REVIEW

Short running header: Review of clinical effectiveness for long-term follow-up of hip arthroplasty

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Systematic review of the clinical effectiveness for longterm follow-up of total hip arthroplasty

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Abstract:

Objectives

Total hip arthroplasty (THA) is highly successful but national registries indicate that average age has lowered and that younger patients are at higher risk of revision. Long-term follow-up of THA was historically recommended to identify aseptically failing THA, minimising the risks associated with extensive changes, but follow-up services are now in decline. A systematic review was conducted to search for evidence of the clinical or cost-effectiveness of hip arthroplasty surveillance.

Methods

The study was registered with PROSPERO International Prospective Register of Systematic Reviews and conducted according to PRISMA guidelines; databases included MEDLINE and Embase, and all studies were quality assessed. Original studies (2005 to 2017) reporting follow-up of adults with THA in situ >5 years were included. Researchers extracted quantitative and qualitative data from each study.

Results

4137 studies were screened for eligibility: 114 studies were included in final analysis, representing 22 countries worldwide. Data extracted included study endpoint, patient detail, loss to follow-up, revisions, scores and radiographic analysis. Six themes were derived from inductive content analysis of text: support for long-term follow-up, subgroups requiring follow-up, effect of materials/techniques on THA survival, effect of design, indicators for revision, review process.

Main findings - follow up was specifically recommended to monitor change (e.g. asymptomatic loosening), when outcomes of joint construct are unknown, and for specific patient subgroups.

Outcome scores alone are not enough, and radiographic review should be included.

Conclusions

There were no studies directly evaluating the clinical effectiveness of the long-term follow-up of THA but expert opinion from a range of international authors advocated its use for defined subgroups to provide patient-centred care. In the absence of higher level evidence, these

opinions in conjunction with emerging outputs from the national joint registries should be used to

inform services for long-term follow-up of THA.

Keywords: Hip joint, replacement, surveillance, revision, continuing

Introduction

For many people, total hip arthroplasty (THA) is successful for treating a painful, arthritic hip but

national registries indicate that 10% of implants will subsequently require revision, which

increases to 30% for those under 50 years old at primary surgery. 1 Up to five years post-

operatively, revision is predominantly undertaken for dislocation, infection or prosthetic failure, 2-4

all of which present with pain. In the longer term, there is an increase in revision for aseptic

loosening which can be asymptomatic and thus, surveillance offered identification of a potential

problem for these patients. This was predominantly attributed to osteolysis generated by the

wear debris from the widespread use of polyethylene⁵ but with the change to cross-linked

polyethylene, future patterns of presentation may differ.

Although there is mandatory surveillance of metal-on-metal hip arthroplasty in the United

Kingdom (UK),6 there is no mandatory requirement for follow-up of other types of THA, and

concern about follow-up is widespread as arthroplasty surveillance has been reduced.⁷⁻⁹ Some

suggest it can be conducted by general practitioners, others maintain that it should be the

orthopaedic team^{10,11} and still others are undecided about such services. In view of economic

constraints on health services, plus concerns about medicalisation and over-diagnosis, 12 long-

term follow-up of any patient group must be justified by evidence that it offers patient-centred

clinical effectiveness and cost-efficiency. We conducted a systematic review of the literature to

search for evidence of the clinical or cost-effectiveness of hip arthroplasty surveillance services.

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Methods

The systematic review was registered with PROSPERO International Prospective Register of Systematic Reviews (https://www.crd.york.ac.uk/prospero/display_record.php?RecordID=20517); methods were adapted from the Cochrane Handbook¹³ and it was conducted according to PRISMA guidelines,¹⁴ although not limited to randomised trials.

Inclusion and exclusion criteria

The selected population were adults with THA in situ for longer than five years. Studies were included if they reported any form of follow-up or surveillance or review of people with THA, whether face-to-face or by questionnaire or by virtual methods. Studies were excluded if reporting the development of an outcomes tool or a surgical, radiographic or chemical intervention, or were reporting secondary data analysis. Evaluations of interventions in randomised controlled trials were considered as cohort studies.

Literature search

We searched: MEDLINE, Embase and PsycINFO on Ovid, CINAHL on EBSCOhost, the Cochrane Library and abstracts of scientific meetings. Searches were limited by date (January 2005 to May 2017) and to English language. All types of original research study were considered, including prospective or retrospective longitudinal studies, cross-sectional studies and randomised trials. Where a report existed of an earlier study, the most recent published paper was retrieved. The search strategy was developed for MEDLINE and terms were adapted for use in other databases (Table 1).

Study selection

Titles and abstracts were screened for eligibility by two reviewers before proceeding to the full text: inconsistencies between reviewers were resolved by discussion based on full text articles.

Data extraction

The records of all saved searches were downloaded into Refworks® (ProQuest L.L.C.); then transferred to a Microsoft Excel spreadsheet for cataloguing decisions on inclusion and exclusion. A second spreadsheet was developed for data extraction which included: study details and period, setting and country, assessment of study endpoint, method of statistical analysis, number and age of patients, loss to follow-up, number of revisions, outcome scores and radiographic analysis, reports of asymptomatic loosening of THA and any report of costs or cost effectiveness.

Following the registration in PROSPERO, a secondary method was employed to capture text and opinion relating to the research question as early stages of our review suggested a lack of studies that directly evaluated follow-up services. The Joanna Briggs Institute propose that inclusion of text, to which qualitative review techniques are subsequently applied, provides the opportunity to describe the insights and opinions of authors to inform the quantitative evidence. A summary sentence or paragraph reporting the authors' interpretation of the findings of each study was extracted for qualitative analysis.

A check between researchers for consistency and quality of the extracted data was conducted after completion of the initial 10 studies, and a further check was completed on a random sample of 20 papers at the end of data extraction.

Methodological quality

All the included studies were assessed for quality and rigour against the methodological index for non-randomized studies (MINORS)¹⁶ and a global score was assigned to each. The MINORS score is a summation of individual item scores (zero to 2 for each item), with maximum of 24 for comparative studies and 16 for non-comparative studies (Table 2).

Data analysis

Descriptive statistics were used to present quantitative data and a method of hybrid content analysis was used for the qualitative data.¹⁷ Primary outcome measures were the number of joints that survived, number that failed and number revised (or planned for revision) as a proportion of the number and type of hip replacements included in each study, plus any data on costs or cost-effectiveness. Secondary outcomes were mean patient reported outcome scores and health related quality of life.

The qualitative analysis was completed in two phases: the first was to apply inductive content analysis to the data extracted from each study to inform a thematic framework that summarised the text on clinical and cost effectiveness (primary author). The second phase was a deductive analysis, guided by the framework, to verify the inductive analysis and to further synthesise the data relating to the research question. This second phase was conducted by two co-authors and was an iterative process, during which the framework was reviewed and amended to provide a final analysis agreed by all. The results were reported with the quantitative data and a MINORS score for each study, to allow readers to assess the textual evidence as unequivocal, credible or unsupported.¹⁵

Results

Studies included

The review process identified 4943 articles (4137 after removal of duplicates) which were screened for eligibility. Many records were excluded because they were not THA or presented short term follow-up, leaving 159 potentially eligible full-text articles. A further 45 were subsequently excluded after full-text review for reasons listed in Figure 1, leaving 114 studies for inclusion in the final analysis. The dates of primary surgery ranged from 1965 to 2011 and there

were 22 countries of origin. Five studies utilised a case control method, 96 were case series, 10 were randomised controlled trials (RCT) and three were cohort studies. An overview of study characteristics is shown in Table 3 and details from each study are presented in Appendix I.

Quality assessment

All studies included clear aims and outcomes, and the design was prospective in 50%. The MINORS scores can be seen in Figures 2&3. Three of the studies reported a sample size calculation and statistical analysis was most commonly a prosthesis survival statistic.

Clinical effectiveness

The data showed a wide range in age and number of patients (Table 4). None of the studies specifically evaluated the clinical effectiveness of follow-up in terms of benefit to the patients or the providers through diagnosis of asymptomatic changes although data relevant to the clinical effectiveness of follow-up included the reporting of radiographic review of THA (86% of studies), reports of asymptomatic loosening (36% of studies) and the number of revision hip arthroplasties (Table 4). The use of patient reported outcome measures, which are designed to capture changes in function and symptoms as perceived by the patient, increased over time. The most frequently used outcome measure was the Harris Hip Score, which became widely adopted by English speaking orthopaedic communities as a surgeon-completed score following initial publication in 1969¹⁸. The geographical and time related use of outcome scores can be seen in Table 5.

Content analysis

Inductive content analysis was applied to extracted text and summarised by a representative phrase. Two of the authors deductively reviewed and revised the framework until agreement was

reached between all authors that it related to the research question. Six themes emerged that encapsulate the findings. These are summarised as follows with illustrative text for each theme (Table 7) and further details in Appendix I.

1. Support for long-term follow-up

Long-term follow-up was directly advocated by the authors in 41 studies, 21 to monitor changes and 20 for unknown outcomes. The reasons given were evaluation of the temporal effect on fixation and materials, continued observation of host response to implanted materials, and to provide understanding of progressive and potentially damaging changes, especially in younger patients.

2. Subgroups requiring follow up over time

The outcomes of THA in specific subgroups of patients was reported in 28 studies - nine monitored changes around the prosthesis and 19 assessed the patients for unknown outcomes. The categories included age of patient (10 studies), weight (3 studies), activity levels (3 studies), gender (1 study), and a range of diagnoses listed in Table 6. Some reported survival of the THA in the subgroup; others reported mid-term results. Many authors advocated longer follow-up (either explicitly or implicitly) due to concerns about patterns of failure of the THA in the defined subgroup of patients and the need for revision.

3. Effect of materials and techniques on survival of THA

Twenty studies described the effect of a range of materials and techniques for THA. Materials included titanium, hydroxyapatite coatings, ceramic-on-ceramic bearings, metal-on-metal bearings, and polyethylene (the wear reduction of highly cross-linked polyethylene was demonstrated at mid-term). Authors in 13 of the studies claimed that the results supported

continuation of their practice and in the others, further long-term follow-up was advocated to assess THA survival; some emphasised the importance of follow-up into the second and third decades.

4. Effect of design on survival of THA

Thirteen studies examined the effect of construct design on THA survival and described outcomes and failure mechanisms related to fixation, shape of femoral stems and size of the femoral head.

5. Indicators for revision

Factors that might predispose to revision THA were addressed in five studies; two addressed high polyethylene wear rates (both pre-dated the introduction of cross-linked polyethylene), one reported on primary hospital type (no effect on long-term survival) and two others reported on the use of radiographic monitoring to identify asymptomatic loosening.

6. Elements of the review process

Many studies described the methods of follow-up and, although most were research studies, some were reporting results from ongoing surveillance services. 19-21 Radiographic assessment was widespread with 101 studies (89%) reporting radiographic results (Table 4) and most included a patient reported outcome score (Table 5). The use of validated patient centred outcome scores has increased over time, with some studies adding a contemporary measure to a more traditional one. 19,22

Ten defined the processes that should be included in long-term follow-up of THA, predominantly the inclusion of radiographic review and the use of outcome scores. Two studies referred to

loosening identified on x-ray in the absence of symptoms and highlighted the lack of correlation between the two. Both studies were of a cohort of cemented THA with polyethylene that predated the use of cross-linked polyethylene.

There were no studies on the cost-effectiveness of the review process. One paper presented data on the cost-effectiveness of the primary hip arthroplasty and the authors emphasised the importance of patient selection to maximise value for THA in the longer term.²³

Discussion

There were no studies which directly evaluated the clinical or cost-effectiveness of THA surveillance and so the studies were analysed using a combination of descriptive analysis and qualitative techniques. The summary data demonstrate the wide range of countries (22 in total) and the significant length of follow-up (up to 27 years) that have contributed to this review. In addition to the summary data, analysis of authors' opinions showed that 41 studies specifically advocated follow-up and none suggested that it should be abandoned. The reasons for continued surveillance were because the effect of time, interaction with the host body and outcome of specific techniques are unknown factors, plus the need for evidence of the outcomes of newer materials and alternative fixation methods, and most importantly, to provide patient-focussed care. In addition, the use of follow-up was advocated for subgroups of patients such as those with dysplasia or avascular necrosis, or patient characteristics such as the super-obese due to poorer long-term outcomes which predispose them to revision arthroplasty. Other studies emphasised the need for follow-up of younger or more active patients due to the increased risk of revision. These comments form a body of expert opinion for consideration in provision of long-term follow-up services.

As described earlier, long-term follow-up has often been used to identify asymptomatic failure following THA. There were 41 studies (Table 4) that specifically referred to asymptomatic failure

and of these, 29 studies (70%) were of patients whose primary surgery took place before the year 2000, which is before the widespread use of cross-linked polyethylene, the long-term outcomes of which may change the pattern of presentation. Newer materials have improved the survival rates and reduced the need for surveillance in the first decade following THA,⁴ but surveillance in the second and third decades was still considered important by many of the authors. Although new or modified designs of THA that are introduced in the UK can now be closely monitored,²⁴ and national joint registries provide data on the longevity of components, experiences with metal on metal hip arthroplasty have highlighted the negative effect of insufficient surveillance.²⁵

Discoveries in relation to the failure of THA mean that the interpretation of failure is still evolving, and some long-term follow-up may still be required to assess the patterns of impending failure and to inform the future care of patients.^{1,26,27}

The methods used in long-term follow-up have not been precisely defined⁹ and, although the combination of outcome scores and radiographic evaluation is common, their correlation with each other is not guaranteed.^{28,29} The implication is that the use of an outcome score without radiographic evaluation will not be sufficient to monitor THA.³⁰ Some orthopaedic surgeons will consider revision for radiological loosening in the absence of significant symptoms,³¹ as 'an early revision on adequate bone stock presents more chance of success and a better functional prognosis for the patient'.³² This illustrates that the threshold for progression to revision surgery in cases of aseptic loosening is not a fixed and definable point, and that the decision-making process includes both objective and subjective elements together with patient choice.

We found no evidence of the cost-effectiveness of THA surveillance. The lack of evidence threatens the continuation of follow-up services as cost implications are unknown: can follow-up services reduce costs through simple, timely revision instead of more complicated, reconstructive surgery or emergency surgery?³³ Although some studies have evaluated the cost-effectiveness of THA, ³⁴⁻³⁶ they do not discuss the use of surveillance as a tool to facilitate 'timely' revision. One

study which evaluated the economics of three models of follow-up recommended less intensive early follow-up.³⁷

Limitations

The strengths and weaknesses of this review are not unique and are associated with inclusion of observational cohort studies which are subject to confounding factors and bias, and impacted by loss to follow-up, particularly when the study extends over many years.³⁸ The geographic removal of patients, development of comorbidities or death because of advanced age, are all known barriers to completion of longitudinal studies.³⁹ In this review, 63% of studies had loss to follow-up of ≤20% and the quality was also compromised by lack of independent assessment of study outcomes; long-term, single centre studies often have a limited choice of staff available to obtain study outcomes.⁴⁰

Future

The growing number of primary THA leads to a growing number of revision surgeries⁴¹ with associated costs. It is unclear if the use of long-term follow-up can lessen this burden by identifying patients in time for a relatively simple revision or reducing the number of those requiring emergency surgery for peri-prosthetic fracture. Currently, the provision of THA surveillance is sporadic and the cost of delivering it proves prohibitive for many hospitals, leading to consideration of alternative models of follow-up.^{42,43} A research programme in the UK is currently exploring the implications for disinvestment and the outcomes will be relevant for patients, health professionals and commissioners when considering future services.⁴⁴ With the current emphasis on patient-centred care and long-term conditions, there may be benefit in offering selected subgroups of patients a choice for follow-up. The model of delivery of such a service should be time and cost efficient, and responsive to change as new evidence emerges from national joint registries.

Conclusion

We systematically reviewed the literature for evidence of the clinical effectiveness of long-term follow-up of hip arthroplasty. We were unable to identify specific quantitative evidence but the evaluation of authors' comments from a wide range of countries offers expert insight into the use of follow-up in the continuing provision of long-term, patient-centred care following total hip replacement.

Disclosure

The authors report no conflicts of interest in this work.

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Table 1 Search strategy

STEPS	TERMS					
1	hip AND replace* {No Related Terms}					
2	limit 1 to (English language and humans and yr="2005 -Current")					
3	limit 2 to "all adult (19 plus years)"					
4	(surveillance or observ* or "follow up").af.					
5	3 and 4					
6	hip AND arthroplasty {No Related Terms}					
7	limit 6 to (English language and humans and yr="2005 -Current")					
8	limit 7 to "all adult (19 plus years)"					
9	4 and 8					

Table 2 Methodological items for non-randomized studies (MINORS)

- 1 A clearly stated aim
- 2 Inclusion of consecutive patients
- 3 Prospective collection of data
- 4 Endpoints appropriate to the aim of the study
- 5 Unbiased assessment of the study endpoint
- 6 Follow-up period appropriate to the aim of the study
- 7 Loss to follow-up less than 5%
- 8 Prospective calculation of the study size

Additional criteria in the case of comparative study

- 9 An adequate control group
- 10 Contemporary groups
- 11 Baseline equivalence of groups
- 12 Adequate statistical analysis

Table 3 Characteristics of included studies

Data type	Range	Number of
		studies
Country & No. of studies	Argentina 1, Australia 4, Canada 7, China	114
	6, England 8, Finland 1, France 9,	
	Germany 3, Greece 4, Japan 15, Norway	
	2, Poland 1, Scotland 1, South Korea 16,	
	Spain 7, Sweden 2, Switzerland 3, Taiwan	
	2, The Netherlands 6, Turkey 1, UK 1,	
	USA 17	
Contemporary groups	Yes	44
	With baseline equivalence of groups	20 of 44
	No	69
	Unclear	1
Inclusion of consecutive patients	Yes	69
	No	30
	Unclear	15
Setting	Single centre	104
	Multicentre	10
Clearly stated aim	Yes	114
Prospective collection of data	Prospective	57
	Retrospective	57
Endpoints appropriate to the aim of	Yes	114
the study		
Unbiased assessment of the study	Yes	39
endpoint		
	No	28
	Unclear	47

Loss to follow up	Unknown	13
	Zero	19
	<5%	8
	5 to 10%	21
	10.1 to 20%	24
	20.1 to 30%	11
	30.1 to 40%	9
	40.1 to 50%	4
	More than 50%	5

Table 4 Summary of extracted data

Data type

	Value	Range
Age of patient (years)	55.7 (mean)	17 to 98
Number of patients in study	107 (median)	6 to 18968
Length of follow up (years)	11.05 (median)	3.6 to 26.7
Percentage of cohort revised (all causes) in each study	5 % (median)	0 to 74%
Radiographic changes results reported in study	Yes	101
	No	13
Asymptomatic loosening reported in study	Yes	41
	No	43
	Unclear	30

Table 5 Use of outcome scores by country and time

		Number		
		of		
		studies		
Name of	Year of	using		Study period
score	publication	score	Country of study	covered
Scores originally completed by orthopaedic surgeon				l
			England, USA, Sweden, France, Korea, China,	
			Ireland, Australia, Germany, Greece, Japan,	
HHS	1969	73	Turkey, The Netherlands, Taiwan	1982 to 2011
			France, Korea, Greece, The Netherlands, Taiwan,	
PMA	1954	15	Japan, Poland, India	1976 to 2010
JOA hip				
score	1993	5	Japan	1996 to 2005
Scores comple	eted by the pat	tient		
HOOS	2003	1	France	2000 to 2008
EQ-5D	1990	3	England, France, Scotland	2000 to 2010
VAS PAIN	1974	2	Argentina, The Netherlands	1985 to 2006
			USA, Switzerland, England, Greece, Korea,	
UCLA	1984	10	Canada, China	1993 to 2011
SF36	1992	7	USA, Japan, England, Canada, The Netherlands	1994 to 2010
OHS	1996	10	England, Finland, Scotland, The Netherlands, UK	1988 to 2010
WOMAC	1988	12	USA, Canada, Spain, Australia, Korea, Greece	1984 to 2006
TEGNER	1985	2	USA	1994 to 2003
SF12	1996	4	Spain, Canada, Australia, Switzerland	1992 to 2011
Unknown sco	res	<u> </u>		

Unvalidated				
scores	n/a	2	Switzerland, France	1965 to 2008
No score			England, Germany, Japan, France, Sweden,	
used	n/a	11	Norway, Greece, USA, Spain	1972 to 2013

Abbreviations: HHS Harris hips score, PMA Merle d'Aubigne & Postel, JOA Japanese
Orthopaedic Association, HOOS Hip osteoarthritis outcome score, EQ-5D EuroQol health-related questionnaire, VAS Visual analogue scale, UCLA University of California, Los Angeles activity scale, SF36 Medical Outcomes Study short form 36 item questionnaire, OHS Oxford hip score, WOMAC Western Ontario and McMaster University osteoarthritis index, TEGNER Tegner activity scale, SF12 Medical Outcomes Study short form 12 item questionnaire.

Table 6 Subgroup diagnoses in THA studies

Diagnosis	No. of	Diagnosis	No. of
	studies		studies
Sickle cell anaemia	1	Inflammatory arthritis	1
Acetabular fracture	1	Developmental dysplasia of the hip	1
Fractured neck of femur	1	Osteonecrosis of femoral head	2
Haemophilia	1	Avascular necrosis of the femoral	1
Poliomyelitis	1	head	

Table 7 Themes and illustrative quotes from content analysis

Theme

Representative quote

Support for long term follow-up

The fact that expansile osteolysis does not always lead to symptomatic loosening points to the necessity of close radiographic monitoring of the patients with total hip arthroplasty, especially in those with uncemented acetabular components.

Hartofilakidis et al (45)

For interpretation of their clinical relevance, they need correlation with long-term clinical results, radiographic scores or implant survival. Consequent follow-up is obligatory and will be performed to clarify the link between early predictions and real long-term outcome.

Broeke et al (46)

Subgroups requiring follow-up over time

In this randomized controlled design, we found age and gender to be important prognosticators for THA failure. ... The requirements of implants to withstand the activity level of patients thus are gender-specific with the most strenuous requirements being for male patients.

Corten et al (47)

Further studies with longer follow-up are needed to better evaluate the outcomes of these patients......super-obese patients achieved... lower clinical outcome scores, a higher revision rate, and higher complications ...compared with the matched group of non-obese patients at a mean follow-up of six years Issa et al (48)

 Effect of materials and techniques on survival of THA Reporting the long-term...results of ABG-1TM implants used in primary implantation for THAs underscores the frequency of retroacetabular osteolysis... encourages us to propose regular monitoring of these patients after 10 years of implantation as well as

early preventive acetabular revision when progressive osteolysis occurs.

Bidar et al (31)

 Effect of design on survival of THA Charnley cemented and Furlong HAC-coated uncemented hip prostheses had similar survival rates at 12 to 16 years...The commonest cause of revision in the Furlong group was severe polyethylene wear, and all revisions in the Charnley group were due to aseptic loosening of the stem.

Chandran et al (49)

5. Indicators for revision

We consider radiological loosening as an indication for surgical revision, as osteolysis progresses at least linearly, so an early revision on adequate bone stock presents more chances of success and a better functional prognosis for the patient.

Boyer et al (32)

Elements of the review process

The other conclusion that can be drawn from our study is that radiological evidence of loosening does not necessarily have to correlate with clinical symptoms in long-term follow-ups

Shaju et al (29)

Figure 1 Flow diagram showing the results of the literature search.

Figure 2 Histogram showing number of studies with MINORS scores for comparative studies (zero=poor, 24=good).

Figure 3 Histogram showing number of studies with MINORS scores for non-comparative studies (zero=poor, 16=good).

Appendix I Studies included in review and summary data