Automated Cyclic Testing of Prosthetic Knee Joints Using a 4-Axis Robotic Arm: Enhancing Biomechatronics and Human-Machine Interaction

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***Abstract*—The complex nature of knee joints makes designing and testing prosthetic replacements challenging. The ISO 10328:2016 standard requires rigorous static, constant, and cyclic force testing, which involves high forces and variable angles, adding to the complexity. Current prosthetic knee testers are often expensive, high-maintenance, and space-consuming, and many do not meet the ISO 10328:2016 requirements. This paper reviews existing testing methodologies and identifies their limitations. It then introduces a novel solution using a 4-axis robotic arm and a scaled prosthetic knee joint to perform the ISO 10328:2016 tests as a proof of concept. This approach aims to provide an affordable, low-maintenance, and compact testing method, advancing the field of biomechatronics and human-machine interaction.**

***Index Terms*—Prosthetic Knee, Cyclic Testing, Biomechatronics, Human-Machine Interaction.**

I. Introduction

Affordable automated cyclic testing of prosthetic knee joints would provide time-saving benefits and allow one person to test multiple variations of knee joints easily, even allowing testing to be completed while a person is not present. Automating testing is expensive and increases the Research and Development (RnD) costs. Increased RnD costs increase the final product cost applying financial strain to those in need. Higher RnD costs also limit the amount of innovation in the space, limiting the rate of improvement for the final user, possibly causing unnecessary discomfort and/or limiting people's physical abilities/increasing recovery time post-surgery/accident.

This paper explores current testing methodologies, how they work, and breaks down the pros and cons. It is paired with an additional paper exploring a solution utilising a 4-axis robotic arm and spring-powered actuation unit for force application. A thorough review concludes that the current methods are not financially viable for smaller design teams not directly affiliated or funded by large research institutions (with limited funding), or are not compatible with the necessary ISO 10328:2016 specification.

Current methodologies allow testing of constant and gradual forces but shock loads are more difficult to test and imitate the type of force experienced during everyday use. Forces experienced while descending stairs are not gradually applied and are defined as shock loads. These loads often exceed the maximum static loads experienced. Shock testing prostheses is vital for ensuring they are suitable for years of use, multiple years of worst-case loading needs to be tested and evaluated before implementation into human subjects.

An in-depth analysis of the anatomy and biomechanics of knee joints was completed by a team in Bristol [1]. This breakdown provides ample knowledge to understand how the joint moves and acts, providing a good insight into how it should be tested.

II. Review into current testing methodologies

A. Mathematical model testing

Mathematical modelling utilises Finite Element Analysis (FEA) software to model knee joint geometry and simulate the force application. Once validated this methodology can be used to test a prosthetic for varying forcing applications and angles. This method requires a large amount of computing power and FEA simulation software, both at relatively high expense respectively, but can be completed with little to no physical testing once a methodology is validated. Cyclic testing can be completed using FEA software as long as necessary stress analysis and fatigue testing has been completed on the materials being simulated.

Each simulation set-up and meshing process is required to be sufficiently validated for meaningful results. This is a complicated process, however, once an FEA methodology and meshing process is adequately validated the results can give an accurate and precise idea of the capabilities of a design and allow minor changes to be made immediately and 'retested' without the need for physical testing.

Using FEA to simulate additive manufactured products is tricky. The method of manufacturing (e.g. Direct Energy Deposition, Material Extrusion etc) and the quality of the manufacturing process has a great effect on the material properties of the final product. High-fidelity FEA can be used to accurately model additive manufactured products incurring additional time and computing cost [2].

Research published in 2013 validated using this methodology for simulating four-bar linkage models of prosthetic knee joints with cyclic testing [3]. Figure 1 shows the simulation data correlates with the experimental data, having an average difference of 25% and 22% for the two loading scenarios. Large stress overshoots are likely caused by singularities in the simulations mesh and can be reduced through improved meshing.

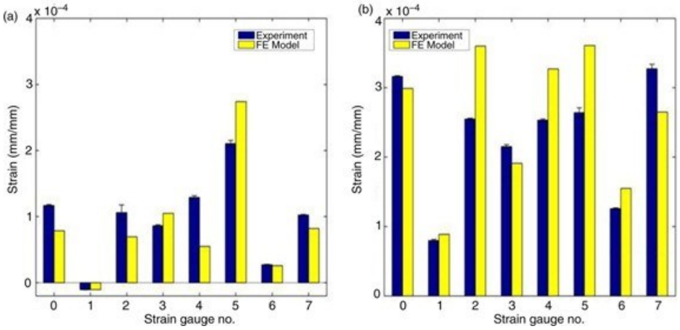

Fig. 1: Validation of simulation data to experimental data for two loading scenarios in cyclic testing: (a) Loading condition I. (b) Loading condition II [3]

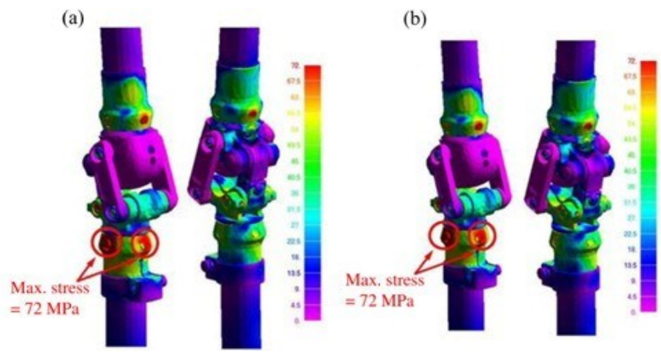

Fig. 2: FEA tested four-bar linkage knee [3]

FEA allows a great opportunity to analyse stress concentrations which is not possible with physical testing. Figure 2 shows where the areas of maximum stress are located allowing designs to be altered, reducing stress concentrations and ultimately increasing the strength of the prosthetic knee joint without needing to manufacture multiple variations of knee joint and test them to failure. This ability also allows areas of low stress to be identified and material removed decreasing weight and material cost. This information is not achievable from physical testing, analysis of the broken test subject can indicate what needs improving but can't show the level of detail provided by an accurate FEA simulation. Internal forces are also available throughout the model allowing internal analysis.

Lapapong et al. [3] modelled a prosthetic knee joint using LS-DYNA. LS-DYNA is an ANSYS product designed for extreme material deformation [4]. The model was meshed using 604,250 tetrahedral elements. No mention of additional meshing techniques (e.g. structured mesh or cartesian cut-cell mesh), or mesh quality (i.e. orthogonal quality or skewness) is made, increasing mesh efficiency and quality would decrease simulation time and increase model accuracy. Two straight "leaver arms" are attached to either side of the joint, easing the strength test simulations. Force was applied in the direction of the loading line seen in Figure 3 with transitional constraints applied to reduce movement. Table I indicates the material properties used for the simulation. For computational and time efficiency Lapapong et al. use explicit nonlinear transient stress analysis, this method deals with nonlinear contact problems accurately.

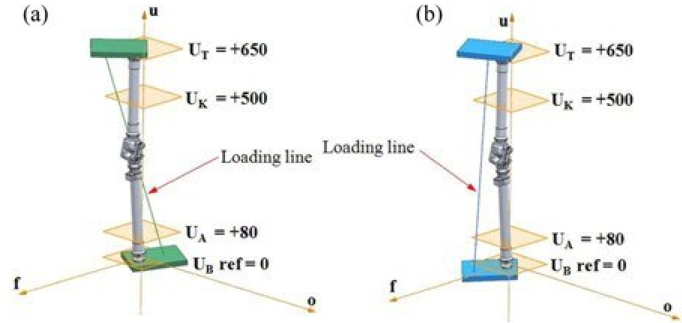

Fig. 3: Line of Loading [3]

TABLE I: Material Properties FEA Testing [3]

Property	Stainless Steel	Plastic	Aluminium
Modulus of Elasticity (GPa)	200	110	70
Poisson Ratio	0.30	0.42	0.33
Density (kgm^{-3})	7,850	950	2,800

The FEA model is validated using a physical experiment which recreates the simulated environment using a knee prosthetic with applied stress gauges connected to a computer using LabVIEW SignalExpress at 100Hz sampling rate. A large servo-pneumatic machine was used to recreate the static and cyclic loads in accordance with ISO 10328:2006.

The specialist equipment needed is a computer and software which are not exclusive to testing prosthetic knee joints and can be used for other purposes. This method can be easily transferred to other types of prosthesis testing. Simulations can also run independently of other work and don't need to be constantly monitored. There is limited safety considerations for the simulations. The physical testing methodology used for validation can recreate loading conditions with a high degree of accuracy using the servo-pneumatic test machine. This could be run independently, without supervision, providing test data for FEA validation or testing of different prosthetic designs.

If the FEA software is not properly set up the results are unreliable meaning a someone with FEA skills needs to be present during setup at a minimum. To ensure the results are correct physical testing is needed at the later stages, before implementation physical testing will need to be completed to achieve standards specification. The validation presented indicates that there is a correlation between physical and simulation testing but the results are not accurate enough for implementation into a physical subject. Both Ansys "LS-DYNA" and MSC Fatigue software are prohibitively expensive for commercial use and greatly increase the barrier to entry for this method for smaller organisations.

The servo-pneumatic test machine lacks the ability to automatically test various angles of force application. The testing of various angles, as specified in ISO 10328:2016, is key to ensuring that the prosthetic has adequate endurance for different loading scenarios.

Simulations take time to set up correctly and Modeling a prosthetic accurately is tricky if the design is not already in the correct CAD format, this can be made easier using a 3D scanner (such as an Einstar Handheld 3D Scanner by 3D GBIRE (£1042.80) [5]) if a physical model is present. Accurate scans will take time and care from a trained individual. This cost is compounded on the cost of server time (e.g. rescale) or computer hardware, not accounting for electrical costs of high-powered simulations (very regionally dependent).

This paper lacks any clarity regarding the mesh quality, there could be stress inaccuracies due to high skew mesh elements, or areas of inaccuracy due to poor orthogonal quality. A low-quality mesh lowers the accuracy and repeatability of the results.

The physical test force was only applied along one axis, to test multiple angles would require physical intervention by a human operator or integration of another system to alter the experimental set up. The equipment used also has a high initial cost, limiting its use by small operations.

For cyclic testing the max stress is obtained from the LS-DYNA simulation, this value is input into the MSC Fatigue model to estimate the fatigue life of the prosthesis. The addition of more software further increases cost (MSC Fatigue costs €20,000-42,000 [6]). There are also key estimations made throughout the process (e.g. The S–N curve of stainless steel is estimated based on an empirical formula from another paper) that limit the accuracy of the method.

B. Human testing

Human testing requires the knee prosthetic to be attached to a lower leg assembly. Once implemented in a full lower leg assembly, this can be used by an able-bodied test subject using a bypass orthosis. Lenzi et al. [7] created a complete lower leg replacement and used a bypass orthosis to test it using a two-legged subject. Human testing gives a great view of how a user will use a prosthetic. However, due to difficulty creating repeatable experiments (consistency), the constant need to have a human present, and the lack of force required for the ISO 10328:2016 specification. For these reasons linked with the purpose of this review paper, this method is acknowledged but excluded from this paper.

C. Mechanical Simulation

Similar to the testing methodology described in the validation of Lapong et al.'s [3] FEA simulation, mechanical testing uses machines to apply forces to the prosthetic knee joint. Depending on the machine it can also be used to alter the angle of the knee joint for testing at various angles.

Knee movement is a key aspect of a knee prosthetic, Lowery and Walker [8] use a dual-axis 'Oxford-type' machine to complete repetitive testing simulating a human squatting. An Oxford machine "...was designed for biomechanical testing of post-mortem human knee-joint specimens during simulated flexed-knee stance..." [9], working in one axis to complete cyclic testing, Figure 4 shows Lowery and Walker's set up. The vertical movement of the machine causes a bending motion in the simulated knee joint.

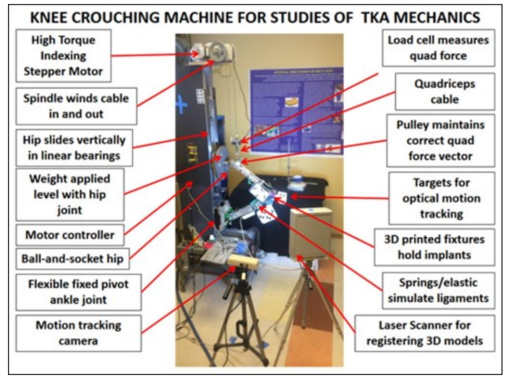

Fig. 4: Oxford Loading Machine [8]

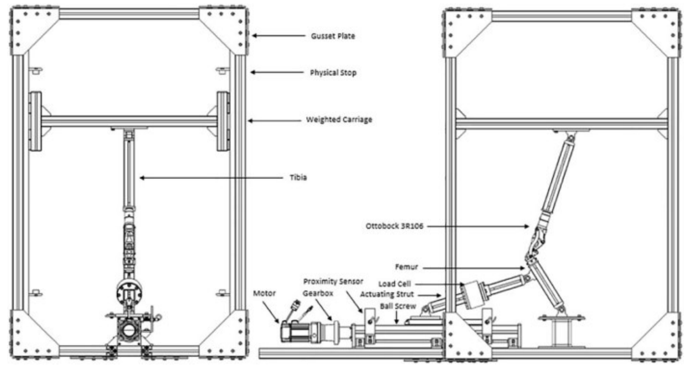

Fig. 5: Universal testing Rig [10]

The test rig described [8] works well for testing mobility, and bending toughness (work hardening), however, does not allow testing of different force conditions. Etoundi et al. designed a Universal Testing Rig (UTR) that allows prosthetic testing from copious angles. This rig can test a knee joint at all necessary angles for ISO 10328:2016.

Figure 5 shows the rig schematic designed by Etoundi et al. [10]. This was created using aluminium extrusion to create a frame around a brushless AC servo motor, linear ball screw actuator and gearbox which allows the knee joint to be moved into various angles and tested. Being able to change the angle of the joint allows complete testing of the knee joint within one machine. The motors are run and results are measured from strain gauges through a PC using a myRIO and NI LabVIEW for input and output control. SVX Servo Suite was supplied with the motors and used for basic motor control. Once the prosthetic is loaded into the rig a complete suit of tests can be completed autonomously without removing the prosthetic from the rig.

Testing is able to be completed for all loading conditions and angles of ISO 10328:2016 while a person is not present, allowing testing to be completed overnight if necessary. Decreasing the time taken decreases the cost of RnD and the final prosthesis. The strain gauges applied to the tested knee prosthetic allow the measuring of the force through the joint, verifying that the testes would validate ISO 10328:2016.

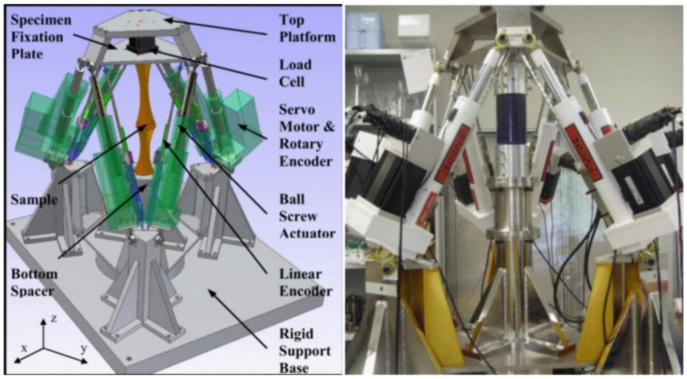

Fig. 6: Hexapod Render & Design [16]

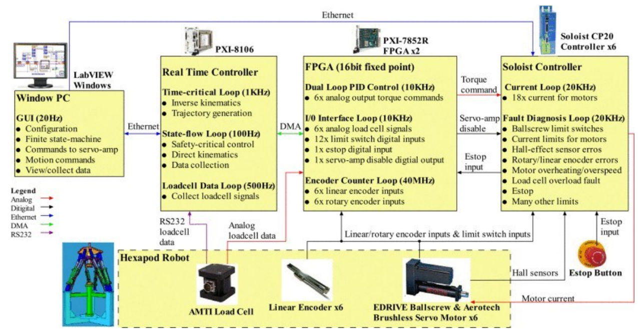

Fig. 7: Hexapod Control Schematic [16]

The maximum load that can be applied is equivalent to 50kg ($\approx 490.33N$), increasing this value by increasing motor voltage (to 8V) surpassed the limits of the equipment causing sporadic loading. Having non-consistent loading leads to inconsistent testing drastically decreasing experimental repeatability. This renders results (over 50kg of loading) redundant. There is a high probability of a load greater than 50kg going through one knee joint. Assume an average female weight (71.8kg [11]) wearing an 8kg backpack missteps while walking, a load of 79.8kg could pass through one leg (and one prosthetic joint) as a shock load, which is not possible to be tested using the current design. The rig has a large working and physical envelope and requires a high degree of safety elements, further increasing its size.

It is assumed that there is a large budget and workspace, with the cost of the motors (designed by Applied Motion for £539.24 [12]), linear ball screw actuator (designed by HepcoMotion for £2,300 [13]), gearbox (designed by Wittenstein for £378.00 [14]) and myRIO (designed my National Instruments for £572.24 [15]) equaling £3,789.48 excluding connecting hardware, external hardware, safety hardware and software/computer costs, this rig incurs a large upfront cost.

Ding et al. [16] designed and manufactured a hexapod machine, Figure 6, controlled with a Feild Programable Gate Array (FPGA) processor through LabVIEW. This setup allows 6 degrees of freedom (DoF) for the load applicator, all being measured through a load cell on the subject. Each of the six actuators have a maximum force of 4kN, with a maximum velocity of 200mm/s, allowing rapid testing of ISO 10328:2016.

The architecture used, figure 7, allows full control over the machine and data collection through a PXI-8106 [15]. LabVIEW Real-Time is used to "generate the deterministic trajectory, perform inverse/direct kinematics, implement safety-critical control, and collect data from ... [the] (FPGA)..." [16]. The kinematics control scheme can be found in the paper.

The design created allows the full testing of ISO 10328:2016 to be completed without human intervention between testing scenarios (assuming no critical failures). The mechanical, electrical, kinematic and system architecture design has been proven as suitable for bio-medical testing [16]. Implementation of this design for testing knee prosthesis would be a simple switch and allow the autonomous testing of one prosthetic at a time. Testing is completed on a replica spine indicating that the working envelop is adequate for knee testing.

The cost of Ding et al's. [16] design is exceedingly high with the six linear ballscrew actuators (EDRIVE designed VT209 at £329.04 [17]), six DC brushless rotary servomotor's (AEROTECH's BM250 (Price not avalable)) [18]), six encoders (MicroE systems designed LDM-54 £317.64 (competitors costs provided), [19]), the frame is made of surgical grade 316L stainless steel (£23.00 per 23x10000mm bar [20]), 6-DOF load-cell (the MC3A-6–1000 designed by AMTI (Price not avalable))), two FPGA boards (National Insruments designed PXI-7852R at £11,100.00 [21]) combining (excluding cost of frame, connecting hardware, external hardware, safety hardware and software/computer costs) to cost £25,880.08 for this design.

Figure 6 shows the size of the final design. Similar to the UTR [10], on a greater scale, the large size is a hindrance. Etoundi et al's. design could be relatively easily disassembled for long-term storage, allowing a design team to store the machine in periods where it is not necessary. Due to the complexity of Ding et al's. design disassembly is not feasible limiting storage possibilities, in addition the rate of failure is likely to be higher, as well as the repair costs. The higher complexity increases the lifetime costs, pushing it further out of reach for smaller research teams.

If testing of multiple prosthesis or designs is needed a human is needed to load the cell up, design of an automatic loading system would allow more rapid automatic testing to be completed. This issue is also shared by the design proposed by Etoundi et al. Despite this design providing good results when tested, the test subject was not a knee joint/prosthetic and it is not clear whether it can achieve movement testing such as Lowery and Walker's design. Although the design has 6 DoF there is no mention of the working envelope which may limit the size of prosthetic that can be tested. The largest shortcoming of this design is the severe cost which limits its use to large biomedical companies or universities. The large size and complexity both reduce the usability of this design.

Although most mechanical test methodologies use solely ac-

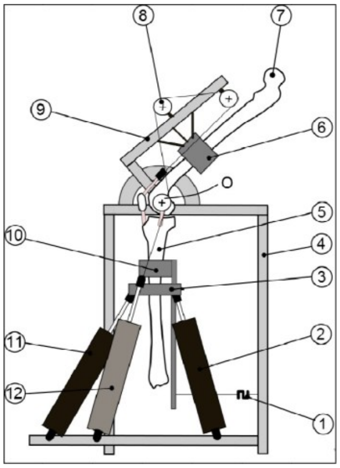

Fig. 8: Schematic representation of Forlani's test rig (For numbers see ref) [22]

Fig. 9: "Classical 6-6 Gough-Stewart architecture with base diameter of 800 mm and platform diameter of 240 mm" [22]

tuators for movement simulation and force application Forlani el al. [22] designed a system that uses a combination cable-electric system that moves and applies force to the joint. Figure 8 shows a schematic of the system. This form of testing allows changes in joint angle, high force application and measuring of the force passing through the joint.

Initially an investigation into what type of actuator would be ideal for this application was completed, concluding that use of a linear ball screw with a rotary stepper motor through a reducing gearbox is the best solution. Matlab was used to calculate the maximum force experienced during "wrenching" and "experimentally measured trajectories have been simulated [to] understand the required velocities." [22]. These forces informed the motor buying procedure. Each motor can apply 4kN of force and this is controlled and measured by a closed loop system.

Several configuration architectures have been reviewed in depth, the 6-6 Gough-Stewart platform architecture was chosen as seen in Figure 9. The method of fixation for the femur and tibia (what would be the femur and tibia replacements in the testing of a prosthetic) were then designed, seen in Figure 10. The pulley system for muscle simulation was then designed, using electric motors for control.

The rig designed allows incredibly accurate measurement

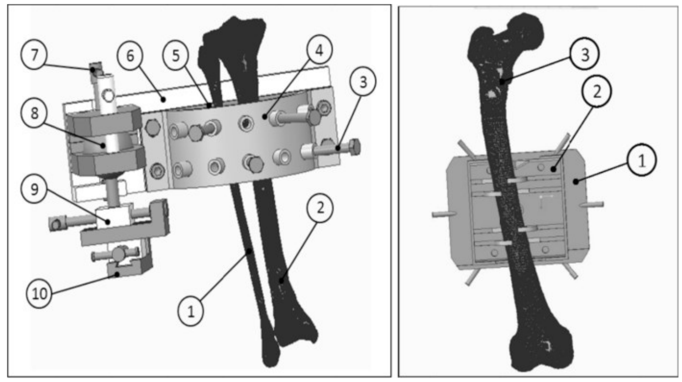

Fig. 10: Tibia and Femur Fixation Methods (For numbers see ref) [22]

and completion of cyclic testing. The force that can be exerted and movement available allow the rig to meet the rigorous standards set by ISO 10328:2016. The fixation methods created are non-destructive and would facilitate the rapid changing of different prosthesis when testing of multiple designs in quick succession is needed.

The rig designed is highly complex, increasing the maintenance difficulty/cost and the possibility of a malfunction. The rig has not been validated for the use of testing prosthesis specifically or for the direct requirements of ISO 10328:2016 despite its apparent ability to meet these requirremnts. The design process focused on applying accurate muscle movements on an in-vitro knee joint to evaluate its behaviour. This is likely to be able to accurately test knee prosthetics but will need to be valided for this use.

Although the control system is detailed it is not mentioned what equipment or software is used or needed. It is assumed that the control system is known or designed bespoke for each application which increases cost and time needed to get the rig functioning at the offset.

III. Results and Discussion

Figure 11 is a comparison table of all the discussed methodologies allowing assessment and comparison between methods. It is clear that there are methods that can complete the necessary testing for ISO 10328:2016, however, these incur a high costs that restricts the ability of design teams to test their designs. The use of a validated FEA model for testing would allow rapid development of designs, however, this requires a high level of knowledge in FEA simulation as well as simulation software and computer hardware powerful enough to run the simulations in an appropriate time. This last point can be countered by the use of services such as rescale, again at high cost, although FEA can't be used for certification and physical testing is still required of the final product. This could be completed on loaned/borrowed equipment. There is a clear discrepancy in the methodology market for a cheap easy to use mechanical tester that can complete cyclic testing of prosthetic knee joints automatically. All cheap testing method either lacks the force required to test or the ability for cyclic/rapid cyclic testing.

Name [Source]	Form of Testing	Validation Method	Ammount of applicable force (N)	Physical requirements	Sorftware requirements	How often is human interaction necessary	Can it apply the ISO 10328:2016 test suit	Is this method viable for a small - medium team (and why)
Finite element modeling and validation of a four-bar linkage prosthetic knee under static and cyclic strength tests by Lapapong et al. [3]	Finite Elemenet Analysis	Physical Testing	Hypothetically infinite	Computer (Power of computer directally relates to time to complete simulation)	ANSYS LS-DYNA	Once per Simulation - Multiple tests can be run simultaniously with FEA (Will take more time for simulations to complete)	ISO standrd currently requires physical testing but the FEA process can be used to create the final design that goes to the final/physical testing	ANSYS LS-DYNA is expensive specilised softeware that is out of the reach of small - medium teams not affiliated with a university or large funding body/research institute
Evaluation of total knee mechanics using a crouching simulator with a synthetic knee substitute by Lowry et al. [8]	Oxford Style machine	Physical Testing	N/A	Oxford Style machine	N/A	Once per prosthetic	Partially (non-forcing requirements)	Relativly viable cost and working envelope, doesnt test for force application
A robotic test rig for performance assessment of prosthetic joints by Etoundi et al. [10]	Universal Joint Testing Rig	Physical Testing	50kg (≈490.33N)	Universal Joint Testing Rig + Computer + myRIO	LabVIEW	Once per prosthetic	Partially (non-forcing requirements)	Viable working envelope, doesnt test for force application, high inital cost
Real-time fpga control of a hexapod robot for 6-dof biomechanical testing by Ding et al. [16]	Hexapod	Physical Testing	4,000	Hexapod + FPGA + I/O Module + Computer + myRIO	LabVIEW & LabVIEW Real-Time	Once per prosthetic	Fully	Completely unviable due to cost, size and complexity and controll complexity
A NEW TEST RIG FOR IN-VITRO EVALUATION OF THE KNEE JOINT BEHAVIOUR by Forlani. M [22]	Cable-Electric Rig	Physical Testing	4,000	Testing Rig + Load cell + Unknown Controll System	Unknown	Once per prosthetic	Not mentioned in paper - Partial	Not viable due to complexity, cost and lack of information about the controll systems

Fig. 11: Comparison Table

IV. Conclusion

There is a significant gap in the market for an affordable and easy-to-use testing method for prosthetic knee joints, particularly for smaller design teams not affiliated with large research institutions. Addressing this gap would enable these teams to test their designs more effectively, accelerating the safe development of prosthetic knee joints. By integrating computational simulations with a cost-effective physical testing rig, the R&D process can be streamlined. This approach allows for rapid iteration and testing of designs, ultimately increasing the likelihood of achieving an optimal prosthetic knee joint.

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