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Low evidence for implementation of well-documented implants regarding risk of early revision: a systematic review on total hip arthroplasty

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- When introducing an implant, surgeons are subjected to steep learning curves, which may lead to a heightened revision rate. Stepwise introduction revolutionized implant introduction but lacks a last step.
- No guidelines exist for the introduction of a well-documented implant not previously used in a department. This is problematic according to the European Union's legislated tendering process, potentially leading to increased revisions. In this systematic review, the introduction of a well-documented total hip arthroplasty implant to experienced surgeons is explored amid concerns of higher revision rate.
- Literature search strategies were deployed in the Embase and Medline databases, revealing a total of 14,612 articles. Using the Covidence software (Cochrane, London), two reviewers screened articles for inclusion.
- No articles were found that fulfilled our eligibility criteria. A post hoc analysis retrieved two national register-based studies only missing information about the surgeon's knowledge of the introduced implant. None of the introduced implants decreased the revision rate and around 30% of the introduced implants were associated with a higher revision rate.
- The review showed that no data exist about revision rates when introducing well-documented implants. In continuation thereof, the introduction of well-documented implants might also be associated with increased revision rates, as has been shown for total knee arthroplasty. We therefore suggest that special attention should be focused on changes of implants in departments, which can be achieved by way of specific registration in national registers.

Keywords: experienced surgeons; implementation; learning curve; systematic review; total hip arthroplasty; well-documented implants

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Introduction

Increasing numbers of patients each year are undergoing total hip arthroplasty (THA) due to osteoarthritis (OA).[1,2] The procedure requires reliable implants and the involvement of competent surgeons to minimize the risk of revision and other patient-related complications.[3] Well-documented orthopaedic implants already exist on the market, yet new ones are still continually being introduced to obtain a higher market share and improve patient outcomes.[4] Even though new implants are strictly regulated, some may not be properly tested and documented, which can result in a disaster such as previously seen in history.[5] Disasters might be avoided by applying stepwise introduction[6] for the introduction of brand-new implants.

Due to regulatory requirements, the tender of implants is mandatory in the European Union in order to have free-market regulation and a better price of a given product.[7] Minimum requirements are defined in these processes, supporting why only well-documented implants should win. However, even though an implant is well-documented, the experienced surgeon may not have used it before. Due to the tender process, orthopaedic surgeons and operation staff may change implants for a standard primary THA within a few years. The use of a well-documented

implant for a surgeon with no experience regarding this implant will initiate a learning curve which could lead to higher revision rate during the first years.[8] We initiated this systematic review to examine the following issue: does the introduction of a well-documented implant to an experienced surgeon with no prior history regarding the implant lead to a higher revision rate among patients with OA undergoing primary THA?

Methods

The present study is reported according to the Preferred Reporting Items for Systematic Reviews and Meta-analysis (PRISMA) guidelines. The protocol was registered in the International Prospective Register of Systematic Reviews (PROSPERO) database (identification no. CRD42018093441) before data extraction was performed.

Eligibility criteria

All study designs were eligible for inclusion other than case reports and systematic reviews. A patient intervention compared outcome of interest (PICO) model was used. Patients aged older than 18 years with primary or secondary OA for any reason undergoing primary THA were selected as participants. The intervention of interest included introducing a well-documented implant to experienced surgeons who had performed more than 50 THA procedures[9] yet had no experience with the implant in question. A well-documented implant was defined as an implant showing a rate of revision of 5% or less over a 10-year period.[10] As a comparison group, we considered patients undergoing primary THA performed by the same surgeon using a well-documented implant already known to the surgeon. Our outcome was set as the difference in revision rate between the two groups. Other outcomes such as biomechanical, radiographic, or laboratory results were of no interest in this study. However, they were not considered as exclusion criteria either.

Eligible studies were required to have a minimum follow-up period of one year and a maximum of three years. When revisions occurred later than three years after the initial surgery, such were considered more likely related to normal wear and tear.[11]

Information sources

Literature search strategies were developed using medical subject headings (MeSH) and text words related to the aim of this study. Medline (Ovid interface, 1948 onwards) and Embase (Ovid interface, 1980 onwards) were searched, using the search strategy that follows. To ensure literature saturation, the reference lists of included studies or relevant reviews identified through the search period were also screened for further eligible reports. Finally, materials found by other search methods in the process of obtaining general knowledge in this field of research were screened.

Search strategy

No study design, date, or language limits were imposed on the search, although only studies in languages other than English that could be translated adequately using Google Translate (Google, Mountain View, CA, USA) were included, due to resource limitations. The specific search strategy used herein was created by the authors of this report in collaboration with a librarian with expertise in systematic reviews. The search strategy can be found in the appendix.

Study selection

Literature search results were uploaded to the Covidence Software[12] (Cochrane, London, UK) and two authors (PB and JG) independently screened the titles and abstracts against the eligibility criteria. In the case of disagreement, a consensus was reached by discussion between these authors. If a consensus was not reached by way of this discussion, an experienced abstractor and co-author (either BV or SO) became involved as a referee to ensure agreement. The full texts of the selected articles were then screened before inclusion. A random sample of 25 articles during the full-text screening process was selected and an independent full-text screening was performed by an experienced abstractor to ensure that nothing was missed in the process. The review authors were not blinded to the journal titles.

Data collection process

Based on a post hoc analysis, two studies were included. Data were independently extracted by the co-first authors and subsequently presented in agreement with the other authors.

Data items

The main outcome of interest in this investigation was the change in revision rate concerning patients who underwent primary THA with newly introduced, well-documented implants.

Risk of bias and quality of studies

This investigation covers a new way of thinking and concerns comparative studies only. Since studies of this type are limited at this time, these kinds of studies would presumably be published irrespective of their findings. As such, publication bias was not suspected as being sizable in this study. To assess the risk of bias within the included studies, their methodological quality was assessed by using the critical appraisal skills programme (CASP) cohort checklist for assessing the quality of non-randomized studies (Table 1).

Data analysis

A narrative synthesis is provided with information presented in the text to summarize and explain the characteristics and findings of the included studies. The narrative

Table 1. Critical appraisal skills programme checklist for assessing the quality of non-randomized studies

Questions 1–12	Paper 1 (Anand et al, 2011)	Paper 2 (Peltola et al, 2013)
1. Did the study address a clearly focused issue?	Yes	Yes
2. Was the cohort recruited in an acceptable way?	Yes	Yes
3. Was the exposure accurately measured to minimize bias?	Yes	Yes
4. Was the outcome accurately measured to minimize bias?	Yes	Yes
5. (a) Have the authors identified all important confounding factors?	Yes	Yes
5. (b) Have they taken account of the confounding factors in the design and/or analysis?	Yes	Yes
6. (a) Was the follow-up of subjects complete enough?	Yes	Yes
6. (b) Was the follow-up of total subjects enough?	Yes	Yes
7. What are the results of this study?	See Results section	See Results section
8. How precise are the results?	See Results section	See Results section
9. Do you believe the results?	Yes	Yes
10. Can the results be applied to the local population?	Yes	Yes
11. Do the results of this study fit with other available evidence?	Yes	Yes
12. What are the implications of this study for practice?	Yes	Yes

synthesis explores the relationships of and findings both within and between the included studies.

Results

Study selection

Using our database search process, we retrieved and assessed 14,612 titles and abstracts. A total of 176 articles were assessed for full-text screening (Fig. 1). None of the studies met our intervention criteria fully and most of them did not inform about the experience level of the surgeons concerning the introduced well-documented implants. Due to the lack of evidence regarding the aim of this study, we performed a post hoc analysis for articles meeting most of our inclusion criteria instead. We found two studies which met all of the inclusion criteria except for the criteria regarding the experience of the surgeons and the documentation behind some of the implants introduced. Thus, we do not know whether well-documented implants are among those used in the two selected studies.

Risk of bias within studies

The two post hoc included studies have a low risk of bias and fulfilled all of the demands for providing valid results (Table 1).

Results of individual studies

Paper 1: What is the benefit of introducing new hip and knee prostheses?

This paper was a national register-based study including data from the Australian Orthopaedic Association National Joint Replacement Registry (AOA NJRR). It analysed all hip and knee arthroplasty implants introduced to the Australian market between 1 January 2003 and 31 December 2007. Implants selected for the study had to be used in at least 100 procedures and have a minimum of one year of follow-up. An introduced implant was defined as an implant whose first use was recorded by the AOA NJRR during the study period. Each of the introduced implants was compared with the combined results of the three best-performing implants in its class. Of the 167 new hip implants introduced during the study period, less than 20% (n = 33) were used in more than 100 procedures. The comparative analysis demonstrated that 10 of the 33 implants had a significantly higher revision rate than the established prostheses. It should also be mentioned that none of the introduced implants performed better than the older implants.

Paper 2: Hip prosthesis introduction and early revision risk

This paper was a national register-based study from the Finnish Arthroplasty Register (FAR) that included 39,125 primary THA procedures from 1998 to 2007. The aim was to investigate the survival of a THA implant after the introduction of an implant to the hospital when at least 100 THA procedures had been undertaken. Ultimately, the first 15 operations with an introduced implant displayed a higher risk of revision, yielding an adjusted hazard ratio of 1.3 with a 95% confidence interval of 1.1 to 1.5.

Discussion

Experienced surgeons are regularly forced to shift among well-documented implants due to required tendering of implants. This systematic review sought to evaluate the outcomes of the introduction of a well-documented implant to surgeons without any prior experience with the specific implant. This review did not locate any studies focusing on this issue, although several national registers may have the possibility to obtain this information. However, a post hoc analysis retrieved two national register-based studies from Finland and Australia, respectively, matching the eligibility criteria apart from offering information about the experience of the surgeons and the documentation behind the implants used.[4] These studies showed that the introduction

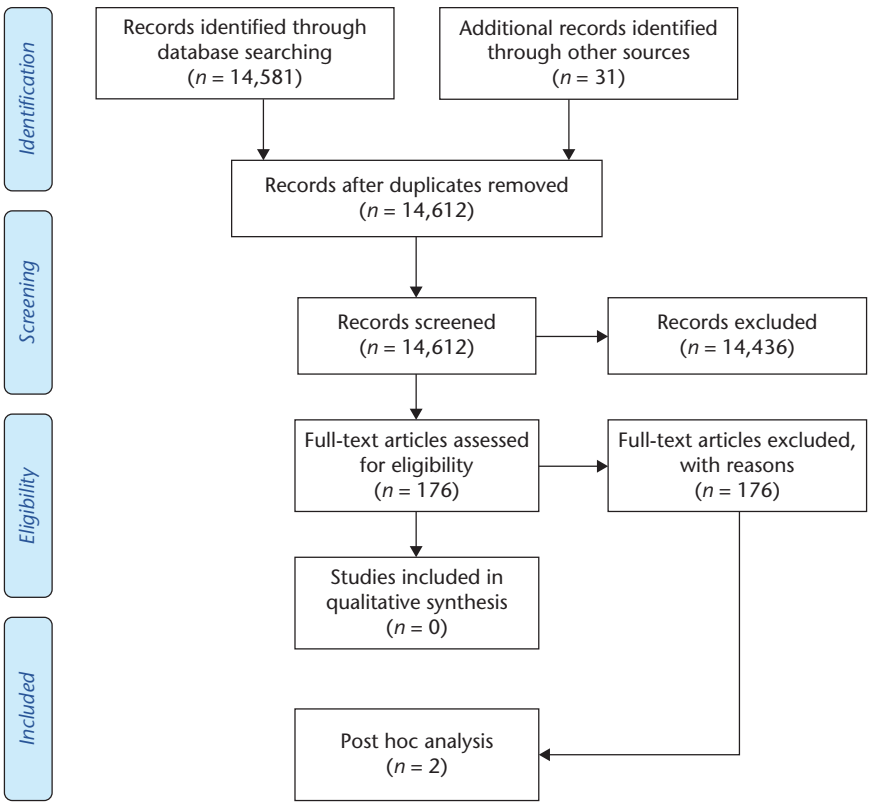

Fig. 1 Flow diagram of the record screening process and post hoc analysis

of implants, not used before in the departments investigated, were associated with a higher revision rate, and that 10 out of 33 newly introduced implants had a significantly higher revision rate. In continuation of this, the German Arthroplasty registry,[12] found an increased failure of THA treatment over time when the hospitals changed their hip implants compared to the hospitals not changing implants. Therefore, the introduction of a well-documented implant might also be associated with an increased revision rate. Of note, Hallan et al[13] showed this in an unpublished study involving total knee arthroplasty (TKA). In their report, the shift in the use of well-documented implants was caused by a tender process and was associated with a nearly two-fold increased risk of revision.[13] A Swedish register study did not find significant increased risk of early revision during the implementation phase of new cup designs. The authors claimed that less than 5% of patients who underwent a THA had revision.[14] However, the change of a stem contrary to changing the cup is claimed to be more advanced and could therefore lead to a higher revision rate.

Learning curve

A learning curve occurs when a surgeon initially starts to use a new implant. Increased attention has been paid to learning curves, because of the public and professional decreased tolerance regarding these.[15,16] Few studies concerning the effects of learning curves and how to minimize them have been published to date.[17] We do not know whether the two register studies from the post hoc search selected in this investigation included well-documented implants, but we can postulate that the same risk in THA could exist as that shown previously for TKA.

Introduction of a well-documented implant

The question of how to introduce well-documented implants while still retaining an expected high-quality outcome following surgery is key. Clear guidelines for the implementation of a well-documented implant into daily clinical practice could not be found in the literature.[17] Four proposed methods to minimize or avoid a learning curve in pancreaticoduodenectomy – *training, mentoring, supervision* and *assimilation* – could potentially be adapted in the present area. Other relevant methods with the same purpose could be *teaching*, in which the surgeon gets familiar with the introduced implant, and *audit*, in which the surgeon will continuously present his cases at an audit, followed by an evaluation process concerning his performance during the initial learning curve.

Stepwise introduction

Several strategies[6,18] have been suggested before introducing new implants to the market. One of the most

accepted strategies is known as stepwise introduction, presented by Henrik Malchau in 1995.[19] However, this approach does not include well-documented implants. Stepwise introduction is also mentioned by van Susante, who also has a similar approach. He mentions that the ideal first step with introduction of an innovation would be careful monitoring of a limited number of patients treated. Only after clinical success has been warranted at least at short-term follow-up, without the introduction of new complications, could this lead to clinical use.[20]

The European Union legislation for the tender process will progressively become a bigger part of daily life in medical clinics, while surgeons will continue to be subjected to adopting and using different well-documented implants. If we wish to avoid an increased revision rate following this phenomenon, more focus needs to be directed toward the tender process and towards the associated complications and risk of revision. We propose that national registers or similar methods could be used when departments change implants, even though the new implants are well-documented. This method may ensure safer use of implants when they are first introduced in such departments.

Conclusion

The review showed that no data exist about revision rate when introducing well-documented implants. A post hoc analysis revealed that introductions of new implants are associated with higher revision rates. In continuation thereof, the introduction of well-documented implants might also be associated with increased revision rates, as has been shown for TKA. We therefore suggest that special attention should be focused on changes of implants at the departments, which can be achieved by way of specific registration in national registers.

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SUPPLEMENTAL MATERIAL

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ICMJE CONFLICT OF INTEREST STATEMENT

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REFERENCES

1. **Neogi T.** The epidemiology and impact of pain in osteoarthritis. *Osteoarthritis Cartilage* 2013;21:1145–1153.

2. **Petis S, Howard JL, Lanting BL, Vasarhelyi EM.** Surgical approach in primary total hip arthroplasty: anatomy, technique and clinical outcomes. *Can J Surg* 2015;58:128–139.

3. **Wills BW, Sheppard ED, Smith WR, et al.** Impact of operative time on early joint infection and deep vein thrombosis in primary total hip arthroplasty. *Orthop Traumatol Surg Res* 2018;104:445–448.

4. **Anand R, Graves SE, de Steiger RN, et al.** What is the benefit of introducing new hip and knee prostheses? *J Bone Joint Surg Am* 2011;93:51–54.

5. **Morlock MM.** The taper disaster – how could it happen? *Hip Int* 2015;25:339–346.

6. **Malchau H, Bragdon CR, Muratoglu OK.** The stepwise introduction of innovation into orthopedic surgery: the next level of dilemmas. *J Arthroplasty* 2011;26:825–831.

7. **European Commission.** Regulatory framework: European Commission, 2018. https://ec.europa.eu/growth/sectors/medical-devices/regulatory-framework_en#new_regulations (date last accessed 16 May 2018).

8. **Padilla JA, Anoushiravani AA, Feng JE, Schwarzkopf R, Slover J, Marwin S.** The learning curve following adoption of a novel short-stem prosthesis in total hip arthroplasty: implications on short-term patient outcomes. *Eur J Orthop Surg Traumatol* 2019;29:819–825.

9. **Lee YK, Biau DJ, Yoon BH, Kim TY, Ha YC, Koo KH.** Learning curve of acetabular cup positioning in total hip arthroplasty using a cumulative summation test for learning curve (LC-CUSUM). *J Arthroplasty* 2014;29:586–589.

10. **NICE.** Total hip replacement and resurfacing arthroplasty for end-stage arthritis of the hip | Guidance and guidelines, NICE, 2018. https://www.nice.org.uk/guidance/ta304/chapter/1-Guidance (date last accessed 16 May 2018).

11. Mäkelä KT, Eskelinen A, Paavolainen P, Pulkkinen P, Remes V. Cementless total hip arthroplasty for primary osteoarthritis in patients aged 55 years and older. *Acta Orthop* 2010;81:42–52.

12. Grimberg A, Jansson V, Thoralf L, Oliver M, Arnd S. Jahresbericht 2017. The German Arthroplasty Register. Endoprothesenregister Deutschland (EPRD) 2017.

13. Hallan G, Fenstad AM, Havelin LL, Husby OS, Furnes O. Can tenders affect clinical outcome of total joint arthroplasty? *1st Congress of International Society of Arthroplasty Registries (ISAR)*, 20-22 May 2012. Bergen, Norway.

14. Mohaddes M, Björk M, Nemes S, Rolfson O, Jolbäck P, Kärrholm J. No increased risk of early revision during the implementation phase of new cup designs. *Acta Orthop* 2016;87:31–36.

15. Flamme CH, Stukenborg-Colsman C, Wirth CJ. Evaluation of the learning curves associated with uncemented primary total hip arthroplasty depending on the experience of the surgeon. *Hip Int* 2006;16:191–197.

16. Peltola M, Malmivaara A, Paavola M. Hip prosthesis introduction and early revision risk: a nationwide population-based study covering 39,125 operations. *Acta Orthop* 2013;84:25–31.

17. Tsamalaidze L, Stauffer JA. Pancreaticoduodenectomy : minimizing the learning curve. *J Vis Surg* 2018;30:64

18. McCulloch P, Altman DG, Campbell WB, et al; Balliol Collaboration. *No surgical innovation without evaluation: the IDEAL recommendations*. *Lancet* 2009;374:1105–1112.

19. Malchau H. *On the importance of stepwise introduction of new hip implant technology* (PhD thesis). University of Gothenburg, 1995.

20. van Susante JLC. The (r)evolution of hyped innovations in orthopedic implants: can prudent introduction avoid throwing the baby out with the bathwater? *Acta Orthop* 2019;90:507–510.