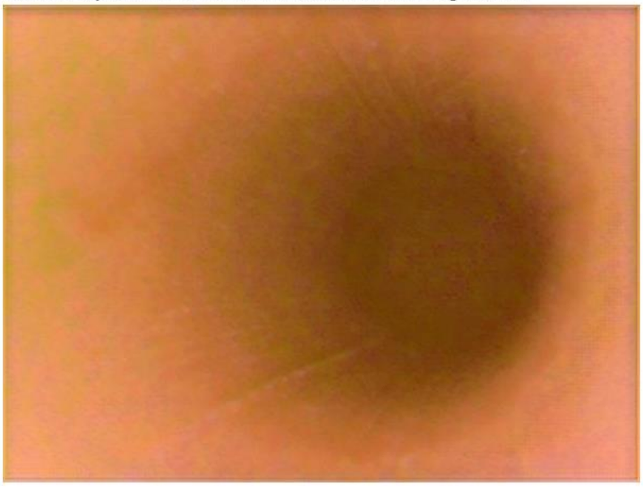
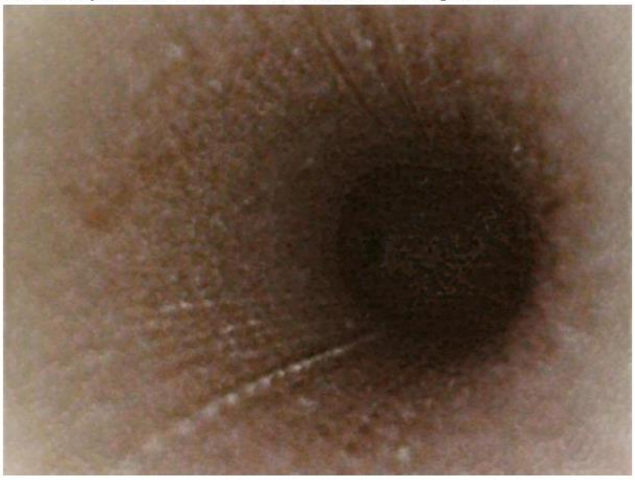
Evaluation of the Simulated Bile Duct (Choledochoscopy) in term of colour differentiation:

How would you rate the realism of the colours of the image below?



- ◯ 0 (totally missing)
- ◯ 1 (bad)
- ◯ 2 (acceptable)
- ◯ 3 (good)
- ◯ 4 (compelling)

How would you rate the realism of the colours of the image below?

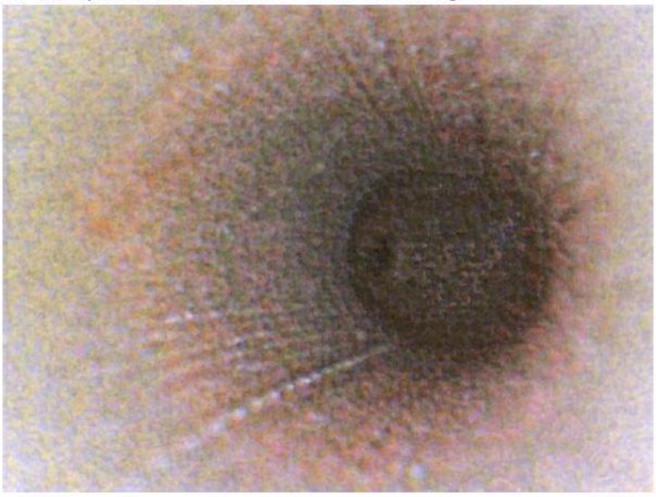


- 0 (totally missing)
- 1 (bad)
- 2 (acceptable)
- 3 (good)
- 4 (compelling)

How would you rate the realism of the colours of the image below?

- 0 (totally missing)
- 1 (bad)
- 2 (acceptable)
- 3 (good)
- 4 (compelling)

How would you rate the realism of the colours of the image below?



◯ 0 (totally missing)

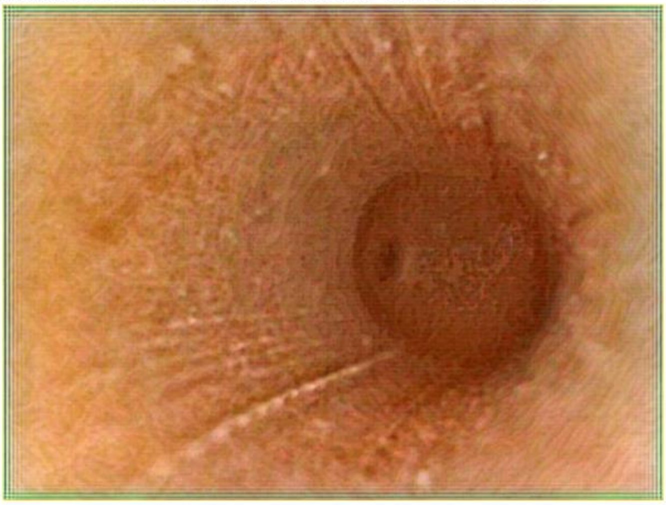
◯ 1 (bad)

◯ 2 (acceptable)

◯ 3 (good)

◯ 4 (compelling)

How would you rate the realism of the colours of the image below?



◯ 0 (totally missing)

◯ 1 (bad)

◯ 2 (acceptable)

◯ 3 (good)

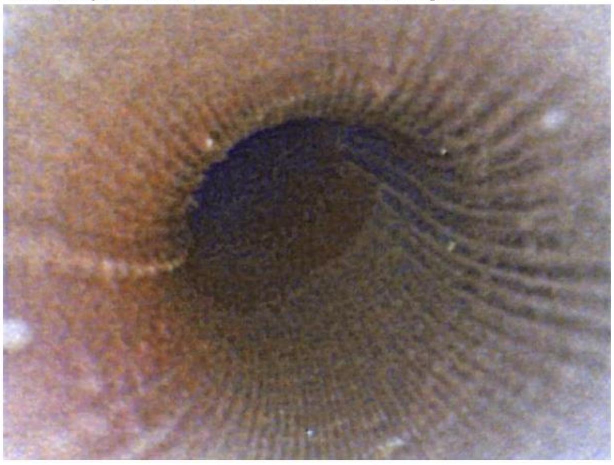
◯ 4 (compelling)

Do you have any comments on the images that you would like to add?

UWE Bristol | University of the West of England

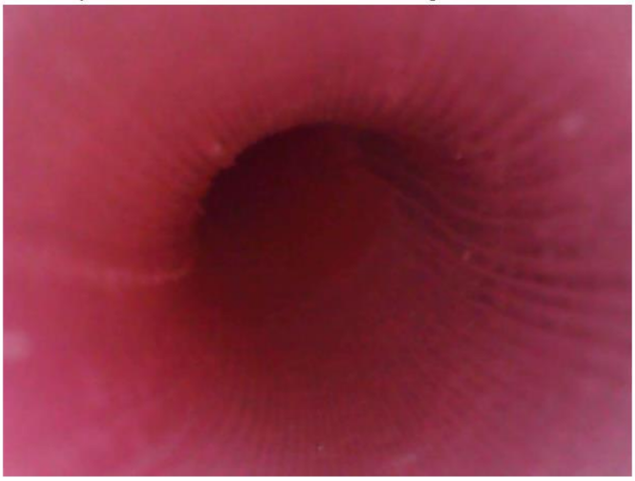
Evaluation of the Simulated Bile Duct (Choledochoscopy) in term of colour differentiation:

How would you rate the realism of the colours of the image below?



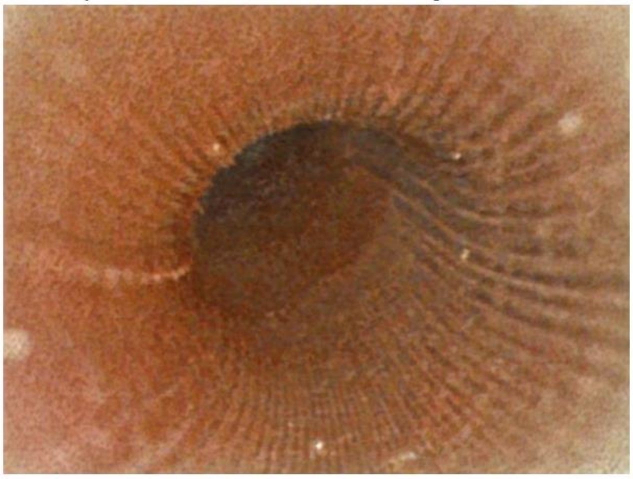
- ◯ 0 (totally missing)
- ◯ 1 (bad)
- ◯ 2 (acceptable)
- ◯ 3 (good)
- ◯ 4 (compelling)

How would you rate the realism of the colours of the image below?



- ◯ 0 (totally missing)
- ◯ 1 (bad)
- ◯ 2 (acceptable)
- ◯ 3 (good)
- ◯ 4 (compelling)

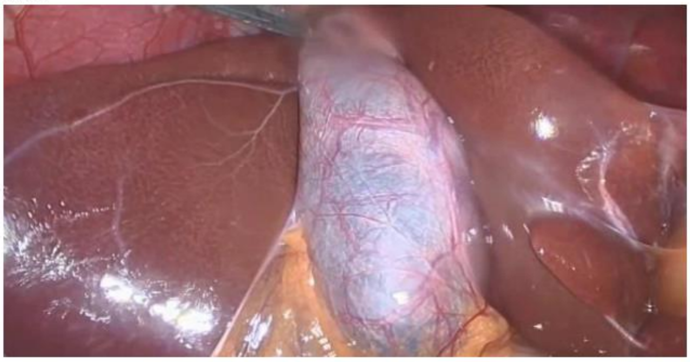
How would you rate the realism of the colours of the image below?



- ◯ 0 (totally missing)
- ◯ 1 (bad)
- ◯ 2 (acceptable)
- ◯ 3 (good)
- ◯ 4 (compelling)

Do you have any comments on the images that you would like to add?

Evaluation of the gallbladder on a plastic liver in term of resemblance to the anatomical image below:



How would you rate the realism of the colours of the image below?

- ◯ 0 (totally missing)
- ◯ 1 (bad)
- ◯ 2 (acceptable)
- ◯ 3 (good)
- ◯ 4 (compelling)

How would you rate the realism of the colours of the image below?

- 0 (totally missing)
- 1 (bad)
- 2 (acceptable)
- 3 (good)
- 4 (compelling)

How would you rate the realism of the colours of the image below?

- 0 (totally missing)
- 1 (bad)
- 2 (acceptable)
- 3 (good)
- 4 (compelling)

How would you rate the realism of the colours of the image below?

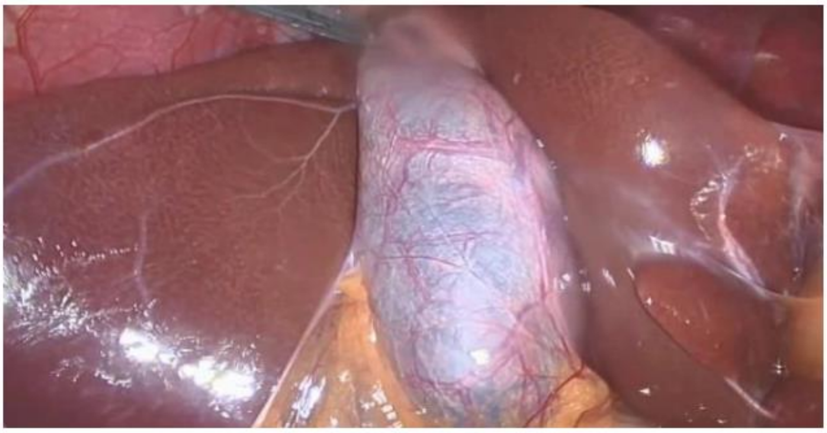
- 0 (totally missing)
- 1 (bad)
- 2 (acceptable)
- 3 (good)
- 4 (compelling)

How would you rate the realism of the colours of the image below?

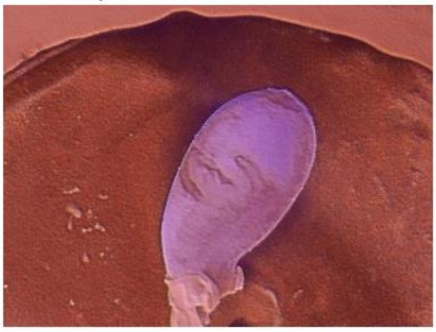
- 0 (totally missing)
- 1 (bad)
- 2 (acceptable)
- 3 (good)
- 4 (compelling)

Do you have any comments on the images that you would like to add?

Evaluation of the gallbladder on a plastic liver in term of resemblance to the anatomical image below:



How would you rate the realism of the colours of the image below?



- ◯ 0 (totally missing)
- ◯ 1 (bad)
- ◯ 2 (acceptable)
- ◯ 3 (good)
- ◯ 4 (compelling)

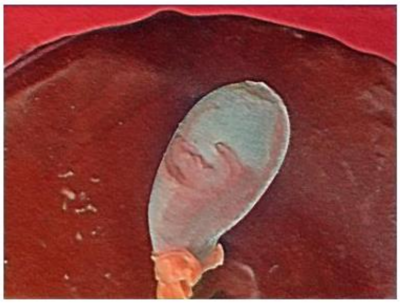
How would you rate the realism of the colours of the image below?

- ◯ 0 (totally missing)
- ◯ 1 (bad)
- ◯ 2 (acceptable)
- ◯ 3 (good)
- ◯ 4 (compelling)

How would you rate the realism of the colours of the image below?

- ◯ 0 (totally missing)
- ◯ 1 (bad)
- ◯ 2 (acceptable)
- ◯ 3 (good)
- ◯ 4 (compelling)

How would you rate the realism of the colours of the image below?



- ◯ 0 (totally missing)
- ◯ 1 (bad)
- ◯ 2 (acceptable)
- ◯ 3 (good)
- ◯ 4 (compelling)

How would you rate the realism of the colours of the image below?

- ◯ 0 (totally missing)
- ◯ 1 (bad)
- ◯ 2 (acceptable)
- ◯ 3 (good)
- ◯ 4 (compelling)

Do you have any comments on the images that you would like to add?

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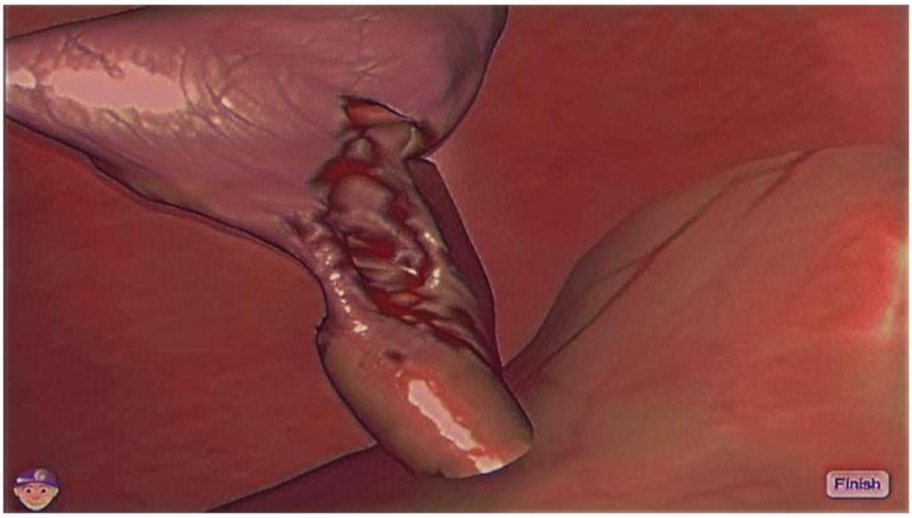
Evaluation of the computer simulation of dissection (LapSIM) in term of colour differentiation of the tissues:

How would you rate the realism of the colours of the image below?



◯ 0 (totally missing)

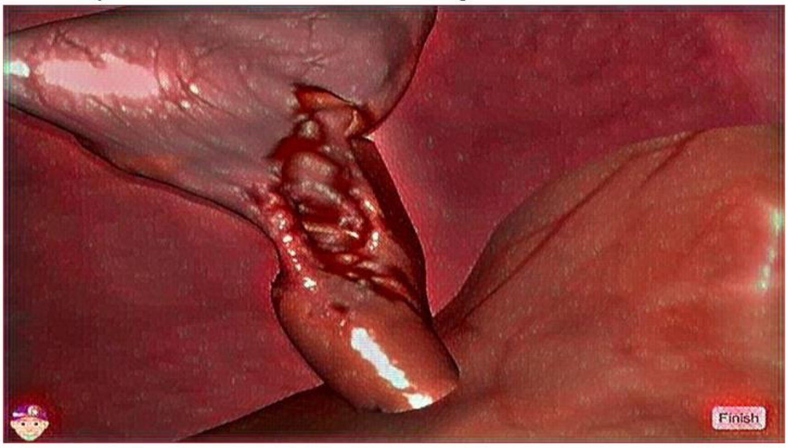
◯ 1 (bad)

◯ 2 (acceptable)

◯ 3 (good)

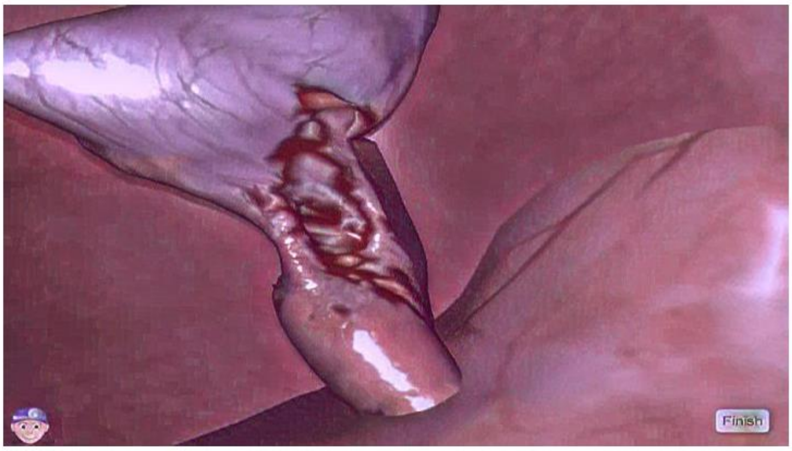
◯ 4 (compelling)

How would you rate the realism of the colours of the image below?



- 0 (totally missing)
- 1 (bad)
- 2 (acceptable)
- 3 (good)
- 4 (compelling)

How would you rate the realism of the colours of the image below?



- 0 (totally missing)
- 1 (bad)
- 2 (acceptable)
- 3 (good)
- 4 (compelling)

How would you rate the realism of the colours of the image below?

- ◯ 0 (totally missing)
- ◯ 1 (bad)
- ◯ 2 (acceptable)
- ◯ 3 (good)
- ◯ 4 (compelling)

How would you rate the realism of the colours of the image below?

- ◯ 0 (totally missing)
- ◯ 1 (bad)
- ◯ 2 (acceptable)
- ◯ 3 (good)
- ◯ 4 (compelling)

Do you have any comments on the images that you would like to add?

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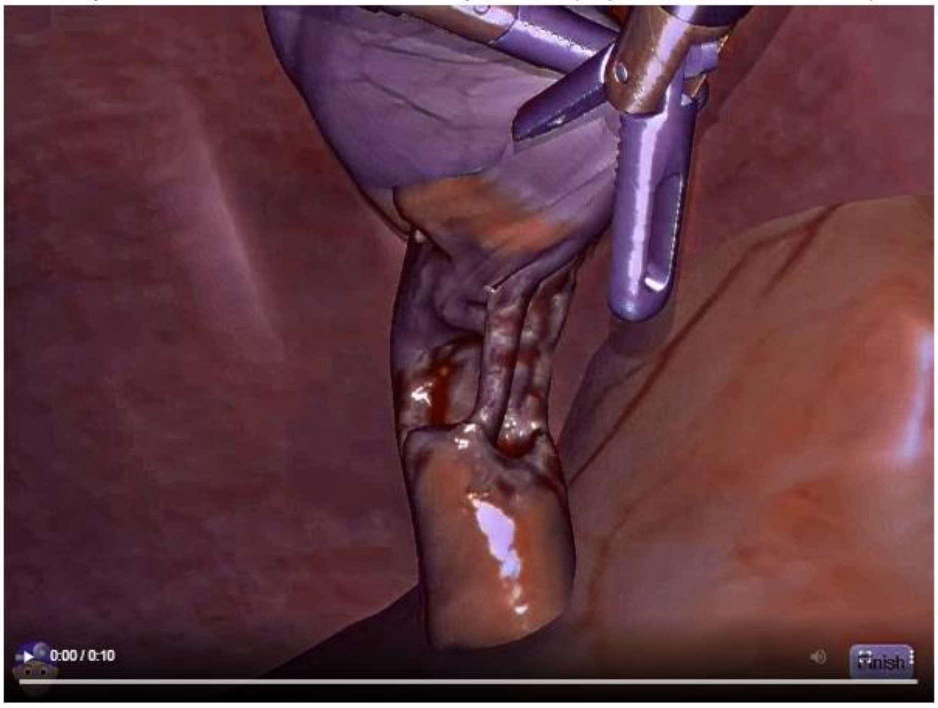
The image processing algorithm can apply different styles onto the video as visible below. Evaluation of the computer simulation of Calots dissection (LapSIM) in term of colour of the tissue and fluidity of the videos (temporal fluctuations between frames).

How would you rate the realism of the colours and the fluidity of the video (temporal fluctuations between frames)?



- 0 (totally missing)
- 1 (bad)
- 2 (acceptable)
- 3 (good)
- 4 (compelling)

How would you rate the realism of the colours and the fluidity of the video (temporal fluctuations between frames)?

- 0 (totally missing)
- 1 (bad)
- 2 (acceptable)
- 3 (good)
- 4 (compelling)

How would you rate the realism of the colours and the fluidity of the video (temporal fluctuations between frames)?

- 0 (totally missing)
- 1 (bad)
- 2 (acceptable)
- 3 (good)
- 4 (compelling)

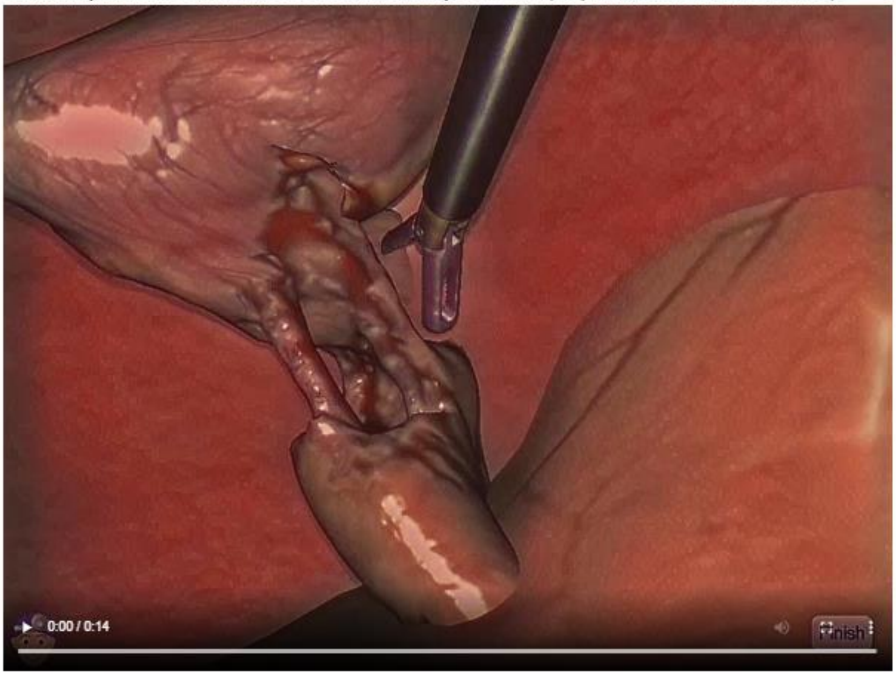
How would you rate the realism of the colours and the fluidity of the video (temporal fluctuations between frames)?

- ○ 0 (totally missing)
- ○ 1 (bad)
- ○ 2 (acceptable)
- ○ 3 (good)
- ○ 4 (compelling)

How would you rate the realism of the colours and the fluidity of the video (temporal fluctuations between frames)?

- ○ 0 (totally missing)
- ○ 1 (bad)
- ○ 2 (acceptable)
- ○ 3 (good)
- ○ 4 (compelling)

How would you rate the realism of the colours and the fluidity of the video (temporal fluctuations between frames)?



- ◯ 0 (totally missing)
- ◯ 1 (bad)
- ◯ 2 (acceptable)
- ◯ 3 (good)
- ◯ 4 (compelling)

Do you have any comments on the videos that you would like to add?

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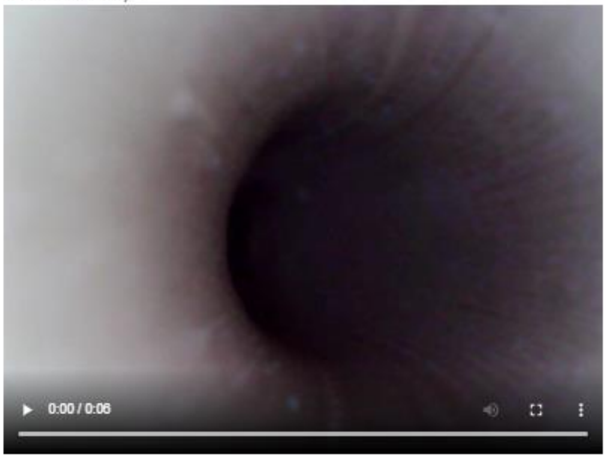
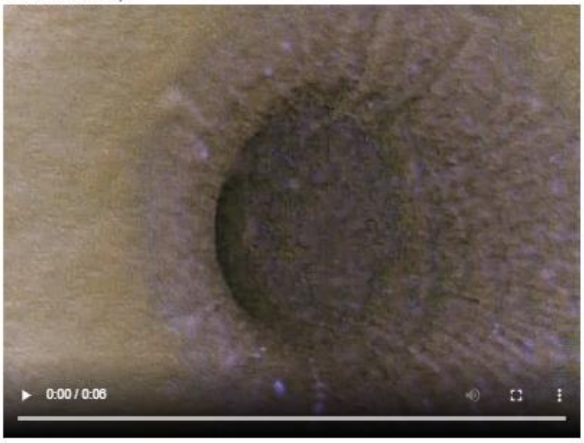
The image processing algorithm can apply different styles onto the video as visible below. Evaluation of the video of the bile duct simulator in term of colour of the tissue and fluidity of the videos (temporal fluctuations between frames).

How would you rate the realism of the colours and the fluidity of the video (temporal fluctuations between frames)?



- ○ 0 (totally missing)
- ○ 1 (bad)
- ○ 2 (acceptable)
- ○ 3 (good)
- ○ 4 (compelling)

How would you rate the realism of the colours and the fluidity of the video (temporal fluctuations between frames)?



- 0 (totally missing)
- 1 (bad)
- 2 (acceptable)
- 3 (good)
- 4 (compelling)

How would you rate the realism of the colours and the fluidity of the video (temporal fluctuations between frames)?

- 0 (totally missing)
- 1 (bad)
- 2 (acceptable)
- 3 (good)
- 4 (compelling)

How would you rate the realism of the colours and the fluidity of the video (temporal fluctuations between frames)?

- 0 (totally missing)
- 1 (bad)
- 2 (acceptable)
- 3 (good)
- 4 (compelling)

How would you rate the realism of the colours and the fluidity of the video (temporal fluctuations between frames)?

- 0 (totally missing)
- 1 (bad)
- 2 (acceptable)
- 3 (good)
- 4 (compelling)

How would you rate the realism of the colours and the fluidity of the video (temporal fluctuations between frames)?

- ○ 0 (totally missing)
- ○ 1 (bad)
- ○ 2 (acceptable)
- ○ 3 (good)
- ○ 4 (compelling)

Do you have any comments on the videos that you would like to add?

Appendix H: Participant information sheet (interviews)

University of The West of England - Participant Information Sheet

In case of any queries contact:

Researcher: Marine Shao, Research associate

CFPR, UWE Bristol Bower Ashton Campus, Kennel Lodge Road, Bristol BS3 2JT, United Kingdom

Tel: +44 (0) 117 32 86352

Email: marine.shao@uwe.ac.uk

Director of Studies: David Huson, Expert Research Fellow

CFPR, UWE Bristol Bower Ashton Campus, Kennel Lodge Road, Bristol BS3 2JT, United Kingdom

Tel: +44 (0) 117 32 84979

Email: david.huson@uwe.ac.uk

Study title: Realistic physical patient simulator for surgical training

Outline of invitation:

You are being invited to take part in a research study concerning surgical simulation. Before you decide it is important for you to understand why the research is being done and what it will involve. Please take time to read the following information carefully and the list of interview questions enclosed and discuss it with others if you wish. Please ask me if there is anything that is not clear or if you would like more information.

What is the purpose of the study?

This research is part of my PhD study (full-time 2019-22) which intends to examine how surgical training can be improved by the use of patient simulators, seeking understanding on how to reproduce a procedure.

Why have you been chosen?

I have asked you to participate because of your involvement in the field of laparoscopic common bile duct exploration.

Do you have to take part?

It's up to you to decide whether or not to take part.

What will happen to me if I agree to take part?

If you do decide to take part, I will get in contact with you to arrange a suitable time to undertake the interview. You will be given this information sheet to keep and be asked to sign a consent form. If you do not wish to be identified, then please make sure that you clearly state this by contacting me at the address above, and on the consent form.

What will be the structure and format of the survey?

The surveys will be performed online on Qualtrics. Each participant will be asked a series of questions. The questions will range from the description of the soft tissues to the evaluation of images. This may also include any other relevant information the participant may wish to contribute during the survey.

The surveys should last up to 10 minutes.

What are the possible disadvantages of taking part?

I do not foresee any disadvantages or risks in taking part. You can refuse to answer any of the questions asked without having to state a reason why. If you decide to take part, you are free to withdraw at any time and without giving a reason.

How and when can I withdraw from participating?

You can withdraw from participating at any point until anonymisation by using the contact details supplied above.

What if you have a concern about anything after the interview has been conducted?

I am conducting a funded research project as a PhD student at the Centre for Fine Print Research. It has been approved by UWE Bristol's Research Ethics Committee. I do not anticipate anything going wrong, but if you feel you have any concerns about the interview or my conduct as an interviewer, please feel free to contact my Director of Studies, David Huson (contact as above).

What data will be collected?

Personal data is information that relates to an identified or identifiable individual. What identifies an individual could be as simple as a name or a number or could include other identifiers such as an IP address or a cookie identifier, or other factors. During this project, the following personal data will be processed:

- Name of participant,
- Occupation,
- Recordings,
- Contact details.

What are the precautions taken to prevent collection of clinical information that would breach the confidentiality and privacy rights of patients of the medics involved?

Any notes/recordings will be shared with surgeons to check for redaction of any sensitive information.

Will taking part in this study be kept confidential?

The purpose is to provide source material via interview for a PhD thesis evidencing what should be the patient simulators' specifications in order to get a useful surgical training tool. The information will be used as reference, to acknowledge the work of current practitioners and their specialist experience in the field of study.

The research will identify participants as it is important to acknowledge their contribution as key authorities and valued practitioners within the field of study. Any usage of this information other than for educational and research purposes will need to be approved by the interviewer and the interviewee.

Who will be able to access the data?

The researcher and the Director of Study (David Huson, David.huson@uwe.ac.uk) will have access to the data.

What will happen to the results of the research study?

The results of this research will be used towards a PhD thesis, which will be published in 2022 and be made available at The University of the West of England's ACE Library. The findings would also be documented for potential publication as a series of articles, case studies, conference presentations and interviews, from hard copy to free PDF downloads and podcasts. This would enable wider dissemination to an international field, to build upon critical engagement, creative collaboration and dialogue between academics and medical specialists.

Large amounts of specific recorded interviews will be edited for publication as text or podcasts, so if I have interviewed you for this purpose, I will supply you with a copy of the edited text or audio for approval and/or editing before it is published or broadcast. Any usage of the information supplied by you for use other than the purposes of this project would need to be approved by you. Audio/text and visual data gathered will be destroyed at the end of the research project (September 2022).

Who is organising and funding the research?

This project has received funding from the European Union's Horizon 2020 research and innovation programme under the Marie Sokolowski-Curie grant agreement No 814158.

Contact for further information: Marine Shao and David Huson address as above.

Thank you for taking part in this project

Appendix I: Consent form

The University of the West of England, Bristol

PARTICIPANT CONSENT FORM

Study title: Realistic physical patient simulator for surgical training

Researcher: Marine Shao

Email: marine.shao@uwe.ac.uk

Director of studies: David Huson

Email: David.huson@uwe.ac.uk

Study type:

☐ Interview 1

☐ Interview 2

☒ Workshop 1

☐ Workshop 2

Thank you for your interest in participating in this University of the West of England research project. Please complete the following form to confirm your consent to take part.

This consent form will have been given to you with a Participant Information sheet. Please ensure that you have read and understood the information contained in the Participant Information Sheet and asked any questions before you sign this form. If you have any questions please contact a member of the research team, whose details are given over the page.

If you are happy to take part in an interview and/or workshop for this research, please sign and date the form. You will be given a copy to keep for your records.

- I have read and understood the information in the Participant Information sheet which I have been given to read before being asked to sign this form.
- I have been given the opportunity to ask questions about the study.
- I have had my questions answered satisfactorily by the research team.
- I agree to take part in an interview and/or workshop for this research, and for my anonymised data to be used in publications or presentations.
- I understand that my participation is voluntary and that I am free to withdraw at any time until three months after the participation, without giving a reason.

The material recorded, photographed, filmed or supplied is to be used for research purposes and could be potentially published as part of project outcomes in text, images or audio form.

Audio recording - please highlight your preference:

• I **do / do not** consent for my interview and/or workshop to be audio recorded.

Photo consent - please circle your preference:

• I **do / do not** consent to be photographed within this research. I understand that if I agree, my picture may be used for educational purposes only, in an academic paper or conference report.

Video consent - please circle your preference:

• I **do / do not** consent to be filmed within this research. I understand that if I agree, videos may be used for educational purposes only, in an academic paper or conference report.

If you have agreed for your photograph/video to be used:

• I **do / do not** require photographs and videos to be anonymised so that my face or other identifying features are not shown.

NHS ethics - please highlight your preference:

I **do / do not** confirm I do not need approval from the Ethics panels from NHS to participate in this study.

The moral rights of the participant are to be identified with their artefacts and ideas, and are asserted under Chapter IVC of the Copyright, Designs and Patents Act 1988.

Participant name (printed)…………………………………………………………

Participant signature…………………………………………………………........

Address……………………………………………………………………………
……………………………………………………………………………………

Phone………………………

Email address……………………………………………..

Signature of UWE, Bristol Researcher……………………………………………

Date …………..

Appendix J: Interview 1 guide

Realistic physical patient simulator for surgical training

version 1.1

INTERVIEW 1 GUIDE (30 minutes)

SECTION 1

Introduction: **Researcher to tick the box when complete:**

1.	1 min	Thank the participant for participating	
2.		Explain the study in brief: This study aims to develop a prototype of a surgical simulator for laparoscopic common bile duct exploration. It will start by understanding the procedure and defining the tactile feedback during the surgery during two sets of interviews.	
3.	1 min	Explain the aim of the interview 1: understand the procedure The second one will focus on the tactile feedback and will be conducted later on.	
4.		Explain that an audio-recording device will be used	
5.		Explain what will be done with the data o Anonymity and use of alias, thus we cannot trace back any persons	

	2 min	o The recording files will be stored in a secure location at the University of the West of England until the completion of the PhD o The findings will be published hopefully in 2022 Ask address details if participant wants to receive the report of the findings when they are published	
6.	1 min	Explain that the interview will take between 25 – 30 minutes	
7.		Ask if all information is clear and if there are any questions before starting the interview	

Researcher to switch on the recorder and explain to the surgeon:

SECTION 2 – AUDIO-RECORDER SWITCHED ON

THE INTERVIEW

We are now going to move on to the specific procedure of laparoscopic common bile duct exploration.

Warm up: Can you confirm who you are and where you work and what are your responsibilities?

8.	**2 min**	**Could you list the organs/types of soft tissues that you are in contact with during the procedure in a chronological order?** *Expect around 5 - 10 tissues: gall bladder, liver, duodenum, pancreas, hepatic artery, portal vein, (stomach?), common bile duct, fat, (large intestine?)*	

9.	**2 min**	**Could you list the tools <u>you</u> would use during the procedure of laparoscopic common bile duct exploration using ultrasounds in a chronological order?** **Could you divide this list of tools into categories of tools sharing the same type of action (example: cutting, clamping or any other categories you could think of)?** (remember to list back the tools to have each one) *Expect around 15 tools*	
10.	**8 min**	**Could you describe the steps/stages that you take during this procedure in chronological order from the moment you arrive in the theatre?** (think of it like a recipe) **At each of these steps, are there different surgical scenarios that might influence what you would need to do? Could you describe them?** (at what points of the surgery would you need to make a decision that could influence what you need to do? That's your normal procedure. When you're going through the procedure, where could it be different?)	
So far, we have talked about the procedure when you perform it on a patient. Now, we are going to move on to the simulation of the same procedure.			

On the market, you can find physical simulators made of plastic and that you can touch and virtual reality-based ones. I am going to ask your opinion on the simulation of laparoscopic common bile duct exploration.			
11.	**2 min**	**Have you used simulators before? What kind of simulators did you use before? What did you think of them? What are the most important elements?** (can add suggestions if they do not know: realism, tactile feel, complexity, price, movement, variety, reusability…)	
12.	**5 min**	**According to you, what are the most important aspects of the surgery of laparoscopic common bile duct exploration that need to be included in the simulator?** **For the different surgical steps that you mentioned previously *(repeat them in their chronological order),* how long should each of them last during the simulation practice?** (some steps might be more critical and require more training, could you please let me know on which I should focus the most in the simulator? For instance, a difficult step with multiple scenarios should require 10min of training, while other steps can require only 2min)	

13.	1 min	Is there anything else about the simulator that you would like to tell me or to ask?	
14.		Thank you	
15.		If you know someone who might be suitable and willing to participate, could you please tell them about this study and ask them to contact me? Or could you give me their contact, and let me tell them that it was you who referred me to this person? Can you send me an email with the contact details? Or shall I email you so you can respond with the contact details?	
16.		Reminder that you have the right to withdraw from this study within the next three months.	
17.		Reminder that any notes/recordings will be shared with surgeons to check for redaction of any sensitive information.	
18.		Thank you & Close + talk about broad study and second interview and explain that I might go back to them	

- **SWITCH OFF RECORDER**

Appendix K: Report interview 1

1. Recruitment

Number of invitations: 23

Number of participants: 8

Acceptation rate: 36%

Reason for not participating:

- Not performing the surgery (2)
- No time (1)
- No response (12)

2. Results of the interviews

Table 25: Responses of the participants during interview 1

7.	Can you confirm what are your responsibilities?
Participant 1: upper GI and bariatric surgeon; specialty lead for surgery and research lead regionally. Participant 2: clinical research fellow; registered in upper GI surgery. Participant 3: surgical intermediate on a vascular training; have done about three years of general surgery. Participant 4: expert; upper GI bariatric surgeon. Participant 5: associate specialist; do a lot of bile duct explorations and laparoscopic choledochotomy (have a weekly list and do the on calls as well). Participant 6: upper GI surgical expert; perform upper GI surgery operations including bile duct exploration. Participant 7: clinical fellow; mainly upper GI and bariatric.	
Analysis: Participants 2 and 3 are novice surgeons. The other participants are expert surgeons.	

8.	Could you list the organs/types of soft tissues that you are in contact with during the procedure in a chronological order?

Participant 1: skin, fat, muscle, abdominal cavity, gallbladder, liver, cystic duct, bile duct, peritoneum, cystic artery, stones, bile

Participant 2: gallbladder, cystic duct, cystic artery, bile duct

Participant 3: fat, bile duct, cystic duct, peritoneum, gallbladder

Participant 4: skin, gallbladder, cystic duct, peritoneum, bile duct, stone, pancreas, duodenum, liver, bile, artery

Participant 5: skin, abdominal wall, gallbladder, Calots triangle, bile duct, liver, bowel like duodenum, stomach maybe, stones, pancreas

Participant 6: gallbladder, liver, bile duct, stones, skin, abdominal wall, peritoneum, bile

Participant 7: skin, fat, muscles (these are the layers in the abdominal wall), gallbladder, liver, common bile duct, the stones (there will be different type of stones, some of these stones are friable, some of them are very hard), small bowel duodenum, intrabdominal fat, artery

Analysis:

- The most important organs to include in the simulator are the gallbladder, and the bile duct.
- Then, other tissues to include will be the abdominal wall (skin, fat, and muscle), the liver, the peritoneum, the cystic artery, and the stones.
- Finally, it might also be interesting to include the pancreas, the duodenum, the stomach, and bile.

Difference between participants: The expert surgeons mentioned more soft tissues: the abdominal wall, the liver, and the stones. The novice surgeons mostly focused on the main part of the surgery and do not include any peripheric soft tissues, which are also important during the surgery.

9. 1	Could you list the tools you would use during the procedure of laparoscopic common bile duct exploration using ultrasounds in a chronological order?

Participant 1: heavy graspers, graspers, electric hook, clips, knife, scissors, choledochoscope, needle holders, suction wash

Participant 2: ports, graspers, scissor, clips, knife, choledochoscope, suture

Participant 3: short Johan, diathermy, Shroeder grasper, Maryland, knife (the retractable one), suction, choledochoscope, basket, ultrasound.

Participant 4: ports, scalpel blade, Littlewoods retractor, Fraser-Kelly (forceps), 30-degree camera which is normally 10 mm, Keyhole Grasper, 5050 grasper, Hook, Maryland's grasper, Ultrasound, short Johan's, Tonsil swabs, Knife, Scissors, 5-millimeter choledochoscope, Dormia basket, needle holder, suture, clips, Espiner bag, Sucker, 20 Robinsons drain, forceps

Participant 5: Ports, Sucker-irrigator, Hook diathermy, Maryland's grasper, Clips, Scope, 5050, Hard grasper / assertive retractor, Sharp pincers, Ultrasound probe, choledochoscope

Participant 6: port, camera, laparoscopic grasper, grasping forceps, hook, dissecting forceps, clips, ultrasound probe, knife, choledochoscope, Dormia basket, needle holder, needle, thread, drain

Participant 7: knife, camera (30 degree), two ports 10 millimeter or more and two 5-millimeter ports, general laparoscopic set (Johan's, bowel graspers, Maryland...), insufflation gas, suction, choledochoscope (3 or 5mm diameter), basket, balloon, clips, endoloop, staplers, absorbable sutures vicryl, drain, scissors

Description of the tools:

- Heavy graspers: these are tooth forceps, they have quite jagged edges to increase friction so that you can grab the tissue. They are quite aggressive, so when you put them on to specific parts of the body, those parts are damaged and they would need to be removed. When we are acting on the gallbladder, we need the force and we need the retraction to push it up and over the liver and that requires we use instruments that have these higher frictions and therefore teeth tooth on it that allows us to grip better. They have a ratchet mechanism so you can hold onto it without having to squeeze the handles closed the whole time.
- Electric hook: An electric current is passed through it, which acts like a knife that cauterises as it goes. It is an alternating current that runs through the system that allows that to happen. That burns the tissues gently enough to just dissect it.
- Clips: They are used to close off the bile duct or the vessels. They will get scarred over by the body in time, but they do not dissolve. We call these Hem-o-lok clip. Some people also use ligature clips or microline clips, which are metal versions.
- Knife. It is called a Bercy knife, and it is a pressure activated knife. I work just like a pen, when you press the top, the knife comes out and then you can press a button on the side and the knife goes back in.
- Needle holder: We use two needle holders or one needle holder and a short softer grasper (one of the softer ones) to suture the bile duct. But we tend to use the needle holders because they have a ratchet that

allows you to grip the needle and the friction is very high and does not allow the needle to spin around.
- Ports: Port is simply a hollow tube with a valve at the end that allows us to put instruments in and out without losing any gas within the abdomen.
- Choledochoscope: It is a flexible telescope, which is either 3 millimeters or 6 millimeters in diameter.
- Dissection graspers: The surgeon puts that into the tissue and then open it up to tease the tissue apart. They are similar to a pair of scissors without short blades on them.

Analysis:

- The most important tools to include during the simulation practices are: the ports, the graspers, the clips, the knife, the choledochoscope, the electric cautery device (or equivalent), the sutures and needle, the suction, the ultrasound probe, the scalpel, the camera, the scissors, and the basket.
- Tools mention less than 2 times are not used by all the surgeons, or are repetitions of the same tools under the same name, or are not used during the most critical part of the surgery.

Differences between participants: Expert surgeons mentioned more tools because they described the whole surgery (from patient positioning to closure) and not just the main part.

9.2	Could you divide this list of tools into categories of tools sharing the same type of action (example: cutting, clamping or any other categories you could think of)?

Participant 1:

- the graspers for gripping and pulling,
- the clips to clip the pipes,
- scissors for cutting,
- the sutures for driving through with the needle holders.

Participant 2:

- grasping instruments,
- dissecting instruments, for example the hook diathermy and the Maryland Dissection tool,
- sharp instrument like the internal knife,
- the ultrasound probe,
- the scope instrument, which is a small camera.

Participant 3:

- cutting instruments: the diathermy and the bile duct knife,
- clamping or holding instruments: the Schroeder grasper and Maryland's,

- Scoping instruments: ultrasound, choledochoscope, and the basket.

Participant 4:

- the aggressive tooth grasper is more for retraction. The 5050 is slightly softer but it is also for retraction of the gallbladder,
- the hook is for dissection specifically and hemostasis. The Maryland is also for dissection,
- suction is for suctioning,
- the short Johan's grasper is to divide peritoneum on the bile duct,
- needle and sutures are for suturing,
- the knife and scissors and forceps on the outside are for making skin incisions and closing the skin incisions.

Participant 5:

- retraction tools: 5050, assertive retractor,
- tools for dissection: the hook diathermy and the Maryland's grasper,
- the sucker irrigator for blunt dissection, and also for cleaning and mopping up blood and washing out,
- clipping tools.

Participant 6:

- the hook, which is an electrocautery device,
- grasping tools,
- dissecting tools,
- the scissors and knife as cutting tools,
- the clips in clipping category.

Participant 7:

- cutting tools: knife, scissors,
- dissection: diathermy,
- grasping: most laparoscopic tools

Analysis:

The most important tools to include during the simulation practices are the ports, the graspers, the clips, the knife, the choledochoscope, the electric cautery device (or equivalent), the sutures and needle, the suction, the ultrasound probe, the scalpel, the camera, the scissors, and the basket.

- ➔ Ports would be already included in the setting of the simulator, so no placement need: don't need to mimic the tactile feedback from that part
- ➔ Grasping and pulling tools: graspers
- ➔ Clipping tools: clips
- ➔ Cutting tools: knife, scalpel, scissors
- ➔ Dissection tools: electric cautery device, graspers

- ➔ Suturing tools: suture and needles
- ➔ Scoping tools: choledochoscope, ultrasound probe, camera, basket
- ➔ The suction has no direct contact, or limited contact

Having good tactile feedback with the synthetic materials means being able to mimic the bold action categories above.

These actions are included in the physical actions of: extension (gripping and pulling, dissection?), compression (clipping, cutting?), wear (scoping, suturing, cutting?), strain limit (dissection). Extension, compression (Young modulus) and strain limit will be tested using a tensiometer. Wear depends on the two materials and won’t be tested mechanically.

10. 1	Could you describe the steps/stages that you take during this procedure in chronological order from the moment you arrive in the theatre?

Participant 1:

1. Port placement: We would incise the skin into the subcutaneous fat through the muscle layer, and then into the abdominal cavity. Most of that is using a port which is a small tube that allows us to access the abdominal cavity. Once we are inside, we will use instruments that we pass through these ports or tubes through the skin to perform the surgery.
2. Gallbladder exposure: The first part of the procedure is to expose the area where we are operating; and that usually requires us to retract the gallbladder. This is a method of being able to lift the gallbladder up over the top of the liver, as it currently anatomically sits below it. As the gallbladder is lifted over, it exposes the bile duct and the cystic duct. The cystic duct is the branch of the bile duct that goes to the gallbladder. Then the overlying tissue over the gallbladder called the peritoneum, which is a thin fibrous type of tissue with a nerve supply, is opened to expose the gallbladder itself.
3. Dissection of Calots triangle: We can dissect the gallbladder along a defined anatomical area called Calots triangle. This exposes not only the cystic duct, but also the artery called the cystic artery, which supplies the gallbladder.
4. Clipping of cystic duct and cystic artery: We would then clip both the cystic duct and artery and divide them. But before we do that, we would put a clip on the cystic duct and fill the upper part of the abdomen with water to perform an ultrasound scan using a laparoscopic or a keyhole ultrasound instrument, which we would run along the side of the bile duct to identify if there are any stones within it.
5. Bile duct exploration: We take a measurement of the diameter of the of the bile duct, it is usually between two to six millimetres, anything bigger

than that would suggest that there have been stones in the bile duct and we would check for stones. If there are stones identified, the consideration would then be two options.

- Option 1: we would divide the cystic duct by putting a second clip on the pipe and dividing it into two parts. We would then remove the gallbladder through a dissection process whereby we use electric cautery to dissect the tissue which holds the gallbladder onto the liver bed until the gallbladder is removed. That would leave the cystic artery stump and the stump of the cystic duct alone. We would then send the patient for a second procedure, which is an endoscopic procedure at which point they would remove the stones by a procedure where a camera is passed down the throat into the stomach and then into the outlet pipe of the stomach. This is called an ERCP Endoscopic Retrograde Cholangiopancreatography. This allows us to pass a wire up the bile duct from the bowel side and blow up a small balloon to draw those stones out.
- Option 2: the second option is if the bile duct is of a size greater than eight millimetres diameter, then we could perform a bile duct exploration. We would take a knife and make an incision over the bile duct, once the tissue overlying which is peritoneum is removed or opened to expose the bile duct wall itself. Then scissors are taken to make that hole slightly bigger: about five millimetres is the optimum size. Then a suction instrument that allows us to flush water down is pumped into the small hole, and the bile duct is flushed to flush the stones out from the hole. If they do not come out, then we will introduce a second instrument called a choledochoscope. This is a flexible camera, five millimetres or three millimetres in diameter, which is controlled externally with the tube passed down through a port and into the hole made in the bile duct. We can visualise inside the bile duct both looking down and upwards to identify the stones. There is a small channel in that choledochoscope that allows us to pass a basket that can open, catch the stones, and retract them out of the bile duct to remove them. Once all stones are removed, the pipe is both checked on its downward flow as well as his upward flow to make sure no further stones are found.

6. <u>Closure of bile duct</u>: We can then take some keyhole needle holders to suture up that hole with a very fine thread. The tissue is a fibrous tissue, so it is much harder than fat tissue, but it is perhaps not as hard as scar tissue; it is in between that sort of textures. It holds needles quite well when you stitch it. However, bile is very thin in the sense that it will go

through even small stitch holes, making it important that the stitching is made secure enough to close the hole, but also not too far away from the hole or too narrow. You have to close very close to the edges of the wound of the of the hole but not too far away because otherwise you can narrow the pipe down so much that it causes a blockage in the long term and that is detrimental.

7. <u>Gallbladder removal</u>: Once that is done, we would place another clip on the cystic duct that branch to the gallbladder and remove the gallbladder. The gallbladder is in place in a bag and removed through one of the portholes that we make usually in the belly button or around the belly button.
8. <u>Closure</u>

<u>Participant 2:</u>

1. Insertion of the ports in the abdomen,
2. Proper dissection of the Gallbladder Calots triangle to reach the critical view of safety,
3. Clipping under section of the cystic artery,
4. Common bile duct exploration through the cystic duct OR the common bile duct. There are some very important tools that help you with doing this, for example the ultrasound for the cholangiogram or the Fluorescence guided Ultra cholangiography, which is an X Ray,
5. If you opened the common bile duct you need to close it with some suturing OR if you done through the cystic duct, you just clip the cystic duct,
6. Removal of the Gallbladder,
7. Ensure the haemostasis,
8. Closure of the both sides,
9. Scaling.

<u>Participant 3:</u>

1. Entry near peritoneum,
2. Find the Gallbladder,
3. Dissect the important structures out,
4. Get it up on the critical view of safety.
5. Put a clip on the cystic duct and isolate the bile ducts,
6. Find the bile duct,
7. Clear the bile duct to get your access,
8. Make some incision into it with the bile duct knife,
9. Gain access to the choledochoscope.

<u>Participant 4:</u>

<u>Patient positioning</u>

1. The patient positioning is supine, the arms are wrapped. It is necessary to make sure that the table can potentially include X Ray cholangiogram if you need it. Then I normally drape sides top bottom to expose the abdomen.
2. Entry into the abdomen: lifting the umbilicus with the Littlewoods retractor, making a skin incision transversely beneath the umbilicus, making incision in the umbilical stalk and placing the first terminal port, placing the camera, putting on the gas and getting gas insufflation and having a look inside.
3. Putting in the remaining ports: one in the epigastrium and two in the right upper Quadrant. Then get the patient in a head up position and a left lateral tilt.

Then the procedure starts:

4. Retracting the gallbladder by the fundus up to expose Hartmann's pouch: I grasp it with my left hand with the 5050 Grasper and start on the anterior surface of the cystic duct with my hook and work up as far as I can towards the fundus in the peritoneum. I then swing it the other way and do the same,
5. Work on Calot's triangle using a combination of the hook and the Maryland's to create a safe window,
6. Clipping the cystic duct on the gallbladder side,
7. Table ultrasound to measure the size of the bile duct and to confirm if there is a stone: I lay the ultrasound probe on the cystic duct, and I run it down distally onto the main common bile duct, then continue to run it all the way down along the main common bile duct beneath the pancreas down to the level where the ampulla is on the duodenum. Then I go to look at the common hepatic duct, that means laying it on the common hepatic duct just following the probe up towards the liver. Then I would have a look over the duodenum itself to get a slightly better view of the ampulla side. Then I lay the probe on the duodenum and run it around the top of the duodenum,
8. After the table ultrasound:
    - if there is no stone I would then place my remaining clips on the cystic duct on the cystic artery. Divide with scissors and then to start dissecting the gallbladder
    - if there is a bile duct stone, then the next stage is to expose the bile duct: I will exchange the fundus grasp with my assistant after I put it lower down on the gallbladder near the Hartmann's pouch, so I get slightly better retraction to lift the gallbladder up. Then I would divide the peritoneum over the anterior surface of the bile duct. I then place a clip onto the cystic duct on the gallbladder side to stop any further stones dropping down before

I do the exploration. I then make a longitudinal choledochotomy in the common bile duct beneath the level where the cystic duct enters. I then often use a wash and suction device, placed that through the choledochotomy first and flush it with saline under high pressure, and then remove the suction just to see if any stones or debris washed out on their own. And then I take my 5-millimeter choledochoscope, passed that in through the choledochotomy, and then look distally first. So, I would normally have a look down all the way to the ampulla first. If I detect any stones, remove those. Once I am happy I have cleared distally, I would then come out and then go proximately and look up each side, into the right and the left hepatic, as far as I can get up each side. If there is no stone, then I normally turn off the wash. Make sure there's bile flow coming down from each side, put back on the wash again, and do that again, just to make sure there's definitely no evidence of any other stones washing down, and then if I'm happy I have a final look distally to make sure there's no stones and I do the same again when I turn off the wash to see if bile starts to drain down alongside the camera and make sure there's no other debris.

9. Placing the remaining clips on the cystic duct and artery to divide them, and then dissect the gallbladder off. The dissection is done with the hook working up each side until it is completely free from the liver.
10. Placing the gallbladder into an Espener bag. The bag is inserted through the epigastric port over the liver and I use my two graspers to open the bag, and my assistant places the gallbladder in,
11. Washing, hemostasis, and placement of a drain,
12. Retraction of the gallbladder through the umbilicus,
13. Closing the port sites,
14. Applying dressings and completing the procedure.

<u>Participant 5:</u>

1. Put the ports in: prep the patient around the port sites by putting local anesthetic into the muscle where the nerves are. I put 40 mils of 0.25% lignocaine around the port sites under vision. Then I make the cuts in the skin and put the port in under direct vision. After I put the umbilical port in:
   - In a standard patient, I just do a sub lateral cut down and put the port in, then I put the other ports in under vision.
   - Sometimes if the patient is big, I use a various needle and then put one of these special ports.
2. Having a look around to evaluate the situation,

3. Retracting the gallbladder over the liver and click it into the drapes so that the system does not lean over,
4. Dissecting and delineating Calot's triangle: taking down the adhesions, identifying Hartman's pouch, identifying Calot's triangle to get an idea of the anatomy,
5. Diathermy of the cystic artery or clipping of it,
6. Manipulation of the cystic duct to milk it to make sure there's no stones in it and then put a clip up the top,
7. Ultrasound examination: There are two reasons for doing that: I can learn a lot, and it takes only a few minutes,
8. Decision of the approach: trans-cystic or trans-ductal,
9. Bile duct exploration,
10. Putting more clips on,
11. Cutting the cystic duct and then dissecting the gallbladder off the liver,
12. Putting the gallbladder in a bag,
13. Washout,
14. Deciding whether I need to place a drain,
15. Pulling the bag out.

<u>Participant 6:</u>

1. Obtaining safe access into the abdomen: making a cut around the belly button to put the port in. Once we have the first hole, we put a camera inside and inflate the abdomen with CO2,
2. Inserting additional ports to allow you to manipulate structures within the abdomen,
3. Holding and retracting the gallbladder using a laparoscopic grasper to grab hold of the gallbladder and lifting it up. The view is initially obscured because the liver lies down over there, and you cannot see the gallbladder or the bile duct fully until you lift the gallbladder,
4. Dissecting free Calot's triangle: We use grasping forceps to move the gallbladder from side to side and open up the peritoneum which is the covering on the gallbladder. It's like a membrane lying over the gallbladder. We divide that using a hook which is a diathermy hook, so there's a concentrated AC current goes through that to burn the tissues and it sort of burns and divides the tissues, thereby cutting the tissues and stopping any bleeding,
5. Putting metal clips on the cystic duct which runs between the gallbladder and the bile duct,
6. Performing an ultrasound: you put water then you lie the probe against the side of the bile duct. The areas of the ultrasound probe that are not in direct contact with the bile duct use the water as a connecting media, because if there is just air or CO_2 you get reverberation and no picture,

7. Dissecting out the bile duct to free it from the surrounding tissue. The surrounding tissue consists of peritoneum, which is like a membrane that can be easily torn. I usually just tease it apart by grabbing hold of it with the instruments and pulling it apart. Then I use the dissecting instrument to tease the fat off the duct as well as connective tissue which is kind of filmy sort of fiberglass like tissue. It looks like fluffy fiberglass, but it does not behave like fiberglass, it behaves more like fatty tissue,
8. Making a vertical incision in the bile duct,
9. Introduction of a flexible choledochoscope into the bile duct to withdraw the stones: you put the basket over the stone and close it, it holds the stone and then you pull the stone and the choledochoscope out of the cut in the bile duct,
10. Stitching of the bile duct using a needle holder, a needle, and a thread,
11. Removing the gallbladder,
12. Placing a drain: we place a drain which is just a silicon plastic tube, that we place in case the bile leaks

<u>Participant 7:</u>

1. Make sure that you have all the instruments
2. Positioning of the patient would be the same as the common gallbladder operation so supine position. During the procedure, we change the positioning to have the head up a bit and then the right side of the patient to be up and that to make the exposure a bit better.
3. Cleaning and draping and all that stuff
4. Have your assistant, the camera man or woman, on your left side.
5. Access to the abdomen: Different way for access, either open or closed technique. Then we start with the umbilical port or a bit sub umbilical if the patient is really large, then any gastric port, and then two other ports in the right upper quadrant.
6. Retraction of the gallbladder
7. Clarifying the anatomy of Calots triangle: find the cystic duct, cystic artery, and the common bile duct to achieve the critical safety view
8. Clip and divide the artery to only have the cystic duct to connect to the common bile duct,
9. Radiological diagnosis: (even if you have had any radiological diagnosis preoperatively, MRCP, ultrasound, CT, intra operatively you need radiological confirmation because some of these stones may slip on its own before the operation) to confirm the presence of stones in the CBD before you explore. There are two ways: either on table cholangiogram or ultrasound. For the ultrasound:
   - when you find the anatomy, clip the cystic duct very high, close to the gallbladder,
   - fill the Morison pouch with saline

- make the position flat again for the patient
- use the laparoscopic ultrasound: start from the cystic duct going down to the ampulla. You need to measure the cystic duct diameter, the common bile duct diameter, the size of the stones, and confirm the presence of the stones and the number of them as well.

10. Decide if you are going to do a trans-cystic approach or a trans choledochal approach:
    - trans cystic approach:
        - put the one clip on the cystic duct, very high, close to the Hartmann pouch of the gallbladder.
        - open the cystic duct with scissors.
        - access the common bile duct using this 3-millimeter scope
        - remove the stones
        - check if it is clear: do another OTC if you've been using on table cholangiogram to confirm the clearance, or do ultrasound again, or use the choledochoscope itself.
    - trans choledochal approach:
        - open the common bile duct with a special type of knife: we usually do around 1-centimeter choledochotomy, and usually we go as down as we can close to the duodenum. It's very important to be low rather than high
        - use the 5 millimetres choledochoscope to look both sides: downstream toward the ampulla, and upstream toward the common hepatics where you need to see both the right and left branches.
        - if there's any stones, clear it using the different methods: either with a basket or a balloon, or maybe just milking the stone or using grasper to grasp it.
        - flush the CBD with saline
        - do a choledochoscopy again to verify it is cleared: use the choledochoscope
        - suture the CBD using continuous suturing vycril starting up going down
11. do the cholecystectomy
    - clip the cystic duct: we have one clip proximally, now you put two clips to stay in the patient
    - divide the cystic duct
    - dissect the gallbladder from the liver.
    - retrieve the gallbladder in a bag (if the stones are really large and not going in the suction you can you put them as well in the bag)
    - wash out,
    - haemostasis

o Put a drain if you've done a trans choledochal approach o make sure there's no bleeding from the ports sites. o close the ports and skin	
Analysis: The steps are: (Not necessary to include, could include but not vital, need to be included) - Patient positioning and port placement - Gallbladder exposure - Dissection of Calots triangle - Ultrasound examination - Bile duct exploration - Clipping of bile duct and artery - Suturing of bile duct - Gallbladder removal - Closure Difference between participants: The expert surgeons gave more details	
10.2	At each of these steps, are there different surgical scenarios that might influence what you would need to do? Could you describe them?
Participant 1: - The first step could be if you cannot identify the cystic duct and artery very well. The decision is if there is lots of scarring, and you cannot identify the cystic artery and the cystic duct, then it may be that you must take the gallbladder higher up, we call that a subtotal colectomy. We only remove about three quarters of the gallbladder rather than the whole thing, which is not a problem because if you remove all the stones. But you cannot get access to the bile duct to see whether there are stones there. - At the laparoscopic ultrasound of the bile duct, you will decide whether to do a bile duct exploration or not. The decision would be whether you do that through making a cut on the bile ducts, or whether putting it down the cystic duct side branch. Participant 2: - During the dissection of the Calot's triangle to get to the cystic duct and cystic artery, - While you are doing the cholangiogram with the ultrasound or the cholangiography, you identify if there are any stones in the common bile duct or any other sites. That will define if you need to do a proper common bile duct exploration through opening the common bile duct.	

Participant 3: if you look at the bile duct and it looks small then you might not proceed. Majority of the decisions would be if it is not appropriate to do the procedure because there are some sort of access problems.

Participant 4:

- Sometimes you cannot get into the abdomen, for example, if the patients have had a previous abdominal surgery, they might have a scar. In that case I would often use a left upper quadrant various needle. I need to go in at the epigastrium to start with an optical port or sometimes even go in the left upper Quadrant with a 5-millimeter optical port and camera to help me see where I need to get access.
- Sometimes you cannot retract the gallbladder, so you may have to make the decision that you are going to decompress the gallbladder. Quite often with that, I push the 5-millimeter port into the fundus of the gallbladder and place the sucker straight down through the port and just drain the gallbladder that way.
- Once you start dividing the Calot’s triangle, sometimes it is so difficult and challenging that you cannot do it the standard route. Sometimes you must dissect the entire gallbladder down, fundus first, by starting at the top and bring it all down back to front.
- If you cannot safely see a critical window, then you might do a subtotal. This means I would open the gallbladder, make sure any stones are cleared, and use either a large clip or a stapler to staple the gallbladder Hartmann's pouch closing to the bile duct but preserving the cystic duct.
- if the cystic duct is very wide, you might choose to do a trans-cystic bile duct expiration. In which case I would open the cystic duct and use 3-millimeter telescope and go that way instead.
- If the bile duct is less than 8 millimeters, opening it can cause strictures. I often try a trans-cystic, and if I really cannot because the bile duct is too small, then I would not even try to do a bile duct exploration.
- Once you are in the bile duct, sometimes you have to make a decision about how you will remove the stone:
    - sometimes you can use a basket
    - sometimes you cannot use a basket and you may have to use lithotripsy
    - it may be easier to take the stone through the ampulla into the duodenum
    - sometimes you may have to extend your incision up onto the cystic duct if there is a stone stuck across the junction.

Participant 5:

- Unusual anatomy or too many adhesions: might need to do a subtotal, convert to an open procedure, or abandon the procedure,

- Handling complication: bleeding, friable tissues, gallbladder perforation,
- Retraction of the liver depends on its size, sometimes it is impossible,
- Port entry depends on the size of the patient,
- Trans-cystic or trans-ductal exploration depending on the ultrasounds.

Participant 6:

- If you cannot identify the anatomy safely, you may either abandon the operation or convert to an open operation and perform the operation with your hands rather than with instrument,
- If you do an ultrasound and find there are no stones in the bile duct then you would not perform an exploration,
- If you perform an ultrasound scan and you find stones in the bile duct, but the diameter of the bile duct is less than 8 millimeters, you would not perform a bile duct exploration. The reason for that is if you do perform a bile duct exploration in a narrow bile duct, then you have problems when you suture it up because you would make it too narrow to function. So, it has to be at least 8 millimeters before you would make a cut in it.

Participant 7:

- Different way for access: either open or closed method / the umbilical port becomes a bit sub umbilical if the patient is really large
- do trans-cystic approach or trans choledochal approach
    - sometimes you can’t do the trans cystic approach because the cystic duct is very spirally, and you can't approach it with the three-millimetres scope, then you need to cancel this approach and go for trans choledochal one.
    - If you are starting with the trans cystic approach and then the stone you find is a very big stone, then this means that you will struggle to get it out from the trans cystic approach, and then you need to change your approach, and go for trans-choledochal
    - The main thing will be the size of the stones, size of the cystic duct, anatomical variations.
    - Sometimes you can go around that a complex anatomy and open the cystic duct very low at the confluence with the common bile duct, without opening the common bile duct, that is another way
    - there is a safety diameter for the common bile duct when you can do a choledochotomy: you need a big CBD to prevent having strictures in the future. HPB surgeons, most of them they are happy to do it up to 8-millimeters. With the upper GI surgeons, they are reluctant to open CBD if it's less than 10 millimetres. There is no consensus on it.
    - if it's a small CBD, it's better to go for trans cystic approach. If you can't do the trans cystic approach and the CBD is really small,

then you need to stop the operation and proceed with the postoperative ERCP or intra operative ERCP.
    - number of stones: if you have really large number of stones trans cystic will be very fiddly, it will take you very long time to play it, so it is better to go for trans-choledochal approach.
- different methods to clear the stones either with a basket or a balloon, or maybe just milking the stone or using grasper to grasp it
- differences in the anatomy or bleeding

Analysis:

Important scenarios to include:

- ultrasound examination (measure size of duct, location, size, and number of stones)
- way to remove the stone

Not included: port placement, identification of Calots triangle

Difference between participants: The expert surgeons also mentioned scenarios during the port placements, which is at the beginning of the surgery when novice surgeons focused on the main part of the surgery.

11. 1	Have you used simulators before? What kind of simulators did you use before?

Participant 1:

- Virtual reality,
- Physical simulators: animal models (box trainers with animal parts in them), human cadaver models, animal cadaver models, live animal models, box trainers.

Participant 2: laparoscopic set simulator and it was the augmented reality/virtual reality.

Participant 3: laparoscopic simulators, and surgical models (for example models for anastomosis, angiographic simulators, and angiography and intravascular ultrasound (IVUS) to understand the graph deployments).

Participant 4: fake torso, cadavers and computer based.

Participant 5:

- Ultrasound simulator that was quite clever to look at the basics of ultrasound,
- Simulators for laparoscopic work such as technical challenges like stacking bolts and tying knots.

Participant 6:

- Limbs and Things gallbladder simulator, which is good because you can dissect out the bile duct because they have a sort of a filmy fiberglass textured layer. You can isolate the bile duct, which is a rubber tube, incise it, and then put the choledochoscope in and out of it. However, there is no capacity for doing an ultrasound with that simulator.
- The simulators from the Southwest Surgical Training Network Courses where the course coordinator made simulators herself out of gelatin and rubber tubes.
- Virtual reality laparoscopic simulators, but they are not operations specific.

Participant 7: virtual reality and physical simulators

Participant 8: the old fashion lap boxes with hard plastic with a bit of neoprene and a laparoscope connected to stack, one of my computers (I did not think was typically helpful because you didn't get any real haptic feedback), VR one (a little bit of feedback from that, but not much)

Analysis: frequently used training simulator: box trainers and virtual reality

Difference between participants: Novice surgeons did not mentioned training on cadavers and seems to have more training using virtual reality or box trainers.

11.2	What did you think of them? What are the most important elements?

Participant 1:

- It must be challenging enough that the average person of the street cannot do it without training or understanding what they are doing. It must differentiate between experts and novices.
- It needs to be able to clearly identify the steps of the procedure, it must be constructed in a validated way.
- It is important that it can demonstrate that if somebody uses the simulator over a period, they are able to perform the procedure better in real life.
- The way it looks, although it is important to an extent, is not vital. But it should have a similar feel to the soft tissues, to create the realism that engages the trainee or the to be able to feel that it is a proper challenging environment.

Participant 2:

- technical limitations, for example lagging,
- no haptic feedback,
- good tool for educational purposes, for medical students or novice grade doctors.

Participant 3:

- skill is transferable to the activity that you are doing in real life,
- materials are very similar to what you have in real life,
- does not include all the real details of the actual procedure itself,
- with the hybrid virtual reality laparoscopic ones, the thing that you are seeing on the screen does not really represent what you do in the operation or the steps that you are asked to do.

Participant 4:

- When using a torso, you are putting the ports and the instruments in, and using a camera. It is relatively realistic in terms of enabling you to put in the ports properly and getting tactile feedback when you are moving things around. But there is a limit to what you can do with it because you normally use sugar cubes, or sponges, or bits of meat, so it does not have quite the same feel as real live tissue.
- Training on cadavers, like pigs for example, provides some quite good simulation, it feels much more realistic,
- Virtual cholecystectomy is a computerized image of a gallbladder with two laparoscopic instruments going into it; it is helpful but it does not provide any proper tactile feedback of what it is like to do a real operation.

Participant 5:

- Simulating the difficult cases like bleeding, really inflamed tissues, the big liver, the abnormal things, and making the surgeon make a decision of what to do in a difficult case,
- If it is too simplified, it is good to learn the anatomy, what to do, and what the steps are.

Participant 6:

- resemble the anatomy, look like the thing they simulate,
- the haptic feedback when you dissect needs to feel the same,
- then everything else comes from what is ideal and what is acceptable: the ideal simulation would allow you to use a hook and electrocautery, because that is what you do in life, but I accept that that may be difficult in a simulator.

Participant 7:

- I prefer not the virtual, electronic ones, like the computer one. I prefer the real physical one because that will give you normal physical touch type of things.
- virtual ones I still feel it's like not real.
- physical simulators, not the virtual one, are bit closer to reality and you know it will give you, you know I think more of a better simulation and better training and better outcome.
- the best thing is the real life: this is no way to achieve that.

- all these simulators will help in improving the training and making the learning curve shorter,
- in very complex laparoscopic procedures, for example suturing, you need to keep practicing, because you can't do that in real life: you don't have loads of these cases if you compare it to the number of trainees

Participant 8:

- computer-based and VR: bad haptic feedback or no feedback
- lap-boxes: lack half or a quarter amount of the patient, so you're not stood in the right place. Your camera person is not in the right place. So it becomes easier ergonomically for you.
- lack of widely available realistic tissue

Analysis: The most important aspects for the simulator are the tactile feedback and the realism. During the evaluation, it would also be good to prove that:

- it can differentiate
- it can improve performance in theatre (transferrable)
- it can teach the steps of the procedure
- eventually include complications

The available simulators can teach young students the use of tools and the steps of surgery, but they have several limitations including unrealistic tactile feedback, and being too simplified and not able to translate to real life.

Difference between participants: The main aspects of the simulator are not perceived similarly between novice and expert surgeons: novice surgeon focused on the realism and tactile feedback; expert surgeons are also focused on that but also on the training potential of the simulator (differentiate, improve performance)

12. 1	According to you, what are the most important aspects of the surgery of laparoscopic common bile duct exploration that need to be included in the simulator?

Participant 1:

- Identification of stones in the bile duct ultrasound,
- Ability to find a material that allows to make a cut in the pipe, access it is using the choledochoscope, and close it up afterwards,
- Ability to reproduce the model,
- Having a model versatile enough to be put inside an abdominal trainer,
- Have the port sites positioned in the challenging way that we find them in real surgery. What you often find some of these simulators is that the instrumentation is placed in an optimal position for the surgeons to do the operation. In reality, you are often operating in a much more sort of awkward way, and you have to learn how to do it in an awkward way

Participant 2:

- Represent the Calot's triangle dissection,
- Identification of the common bile duct,
- How to do the cholangiogram or the ultrasound,
- How do you start doing the opening of the common bile duct and introducing or removing all these stones with the scope.

Participant 3:

- Ultrasound to check the ducts (if there are stones and the dimension),
- Dissecting out the bile duct to get access,
- Inspection with the choledochoscope,
- Stitching of the bile duct.

Participant 4:

- Learning how to do the ultrasound and that includes the feel of how you move your ultrasound machine with your hand because you have to rotate it clockwise and push it forward. You need to learn the muscle memory,
- Ability to practice putting a telescope into the duct and learning to get the angles correct, moving it up and down,
- Learning to suture on the bile duct, which can be quite difficult.

Participant 5:

- The most important step is the dissection of Calot's and obtaining critical view. I think the important parts are avoiding the bile duct injury and good liver retraction. The tissues can also vary a lot: you can have very fibrous, difficult, inflamed Calot's. Some of that tissue is like butter, and it all falls apart as soon as you touch it, so I that would be difficult to simulate. So simulating tissues which bleed, would be interesting.
- Good exposure: setting yourself up to succeed. Taking a minute just to set the patient up properly, and putting your ports in the right position, so you're comfortable when you're operating and that comes with experience.

Participant 6: The important things in terms of bile duct exploration and ultrasound is that you have to be able to perform the ultrasound in a very similar way to how you perform it *in vivo* in life. In terms of bile duct exploration, you have to be able to use all the appropriate instruments to get stones out; and it's very helpful if there's actually stones in the simulator.

Participant 7:

- good suturing techniques: but you can train for suturing on a general laparoscopic simulator not specific to CBDE. It is not a must for this simulator, but you can't do CBD exploration without being competent in suturing, because bile leak is one of the most important problems after these trans choledochal approaches.

- using the choledochoscope as well is very challenging, specially the three-millimeter trans cystic one:
  - how to prepare the choledochoscope, how to do the connection. It's a really very important part, but you can learn this without patients, on the side of the theater, so it's not a big issue
- how to open the CBD?
  - open the common bile duct with one of the different instruments because some surgeons open it with a knife, some surgeons open it with the scissors
  - where to open the CBD? You need to do it as low as you can. The size of the opening should be around 1 centimetre. Or you may increase that depending on the size of the stone. And how to open it? Is that vertical or horizontal?
- using ultrasound: pick the stones and measure the stones as well, measure the cystic duct, find the confluence between the cystic duct and the common bile duct, measure the common bile duct just at the confluence between this and cystic duct
- how to suture the CBD,
- how to retrieve the stones: this is sometimes very challenging if it's very deeply impacted stones at the ampulla, they are really big. Then you need to, I mean baskets catheters to get it, or balloon catheters, all that stuff. Definitely basket is important to know how to use it, because this is the most common technique to get these stones out.

<u>Participant 8</u>: the process of manipulating and choledochoscope, which can be very challenging, especially 3-millimeter scope. And it's not an ideal position to be suturing in, so I think more of the repetitive process and bring your brain adapt to those things is the most important aspect compared to different types of silicon or plastic or whatever it may be that holds a suture. That's less important than getting someone used to the awkwardness of the operation.

<u>Analysis:</u> The most important steps to include are:

- The ultrasound examination,
- The access to and opening of the common bile duct
- Introducing the scope and removing the stones
- To suture the bile duct

<u>Difference between participants</u>: The expert surgeons also consider ports positioning as an important aspect during the simulation, that the novice surgeons did not mention. The novice surgeons also mentioned the identification of the common bile duct, that none of the expert surgeons mentioned.

12.2	For the different surgical steps that you mentioned previously how long should each of them last during the simulation practice?

Participant 1: I can take a gallbladder out in 20 minutes or in five hours, it depends on the patient. In a simulated setting, you want to keep it short and simple as you want to just learn the steps. When it comes to a simulator, you want that it is easily done in a timeline that fits with learning the steps, so shorter is better. So, I would personally go with half an hour. Because you want it to be repeatable, able to learn the steps, but you are not wanting to challenge them to the extreme.

Participant 2: The main steps are: opening the common bile duct, introducing of the scope, and removing the stones. Because this is the most challenging and more difficult step of the surgery. I think maybe from 10 to 15 minutes because more than that, the surgeon will get a little bit uninterested.

Participant 3: It should last half an hour or something. Half an hour is probably a good amount of time, because it is about the right amount of time that it takes to do it in real life in a simple case problem.

Participant 4: In a simulation you do not have to deal with bleedings and you do not have to deal with unusual anatomy so it should be more straightforward. The ultrasound section is going to be 1 or 2 minutes, the bile duct exploration maybe 5 to 10 minutes, suturing may take you up to 10 minutes.

Participant 5: you need to simulate in certain different situations. So, I think doing a course on a simulator should last a morning with someone, so you've got time to discuss it. I think doing half an hour simulation, that would not be very good, though it would help. It depends on what you're trying to achieve: if you're just looking at how to look with a camera or just stitching, it can be shorter. But we do a stitching course that takes a morning to do. So, you've got multiple people doing it and then it holds nearly all afternoon, so it needs time, and you need a mentor, and you need someone just going around and looking and see how you do. The more time the better.

Participant 6: About half an hour in my experience. From when we've done courses teaching this, we tend to have two people per simulator, so one person holding the camera and one person doing the operating, and they should be able to progress in about 15 minutes. If it takes longer than half an hour, they lose interest. The dissecting of the gallbladder should take 5 to 10 minutes because that's not what people are there to learn, the ultrasound probably should take half of the remainder of the time, and the bile duct exploration the other half.

Participant 7: I don't think you need to put the gallbladder bit in it, and I don't know if you're going to do a cholecystectomy in this simulation of the CBD exploration, but if it's without 30 minutes will be good, 30 to 45. You don't need to train on 20 stones, you do it on one or two stones actually. It is just you need to know how to open the CBD, how to close it and how to manipulate the choledochoscope.

5 minutes to open CBD (find the CBD, do the dissection around it, open it), then simulation on using this scope up to 15 minutes, and then 10 minutes to get the stoned out. Then we need to close it in 10 to 15 minutes.

Participant 8: 30 minutes

Analysis: The simulation should last between 20 and 40 minutes: the ultrasound should last around 5 minutes, the opening of the common bile duct 5 minutes, the choledochoscope should last around 10 minutes, the stones 10 minutes, and the suturing 10 minutes.

Difference between participants: The expert surgeons consider that the training session should last longer than novice surgeons.

13.	Is there anything else about the simulator that you would like to tell me or to ask?

Participant 1: The simulator got to be able to learn the steps of the procedure and the most challenging parts in the most repeatable and reliable way

Participant 2: No

Participant 3: No

Participant 4:

- Trying to get a good anatomical setup so that it really does feel realistic when you run the ultrasound machine up and down. I know that people have simulators for ultrasound but until you do it on someone it never feels quite the same.
- Making something like the bile duct is very difficult as well, because you want something that holds it shape, like the bile duct that normally holds its shape quite nicely, but it is also incredibly thin and so, it is very, very delicate to handle.

Participant 5:

- One of the problems in surgery is that you often teach people in quite high stress environment. If you've got a good simulation, people should be having a day on the simulator before they do a surgery, then they should go in back to the simulator and do it again.
- The reason for simulation is also it does not waste time in theater. In theater a lot of things are stressful: the team wants to go home, and it is expensive (20 pounds a minute). In a simulator, it can be £20.00 an hour.

- Training lists are 70% efficient, but I think it will also give someone confidence. You can have a programme saying that after 10 simulation sessions "I've done this, I've been graded by this by the AI, I can move my instruments, etc." You can also grade surgeons and say whatever they need to work on. You can document that and do it in a non-stress environment.

Participant 6: The simulator I did before had to be made the day before and kept it in the fridge. Then you have to take them to the course in an ice box and over the course of the day, it just gradually melts away. The other issue is that when you move the probe up and down on the duct, it needs to be resilient and allow for smooth movement of the probe. Although in a simulator you could just put some lubricating gel, so that would not be a big issue.

Participant 7:

- it's a new technique and becoming a standard.
- I went into maybe two courses before for CBD exploration and they mainly concentrate on how to open the CBD, how to suture that. I think for the suturing whatever the material you are using it should be fine actually, the same for the choledochoscope.
- I think we are still at the beginning in training because there's still no special training for CBD's. There's for gallbladders but there's nothing special yet for the common bile duct. And yeah, I think trainees should be a bit more involved in this procedure these days, because I said it's really very well for a high-level trainees and experts.

Analysis:

- Fabrication of the bile duct: the bile duct is very difficult as well, because you want something that holds it shape, like the bile duct that normally holds its shape quite nicely, but it is also incredibly thin and so, it is very, very delicate to handle. It should also be resilient enough not to break when you run the probe along it.
- Training for surgery: One of the problems in surgery is that you often teach people in quite high stress environment. If you've got a good simulation, people should be having a day on the simulator before they do a surgery, then they should go in back to the simulator and do it again.

The reason for simulation is also it does not waste time in theater. In theater a lot of things are stressful: the team wants to go home and it is expensive (20 pounds a minute). In a simulator, it can be £20.00 an hour.

- This technique is quite new and need training to become standard.

Appendix L: Interview 2 guide

Realistic physical patient simulator for surgical training

version 1.1

INTERVIEW 2 GUIDE

SECTION 1

Introduction:

Researcher to tick box when complete:

19.	1 min	Thank the participant for participating	
20.		Explain the study in brief	
21.	1 min	Explain the aim of the interview: understand the tactile feedback of the organs	
22.		Explain that an audio-recording device will be used	
23.	2 min	Explain what will be done with the data o Anonymity and use of alias, thus we cannot trace back any persons o The recording files will be stored in a secure location at the University of the West of England until the completion of the PhD o The findings will be published hopefully in 2022 Ask address details if participant wants to receive the report of the findings	
24.	1 min	Explain that each part of the interview will take between 25 – 30 minutes	
25.		Ask if all information is clear and if there are any questions before starting the interview	

Researcher to switch on the recorder and explain to the surgeon.

SECTION 2 – AUDIO-RECORDER SWITCHED ON

THE INTERVIEW

We are now going to move on to the characterisation of the texture of the organs in laparoscopic common bile duct exploration.

The interviewer will provide a list of soft tissues to the interviewees (to display on the screen). These soft tissues will include the organs involved during the surgery and other types of soft tissues. The interviewer will also provide the list of tools used during the surgery.

Warm up: Can you confirm who you are and where you work and what are your responsibilities?

26.	**8 min**	**Describe the texture of each organ from the list when you are using the gloves?** (eventually give examples for better understanding: what do you feel when you touch the liver directly?) (IF there is a word that I am not sure with, can ask for a definition)	
27.	**10 min**	**Let me go to each stage of the surgery with you. During these stages, you handle the soft tissues not directly, but with different tools.** **When you are using different types of tools, does the tactile feedback change?** *During the surgery, you use around 15 different tools, that we can divide into categories:* - *tools that cut (monopolar forceps, scalpels, scissors),* - *tools that clamp (clip applier)* - *tools that move the tissues (forceps, irrigation/suction, dilatator)* - *tool that grasps (grasper, different types of pliers)* - *tools that explore (move in the CBD) (choledochoscope, wire basket, balloon)* **Do you agree with this categorisation of the tools?** **Could you describe how each category of tools influences the tactile feedback on the soft tissues?** **Could you imagine doing the same manipulation but on other tissues from the list, would it change the sensation?**	
28.	2 min	Is there anything else I've missed?	

29.		Thank you	
30.		If you know someone who might be suitable and willing to participate, could you please tell them about this study and ask them to contact me? Or could you give me their contact, and let me tell them that it was you who referred me to this person?	
31.		Reminder that you have the right to withdraw from this study within the next three months.	
32.		Reminder that any notes/recordings will be shared with surgeons to check for redaction of any sensitive information.	
33.		Thank you & Close + talk about broad study and workshop1 and explain that I might go back to them	

- **SWITCH OFF RECORDER**

Appendix M: Report interview 2

1. Recruitment

Number of invitations: 11

Number of participants: 9

Acceptation rate: 82%

2. Results of the interviews

Table 26: Responses of the participants during interview 2

14.	Do you agree with this list of soft tissues to include in a simulator? Would you add or remove any of the elements?

Participant 1: Yes.

Participant 2: Yes.

Participant 3: Yes.

Participant 4: Yes, but you could distinguish the cystic duct from the bile duct in the list.

Participant 5: You could also have bowel, colon, small bowel, and stomach… The omentum because it is probably there, sometimes stuck up because they can have quite bad adhesions.

Bowel: soft, pliable, depends a bit about which part:

- if it is part of the colon: quite thin, a lot made of collagen and stuff like that so it is quite tough, quite slippery
- the upper part of the bowel: quite thick, like a cuff, difficult to cut into, soft, pliable.

Participant 6: could add: fat and connective tissues. When you dissect down onto the bile duct, it usually by a thin layer of peritoneum and fat. And between the peritoneum and the bile duct itself is often connective tissue with just looks like spiders' webs.

Participant 7: could add fluids, like bile and water

Participant 8: could add cystic duct too

Participant 9: could add pancreas and remove skin

Analysis: Generally OK. Could add cystic duct, pancreas, upper bowel, stomach, fat, connective tissues, and fluids. Bowel is soft, pliable, thick, difficult to cut into, like a cuff. Stomach is thicker. The fat near the bile duct is less fibrous than the fat in the abdominal wall / feels the same. Connective tissue: like angel hair or spiders' webs, lots of little strands meshed together, like the lining of a coat, the sort of the polyester fleece on the inside of a warm coat or the stuff that's in the middle of a sleeping bag, fibrous, firm, hard to divide	
15.	Describe the texture of each item from the list when you are using the gloves?
Skin	
Participant 1: hard, tough, coarse, variable, coarse or smooth depends on where, elastic/there is elasticated elements, like an elastic band Participant 2: something elastics that is holding each other. Participant 3: quite variable, kind of soft, smooth Participant 4: skin around the umbilicus is: quite variable, sort of stretchy, slightly tough compared to other areas of skin, not like leather because that's probably too tough, like the skin of a pig, sort of slightly stretchy but firm. Participant 5: firm, elastic, depends on what type of skin it is (old skin, new skin, young skin). Normal skin: quite firm, blunt a knife when you cut through it, like pork skin or orange peel, elastic, soft Participant 6: like skin Participant 7: soft Participant 8: smooth or hairy, soft, or leathery, malleable (you can move it).	
Analysis: hard, tough (2), coarse (2), variable (3), smooth (3), elastic/there is elasticated elements (4), like an elastic band, soft (4), stretchy (2), firm (2), like pig skin (2), blunt a knife when you cut through, hairy, leathery, malleable	
Fat	
Participant 1: very soft, often oily after some manipulation, great deal of compressibility, very little elasticity, tends to tear easily, in a sort of	

proteinaceous sort of cocoons (these are sort of like some lipid pavement system space, but sort of slightly stronger, so capsules). Participant 2: something mushy, can be easily separated. Participant 3: slippery, soft, quite mobile. Participant 4: quite sort of soft, spongy, feels a bit like a mouse mat. Participant 5: gooey, quite slippery, less solid than skin Participant 6: slightly fibrous, not as resistant as skin, easy to get through, a bit like tough butter. Participant 7: soft Participant 8: soft, easily disruptable, easy to emulsify, you can rub it and fracture it
Analysis: soft (5), oily, compressibility, elasticity, tear easily (2), contained in capsules, mushy, slippery (2), mobile, spongy, like a mouse mat, gooey, not solid, fibrous, resistant, easy to get though, like tough butter, easily disruptable, easy to emulsify, you can rub it and fracture it
Muscle
Participant 1: soft, incompressible (not to the same extent as fat), slippery, respond to twitching when you bring electricity to it, the fibers will tend to split easily, but the fibers themselves are difficult to tear (easily splayed, but not torn), tendency to bleed, because they've got blood vessels through them whilst the fat less so and skin less so. The layers of your abdominal wall only make about 3 or 4 centimeters. The skin is the narrower portion, then the fat the larger, and then the muscle fairly consistently about 1-1.5cm. Muscle tends to be surrounded by a dense and fibrous material, which is much a harder fibrin. This is collagen based and is tougher and needs to be cut, which is difficult, but it's quite thin so you cut a couple of millimeters only. Participant 2: like a row steak. Participant 3: tense, kind of rubbery, dense. Participant 4: a little bit firmer, almost like stress balls that you can squeeze in your hand, slightly firm, you can also squash it. Participant 5: quite firm, depends what type of muscle it is, you don't often cut into it during a laparoscopy because you just put ports in, more live, twitches

when you touch it, respond a bit to diathermy it (it twitches because of the electricity). Participant 6: quite hard to get through, like trying to get through a steak or a piece of chicken. Participant 7: in between firm and soft Participant 8: tight, tense, firm encased in fibrous, tough tissue.
Analysis: soft (2), incompressible, slippery, respond to twitching when you bring electricity to it (2), fibers split easily, fibers difficult to tear, tendency to bleed, like row steak (2), tense (2), rubbery, dense, firm (4), like stress balls, can squash, live, difficult to get through, tight, tough, fibrous
Liver
Participant 1: soft, pliable, variable, variable concessions in textures depending upon how much fat infiltration and diseases, you can have a coarse outline, but the outline is generally smooth and soft, degree of compressibility (liver really compressed within the first centimeter or half a centimeter, after that you won't be able to compress it flat) and elasticity (it will bend over the top rather than tear), it has a compliance, it has a very thin fibrous capsule, which if broken, you will get a lot of bleeding from it and from the liver itself. Participant 2: very friable, with the capsule around it. When you touch this capsule, you feel that there is something protecting that very friable thing, but this capsule at the same time is very gentle. Participant 3: maybe like squid, very mobile, floppy, slippery Participant 4: very unusual, very smooth, feel like a kind of firm jelly, very soft, quite malleable, it doesn't sort of break Participant 5: quite soft, pliable, it will bleed a lot if you break the capsule to it, if it's very fatty it can be quite squidgy, if it is a big fatty liver, it's very difficult to retract, if it's a small liver you can bend it quite easily. Participant 6: like cold butter, quite resistant, easily penetrated. Participant 7: soft, depends if it is diseased Participant 8: soft, firm, fragile, can fracture, bleed easily
Analysis : soft (5), pliable (2), variable, depends on fat infiltration and diseases (2), compressible (liver really compressed within the 0.5-1 centimeter, after that you won't be able to compress it flat), elastic (it will bend over the top rather than tear), has compliance, friable, like squid, mobile, floppy, slippery, like firm jelly,

malleable, doesn't break, bleeds if capsule breaks (3), like cold butter, quite resistant, easily penetrated, firm, fragile, can fracture - Outline: sometimes coarse outline, generally smooth (2), generally soft, has a very thin fibrous capsule (2), gentle capsule, - If big and fatty: squidgy, difficult to retract, - if it's a small liver you can bend it quite easily.
Gallbladder
<u>Participant 1:</u> very soft, very thin walls (usually only a few millimeters), smooth in outline, can be overlaid with peritoneum (which is a, which again is a sort of thin fibrous lining which covers all the organs in the body, and that can sometimes be thickened), smooth, often blue/grey in color. If it's really full intense it has no compressibility, no grippability on it, and very little compliance. Once you take some of the fluid out from it, it becomes just like any bag and it just it will collapse on itself and then it becomes very compliant. It's fixed onto the liver, so it will move as the liver moves until it's removed. <u>Participant 2:</u> when you have a balloon and you inflate it and you deflate it and you have some water inside of it and some stuff. <u>Participant 3:</u> quite tense, like pressing on a balloon, there is fluid inside it, so it's kind of deformable, but there's a bit of back pressure when you press on it. <u>Participant 4:</u> incredibly variable, depends on how inflamed it is: - if it's a completely normal, thin-walled pristine Gallbladder, it's very, very soft and delicate, almost like sort of ribbon. - if it's really inflamed, it can be incredibly tough. More like leather, you almost can't get hold of it at all. It's so inflamed. <u>Participant 5</u>: the gallbladder, the bile duct and the cystic duct are all made of the same thing. There're just two which are tubes and one is big bag. So quite soft, pliable, quite easy to cut into. <u>Participant 6</u>: can grab hold of it and move it from side to side without tearing, like a thick children's balloon partially filled with water but not stretched. <u>Participant 7:</u> like a balloon full of water <u>Participant 8</u>: feels like a small partially filled balloon with grit, small stones inside it. It's smooth, it's difficult to grasp, it's a bit compressible, so it's a bit like a balloon with a... small balloon partially filled with stones in it.
<u>Analysis</u>: soft (3), thin walls (a few millimeters), smooth in outline (2), can be overlaid with peritoneum, smooth, often blue/grey in color, move with the liver, like a balloon with some water inside (5), tense, deformable, back pressure,

variable, pliable, easy to cut into, can grab hold of it and move it from side to side without tearing, compressible - if it's full: no compressibility, no grippability on it, little compliance. - If empty: collapse on itself, very compliant, like a bag (2) - if it's a completely normal, thin-walled pristine Gallbladder: very soft, delicate, like a ribbon. - if it's really inflamed: tough, like leather, difficult to get hold of it (2)
Cystic artery
Participant 1: 1 to 2.5 mm in diameter, the consistency like an arterial vessel surrounded by some fat, difficult to tear, can't pull it, very strong, tear at the weak point (entry of gallbladder), wouldn't be able to pull it to tear it, has tensile strength. Participant 2: slender shape structure, friable, some tense on it Participant 3: firm, you get the pulsations from it. Participant 4: tiny little thing, just like a little strand, almost like a little bit of spaghetti, sort of tough, like al dente spaghetti. Participant 5: like a piece of string, but not that tough piece of string, firm Participant 6: can dissect around it, can grab hold of it and move it side to side, element of fragility with it. Participant 7: soft Participant 8: tiny, feels like a small bit of string. That you can grab, it bleeds very easily.
Analysis : 1 to 2.5 mm in diameter, consistency of arterial vessel surrounded by fat, difficult to tear, very strong, tear at the weak point (entry of gallbladder), can’t pull it to tear it, has tensile strength, friable, tense, firm (2), pulsatile, like a strand, like al dente spaghetti, tough, like a not very tough piece of string (2), soft, can dissect around it, can grab hold of it and move it side to side (2), element of fragility with it, tiny, bleeds easily
Peritoneum
Participant 1: thin fibrous lining which covers all the organs in the body, and that can sometimes be thickened, overlying fibrous sheet, smooth, reflective, thin, very strong, a strong lining, once it's open it will easily tear along that line, can bleed. It will also be seen on the underside of the abdominal wall; once you go through the muscle, you will hit the peritoneum as being part of the abdominal wall, and that peritoneum will continue itself all around all the internal organs as well.

Participant 2: slightly elastic, friable tissue, like a sheet around the tissue

Participant 3: kind of very slippery, it's just such a thin film so it's all the stuff that's underneath it that kind of give how it feels

Participant 4: completely smooth, and very delicate, almost like silk, a bit stretchier than silk, maybe like lycra, like women's tights, smooth, can stretch.

Participant 5: quite firm, like a covering sheet,

- if it's non inflamed it can be quite tough and fibrous,
- if it's inflamed it can be quite easy to cut, quite gooey.

Participant 6: very thin, fragile layer, easily penetrated, easily teased apart, like the lining inside the cheek, bleeds easily

Participant 7: soft

Participant 8 : feels a bit like clingfilm, very easily disruptable, stretchy, you can sometimes see through it.

Analysis: fibrous, overlying sheet (4), thick sometimes, smooth (2), reflective, thin (3), strong (2), once it's open it will easily tear along that line (2), can bleed (2), elastic, friable, slippery (2), like a film, delicate, like woman thighs, stretchable (2), firm, soft, fragile, easily penetrated, like the inside of the cheek, like clingfilm, disrupatble, can see through it

- if it's non inflamed: tough, fibrous,
- if it's inflamed: easy to cut, gooey.

Bile duct and cystic duct

Participant 1:

- bile duct: fixed, dense fibrous material, compressible, can't elongate it, can't stretch it to any great degree, fixed by fibrous attachments to the blood vessels around and to the underlying structures (the pancreas gland and the duodenum), compressible if you push on it like a finger (get compression, but won't necessarily be able to stretch it or have any compliance), thick walled structure most of the time, consistency similar to the cystic duct, but the cystic duct predominantly has some muscle element in it, whilst the bile duct is mainly fibrous tissue, much harder.
- cystic duct: around 1- 2.5 mm to 5 or 6 mm, strong tensile strength, same consistency as the Gallbladder, wall thickness is probably about two or three millimetres, no compliability, won't stretch when you pull it, it will tent up the bile duct.

Participant 2: similar structure to arteries, more elasticity in the wall, rubberier than the artery itself, the cystic duct is slightly smaller and the bile duct is bigger.

Participant 3: firm, very similar to the artery to be fair, often it will be dilated during a CBDE, so it would be quite large, kind of firm, and tense The cystic duct often has these spiral valves so you can feel like there's bits to it rather than just a straight pipe. Participant 4: very soft, smooth like a normal Gallbladder and it feels much the same, can cut into it easily, got a little bit of stretch but not much, like sort of giant penne pasta. Bile duct and cystic duct are pretty similar. Participant 5: quite soft, pliable, quite easy to cut into. Participant 6: like the gallbladder, slightly thicker than the gallbladder, slightly more resistant to being damaged, easily cut open, like a thick silicone rubber tube, (about 1 millimetre in thickness). The cystic duct has the same consistency but the cystic duct diameters about two or three millimetres. Participant 7: soft, thick delicate/ cystic duct has some valves, tortuous Participant 8: cylindrical tubes, soft, can feel stones within them quite easily, can fill stents within them easily, compressible, smooth, can bend them, difficult to break
Analysis : bile duct: fixed, dense, fibrous, compressible (2), can't elongate it, can’t stretch it to any great degree, fixed by fibrous attachments to the blood vessels around and to the underlying structures (the pancreas gland and the duodenum), don’t have compliance, thick walled (2), hard, similar structure to arteries (2), elastic, rubbery, firm (2), often dilated, large, tense, soft (4), smooth (2), can cut into it easily (3), got a little bit of stretch but not much, like a penne pasta, pliable , thick, delicate, resistant, like the gallbladder, like a thick silicone tube, cylindrical tube, can bend them, difficult to break, can feel trough them cystic duct: some muscle element in it, around 1- 2.5 mm to 5 or 6 mm, strong tensile strength, very soft (3), very thin walls (usually only a few millimeters), smooth (3), can be overlaid with peritoneum, no compliability, not very stretchable (2), has these spiral valves so you can feel like there's bits to it rather than just a straight pipe, cut into it easily (2), a penne pasta, with valves, tortuous, resistant, compressible, cylindrical tube, can bend them, difficult to break, can feel trough them
Stones
Participant 1: variable, tend to be quite breakable, tend to be quite easily fractured, solid, can crumble, some are much harder and are literally as fixed as a stone would be. It varies from being yellow which are cholesterol-based stone, they tend to crumble quite easily. And then there's black ones which are from

breakdown products of blood, so they're harder. And then you get the mix lot in between.

Participant 2: there's different types of stones, but in general's it feels like Himalayan salt

Participant 3: hard, sometimes they're like gemstones, sometimes they are like gravel and they just disintegrate.

Participant 4: stones are literally just like stones. It's like tiny little pebbles, or sometimes they're more gritty, like gravel.

Participant 5: the stones can be quite so hard, or they can be quite crumbly. It depends on what they're made of. So, if there's sort of calcified stones, it can be quite tough and big, but if there are smaller ones, lots of small things, you can crush them quite easily.

Participant 6: like piece of pastry, can pick it up and move it around, but if you squeeze it, it crushes and falls to bits.

Participant 7: hard, firm, fragile

Participant 8: like stones, hard, variable

Analysis: variable (2), quite breakable, quite easily fractured, solid, can crumble (2), like Himalayan salt, hard (4), like gemstones, like gravel (2), disintegrate, like pebbles, gritty, firm, fragile

- Black stones: some are much harder, as fixed as a stone (2), tough, big
- cholesterol based stone: yellow, crumble quite easily, crush easily (2)

Should I include different types of stones in the simulator?

Participant 1: it doesn't matter about the type of stone. I think you just got to imagine it's hard and solid because the idea is you want to grip it and take it out, not really crumble it.

Participant 2: So usually if the stone goes to the bile duct, it should be a small stone, like a couple of millimeters, something very small.

Participant 3: if you got the nice stones that stay intact then it's much easier, the other type of stones, they just fall apart and then they're quite difficult to get out of that.

Participant 4: I mean, probably one type is probably OK. I mean, you know sometimes when you put the basket on, they can sort of they can start of crushing and crumbling into multiple pieces. I guess if you really wanted to make it realistic, I suppose you could have different types of stones, but I don't think that's such an issue. I think it's more about how you access the bile duct, make the cut in the bile duct, manipulate the instruments. Getting a basket around. If

you then start making the stones or crumbling difficult, it's just going to make things more complicated like I guess in a way what you're trying to simulate more is how you actually access the bile duct. Participant 5: it's good to have big stones and small stones because they do different things. The big stones tend to stay in the gallbladder and the smaller stones tend to drop out into the bile duct. And collecting them is a bit different sort. Participant 6: No Participant 7: / Participant 8: No, in the simulation it's important to have maybe the stones in different positions so you could have the stones in the Gallbladder, in the cystic duct or in the common bile duct, or in the common hepatic duct. You want to place the gallstones in different positions, because they each make… they all have different intricacies and different, slightly different problems to manage, But what they are doesn't matter. Participant 9: different sizes can be useful, not different types	
Analysis: Most important: different location/sizes not type	
9	Do you agree with this categorisation of the tools?
Participant 1: Yes Participant 2: Yes Participant 3: Yes Participant 4: Yes Participant 5: Yes Participant 6: Yes Participant 7: Yes, you could also separate the energy devices Participant 8: you also need introducers (some cylindrical tube to help introduce the camera into the bile duct into the Gallbladder) and sometimes you need dilators to dilate the cystic duct. Participant 9: Yes	
Analysis: Yes (mostly)	
10.1	When you are using different types of tools, does the tactile feedback change?

<u>Participant 1:</u> When you're dissecting with the hook, you won't necessarily feel the fat tissue the same, but you will feel the peritoneum more. But whilst using the Maryland, you might feel it on the fat tissue more. But so, the tactile feedback wouldn't because of the tools because that's defined by the tissue type, isn't it?

<u>Participant 2:</u> If you touch the tissue directly, you can have a better grip, better tactile feedback, better sense of what structure is underneath you, you can feel some pulsations, you can feel if it's just a structure with some fluid inside of it, like a bile. In laparoscopy, the tactile feedback and haptic the feedback is very different... it mainly depends on gripping and pulling these structures.

<u>Participant 3</u>: you get the same feeling of density with direct touch and with tools. You do get lots of tactile feedback from using laparoscopic instruments, but in terms of how they compare to open surgery, I guess you don't have this broader tactile sense, normally through your hands you can feel everything, all your fingers, whereas with your instruments you've only got the tips of the graspers which are holding stuff. So, I guess you do get that, the density of the tissues, how they respond when you are grasping, but you won't feel how hard, or how soft they are because of the graspers are working mechanically, it doesn't translate as easily through the instrument, I think.

<u>Participant 4:</u> I mean, I suppose. Maybe you get slightly better tactile feedback when you're using a sort of more precise instrument like a Maryland or something as opposed to a 5050 or a bowel grasper. You don't tend to get quite as much tactile feedback in a way. Where when you're using a more, you know, sort of more pointy instrument like a Maryland, you probably get a little bit more sense of what's going on, because the instrument is much smaller and shorter and precise. So, when you're dissecting, for example, if you're so stretching open tissue, you can feel it a lot more than if you were using a big instrument. But otherwise not especially.

<u>Participant 5</u>: /

<u>Participant 6:</u> It's very much reduced when you use laparoscopic instruments.

<u>Participant 7:</u> There is a difference because in laparoscopic surgery, you will lose your tactile sensation. So definitely it's different, but it's difficult to describe how different it is because for skin, for example, you're not going to feel it because you use the ports on the skin. So, in laparoscopy, you are feeling if something is hard or is very soft. For example, if you're grasping the Gallbladder, it’s different from grasping stone, but so the only thing that you can feel is like very hard and soft.

<u>Participant 8:</u> Yes

<u>Analysis:</u> The tactile feedback is influenced both by the type of tool (more feedback when using a more precise pointy instrument), and the type of soft

tissues. The tactile feedback is less precise and complete when using tools comparing to direct touch, but there is still feedback in laparoscopic surgery. You get a sense of the density of the tissue and how they respond to the instrument. You also use a lot of vision, but generally the tactile feedback is very strong because it is reciprocated up the shaft of the instrument. With all the tools, there is a resistance from the tissue; but the haptic feedback mainly depends on what you see, and how much tension can you see during the procedure. There is limited tactile feedback, but it depends mainly on your visual senses rather than the motor senses; while during open surgery, it depends more on your motor sense. You only feel the difference between very soft tissues and very hard tissues.	
10.2	Could you describe how each category of tools influences the tactile feedback on the soft tissues? (what do you feel when you are using this type of tools?)
Gripping/pulling tools	
Participant 1: you're mainly going to grip the gallbladder. Or if you're using bowel graspers, it's gripping on the bowel, so your tactile feedback will change depending upon what you're grasping. So, if you're grasping the Gallbladder and pushing it over or pulling it, that's quite hard and tough, and you need that feeling of […] you don't push too hard and similar with the bowel, you don't want to grip too hard because you don't want to damage the bowels. It really depends upon what you're gripping more than the tool itself, but you've got to make sure that you use the right tool for the job. So, the Maryland wouldn't be a very good bowel grasper because it will make a hole in the bowel and it wouldn't be a good gripping tool to push the Gallbladder over because it would just again make a hole in the Gallbladder, but it's good at dissecting fatty tissue. So […] the tool you use will depend, and it would depend upon the tissues that you're using it on. So, I suppose as a surgeon, I'm looking at the tissues and it's not so much that the type of tool changes the tactile feedback, but where the tool is being used. Participant 2: If you're holding on the gallbladder itself, you have to be very gentle because the gallbladder wall is very thin, and it might rupture. If you're holding to different parts, for example the bowel, the grasp itself, how you close, there is a lot of difference between that and for example when you grasp a gallbladder or something like that. Participant 3: For gripping and pulling tools the tactile feedback is kind of how you're squeezing the tissue between the two bits of the grasper. Participant 4: for the gripping tools you normally put one on the Gallbladder, which is pushed right in and that's handed your assistant and normally all you'll feel on that really is just the tension of the liver pushing back at you and the	

Gallbladder pushing back at you and you pushing into the abdominal wall, so that's what you're kind of feeling. It's really just the liver, Gallbladder in the abdominal wall pushing back against you. When you're holding the Gallbladder, it's more about your gripping and pulling the Gallbladder, but all that's pulling against you is the liver and the Gallbladder, pulling back into the body. <u>Participant 5</u>: The gripping pulling tools are easy. They've got grades of how traumatic they are, so whether they've got sharp teeth on them. The less traumatic are just there for gripping the Gallbladder and retracting it. And then I use what we call the 5050, but it's a bit less traumatic, which is to hold the gallbladder. And then there's the Maryland, the Maryland is also a dissecting tool which we used to put in and blunt dissect all the tissues. Most of the other laparoscopic gripping ones, they have a bit of feedback is whether or not they can do the job they are designed to do really. So, sometimes the gallbladder is very difficult to retract, it's very messy, it's thick walled, it doesn't grip properly, it keeps from falling out and sometimes you just need to use a good thing which will grip properly. Now the gripping tools really is if you can see what, if you can grip it properly and you can feel the grip, but often, it goes into a lock and then that's it I don't feel it anymore, I just pushed the tissues around. <u>Participant 6:</u> feel resistance when you hold onto something and pull it sideways or upper down. <u>Participant 7</u>: like grasping a balloon full of water, if tense and inflamed difficult to grasp <u>Participant 8:</u> resistant, feel that the more you pull on the Gallbladder the higher the resistance goes up, feeling of tearing (resistance gets less)
<u>Analysis</u>: (mainly grasping the gallbladder): hard and tough to push and pull (2), depends on what type of tissue (2), *need a feel of "not pushing too hard", gentle when you are holding it*, resistance when you are squeezing the tissue, tension from the tissues pushing back, pulling back, difficult to retract, hard to grip (2), feeling of griping (2), like grasping a balloon full of water, resistant, feel that the more you pull on the Gallbladder the higher the resistance goes up, feeling of tearing (resistance gets less)
Dissecting tools
<u>Participant 1:</u> if I'm using the Maryland correctly and I'm peeling the fat away or I'm peeling the peritoneum down, then I expect a little bit of resistance as the fat is attached to the gallbladder and I want to just get down and I'm using it in a very controlled way or I'm pulling it up whichever. Or I'm dissecting it to watch the planes opening up in the gallbladder. But I wouldn't use it in the same way if I was gripping bowel. In fact, I wouldn't use the gripping up at all, I would probably just used it as a rod and just try to sweep with the rod so it does. Visually I will use

what I see, the tool being used for to change how I use it and therefore the tactile feedback will change. Participant 2: mostly we can do the dissection with the Maryland because it has a slightly blunt, at the same time, tipped. And there is also the suction. We can do a little bit of dissection with it and there is a big difference between the two. The suction can cause more tissue to be to be dissected at the same time, it has a more of a sharp tip that can cause a little bit of tear into the tissue. And there is also the hook. And the hook is this small tool. The tip on it that's hooked like this usually can do more final dissection with it, but you got to be careful about the energy or the thermal spread that happened from the tip of the instrument because it uses energy. And there are also different types, but they don't use it in laparoscopic common bile duct exploration […], it has different grips. And it does take the tissue in different ways. Participant 3: you're often not doing too much with the dissecting tool in terms of tactile feedback. Often, you get the hook behind the peritoneum and pull, so it's a pulling sensation, which is the difference between open surgery and laparoscopy. In open surgery, you wouldn't be pulling stuff, you wouldn't be picking at it with the hook because you would just be using the diathermy to open up the peritoneum. Participant 4: When you're dissecting, you're not feeling a pull. It's more you can feel if something's feels hard or soft; when you're pushing against it, you can tell whether it's going to be something that easily separate, so it feels really hard. Participant 5: Oh, I suppose not. Well, […] I use it to dissect things bluntly, to push things down. And it's quite a useful tool actually, so this this the sucker is quite good blunt dissector which you can just use. Yeah, the dissecting tools are really either sharp dissection or blunt... Participant 6: they're used to tease things apart so imagine you put a pair of scissors into something and then open the scissors to tease things apart. Participant 7: no resistance, very smooth, resistance if dealing with hard stuff Participant 8: feel that plunging into tissue, feel pulling back and feeling the tissues give way.
Analysis: resistance (4), pulling sensation (2), feel if something is hard or soft when you're pushing against it, *feeling of if it's going to easily separate*, feel the thickness, very smooth, feel that the more you pull on the Gallbladder the higher the resistance goes up, feeling of tearing (resistance gets less), feel that plunging into tissue, feeling the tissues give way.
Clamping tools

Participant 1: I'm listening out for the click. But not all clips have that noise, some don't and you have to pull really hard, and you don't know how hard that's why I don't particularly like them because they say "I want to squeeze it really hard" again and you're trying to put this clip across the duct like a 2mm metal pawns, squeeze it across and obviously it's a really thickened duct you're never going to: the clip will bend over rather than they've been pinched it together. But we use these particularly special ones here at the hospital, they have a little clip on it which goes click and you know that then it's locked in place. So, these are different but not everywhere has those. So, some you have to really squeeze hard until your knuckles are white. And then you put another on above it, and some people even put another one on to make sure it's secure. And these are these are metal ones. So, the feedback you get from the ones we'd use in my hospital we listen out for the Click but perhaps the rest of the country don't, and the rest of the country may use these clipping one, which you then have to really squeeze tight. Participant 2: Usually clamping tools are in open surgery. It's very useful as it gives you this grasp on the tissue and also for laparoscopy, we use it sometimes but we use different type of tools that usually we use it as a gripping at the pulling tool, but we use it also as a clamping tool. Participant 3: you get that "click" when the clip is properly applied. Tactile feedback wise, unless you're clipping on top of the stone, which you shouldn't be, that should be a relatively straightforward movement because you've removed all the tissues surrounding the thing you're going to clip. Participant 4: The clamping tools, to be honest, you get absolutely no feedback from the tool because they're just a metal. The ones I used for putting on my clips, you literally slide behind the thing and then you just you just click it, and it fires the clips, I don't really get feedback about whether it feels. Really, it's rare that I really feel that it's particularly hard or particularly easy. Participant 5: But Clamping tools, I mean, they're really clips, but I don't really clamp anything during that, but I do use clips and I use hammerlock clips quite a lot. For that, so that would there's sort of vascular plastic clips which you put around cystic ducts and stuff and the artery. You can also use metal clips. You can put around there as well. They're quite good. Participant 6: not much feedback, feel the squeeze Participant 7: hard feeling when you put the clips, bit of resistance, bit of pressure when you manage it.
Analysis: you do not get much feedback and are just listening for the "click" to know when the clips is properly applied. You only get feedback if you are clipping

on top of a stone, which you should not do. But there could be a bit or resistance or pressure otherwise.
Cutting tools
Participant 1: As you would expect when you are cutting an elastic band with a pair of scissors on a long shaft, you'd expect to get that sort of toughness. Sometimes the scissors are sharp and then you don't really get much feedback and sometimes, most often they're blunt and you have to sort of chump away like your kitchen scissors. It's awful, but you are cutting through very thick, dense tissue. Once you've squeezed the pipe together, you're obviously going to cut through quite a dense piece of tissue. So, you are going to get feedback and then the scissors don't often cut through in one go. They usually take one or two goes to cut through. Participant 2: A cutting tool mainly is the scissor and the laparoscopic scissors is very fine. Of course, these are very smaller than the open scissors. And there's also the Indo knife which we open the common bile duct with it. Participant 3: So, when you're cutting, you're feeling the density of the tissue as you're going into it. Whereas with the gripping and pulling tool you just kind of.... Participant 4: You get a little bit of feedback; I suppose as you cut but not much to be honest. With the hook you definitely get feedback because you are hooking into tissue and pulling up and pulling back away from the Gallbladder so that the peritoneum and the Gallbladder will be sort of pulling into the abdomen. You'll be pulling out of the abdomen so you can definitely feel sometimes when the peritoneum is very thickened. It feels hard when you're cutting through with your hook. Participant 5: And the cutting tools really is a diathermy. So, for the scissors, I always ask for a good pair of scissors because often the scissors we have on a laparoscopic tray, we call them chewers because they chew tissues rather than things. They're alright for cutting things like pieces for this string and stuff like that, but they're not good enough for cutting the bile duct because they'll just macerate the edges and stuff like that, so I often ask for a special clean pair of scissors so they're sharp enough to give a very good clean cut in the bile duct. I don't used diathermy near the bile duct, but you can use the diathermy hook for cutting things like the cystic artery and stuff like that. Participant 6: very little feedback, with feedback is more visual than haptic. You see it cutting rather than feel it cutting. There is a little bit of resistance when you cut the bile duct, you put the knife on the bile duct, then you press and there's a bit of resistance which suddenly gives way as the as the knife goes in. There's not a lot of feedback you do most of that by vision.

<u>Participant 7:</u> resistance but very minimal, depends on the type of scissors (sharp or blunt), depends on what you are cutting, cut something soft <u>Participant 8:</u> very gentle, like a knife cutting through cobwebs, very easy
<u>Analysis:</u> similar to cutting an elastic band with a pair of scissors on a long shaft, toughness, *need several goes to cut through*, feeling the density of the tissue, hard to cut (2), feeling of thickness, resistance, depends on what you are cutting, feel softness of tissue, resistance when you start to cut, like a knife cutting through cobwebs - if the scissors are sharp you don't get much feedback (2) - if they're blunt: more feedback
Scoping tools
<u>Participant 1:</u> it's quite tricky because you got to guide your scope through the laparoscopic porthole, put it down and the [..] guide it into the bile duct opening […], and then you got to change your view and look at what the scope is looking at and it's a matter of guiding it through what you see at the end of the scope rather than what you're watching in the camera […], and that's quite tricky. Sometimes you don't get the feedback that you expect because the camera is not moving forward. So, if you were pushing in, you would expect the camera to move forward, but it doesn't because you're working with a bended instrument inflexible instrument, so when you're pushing all it's doing is create more bend, rather than actually directing it to the end of the scope and pushing the scope forward. So, tactile feedback can be misinterpreted with the scope. It's very, very difficult to get a clear view but, […] scoping, once you put it in, there's some element of it being mis-interpretable. <u>Participant 2:</u> so, I don't have any experience with the choledochoscope or the common bile duct scope that they use. I've seen other people use it. It looks quite similar to the other endoscope but more fine of course, and small diameters, and I think it's manipulation and orientation is very, very gentle rather than the other scoping devices. <u>Participant 3</u>: I guess the tactile feedback from putting the scope and things in is very different because it is a different movement, you're pushing something through a pipe as opposed to just holding and moving stuff. So, scoping tools wise, if there's a lot of kind of crowd in the bile duct then it can be quite difficult to advance the scope or you can't get a view. And tactile feedback wise, I guess, sometimes it can be difficult to advance the scope, but often we'd only be doing a laparoscopic common bile duct exploration if the bile duct is big enough so it should go down pretty easy. <u>Participant 4:</u> The scoping tools you do get feedback. Putting in the laparoscope you'll get feedback in terms of if you are having to push quite far into the

abdomen, […] you can feel on the abdominal wall when you're moving on the outside where there's a little bit of tension moving from side to side but that's about it. But when you're using the choledochoscope, you get a little bit of feedback in terms of it feels like it's running smoothly down into the bile duct or whether it feels like it's hitting an obstruction, you can feel that. Normally if it's getting stuck, it's more sort of catching on the port of it or you sort of pushing in too much and it's all bending inside the abdomen which is why I tend to have quite long ports so I can push it right down onto the bile duct. Once you're inside the body, I normally tend to sort of use my thumb to move the tip up and down and then twist my hand clockwise anticlockwise just to try and get myself centralised so that you can see the lumen and once you've got the lumen it's normally just the case of experiment. As you move down to sort of going up, down, left, right? Or twisting. I mean it's normally an anticlockwise clockwise in an Uptown with your thumb and that's how you sort of advance the instrument, I mean, if you try and think about it too much, I find it becomes too difficult. You just literally have to kind of move it around and advanced it where you can see the lumen and not try to think too much about it. But you'll feel if it's getting… Sometimes it just feels really difficult to advance, and it may be that you haven't quite got your scope aligned at the right angle.

<u>Participant 5</u>: we used two different types of choledochoscope as we well, I used to use a 3 millimeter one and the 5 millimeter one. There are two types of approaches to the bile duct, when doing trans-cystic approach, you can use a 3-millimeter choledochoscope put it through there and sneak down and stick down as the bile duct, but you often get caught out because the stones are too big to attract down there, so you end up sort of... Sometimes it's just easier to do a trans-ductal one when you make a hole in the bile duct and just scoop out the stones like that. In that case I always use the 5 millimeter one because it has a better view, and you get more light down there. It's easier to control, the 3 mm one it can bend very easily, it can be quite difficult to control and get down into the right place.

<u>Participant 6:</u> You don't really get feedback with those because they are so remote from the end that you're working with, it is very distant to the to the handpiece. So, there's not a lot of feedback. Most of the feedback there is by watching where it's going and what the view is like rather than actual any haptic feedback.

<u>Participant 7</u>:

- trans cystic approach: sometimes there will be a bit of resistance because there are some valves sometimes and the cystic duct will be a bit tortuous. Or if there is a stone blocking the cystic duct, there will be loads of resistance.

- when you're putting the scope in the CBD there should be no resistance except if there is a really very big, impacted stone that you are pushing on it, but most of the time there will be not resistance.

Participant 8: they'll be resistance. You need to twist and have mobility in bi-planar. But also, you're going round corners, you may not see any resistance. It looks like a totally open tunnel, but because you're kinked up here, you can't…. You're getting resistance here, although it looks clear down here, I can't go because of this bit is bent and pushing. Sometimes you have to have what's called off camera resistance, and that's because you've kinked the choledochoscope in such a way that it's causing resistance.

Participant 9: resistance

Analysis: tension to put the scope inside the duct, pull and push (4), resistance in cystic duct, resistance against a stone, *tactile feedback can be misinterpreted (2), manipulation and orientation very gentle,* if there's something in the bile duct then it can be quite difficult to advance the scope (2), often we'd only be doing a laparoscopic common bile duct exploration if the bile duct is big enough so it should go down pretty easy/running smoothly (3), *scope bends easily (2), difficult to control and get down into the right place,* not much feedback

the laparoscope: on the abdominal wall there's a little bit of tension moving from side to side.

Suturing tools

Participant 1: you feel that quite a lot actually. Thick fibrous tissue: when you're stitching the bile duct closed, you'll feel the thickness of the tissue as you're pushing the needle through it. So that's really important to have a feel of knowing that you've taken a good bite. You take a good bite of the tissue, but you don't want to go too far away from the edge. But you do feel that when you've got in a good bit of wall of the bile duct, because you can feel its resistance. And because you've got a hole in the bile duct and you've got to put your stitch through it, you will feel that the bile duct will compress because you've got a hole there so it will compress more and you've got to push through what is effectively quite a thick bit of fibrous tissue and drive the needle through without catching the back wall of the bile pipe, so you don't want to push it through too hard and then pick up the bottom of the pipe, because then you just close the pipe off. So, you've got to have some feedback, so that's really important that you know that you've gone through the wall but haven't picked up the back wall.

Participant 2: Suturing tool is the needle Holder. There is a couple of type of needle holders: there are straight ones, and the curved ones, there is right-handed and left-handed. But in general, the movement itself is quite different because there is a passing point in the open surgery you have these small needle holder which is exactly like a distance of maybe 10, sorry 20 centimeters, 15

centimeters, but this new trim tool in the laparoscopy has a more taller and so it's about more than 30 centimeters and usually to handle that you got to give the force with the same exact what you call precision to give that movement at the tip of the 30 centimeters tool. So, it's a little bit more challenging. <u>Participant 3</u>: you're pushing the needle through the duct tissue so that's something that's slightly different. Although for the suturing portion perhaps there's no real difference, in terms of laparoscopic surgery or open surgery in terms of tactile feel, I don't think so to be honest. I don't think there's a huge difference between open and laparoscopy for the tactile feel of a lot of the things, broadly speaking. And in suturing tools, I guess sometimes the tissues are a bit kind of tough, so getting a bite in can be quite difficult. So, I guess tactile feedback from that... of Almost like a rubbery feeling as you're going through the tissues. <u>Participant 4:</u> when you are pulling the needle, I suppose you will get some feedback. I mean normally when you're suturing a bile duct, it's so thin, you can you sort of see yourself pulling it through, but you don't normally feel much resistance from it, it normally just glide straight through the bile duct, but when you're pulling with your left hand to pull the thread through, you can sort of feel tension when you're tying your knots and with your main needle Holder, you feel the tension as you tighten the knot. But that's about it really. I don't tend to get too much feeling on the bile duct itself, because it's such a thin, delicate structure. <u>Participant 5</u>: And the suturing tools. There's a variety of things, really. I use a variety of different needle holders. We have three different types, I think, and it depends on the day, which ones comes. I mean, I like the type X and I can't remember what the other ones are called, but I use them sometimes when they're around, so it's it. It really depends. It's a bit of a mix and match. So, I didn't bile duct exploration three days two days ago now, but I use the S collapse suturing things. The 5-millimeter camera and good scissors. And the hammerlocke clips? Yeah, so that's all really what I used. <u>Participant 6:</u> feel the hold of the needle, very visual <u>Participant 7:</u> very minimal resistance because very soft tissue <u>Participant 8:</u> feel the point of the needle is going through different tissues, initial resistance, that gives, turn it through pull it, pull it through, resistance as you're pulling through
<u>Analysis (</u>stitching of the bile duct): Feel: thickness of the tissue when you put the needle, *"you've taken a good bite",* resistance from the bile duct wall, *the bile duct will compress because it has a hole*, resistance when you push through thick fibrous tissue and drive the needle, *need to not push it through too hard* (to avoid catching the back wall of the bile

pipe), tough tissue, difficult to get a bite (2), rubbery feeling, not much resistance form the bile duct (because it is thin and soft) (3), glide easily, tension when you're tying the knots.	
10.3	Could you imagine doing the same manipulation but on other tissues from the list (example: suturing the liver), would it change the sensation? Or do you feel the same thing using the tools despite changing the type of tissue you perform an action on?
Gripping/pulling tools	
<u>Participant 1:</u> it's all really determined by the tissue that you're dealing with. You do get good tactile feedback. You use a lot of vision and you use a lot of shapes and shadows, but generally the tactile feedback is very strong. It's reciprocated up the shaft of the instrument, so you do feel it and that's lost in something like robotics when you do robotic surgery. That feedback is definitely lost because it's going through the controls, so you don't have that. <u>Participant 2:</u> with all these tools you have resistance on the tissue when you pull it out, pull... for example, the gripping or the pulling tools as the clamping tools usually, the haptic feedback itself, it depends more as what you see, how much tension can you see during the procedure that you're making through the instrument? However, you can feel, of course limited tactile feedback, but mainly it depends on your visual senses rather than the motor senses, which in comparison, if you compare it to open surgery, it depends more on your motor or the feeling that you have in the inside and the tissue while you're gripping and pulling. And that's what I can think about out of my experience. <u>Participant 3</u>: So, like the Gallbladder, if it's tense, it would be very difficult to grip, but very easy to slip off. If you're grabbing muscle or something, then it's again, it's more tense versus if you're gripping fat often it taps and tears, it’s soft, so you can tell that it's not much strength to it. But again, if you're moving the liver, for example with the gripping or pulling tool, you couldn't, you feel it like flop around. It's not very kind of stable, it often.... it moves around your instrument quite freely because quite slippery. <u>Participant 4:</u> If you are gripping the colon, you'll get some feedback, because if you pull it when its peritoneal attachments are, it'll kind of it'll pull against you. If you've lifting up the small bowel, if it's all on mesentery, it'll just lift up very easily and you won't feel much resistance at all. So, when you walk in the small bowel, you don't tend to feel much resistance, you're feeling a little bit just to the weight of the bowel, but that's about it. Whereas if you're manipulating colon or something like you're trying to lift up the appendix, you'll feel the tension on the appendix, so if you're lifting up the uterus to have a look at the ovaries, you'll feel the tension of those peritoneal attachments, and that's normally what's giving you the resistance. It’s normally attached but sometimes with small bowel or	

colon it might be the weight, the weight of the structure itself. You know if you're trying to lift up the sigmoid, for example, sometimes that can be quite heavy because it's by gravity. Trying to drop back into the pelvis all the time. And it's got poo in it, so it tends to be a bit heavier.

Participant 5: Most of the other laparoscopic gripping ones, they have a bit of feedback is whether or not they can do the job they are designed to do really. So, sometimes the gallbladder is very difficult to retract, it's very messy, it's thick walled, it doesn't grip properly, it keeps from falling out and sometimes you just need to use a good thing which will grip properly. Now the gripping tools really is if you can see what, if you can grip it properly and you can feel the grip, but often, it goes into a lock and then that's it I don't feel it anymore, I just pushed the tissues around. But that really is... a lot of that gaining that haptic feedback is a lot when you learn laparoscopic surgery, you need to do it hundreds of times before you get confident. I mean, you can get confident doing it a couple of times, but to get good and confident. You can you need to hundreds of times. And it comes very natural, what tissues, I mean I know when I press the liver I sort of I can see, it's on screen and I sort of know how much to do it now and I rarely would damage it, but in the past I get bit... when I see novices doing it, I sort of get quite worried this yeah.

Participant 6: you can tell whether you're holding onto a resistant tissue or a pliable tissue, or off fatty tissue, you can tell a degree

Participant 7:

- Gallbladder: like you're grasping a balloon full of water. There are different grasping feelings for it: if it's really full of stones, if it's very inflamed, distended, sometimes we can't even grasp it. You need to aspirate before you cross because it will be really very tense, it's difficult to grasp it. So, it depends on the type of the Gallbladder actually.
- common bile duct again: manipulate it very minimally.
- Liver: a bit harder than the gallbladder if we grasp it but we try to avoid that.

Participant 8: if you're pulling on bowel, that's quite fixed, so you know you'll get a lot of resistance; the liver, also fixed you're trying to push a heavy weight up against itself so you can get different sensations when you're doing that. The intra-abdominal fat at the omentum is really easy to pull out, that whizzes around, you can move that with very little resistance

Participant 9: there is quite difference between gripping the duodenum or stomach or Gallbladder. But then the Gallbladder itself can have quite a lot of variation. If it's a very thin-walled Gallbladder compared to a chronically inflamed gallbladder with an impacted stone, and I think that's one of the differences if you trying to grip the stone within the bile duct or milk it, then you can you feel more

resistance there if you're using grasper. Between omentum or other things, you won't feel much feedback at all.
<u>Analysis:</u> it's all determined by the tissue you're dealing with. If you're holding to different parts, the grasp itself, how you close, there is a lot of difference. You can tell if a tissue is resistant or pliable or fatty. - on the bowel: *not to grip too hard to avoid damage,* fixed, lot of resistance - on a normal gallbladder: hard and tough to push and pull, *feeling of "you don't push too hard",* - on a tense gallbladder: difficult to grip (3), easy to slip off, depends on if it is inflamed or not - on muscle: tense - on fat: taps and tears, soft, *so you can tell that it's not much strength to it*, easy to pull out, whizzes around, can move with very little resistance - on the liver: feel it flop around, not stable, moves around your instrument quite freely, slippery, hard to grasp, fixed - on the colon: peritoneal attachments pull against you, tension from those peritoneal attachments, resistance - on the small bowel: if it's all on mesentery: lift up very easily and you won't feel much resistance at all, feel a little bit just to the weight of the bowel
Dissecting tools
<u>Participant 1:</u> it's all really determined by the tissue that you're dealing with. You do get good tactile feedback. You use a lot of vision and you use a lot of shapes and shadows, but generally use the tactile feedback is very strong. You know it's reciprocated up the shaft of the instrument, so you do feel it and that's lost in something like robotics when you do robotic surgery. You know that feedback is definitely lost because it's going through the controls, so you know you don't have that. <u>Participant 2:</u> <u>Participant 3</u>: the density... it is very similar to cutting, so the skin will be more dense than the fat and then the Gallbladder and the surrounding structures. So, it's very similar to the subcutaneous stuff in terms of its density and its tactile feel. And so probably use this is cutting and dissecting as being very similar in a way. Although realistically dissecting wise in a lap chole you're going to be taking the fat away from everything to free up those structures that you're going to cut. So, I guess you cannot use the dissecting tool and the cutting tool on the same thing. I mean this is very difficult to give like a comparative. You know a comparative description because you just really use dissecting tools on the artery per say.

Participant 4: the only other sort of dissection I would be doing would be for things like when you're doing hernia repairs or bariatric surgery. Normally when I'm doing a hernia repair, when you're dissecting, it tends to be a lot of pushing and pulling, so I tend to use kind of two bowel graspers. And I'm sort of pushing one up pulling the other one down, and that that you tend to feel the force of pushing apart tissue where you're sort of separating out the areola tissue. And sometimes you're pulling on the hernia sac and dissecting structures off it, so you'll feel the tension as things peel down off the cord and the cord, of course, is under tension because it's going to be pulling up on the testicle in a man. Still have that sort of force against you. Participant 5: the haptic feedback is a very important part of it, and especially when you're dissecting. You know when you're using the, let's say the hook diathermy, you often feel the tissue first before you start applying any electricity to it. You bounce the tissue in your hands and you feel what it feels like and see how you know... and then you use diathermy. When you've got that feedback and you're in, it's a very natural movement for me now, but I'm sure I've learned it over the years, what's easy to cut, what will cut. And it's the springiness and sort of like elasticities of it as well, which tells you a lot about the tissues inside. Participant 6: you can tell whether you're holding onto a resistant tissue or a pliable tissue, or off fatty tissue, you can tell a degree Participant 7: dissection depends on the tissue that you dissect and usually dissection will be for the gallbladder. For the CBD, we do very minimal dissection actually in or around it. And it depends If the gallbladder is inflamed there will be a bit of resistance, there will be a bit of hard tissue, but if it's not inflamed, usually it's really very soft, no resistance, especially if you're in the right place. So, it will like you are dissecting air. Participant 8: Trying to take the Gallbladder off the liver should be very easy with just fine cobwebs, but if the Gallbladder is in inflamed and angry and it's been left for six weeks then that'll be hard scar tissue or that connective tissue. And that that's very firm and difficult to sort of get through and has a much harder, fibrotic feeling.
Analysis: depends on the density. You can tell if a tissue is resistant or pliable or fatty. If hard inflame tissues: a bit of resistance/otherwise no resistance (2)-> difficult to get through, hard feeling - skin is more dense than the fat. The gallbladder and the surrounding structures are similar to the subcutaneous layers in terms of its density and its tactile feel. - Force from the tissues under tensions pulling

- using the hook diathermy: you often feel the tissue first before you start: you bounce the tissue: learn if it will be easy to cut, if it will cut, springiness and elasticity of the tissues
Clamping tools
Participant 1: it's all really determined by the tissue that you're dealing with. You do get good tactile feedback. You use a lot of vision and you use a lot of shapes and shadows, but generally use the tactile feedback is very strong. You know it's reciprocated up the shaft of the instrument, so you do feel it and that's lost in something like robotics when you do robotic surgery. You know that feedback is definitely lost because it's going through the controls, so you know you don't have that. Participant 2: Participant 3: you don't need clamping after the cystic artery and the cystic duct, you tend not to have to clamp anything else. There's no real difference, I found, because you should have cleared everything both sides, so it's just putting out the clips into these large. No big difference. Participant 4: In terms of clamping things, when I'm using staplers and clips the stuff, normally with the staplers, you'll sometimes get a little bit of tactile feedback if you're clamping a particularly large piece of bowel, you can sometimes feel that it feels quite hard when you clamp across it. But you will seek out a bit of feedback by watching it on the screen. You can see where it looks like it clicks together easily. And that you tend to sort of feel in your hand as you crunch the stapler shut. Participant 5: / Participant 6: / Participant 7: No resistance because all very soft
Analysis: There's no real difference between tissues except if you are clamping something very large you can sometimes feel that it is quite hard when you clamp across it. But you will seek out a bit of feedback by watching on the screen, you can see where it looks like it clicks together easily.
Cutting tools
Participant 1: it's all really determined by the tissue that you're dealing with. You do get good tactile feedback. You use a lot of vision and you use a lot of shapes and shadows, but generally use the tactile feedback is very strong. You know it's reciprocated up the shaft of the instrument, so you do feel it and that's lost in something like robotics when you do robotic surgery. You know that feedback is

definitely lost because it's going through the controls, so you know you don't have that.

Participant 2: there is a big difference if you cut through connective tissue or just peritoneum fat, it's very gentle to cut, it's very easy. When you cut through something with the wall on it, like for example the common bile duct or the cystic duct, there is more rigid, more resistance as these tissues has walls on it. It has more connective tissue, an elastic connective tissue.

Participant 3: for cutting you would have a difference in the density. So, cutting skin then that would obviously be tougher than if you're cutting fat, which tends to pull, go through easily, muscle again, it's fibrous, it's like cutting through meat. And then Gallbladder, all that kind of stuff, the Calots which you are dissecting is largely fat so it is similar to the fat intra subcutaneous fat. And in terms of artery and bile duct and all that there's a more density, it's denser than skin and the subcutaneous fat.

Participant 4: if you're if you're cutting through the thick and inflamed appendix, you definitely feel a bit tougher than cutting through the cystic duct normally. So, you will feel as you cut, it just feels slightly harder to move the blades together to cut.

Participant 5: I'm very fussy about the knife. This is called a micro-French knife, because sometimes we've used a knife which is called the Berci knife, we used to use this one and it was often blunt because it was a reusable blade. And it was frightening because it wouldn't cut through the bile duct and you're pressing it and you thought you were damaging the back end and stuff like that. But actually, having a good, very good sharp knife is very important to make the incision into the bile duct. Sometimes I use an 11 blade and I wrapped it onto the one of the things with the steril strip. A cutting tool... cutting tools, really is scissors. Good sharp scissors are very important. I'm not trying to use the usual ones; I mean you can really macerate the bile duct by not using it properly.

Participant 6: /

Participant 7: Not much feeling when cutting because very soft. Cutting the cystic artery, cystic duct, and bile duct feel all the same, minimal resistance.

Participant 8: The peritoneum cuts very easily, like there's no resistance at all, so that's much easier to cut than the fat Surrounding the Gallbladder, which has a bit more resistance

Analysis: for cutting you would have a difference because of the density and softness.

- peritoneum fat: it's very gentle to cut, it's very easy (3), tends to pull

- something with the wall (common bile duct or the cystic duct): more rigid, more resistance, more elastic connective tissue, it's denser than skin and the subcutaneous fat
- Skin: tougher than if you're cutting fat,
- Fat: tends to pull, go through easily, a bit resistance
- muscle: it's fibrous, it's like cutting through meat.
- if you're if you're cutting through the thick and inflamed appendix, feels a bit tougher than cutting through the cystic duct: harder to move the blades together to cut.

Scoping tools

<u>Participant 1:</u> it's all really determined by the tissue that you're dealing with. You do get good tactile feedback. You use a lot of vision and you use a lot of shapes and shadows, but generally use the tactile feedback is very strong. You know it's reciprocated up the shaft of the instrument, so you do feel it and that's lost in something like robotics when you do robotic surgery. You know that feedback is definitely lost because it's going through the controls, so you know you don't have that.

<u>Participant 2:</u> I don't have any experience regarding the scoping, and I think the expert members can give you more about this, but I can feel that when they start the procedure itself, there is a little bit of tension that can happen until you get the scope inside the duct because it's very small and it's millimeters of distance that can travel. There is a little bit of pull and push that can happen, but I don't have experience with that.

<u>Participant 3</u>: Probably not. If you're scoping something that's hollow, you would probably get the same kind of sensation as you're pushing the scope through.

<u>Participant 4:</u> Scoping tools I mean you don't normally use the choledochoscope anywhere else? It's just the laparoscope and that again is just going to be the same. It's just the tension on the abdominal wall as you move it around.

<u>Participant 5</u>: it's very important to get it right, so there's a real technique to it, and visualizing the bile duct it depends very much on how you position the scope and how you use it in your hand and how you twist it, because twisting it as well you got to look down from the cystic duct. Let's say you going in doing trans-ductal, you look down first of all and then you need to go down and look towards the ampulla. So, as you go down you need to twist the scope and bend the end as well so it bends and going up stream, you need to go up to the sum of the 4th orders of the bile duct sometimes you can get quite far up but it's very... endoscopic haptic feedback, it's difficult to quantify. Yeah, yeah, there's. But the important thing is keeping it steady when you're doing the bile duct exploration it. So, you need to... I sometimes use a for the smaller one, for the three-

millimeter scope, I use a metal sheath to go through and that helps to you, it helps to just keep the scope in place, while you can go up and down. Participant 6: / Participant 7: for the laparoscope it will be all the same because you are in a port. But it isn't comparable to endoscopy because it's other types of scopes.
Analysis: If you are scoping something that is hollow, you would probably get the same kind of sensation as you are pushing the scope through.
Suturing tools
Participant 1: it changes this dependent on the tissue type, so I do lots of suturing on bowel and the bowel is very thin wall and it's easier to do. Again, you need the feedback to know what layer you've gone through the bowel, because you got to go through one layer, but not through the whole layer. So, so you want to have some feedback to know where you are. You use a lot of vision for that. The bowel is thin and it's a bit easier to put stitch in it. I also stitch up at the muscle in the diaphragm and the muscles easy to stitch as well because you're going between the fibers, so between the fibers of the muscle it's quite weak, but when you're going across fibrous tissue, which is what the bile duct is made of, you can really feel that, so that's the thickest, probably in terms of native organ without there being a pathology. I'd say that was the toughest material to push through. It isn't difficult, it goes through, but you feel it. You do get feedback during the suturing because you're turning your wrist and you're driving the needle through and you do feel it when you're pushing it through. There is a lot of tactile feedback in it. Participant 2: When you go through the tissue it feels very different from the bowel, from the bile duct, from different tissue with soft tissue like the liver or even if it's just peritoneum fat that we use in suturing. The liver feels like a small resistance that can happen at the beginning, then it disappears when the tissues hit the capsule. In the common bile duct, the resistance is very fine. I haven't done any suture, but that's what I feel with other people do it. the suturing the bowel also feels very different, there is not the induction, so the tissue itself in the bowel it's very small resistance that you start with then it goes easier, if you compare for example to a liver or muscles. Participant 3: if you're suturing an artery or a bile duct or something kind of tubular, they often feel kind of similar, whereas […] if you're suturing skins would be much firmer in general, then the fat has gradients to hold on to, muscle will again have a bit more density to it when you're pushing the needle through. But the Gallbladder and liver, we never really have suture to do anyway, but the consistency is quite soft and it is slightly different to the artery in the bile duct. Participant 4: when you're suturing bowel […] or suturing the stomach, you can feel the as you pick up the stomach, it's definitely thicker, much thicker material

than suturing the bile duct, so you do get some feedback there. And suturing the small bowel, it doesn't feel quite so tough, but it definitely is a bit thicker than bile duct. You can just feel a little bit of tension as you as you're pulling up on the bowel. It's a little bit more mobile and the whole bowel can lift up, where the bile duct is fixed. Participant 5: it feels different as you put the needle for it. I mean, there's no doubt about it and it depends what type of needle you're using, but the bile duct feels a bit different than putting into the bowel, and it feels a bit different... I do laparoscopic suturing for peritoneum and hernias, and it feels a bit different then it's... Yeah, you get to know what each tissue feels like. And then you know how the needle goes through it as well, and how it holds the needle. So, if you can pull against it, I mean one of the feedback things, if you're looking at when you bring tissue into the fascia, you know it's how it feels within the fascia. It's quite an important indicator. Participant 6: when you suture, you can tell when the needle goes through, you can tell whether it's going through tough tissue or whether it's going through sort of less tough tissue. Participant 7: if you stitch up the stomach, for example, there is difference because the thickness of the tissue is really bigger and so you will feel more resistance. But with the CBD, most of the time we have really very thick walled CBD, but otherwise it should be very soft and very delicate, we need to be very careful when you stitch out the CBD because if you put lots of pressure you may injure it
Analysis: it depends on the tissue type; it feels very different from the bowel, the bile duct, the liver or even if it's just peritoneum fat that we use in suturing, you can tell the toughness of tissues - bowel: very thin wall (2), easy to do (2), need the feedback to know what layer you've gone through the bowel, very small resistance that you start with then it goes easier - muscle in the diaphragm: easy to stitch because you're going between the fibers, between the fibers it's quite weak, density when you're pushing the needle through. - fibrous tissue (bile duct): thickest, toughest material to push through, fixed, need to be careful - liver: small resistance at the beginning, then it disappears, the consistency is quite soft - tubular structure (artery, bile duct): feel similar - skin: firm, - fat: gradients to hold on to, - Gallbladder: the consistency is quite soft

- Stomach: much thicker material than suturing the bile duct (2) so more resistance
- small bowel: not so tough, thicker than bile duct, tension as you're pulling up on the bowel, mobile, whole bowel can lift up

11. 1	Would you agree with that: "Colour, appearance and location are more important than texture"?

Participant 1: to some extent I think I probably would agree, in the simulation environment. And […] there's a lot of variation in terms of the feel because it's to do with the thickness of the tissue and it will vary depending upon from person to person. But if you were to say how to take a relatively normal gallbladder out, you would recognise the different tactile feedbacks from someone that has got a very thick and inflamed Gallbladder. I think I don't know how true that is. I use tactile feedback, perhaps more than just the texture and the color.

Participant 2: I agree with that for laparoscopic surgery. With open surgery, it's the other way. […] so, the tactile feedback in laparoscopic surgery, it depends in multiple things rather than the feeling that you have or the motor feeling that you have in your hand, it depends on what you see and how much is the tissue stretched and what you see using the camera. Of course, there is a limit of tactile feedback, but it's not that by itself, it doesn't help, so it's multiple things to attack it.

Participant 3: I think to make an initial assessment the appearance and the location is most important, because you're basing it on anatomy. Texture is then important in making sure that you're on the right thing, obviously with surgery often you've got, like a bile duct or an artery coming close by, you often feel both and just feel which one has a pulse in it to make sure which is the right one. But again, you can see that with laparoscopy you have a look and you can see whether it's moving or not. So, I think I think appearance and locations is of primary importance. That tactile is also important as well.

Participant 4: I'm not sure whether necessarily the colour always is so important, because the colours can be so variable. Sometimes you can be fooled by the colour. And the texture again can vary so much, but again, you can be a little bit fooled. I mean sometimes when you're opening up tissue, you can tell that something is more likely to be an artery, because you're dividing or dissecting tissue and it's not dividing, and that's because it's actually a proper solid structure, so… It's a bit of a mixture, I mean I would say colour is less important, it's more about the texture and the feel of it gives you some sense of what it is, because when you when you're pushing around on the duodenum and looking where you think the bile duct is, etc. you can sort of feel you can feel the artery, for example and you can feel that stomach and duodenum and that has quite different feel to the bile duct, and knowing that things are in the location you expect them to be, those are kind of the important things to my point of view.

<u>Participant 5</u>: I think it's important to have the right color. I mean, I've done a lot of animal dissection and stuff like that and one of the best models is the pig. It's quite good to use and quite easy to obtain really, so it really is the best model. And you could sort of cut all these things off and sort of put blood into them, and some red juice through it and bile and stuff like that. So, making yeah... I mean I've done ultrasounds and rubber tubes and stuff like that and you can do it, and you can make sort of models and you can show, but it's a poor substitute for the real thing. But just getting techniques, I mean it's good for an afternoon to get techniques ready and see how different things are used. But there's a limit to that answer, really. It depends if it was all made of wood. I would say no. If it was all painted psychedelic colors but felt brilliant. I'd say no as well so. I would say they balance each other; I think.

<u>Participant 6:</u> equally important: texture, appearance, and location. Colour less important.

<u>Participant 7</u>: I agree

<u>Participant 8:</u> you need the colour to be as accurate as possible because otherwise it's not going to feel like a simulation. The fat has to be yellow; liver has to be Brown. Gallbladder needs to be a sort of greyish yellow depending on how much fat it is. Cystic artery needs to spur a bit of blood. You know the cystic duct needs to be yellowish. Common bile duct that needs to be yellowish, but there are deeper yellow than fat, bowel needs to be a pink pale pink colour.

<u>Participant 9:</u> I think it would be useful perhaps for the common bile duct to have a similar kind of marking so that it perhaps appears more black, green, and has some smaller crossing vessels to help distinguish it from the artery. I think the texture is quite important because it is quite thin and can be quite awkward to suture.

<u>Analysis:</u>

- I agree that colour appearance and location are more important than texture, in the simulation environment (4)
- I use tactile feedback more (do not agree) (2)
- they balance each other (3)
- Reasons:
    - lot of variation of the tactile feedback because it depends on thickness of the tissue and it will vary depending on the patient. (2)
    - tactile feedback in laparoscopic surgery depends on multiple things: the motor feeling, how much the tissue is stretched and what you see using the camera.

	- the colours are variable. - when you when you're pushing around on the duodenum and looking where you think the bile duct is you can feel the artery, and you can feel that the stomach and duodenum have quite different feel to the bile duct and knowing that things are in the location you expect them to be, those are kind of the important things to my point of view.
11.2	Or using the same material for different types of tissue that are not supposed to feel the same: gallbladder and liver?

Participant 1: there was a very good simulator […] that was really nice, it had different layers and you'd cut through what was like the skin, which was thick silicon, then you'd go through into a fatty layer, and I'm not quite sure how he made it, but it was definitely much more... you could say it was Fatty and you cut into it and it would part and it was very.... And then you got down to a thicker fibrous sheet, which we made from a material like a sheet of cotton. And it worked really well. And then you cut into that and opened up and underneath there was where you had to operate. And I thought that was really nice and it was variation and it did look much.... It did feel better. Actually if you want to do something slightly different, I think actually you want to try and make things slightly different. So certainly, I wouldn't get too drawn into the skin, Muscle, fat, that sort of thing because that's access. Once you're in, it's the Gallbladder, the fatty tissue around the base of the Gallbladder and the feel of the bile duct pipes that you need to you need and the bowel that might be around that area and the liver that might be the areas that you want to make slightly different.

Participant 2: sometimes when you cut through tissue you understand what you are you cutting and if there is a little bit more resistance, you get hesitant to what you're cutting exactly. But it's multiple factors in laparoscopic surgery, rather than open surgery you can do that just depending on the tension appearance in your hand or the haptic feedback in hand.

Participant 3: I mean, if you want to make it as realistic as possible, then using different materials for each of those things is useful because it mimics real life. Each of them has a subtle change in its density and stuff. There are similarities I mentioned before: the subcutaneous fat and the fat in the Calots are similar but again, they're not exactly the same. The fat in Calots is often softer. It falls apart easier, versus subcutaneous fat is slightly denser. So, I think using different textures would be a benefit in a simulator if you want to get as close to that to real life as possible.

Participant 4: I don't know. It wouldn't feel so realistic if everything was the same tissue. But you know, I mean it is a simulator, but it's quite nice to have different

feel for the tissue because that's what happens in reality when you do it, everything feels slightly different. Participant 5: it is important to get the bile duct right. What it looks like is not too important, but for sewing it up and stuff like that, it would be nice to get a good model for that, and cutting into it is quite important. Participant 6: if you have the same type of tissue for the Gallbladder, the cystic duct in the bile duct, that would be acceptable. For other tissues, it probably would be ok if the tissues were within the sort of elasticity, etc, boundaries of the material. I think you've got quite wide boundaries and I think if everything was within certain range of boundaries it would be fine. Participant 7: it would be ok Participant 8: Well, depends on how accurate you want to be. You know the difference between intra-abdominal fat and subcutaneous fat, pretty much the same. But between fat and liver is incredibly different. Participant 9: just need some resistance, but not much difference in between tissues. Would be fine to use same material
Analysis: - Having different types of materials for the different tissues is important (5) o Example of good simulator: it had different layers and you'd cut through what was like the skin, which was thick silicon, then you'd go through into a fatty layer, and it was definitely much fattier and you cut into it and it would part. Then there was a thicker fibrous sheet to mimic muscle, made out of a material like a sheet of cotton, and it worked really well. o It is important to make things slightly different: in particular: the gallbladder, the fatty tissue around the base of the Gallbladder and the feel of the bile duct pipes, the bowel and the liver o Why it is important: Sometimes when you cut through tissue you understand what you are you cutting and if there is a little bit more resistance, you get hesitant to what you're cutting exactly. o If you want to make it as realistic as possible, then using different materials for each of those things is useful because it mimics real life. Each of them has a subtle change in its density and properties. There are similarities I mentioned before: the subcutaneous fat and the fat in the Calots are similar, but they're not exactly the same. The fat in Calots is often softer, it falls apart easier, versus subcutaneous fat is slightly denser. Using different textures would be a benefit in a simulator if you want to get as close to that to real

life as possible. It wouldn't feel so realistic if everything was the same

- it's multiple factors in laparoscopic surgery,
- The skin, muscle, and fat are less important because that's access.
- it is important to get the bile duct right. What it looks like is not too important, but for sewing it and cutting it, it would be nice to get a good model

a.	Is it important that the simulator is moving?

Participant 1: No, I wouldn't get too into that. It is moving when you put your hand on the pulse, but we're doing it laparoscopically, most patients when they have laparoscopy are completely sedated and completely muscle relax so don't tend to move at all. Occasionally when you cut the cystic artery you can see the stump sort of pulsate and know that you've cut the artery rather than the duct, so that's quite a nice feature, but is it vital? Not really because you don't see it all the time.

Participant 2: /

Participant 3: /

Participant 4: No

Participant 5: Not so much, but what comes out of each tube would be quite good. And, if you're cutting into bile, you can see bile, it would be nice to see the fluid coming out. I think that would be important. That's a definite confirmation.

Participant 6: /

Participant 7:/

Participant 8: it is quite good when we use energy devices, seeing the blood vessels have a straight blood vessel pressurised. You make a cut in it. You can see it. Pausing away, jetting away and you take your energy device in and it breaks and seals, job done

Participant 9: Not very important (not much movement and don't think the bleeding is very important in simulation)

Analysis: No, but it would be nice to be able to see the fluid get out when you are cutting (bile/blood)

12.	Is there anything else about the simulator that you would like to tell me or to ask?

Participant 1: It depends, people's feelings on it will vary upon their experience. So, I think if you interview one surgeon and then, I suspect that you'll get variations in it but my personal opinion and my experience of seeing simulators is I felt that it was a much better experience learning a procedure which I felt was

more realistic and closer to the real life environment. I think having everything the same if you're going to sort of overlay an image over the top of a blank canvas sort of thing, I think the colors and the texture I think will make a difference because it will be nice to see if I go for the fatty bits around the Gallbladder, where the where the cystic duct and the cystic artery are, and if they feel differently that and they look differently they look different then, to my mind that that gives a good feel and if when I then identify the cystic artery in the cystic duct, they do feel like they are hard structure, solids, they're sort of a fixed structures. I would feel “Oh yeah, that's really it”. And you get that you'll get more of the feeling when you do a complex simulator like this. I think it would be better to have it if you could.

Participant 2: No

Participant 3: No

Participant 4: No

Participant 5: it's really difficult, I think human tissues are very difficult to replicate. The beauty of them is that they are so unique. Skin is an amazing thing, you can push and pull it, stretch it, it's very elastic and it's waterproof. It's evolved over 4 billion years because of exactly those properties it has and there's not many other things which share the properties of skin and I think it's quite difficult to replicate and all these things have unique functions. They're all quite unique things. My favourite would always be the live model, there's no doubt about it the. Tissues need to be elastic, but also bit fibrous as well, so they've got to have fibers and they're going to be a special type of rubber sheet, but it doesn't ping back like some rubber.

Participant 6: the attachment is important: if the bile duct was a piece of tubing strung between two fixed points, then that would be quite different to how it is in life because in life the bile duct is embedded in tissue throughout its length, so that would make a big difference to how that felt and how it performed in a simulator. Similarly, the Gallbladder is attached on one surface of it, so you can move it from left to right, but it moves around a central locus, so it's tethered.

I think the images are probably more important than the tactile feedback to be honest.

I think one of the things that is important in bile duct exploration is the relative distances of the port, and the skin from the bile duct itself, because one of the most important things to teach people is how to manoeuvre the port and the scope together to achieve your aim. And in order to do that, distance needs to be similar. For example, on a lot of simulators the distances in the realm of perhaps 20 centimetres, whereas in life it's more in the realm of about 10 centimetres.

Participant 7: It is influence by the thickness, the softness, and the attachment. Participant 8: Exactly it is what is it attached to and what is the consistency of the material you're trying to cut through. Peritoneum is the fine. Fibrotic scar tissue is the hardest; liver is quite firm. Gallbladder and cystic ducts there quite firm. Fat is very soft. Skin is actually hard to go through the skin, but once you're through then you're into fat and that's very soft and easy to push through. So, they kept their different feelings. Participant 9: I think the ultrasound, that is very easy to practice because it takes two or three minutes. And the main thing about that is trying to get position to acquire the image and learn how to manipulate the image. I think the main value in a model like this would be a) if you have a choledochoscope, getting them to manipulate that to get centred in the image, and then all trainees need improvement in laparoscopic suturing.
Analysis: - Tissues need to be elastic, but also bit fibrous as well, so they've got to have fibers and they're going to be a special type of rubber sheet, but it doesn't ping back like some rubber. - people's feelings on it will vary upon their experience. - it was a much better experience learning a procedure which I felt was more realistic and closer to the real life environment. I think the colors and the texture will make a difference because it will be nice to see if I go for the fatty bits around the Gallbladder, where the cystic duct and the cystic artery are, and if they feel differently and they look differently then that that gives a good feel and if when I then identify the cystic artery in the cystic duct, they do feel like they are hard structure, solids, they're sort of a fixed structures, then I would I would feel "Oh yeah, that's really it". I think it would be better to have it if you could. - Ultrasound images is more important than the tactile feedback - Importance of the realism in port placement - Depends on attachment and consistency (thickness, softness)

Appendix N: Validation of the number of participants

During phase 2 of HCD based studies, multiple evaluations are implemented to evaluate and improve the prototypes; for this reason, some studies suggest that the workshops should be concise with a low number of participants (Harte *et al.*, 2017). However, a low number of participants cannot offer statistically significant results. For medical devices testing, the FDA suggests that to identify 90-97% of the *usability problems**, a sample composed of 15 participants per major group or a minimum of 25 users should be enough. However, previous research defined models aiming to evaluate if it is possible to use smaller *sample size**. In their studies, they started with a smaller sample group of 5 participants and then conducted an analysis of the homogeneity of the group. The analysis consists of calculating the p-value of the group and the *discovery likelihood** of the problems. It allows to decide if it is necessary to find more participants in the study or if most usability problems were already discovered by the first participants (Borsci *et al.*, 2014).

Analysis of the discovery likelihood in the interview on the tactile feedback

To evaluate if the interview includes enough participants to be representative of what most surgeons think, I conducted a study to estimate the percentage of discovery or discovery likelihood of the responses to the problem brought by the interviewed participants. The percentage of discovery evaluates to what extend the problem has been covered by the interviewed surgeons.

To estimate the percentage of discovery, it is first necessary to calculate the p-value. The p-value can be estimated using different methods, in this research project it is calculated using two different methods described in the literature:

- The first method is the ROI method (Nielsen and Landauer, 2001),
- The second method is the GT method (Nielsen, Lewis and Turner, 2006).

Using the ROI method, the following equation defines the p-value:

$$p_{-value,ROI} = \frac{1}{n}\sum_{i=1}^{n}\frac{Number\ of\ problem\ discovered\ by\ participant\ i}{Total\ number\ of\ problems\ discovered\ by\ all\ the\ participants}, \qquad (15)$$

where n is the number of participants.

The GT method defines the p-value as follow:

$$p_{-value,GT} = \frac{1}{2}\left[\left(\frac{p_{-value,ROI}}{1+\frac{E(N_1)}{N}}\right) + \left[\left(p_{-value,ROI} - \frac{1}{n}\right)\left(1 - \frac{1}{n}\right)\right]\right], \qquad (16)$$

where $E(N_1)$ is the number of problems discovered by only one participant, N is the total number of problems, and n is the number of participants.

From the p-value, it is possible to calculate the estimated percentage of discovery by:

$$D = 1 - (1 - p_{-value})^n \qquad (17)$$

The discovery likelihood of the interviews on the tactile feedback is summarised in Table 27.

Table 27: Analysis of the discovery likelihood of the interview on the tactile feedback

Question	$p_{-value,ROI}$	D_{ROI}	$p_{-value,GT}$	D_{GT}
Descriptive of the soft tissues	0.287212	0.952505	0.179748	0.831917
Comparison of the tissues to other materials	0.163194	0.798803	0.071502	0.487105
Indirect touch through tools	0.333333	0.973988	0.225577	0.899815

With both calculation methods, the discovery likelihood is above 80% for the descriptive of the direct touch and indirect touch; however, it is below 80% for the comparisons. The comparisons are more subjective because the surgeons used comparisons coming from their personal experience like a comparison to the lining of a sleeping bag.

With these two models, it is also possible to estimate the number of participants required to get a given percentage of discovery likelihood. I estimated how many participants would be required to get 90%, 95% or 99% of discovery likelihood to each question and with each criterion. Because of the subjectivity of the comparison, I excluded this question from the rest of this study on the evaluation of the number of participants.

Table 28: Number of supplementary participants needed to increase the discovery likelihood according to the GTcriteria

Number of additional participants	Number of questions with less than 90% of discovery	Number of questions with less than 95% of discovery	Number of questions with less than 99% of discovery
0	2	2	2
1	1	2	2
2	1	2	2
3	0	1	2
7	0	0	2
8	0	0	1
13	0	0	0

According to the model, to get more than 90% of discovery likelihood to every question I would require 3 more participants; for more than 95% I would require 7 more participants; for more than 99% I would require 13 more participants.

Interviewing more surgeons does not guarantee more results because most of the surgeons gave very homogenous responses. This can be due to the fact that most of the participants are working at the same surgical unit in the same hospital. This is a limitation to the generalisation of the results; however, interviewing more surgeons from the same group does not guarantee a benefit to the study.

The low discovery likelihood can also be explained by the nature of this study which is based on the description of a sensation; the diversity of the vocabulary available to describe tactile feedback can explain such an outcome. This is visible in the study of Xue *et al*. (Xue *et al.*, 2014) which gathered more than 200 descriptive of fabrics with only 5 participants.

Analysis of the discovery likelihood in the interview on surgical simulation

To evaluate if the interview includes enough participants to be representative of what most surgeons think, I conducted a study to estimate the percentage of discovery or discovery likelihood of the responses to the problem brought by the interviewed participants.

Table 29 summarises the p-value and estimated discovery likelihood calculated using the two methods for each question of the interview:

Table 29: Evaluation of the percentage of discovery during interview 1

Question number	$p_{-value,ROI}$	D_{ROI}	$p_{-value,GT}$	D_{GT}
Soft tissues to mimic	0.626374	0.998984	0.498038	0.99197
Types of tools used during surgery	0.474654	0.988956	0.321641	0.933898
Categorisation of the tools	0.530612	0.99498	0.398324	0.971454
Big steps of the surgery	0.873016	0.999999	0.640306	0.999221
Small steps of the surgery	0.541528	0.995742	0.418579	0.977539
Decision points of the surgery	0.607143	0.998556	0.502551	0.992462
Types of simulators used previously	0.392857	0.981536	0.269965	0.919323
Important aspects of the simulator	0.275	0.923668	0.174536	0.784431
Aspect of the surgery to include	0.428571	0.988632	0.299479	0.942008
Timeframe for the simulation	0.333333	0.960982	0.216146	0.857478

The evaluation shows that the GT criteria is less optimistic than the ROI criteria, because the ROI method over-estimate the p-value in the calculation's method. I will focus on the GT method for further analysis.

The evaluation shows that the interviewed surgeons identified more than 90% of the problems for each question except the ones on the important aspects of a simulator and the one of the lengths of the simulation. In this first question, surgeon A identified several problems that none of the other surgeons identified; a possible explanation is that surgeon A is the only one with experience in building a simulator instead of just using them, making this surgeon more aware of the technical requirements. Therefore, surgeon A identified multiple problems connected to the fabrication of the simulator and not about its usage. The question on the length of the simulation has this result because surgeon E wanted a training system as long and complex as possible, and the others wanted quicker simulation systems.

According to this model, Table 30 summarises the number of supplementary participants needed to increase the discovery likelihood.

Table 30: Number of supplementary participants needed to increase the discovery likelihood

Number of additional participants	Number of questions with less than 90% of discovery	Number of questions with less than 95% of discovery	Number of questions with less than 99% of discovery
0	2	5	7
1	2	3	5
2	1	2	5
3	1	2	5
4	1	1	3
5	0	1	3
6	0	1	2
8	0	0	2
10	0	0	1
15	0	0	0

According to the model, to get more than 90% of discovery likelihood to every question I would require 5 more participants, for more than 95% I would require 8 more participants, and for more than 99% I would require 15 more participants. The number of participants to interview to get 90% of discovery is quite high and the low discovery can be explained by individual surgeons within the cohort having very different opinions than the rest of the group.

Similarly, as for the previous interviews, the surgeons are all from the same surgical unit in the same hospital, therefore, the results are not generalisable. Interviewing more surgeons from the same location would not bring benefits to this study; indeed, interviewing more surgeons does not guarantee more results because most of the surgeons gave very homogenous responses.

Appendix O: Responses survey tactile feedback

Softness	Thickness	Smooth	Elastic	Attachment	Resistance to gripping	Resistance to suture	Resistance to cutting	Resistance to pulling	Resistance to tearing	Tissue	Participant
1.5	2.6	6.6	10	5	10	10	10	10	10	Skin	1
10	9.1	8.9	0.3	4.8	1.2	0.4	0.3	0.4	0.3	Fat	1
5.4	8.7	1.7	9.6	4.4	9.8	9.5	9.4	9.6	9.4	Muscle	1
9.6	10	7	4.8	8.8	4.9	0.9	6.6	5.5	2	Liver	1
7.3	2.1	8.2	4.4	9.2	7.6	5.7	4.2	5	5.8	Gallbladder	1
6.4	1.7	7.2	4.5	9.4	6.7	5.1	4.7	4.7	5	Cystic artery	1
7	1.5	7.7	4.1	9.6	7.2	4.9	5	4.2	4.3	Cystic duct	1
8.5	0.1	10	9.2	0.3	0.2	4.7	0.6	1.8	1.4	Peritoneum	1
7.1	1.4	7.7	4.2	10	3.6	5.4	5.2	2.8	3.6	Bile duct	1
4.2	6.1	3	8.9	0	10	10	10	10	10	Skin	2
10	5.5	10	2.7	2.5	0	0	0.3	0	0.8	Fat	2
7.9	6.2	7.7	10	2.6	7.2	8.5	7.5	8.7	9.2	Muscle	2
8	10	10	8.6	10	6.6	3.8	2.7	8.6	3.8	Liver	2
7.1	4.6	10	6.7	7.2	5.2	7	7.2	8.4	3.7	Gallbladder	2
6.5	6.5	9.2	5.4	6.8	4.3	6.8	3.3	8	3.4	Cystic artery	2
6.3	4.4	9.2	5.5	7	4.3	7.2	6.2	8	3.4	Cystic duct	2
6.1	1	10	7	5.7	2.3	5.6	3	8.6	8.8	Peritoneum	2
7.5	3.9	9.2	6.3	7.9	4.1	7.7	6.4	8	3.4	Bile duct	2
3	7	3	7	1	9	9	9.5	8	10	Skin	3
8	6	6	4	3	5	2	1	2	1.3	Fat	3
2	8	4	2	3	8	8	9	10	9.5	Muscle	3
7	6	9	2	5	2	2	2	7	3.3	Liver	3
5	4	10	5	8	6	4	7.5	7.5	8.8	Gallbladder	3
6	4	5	5	7	3	3	5	5	5.3	Cystic artery	3
6	4	7	5	8	3	3	5	5	5.4	Cystic duct	3

4	1	5	6	10	7	2.5	3	3.5	5	Perito neum	3
6	3	7	5	8	3	3	5	5.5	7.9	Bile duct	3
7	6	8	10	2	10	10	10	8.5	10	Skin	4
5	9	6	8	2	8	8	7.5	5.5	5	Fat	4
4.5	9	7	9.5	2	8.5	8	9.5	8.5	8.5	Muscl e	4
4	10	9.7	7	10	9	9.5	9	10	7.5	Liver	4
8.5	9	9.5	9.7	8	9.7	7.5	9	10	9	Gallbl adder	4
9	3.5	9.5	8.5	8	9.5	7	7	9.5	7	Cystic artery	4
9	4.5	9.5	9	8	9.5	6.5	6.5	9.5	7	Cystic duct	4
10	0	10	10	2	8	2	2	1	1.5	Perito neum	4
9	5	9.5	9	8	9.5	6.5	6.5	10	7.8	Bile duct	4
1.8	3.2	1.4	1.4	10	10	10	9.3	9.6	10	Skin	5
9.2	9.1	7.6	7	2.3	0	3.2	5.6	3.8	2.1	Fat	5
3.1	9.7	4.3	0	10	8.7	9.2	10	10	9.3	Muscl e	5
5	10	8.2	1.8	8.8	6.8	5	4.6	5	5	Liver	5
8.6	2.5	8.3	6.9	5	6.5	3	3.9	4.1	2.9	Gallbl adder	5
4.6	3.2	5.5	5.7	5	5.9	3.4	6.2	4.1	5	Cystic artery	5
6.1	3.2	6.1	5.3	5	5.9	7	7.3	6.6	8.3	Cystic duct	5
10	0	10	7.5	10	1.4	2.7	5	6.3	6.8	Perito neum	5
6.1	3	6.2	6.2	5.1	4.9	7	7.1	5.7	7.2	Bile duct	5
5	7.3	5	8.4	9.1	2.3	9.1	8.9	8.6	8.2	Skin	6
6	7	5.5	6.8	7.1	4.2	6.9	8.2	8	6.6	Fat	6
2.1	6.6	2	8.5	6.8	3.7	6.8	6.3	7.6	5.9	Muscl e	6
7.3	4.4	8.3	1.9	5.5	10	6.1	3.3	2.3	2.9	Liver	6
8.3	3.5	8.6	6.6	8.4	2.5	4.2	3.9	5	1.3	Gallbl adder	6
7.1	2.8	6.3	4.8	5.6	5.8	4.1	5	3.3	5	Cystic artery	6
7.7	2.4	7.7	4	6	5.7	3.6	5.6	4	4.2	Cystic duct	6
8.6	2	9	10	1.2	1	1.7	2.3	1.2	3	Perito neum	6

9.1	0.4	9.2	1	4.4	8.6	0.7	1.2	6	2.2	Bile duct	6
7		4.6								Skin	7
10		8.6								Fat	7
6.3		5								Muscle	7
5		8.3								Liver	7
5		6								Gallbladder	7
5		7.9								Cystic artery	7
5		6								Cystic duct	7
5		10								Peritoneum	7
0		6								Bile duct	7
2	10	1.2	8.2	10	10	10	10			Skin	8
10	0	6.9	1.7	0	0	5	0			Fat	8
5	5	0.4	6.4	5	5	5	5			Muscle	8
7.8	5	10	4.5	5	5	5	5			Liver	8
5	5	5.3	5.2	5	5	5	5			Gallbladder	8
5	5	5.9	4	5	5	0	5			Cystic artery	8
5	5	4.3	4.9	5	5	5	5			Cystic duct	8
5.4	5	4.5	5.4	5	5	5	5			Peritoneum	8
5	5	4.3	4.7	5	5	5	5			Bile duct	8

Appendix P: Participant information sheet (workshop)

In case of any queries contact:

Researcher: Marine Shao, Research associate
CFPR
UWE Bristol Bower Ashton Campus
Kennel Lodge Road
Bristol BS3 2JT, United Kingdom
Tel: +44 (0) 117 32 86352
Email: marine.shao@uwe.ac.uk

Director of Studies: David Huson, Expert Research Fellow
CFPR
UWE Bristol Bower Ashton Campus
Kennel Lodge Road
Bristol BS3 2JT, United Kingdom
Tel: +44 (0) 117 32 84979
Email: david.huson @uwe.ac.uk

Study title: Realistic physical patient simulator for surgical training

Outline of invitation:

You are being invited to take part in a research study concerning surgical simulation. Before you decide, it is important for you to understand why the research is being done and what it will involve. Please take time to read the following information carefully and the description of the workshop enclosed and discuss it with others if you wish. Please ask me if there is anything that is not clear or if you would like more information.

What is the purpose of the study?

This research is part of my PhD study (full-time 2019-22) which intends to examine how surgical training can be improved by the use of patient simulators, seeking understanding on how to reproduce a procedure.

Why have you been chosen?

I have asked you to participate because of your involvement in the field of laparoscopic common bile duct exploration.

Do you have to take part?

It's up to you to decide whether or not to take part.

What will happen to me if I agree to take part?

If you do decide to take part, I will get in contact with you to arrange a suitable time to undertake the workshop. You will be given this information sheet to keep and be asked to sign a consent form. If you do not wish to be identified, then please make sure that you clearly state this by contacting me at the address above, and on the consent form.

What will be the structure and format of the workshop?

I will be asking you to test prototypes or samples during the workshops, and to evaluate them. During workshop 2, each participant will also be asked a series of questions that will be recorded verbally on a digital device. The questions will concern the evaluation of the simulator by the participant. This may also include any other relevant information the participant may wish to contribute during the workshop.

What are the possible disadvantages of taking part?

I do not foresee any disadvantages or risks in taking part. You can refuse to answer any of the questions asked without having to state a reason why. If you decide to take part, you are free to withdraw at any time and without giving a reason.

How and when can I withdraw from participating?

You can withdraw from participating at any point until three months after the participation by using the contact details supplied above. If you would like to withdraw from a scheduled workshop, we ask wherever possible to give us two days' notice.

What if you have a concern about anything after the workshop has been conducted?

I am conducting a funded research project as a PhD student at the Centre for Fine Print Research. It has been approved by UWE Bristol's Research Ethics Committee. I do not anticipate anything going wrong, but if you feel you have any concerns about the interview or my conduct as an interviewer, please feel free to contact my Director of Studies, David Huson (contact as above).

What data will be collected?

Personal data is information that relates to an identified or identifiable individual. What identifies an individual could be as simple as a name or a number or could include other identifiers such as an IP address or a cookie identifier, or other factors. During this project, the following personal data will be processed:

- Name of participant,
- Occupation,
- Contact details,
- Videos,
- Recording,
- Photographs.

What are the precautions taken to prevent collection of clinical information that would breach the confidentiality and privacy rights of patients of the medics involved?

Any notes/recordings will be shared with surgeons to check for redaction of any sensitive information.

Will taking part in this study be kept confidential?

The purpose is to provide source material via workshop for a PhD thesis evidencing what should be the patient simulators' specifications in order to get a useful surgical training tool. The information will be used as reference, to acknowledge the work of current practitioners and their specialist experience in the field of study.

The research will identify participants as it is important to acknowledge their contribution as key authorities and valued practitioners within the field of study. Any usage of this information other than for educational and research purposes will need to be approved by the researcher and the participant.

Who will be able to access the data?

The researcher and the Director of Study (David Huson, David.huson@uwe.ac.uk) will have access to the data.

What will happen to the results of the research study?

The results of this research will be used towards a PhD thesis, which will be published in 2022 and be made available at The University of the West of England's ACE Library. The findings would also be documented for potential publication as a series of articles, case studies, conference presentations and workshops, from hard copy to free PDF downloads and podcasts. This would enable wider dissemination to an international field, to build upon critical engagement, creative collaboration and dialogue between academics and medical specialists.

Data from the workshops will be edited for publication as text or podcasts, so if I have recruited you for this purpose, I will supply you with a copy of the edited text or audio for approval and/or editing before it is published or broadcast. Any usage of the information supplied by you for use other than the purposes of this project would need to be approved by you. Audio/text and visual data gathered will be destroyed at the end of the research project.

Who is organising and funding the research?

This project has received funding from the European Union's Horizon 2020 research and innovation programme under the Marie Skłodowska-Curie grant agreement No 814158.

Contact for further information: Marine Shao and David Huson address as above.

Thank you for taking part in this project.

Appendix Q: Workshop 1 guide

Realistic physical patient simulator for surgical training

version 1.1

WORKSHOP 1 GUIDE (30 minutes)

The participant will participate individually in this workshop to avoid any influence from other participants.

SECTION 1

Introduction: **Researcher to tick the box when complete:**

34.	1 min	Thank the participant for participating	
35.		Explain the study in brief	
36.	1 min	Explain the aim of the workshop: choose the right materials for the simulator	
37.		Explain that an audio-recording device will be used, as well as a video-recorder (if accepted in the participant information list), and a camera (if accepted in the participant information list)	
38.	2 min	Explain what will be done with the data: o Anonymity of the recording in transcription and use of alias, thus we cannot trace back to any persons o Anonymisation of the photographs and videos o Recording files will be stored in a secure location at the University of the West of England until the completion of the PhD o The findings will be published hopefully in 2022 □ Ask address details if participant wants to receive the report of the findings	
39.	1 min	Explain that the interview will take between 60 – 90 minutes	

40.		Ask if all information is clear and if there are any questions before starting the interview	

Researcher to switch on the recorder and the video recorder (if accepted by the participant) and explain to the surgeon:

SECTION 2 – AUDIO-RECORDER AND VIDEO RECORDER (IF ACCEPTED BY PARTICIPANT) SWITCHED ON

THE WORKSHOP

The researcher might take pictures during the workshop, if the participant has agreed to being photograph in the participant information sheet.

Description of the aim:

The aim is to find the materials to reproduce the following soft tissues:

- gallbladder,
- cystic duct, the cystic artery and bile duct (grouped together),
- skin,
- fat,
- muscle,
- liver,
- peritoneum,

Using one of the following materials:
Very soft (6): Ecoflex gel, Ecoflex 0010, 50% Ecoflex gel/50%Ecoflex 0010, Ecoflex gel 25%-part A, Ecoflex gel 75%-part A, Ecoflex gel + 10% thinner

Hard (7): Ecoflex 0030, DragonSkin Slow, DragonSkin Fast, 50% Ecoflex 0030/50% DragonSkin, DragonSkin 25%-part A, DragonSkin 75%-part A, DragonSkin + 20% slacker

The researcher will provide:

- Different samples for each organ/type of tissue evaluated. The samples will have the shape of the organ evaluated.

Evaluated characteristics:

- softness, smoothness, thickness (free description), elasticity, attachment to other tissues, resistance to gripping, resistance to cutting, resistance to suture, resistance to pulling, and resistance to tearing (properties through indirect touch correlated, so just evaluate one)

Questions:

- ➔ Free description of the samples (keeping in mind the evaluated characteristics),
- ➔ Select the best sample for the organ overall (not looking at the characteristics),
- ➔ State for each sample what is the most important characteristic.

List of the organs: (1) liver, (2) gallbladder, (3) cystic duct, bile duct, and cystic artery (4) fat, (5) skin, (6) muscle, (7) peritoneum

<table>
<tr><td colspan="5">In this workshop, the researcher will proceed by slow reveal of the selected samples for each organ, one by one. The participant will be asked to touch and evaluate the resemblance of the samples to the organ. A photograph of the organ will be provided to the participant.
For the liver (1), gallbladder (2), and vessels (3), all the samples are given together.
For the fat (4): all the soft homogenous/smooth samples are given together.
For the skin and muscle: first give all the hard homogenous/smooth materials -> select best /Then add the fibres in best material and two surrounding (unidirectional for muscle and bi for skin)/ Then show samples with texture.
For the peritoneum, act similarly (first homogenous, then the three surrounding the best with the fabric in them)</td></tr>
<tr><td>Liver</td><td>41.</td><td>4 min</td><td>Free description of the 5 samples
1. Ecoflex gel:</td><td></td></tr>
</table>

			2. Ecoflex 0010: **3. 50% Ecoflex gel/50%Ecoflex 0010:** **4. Ecoflex gel 25%-part A:** **5. Ecoflex gel 75%-part A:**	
	42.	**1 min**	**Among these adjectives (**softness, smoothness, thickness, elasticity, resistance to pulling) **which ones are the most important?**	
	43.		**Select the best sample for the organ overall (not looking at the characteristics)**	
Gallbladder	**44.**	**4 min**	**Free description of the 5 samples** **1. Ecoflex 0030:** **2. DragonSkin Fast:** **3. DragonSkin 25%-part A:** **4. DragonSkin 75%-part A:** **5. DragonSkin 20% slacker:**	

	45.	**1 min**	**Among these adjectives (**softness, smoothness, thickness, elasticity, resistance to pulling) **which ones are the most important?**	
	46.		**Select the best sample for the organ overall (not looking at the characteristics)**	
Vessels	**47.**	**4 min**	**Free description of the 5 samples** **1. Ecoflex 0030:** **2. DragonSkin Fast:** **3. DragonSkin 25%-part A:** **4. DragonSkin 75%-part A:** **5. DragonSkin 20% slacker:**	
	48.	**3 min**	**Among these adjectives (**softness, smoothness, thickness, elasticity, resistance to pulling) **which ones are the most important for?** - **The bile duct:** - **The cystic duct:** - **The cystic artery:**	
	49.		**Select the best sample for the organ for?** - **The bile duct:**	

			- **The cystic duct:** - **The cystic artery:**	
Fat	**50.**	**4 min**	**Free description of the 5 samples** 1. **Ecoflex gel:** 2. **Ecoflex 0010:** 3. **50% Ecoflex gel/50%Ecoflex 0010:** 4. **Ecoflex gel 25%-part A:** 5. **Ecoflex gel 75%-part A:**	
	51.	**1 min**	**Among these adjectives (**softness, smoothness, thickness, elasticity, resistance to pulling) **which ones are the most important?**	
	52.		**Select the best sample for the organ?**	
Skin	**53.**	**4 min**	**Free description of the 6 homogenous and smooth samples** 1. **Ecoflex 0010:** 2. **Ecoflex 0030:** 3. **DragonSkin Fast:**	

			4. DragonSkin 25%-part A: **5. DragonSkin 75%-part A:** **6. DragonSkin 20% slacker:**	
	54.	**5 min**	**Among these adjectives (**softness, smoothness, thickness, elasticity, resistance to pulling) **which ones are the most important?**	
	55.		**Select the best sample for the organ?**	
	56.		**(show samples with bidirectional fibres (2 layers first) for this material and the two surrounding): Is adding fibres making the tactile feedback more realistic? If yes, show samples with 3 and 4 layers too (Y/N, tights/power mesh, 2/3/4)**	
	57.		**(show the sample with texture) for the selected material: Is texture making the feedback better? (Y/N)**	
Muscle	**58.**	**4 min**	**Free description of the 6 homogenous and smooth samples** **1. Ecoflex 0010:**	

			2. **Ecoflex 0030:** 3. **DragonSkin Fast:** 4. **DragonSkin 25%-part A:** 5. **DragonSkin 75%-part A:** 6. **DragonSkin 20% slacker:**	
	59.	**5 min**	**Among these adjectives (**softness, smoothness, thickness, elasticity, resistance to pulling) **which ones are the most important?**	
	60.		**Select the best sample for the organ?**	
	61.		**(show samples with unidirectional fibres for this material and the two surrounding): Is adding fibres making the tactile feedback more realistic? (Y/N, low/medium)**	
Peritoneum	**62.**	**4 min**	**Free description of the 6 homogenous and smooth samples** 1. **Ecoflex 0010:** 2. **Ecoflex 0030:**	

			3. **DragonSkin Fast:** 4. **DragonSkin 25%-part A:** 5. **DragonSkin 75%-part A:** 6. **DragonSkin 20% slacker:**	
	63.	**5 min**	**Among these adjectives (**softness, smoothness, thickness, elasticity, resistance to pulling) **which ones are the most important?**	
	64.		**Select the best sample for the organ?**	
	65.		**(show samples with fibres for this material and the two surrounding): Is adding fibres making the tactile feedback more realistic? (Y/N, tights/power)**	

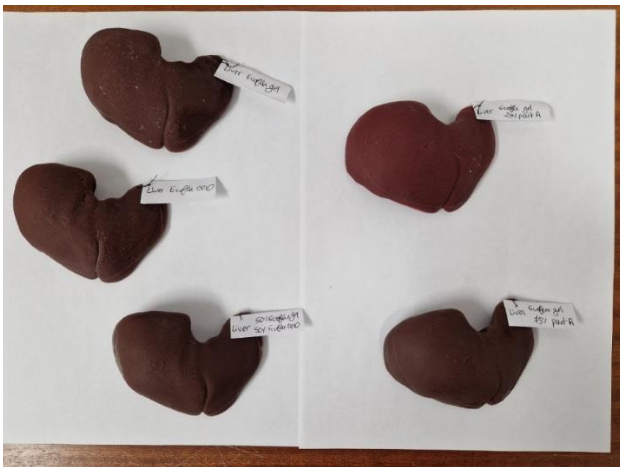
66.	**1 min**	Is there anything else about the simulator that you would like to tell me or to ask?	
67.		Can you recommend anyone who could participate in this study?	
68.		Thank you & Close	

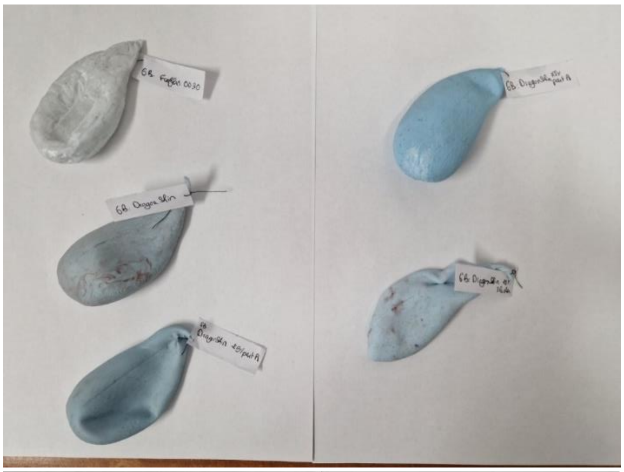
- **SWITCH OFF RECORDER AND VIDEO RECORDER (IF ACCEPTED BY PARTICIPANT)**

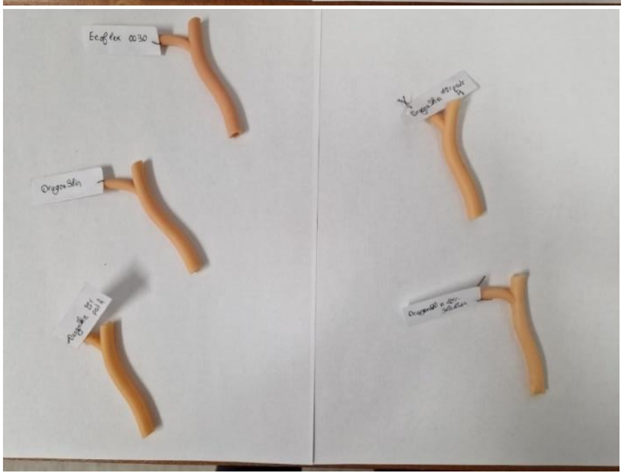
Appendix R: Full report workshop tactile feedback

1. Conduction

During the workshop, the samples were presented to the surgeon as shown in the pictures below.







2. Result

The surgeons selected the following materials to mimic each soft tissue. The price of the materials and the remarks from the surgeons are detailed in the tables below.

Table 31: Materials used to mimic the soft tissues in the simulation by Marine Shao, used under CC BY 4.0

Soft tissue	Material	Price of the material (for 910 grammes)	Price for one part
Duodenum	Ecoflex 0030 (Smooth-On, Macungie, USA)	£39.64	£2.2
Fat	Ecoflex gel (Smooth-On, Macungie, USA)	£39.05	£58
Skin	Ecoflex 0030 (Smooth-On, Macungie, USA) and stretchy fabric	£39.64	£24
Muscle	Ecoflex 0030 (Smooth-On, Macungie, USA) and cotton fibres	£39.64	£30
Gallbladder	DragonSkin (Smooth-On, Macungie, USA)	£43.48	£1
Bile duct	DragonSkin 75% part A (Smooth-On, Macungie, USA)	£43.48	£1
Vein	DragonSkin 75% part B (Smooth-On, Macungie, USA)	£43.48	£1
Artery	DragonSkin 75% part B (Smooth-On, Macungie, USA)	£43.48	£0.5
Liver capsule	DragonSkin (Smooth-On, Macungie, USA)	£43.48	£1
Liver	Ecoflex gel 75% part B (Smooth-On, Macungie, USA)	£39.05	£52

Table 32: Selection of the best materials and comments from the surgeons

Tissue	Material	Surface	Other work to do
Liver	Ecoflex gel 25%part A	Smooth, wet, slippery, not sticky	Colour reddish
Gallbladder	DragonSkin for direct touch, DragonSkin 25% for the cutting, and DragonSkin 75% for the suture. The issue with DragonSkin for the suture is that it is too thick; for the cutting it is acceptable. This is why the best material to mimic the gallbladder is the DragonSkin. The DragonSkin 25%A and 75%A are also acceptable because we mimic a laparoscopic surgery, so the indirect touch is more important.	wet, slippery, not sticky	Thin wall (1mm)
Bile duct	DragonSkin 25%-part A (best for direct touch, acceptable for cutting and suturing) or DragonSkin 75%A (best for cutting and suturing, bad for direct touch).	not sticky	Colour, Wider with thin walls (8mm/1mm)
Cystic duct	DragonSkin 25%-part A (best for direct touch, acceptable for cutting and suturing) or DragonSkin 75%A (best for cutting and suturing, bad for direct touch).	not sticky	Colour, small with thin walls (4mm/1mm)
Cystic artery	DragonSkin 25%-part A		Thick with small calibre (6mm/1.5mm), pulsatile 5-7 mm Common Hepatic Artery 4-6 mm Proper Hepatic Artery 3-5 mm Right Hepatic Artery 3-5 mm Left Hepatic Artery 1-2 mm Cystic Artery
Vein	DragonSkin 25%-part A		13mm/1.5mm
Skin	Ecoflex 0030 / DragonSkin 20% slacker 1 layers of fibres (thighs) Texture	Texture, not sticky	2mm thin (10mL)

	2mm		
Fat	Ecoflex gel (but not sticky)	Oily, slippery, not sticky	Yellow, thinner 20mm (50mL x2 in two steps) Visceral fat: yellow and globulous (in little capsule)
Muscle	Ecoflex 0030 / DragonSkin 20% slacker. low density unidirectional cotton fibres	Slippery, not sticky	10mm (50mL) Brown/red
Peritoneum	DragonSkin or DragonSkin 25%-part A No fibres -> DragonSkin and Platcat (7.5/7.5/3) – 1/6 de Platcat	Smooth, slippery, not sticky	Very thin (0.1mm), reap easily when we stretch it x200. Like what is on chicken breast
Duodenum	Ecoflex 0030		Thick (2mm) More purple than pink
Stomach	Ecoflex 0030		Thick (2-3mm)

3. Details

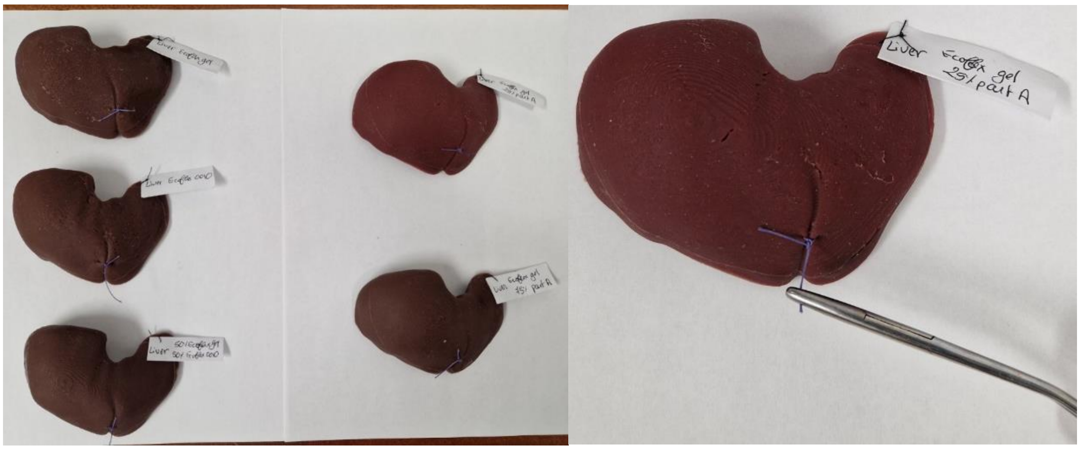
3.1 Liver

	Liver	frequency	Comments
Direct touch (12 participants)	Ecoflex gel	2	Need to be smooth (with a coating) + wet/slippery Colour: more reddish than brown Elasticity and pliability (ability to move it + how it reacts when you press it, time to go back to shape (quite slowly))
	Ecoflex 0010	2	
	50% Ecoflex gel 50% Ecoflex 0010	3	
	Ecoflex gel 25% A	5	
	Ecoflex gel 75% A	4	
Cutting (1 participant)	Ecoflex gel		
	Ecoflex 0010	Bad	
	50% Ecoflex gel 50% Ecoflex 0010		
	Ecoflex gel 25% A	Best	
	Ecoflex gel 75% A		

Suture (puncturing)	Ecoflex gel	2	Good consistency but tougher than human liver
	Ecoflex 0010	1	Much tougher than human liver
	50% Ecoflex gel 50% Ecoflex 0010	3	Intermediate consistency
	Ecoflex gel 25% A	4	Closest to human liver
	Ecoflex gel 75% A	2	Tougher than human liver

Suture (driving needle)	Ecoflex gel	2	Good consistency but tougher than human liver
	Ecoflex 0010	1	Much tougher than human liver
	50% Ecoflex gel 50% Ecoflex 0010	2	Intermediate consistency
	Ecoflex gel 25% A	3	Closest to human liver
	Ecoflex gel 75% A	1	Tougher than human liver
Suture (hold suture)	Ecoflex gel	2	Good consistency but tougher than human liver
	Ecoflex 0010	1	Much tougher than human liver
	50% Ecoflex gel 50% Ecoflex 0010	2	Intermediate consistency
	Ecoflex gel 25% A	4	Closest to human liver
	Ecoflex gel 75% A	2	Tougher than human liver

The results of the analysis show that the best material to mimic the liver well is Ecoflex gel 25%part A. The surface of the liver needs to be smooth (with a coating) and feel wet and slippery. The colour is redder than brown. The tactile properties we are looking for are elasticity and pliability (ability to move it + how it reacts when you press it, time to go back to shape (quite slowly)).

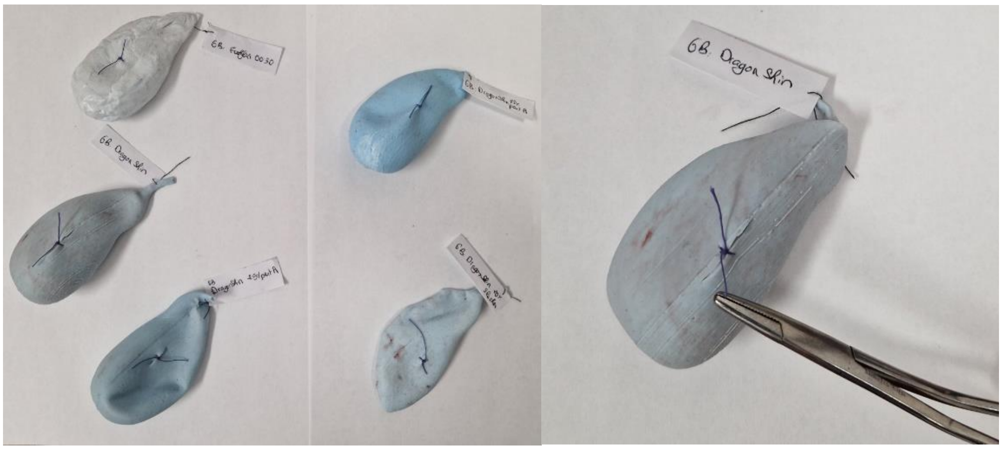


3.2 Gallbladder

	Gallbladder	frequency	Comments
Direct touch (12 participants)	Ecoflex 0030	2	Thin walled Not sticky (slippery/wet) able to squeeze it and move it without it tearing. consistency (softness, a bit tense) feel impacted stones
	DragonSkin	6	
	DragonSkin 25% A	3	
	DragonSkin 75% A	2	
	DragonSkin 20% slacker	2	
Cutting (1 participant)	Ecoflex 0030	no	
	DragonSkin	ok	
	DragonSkin 25% A	best	

	DragonSkin 75% A	ok	variable
	DragonSkin 20% slacker	no	

Suture (puncturing)	Ecoflex 0030	1	Doughier
	DragonSkin	3	Some similarity but thicker
	DragonSkin 25% A	3	Some similarity
	DragonSkin 75% A	3	Closest to human gallbladder
	DragonSkin 20% slacker	0	More elastic and softer consistency
Suture (driving needle)	Ecoflex 0030	2	Doughier
	DragonSkin	2	Some similarity but thicker
	DragonSkin 25% A	3	Some similarity
	DragonSkin 75% A	4	Closest to human gallbladder
	DragonSkin 20% slacker	1	More elastic and softer consistency
Suture (hold suture)	Ecoflex 0030	3	Doughier
	DragonSkin	2	Some similarity but thicker
	DragonSkin 25% A	2	Some similarity
	DragonSkin 75% A	4	Closest to human gallbladder
	DragonSkin 20% slacker	1	More elastic and softer consistency



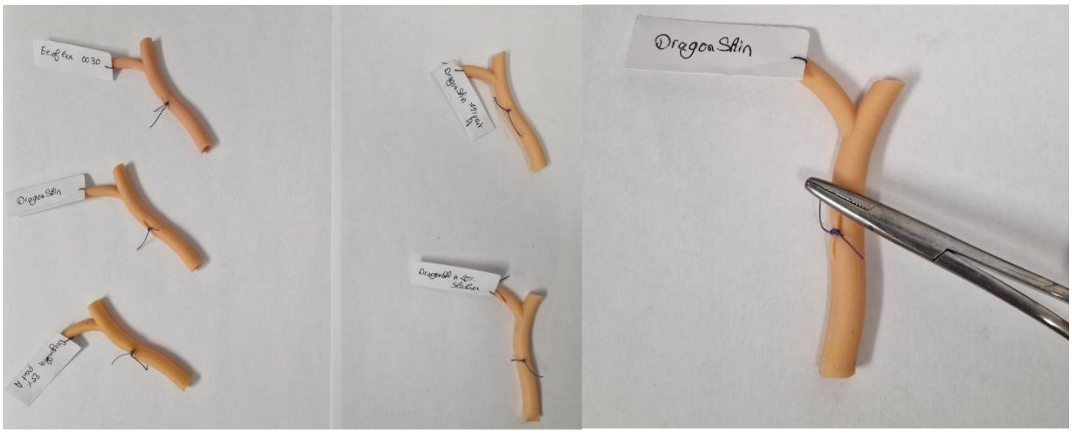
The result of the analysis shows that the best material to mimic the gallbladder is DragonSkin for direct touch, DragonSkin 25% for the cutting, and DragonSkin 75% for the suture. The issue with DragonSkin for the suture is that it is too thick; for the cutting it is acceptable. This is why the best material to mimic the gallbladder is the DragonSkin. The DragonSkin 25%A and 75%A are also acceptable because we mimic a laparoscopic surgery, so the indirect touch is more important. The Gallbladder must be thin walled. The surface is wet and slippery and not sticky. It has some consistency because it is possible to squeeze and move it around without it tearing.

It feels soft but a bit tense. If there are impacted stones, we can feel them too. It is very variable between patients.

3.3 Bile duct

	Bile duct	frequency	Comments
Direct touch (12 participants)	Ecoflex 0030	4	Colour: something blue/green then put it in a white structure (looks grey) don't touch the bile duct with the fingers, just with the instrument (reason not to select 0030) -> need to feel realistic with instruments Wider tube with thin wall texture: not sticky Consistency: softness, some strength, elasticity
	DragonSkin	2	
	DragonSkin 25% A	4	
	DragonSkin 75% A	1	
	DragonSkin 20% slacker	1	
Cutting (1 participant)	Ecoflex 0030	don't cut	
	DragonSkin	ok	
	DragonSkin 25% A	ok	
	DragonSkin 75% A	best	
	DragonSkin 20% slacker	don't cut	

Suture (puncturing)	Ecoflex 0030	2	acceptable
	DragonSkin	2	Thick and tough
	DragonSkin 25% A	2	acceptable
	DragonSkin 75% A	4	Closest to human
	DragonSkin 20% slacker	1	More elastic and softer consistency
Suture (driving needle)	Ecoflex 0030	2	acceptable
	DragonSkin	1	Thick and tough
	DragonSkin 25% A	3	acceptable
	DragonSkin 75% A	4	Closest to human
	DragonSkin 20% slacker	0	More elastic and softer consistency
Suture (hold suture)	Ecoflex 0030	2	acceptable
	DragonSkin	1	Thick and tough
	DragonSkin 25% A	3	acceptable
	DragonSkin 75% A	3	Closest to human
	DragonSkin 20% slacker	1	More elastic and softer consistency



The result of the analysis shows that the best material to mimic the bile duct is DragonSkin 25%-part A (best for direct touch, acceptable for cutting and suturing) or DragonSkin 75%A (best for cutting and suturing, bad for direct touch). The colour of the bile duct is similar to the gallbladder (something blue/green then put it in a white structure (looks grey)). They just touch it through instruments and not directly which is why the touch through tools is more important for the selection. The tube is wider but has thin walls. The texture is not sticky. It is soft, elastic, but has some strength.

3.4 Cystic duct

	Cystic duct	frequency	Comments
Direct touch (12 participants)	Ecoflex 0030	4	Colour: something blue/green then put it in a white structure (looks grey) Need to feel realistic with instruments small tube with thin wall Texture: not sticky Consistency: softness
	DragonSkin	2	
	DragonSkin 25% A	3	
	DragonSkin 75% A	1	
	DragonSkin 20% slacker	2	
Cutting (1 participant)	Ecoflex 0030	don't cut	
	DragonSkin	ok	
	DragonSkin 25% A	ok	
	DragonSkin 75% A	best	
	DragonSkin 20% slacker	don't cut	

The result of the analysis shows that the best material to mimic the cystic duct is DragonSkin 25%-part A. The colour of the bile duct is similar to the gallbladder (something blue/green then put it in a white structure (looks grey)). They just touch it through instruments and not directly which is why the touch through tools is more important for the selection. The tube is small with thin walls. The texture is not sticky. It is soft.

3.5 Cystic artery

	Cystic artery	frequency	Comments
Direct touch (12 participants)	Ecoflex 0030	0	Thicker tube and small calibre more solid/stiff/tough/elastic/springy than ducts pulsatile
	DragonSkin	2	
	DragonSkin 25% A	6	
	DragonSkin 75% A	3	
	DragonSkin 20% slacker	1	

The result of the analysis shows that the best material to mimic the cystic artery is DragonSkin 25%-part A. The tube is thick with a small calibre. It is solid, stiff, elastic, and springy than the ducts (because thicker). It is also pulsatile.

I will use the same material for the vein, as the surgeons don’t touch it during the surgery, it is not as important.

3.6 Skin

Skin (direct touch)	frequency		frequency	Fibres %?	frequency
Ecoflex 0010	0	Fibres		2	2
Ecoflex 0030	6	Yes	9	3	2
DragonSkin	0	No	2	4	5
DragonSkin 25% A	2	Texture		Thinner than the samples (~2mm) Texture: softness/firm (harder than subcutaneous layers)/elasticity Don't tear or reap Sensation when you cut/stitch it Not sticky variable	
DragonSkin 75% A	0	Yes	11		
DragonSkin 20% slacker	5	No	1		

The result of the analysis shows that the best materials to mimic the skin are Ecoflex 0030 or DragonSkin 20% slacker. It feels better with 4 layers of fibres (tights) in it and with texture. However, it is thinner than the samples (~2mm), so I should include only one layer of fabric. It is both soft and firm, and we can feel that it is harder than the other subcutaneous layers. It has some elasticity and doesn't tear or reap when you cut/stitch it. It is not sticky. It is also variable.

3.7 Muscle

Muscle (direct touch)	frequency	Fibres	frequency	Comments
Ecoflex 0010	2	Yes		Consistency: tension / elasticity softness / less compressible than skin Slippery (not sticky) / smooth Shouldn't rip, can move it and dissect it, don't tear bleeds a lot unidirectional fibres
Ecoflex 0030	6	No	8	
DragonSkin	1	Density	3	
DragonSkin 25% A	0	Low		
DragonSkin 75% A	0	Medium	4	
DragonSkin 20% Slacker	6			

The result of the analysis shows that the best materials to mimic the muscle are Ecoflex 0030 or DragonSkin 20% slacker. It feels better with low density unidirectional cotton fibres in it. In term of consistency, it has tension, elasticity, softness, and is less compressible than skin (because thicker). It is smooth and slippery (not sticky). It shouldn't rip, we can move it and dissect it, it doesn't tear. It bleeds a lot.

3.8 Fat

Fat (direct touch)	frequency	Comments
Ecoflex gel	5	Colour: yellow Consistency: very soft, springy, doesn't indent Thinner than the samples Surface: not sticky, slippery, very oily (can spill when cutting)
Ecoflex 0010	4	
50% Ecoflex gel/50% Ecoflex 0010	0	
Ecoflex gel 25% A	1	
Ecoflex gel 75% A	3	

The result of the analysis shows that the best materials to mimic the fat is Ecoflex gel. The colour should be yellow. It is very soft, and springy and it doesn't indent. It should be thinner than the samples. The surface is not sticky but slippery and oily.

3.9 Peritoneum

Peritoneum	frequency	Fibres?	frequency	Comments
Ecoflex 0010	2	Fibres		Smooth/slippery -> not sticky Thin reap easily (when x2) -
Ecoflex 0030	1	Yes	2	
DragonSkin	3	No	10	
DragonSkin 25% A	4			

DragonSkin 75% A	2			> dissect easily elastic/stretchy/some strength
DragonSkin 20% slacker	0			

The result of the analysis shows that the best materials to mimic the peritoneum are DragonSkin or DragonSkin 25%-part A. It feels better without fibres. It needs to be smooth and slippery instead of sticky. It is very thin. It can reap easily when we stretch it x200 and dissect easily. It has some elasticity and strength.

3.10 Other

The best materials for the duodenum and the stomach are ecoflex 0030. The stomach is thick. The surgeons don’t touch them directly, so it isn’t as important.

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Appendix S: Workshop 2 guide

Realistic physical patient simulator for surgical training

version 1.1

WORKSHOP 2 GUIDE

The participant will participate individually in this workshop to avoid any influence from other participants.

SECTION 1

Introduction:

1.	Thank the participant for participating
2.	Explain the study in brief
3.	Explain the aim of the workshop: evaluate the simulator
4.	Explain that an audio-recording device will be used, as well as a video-recorder (if accepted in the participant information list), and a camera (if accepted in the participant information list)
5.	Explain what will be done with the data: o Anonymity of the recording in transcription and use of alias, thus we cannot trace back to any persons o Anonymisation of the photographs and videos o Recording files will be stored in a secure location at the University of the West of England until the completion of the PhD o The findings will be published hopefully in 2023

	? Ask address details if participant wants to receive the report of the findings
6.	Explain that the study will take around 30 minutes
7.	Ask if all information is clear and if there are any questions before starting the interview

Researcher to switch on the recorder (if accepted by the participant) and the timer and explain to the surgeon:

SECTION 2 – AUDIO-RECORDER AND VIDEO RECORDER SWITCHED ON

THE WORKSHOP

If the participant has agreed to being photograph in the participant information sheet, the researcher might take pictures during the workshop.

Description of the aim:

The aim is to evaluate the simulator during three phases: face, content, and construct validations.

The researcher will provide:

- The simulator and the box trainer,
- Tools,
- A computer with the augmented reality system.

Tasks evaluated with the simulator:

During the training sessions, the surgeons performs the following training tasks:

- Task 1: Port insertion

- Task 2: Ultrasound evaluation using the AR system (during this step, the aims are to assess the number of stones and to locate them)
- Task 3: Decision of the approach from the ultrasound scan (trans-cystic or trans-choledochal).
- Task 4: Opening of the bile duct of cystic duct.
- Task 5: Insertion of the choledochoscope and stone removal.
- Task 6: Closure of the bile duct or of the cystic duct.

<table>
<tr><td colspan="2">Before testing the simulator, the participant must answer the following preliminary questions</td></tr>
<tr><td>8.</td><td>Background questions
How many laparoscopic procedures have you been involved in the past? Please circle.
0 - 10 / 10 - 40 / more than 40
How many laparoscopic procedures have you done in the past as primary surgeon? Please circle.
0 - 10 / 10 - 40 / more than 40
How many LCBDE have you been involved in the past? Please circle.
0 - 10 / 10 - 40 / more than 40
How many LCBDE have you done in the past as primary surgeon? Please circle.
0 - 10 / 10 - 40 / more than 40
How often do you use laparoscopic ultrasound? Please circle.</td></tr>
</table>

	Less than once a month / Once a month / Once a week / More than once a week • How often do you undertake laparoscopic suturing? Please circle. Less than once a month / Once a month / Once a week / More than once a week • How often do you perform laparoscopic bile duct exploration? Please circle. Less than once a month / Once a month / Once a week / More than once a week

Stage 0: the participant looks at the model and touches it.	
9.	How realistic are the soft tissues with direct vision? Please circle. From 1 (poor) to 5 (excellent). - Liver: 1 2 3 4 5 - Artery: 1 2 3 4 5 - Vein: 1 2 3 4 5 - Bile duct: 1 2 3 4 5 - Gallbladder: 1 2 3 4 5 - Duodenum: 1 2 3 4 5 - Abdominal wall: 1 2 3 4 5
10.	How realistic does the soft tissues feel? Please circle. From 1 (poor) to 5 (excellent).

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	- Liver: 1 2 3 4 5 - Artery: 1 2 3 4 5 - Vein: 1 2 3 4 5 - Bile duct: 1 2 3 4 5 - Gallbladder: 1 2 3 4 5 - Duodenum: 1 2 3 4 5 - Abdominal wall: 1 2 3 4 5
11.	Does the trainer include all the relevant soft tissues? Please circle. Yes No If no, which ones are missing:
12.	How would you evaluate your procedural confidence (knowing the steps of the procedure)? Please circle. From 1 (poor) to 5 (excellent). 1 2 3 4 5
13.	How would you evaluate your confidence level in performing the following tasks? Please circle. From 1 (poor) to 5 (excellent). • Task 1: Port insertion 1 2 3 4 5 • Task 2: Ultrasound evaluation 1 2 3 4 5 • Task 3: Decision of the approach from the ultrasound scan 1 2 3 4 5 • Task 4: Opening of the bile duct of cystic duct.

	1 2 3 4 5 • Task 5: Insertion of the choledochoscope and stone removal. 1 2 3 4 5 • Task 6: Closure of the bile duct or of the cystic duct. 1 2 3 4 5

Stage 1: the participant will perform task 1 on the simulator: insertion of one port. **Start chrono.**	
14.	How realistic does the abdominal wall feel during the port insertion? Please circle. From 1 (poor) to 5 (excellent). 1 2 3 4 5
15.	Perceived utility: How useful would this simulator be to teach this task? Please circle. From 1 (poor) to 5 (excellent). • Task 1: Port insertion. 1 2 3 4 5
16.	How would you evaluate your confidence level in performing the following task? Please circle. From 1 (poor) to 5 (excellent). • Task 1: Port insertion. 1 2 3 4 5
17.	How would you rate the usefulness of this training tasks? Please circle. From 1 (poor) to 5 (excellent). Task 1: Port insertion. 1 2 3 4 5
18.	**Construct validation (Researcher to complete this session):**

	1. Insertion of the port (succeed / fail) **Time to completion:**

Stage 2: the participant will perform task 2 on the simulator: An ultrasound evaluation using the AR system; during this step, they have to assess the number of stones and locate them. The researcher will first explain how the AR system works then the surgeon will test it. **Start chrono.**	
19.	How realistic are the ultrasound images? Please circle. From 1 (poor) to 5 (excellent). 1 2 3 4 5
20.	Perceived utility: How useful would this simulator be to teach this task? Please circle. From 1 (poor) to 5 (excellent). • Task 2: An ultrasound evaluation. 1 2 3 4 5
21.	How would you evaluate your confidence level in performing the following task? Please circle. From 1 (poor) to 5 (excellent). • Task 2: An ultrasound evaluation. 1 2 3 4 5
22.	How would you rate the usefulness of this training tasks? Please circle. From 1 (poor) to 5 (excellent). • Task 2: An ultrasound evaluation. 1 2 3 4 5

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23.	How useful is it to have different scenarios available? Please circle. From 1 (poor) to 5 (excellent). 1 2 3 4 5
24.	**Construct validation (Researcher to complete this session): Ask the participant the three following questions:** **2. Identify anatomical structure on the ultrasound images from 1 (poor) to 5 (excellent)** **3. Identify the number and location of stones from 1 (poor) to 5** **4. Measure of the dimensions (succeed / fail)** **Time to completion:**

Stage 3: the participant will perform task 3 on the simulator: From the ultrasound scan, the surgeon then decides the approach of the surgery: trans-cystic or trans-choledochal. **Start chrono** **From now on, the models all represent scenario 1.**	
25.	Perceived utility: How useful would this simulator be to teach this task? Please circle. From 1 (poor) to 5 (excellent). • Task 3: Decision of the surgical approach 1 2 3 4 5
26.	How would you evaluate your confidence level in performing the following task? Please circle. From 1 (poor) to 5 (excellent).

	• Task 3: Decision of the surgical approach 1 2 3 4 5
27.	How would you rate the usefulness of this training tasks? Please circle. From 1 (poor) to 5 (excellent). • Task 3: Decision of the surgical approach 1 2 3 4 5
28.	**Construct validation (Researcher to complete this session):** **5. Success in identifying the right approach: (succeed / fail)** **Time to completion:**

Stage 4: the participant will perform task 4 on the simulator: opening of the bile duct or of cystic duct. **Start chrono.**

29.	How realistic is the cutting of the bile duct? Please circle. From 1 (poor) to 5 (excellent). 1 2 3 4 5
30.	Perceived utility: How useful would this simulator be to teach this task? Please circle. From 1 (poor) to 5 (excellent). • Task 4: Opening of the bile duct or cystic duct. 1 2 3 4 5
31.	How would you evaluate your confidence level in performing the following task? Please circle. From 1 (poor) to 5 (excellent).

	• Task 4: Opening of the bile duct or cystic duct. 1 2 3 4 5
32.	How would you rate the usefulness of this training tasks? Please circle. From 1 (poor) to 5 (excellent). • Task 4: Opening of the bile duct or cystic duct. 1 2 3 4 5
33.	**Construct validation (Researcher to complete this session):** **6. Adjusting the camera: from 1 (poor) to 5 (excellent)** **7. Success in opening the duct: from 1 (poor) to 5 (excellent)** **Time to completion:**

Stage 5: the participant will perform task 5 on the simulator: The surgeon inserts the laparoscope into the bile duct to remove the stone(s). **Start chrono.**	
34.	How realistic is the scoping inside the duct? Please circle. From 1 (poor) to 5 (excellent). 1 2 3 4 5
35.	How realistic is the stone retrieval from inside the duct? Please circle. From 1 (poor performance) to 5 (excellent performance). 1 2 3 4 5

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36.	Perceived utility: How useful would this simulator be to teach this task? Please circle. From 1 (poor) to 5 (excellent). • Task 5: Scoping the bile duct and stone retrieval. 1 2 3 4 5
37.	How would you evaluate your confidence level in performing the following task? Please circle. From 1 (poor) to 5 (excellent). • Task 5: Scoping the bile duct and stone retrieval. 1 2 3 4 5
38.	How would you rate the usefulness of this training tasks? Please circle. From 1 (poor) to 5 (excellent). • Task 5: Scoping the bile duct and stone retrieval. 1 2 3 4 5
39.	**Construct validation (Researcher to complete this session):** **1. Choledochoscope insertion and manoeuvring from 1 (poor) to 5 (excellent)** **2. Stone capture from 1 (poor) to 5 (excellent)** **3. Stone extraction from 1 (poor) to 5 (excellent)** **4. Verification of stone clearance from 1 (poor) to 5 (excellent)** **Time to completion:**

Stage 6: the participant will perform task 6 on the simulator: The surgeon closes the bile duct or the cystic duct. **Start chrono.**	
40.	How realistic is the suturing of the bile duct? Please circle. From 1 (poor) to 5 (excellent). 1 2 3 4 5
41.	Perceived utility: How useful would this simulator be to teach this task? Please circle. From 1 (poor) to 5 (excellent). • Task 6: Suturing of the bile duct. 1 2 3 4 5
42.	How would you evaluate your confidence level in performing the following task? Please circle. From 1 (poor) to 5 (excellent). • Task 6: Suturing of the bile duct. 1 2 3 4 5
43.	How would you rate the usefulness of this training tasks? Please circle. From 1 (poor) to 5 (excellent). • Task 6: Suturing of the bile duct. 1 2 3 4 5
44.	**Construct validation (Researcher to complete this session):** **1. Success in suturing the bile duct: from 1 (poor) to 5 (excellent)** **2. Test of the waterproofness of the suture: (succeed / fail)** **Time to completion:**

Stage 7: Overall examination.	
45.	How useful would this simulator be to teach the steps of the procedure? Please circle. From 1 (poor) to 5 (excellent). 1 2 3 4 5
46.	Was the simulation challenging enough? Please circle. From 1 (poor) to 5 (excellent). 1 2 3 4 5
47.	Would you like to use more simulation similar to this one incorporated in your training/surgeons' training? Please circle. From 1 (poor) to 5 (excellent). 1 2 3 4 5
48.	Free comments

- **SWITCH OFF RECORDER AND VIDEO RECORDER (IF ACCEPTED BY PARTICIPANT)**

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Appendix T: Results of the evaluation workshop (workshop 2)

Table 33: Experience level of the participants recruited in the study

Participant number	1	2	3	4	5	6	7	8	9	10	11	12	13
Level	Expert Intermediate	Expert	Intermediate	Intermediate	Expert	Expert Intermediate	Expert	Intermediate	Expert	Intermediate	novice	novice	Intermediate
How many laparoscopic procedures have you been involved with in the past?	more than 40	more than 40	more than 40	more than 40	more than 40	more than 40	more than 40	more than 40	more than 40	more than 40	more than 40	more than 40	more than 40

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How many laparoscopic procedures have you done in the past as primary surgeon?	more than 40	more than 40	more than 40	more than 40	more than 40	more than 40	more than 40	more than 40	more than 40	more than 40	0-10	0-10	more than 40
How often do you undertake laparoscopic suturing?	Less than once a month	Once a week	more than once a week	Less than once a month	more than once a week	more than once a week	more than once a week	Less than once a month	Once a month	Once a month	Less than once a month	Less than once a month	Once a week

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How many laparoscopic bile duct exploration (LCBDE) have you been involved with in the past?	10-40	more than 40	0-10	0-10	more than 40	0-10	more than 40	0-10	0-10	0-10	0-10	0-10	10-40
How many LCBDE have you done in	0-10	more than 40	0-10	0-10	more than 40	0-10	more than 40	0-10	0-10	0-10	0-10	0-10	0-10

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the past as primary surgeon?													
How often do you use laparoscopic ultrasound?	Less than once a month	more than once a week	Less than once a month	Once a month	Once a week	Once a month	Once a week	Once a week	Once a week	Once a week	Less than once a month	Less than once a month	Once a week
How often do you perform LCBDE?	Less than once a month	Once a month	Less than once a month	Less than once a month	Once a week	Once a month	Once a month	Less than once a month	Less than once a month	Less than once a month	Less than once a month	Less than once a month	Once a month

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Table 34: Face validation of the simulator

Participant number	1	2	3	4	5	6	7	8	9	10	11	12	13
How realistic are the soft tissues with direct vision?													
Liver	5	4	5	5	4	4	4	4	4	5	5	5	4
Artery	4	4	3	4	3	2	4	3	3	4	4	3	3
Vein	4	3	3	4	3	3	4	3	4	5	5	4	3
Bile duct	4	3	5	3	3	3	4	3	3	4	4	4	3
Gallbladder	5	4	4	4	4	3	4	4	3	4	5	5	4
Duodenum	5	4	3	5	4	3	4	4	3	4	4	5	4
Abdominal wall	4	4	4	5	5	4	4	4	4	5	4	5	4
How realistic do the soft tissues feel?													
Liver	4	3	5	5	5	4	4	4	3	4	4	5	4
Artery	4	3	4	3	2	2	4	3	2	4	5	5	4
Vein	4	3	4	3	2	2	4	2	2	3	5	4	4
Bile duct	4	3	5	4	3	3	4	4	2	4	4	4	4
Gallbladder	5	3	5	5	4	2	4	5	2	4	4	5	4
Duodenum	4	3	3	4	4	3	4	5	3	4	5	5	4
Abdominal wall	4	3	4	4	5	5	4	4	3	4	4	5	4
Does the trainer include all the relevant soft tissues?	Y	N	Y	Y	Y	Y	N	Y	Y	Y	Y	Y	Y
How realistic does the abdominal wall feel during the port insertion?	3	4	4	2	/	4.5	4	3	3	4	3	3	4
Perceived utility: How useful would this simulator be to teach this task?	4	3	4	3	5	4.5	4	5	4	4	4	4	4
How realistic are the ultrasound images?	/	/	/	/	4	3	4	4	3	/	4	5	2
Perceived utility: How useful would this simulator be to teach this task?	/	/	/	/	2	3	3	5	5	/	5	5	2
How useful is it to have different scenarios available?	/	/	/	/	5	3	5	4	5	/	4	5	2

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Perceived utility: How useful would this simulator be to teach this task?	/	/	/	/	5	/	4	4	5	4	4	4	2
How realistic is the choledochotomy?	4	3	4	4	4	3	3	4	2	4	5	4	3
Perceived utility: How useful would this simulator be to teach this task?	4	3	5	5	5	4	4	5	5	5	5	5	3
How realistic is the choledochoscopy?	5	3	5	4	5	4	5	4.5	5	5	5	4	3
How realistic is the stone retrieval from inside the duct?	5	5	5	4	5	4	5	4.5	5	5	5	4	2
Perceived utility: How useful would this simulator be to teach this task?	5	4	5	5	5	4	5	5	5	4	5	5	4
How realistic is the suturing of the bile duct?	3	3	4	4	5	/	/	/	/	5	5	5	3
Perceived utility: How useful would this simulator be to teach this task?	4	3	4	5	5	/	/	/	/	5	5	5	3
Was the simulation challenging enough?	5	5	4	5	5	5	3	4	5	5	/	4	3
Would you like to use more simulation similar to this one incorporated in surgeons' training?	4	4	4	5	5	4	4	5	5	5	/	5	4

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Table 35: Content validation of the simulator

Participant number	1	2	3	4	5	6	7	8	9	10	11	12	13
Port insertion (before training)	5	5	5	5	5	5	5	5	5	5	4	4	5
Port insertion (after training)	5	5	5	5	5	5	5	5	5	4	4	4	5
Ultrasound evaluation (before training)	4	5	1	1	5	3.5	5	4	3	4	1	1	3
Ultrasound evaluation (after training)	/	/	3	/	5	3	5	5	3	/	3	3	3
Decision of the approach (before training)	3	5	1	1	5	1	5	4	3	3	1	1	4
Decision of the approach (after training)	4	4	4	/	5	/	4	5	5	5	4	4	3
Choledochotomy (before training)	4	5	4	3	5	5	5	3	4	2	1	1	4
Choledochotomy (after training)	5	3	5	3	5	4	5	5	3	3	2	2	3
Insertion of the choledochoscope and stone removal (before training)	3	5	4	1	5	4	5	3	4	2	1	1	4
Insertion of the choledochoscope and stone removal (after training)	5	4	5	2	5	3.5	5	5	5	2	2	3	3
Suture of the bile duct/cystic duct (before training)	3	5	4	2	5	4	5	2	4	2	1	1	4
Suture of the bile duct/cystic duct (after training)	1	3	3	3	5	/	/	/	/	2	2	1	3
How would you evaluate your procedural confidence (knowing the steps)?	3	5	4	4	5	4	5	4.5	5	3	1	3	4
How useful would this simulator be to teach the steps of the procedure?	4	3	4	5	5	4	4	4	5	5	/	5	4

How would you rate the usefulness of this training task? (port)	3	4	4	3	5	4	4	5	5	4	4	3	4
How would you rate the usefulness of this training task? (ultrasound)	/	/	5	/	/	3	3	4	5	/	4	4	3
How would you rate the usefulness of this training task? (decision)	4	3	4	/	5	/	4	5	5	5	4	4	3
How would you rate the usefulness of this training task? (choledochotomy)	4	4	5	5	5	4	3	5	5	5	5	5	4
How would you rate the usefulness of this training task? (choledochoscopy +stone removal)	5	4	5	5	5	4	5	4.5	5	5	4	5	3
How would you rate the usefulness of this training task? (suture)	4	4	4	5	5	/	/	/	/	5	4	5	3

Table 36: Construct validation of the simulator

Participant number	1	2	3	4	5	6	7	8	9	10	11	12	13
Completion of the task													
Clip and divide the cystic artery (success?)	yes	yes	yes	yes	yes	yes	yes	yes	yes	yes	yes	yes	yes
Milk and clip Cystic Duct (success?)	yes	yes	yes	yes	yes	yes	yes	yes	yes	yes	yes	yes	yes
Choledochotomy (success?)	yes	yes	yes	yes	yes	yes	yes	yes	yes	yes	yes	yes	yes
Choledochoscopy (success?)	yes	yes	yes	yes	yes	yes	yes	yes	yes	yes	yes	yes	yes
Stone retrieval (success?)	yes	yes	yes	no	yes	no	yes	yes	yes	yes	yes	yes	yes

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Suture close defect (success?)	no	yes	yes	yes	yes	/	/	/	/	yes	yes	no	yes
Assistance level													
Clip and divide the cystic artery (assistance level)	1	1	1	1	1	1	1	1	1	1	2	1	1
Milk and clip Cystic Duct (assistance level)	1	1	1	1	1	1	1	1	1	1	2	1	1
Choledochotomy (assistance level)	1	1	1	1	1	1	1	1	1	1	3	3	1
Choledochoscopy (assistance level)	1	1	2	3	1	3	3	2	2	2	4	4	1
Stone retrieval (assistance level)	2	2	2	5	1	4	3	2	2	3	4	3	1
Suture close defect (assistance level)	5	2	1	2	1	/	/	/	/	2	3	3	1
Time to completion													
Clip and divide the cystic artery (time)	3	3	1	1	2	2	1	1	1	1	4	2	2
Milk and clip Cystic Duct (time)	4	3	2	1	1	1	1	1	2	1	3	3	2
Choledochotomy (time)	5	2	1	1	1	2	2	1	2	4	3	2	1
Choledochoscopy (time)	5	4	4	6	2	8	4	1	3	2	14	4	2
Stone retrieval (time)	6	4	1	>10	4	6	2	2	1	2	4	2	1
Suture close defect (time)	>10	14	6	14	9	14	6	6	19	14	22	13	8
Total time	33	30	15	33	19	33	16	13	28	24	40	26	16
Instrument exchanges													

Number of instrument exchange	29	17	13	18	17	34	19	22	23	21	27	26	19