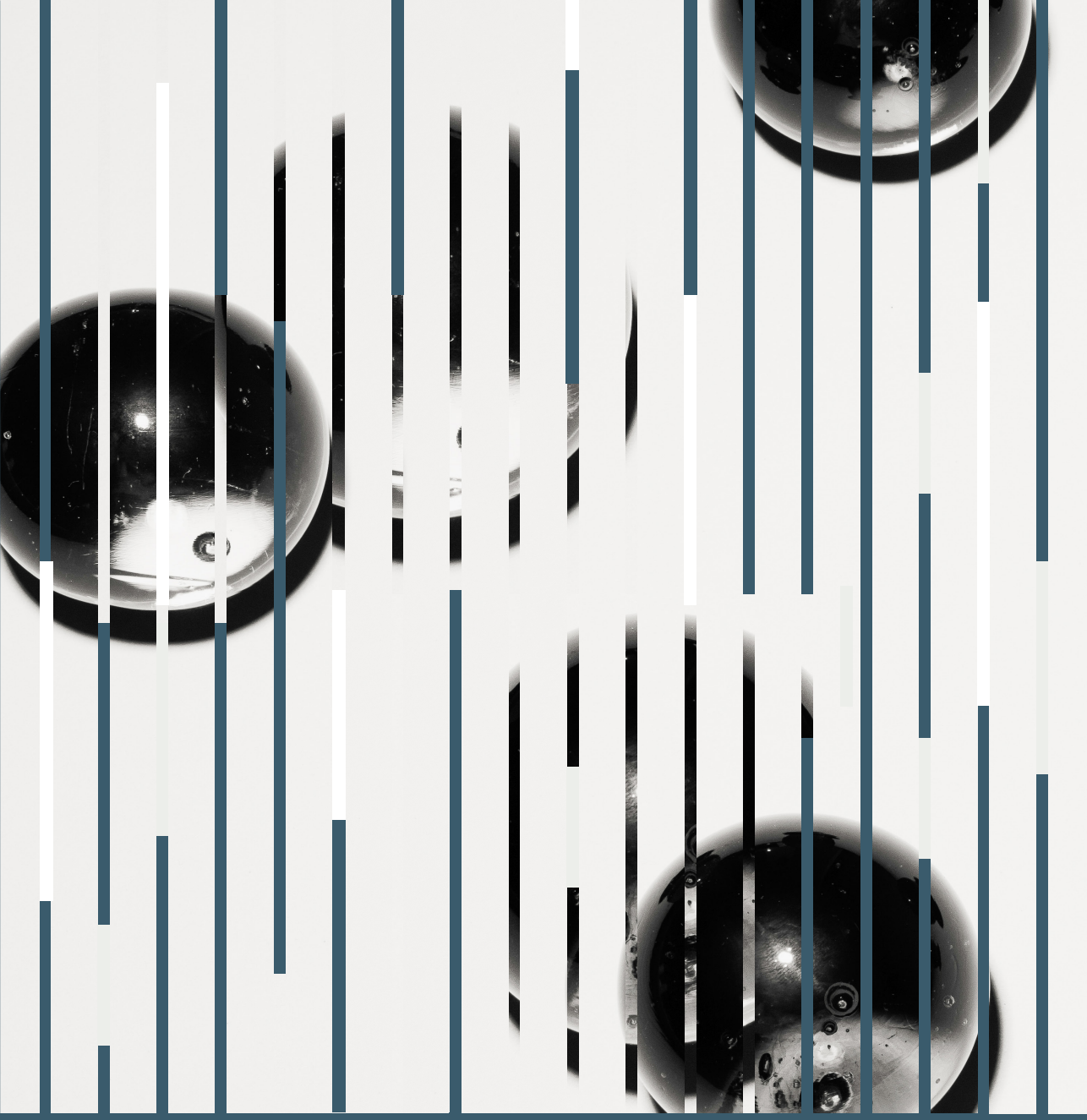


Clinical evidence of novel arthroplasty implants

The essential contribution of implant migration analysis

Thies J.N. van der Lelij

Clinical evidence of novel arthroplasty implants

The essential contribution of implant migration analysis

Thies J.N. van der Lelij

The work described in this thesis was performed at the Department of Orthopaedics, Leiden University Medical Center, the Netherlands and the Department of Orthopaedics, Hässleholm Hospital, Sweden.

Cover design and layout: Sybren Dallinga
Printing: Gildeprint
ISBN: 978-94-6496-431-8

The printing of this thesis was financially supported by Nederlandse Orthopaedische Vereniging, Vakgroep Orthopedie Alrijne, ABN AMRO.

Clinical evidence of novel arthroplasty implants

The essential contribution of implant migration analysis

Proefschrift

ter verkrijging van
de graad van doctor aan de Universiteit Leiden,
op gezag van rector magnificus prof. dr. ir. H. Bijl,
volgens besluit van het college voor promoties
te verdedigen op woensdag 17 september 2025
klokke 16:00 uur

door

Thies Johannes Nicolaas van der Lelij

geboren te Woerden
in 1996

Promotores

Prof. dr. R.G.H.H. Nelissen

Dr. P.J. Marang-van de Mheen Technische Universiteit Delft

Copromotor

Dr. ir. B.L. Kaptein

Leden promotiecommissie

Prof. dr. R.W. Poolman

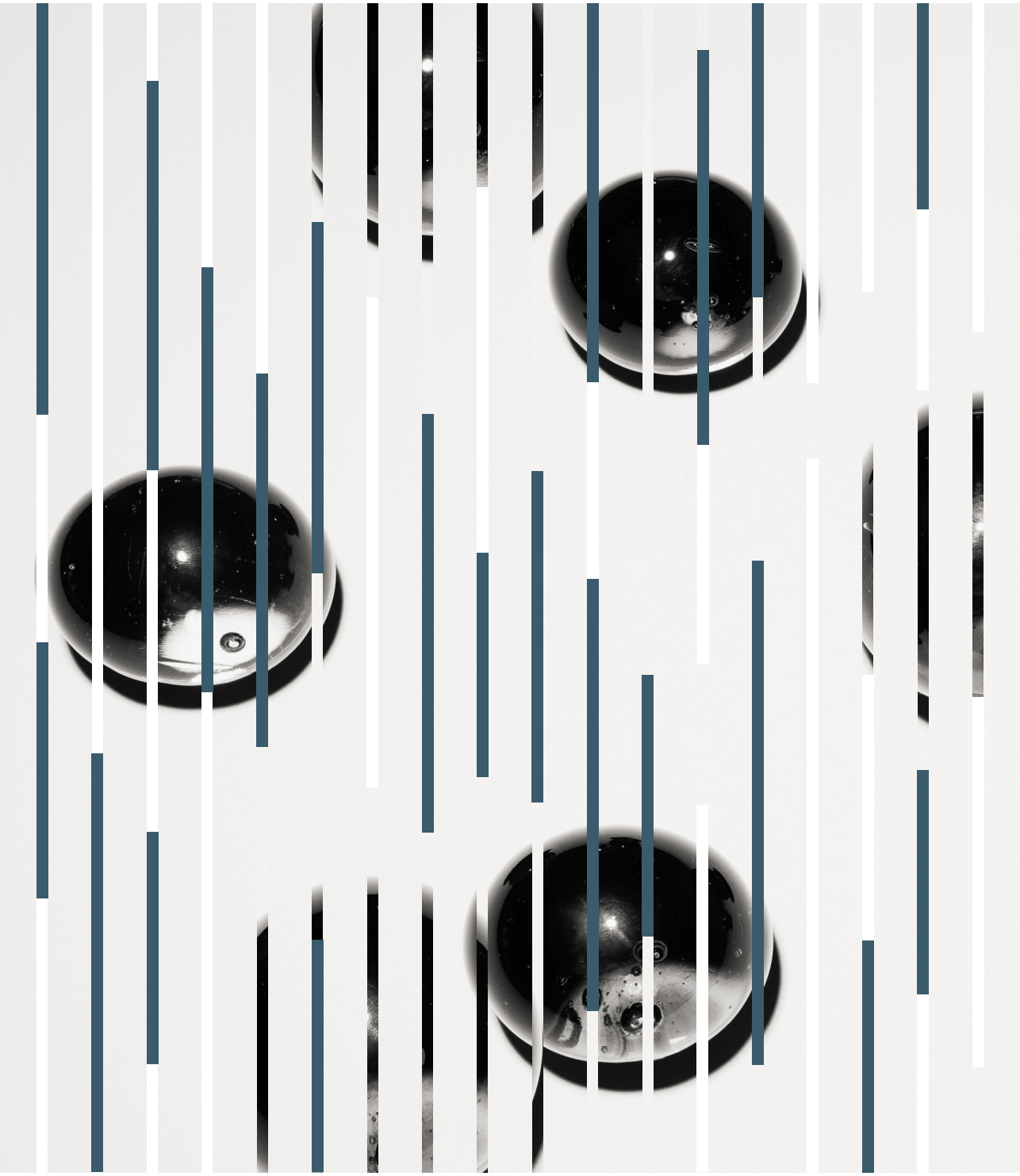
Prof. dr. I.B. Schipper

Prof. dr. S.C. Cannegieter

Prof. dr. S. Overgaard Copenhagen University Hospital, Denmark

Prof. dr. S.M.H. Röhrl Oslo University Hospital, Norway

Table of contents



Chapter 1

General introduction

Total hip and knee arthroplasty

When conservative treatment has failed, end stage osteoarthritis of the knee and hip joint can be successfully treated with total knee arthroplasty (TKA) and total hip arthroplasty (THA), respectively. Both TKA and THA have shown to be extremely effective procedures that result in substantial improvement in health-related quality of life for patients (1). In Western countries, about 10-23% of women and 6-16% of men will receive a TKA during their life (2). For THA, the lifetime risk for women is 12-16% and 8-11% for men (3). In the past decades, a continuous increase in the number of annually performed TKA and THA procedures has been observed in Western European countries (4-6). Due to aging of our population and a growing number of people with obesity, a further increase is expected in the near future (7).

With an increase in the number of primary arthroplasty procedures, the absolute number of revision arthroplasties is also expected to rise. The 10 year cumulative revision percentage of the best-performing TKA implants nowadays is around 3% (4, 5). As for THA, cumulative revision percentages of the best-performing implants have been reported to be around 2% after 10 years (4). Although these mean revision percentages are small, the absolute annual number of these implants is large, and there are still many implants on the market with much higher revision rates. Furthermore, considerable variation between patient age groups in 10 year cumulative revision risk after primary TKA exists, ranging between 1.6% and 13% (8). For example, patients who are aged 55 years and younger have an increased lifetime risk of revision (8, 9).

Revision procedures are technically demanding for both surgeon and patient and often require removal of some or all components, management of bone loss, and complex wound closures (10). Besides the high perioperative morbidity that patients are subjected to during revision surgery, it is also an expensive procedure and requires extensive resources (11). The expected increased total number of revision surgeries will therefore pose a significant (financial) burden on our national healthcare systems (12, 13). Given the foreseen limited healthcare resources in the near future, it is of major importance to avoid the use of underperforming implants. Limiting the use of implants with high revision rates may help to reduce the burden on patients overall quality of life and healthcare costs for society.

New implant designs

Novel arthroplasty implants are introduced to the market every year (14, 15). Such new implants are mostly expected to provide better clinical outcome compared with implants that are already available. However, the introduction of new implants in the past has not always resulted in lower revision rates or improved patient-reported outcomes. As for the latter, patient-reported outcomes are generally related to the patients' preoperative expectations regarding the potential benefits of the arthroplasty procedure, rather than the implant itself (16, 17). Most new implants have limited or no clinical evidence when they are released to the market to justify their use or to enable surgeons to compare their outcome with well-established implants (14). To ensure patient safety, and proof of clinical evidence and at the same time accommodate innovation, adequate regulations needed. In the European Union (EU), uncertainties on "adequate" clinical evidence for implantable medical devices, as well as presence of software applications within the clinical domain, were some of the reasons to have the EU Medical Device Regulation (MDR) (2017/745) implemented in May 2021 (18, 19). The MDR has increased the requirements for clinical evidence before new, high-risk, devices can be approved, and attributed post-market responsibilities to the manufactures and national regulatory agencies (18). Hip and knee arthroplasty implants are considered high-risk (class III) implantable medical devices, which have to adhere to the MDR.

A predominant reason for revision surgery after arthroplasty of both the hip and knee joint is aseptic loosening, which is the failure of fixation of an implant within its surrounding bone in the absence of an infection (4, 5, 20). Following primary THA, aseptic loosening of the acetabular component is one of the most common causes for revision surgery (20% to 35%) (4, 21). This indicates the need for the development of acetabular components with better and longer-lasting fixation within the bone. However, new implants are not always created because of an expected (theoretical) improved implant fixation in the bone. Medical device companies may also launch new implants to the market because of they have adapted a new manufacturing technique to optimize the production process and meet production demands. Even though changes to the manufacturing process of an established implant may seem minimal, such small changes to the manufacturing process and/or implant surfaces have been associated with unacceptable long-term failure rates in the past (22-26). It has also been shown that (accidental) changes in the manufacturing process of orthopaedic

implants may significantly affect their clinical performance (27). Therefore, even when only "minor" changes to an implant or its production process have occurred, critical early post-market evaluation of new implants is important to prevent disasters to patients. As for total knee implants, aseptic loosening of the tibial baseplate remains one of the leading causes of revision surgery after primary TKA (4, 5, 20). Therefore, achieving long-lasting fixation of tibial implants is crucial To overcome the problem of tibial baseplate loosening in TKA, numerous implant designs and fixation techniques have been proposed. In Northwestern Europe, cemented fixation of the tibial baseplate is still used in the majority of primary TKAs (4, 6). However, because of observed loss of cement-bone interlock and debonding at the cement-implant interface, the use of primary cementless TKA continues to grow (28, 29). In the past decade, the use of metallic three-dimensional (3D)-printing has gained popularity in the field of Orthopaedic surgery (30, 31). 3D-priting facilitates the production of cementless implants with complex porous structures, which could potentially improve the bone-implant fixation. However, as with most new designs, clinical evaluation of 3D-printed tibial baseplates remains limited to short-term and midterm follow-up studies. The latter warrants further clinical evaluation because loosening may only occur at longer follow-up.

To ensure the quality of orthopaedic implants and safeguard patient safety, the need for a phased evidence based introduction of new THAs and TKAs that are released has been argued previously (32-35). Such a phased introduction is needed when an implant is produced with a completely new manufacturing process (e.g. 3D printing), but also when only seemingly small changes to the manufacturing process of an implant have been made (e.g. a different process for applying the titanium surface). Early detection of underperforming implants may prevent their widespread use and limit the potential harm to patients. Additionally, the profound impact on health-related costs by introducing implants with a high revision risk can be constrained.

Implant loosening, as one of the major causes for revision surgery, starts with sub-millimetre migration of the implant relative to its surrounding bone, before gradually evolving into gross movement that translates to clinical symptoms such as pain (36-38). Early micromotion of an implant can be accurately detected by a radiographic technique called radiostereometric analysis (RSA).

Radiostereometric analysis: Background

The technique of measuring the 3D positions of objects in space using roentgen rays dates back to the time when X-rays were discovered. Already in 1987, Davidson and Hedley reported the use of two roentgen foci to determine the 3D position of an object (39). However, the basic principles of modern radiostereometric analysis (RSA) were first described by Göran Selvik in the 1970s in Sweden (40, 41). Selvik developed RSA to assess the movement of orthopaedic implants in patients relative to its surrounding bone. For this, the 3D position of radiopaque markers that are inserted into the bone and prostheses can be determined by taking simultaneous X-ray images (Figure 1).

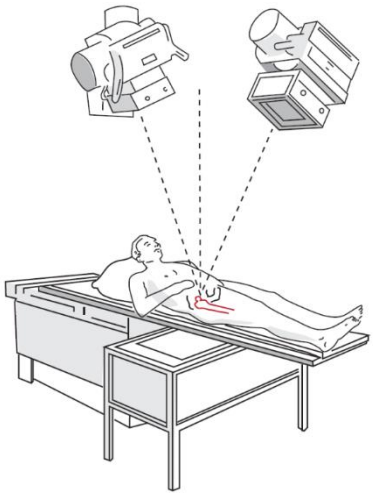


Figure 1. Standard RSA setup with an uniplanar calibration cage underneath the prosthesis of interest. Two roentgen tubes are focused on the joint of interest angled at a 40° angle to each other. The roentgen detectors are placed in below the calibration cage. Published in: Valstar et al. Guidelines for standardization of radiostereometry (RSA) of implants. Acta Orthopaedica. 2005;76(4):563-572.

By taking subsequent RSA images of the same implant in a patient over time, the micromotion of an implant relative to its surrounding bone over time can be calculated. RSA allows for the assessment of implant migration with sub-millimetre and sub-degree accuracy (40, 42).

In 1995, Ryd et al. (37) showed that continued migration in the 2nd postoperative year of individual tibial components, as measured with RSA, is predictive of long-term implant survival in patients. Twenty years later, Pijls et al. (43) showed that there is a clinically relevant association between early (1-2 years) implant migration and late (10 years) revision because of loosening at group level for tibial components in TKA, and later for acetabular cups in THA (44, 45). Based on these studies, specific migration thresholds were proposed that could be implemented in a phased evidence-based introduction of new types of total knee implants and acetabular cups (43, 44). With these thresholds and given its high accuracy, RSA allows for the early detection of total knee implants with a high risk of loosening while exposing only a small number of patients (43). Similar as for TKA, early migration of acetabular cups and hip arthroplasty stems have also been associated with late revision due to loosening (44, 46).

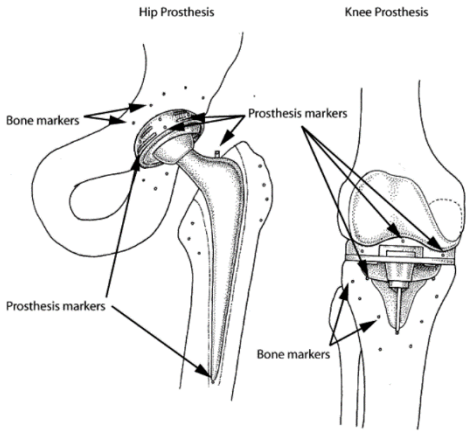


Figure 2. Hip and knee prosthesis with bone markers and prosthesis markers. For accurate definition of the 3D position of the bone and prosthesis, tantalum markers are inserted in the bone and markers are attached to the prosthesis or inserted into the polyethylene component of the prosthesis. Published in: Valstar et al. Guidelines for standardization of radiostereometry (RSA) of implants. Acta Orthopaedica. 2005;76(4):563-572.

Radiostereometric analysis: Methods

Different RSA methods are available to analyse implant migration over time, including marker-based RSA, model-based RSA, and computed tomography (CT)-RSA. Marker-based RSA requires the implant and bone to be defined in 3D by inserting small radiopaque markers in both segments (47) (Figure 2). To define the implant, markers can be fixed to the tibial component or inserted in the (modular or non-modular) poly-ethylene (PE) insert.

Model-based RSA eliminates the need for prosthesis markers by matching a virtual projection of a 3D model with the contours of the implant's radiographic projection (48). Previous studies have shown that the results of model-based RSA are comparable with conventional marker-based RSA on a group level, but migration patterns of individual patients (i.e. implants) may differ as a result of distinct types of measurement error (48-51). More recently, CT-RSA has been introduced as another method to analyse implant migration (52-54). CT-RSA does not require markers or a calibration box and seems to have similar accuracy as the other methods. However, limitations of CT-RSA include the higher radiation dose of CT scans compared with conventional radiographs and that it currently lacks quantifiable-control measures similar to what is found in conventional RSA (54).

However, within both marker-based RSA and model-based RSA, different methods for analysing implant migration exist. When markers are used to define the 3D position of a rigid body (i.e. bone or prosthesis), potential problems include that markers can (1) be superimposed by implant projection, (2) be out of view due to incorrect patient positioning, (3) become invisible due to poor roentgen technique, or (4) become unstable and migrate relative to other individual markers. Therefore, a different set of markers that can be used for the migration analyses may be available in subsequent RSA examinations of the same patients. An RSA analyst has to choose whether to calculate implant migration using only those markers consistently visible at all RSA examinations of the patients or use all available markers at each follow-up examination that can be matched to the reference RSA image. To this day, it is often not explicitly reported which marker-selection method has been used in clinical RSA studies and it remains unknown if different marker-selection methods affect individual and/or group level implant migration results. If migration results of an implant would change based on the marker-selection method used, this could potentially influence the interpretation of the result and subsequent estimated long-term risk of revision because of loosening based on specific thresholds. Additionally, this may impair pooling and

comparing RSA migration data of individual studies using different marker-selection methods.

Radiostereometric analysis: Guidelines for standardization

Because of need for standardization of RSA investigations to facilitate comparison of outcomes reported by different research groups, a paper with guidelines was published in 2005 by an international group of RSA experts (55). This paper is considered a "landmark paper" in the field of RSA research and frequently referred to as "The RSA guidelines" (56). After publication of these guidelines, the methodological reporting in RSA studies improved significantly (57). Furthermore, the guidelines formed the basis for the ISO standard on RSA analysis for the assessment of migration of orthopaedic implants (ISO 16087:2013) that was published in 2013 (55, 58). However, both in the RSA guidelines and the ISO standard, the need to report which marker-selection method was used within marker-based and model-based RSA was not included. It is therefore unclear which individual markers should be selected during each RSA follow-up examination to perform the migration analysis. The RSA guidelines and ISO standard do state that if the points of measurement in a rigid body do not correspond between different implant designs, any comparison will be incorrect (55, 58). To overcome this problem, fictive points should be used to assess maximum total point motion (MTPM) (i.e. the length of the translation vector of the point in a rigid body that has the greatest motion) (55). However, in clinical RSA studies on TKA implant migration with markers in the polyethylene insert a tibial component, fictive points are often not used (59-62). Also, the guidelines do not describe the number and location of fictive points that should be used for each implant and how these should be plotted based on the actual tantalum markers (55).

Recently, Kaptein et al. (63) published updated guidelines for standardization of RSA implant migration measurements. These guidelines were the result of discussion with a diverse group of RSA researchers and approved by the board and selected members of the International Radiostereometry Society (64). The goal of the new guidelines was to ensure better adherence in the future of clinical RSA studies to common standards, as migration assessment methods have been further developed in the past two decades. The guidelines include a reporting checklist which is intended to serve as a checklist table specifically for prosthesis migration studies. To accurately assess the reliability and reproducibility of a

study, it is important for clinical RSA studies to adhere to all checklist items. The reporting checklist in the updated RSA guidelines includes several additional items compared with the checklist of standardized output in the old guidelines. For example, the new checklist states that studies using marker-based or model-based RSA should report the marker-selection method that was used (63).

Madanat et al. (57) showed over a decade ago that the old RSA guidelines had improved methodological reporting in RSA studies, but that the adherence to the guideline items still remained relatively low (55). Even though the new guidelines are the result of extensive discussion among experts, which might indicate that any additional items in the new guideline are already reported in contemporary RSA studies, it is unclear to what extent RSA studies adhere to all (additional) items that are stated in the new reporting checklist.

Radiostereometric analysis: Clinical benefit

RSA is considered a valuable tool in the early phase of the clinical introduction of new implants to the market (32, 35). RSA could warn clinicians about new implants that are more likely to have an increased long-term risk of revision because of loosening, thus safeguarding against the widespread use of underperforming implants. Thereby, theoretically, only better-performing implants with low revision risks will remain. The introduction of new implants with short-term RSA migration results as qualitative tool could lead to better patient care and could reduce costs associated with revision surgery (32). However, follow-up in registries is necessary to substantiate this theory.

Only a limited number of all arthroplasty implants available on the market have been tested with RSA. To this day, the additional clinical benefit of RSA studies on TKA implant migration has only been studied by assessing mean all-cause revision rates from aggregate-level survival data (32, 65). Hasan et al. (65) showed that “RSA-tested” TKA implants on average have a lower 10 year revision risk compared with TKAs that have not been tested with RSA (i.e. “non-RSA-tested” TKAs). The latter study assessed the mean all-cause revision risk of RSA-tested TKAs by matching implant designs from published RSA-studies with the performance of these implants as reported in annual reports of national arthroplasty registries. However, it remains unclear if patients receiving an RSA-tested implant are comparable to patients receiving a non-RSA-tested implant. Moreover, the study by Hasan et al. (65) considered all-cause revision whereas early migration as measured with RSA can

be used as a proxy for the risk of revision due to implant loosening, not for other causes of revision (e.g. early infection) (49). Finally, different implant designs exist within a single brand implant portfolio and annual reports of arthroplasty registries do not separately report the outcomes of these different variants of implant designs (66, 67). The latter creates camouflage of outcome results of less favourable performing variations of a type of an implant, as was recently shown by variants of the Nexgen knee arthroplasty that performed significantly worse (68). Therefore, patient-level analyses are needed to accurately compare the revision risk due to loosening of RSA-tested with non-RSA-tested TKA implants and to take more detailed implant information (e.g. identifying the specific implant variants) into account than what is reported in annual registry reports.

Disadvantages of performing (RSA) radiographs during the follow-up of patients after TKA include the costs of 2 radiographs (and analysis) and burden on patients, such as clinical visits. Given the increasing healthcare costs and excellent performance after most modern TKAs, patient-reported outcome measures (PROMs) have been suggested in previous years as a feasible alternative to traditional regular outpatient clinic follow-up after TKA (69, 70). This raises the question if PROMs after TKA could also be used during the phased evidence-based introduction of new implants as a substitute for RSA, to estimate the long-term risk of revision of new implants. If TKA implant migration is associated with a detectable change in PROMs and/or clinical knee scores in patients, this may suggest that these outcome measures measure the same underlying safety issue and therefore can be used interchangeably, thereby eliminating the need for RSA radiographs and reducing costs while maintaining quality and safety for the patients.

Outline of this thesis

The aim of this thesis was to contribute to a better understanding of the value of implant migration analysis (i.e. RSA) in providing clinical evidence on the performance of novel arthroplasty implants. We assessed how RSA can be utilized to improve overall patient outcomes. The associations between quantitative implant migration and qualitative measures perceived by patients (i.e. PROMs) after TKA were studied. Furthermore, we analysed the short-and medium-term migration of novel arthroplasty implants, compared different RSA methods, and assessed the reporting quality of clinical RSA studies. Finally, the clinical performance of implants tested with RSA was studied.

While implant migration analysis is a highly accurate quantitative measure of implant performance (i.e. implant fixation in the bone), also qualitative measures, such as PROMs, are used to assess the clinical outcome for patients after arthroplasty. These PROMs reflect the patient's perspective of their functional status, pain, and overall health before and after TKA. **Chapter 2** explores whether arthroplasty outcomes can be evaluated solely through PROMs, by assessing the association between tibial component migration, as measured with RSA, with postoperative change in PROMs during 10 year follow-up after TKA.

Critical post-market evaluation of new implants produced with different manufacturing processes is needed to detect any potential problems early, in order to and prevent widespread use of underperforming implants. **Chapter 3** evaluates the early migration pattern, using RSA, of a novel cementless hydroxyapatite-coated titanium acetabular shell compared with its well-established predecessor, in patients undergoing THA. **Chapter 4** evaluates a new cementless 3D printed TKA and a conventionally manufactured cemented TKA with a similar design during 5 years.

The methodology and reporting quality of clinical RSA studies on prosthesis migration are essential for interpreting results. **Chapter 5** assessed the impact of marker-selection methods during RSA analysis on TKA migration results. **Chapter 6** studies the adherence to the updated RSA guidelines of all RSA studies on prosthesis published in the last decade.

Finally, the overall societal impact of RSA testing is analysed by using patient-level data from the Dutch Arthroplasty Register (LROI), by comparing RSA-tested and non-RSA-tested TKA implants (**chapter 7**).

Chapter 8 summarises, discusses, and reflects on the findings of this thesis. Finally, future perspectives on providing clinical evidence of arthroplasty implants and tools to assess benefit and risk for patients are discussed.

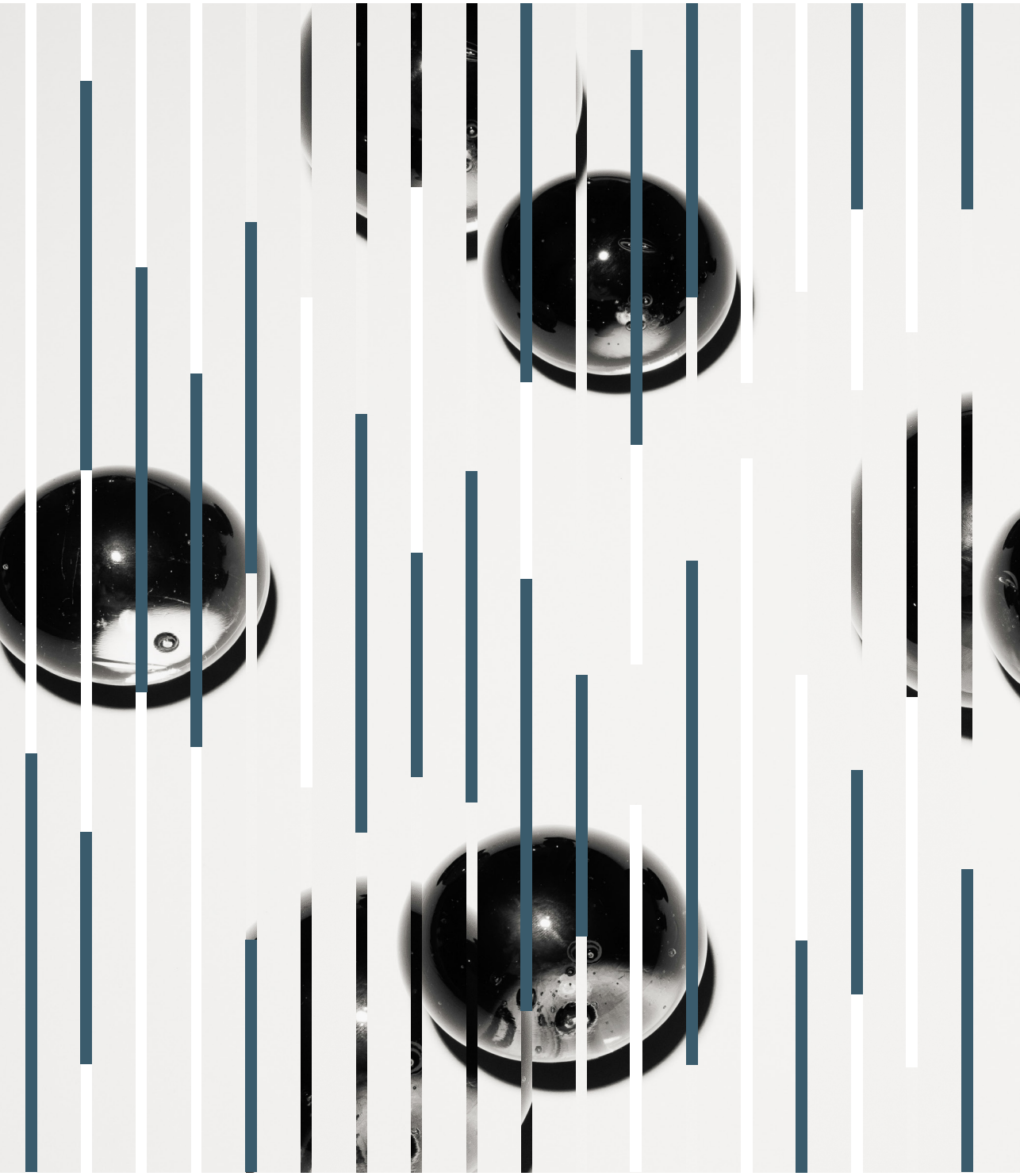
References

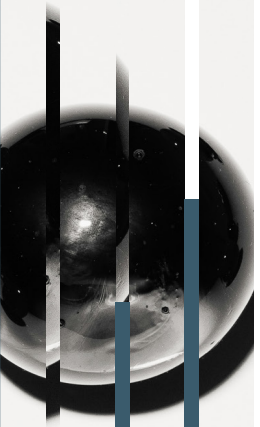
1. Ethgen O, Bruyère O, Richy F, Dardennes C, Reginster JY. Health-related quality of life in total hip and total knee arthroplasty. A qualitative and systematic review of the literature. J Bone Joint Surg Am. 2004;86:5:963-74.
2. Ackerman IN, Bohensky MA, de Steiger R, Brand CA, Eskelinen A, Fenstad AM et al. Substantial rise in the lifetime risk of primary total knee replacement surgery for osteoarthritis from 2003 to 2013: an international, population-level analysis. Osteoarthritis Cartilage. 2017;25:4:455-61.
3. Ackerman IN, Bohensky MA, de Steiger R, Brand CA, Eskelinen A, Fenstad AM et al. Lifetime Risk of Primary Total Hip Replacement Surgery for Osteoarthritis From 2003 to 2013: A Multinational Analysis Using National Registry Data. Arthritis Care Res (Hoboken). 2017;69:11:1659-67.
4. Dutch Arthroplasty Register (LROI). Annual Report 2023. 2023. https://www.lroi-report.nl/app/uploads/2023/10/PDF-LROI-annual-report-2023-1.pdf [Accessed 09-07-2024].
5. National Joint Registry (NJR). 20th Annual report 2023. 2023. https://reports.njrcentre.org.uk/ [Accessed 09-07-2024].
6. Swedish Arthroplasty Register. Annual Report 2022. 2022. https://sar.registercentrum.se/ [Accessed 10-07-2024].
7. Shichman I, Roof M, Askew N, Nherera L, Rozell JC, Seyler TM et al. Projections and Epidemiology of Primary Hip and Knee Arthroplasty in Medicare Patients to 2040-2060. JB JS Open Access. 2023;8:1.
8. Gademan MGJ, Van Steenbergen LN, Cannegieter SC, Nelissen R, Marang-Van De Mheen PJ. Population-based 10-year cumulative revision risks after hip and knee arthroplasty for osteoarthritis to inform patients in clinical practice: a competing risk analysis from the Dutch Arthroplasty Register. Acta Orthop. 2021;92:3:280-4.
9. Stone B, Nugent M, Young SW, Frampton C, Hooper GJ. The lifetime risk of revision following total knee arthroplasty. The Bone & Joint Journal. 2022;104-B:2:235-41.
10. Roof MA, Aggarwal VK, Schwarzkopf R. The Economics of Revision Arthroplasty for Periprosthetic Joint Infection. Arthroplast Today. 2023;23:101213.
11. Roof MA, Levine BR, Schwarzkopf R. The Hidden Cost of Revision Hip and Knee Arthroplasty. Arthroplast Today. 2022;16:167-8.
12. Lavernia C, Lee DJ, Hernandez VH. The increasing financial burden of knee revision surgery in the United States. Clin Orthop Relat Res. 2006;446:221-6.
13. Bhandari M, Smith J, Miller LE, Block JE. Clinical and economic burden of revision knee arthroplasty. Clin Med Insights Arthritis Musculoskelet Disord. 2012;5:89-94.
14. Anand R, Graves SE, de Steiger RN, Davidson DC, Ryan P, Miller LN et al. What is the benefit of introducing new hip and knee prostheses? J Bone Joint Surg Am. 2011;93 Suppl 3:51-4.
15. Nieuwenhuijse MJ, Nelissen RG, Schoones JW, Sedrakyan A. Appraisal of evidence base for introduction of new implants in hip and knee replacement: a systematic review of five widely used device technologies. Bmj. 2014;349:g5133.
16. Tilbury C, Haanstra TM, Verdegaal SHM, Nelissen R, de Vet HCW, Vliet Vlieland TPM et al. Patients' pre-operative general and specific outcome expectations predict postoperative pain and function after total knee and total hip arthroplasties. Scand J Pain. 2018;18:3:457-66.
17. Tilbury C, Haanstra TM, Leichtenberg CS, Verdegaal SH, Ostelo RW, de Vet HC et al. Unfulfilled Expectations After Total Hip and Knee Arthroplasty Surgery: There Is a Need for Better Preoperative Patient Information and Education. J Arthroplasty. 2016;31:10:2139-45.
18. Fraser AG, Nelissen R, Kjærsgaard-Andersen P, Szymański P, Melvin T, Piscoi P. Improved clinical investigation and evaluation of high-risk medical devices: the rationale and objectives of CORE-MD (Coordinating Research and Evidence for Medical Devices). EFORT Open Rev. 2021;6:10:839-49.
19. European Union. Regulation (EU) 2017/745 of the European Parliament and of the Council of 5 April 2017 on medical devices, amending Directive 2001/83/EC, Regulation (EC) No 178/2002 and Regulation (EC) No 1223/2009 and repealing Council Directives 90/385/EEC and 93/42/EEC. https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=uriserv:OJ.L_.2017.117.01.0001.01.ENG&toc=OJ:L:2017:117:TOC [Accessed 09-08-2024].
20. Australian Orthopaedic Association National Joint Replacement Registry (AOANJRR). Annual Report 2023. 2023. https://aoanjrr.sahmri.com/annual-reports-2023 [Accessed 09-07-2024].
21. The New Zealand Joint Registry (NZOA). NZJR 24 Year Report. 2023. https://www.nzoa.org.nz/annual-reports [Accessed 10-07-2024].

22. Johanson PE, Antonsson M, Shareghi B, Kärrholm J. Early Subsidence Predicts Failure of a Cemented Femoral Stem With Minor Design Changes. Clin Orthop Relat Res. 2016;474:10:2221-9.
23. Hauptfleisch J, Glyn-Jones S, Beard DJ, Gill HS, Murray DW. The premature failure of the Charnley Elite-Plus stem: a confirmation of RSA predictions. J Bone Joint Surg Br. 2006;88:2:179-83.
24. Howie DW, Middleton RG, Costi K. Loosening of matt and polished cemented femoral stems. J Bone Joint Surg Br. 1998;80:4:573-6.
25. Petheram TG, Bone M, Joyce TJ, Serrano-Pedraza I, Reed MR, Partington PF. Surface finish of the Exeter Trauma Stem: a cause for concern? Bone Joint J. 2013;95-b:2:173-6.
26. Hutt J, Hazlerigg A, Aneel A, Epie G, Dabis H, Twyman R et al. The effect of a collar and surface finish on cemented femoral stems: a prospective randomised trial of four stem designs. Int Orthop. 2014;38:6:1131-7.
27. Bonsignore LA, Goldberg VM, Greenfield EM. Machine oil inhibits the osseointegration of orthopaedic implants by impairing osteoblast attachment and spreading. J Orthop Res. 2015;33:7:979-87.
28. Miller MA, Terbush MJ, Goodheart JR, Izant TH, Mann KA. Increased initial cement-bone interlock correlates with reduced total knee arthroplasty micro-motion following in vivo service. J Biomech. 2014;47:10:2460-6.
29. Sadauskas A, Engh C, 3rd, Mehta M, Levine B. Implant Interface Debonding After Total Knee Arthroplasty: A New Cause for Concern? Arthroplast Today. 2020;6:4:972-5.
30. Wang X, Xu S, Zhou S, Xu W, Leary M, Choong P et al. Topological design and additive manufacturing of porous metals for bone scaffolds and orthopaedic implants: A review. Biomaterials. 2016;83:127-41.
31. Mumith A, Thomas M, Shah Z, Coathup M, Blunn G. Additive manufacturing: current concepts, future trends. Bone Joint J. 2018;100-b:4:455-60.
32. Nelissen RG, Pijls BG, Kärrholm J, Malchau H, Nieuwenhuijse MJ, Valstar ER. RSA and registries: the quest for phased introduction of new implants. J Bone Joint Surg Am. 2011;93 Suppl 3:62-5.
33. Malchau H. Introducing new technology: a stepwise algorithm. Spine (Phila Pa 1976). 2000;25:3:285.
34. Schemitsch EH, Bhandari M, Boden SD, Bourne RB, Bozic KJ, Jacobs JJ et al. The evidence-based approach in bringing new orthopaedic devices to market. J Bone Joint Surg Am. 2010;92:4:1030-7.
35. Huiskes R. Failed innovation in total hip replacement. Diagnosis and proposals for a cure. Acta Orthop Scand. 1993;64:6:699-716.
36. Kärrholm J, Borssén B, Löwenhielm G, Snorrason F. Does early micromotion of femoral stem prostheses matter? 4-7-year stereoradiographic follow-up of 84 cemented prostheses. J Bone Joint Surg Br. 1994;76:6:912-7.
37. Ryd L, Albrektsson BE, Carlsson L, Dansgård F, Herberts P, Lindstrand A et al. Roentgen stereophotogrammetric analysis as a predictor of mechanical loosening of knee prostheses. J Bone Joint Surg Br. 1995;77:3:377-83.
38. Mjöberg B. Is early migration enough to explain late clinical loosening of hip prostheses? EFORT Open Rev. 2020;5:2:113-7.
39. Davidson JM, Hedley WS. A method of precise localisation and measurement by means of roentgen rays. The Lancet. 1897;150:3868:1001.
40. Kärrholm J, Gill RH, Valstar ER. The history and future of radiostereometric analysis. Clin Orthop Relat Res. 2006;448:10-21.
41. Selvik G. Roentgen stereophotogrammetry. Acta Orthopaedica Scandinavica. 1989;60:sup232:1-51.
42. Fontalis A, Haddad FS. Roentgen stereophotogrammetric analysis: still a very valuable tool in the orthopaedic research armamentarium. Bone Joint Res. 2022;11:4:210-3.
43. Pijls BG, Valstar ER, Nouta KA, Plevier JW, Fiocco M, Middeldorp S et al. Early migration of tibial components is associated with late revision: a systematic review and meta-analysis of 21,000 knee arthroplasties. Acta Orthop. 2012;83:6:614-24.
44. Pijls BG, Nieuwenhuijse MJ, Fiocco M, Plevier JW, Middeldorp S, Nelissen RG et al. Early proximal migration of cups is associated with late revision in THA: a systematic review and meta-analysis of 26 RSA studies and 49 survivalstudies. Acta Orthop. 2012;83:6:583-91.
45. Nieuwenhuijse MJ, Valstar ER, Kaptein BL, Nelissen RG. Good diagnostic performance of early migration as a predictor of late aseptic loosening of acetabular cups: results from ten years of follow-up with Roentgen stereophotogrammetric analysis (RSA). J Bone Joint Surg Am. 2012;94:10:874-80.

46. van der Voort P, Pijls BG, Nieuwenhuijse MJ, Jasper J, Fiocco M, Plevier JW et al. Early subsidence of shape-closed hip arthroplasty stems is associated with late revision. A systematic review and meta-analysis of 24 RSA studies and 56 survival studies. Acta Orthop. 2015;86:5:575-85.
47. van Hamersveld KT, Marang-van de Mheen PJ, Koster LA, Nelissen R, Toksvig-Larsen S, Kaptein BL. Marker-based versus model-based radiostereometric analysis of total knee arthroplasty migration: a reanalysis with comparable mean outcomes despite distinct types of measurement error. Acta Orthop. 2019;90:4:366-72.
48. Kaptein BL, Valstar ER, Stoel BC, Rozing PM, Reiber JH. A new model-based RSA method validated using CAD models and models from reversed engineering. J Biomech. 2003;36:6:873-82.
49. Pijls BG, Plevier JWM, Nelissen R. RSA migration of total knee replacements. Acta Orthop. 2018;89:3:320-8.
50. Kaptein BL, Valstar ER, Stoel BC, Reiber HC, Nelissen RG. Clinical validation of model-based RSA for a total knee prosthesis. Clin Orthop Relat Res. 2007;464:205-9.
51. Hurschler C, Seehaus F, Emmerich J, Kaptein BL, Windhagen H. Comparison of the model-based and marker-based roentgen stereophotogrammetry methods in a typical clinical setting. J Arthroplasty. 2009;24:4:594-606.
52. Christensson A, Nemati HM, Flivik G. Comparison between model-based RSA and an AI-based CT-RSA: an accuracy study of 30 patients. Acta Orthop. 2024;95:39-46.
53. Scheerlinck T, Polfliet M, Deklerck R, Van Gompel G, Buls N, Vandemeulebroucke J. Development and validation of an automated and marker-free CT-based spatial analysis method (CTSA) for assessment of femoral hip implant migration: In vitro accuracy and precision comparable to that of radiostereometric analysis (RSA). Acta Orthop. 2016;87:2:139-45.
54. Sandberg OH, Kärrholm J, Olivecrona H, Röhrl SM, Sköldenberg OG, Brodén C. Computed tomography-based radiostereometric analysis in orthopedic research: practical guidelines. Acta Orthop. 2023;94:373-8.
55. Valstar ER, Gill R, Ryd L, Flivik G, Börlin N, Kärrholm J. Guidelines for standardization of radiostereometry (RSA) of implants. Acta Orthop. 2005;76:4:563-72.
56. Pijls BG. Reflections on the RSA guidelines. Acta Orthop. 2020;91:3:232-3.
57. Madanat R, Mäkinen TJ, Aro HT, Bragdon C, Malchau H. Adherence of hip and knee arthroplasty studies to RSA standardization guidelines. A systematic review. Acta Orthop. 2014;85:5:447-55.
58. ISO 16087:2013(en). Implants for surgery: Roentgen stereophotogrammetric analysis for the assessment of migration of orthopaedic implants. 2013.
59. Puijk R, Puijk RH, Laende EK, Dunbar MJ, Plevier JWM, Nolte PA et al. 6-month migration sufficient for evaluation of total knee replacements: a systematic review and meta-analysis. Acta Orthop. 2023;94:577-87.
60. Molt M, Toksvig-Larsen S. Peri-ApatiteTM Enhances Prosthetic Fixation in Tka-A Prospective Randomised RSA Study. Journal of Arthritis. 2014;3:1-6.
61. Molt M, Toksvig-Larsen S. Similar early migration when comparing CR and PS in Triathlon™ TKA: A prospective randomised RSA trial. Knee. 2014;21:5:949-54.
62. Hilding M, Aspenberg P. Local peroperative treatment with a bisphosphonate improves the fixation of total knee prostheses: a randomized, double-blind radiostereometric study of 50 patients. Acta Orthop. 2007;78:6:795-9.
63. Kaptein BL, Pijls B, Koster L, Kärrholm J, Hull M, Niesen A et al. Guideline for RSA and CT-RSA implant migration measurements: an update of standardizations and recommendations. Acta Orthop. 2024;95:256-67.
64. International Radiostereometry Society. https://radiostereometry.org/ [Accessed 15-07-2024].
65. Hasan S, Marang-van de Mheen PJ, Kaptein BL, Nelissen R, Pijls BG. RSA-tested TKA Implants on Average Have Lower Mean 10-year Revision Rates Than Non-RSA-tested Designs. Clin Orthop Relat Res. 2020;478:6:1232-41.
66. Phillips JRA, Tucker K. Implant brand portfolios, the potential for camouflage of data, and the role of the Orthopaedic Data Evaluation Panel in total knee arthroplasty. Bone Joint J. 2021;103-b:10:1555-60.
67. Wilton T, Skinner JA, Haddad FS. Camouflage uncovered: what should happen next? The Bone & Joint Journal. 2023;105-B:3:221-6.
68. Wilton T, Skinner JA, Haddad FS. Camouflage uncovered: what should happen next? Bone Joint J. 2023;105-b:3:221-6.

69. Kingsbury SR, Dube B, Thomas CM, Conaghan PG, Stone MH. Is a questionnaire and radiograph-based follow-up model for patients with primary hip and knee arthroplasty a viable alternative to traditional regular outpatient follow-up clinic? Bone Joint J. 2016;98-b:2:201-8.
70. Marsh JD, Bryant DM, MacDonald SJ, Naudie DD, McCalden RW, Howard JL et al. Feasibility, effectiveness and costs associated with a web-based follow-up assessment following total joint arthroplasty. J Arthroplasty. 2014;29:9:1723-8.





Chapter 2

Tibial baseplate migration is not associated with change in patient reported outcome measures and clinical scores after TKA: A secondary analysis of 5 radiostereometric analysis studies with 10-year follow-up

T.J.N. van der Lelij
B.L. Kaptein
R. Tsonaka
R.G.H.H. Nelissen
S. Toksvig-Larsen
P.J. Marang-van de Mheen

The Journal of Bone and Joint Surgery (American Volume)
2024 Aug 21;106(16):1479-1485

Abstract

Background

Radiostereometric analysis (RSA) provides highly accurate data about the migration of a total knee arthroplasty (TKA) component. However, patient-reported outcome measures (PROMs) reflect the patients' perspective of their functional status, pain, and overall health after TKA. The aim of this study was to evaluate the association between tibial implant migration and change in postoperative PROMs and clinical scores, using data pooled from long-term follow-up RSA studies.

Methods

Individual implant migration data were collected from 5 randomized RSA studies, including a total of 300 patients with 6 distinct TKA implant designs (all Stryker). Tibial implant migration (maximum total point motion [MTPM]) was evaluated with RSA at 3 months, 1 year, and 2, 5, 7, and 10 years postoperatively. The Knee Society Score (KSS)- Knee and KSS- Function and Knee Injury and Osteoarthritis Outcome Score (KOOS) subscales were collected in all studies at the same follow-up times. Linear mixed-effects models, with adjustment for TKA implant design and patient characteristics, were used to analyze the data. The 3-month follow-up visit was used as the baseline to assess the association between implant migration and PROMs across the 10-year follow-up.

Results

No association between tibial implant migration and change in KSS-Knee ($p = 0.384$), KSS-Function ($p = 0.737$), KOOS-Symptoms ($p = 0.398$), KOOS-Pain ($p = 0.699$), KOOS-Activities of Daily Living ($p = 0.205$), KOOS-Sport and Recreation ($p = 0.702$), or KOOS-Quality of Life ($p = 0.368$) was found across the entire follow-up. Similar results were found when using the 2-year follow-up as the baseline, after which both cemented and uncemented implants are expected to have stabilized.

Conclusions

Tibial baseplate migration was not associated with postoperative worsening in PROMs or clinical scores in patients who underwent TKA. These findings suggest that implant migration, as measured with RSA, measures a different parameter (i.e., implant-bone fixation) than PROMs (i.e., patient perception) and clinical scores. Therefore, to assess the performance and safety of TKA implant designs, RSA and PROMs cannot be used interchangeably during the postoperative follow-up of patients and evaluation of the fixation of knee implants.

Level of evidence

Prognostic level III.

Introduction

Patient-reported outcome measures (PROMs) are increasingly employed in orthopaedics, reflecting the change of focus from volume-based to value-based health-care delivery by evaluating what matters and what is expected by patients after arthroplasty (1-4). Given the increasing health-care costs of and the excellent performance after most total knee arthroplasties (TKAs), PROMs have been suggested as a feasible alternative to the traditional regular outpatient clinic follow-up after TKA (5, 6).

Radiostereometric analysis (RSA) is a highly accurate and objective technique to detect minimal implant migration (0.1 to 0.2 mm) during early follow-up, which is associated with implant (e.g., TKA implant) revision risk (7, 8). If TKA implant migration (i.e., implant fixation in the bone) is associated with a decrease in PROMs and/or clinical knee scores, this would suggest that these scores can be used interchangeably for the follow-up of patients who underwent TKA, thereby reducing costs (e.g., no clinical visits) while maintaining quality and safety for the patients who underwent TKA. To our knowledge, no studies have investigated the association of tibial baseplate migration in patients who underwent TKA and PROMs and clinical scores. Recently, Steiner et al. (9) found that hip stem migration did not significantly influence PROMs at 2 years postoperatively in patients who underwent total hip arthroplasty (THA).

The aim of the present study was to assess whether TKA tibial component migration, as measured with RSA, is associated with changes in postoperative PROMs and clinical scores in patients who undergo TKA. We hypothesized that tibial implant migration is not associated with postoperative improvement in PROMs or clinical scores, as they measure different constructs.

Material and methods

Study design

Pooling individual tibial baseplate migration data from multiple, long-term RSA studies increases the statistical power to detect possible associations (10). Long-term follow-up data were collected from 5 individual RSA studies, all conducted at a single center (Hässleholm Hospital) with inclusion periods between 2006 and 2010 (Table I). Patient

selection, baseline characteristics, and surgical procedures of the studies have been described in previous short-term and mid-term reports (11-17). In short, each study was a randomized controlled trial (RCT) using RSA to assess differences in migration between 2 TKA implant designs. The studies included 300 patients in total and 6 distinct TKA implant designs. The Triathlon cruciate-retaining (CR) cemented implant was included in 4 studies, and the Triathlon CR uncemented peri-apatite (PA)-coated implant was included in 2 studies. The other TKA designs were included in 1 study each: the Duracon CR cemented, Triathlon posterior-stabilized (PS) cemented, Triathlon CR uncemented porous-coated, and Triathlon short-stem (i.e., short-keeled) CR cemented implants (all Stryker).

Table 1. Study characteristics

	Implant designs	Inclusion period	No. of patients	Clinicaltrials.gov registration
Study 1	Triathlon CR cemented Duracon CR cemented	2006	60	NCT00436982
Study 2	Triathlon CR cemented Triathlon PS cemented	2007	60	NCT02522728
Study 3	Triathlon CR uncemented PA-coated Triathlon CR uncemented porous-coated	2007 to 2008	60	NCT03198533
Study 4	Triathlon CR cemented Triathlon short-stem CR cemented	2008 to 2010	60	NCT02525614
Study 5	Triathlon CR cemented Triathlon CR uncemented PA-coated	2009 to 2010	60	NCT02525601

RSA

In all studies, RSA radiographs were made on the first day after the surgical procedure when weight-bearing was achieved. Subsequent examinations were performed at 3 months, 1 year, and 2, 5, 7, and 10 years postoperatively. RSA radiographs were made with the patient in a supine position with the knee in a calibration cage (Cage 10; RSA Biomedical). Migration was calculated using marker-based analysis, with 8 tantalum beads with a diameter of 0.8 mm (RSA Biomedical) inserted into the tibial bone and 5 beads inserted into the polyethylene insert. The same experienced RSA analyst performed the migration calculations in all studies using all available markers at each follow-up that could be matched to the baseline RSA image. The postoperative RSA examination served as the reference for migration calculations in all studies. Analyses were performed with UmRSA software (version 6.0; RSA Biomedical) in concordance with the International Organization for Standardization (ISO) standard and RSA guidelines (18, 19). Maximum total point motion (MTPM), which is the

length of the translation vector of the marker in a rigid body with the greatest migration, was used as the primary outcome measure for implant migration.

PROMs and clinical scores

The Knee Society Score (KSS) and Knee Injury and Osteoarthritis Outcome Score (KOOS) were obtained preoperatively and at 3 months, 1 year, and 2, 5, 7, and 10 years postoperatively in each study (20, 21). The KSS can be divided into the KSS-Knee and the KSS-Function. The KOOS has 5 separately scored subscales: Symptoms, Pain, Activities of Daily Living, Sport and Recreation (SR), and Quality of Life (QoL). All scores can range from 0 to 100, with higher scores indicating better outcomes. Only the KSS-Knee requires clinical assessment of the knee, including the assessment of the range of motion and stability, and was therefore considered to be a clinical score. All patient-reported outcome scores were obtained from validated questionnaires.

Ethics and registration

All studies were approved by the local ethics committee (11–17) and registered at ClinicalTrials.gov (Table I), and all patients gave their informed consent. A protocol to pool the data from the studies was presented to the medical ethics committee of Leiden University Medical Center, which waived the need for approval under Dutch law (P.15.198).

Statistical analysis

A linear mixed-effects model (LMM) was used to assess the MTPM of each specific TKA implant design over the 10-year follow-up period, as this model takes the correlation of measurements performed on the same patient into account and deals effectively with missing values during follow-up; for patients who withdrew from the study (e.g., due to revision), all measurements until withdrawal were included (22, 23). MTPM was log-transformed, computed as log10(MTPM + 1), to obtain a normally distributed variable. The presented values have been back-transformed to the original scale. To assess the PROMs for the different TKA implant groups at the specific follow-up times, a comparable generalized estimating equation (GEE) approach was used, as a normal distribution could not be obtained through transformation.

To assess the association of tibial baseplate migration (MTPM) with PROMs and clinical scores, separate LMMs were used for the different subscores (KSS-Knee, KSS-Function,

KOOS-Symptoms, KOOS-Pain, KOOS-ADL, KOOS-SR, or KOOS-QoL). The 3-month follow-up visit was used as the baseline, as this was the first follow-up time in which RSA examinations and PROMs were collected at the same time. The changes in PROMs and clinical scores at each follow-up visit were calculated, as well as the tibial implant migration (MTPM) relative to the 3-month follow-up. The models included a PROM variable (change in score relative to the 3-month follow-up score), a time variable (3 months, 1 year, and 2, 5, 7, and 10 years), and an interaction term between time and the PROM to reflect that PROM improvement and thereby its association with migration might change over time. TKA implant design was included as a fixed factor, to account for the possible influence of implant design and fixation method. Baseline patient characteristics (age, sex, American Society of Anesthesiologists [ASA] score, and body mass index [BMI]) were added to the model as fixed factors as well. For the random-effects structure, a random-intercept term was used and the remaining variability was modeled with an autoregressive order-1 covariance structure. Beyond 2 years, after the initial settling phase, both cemented and uncemented implants should not show any progression in migration. Continuous implant migration beyond 2 years indicates insufficient fixation in the bone, and these implants are considered at risk for future aseptic loosening. Therefore, we additionally assessed the association between implant migration and PROMs and clinical scores after 2 years postoperatively. Means were reported with 95% confidence intervals (CIs), and significance was set at $p < 0.05$. Analyses were performed using SPSS (version 26.0; IBM) and R software (version 4.1.0; The R Foundation).

Results

A total of 300 patients were initially included in all studies. During the 10-year follow-up period, 7 implants were revised because of infection (n = 2), component loosening (n = 2), instability (n = 1), or insert wear (n = 2). The number of RSA examinations included in our analysis is presented in Figure 1. At the 10-year follow-up, RSA migration data were available for 163 patients (Figure 1). The complete CONSORT (Consolidated Standards of Reporting Trials) flow diagrams of all individual studies are provided in supplementary data Figure A-1. The most common reasons for not including RSA measurements were inadequate quality of radiographs (e.g., not adhering to the RSA guidelines and the ISO standard) or missing RSA radiographs of patients who remained included in the study (e.g., a missed follow-up time) (18, 19).

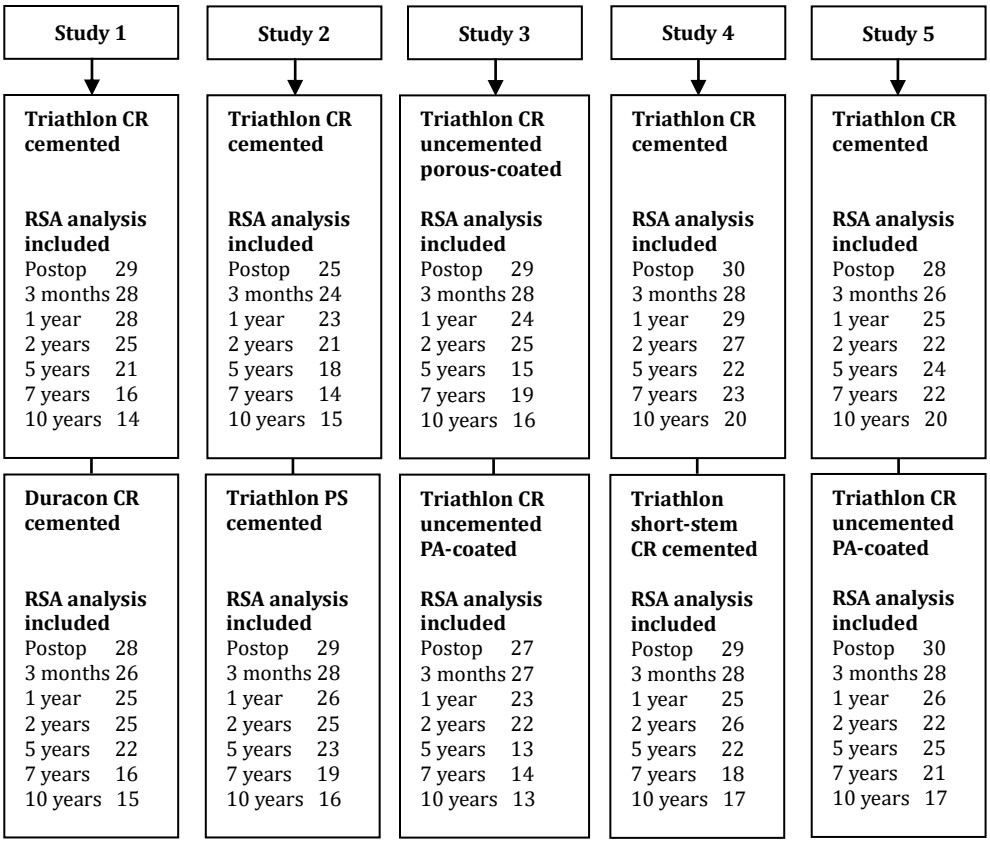


Figure 1. Number of RSA examinations included in the present study at each follow-up time for each individual RCT.

RSA migration measurements

The different TKA implant designs showed distinct long-term migration patterns, with the Triathlon CR uncemented porous-coated TKA implant showing the highest absolute migration (i.e., MTPM) throughout the follow-up period (Figure 2). At the 10-year follow-up, the mean migration of this TKA implant was 1.84 mm (95% CI, 1.59 to 2.12 mm) compared with 0.74 mm (95% CI, 0.58 to 0.92 mm) for the Duracon CR cemented TKA implant, 0.70 mm (95% CI, 0.62 to 0.78 mm) for the Triathlon CR cemented TKA implant, 0.76 mm (95% CI, 0.61 to 0.94 mm) for the Triathlon PS cemented TKA implant, 0.74 mm (95% CI, 0.59 to 0.90 mm) for the Triathlon CR short-stem cemented TKA implant, and 0.88 mm (95% CI, 0.76 to 1.02 mm) for the Triathlon CR uncemented PA-coated TKA implant. There was no

difference in migration pattern (i.e., initial implant migration and later stabilization) of the Triathlon CR cemented TKA implant within the 4 studies in which this implant was included (p = 0.98). Also, the Triathlon CR uncemented PA-coated TKA implant showed a comparable migration pattern during the 10-year follow-up in the 2 studies evaluating this design (p = 0.99) (see supplementary data, Figure A-2).

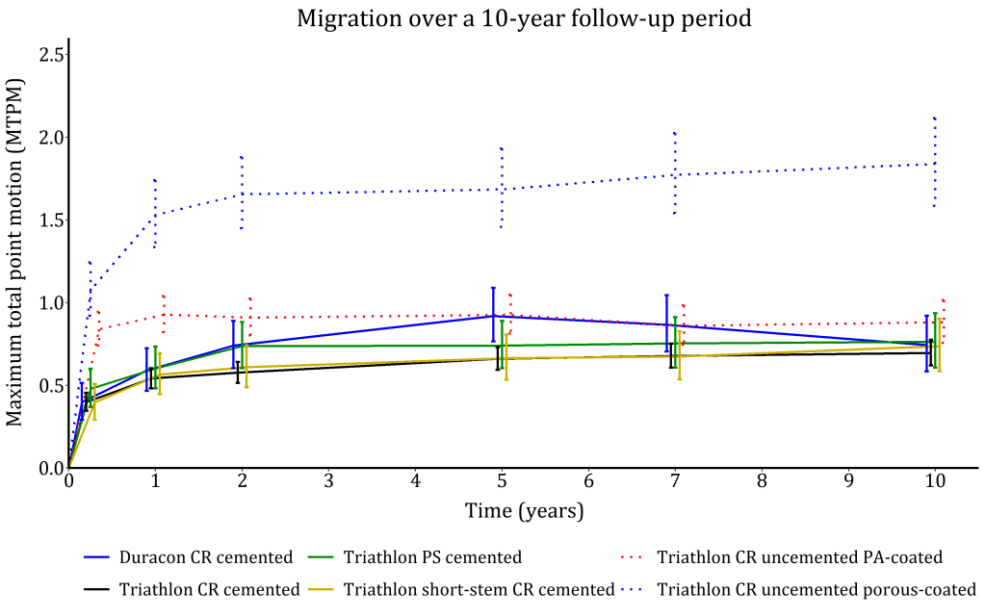


Figure 2. The mean MTPM, derived from the LMM analysis, during the 10-year follow-up. The error bars indicate the 95% Cis. The individual lines represent distinct TKA implant designs.

Association of tibial implant migration with PROMs and clinical scores

The LMMs showed no significant association between KSS-Knee (p = 0.384), KSS-Function (p = 0.737), KOOS-Symptoms (p = 0.398), KOOS-Pain (p = 0.699), KOOS-ADL (p = 0.205), KOOS-SR (p = 0.702), or KOOS-QoL (p = 0.368) and TKA tibial component migration during the 10-year follow-up when 3 months postoperatively was used as the baseline measure. Analyzing tibial baseplate migration beyond 2 years postoperatively (i.e., when implants are expected to show no progression in migration), no association with KSS-Knee (p = 0.063), KSS-Function (p = 0.169), KOOS-Symptoms (p = 0.174), KOOS-Pain (p = 0.476), KOOS-ADL (p = 0.424), and KOOS-SR (p = 0.764) could be found. Only a significant association between MTPM and change in KOOS-QoL between 2 and 10 years of follow-up was found (p = 0.045).

The mean PROMs and clinical scores for each TKA implant design at the specific follow-up times are presented in the supplementary data Table A-1.

Discussion

No association between TKA tibial component migration and postoperative change in PROMs or clinical scores of patients during the 10-year follow-up after TKA was found in the present study, meaning that worsening or less improvement of postoperative PROMs and clinical scores over time does not indicate greater TKA implant migration. Tibial component migration likely measures something different (i.e., the fixation of the implant in the bone) than PROMs (i.e., patient perception) or clinical scores. Thus, when evaluating implant performance, migration cannot be used interchangeably with PROMs or clinical scores. Furthermore, at an individual patient level, PROMs will not provide the ability to detect implant loosening at an early stage, which would be necessary for newly introduced implants to have a guarantee of clinical benefit (i.e., pain relief, function, and bone fixation) and patient safety.

For the primary analysis, the 3-month follow-up visit was used as the baseline, as this was the first follow-up time at which RSA examinations and PROMs were collected at the same follow-up time point. Although the greatest improvement in PROMs and clinical scores relative to the preoperative period generally occurs within the first few months after TKA, this was not of interest for the present study, as our goal was to assess whether implant migration (as measured with RSA) and PROMs could be used interchangeably during a 10-year, long-term follow-up period of patients who underwent TKA. No association between MTPM and any of the PROMs or clinical scores was found in our primary analyses. Using the 2-year follow-up as the baseline, there was no association between MTPM and PROMs or clinical scores, except for a marginally significant association between MTPM and KOOS-QoL ($p = 0.045$). However, the coefficients of the change in KOOS-QoL and of the interaction term of time with the change in KOOS-QoL, as derived from the specific LMM, were both very small and were well outside the range of clinically relevant changes in MTPM that could predict aseptic loosening. Also, even though the Triathlon CR uncemented porous-coated TKA implant group showed the greatest mean migration (Figure 2), the mean KOOS-QoL at all follow-up times was comparable or even slightly higher compared with the other TKA implant groups (see supplementary data, Table A-1).

The societal pressure to control health-care costs has prompted increased emphasis on PROMs as a measure of the outcome of treatment. Although patients' opinions are important, associations with more objective measures of treatment outcome are complex. PROMs have been used as an easy method to control health-care costs in value-based health-care initiatives, where value is measured as dollars relative to quality of care (24). Value-added care is more complex than simply the relation between money and 1 outcome measure, even more so because the outcome measure is a subjective measure such as PROMs, which are complex entities (1, 25). There is a lack of consensus on specific score differences for the various PROMs that are clinically important or important to patients (26-28). Nevertheless, defining a "successful" TKA for a patient is important, although a single validated, reliable, and responsive questionnaire addressing the priorities of patients who underwent TKA has been elusive (29). That elusiveness is related to the multidimensional aspects of outcomes, which are related to the implant-bone fixation (i.e., to the more technical aspects of implant surgery) as well as to whether the patients still have symptoms and whether the surgical procedure met their preoperative expectations (1). Moreover, various patient factors, including age, sex, BMI, and psychological factors, have been suggested to influence the improvement in patient-reported outcomes (30-33). Improvement in PROMs after TKA can be related to aspects other than the prosthesis itself, such as the patient's social context and other patient factors. However, the performance of the implant, such as fixation or loosening, can be measured objectively by RSA. Furthermore, cutoff values for MTPM show implants that are at risk for loosening (and therefore warrant close monitoring).

Clinical RSA studies only need a small number of patients to achieve adequate power, because of the high accuracy of the technique (19). In addition to the primary outcome of implant migration, clinical RSA studies frequently collect multiple PROMs and clinical scores at each follow-up time as secondary outcomes. Collecting these questionnaire responses and clinical scores is a time-consuming and expensive process. However, individual RSA studies are not powered to detect differences in PROMs or clinical scores between TKA implant groups, raising questions regarding the purpose of collecting these scores in the clinical RSA trials. Also, the accuracy of RSA has been described as 0.1 to 0.2 mm, raising the question of whether such small micromotion could translate to clinical symptoms that would indicate an increased risk of implant failure due to aseptic loosening (34). Several RSA migration thresholds, based on either mean migration in TKA implant groups or migration of individual implants, have been described in the literature as being associated with increased

risk of revision due to loosening (7) (34-36). For example, TKA implants with a mean migration between 0.5 and 1.6 mm are considered to be at risk of having revision rates of >5% at 10 years (7). As for individual implants, MTPM of ≥0.3 mm between 2 and 5 years is often used to classify individual implants as continuously migrating and at risk for revision due to loosening (34).

The present study has several strengths. First, by pooling individual patient data (RSA migration data, differences in PROMs, and clinical scores) from multiple studies, the sample size and statistical power were increased. Second, 10-year follow-up RSA migration studies are scarce, as most studies remain limited to 2-year follow-up. Third, detection of implant loosening on standard radiographs by clinicians differs from measurement of implant migration as measured with RSA. Whereas loosening as identified by clinicians is subjective and categorizes implants as either loose or stable, RSA provides highly accurate and objective implant migration measurements on a continuous scale and can detect excessive migration before patients experience clinical symptoms. Finally, all included studies used the same marker-based RSA method and every examination was analyzed by the same experienced RSA analysist, using the same software and marker-selection method, increasing comparability between studies.

This study also had limitations. First, a limited number of TKA implant designs from a single manufacturer were included, which may have limited the generalizability of the results to other designs, although the concept of implant fixation in the bone is a generic principle of all well-performing orthopaedic implants. Second, loss to follow-up was present in all studies. This may have biased the association between tibial implant migration and changes in PROMs if patient withdrawal was related to worsening PROMs or migration. However, only a few patients underwent a revision surgical procedure and the main reason for fewer RSA measurements at later follow-up points involved the quality of RSA radiographs. Furthermore, all data from patients withdrawn from the study were still included in the analysis until their last available follow-up, which will have minimized any bias that might occur.

In conclusion, the lack of association between implant migration and changes in postoperative PROMs or clinical scores suggests that implant migration measures something different (i.e., the implant-bone fixation) than PROMs (i.e., patient function) and clinical scores. This suggests that both are needed for a comprehensive evaluation of TKA implant performance and they cannot be used interchangeably in the follow-up of patients who

underwent TKA. Future studies should address whether our findings can be generalized to other arthroplasty implant designs.

References

1. Tilbury C, Haanstra TM, Leichtenberg CS, Verdegaal SH, Ostelo RW, de Vet HC et al. Unfulfilled Expectations After Total Hip and Knee Arthroplasty Surgery: There Is a Need for Better Preoperative Patient Information and Education. J Arthroplasty. 2016;31:10:2139-45.
2. Tilbury C, Haanstra TM, Verdegaal SHM, Nelissen R, de Vet HCW, Vliet Vlieland TPM et al. Patients' pre-operative general and specific outcome expectations predict postoperative pain and function after total knee and total hip arthroplasties. Scand J Pain. 2018;18:3:457-66.
3. Latijnhouwers D, Vlieland T, Marijnissen WJ, Damen PJ, Nelissen R, Gademan MGJ. Sex differences in perceived expectations of the outcome of total hip and knee arthroplasties and their fulfillment: an observational cohort study. Rheumatol Int. 2023;43:5:911-22.
4. Hossain FS, Konan S, Patel S, Rodriguez-Merchan EC, Haddad FS. The assessment of outcome after total knee arthroplasty: are we there yet? Bone Joint J. 2015;97-b:1:3-9.
5. Kingsbury SR, Dube B, Thomas CM, Conaghan PG, Stone MH. Is a questionnaire and radiograph-based follow-up model for patients with primary hip and knee arthroplasty a viable alternative to traditional regular outpatient follow-up clinic? Bone Joint J. 2016;98-b:2:201-8.
6. Marsh JD, Bryant DM, MacDonald SJ, Naudie DD, McCalden RW, Howard JL et al. Feasibility, effectiveness and costs associated with a web-based follow-up assessment following total joint arthroplasty. J Arthroplasty. 2014;29:9:1723-8.
7. Pijls BG, Valstar ER, Nouta KA, Plevier JW, Fiocco M, Middeldorp S et al. Early migration of tibial components is associated with late revision: a systematic review and meta-analysis of 21,000 knee arthroplasties. Acta Orthop. 2012;83:6:614-24.
8. Nelissen RG, Pijls BG, Kärrholm J, Malchau H, Nieuwenhuijse MJ, Valstar ER. RSA and registries: the quest for phased introduction of new implants. J Bone Joint Surg Am. 2011;93 Suppl 3:62-5.
9. Steiner DK, Drivsholm NS, Buchardt STE, Laursen M. The influence of migration of the exeter V40 stem on patient reported outcome measures: a 2-year follow-up of 112 total hip arthroplasties using radiostereometric analysis. Eur J Orthop Surg Traumatol. 2022;32:1:167-74.
10. Riley RD, Lambert PC, Abo-Zaid G. Meta-analysis of individual participant data: rationale, conduct, and reporting. Bmj. 2010;340:c221.
11. Molt M, Ljung P, Toksvig-Larsen S. Does a new knee design perform as well as the design it replaces? Bone Joint Res. 2012;1:12:315-23.
12. Molt M, Ryd L, Toksvig-Larsen S. A randomized RSA study concentrating especially on continuous migration. Acta Orthop. 2016;87:3:262-7.
13. Molt M, Toksvig-Larsen S. Similar early migration when comparing CR and PS in Triathlon™ TKA: A prospective randomised RSA trial. Knee. 2014;21:5:949-54.
14. Molt M, Toksvig-Larsen S. Peri-ApatiteTM enhances prosthetic fixation in Tka-A prospective randomised RSA study. Journal of Arthritis. 2014;3:3:1-6.
15. Van Hamersveld KT, Marang-Van De Mheen PJ, Nelissen R, Toksvig-Larsen S. Peri-apatite coating decreases uncemented tibial component migration: long-term RSA results of a randomized controlled trial and limitations of short-term results. Acta Orthop. 2018;89:4:425-30.
16. Molt M, Toksvig-Larsen S. 2-year follow-up report on micromotion of a short tibia stem. A prospective, randomized RSA study of 59 patients. Acta Orthop. 2015;86:5:594-8.
17. van Hamersveld KT, Marang-van de Mheen PJ, Tsonaka R, Valstar ER, Toksvig-Larsen S. Fixation and clinical outcome of uncemented peri-apatite-coated versus cemented total knee arthroplasty : five-year follow-up of a randomised controlled trial using radiostereometric analysis (RSA). Bone Joint J. 2017;99-b:11:1467-76.
18. Implants for surgery - Roentgen stereophotogrammetric analysis for the assessment of migration of orthopaedic implants. International Organization for Standardization (ISO) 2013 (standard reviewed and confirmed in 2019).
19. Valstar ER, Gill R, Ryd L, Flivik G, Börlin N, Kärrholm J. Guidelines for standardization of radiostereometry (RSA) of implants. Acta Orthop. 2005;76:4:563-72.
20. Insall JN, Dorr LD, Scott RD, Scott WN. Rationale of the Knee Society clinical rating system. Clin Orthop Relat Res. 1989:248:13-4.
21. Roos EM, Lohmander LS. The Knee injury and Osteoarthritis Outcome Score (KOOS): from joint injury to osteoarthritis. Health Qual Life Outcomes. 2003;1:64.
22. Krueger C, Tian L. A comparison of the general linear mixed model and repeated measures ANOVA using a dataset with multiple missing data points. Biol Res Nurs. 2004;6:2:151-7.

23. Ranstam J, Turkiewicz A, Boonen S, Van Meirhaeghe J, Bastian L, Wardlaw D. Alternative analyses for handling incomplete follow-up in the intention-to-treat analysis: the randomized controlled trial of balloon kyphoplasty versus non-surgical care for vertebral compression fracture (FREE). BMC Med Res Methodol. 2012;12:35.
24. Porter ME. What is value in health care? N Engl J Med. 2010;363:26:2477-81.
25. Squitieri L, Bozic KJ, Pusic AL. The Role of Patient-Reported Outcome Measures in Value-Based Payment Reform. Value Health. 2017;20:6:834-6.
26. Henseler JF, Kolk A, van der Zwaal P, Nagels J, Vliet Vlieland TP, Nelissen RG. The minimal detectable change of the Constant score in impingement, full-thickness tears, and massive rotator cuff tears. J Shoulder Elbow Surg. 2015;24:3:376-81.
27. Keurentjes JC, Van Tol FR, Fiocco M, Schoones JW, Nelissen RG. Minimal clinically important differences in health-related quality of life after total hip or knee replacement: A systematic review. Bone Joint Res. 2012;1:5:71-7.
28. Deckey DG, Verhey JT, Gerhart CRB, Christopher ZK, Spangehl MJ, Clarke HD et al. There are Considerable Inconsistencies Among Minimum Clinically Important Differences in TKA: A Systematic Review. Clin Orthop Relat Res. 2023;481:1:63-80.
29. Ramkumar PN, Harris JD, Noble PC. Patient-reported outcome measures after total knee arthroplasty: a systematic review. Bone Joint Res. 2015;4:7:120-7.
30. Bourne RB, McCalden RW, MacDonald SJ, Mokete L, Guerin J. Influence of patient factors on TKA outcomes at 5 to 11 years followup. Clin Orthop Relat Res. 2007;464:27-31.
31. Khatib Y, Madan A, Naylor JM, Harris IA. Do Psychological Factors Predict Poor Outcome in Patients Undergoing TKA? A Systematic Review. Clinical Orthopaedics and Related Research®. 2015;473:8:2630-8.
32. Sveikata T, Porvaneckas N, Kanopa P, Molyte A, Klimas D, Uvarovas V et al. Age, Sex, Body Mass Index, Education, and Social Support Influence Functional Results After Total Knee Arthroplasty. Geriatr Orthop Surg Rehabil. 2017;8:2:71-7.
33. MacDonald SJ, Charron KD, Bourne RB, Naudie DD, McCalden RW, Rorabeck CH. The John Insall Award: gender-specific total knee replacement: prospectively collected clinical outcomes. Clin Orthop Relat Res. 2008;466:11:2612-6.
34. Ryd L, Albrektsson BE, Carlsson L, Dansgård F, Herberts P, Lindstrand A et al. Roentgen stereophotogrammetric analysis as a predictor of mechanical loosening of knee prostheses. J Bone Joint Surg Br. 1995;77:3:377-83.
35. Pijls BG, Plevier JWM, Nelissen R. RSA migration of total knee replacements. Acta Orthop. 2018;89:3:320-8.
36. Pijls BG, Nelissen RGHH. Strategy for RSA migration thresholds. Acta Orthop. 2016;87:4:432-3.

Supplementary data

Table A-1. Clinical scores and patient reported outcome measurements. Values are mean and 95% confidence intervals.

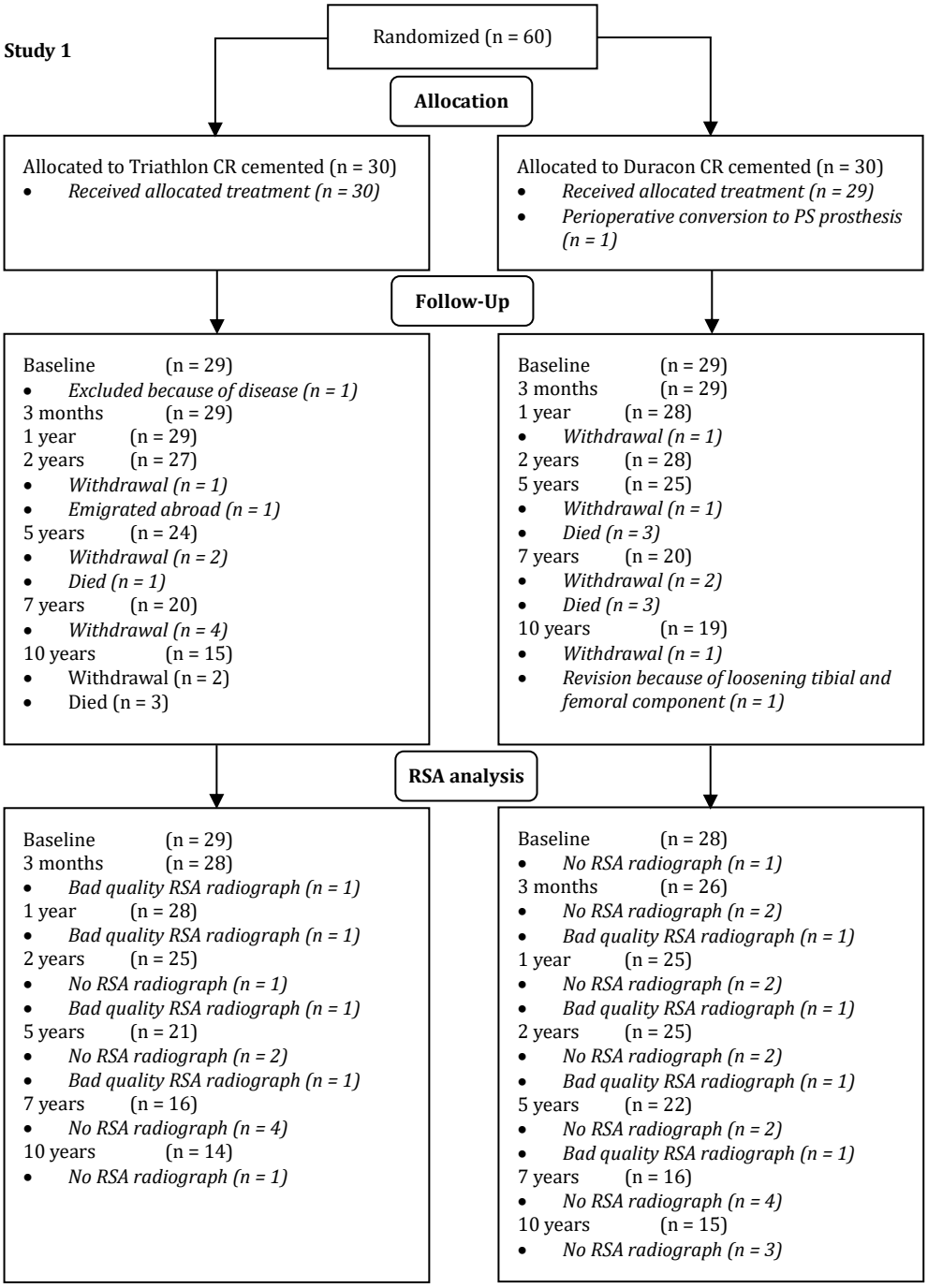
	Duracon CR cemented	Triathlon CR cemented	Triathlon PS cemented
KSS Knee Score			
Preoperative	38.0 (33.5-42.6)	33.7 (31.2-36.1)	33.1 (29.5-36.8)
3 months	83.4 (77.6-89.1)	86.1 (83.6-88.5)	89.2 (84.7-93.8)
1 year	91.2 (86.6-95.7)	92.3 (90.9-93.7)	92.4 (89.0-95.9)
2 years	91.0 (87.2-94.9)	93.9 (92.6-95.2)	95.1 (92.7-97.4)
5 years	90.5 (86.0-95.0)	92.3 (90.3-94.3)	96.4 (94.4-98.3)
7 years	91.3 (85.4-97.2)	91.8 (89.7-94.0)	96.1 (94.0-98.3)
10 years	93.4 (89.1-97.7)	91.0 (88.5-93.6)	95.1 (91.7-98.5)
KSS Function Score			
Preoperative	54.3 (51.9-56.7)	53.9 (51.6-56.3)	51.0 (46.5-55.5)
3 months	73.3 (68.0-87.6)	77.0 (74.5-79.6)	72.1 (65.6-78.5)
1 year	82.7 (76.8-88.5)	88.2 (85.3-91.0)	84.6 (78.6-90.6)
2 years	87.9 (82.2-93.6)	92.4 (90.0-94.8)	89.5 (83.7-95.3)
5 years	80.7 (73.0-88.4)	87.6 (84.4-90.9)	89.1 (82.1-96.1)
7 years	89.2 (81.8-96.6)	85.2 (80.7-89.8)	85.7 (78.4-93.0)
10 years	82.3 (74.2-90.3)	80.1 (75.3-85.0)	88.7 (82.3-95.1)
KOOS-Symptoms			
Preoperative	53.6 (47.9-59.3)	47.3 (43.9-50.7)	54.3 (47.2-61.4)
3 months	66.0 (59.8-72.2)	66.1 (62.8-69.4)	64.9 (58.6-71.3)
1 year	77.0 (70.8-83.2)	77.7 (74.6-80.8)	76.9 (71.7-82.1)
2 years	81.4 (75.3-87.5)	84.1 (81.2-86.9)	82.6 (76.8-88.4)
5 years	83.2 (75.3-91.2)	85.1 (81.7-88.5)	87.3 (82.5-92.0)
7 years	88.2 (81.1-95.4)	84.0 (80.7-87.2)	88.4 (83.7-93.1)
10 years	86.5 (80.3-92.8)	82.2 (78.2-86.2)	85.1 (76.1-91.2)
KOOS-Pain			
Preoperative	43.6 (38.5-48.7)	39.7 (36.7-42.7)	43.2 (36.6-49.9)
3 months	70.2 (62.6-77.9)	71.3 (68.1-74.6)	70.5 (62.9-78.0)
1 year	81.7 (75.1-88.3)	81.3 (78.0-84.6)	80.6 (74.0-87.1)
2 years	84.2 (76.6-91.8)	87.2 (83.9-90.4)	88.4 (82.9-93.9)
5 years	85.0 (77.3-92.7)	86.1 (85.3-89.8)	90.9 (85.3-96.5)
7 years	84.3 (76.0-92.6)	85.0 (81.2-88.9)	88.0 (81.8-94.3)
10 years	82.1 (72.8-91.4)	82.4 (78.1-86.7)	88.4 (82.5-94.3)
KOOS-ADL			
Preoperative	50.6 (45.0-56.2)	44.2 (41.6-46.9)	45.0 (39.6-50.3)
3 months	73.4 (56.2-81.7)	73.6 (70.5-76.7)	73.4 (66.7-80.2)
1 year	83.2 (77.0-89.5)	81.2 (77.7-84.6)	80.7 (73.9-87.5)
2 years	84.6 (77.1-92.1)	84.3 (81.1-87.4)	83.4 (77.7-89.0)
5 years	83.0 (75.1-90.9)	82.9 (79.0-86.7)	86.4 (79.7-93.0)
7 years	80.5 (71.9-89.0)	81.0 (76.9-85.2)	82.4 (74.5-90.3)
10 years	75.8 (64.5-87.2)	79.9 (75.4-84.5)	81.6 (74.0-89.2)
KOOS-SR			
Preoperative	10.0 (4.8-15.2)	10.0 (7.1-12.9)	11.3 (6.1-16.5)
3 months	28.8 (20.9-36.7)	26.7 (23.0-30.5)	28.8 (19.6-37.9)

1 year	38.4 (28.1-48.7)	39.5 (35.1-43.8)	39.6 (31.1-48.2)
2 years	47.1 (35.6-58.7)	42.9 (37.8-47.9)	44.2 (35.9-52.6)
5 years	38.4 (26.2-50.7)	41.4 (35.3-47.6)	56.1 (44.6-67.7)
7 years	35.4 (20.8-50.1)	39.8 (33.4-46.1)	41.8 (31.4-52.2)
10 years	46.1 (33.2-59.1)	41.7 (34.9-48.6)	42.6 (30.5-54.6)
KOOS-QOL			
Preoperative	24.3 (19.0-29.6)	25.5 (22.9-27.5)	23.4 (18.4-28.4)
3 months	54.1 (45.6-62.5)	53.1 (49.4-56.8)	55.7 (47.3-64.0)
1 year	65.3 (57.6-73.0)	64.5 (60.7-68.3)	68.2 (59.7-77.2)
2 years	71.5 (62.4-80.5)	71.9 (67.7-76.0)	78.3 (71.0-85.6)
5 years	81.1 (73.3-88.9)	77.0 (72.0-82.1)	82.4 (75.0-89.8)
7 years	79.2 (71.2-87.2)	70.4 (65.3-75.5)	81.4 (74.3-88.4)
10 years	72.2 (60.0-84.4)	69.9 (64.3-75.6)	76.9 (68.3-85.6)

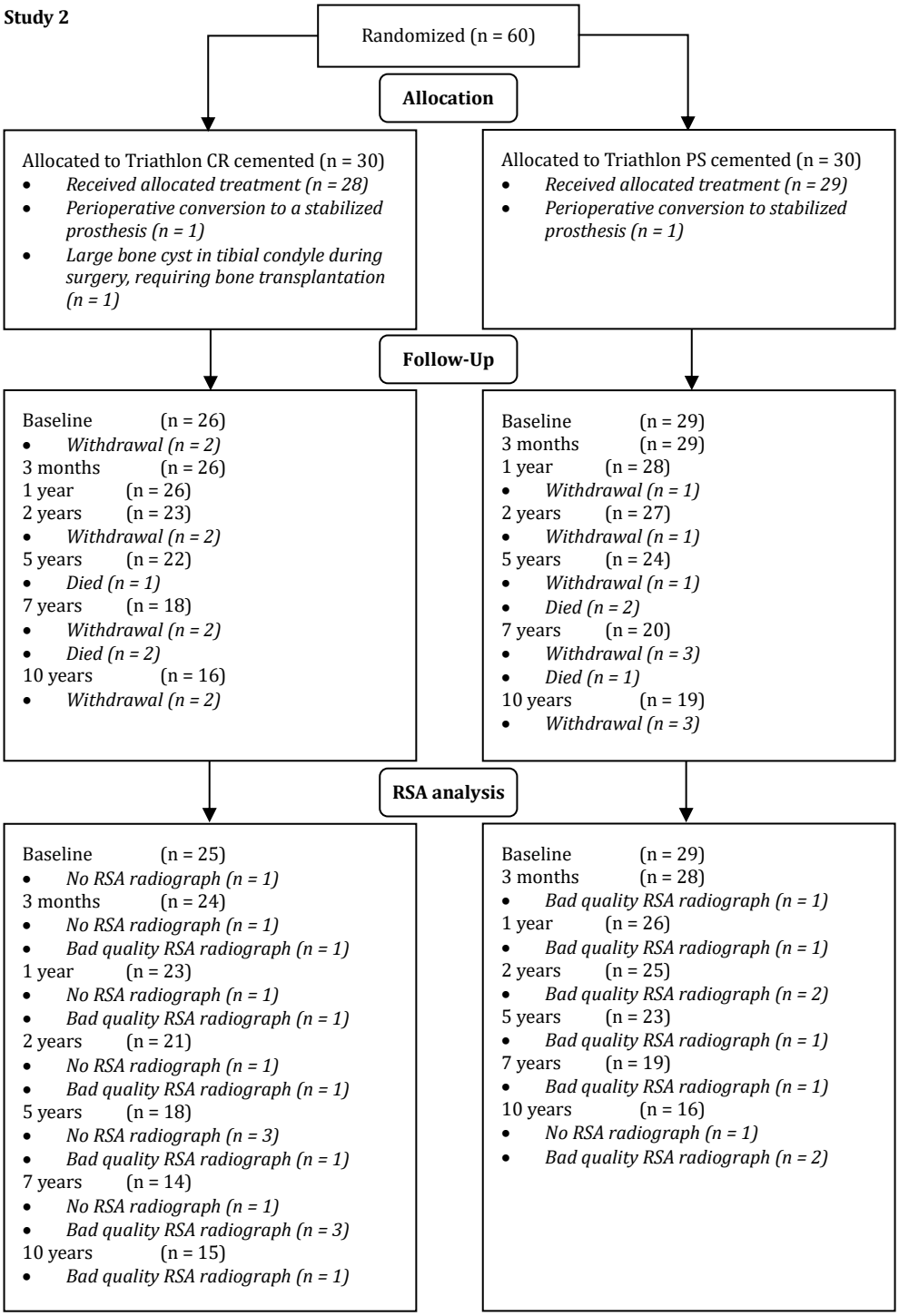
	Triathlon short-stem CR cemented	**Triathlon CR uncemented PA-coated**	**Triathlon CR uncemented porous-coated**
KSS Knee Score			
Preoperative	36.3 (31.9-40.7)	34.9 (32.2-37.5)	35.7 (32.2-39.1)
3 months	86.6 (80.9-92.3)	88.3 (85.1-91.6)	80.9 (73.2-88.6)
1 year	91.6 (88.0-95.2)	93.5 (92.0-94.9)	88.7 (81.2-96.2)
2 years	95.4 (93.7-97.1)	94.1 (92.1-96.1)	89.5 (82.3-96.8)
5 years	95.0 (93.0-96.9)	92.3 (89.1-95.5)	88.8 (80.9-96.7)
7 years	95.8 (94.1-97.6)	93.8 (93.3-96.4)	88.8 (80.5-97.0)
10 years	88.0 (82.5-93.6)	92.3 (87.8-96.3)	89.0 (80.0-98.0)
KSS Function Score			
Preoperative	59.8 (54.1-65.6)	57.3 (53.6-61.0)	56.7 (52.5-60.8)
3 months	81.3 (76.1-86.5)	79.0 (75.1-82.8)	70.1 (64.3-75.9)
1 year	93.2 (87.3-99.2)	93.3 (90.3-96.3)	85.9 (81.3-90.4)
2 years	92.3 (85.8-98.7)	94.7 (82.0-97.4)	87.5 (81.8-93.1)
5 years	89.6 (81.8-97.4)	87.7 (82.5-92.8)	88.1 (80.0-96.3)
7 years	84.6 (76.9-92.2)	87.2 (81.7-92.7)	85.6 (77.7-93.5)
10 years	87.0 (80.4-93.6)	77.4 (69.5-85.2)	82.6 (73.2-91.9)
KOOS-Symptoms			
Preoperative	47.4 (41.4-53.4)	47.2 (42.9-51.6)	46.2 (39.0-53.5)
3 months	60.6 (52.9-68.4)	65.4 (61.2-69.7)	61.3 (55.1-67.5)
1 year	75.0 (69.3-80.8)	82.6 (79.0-86.2)	79.0 (74.5-83.4)
2 years	85.4 (79.9-90.8)	87.1 (83.8-90.5)	80.8 (74.6-86.9)
5 years	88.4 (83.2-93.6)	86.8 (82.9-90.6)	91.3 (86.0-96.7)
7 years	85.8 (80.0-91.5)	81.8 (77.0-86.7)	88.4 (84.1-92.7)
10 years	83.6 (76.8-90.5)	84.6 (79.5-89.8)	90.4 (86.0-94.8)
KOOS-Pain			
Preoperative	45.9 (40.6-51.2)	39.4 (35.7-43.2)	41.3 (35.0-47.6)
3 months	67.8 (60.2-75.5)	70.0 (65.8-74.1)	69.0 (62.0-76.0)
1 year	82.0 (76.0-88.0)	84.2 (80.4-88.0)	80.4 (74.5-86.2)
2 years	87.9 (83.1-92.8)	89.5 (86.1-92.8)	88.2 (82.1-94.2)
5 years	87.8 (81.9-93.8)	86.2 (81.3-91.1)	89.1 (83.2-94.9)
7 years	86.6 (80.9-92.3)	83.1 (77.2-89.4)	86.5 (80.0-93.0)
10 years	87.7 (82.3-93.2)	85.3 (78.9-91.8)	89.3 (84.8-93.9)

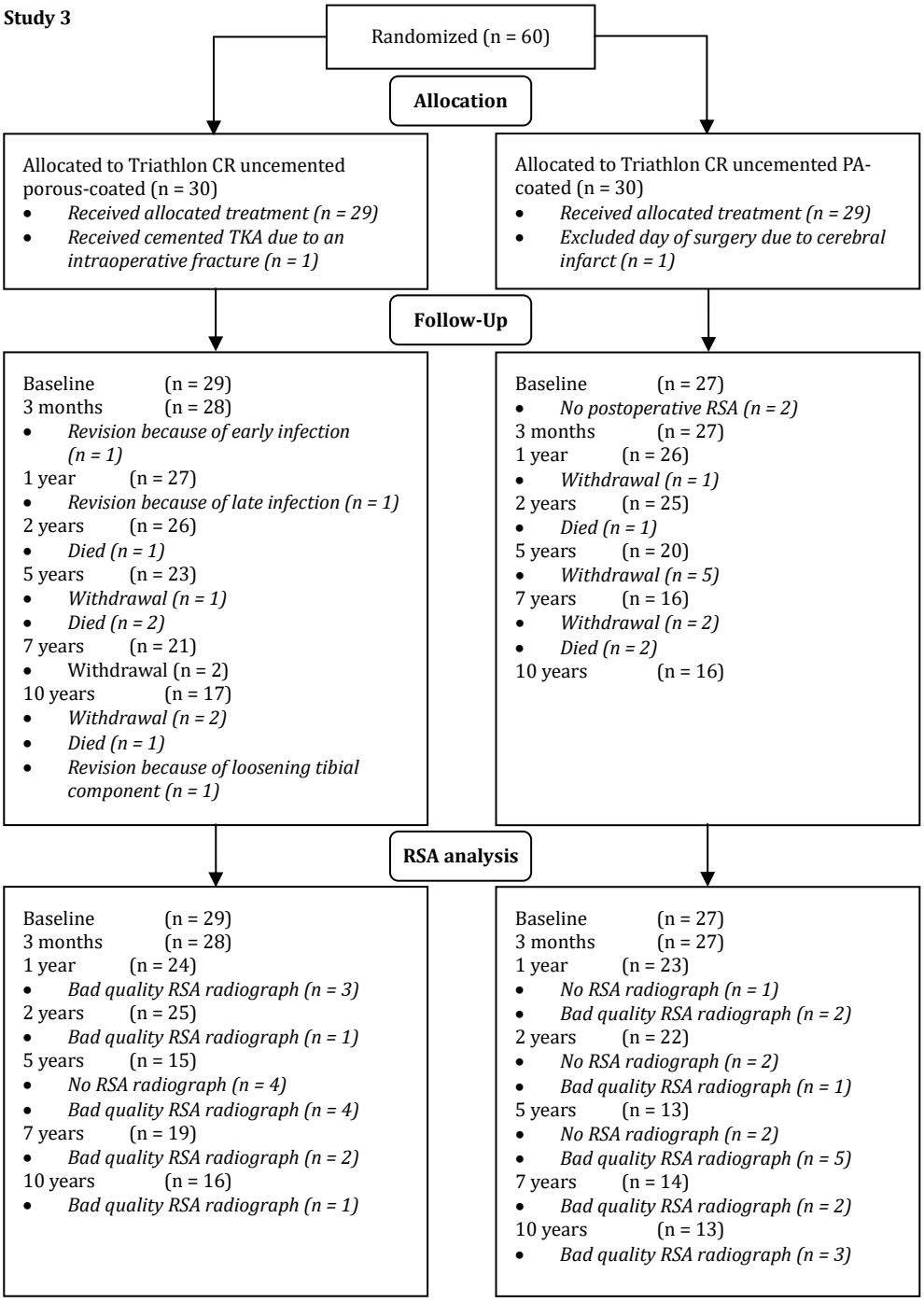
KOOS-ADL				
	Preoperative	48.6 (43.8-53.4)	44.8 (41.1-48.4)	44.1 (37.6-50.6)
	3 months	67.8 (59.9-75.6)	73.3 (69.5-77.2)	72.5 (66.6-78.4)
	1 year	79.6 (72.9-86.3)	83.4 (79.7-87.1)	78.6 (73.1-84.2)
	2 years	85.9 (81.5-90.4)	87.5 (83.6-91.4)	83.9 (77.9-89.9)
	5 years	85.3 (79.5-91.1)	83.5 (78.9-88.2)	85.4 (76.3-94.6)
	7 years	79.2 (71.9-86.5)	80.1 (72.9-87.3)	83.8 (75.3-92.2)
	10 years	83.7 (76.5-90.8)	80.1 (72.8-87.3)	84.4 (77.8-91.0)
KOOS-SR				
	Preoperative	8.7 (4.2-13.3)	7.2 (4.7-9.8)	12.5 (7.7-17.4)
	3 months	27.7 (19.1-36.3)	23.8 (18.8-28.7)	24.7 (17.1-32.4)
	1 year	35.2 (24.6-45.7)	39.5 (33.7-45.3)	31.1 (19.9-42.3)
	2 years	39.2 (29.2-49.2)	41.6 (34.9-48.3)	43.2 (31.5-54.8)
	5 years	34.5 (21.3-47.6)	34.0 (26.3-41.6)	47.1 (33.9-60.3)
	7 years	39.9 (27.4-52.3)	40.1 (31.7-48.4)	45.2 (31.9-58.6)
	10 years	47.2 (34.9-59.4)	46.2 (36.5-56.0)	49.6 (35.7-63.4)
KOOS-QOL				
	Preoperative	28.2 (23.4-33.0)	27.2 (24.1-30.2)	23.2 (18.0-28.4)
	3 months	50.7 (41.9-59.5)	51.6 (46.9-56.3)	54.5 (46.6-62.5)
	1 year	69.7 (60.6-77.6)	63.3 (59.0-67.5)	65.1 (55.5-74.7)
	2 years	73.3 (64.5-82.1)	66.7 (61.8-71.6)	68.5 (59.9-77.0)
	5 years	76.4 (66.9-85.9)	77.2 (71.6-82.8)	84.7 (74.3-95.1)
	7 years	73.5 (62.9-84.1)	60.8 (53.1-68.4)	85.5 (78.1-92.8)
	10 years	72.2 (61.5-82.8)	67.1 (59.2-75.0)	81.0 (74.0-88.1)

Figure A-1. CONSORT flow diagrams of all 5 individual studies.

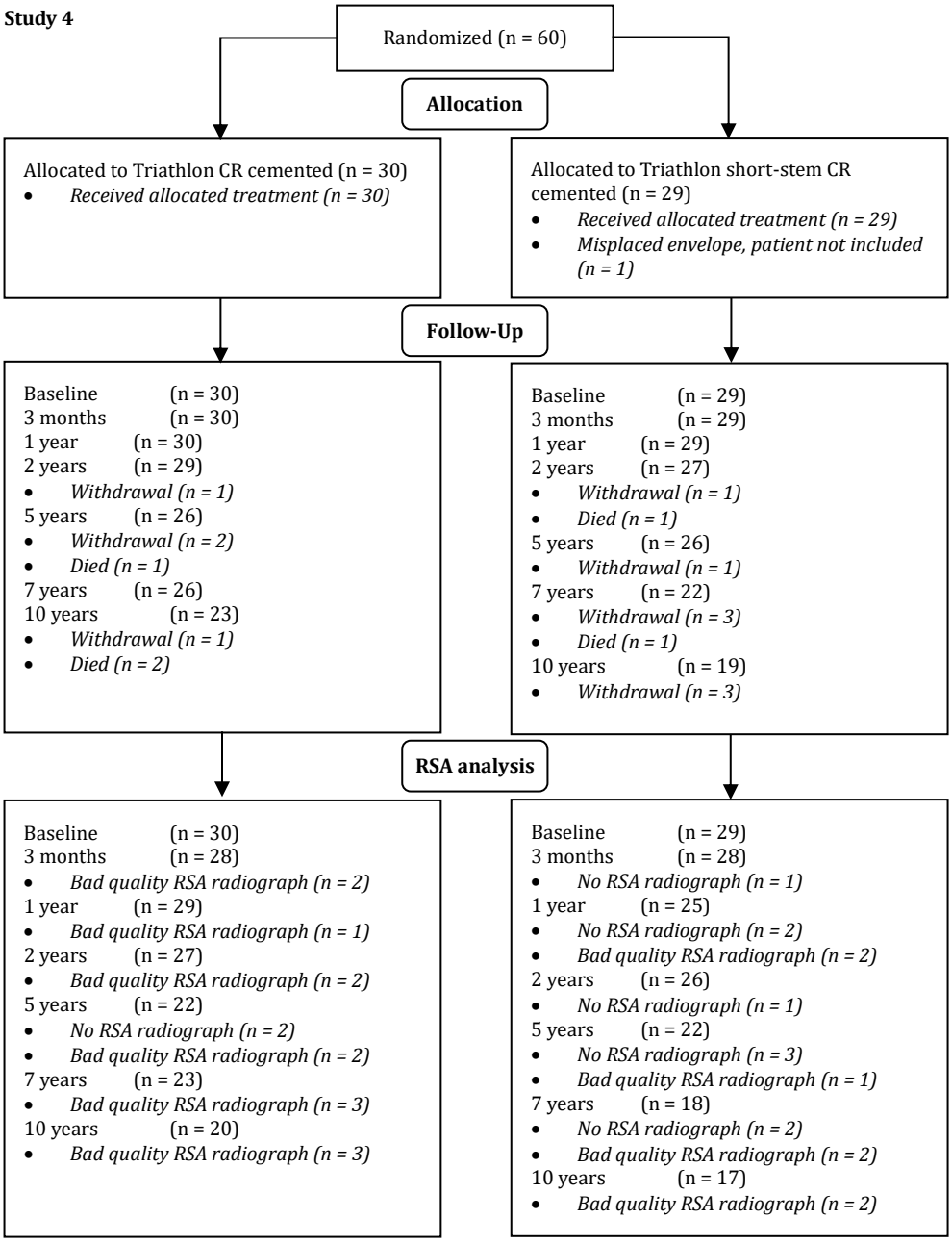


Study 2


Randomized (n = 60)
Allocation
Allocated to Triathlon CR cemented (n = 30)
Received allocated treatment (n = 28)
Perioperative conversion to a stabilized prosthesis (n = 1)
Large bone cyst in tibial condyle during surgery, requiring bone transplantation (n = 1)
Allocated to Triathlon PS cemented (n = 30)
Received allocated treatment (n = 29)
Perioperative conversion to stabilized prosthesis (n = 1)
Follow-Up
Baseline (n = 26)
Withdrawal (n = 2)
3 months (n = 26)
1 year (n = 26)
2 years (n = 23)
Withdrawal (n = 2)
5 years (n = 22)
Died (n = 1)
7 years (n = 18)
Withdrawal (n = 2)
Died (n = 2)
10 years (n = 16)
Withdrawal (n = 2)
Baseline (n = 29)
3 months (n = 29)
1 year (n = 28)
Withdrawal (n = 1)
2 years (n = 27)
Withdrawal (n = 1)
5 years (n = 24)
Withdrawal (n = 1)
Died (n = 2)
7 years (n = 20)
Withdrawal (n = 3)
Died (n = 1)
10 years (n = 19)
Withdrawal (n = 3)
RSA analysis
Baseline (n = 25)
No RSA radiograph (n = 1)
3 months (n = 24)
No RSA radiograph (n = 1)
Bad quality RSA radiograph (n = 1)
1 year (n = 23)
No RSA radiograph (n = 1)
Bad quality RSA radiograph (n = 1)
2 years (n = 21)
No RSA radiograph (n = 1)
Bad quality RSA radiograph (n = 1)
5 years (n = 18)
No RSA radiograph (n = 3)
Bad quality RSA radiograph (n = 1)
7 years (n = 14)
No RSA radiograph (n = 1)
Bad quality RSA radiograph (n = 3)
10 years (n = 15)
Bad quality RSA radiograph (n = 1)
Baseline (n = 29)
3 months (n = 28)
Bad quality RSA radiograph (n = 1)
1 year (n = 26)
Bad quality RSA radiograph (n = 1)
2 years (n = 25)
Bad quality RSA radiograph (n = 2)
5 years (n = 23)
Bad quality RSA radiograph (n = 1)
7 years (n = 19)
Bad quality RSA radiograph (n = 1)
10 years (n = 16)
No RSA radiograph (n = 1)
Bad quality RSA radiograph (n = 2)


Study 3
Randomized (n = 60)
Allocation
Allocated to Triathlon CR uncemented porous-coated (n = 30)
• Received allocated treatment (n = 29)
• Received cemented TKA due to an intraoperative fracture (n = 1)
Allocated to Triathlon CR uncemented PA-coated (n = 30)
• Received allocated treatment (n = 29)
• Excluded day of surgery due to cerebral infarct (n = 1)
Follow-Up
Baseline (n = 29)
3 months (n = 28)
• Revision because of early infection (n = 1)
1 year (n = 27)
• Revision because of late infection (n = 1)
2 years (n = 26)
• Died (n = 1)
5 years (n = 23)
• Withdrawal (n = 1)
• Died (n = 2)
7 years (n = 21)
• Withdrawal (n = 2)
10 years (n = 17)
• Withdrawal (n = 2)
• Died (n = 1)
• Revision because of loosening tibial component (n = 1)
Baseline (n = 27)
• No postoperative RSA (n = 2)
3 months (n = 27)
1 year (n = 26)
• Withdrawal (n = 1)
2 years (n = 25)
• Died (n = 1)
5 years (n = 20)
• Withdrawal (n = 5)
7 years (n = 16)
• Withdrawal (n = 2)
• Died (n = 2)
10 years (n = 16)
RSA analysis
Baseline (n = 29)
3 months (n = 28)
1 year (n = 24)
• Bad quality RSA radiograph (n = 3)
2 years (n = 25)
• Bad quality RSA radiograph (n = 1)
5 years (n = 15)
• No RSA radiograph (n = 4)
• Bad quality RSA radiograph (n = 4)
7 years (n = 19)
• Bad quality RSA radiograph (n = 2)
10 years (n = 16)
• Bad quality RSA radiograph (n = 1)
Baseline (n = 27)
3 months (n = 27)
1 year (n = 23)
• No RSA radiograph (n = 1)
• Bad quality RSA radiograph (n = 2)
2 years (n = 22)
• No RSA radiograph (n = 2)
• Bad quality RSA radiograph (n = 1)
5 years (n = 13)
• No RSA radiograph (n = 2)
• Bad quality RSA radiograph (n = 5)
7 years (n = 14)
• Bad quality RSA radiograph (n = 2)
10 years (n = 13)
• Bad quality RSA radiograph (n = 3)

Study 4


Randomized (n = 60)
Allocation
Allocated to Triathlon CR cemented (n = 30)
• Received allocated treatment (n = 30)
Allocated to Triathlon short-stem CR cemented (n = 29)
• Received allocated treatment (n = 29)
• Misplaced envelope, patient not included (n = 1)
Follow-Up
Baseline (n = 30)
3 months (n = 30)
1 year (n = 30)
2 years (n = 29)
• Withdrawal (n = 1)
5 years (n = 26)
• Withdrawal (n = 2)
• Died (n = 1)
7 years (n = 26)
10 years (n = 23)
• Withdrawal (n = 1)
• Died (n = 2)
Baseline (n = 29)
3 months (n = 29)
1 year (n = 29)
2 years (n = 27)
• Withdrawal (n = 1)
• Died (n = 1)
5 years (n = 26)
• Withdrawal (n = 1)
7 years (n = 22)
• Withdrawal (n = 3)
• Died (n = 1)
10 years (n = 19)
• Withdrawal (n = 3)
RSA analysis
Baseline (n = 30)
3 months (n = 28)
• Bad quality RSA radiograph (n = 2)
1 year (n = 29)
• Bad quality RSA radiograph (n = 1)
2 years (n = 27)
• Bad quality RSA radiograph (n = 2)
5 years (n = 22)
• No RSA radiograph (n = 2)
• Bad quality RSA radiograph (n = 2)
7 years (n = 23)
• Bad quality RSA radiograph (n = 3)
10 years (n = 20)
• Bad quality RSA radiograph (n = 3)
Baseline (n = 29)
3 months (n = 28)
• No RSA radiograph (n = 1)
1 year (n = 25)
• No RSA radiograph (n = 2)
• Bad quality RSA radiograph (n = 2)
2 years (n = 26)
• No RSA radiograph (n = 1)
5 years (n = 22)
• No RSA radiograph (n = 3)
• Bad quality RSA radiograph (n = 1)
7 years (n = 18)
• No RSA radiograph (n = 2)
• Bad quality RSA radiograph (n = 2)
10 years (n = 17)
• Bad quality RSA radiograph (n = 2)

Study 5

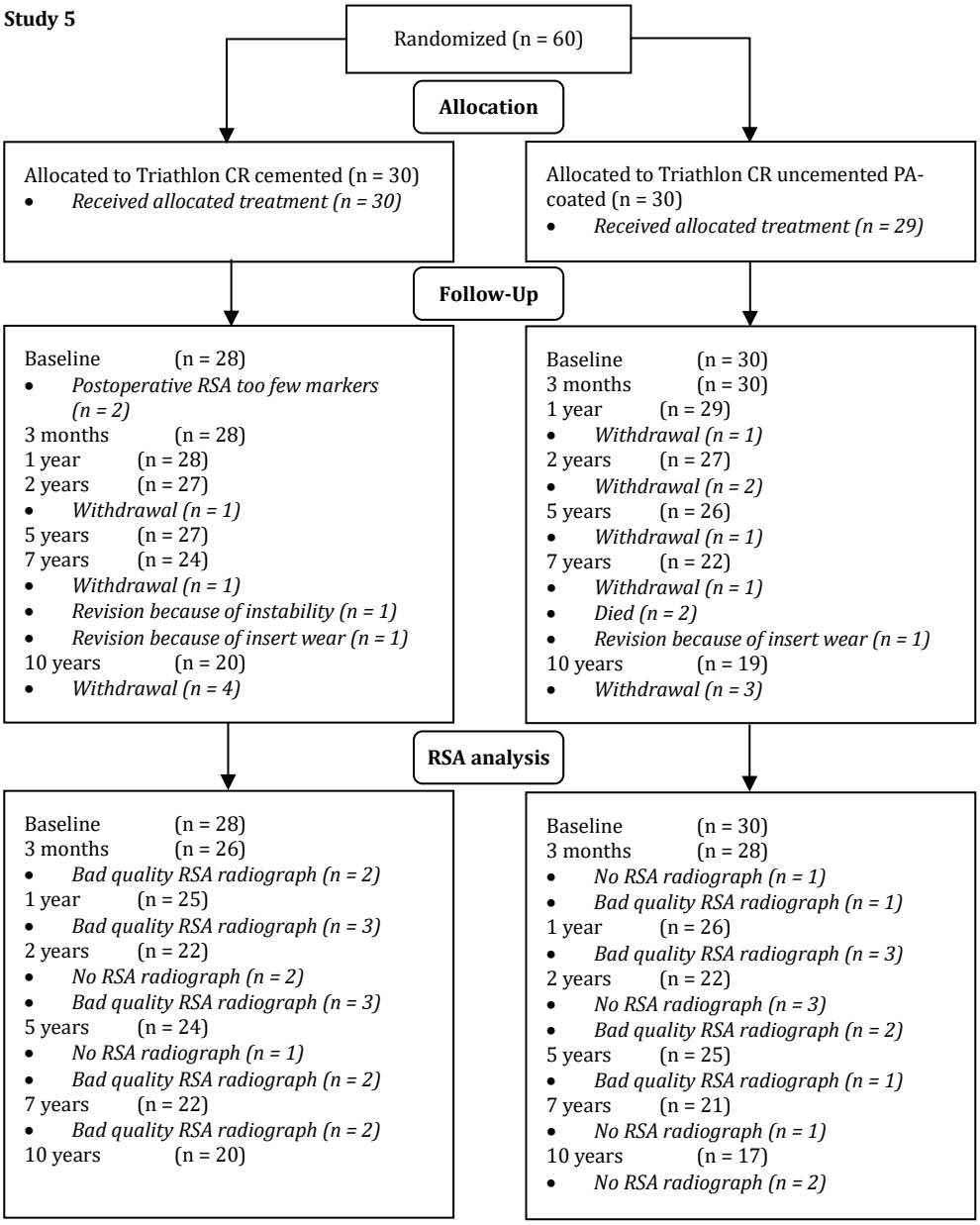
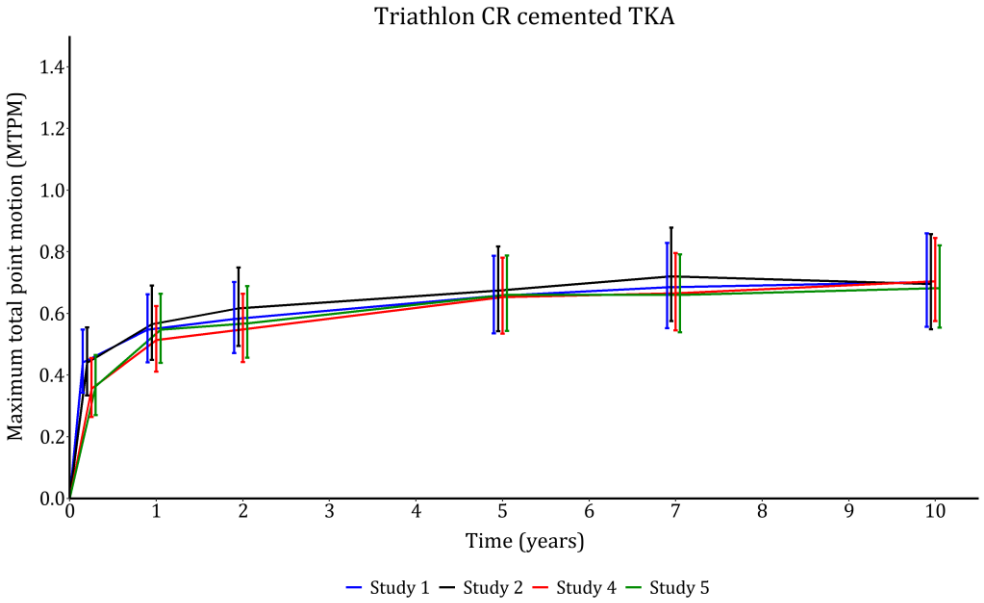
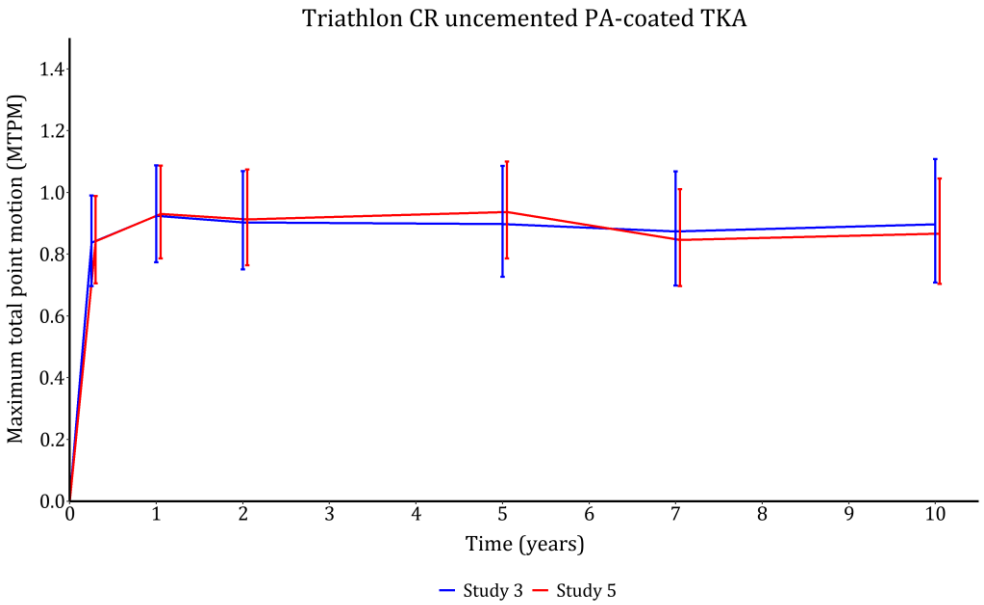
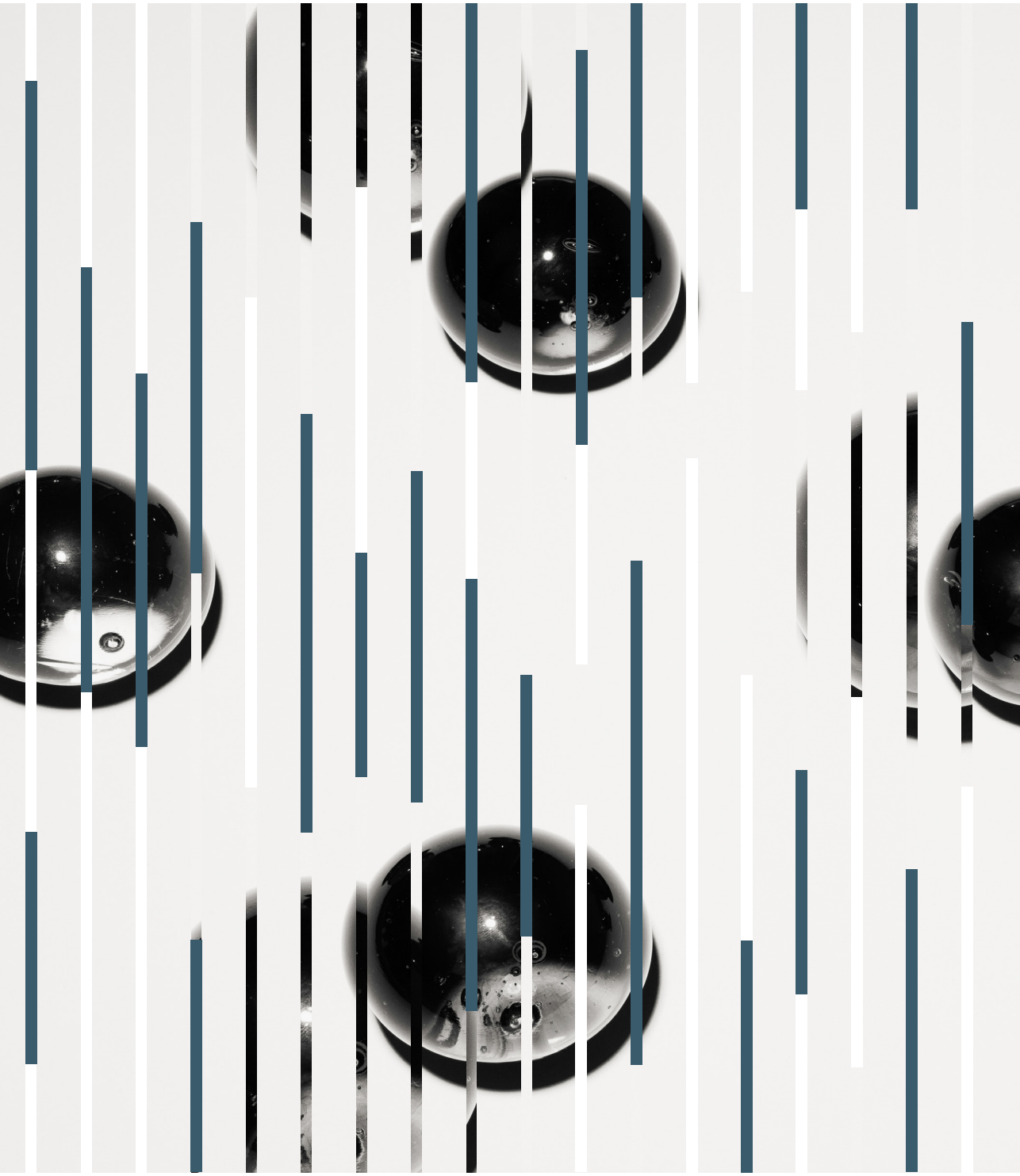
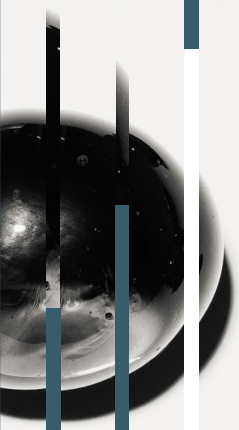

Randomized (n = 60)
Allocation
Allocated to Triathlon CR cemented (n = 30)
• Received allocated treatment (n = 30)
Allocated to Triathlon CR uncemented PA-coated (n = 30)
• Received allocated treatment (n = 29)
Follow-Up
Baseline (n = 28)
• Postoperative RSA too few markers (n = 2)
3 months (n = 28)
1 year (n = 28)
2 years (n = 27)
• Withdrawal (n = 1)
5 years (n = 27)
7 years (n = 24)
• Withdrawal (n = 1)
• Revision because of instability (n = 1)
• Revision because of insert wear (n = 1)
10 years (n = 20)
• Withdrawal (n = 4)
Baseline (n = 30)
3 months (n = 30)
1 year (n = 29)
• Withdrawal (n = 1)
2 years (n = 27)
• Withdrawal (n = 2)
5 years (n = 26)
• Withdrawal (n = 1)
7 years (n = 22)
• Withdrawal (n = 1)
• Died (n = 2)
• Revision because of insert wear (n = 1)
10 years (n = 19)
• Withdrawal (n = 3)
RSA analysis
Baseline (n = 28)
3 months (n = 26)
• Bad quality RSA radiograph (n = 2)
1 year (n = 25)
• Bad quality RSA radiograph (n = 3)
2 years (n = 22)
• No RSA radiograph (n = 2)
• Bad quality RSA radiograph (n = 3)
5 years (n = 24)
• No RSA radiograph (n = 1)
• Bad quality RSA radiograph (n = 2)
7 years (n = 22)
• Bad quality RSA radiograph (n = 2)
10 years (n = 20)
Baseline (n = 30)
3 months (n = 28)
• No RSA radiograph (n = 1)
• Bad quality RSA radiograph (n = 1)
1 year (n = 26)
• Bad quality RSA radiograph (n = 3)
2 years (n = 22)
• No RSA radiograph (n = 3)
• Bad quality RSA radiograph (n = 2)
5 years (n = 25)
• Bad quality RSA radiograph (n = 1)
7 years (n = 21)
• No RSA radiograph (n = 1)
10 years (n = 17)
• No RSA radiograph (n = 2)

Figure A-2. Maximum total point motion during 10 year follow-up (mean and 95% confidence interval presented in the original scale in mm, derived from the linear mixed model analysis) of the Triathlon cruciate retaining (CR) cemented and Triathlon CR uncemented peri-apatite (PA) coated implant. The individual lines represent results from different individual trials.









Chapter 3

Migration and clinical outcomes of a novel cementless hydroxyapatite-coated titanium acetabular shell: Two-year follow-up of a randomized controlled trial using radiostereometric analysis

T.J.N. van der Lelij
P.J. Marang-van de Mheen
B.L. Kaptein
L.A. Koster
P. Ljung
R.G.H.H. Nelissen
S. Toksvig-Larsen

The Bone & Joint Journal
2024 Feb 1;106-B(2):136-143

Abstract

Aims

The objective of this study was to compare the two-year migration and clinical outcomes of a new cementless hydroxyapatite (HA)-coated titanium acetabular shell with its previous version, which shared the same geometrical design but a different manufacturing process for applying the titanium surface.

Methods

Overall, 87 patients undergoing total hip arthroplasty (THA) were randomized to either a Trident II HA or Trident HA shell, each cementless with clusterholes and HA-coating. All components were used in combination with a cemented Exeter V40 femoral stem. Implant migration was measured using radiostereometric analysis (RSA), with radiographs taken within two days of surgery (baseline), and at three, 12, and 24 months postoperatively. Proximal acetabular component migration was the primary outcome measure. Clinical scores and patient-reported outcome measures (PROMs) were collected at each follow-up.

Results

Mean proximal migrations at three, 12, and 24 months were 0.08 mm (95% confidence interval (CI) 0.03 to 0.14), 0.11 mm (95% CI 0.06 to 0.16), and 0.14 mm (95% CI 0.09 to 0.20), respectively, in the Trident II HA group, versus 0.11 mm (95% CI 0.06 to 0.16), 0.12 mm (95% CI 0.07 to 0.17), and 0.14 mm (95% CI 0.09 to 0.19) in the Trident HA group ($p = 0.875$). No significant differences in translations or rotations between the two designs were found in any other direction. Clinical scores and PROMs were comparable between groups, except for an initially greater postoperative improvement in Hip disability and Osteoarthritis Outcome Symptoms score in the Trident HA group ($p = 0.033$).

Conclusion

The Trident II clusterhole HA shell has comparable migration with its predecessor, the Trident hemispherical HA cluster shell, suggesting a similar risk of long-term aseptic loosening.

Introduction

Aseptic loosening of the acetabular component remains one of the most common causes for revision surgery following total hip arthroplasty (THA), according to registry data (20% to 35%) (1, 2). This finding demonstrates a need for better fixation of existing acetabular components. For cementless components this would relate to creating better biological fixation (bone ongrowth) to the implant surface, thus safeguarding long-term fixation.

The Trident acetabular component (Stryker, USA) is a well-proven design with a reported ten-year revision rate of 2.39% (95% confidence interval (CI) 2.26 to 2.53) in combination with the cemented Exeter V40 stem in the National Joint Registry for England, Wales, Northern Ireland, Isle of Man and States of Guernsey (NJR), and 3.9% (95% CI 3.7 to 4.1) in the Australian Orthopaedic Association National Joint Replacement Registry (3, 4). The Trident II acetabular system (Stryker, USA) was recently introduced for implantation, as the manufacturing technique was changed to optimize the production process to meet current production demands. The Trident II system includes different subtypes: the 3D-printed Trident II Tritanium (solidback, multihole, and clusterhole) shells, and the Trident II clusterhole hydroxyapatite (HA) (hemispherical and peripheral self-locking (PSL)) shells. The Trident II HA shells differ from previous Trident HA shells in having a plasma-sprayed rather than an arc-deposited commercially pure titanium (CPTi) surface; both are covered by PureFix HA coating (5, 6). Even though such changes in the manufacturing process may seem minimal, previously small changes in the manufacturing process and implant surfaces have been associated with unacceptable long-term failure rates (7-11). Therefore, safe, phased, evidence-based introduction of new implants is important, even when only 'minor' changes to an implant or its production process have occurred (12). Careful early evaluation, including migration analysis studies, helps to safeguard against the widespread use of new components that perform less well than an earlier version.

Radiostereometric analysis (RSA) is a highly accurate technique for analyzing implant migration (13, 14). Acetabular component migration, specifically proximal translation, as early as one to two years postoperatively is a good prognostic variable for the detection of implants at risk for future aseptic loosening (14, 15). Therefore, RSA is a suitable technique to provide analysis of acetabular components in THA, and monitor new implants to estimate their long-term risk of revision (16).

The aim of the present study was to compare the two-year migration of the new Trident II clusterhole HA shell compared with its predecessor, the Trident hemispherical HA cluster shell, in THA patients. The hypothesis was that the new shell shows comparable migration with its predecessor, as both have exactly the same geometrical design, differing only in the application technique of the titanium surface. The secondary objective was to compare the clinical outcomes and patient-reported outcome measures (PROMs) between groups.

Methods

The present study was conducted in Hässleholm Hospital (Sweden). Between February 2019 and May 2021, THA patients were randomized to a Trident II clusterhole HA cup or Trident hemispherical HA cluster shell. Male and non-pregnant female patients aged between 40 and 75 years who underwent primary THA and gave informed consent were eligible for inclusion. Exclusion criteria were BMI ≥ 35 kg/m2 , rheumatoid arthritis, contralateral THA within the preceding six months, and neuromuscular/neurosensory deficiency. Another exclusion criterion was the need for screw fixation to achieve acceptable initial fixation of the component. Randomization was done using a blocked randomization scheme in a 1:1 ratio. A sealed-envelope technique was used to ensure concealment of treatment allocation, and patients remained blinded to treatment allocation throughout the entire follow-up.

Both acetabular components were hemispherical clusterhole cementless HA-coated and identical in geometrical shape. The surface of the Trident II shell is plasma sprayed CPTi, whereas the Trident shell has an arc-deposited CPTi surface, but both are coated by PureFix HA. The innerchange locking mechanism remained the same for both designs and permitting use of the same liner types. Patients in both groups received the same Trident X3 polyethylene (PE) insert and cemented Exeter V40 femoral stem (Stryker). All operations were performed by four experienced hip surgeons (PL, MA, ML, TH (see Acknowledgements)) using the posterior approach, with a comparable number of procedures performed by each surgeon in both groups. Acetabular preparation comprised under-reaming by 1 mm. All implantations were performed without the use of navigation or robotic assistance.

At operation, nine spherical tantalum markers (ø 0.8 mm; RSA Biomedical, Sweden) per patient were inserted into the acetabular bone to facilitate RSA measurements. RSA radiographs were taken with the patient in supine position over a uniplanar calibration cage

(Cage 41; RSA Biomedical, Sweden). The baseline radiograph, serving as reference for the migration calculations, was taken within two days of surgery (after full weightbearing) and subsequent radiographs were taken after three, 12, and 24 months postoperatively. Double examinations to determine the clinical RSA precision were acquired at one year follow-up (17).

RSA radiographs were analyzed using model-based RSA (RSA*core*; LUMC, Netherlands) with computer-aided design (CAD) models, following the RSA guidelines (Figure 1) (13). A mean error of rigid body fitting below 0.35 mm and a condition number below 120 were set as cut-off points for the pelvic markers. The same set of consistent markers in the pelvis was used in subsequent RSA examinations for each patient. If pelvic bone markers were occluded by the metal implant, a marker configuration model was used where possible to meet the criteria for RSA (18). Acetabular component migration was expressed as translations along and rotations about the transverse axis (x-axis), longitudinal axis (y-axis), and sagittal axis (z-axis) relative to the pelvis. Rotations about the three axes were calculated using the rotations of the y-axis of the CAD model itself, ignoring the rotations of the component about its rotation symmetry axis (19). RSA measurements of left-sided THAs were transformed to match right-sided implants.

The primary outcome measure was the mean proximal (longitudinal) migration at two-year follow-up, as early proximal migration is associated with late revision due to aseptic loosening (14, 15). Secondary outcome measures included the translations along and rotations about the other axes, as well as clinical scores (Harris Hip Score (HSS)) and PROMs at disease and general health level (Hip disability and Osteoarthritis Outcome Score (HOOS), Forgotten Joint Score (FJS), and EuroQol Group five-dimension three-level health-related quality of life instrument (EQ-5D-3L) index) (20-23).

Statistical analysis

To detect a clinically relevant difference in proximal acetabular component migration between groups of 0.2 mm, with an α of 0.05 and power of 90%, 22 patients per group were needed (15, 24). The sample size calculation is based on normally distributed proximal migration within each group with standard deviation (SD) of 0.2 mm. Patients with inappropriate marking of the acetabular bone or poor-quality baseline RSA radiographs could not be analyzed and were excluded. Taking the latter into account, and to compensate for loss to follow-up, our aim was to include at least 40 patients in each group.

Migration results were compared between groups using a linear mixed-effects model (LMM), which deals effectively with missing values and takes within-subject correlation into account. The model consisted of a group variable (i.e. Trident II HA or Trident HA), a time (follow-up visit) variable, and an interaction term between group and time. A random-intercept term was used and the remaining variability was modelled with a heterogeneous autoregressive order-1 covariance structure. As the clinical scores were not normally distributed, a comparable generalized estimating equation (GEE) approach was used to compare these scores between groups during the follow-up period. A p-value < 0.05 was considered statistically significant. Means were reported with SD or 95% CIs. Analyses were performed using SPSS v. 25 (IBM, USA) and R software v. 4.2.1 (R foundation for Statistical Computing, Austria).

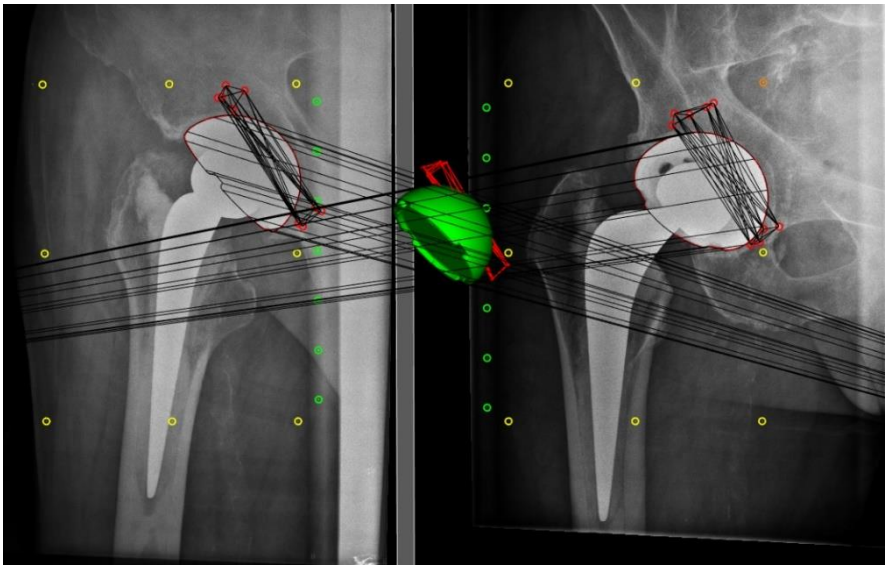


Figure 1. Model-based radiostereometric analysis used for the migration analysis of the acetabular component relative to the pelvis. The computer-aided design model of the component is in green and the pelvic markers in red.

The study was approved by the local ethics committee (entry no. 2018/235), registered at ClinicalTrials.gov (NCT03724058), and conducted according to the CONSORT statement (25). The present investigator-initiated study was funded by Stryker, which had no role in the collection, evaluation, or interpretation of the study results.

Results

A total of 87 patients were randomized for this study: 44 to the Trident II HA and 43 to the Trident HA group. No patients were excluded because of the need for screw fixation. One patient randomized to the Trident II HA group received a Trident acetabular component by mistake and was excluded, as no RSA radiographs were taken. Another patient randomized to the Trident HA group received a solidback instead of a clusterhole component during surgery. In two other patients from the Trident II HA group, no markers were inserted into the pelvis. Finally, five patients (two Trident HA, three Trident II HA) were excluded because no markers were visible in the postoperative radiographs. This left 38 patients in the Trident II HA and 40 patients in the Trident HA group (Figure 2). Baseline characteristics of both groups are shown in Table 1. After two years, 35 patients in the Trident II HA group and 40 patients in the Trident HA group were still enrolled in the study.

Table 1. Baseline characteristics.

Characteristics	Trident HA	Trident II HA
Patients, n	40	38
Mean age, yrs (SD)	70 (3.9)	70 (5.0)
Male sex, n (%)	14 (35)	20 (53)
Mean BMI, kg/m^2 (SD)	27 (3.6)	27 (3.0)
Ahlbäck grade, n (%)		
I	5 (13)	7 (18)
II	18 (45)	22 (58)
III	12 (30)	9 (24)
IV	5 (13)	0 (0)
Charnley classification, n (%)		
A	24 (60)	18 (47)
B	16 (40)	20 (53)
ASA grade, n (%)		
I	5 (13)	6 (16)
II	31 (78)	30 (79)
III	4 (10)	2 (5)

ASA = American Society of Anaesthesiologists. HA = Hydroxyapatite. SD = Standard deviation.

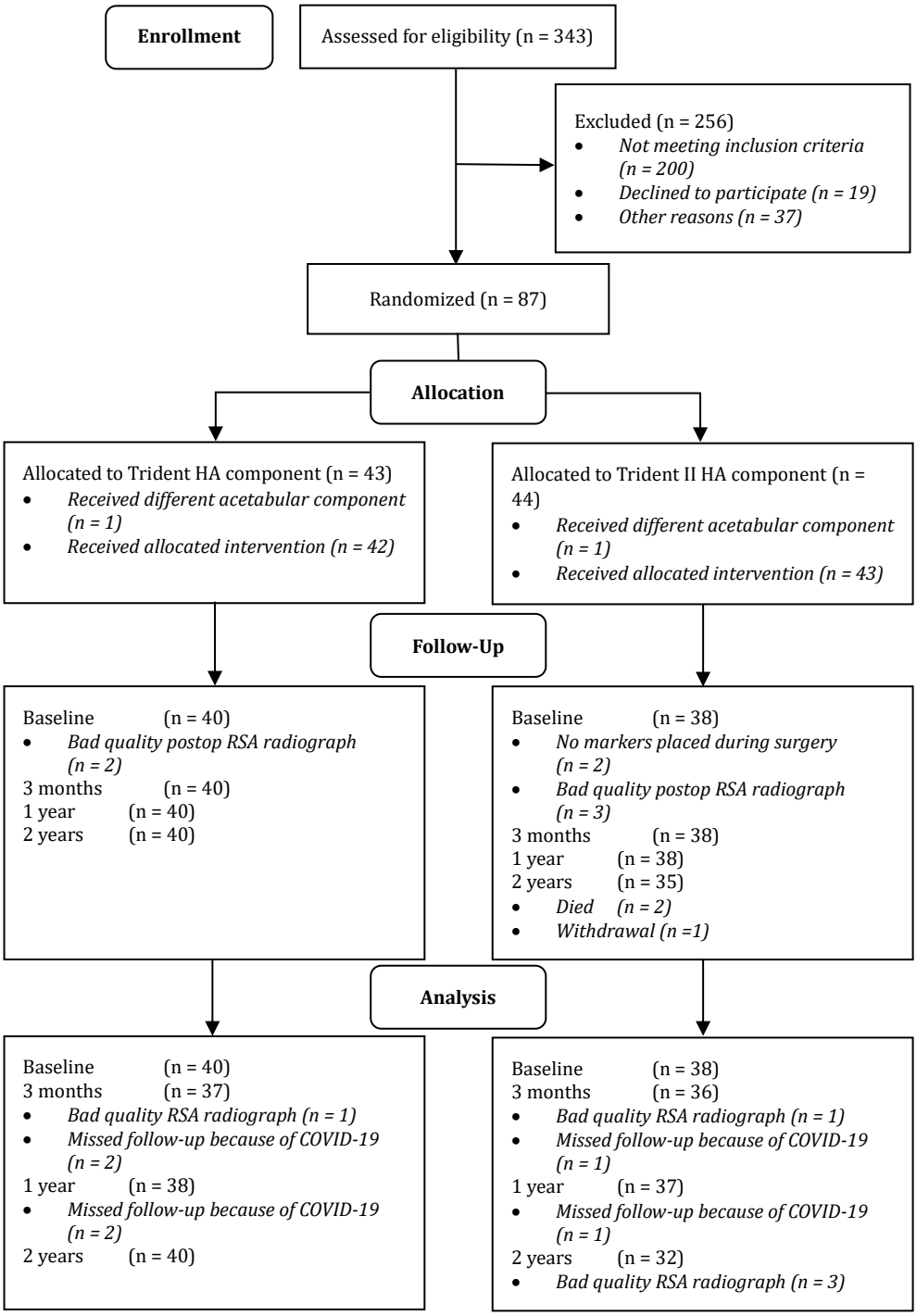


Figure 2. CONSORT flowchart. HA = Hydroxyapatite. RSA = Radiostereometric analysis.

RSA migration results

The clinical precision of the RSA migration measurements of both groups was comparable (Table 2). During the two-year follow-up, there was no significant difference in the proximal migration of the acetabular components along the y-axis (p = 0.875, LMM). Mean proximal migrations of the Trident II HA at three, 12, and 24 months were 0.08 mm (95% CI 0.03 to 0.14), 0.11 mm (95% CI 0.06 to 0.16), and 0.14 mm (95% CI 0.09 to 0.20), respectively. In the Trident HA group for the same intervals, these mean proximal migrations were 0.11 mm (95% CI 0.06 to 0.16), 0.12 mm (95% CI 0.07 to 0.17), and 0.14 mm (95% CI 0.09 to 0.19). Mean RSA migration data are presented in Figure 3. Mean translations along the transverse axis (x-axis) (p = 0.084) and sagittal axis (z-axis) (p = 0.713) were comparable between groups. No statistical differences were found in mean rotations: transverse axis (x-axis) (p = 0.679), longitudinal axis (y-axis) (p = 0.943), and sagittal axis (z-axis) (p = 0.375).

Table 2. Precision of the radiostereometric set-up presented as mean of the migration between the first and second examination of the double examinations.

	Mean translation, mm (SD)			Mean rotation, ° (SD)		
Component	**Tx**	**Ty**	**Tz**	**Rx**	**Ry**	**Rz**
Trident HA (36 doubles)	0.00 (0.07)	0.00 (0.06)	-0.02 (0.13)	-0.02 (0.32)	-0.02 (0.26)	0.05 (0.33)
Trident II HA (33 doubles)	0.01 (0.05)	0.01 (0.05)	0.00 (0.20)	0.01 (0.32)	0.02 (0.25)	0.02 (0.22)

HA = Hydroxyapatite. Rx, Ry, Rz = Rotations. SD = Standard deviation. Tx, Ty, Tz = Translations.

Clinical results

No significant differences in postoperative improvement in mean results for HSS, HOOS Pain, HOOS Activities of Daily Living, HOOS Sport and Recreation, HOOS Quality of Life, FJS, and EQ-5D-3L were found between the groups during the entire follow-up (Table 3). Only the improvement in mean HOOS Symptoms was statistically different (p = 0.033, GEE), which was caused by a greater mean HOOS Symptoms in the Trident HA group at three months compared with the Trident II HA group. However, at two years postoperatively, the mean HOOS Symptoms of the Trident HA was comparable to the Trident II HA group, 91.5 (95% CI 88.1 to 94.9) versus 91.7 (95% CI 88.4 to 95.0), respectively (Table 3).

Table 3. Clinical scores and patient-reported outcome measures of the two groups. Values are presented as means with 95% confidence intervals.

	Trident	Trident II	p-value*
HSS			0.698
- Preoperative	55.6 (52.0 to 59.2)	56.8 (53.3 to 60.4)	
- 3 months	89.2 (87.4 to 90.9)	89.1 (86.3 to 91.8)	
- 1 year	91.5 (88.8 to 94.1)	93.2 (91.7 to 94.6)	
- 2 years	91.4 (88.6 to 94.2)	93.5 (91.3 to 95.7)	
HOOS Symptoms			0.033
- Preoperative	49.6 (46.3 to 53.0)	48.9 (44.2 to 53.2)	
- 3 months	87.0 (83.5 to 90.4)	81.0 (76.6 to 85.4)	
- 1 year	89.7 (86.0 to 93.4)	91.3 (87.4 to 95.3)	
- 2 years	91.5 (88.1 to 94.9)	91.7 (88.4 to 95.0)	
HOOS Pain			0.879
- Preoperative	36.2 (31.6 to 40.9)	35.9 (31.4 to 40.4)	
- 3 months	87.8 (82.9 to 92.6)	84.9 (80.1 to 89.8)	
- 1 year	90.8 (86.2 to 95.4)	88.5 (82.5 to 94.5)	
- 2 years	90.8 (86.7 to 94.9)	90.6 (86.2 to 94.9)	
HOOS ADL			0.856
- Preoperative	42.8 (38.0 to 47.5)	44.4 (39.6 to 49.2)	
- 3 months	81.6 (77.4 to 85.9)	80.5 (76.2 to 84.8)	
- 1 year	87.1 (82.5 to 91.8)	88.0 (83.0 to 92.9)	
- 2 years	89.1 (85.6 to 92.6)	90.3 (86.3 to 94.3)	
HOOS SR			0.750
- Preoperative	19.0 (15.4 to 22.7)	21.4 (15.8 to 26.9)	
- 3 months	61.6 (53.9 to 69.2)	68.1 (60.3 to 75.9)	
- 1 year	74.3 (67.1 to 81.5)	79.9 (71.5 to 88.3)	
- 2 years	74.9 (67.7 to 82.0)	80.1 (73.1 to 87.1)	
HOOS QOL			0.436
- Preoperative	26.5 (22.0 to 30.9)	22.2 (17.5 to 26.9)	
- 3 months	72.2 (66.7 to 77.7)	74.0 (68.2 to 79.8)	
- 1 year	82.9 (77.5 to 87.6)	80.6 (74.2 to 87.0)	
- 2 years	83.2 (78.7 to 87.6)	84.2 (79.4 to 89.0)	
FJS			0.764
- 3 months	62.0 (55.1 to 68.8)	58.6 (51.4 to 65.8)	
- 1 year	72.8 (65.5 to 80.2)	74.3 (66.6 to 82.1)	
- 2 years	72.8 (66.2 to 79.4)	73.2 (65.6 to 80.9)	
EQ-5D-3L			0.432
- Preoperative	0.72 (0.68 to 0.75)	0.75 (0.72 to 0.78)	
- 3 months	0.92 (0.90 to 0.95)	0.91 (0.89 to 0.94)	
- 1 year	0.93 (0.91 to 0.96)	0.94 (0.92 to 0.96)	
- 2 years	0.93 (0.91 to 0.95)	0.94 (0.92 to 0.96)	

*The p-values stated in this table indicate the between-group mean differences in improvement between baseline and two-year follow-up, including all measurements during follow-up, derived with a generalized estimating equation approach. ADL = Activities of daily living. EQ-5D-3L = EuroQol Group five dimension, three-level questionnaire. FJS = Forgotten Joint Score. HA = Hydroxyapatite. HOOS = Hip disability and

Osteoarthritis Outcome Score. HSS = Harris Hip Score. PROM = Patient-reported outcome measure. QoL = Quality of life. SR = Sports and recreation.

Adverse events

There were no revisions of either the acetabular component or stem in any patient at the two-year follow-up. One patient in the Trident II HA group had a deep infection (periprosthetic joint infection) three weeks after surgery. Treatment was debridement, antibiotics, and implant retention (DAIR) (including an exchange of the femoral head and polyethylene liner and 12 weeks of antibiotics). As the acetabular shell and stem were left in place, this patient was not excluded.

Discussion

The cementless Trident II clusterhole HA shell showed a comparable early migration pattern to its predecessor, the Trident hemispherical HA cluster shell. Moreover, mean proximal migration of both designs was below 0.2 mm at two years, which is the threshold predictive value for an increased risk of revision due to aseptic loosening (15). This would suggest that for both components revision rates are expected to be less than 5% at ten years (15). Besides proximal migration, acetabular components showing a mean increase in acetabular inclination of > 2.53° at two years are described to fail due to loosening (14). The present study found no difference in mean sagittal rotation between the two implants with -0.13° (95% CI -0.31 to 0.06) and -0.23 (95% CI -0.40 to -0.06) in the Trident II HA and Trident HA group at two years, respectively, also indicating a comparable low risk for future loosening.

Registries typically report the survival of acetabular shells within the same implant brand portfolio, rather than naming specific subtypes (1-3, 26). It is therefore unclear from registry data whether the Trident hemispherical HA cluster shells perform as well as other shells from the Trident acetabular system, e.g. the Trident hemispherical solidback or the Trident PSL HA cluster shell. Multiple variants within the Trident II acetabular system also exist. Therefore, one should be aware of the potential camouflage effect if a specific variant deviates in performance from other versions of the same brand (27). A recent case series by Ulrich et al. (28) also illustrates the importance of being specific about the subtypes, as they incorrectly assumed that all Trident II shells are produced with 3D printing. Only the Trident

II Tritanium shells are 3D-printed, whereas the Trident II HA shells are produced through a different manufacturing process (forging and machine finishing).

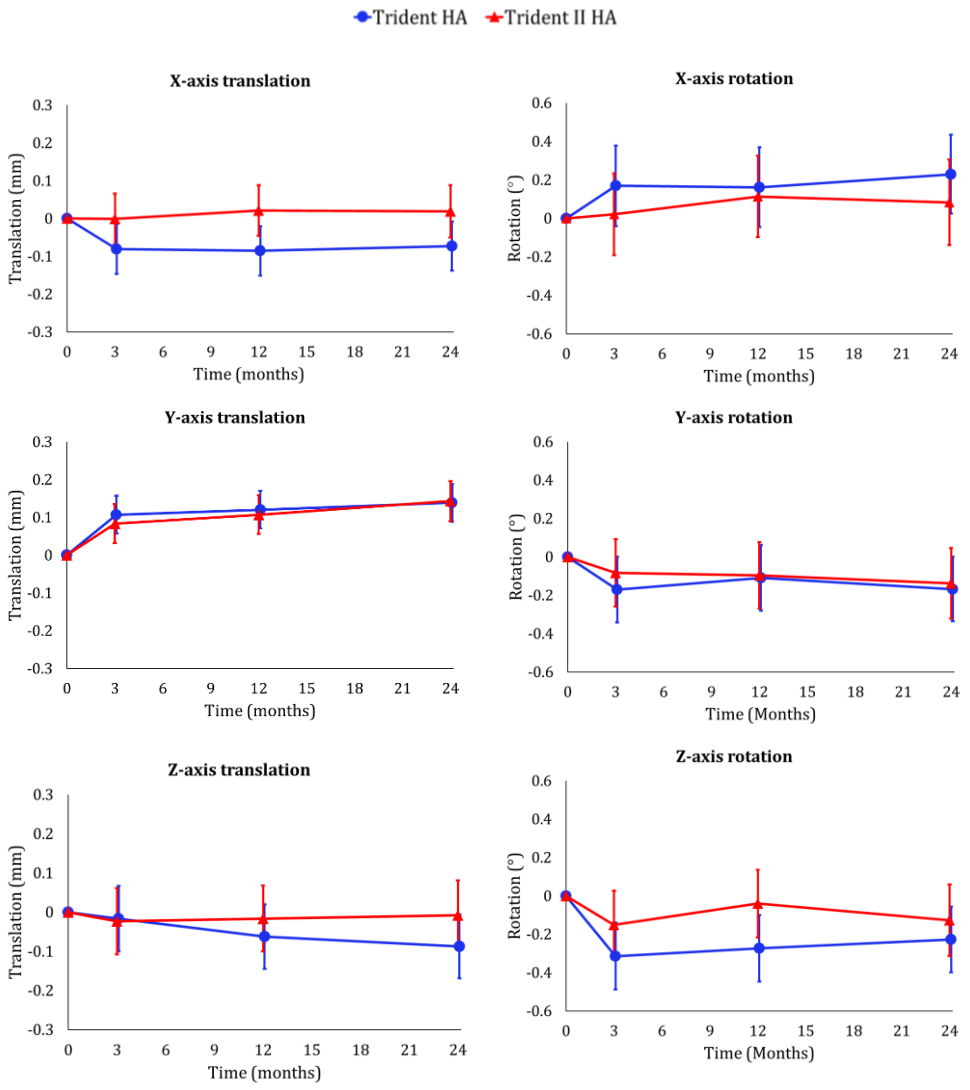


Figure 3. Translations (mm) and rotations (°) of the acetabular components during the two-year follow-up period. Mean values of both study groups are presented with 95% confidence intervals (error bars). HA = Hydroxyapatite.

This RSA study is the first to assess the migration of the Trident II clusterhole HA-coated acetabular component, which is an important part of the phased, evidence-based introduction of new implants (12, 29-31). Other RSA studies have reported early migration of cementless HA-coated acetabular components. A study of a cementless titanium plasma-sprayed acetabular component with HA coating (EP-FIT PLUS; Smith & Nephew Orthopaedics, Switzerland), in combination with a cementless femoral stem, showed a mean proximal migration at two years of 0.10 mm (32). Jørgensen et al. (33) assessed the migration of a cementless hemispherical acetabular component with plasma-sprayed titanium and HA coating (Exceed ABT RingLoc-x; Zimmer Biomet, USA) in combination with a cementless femoral stem and reported a mean proximal migration of 0.20 mm (95% CI 0.10 to 0.30) at two years, which is slightly higher compared with the migration of the implants in our study.

A strength of the present study is its randomized design. This trial compares a cementless HA-coated shell with its geometrically identical predecessor, but which has a different manufacturing process for applying the CPTi coating. This enabled assessment of the effect of differences in applying the titanium layer in cementless shells on the migration of shells relative to the bone, and thereby whether the changes made in the manufacturing process had any impact. RSA was used to measure the component migration, which has been shown to be a highly accurate technique and is recommended in the phased evidence-based introduction of new implants (13, 31).

Limitations are present: first, only the clusterhole HA shell version of the Trident II acetabular system was evaluated in this study. Therefore, we caution against extrapolation of the migration results to other shells of the Trident II acetabular system, as small changes may affect implant stabilization. Our results show an expected low risk of long-term revision from aseptic loosening, but cannot be directly translated to all other subdesigns of the Trident II acetabular shells. Second, we excluded patients if screw fixation of the acetabular component was needed to create acceptable initial fixation. Although no patients were excluded because of this, it limits the generalizability of this study's findings to Trident II clusterhole HA cups when used without screws. A small case series recently reported failure of screw–shell interface of the Trident II clusterhole HA shell in two patients (28). Finally, our study only assessed the migration of the Trident HA and Trident II HA shells in combination with the cemented Exeter V40 stem, which is a well-proven femoral stem (34).

Both shells may show different early migration patterns, and subsequent different long-term risk of loosening, when used in combination with a different femoral stem (35).

In conclusion, the Trident II clusterhole HA shell showed comparable early migration results with its predecessor, the Trident hemispherical HA cluster shell, when used in combination with the cemented Exeter V40 femoral stem. These findings suggest a comparable low risk of future long-term mechanical loosening.

Take home message

- The Trident II clusterhole hydroxyapatite (HA) shell, produced using a different manufacturing process, had early migration comparable to its predecessor during the first two postoperative years.
- The mean proximal migration of the Trident II clusterhole HA shell, when used in combination with the cemented Exeter V40 stem, at two years was lower than 0.2 mm. This indicates an expected revision risk at ten years below 5%.

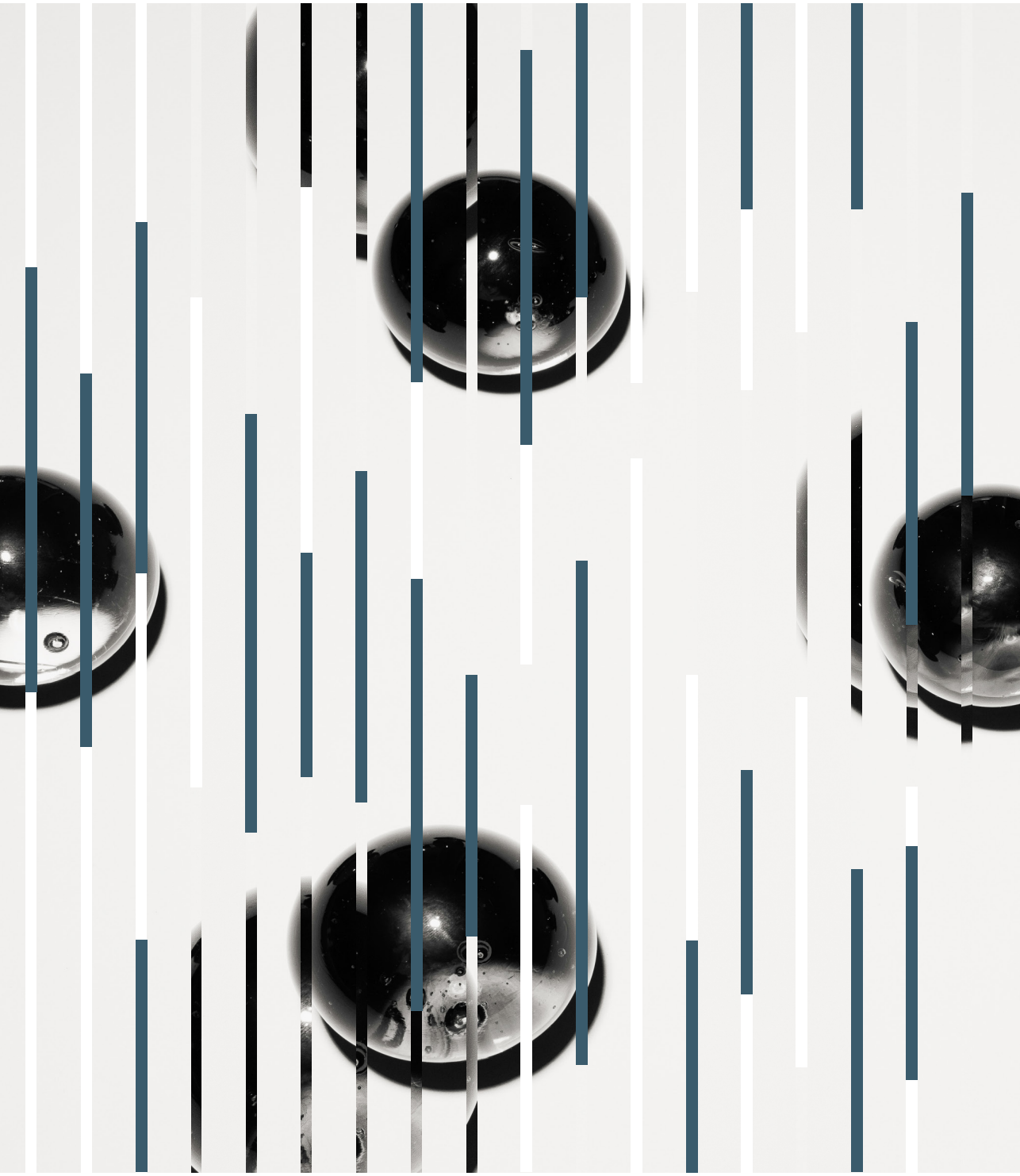
Acknowledgments

Muhanned Ali (MA), Magnus Lindgren (ML), and Tomas Hammer (TH) (performing surgeries).

References

1. Dutch Arthroplasty Register (LROI). Annual Report 2022. 2022. https://www.lroi-report.nl/app/uploads/2023/10/PDF-LROI-annual-report-2023-1.pdf [Accessed 20-07-2023].
2. The New Zealand Joint Registry (NZJR). New Zealand Orthopaedic Association (NZOA) 23 Year Report. 2023. https://www.nzoa.org.nz/annual-reports [Accessed 20-07-2023].
3. National Joint Registry (NJR). Annual report 2022. 2022. https://www.njrcentre.org.uk/njr-annual-report-2022/ [Accessed 01-07-2023].
4. Australian Orthopaedic Association National Joint Replacement Registry (AOANJRR). Annual Report 2022. 2022. https://aoanjrr.sahmri.com/annual-reports-2022 [Accessed 01-07-2023].
5. Stryker. Trident Acetabular Shell Systems. 2023. https://www.stryker.com/us/en/joint-replacement/products/trident.html [Accessed 22-09-2023].
6. Stryker. Trident II Acetabular System. 2023. https://www.stryker.com/at/en/joint-replacement/products/trident-ii/index-eu.html [Accessed 22-09-2023].
7. Johanson PE, Antonsson M, Shareghi B, Kärrholm J. Early Subsidence Predicts Failure of a Cemented Femoral Stem With Minor Design Changes. Clin Orthop Relat Res. 2016;474:10:2221-9.
8. Hauptfleisch J, Glyn-Jones S, Beard DJ, Gill HS, Murray DW. The premature failure of the Charnley Elite-Plus stem: a confirmation of RSA predictions. J Bone Joint Surg Br. 2006;88:2:179-83.
9. Howie DW, Middleton RG, Costi K. Loosening of matt and polished cemented femoral stems. J Bone Joint Surg Br. 1998;80:4:573-6.
10. Petheram TG, Bone M, Joyce TJ, Serrano-Pedraza I, Reed MR, Partington PF. Surface finish of the Exeter Trauma Stem: a cause for concern? Bone Joint J. 2013;95-b:2:173-6.
11. Hutt J, Hazlerigg A, Aneel A, Epie G, Dabis H, Twyman R et al. The effect of a collar and surface finish on cemented femoral stems: a prospective randomised trial of four stem designs. Int Orthop. 2014;38:6:1131-7.
12. Nelissen RG, Pijls BG, Kärrholm J, Malchau H, Nieuwenhuijse MJ, Valstar ER. RSA and registries: the quest for phased introduction of new implants. J Bone Joint Surg Am. 2011;93 Suppl 3:62-5.
13. Valstar ER, Gill R, Ryd L, Flivik G, Börlin N, Kärrholm J. Guidelines for standardization of radiostereometry (RSA) of implants. Acta Orthop. 2005;76:4:563-72.
14. Nieuwenhuijse MJ, Valstar ER, Kaptein BL, Nelissen RG. Good diagnostic performance of early migration as a predictor of late aseptic loosening of acetabular cups: results from ten years of follow-up with Roentgen stereophotogrammetric analysis (RSA). J Bone Joint Surg Am. 2012;94:10:874-80.
15. Pijls BG, Nieuwenhuijse MJ, Fiocco M, Plevier JW, Middeldorp S, Nelissen RG et al. Early proximal migration of cups is associated with late revision in THA: a systematic review and meta-analysis of 26 RSA studies and 49 survivalstudies. Acta Orthop. 2012;83:6:583-91.
16. Fontalis A, Haddad FS. Roentgen stereophotogrammetric analysis: still a very valuable tool in the orthopaedic research armamentarium. Bone Joint Res. 2022;11:4:210-3.
17. Implants for surgery - Roentgen stereophotogrammetric analysis for the assessment of migration of orthopaedic implants. International Organization for Standardization (ISO) 2013 (standard reviewed and confirmed in 2019).
18. Kaptein BL, Valstar ER, Stoel BC, Rozing PM, Reiber JH. A new type of model-based Roentgen stereophotogrammetric analysis for solving the occluded marker problem. J Biomech. 2005;38:11:2330-4.
19. Valstar ER, Spoor CW, Nelissen RG, Rozing PM. Roentgen stereophotogrammetric analysis of metal-backed hemispherical cups without attached markers. J Orthop Res. 1997;15:6:869-73.
20. Harris WH. Traumatic arthritis of the hip after dislocation and acetabular fractures: treatment by mold arthroplasty. An end-result study using a new method of result evaluation. J Bone Joint Surg Am. 1969;51:4:737-55.
21. Nilsdotter AK, Lohmander LS, Klässbo M, Roos EM. Hip disability and osteoarthritis outcome score (HOOS)--validity and responsiveness in total hip replacement. BMC Musculoskelet Disord. 2003;4:10.
22. Behrend H, Giesinger K, Giesinger JM, Kuster MS. The "forgotten joint" as the ultimate goal in joint arthroplasty: validation of a new patient-reported outcome measure. J Arthroplasty. 2012;27:3:430-6.e1.
23. Rabin R, de Charro F. EQ-5D: a measure of health status from the EuroQol Group. Ann Med. 2001;33:5:337-43.

24. Dupont WD, Plummer WD, Jr. Power and sample size calculations. A review and computer program. Control Clin Trials. 1990;11:2:116-28.
25. Schulz KF, Altman DG, Moher D. CONSORT 2010 statement: updated guidelines for reporting parallel group randomised trials. BMJ. 2010;340:c332.
26. Swedish Arthroplasty Register. Annual Report 2022. 2022. https://sar.registercentrum.se/news/download-the-sar-annual-report-2022 [Accessed 21-07-2023].
27. Phillips JRA, Tucker K. Implant brand portfolios, the potential for camouflage of data, and the role of the Orthopaedic Data Evaluation Panel in total knee arthroplasty. Bone Joint J. 2021;103-b:10:1555-60.
28. Ulrich PA, Zondervan RL, Cochran JM. Failure of Screw/Shell Interface in the Trident II Acetabular System in Total Hip Arthroplasty. Arthroplast Today. 2022;17:80-6.
29. Malchau H. Introducing new technology: a stepwise algorithm. Spine (Phila Pa 1976). 2000;25:3:285.
30. Huiskes R. Failed innovation in total hip replacement. Diagnosis and proposals for a cure. Acta Orthop Scand. 1993;64:6:699-716.
31. Pijls BG, Nelissen RG. The era of phased introduction of new implants. Bone Joint Res. 2016;5:6:215-7.
32. Munzinger U, Guggi T, Kaptein B, Persoon M, Valstar E, Doets HC. A titanium plasma-sprayed cup with and without hydroxyapatite-coating: a randomised radiostereometric study of stability and osseointegration. Hip Int. 2013;23:1:33-9.
33. Jørgensen PB, Daugaard H, Jakobsen SS, Lamm M, Søballe K, Stilling M. Higher early proximal migration of hemispherical cups with electrochemically applied hydroxyapatite (BoneMaster) on a porous surface compared with porous surface alone: a randomized RSA study with 53 patients. Acta Orthop. 2020;91:1:26-32.
34. Evans JT, Blom AW, Timperley AJ, Dieppe P, Wilson MJ, Sayers A et al. Factors associated with implant survival following total hip replacement surgery: A registry study of data from the National Joint Registry of England, Wales, Northern Ireland and the Isle of Man. PLoS Med. 2020;17:8:e1003291.
35. Deere KC, Whitehouse MR, Porter M, Blom AW, Sayers A. Assessing the non-inferiority of prosthesis constructs used in hip replacement using data from the National Joint Registry of England, Wales, Northern Ireland and the Isle of Man: a benchmarking study. BMJ Open. 2019;9:4:e026685.



Chapter 4

Continued stabilization of a cementless 3D-printed total knee arthroplasty: Five-year results of a randomized controlled trial using radiostereometric analysis

T.J.N. van der Lelij
P.J. Marang-van de Mheen
B.L. Kaptein
S. Toksvig-Larsen
R.G.H.H. Nelissen

The Journal of Bone and Joint Surgery (American Volume)
2023 Nov 1;105(21):1686-1694

Abstract

Background

Three-dimensional (3D) printing of highly porous orthopaedic implants aims to promote better osseointegration, thus preventing aseptic loosening. However, short-term radiostereometric analysis (RSA) after total knee arthroplasty (TKA) has shown higher initial migration of cementless 3D-printed tibial components compared with their cemented counterparts. Therefore, critical evaluation of longer-term tibial component migration is needed. We investigated migration of a cementless 3D-printed and a cemented tibial component with otherwise similar TKA design during 5 years of follow-up, particularly the progression in migration beyond 2 years postoperatively.

Methods

Seventy-two patients were randomized to a cementless 3D-printed Triathlon Tritanium (Stryker) cruciate-retaining (CR) TKA or a cemented Triathlon CR (Stryker) TKA implant. Implant migration was evaluated with RSA at baseline and postoperatively at 3 months and at 1, 2, and 5 years. The maximum total point motion (MTPM) of the tibial component was compared between the groups at 5 years, and progression in migration was assessed between 2 and 5 years. Individual implants were classified as continuously migrating if the MTPM was ≥0.1 mm/year beyond 2 years postoperatively. Clinical scores were evaluated, and a linear mixed-effects model was used to analyze repeated measurements.

Results

At 5 years, the mean MTPM was 0.66 mm (95% confidence interval [CI], 0.56 to 0.78 mm) for the cementless group and 0.53 mm (95% CI, 0.43 to 0.64 mm) for the cemented group (p= 0.09). Between 2 and 5 years, there was no progression in mean MTPM for the cementless group (0.02 mm; 95% CI, −0.06 to 0.10 mm) versus 0.07 mm (95% CI, 0.00 to 0.14) for the cemented group. One implant was continuously migrating in the cementless group, and 4 were continuously migrating in the cemented group. The clinical scores were comparable between the groups across the entire time of follow-up.

Conclusions

No significant difference in mean migration was found at 5 years between the cementless and cemented TKA implants. Progression of tibial component migration was present beyond 2 years for the cemented implant, whereas the cementless implant remained stable after initial early migration.

Level of evidence

Therapeutic Level I.

Introduction

Although cemented fixation of an implant is predominantly used, the use of primary cementless total knee arthroplasty (TKA) continues to grow (1, 2). Observed loss of cement-bone interlock and debonding at the cement-implant interface contribute to the interest in cementless fixation (3, 4). With aseptic loosening as the leading cause of TKA revision, achieving long-lasting biological fixation of implants is important, especially in those who are ≤65 years of age as they may need durability of the implant for another 25 years (5, 6). The use of metallic 3D printing in orthopaedic surgery has become increasingly popular in the last decade; it enables the production of cementless implants with complex porous structures, which may contribute to enhanced bone-implant fixation (7-9).

Excellent clinical outcomes at short-term and midterm follow-up have been described for cementless 3D-printed TKA implants with highly porous titanium, but it may take a longer time before problems with a particular device are shown in clinical outcomes (10-13). Radiostereometric analysis (RSA) is a highly accurate method to detect implant migration, and it has been shown to predict future aseptic loosening (14, 15). RSA is well-suited for early detection of safety concerns, and it is the recommended technique for providing robust postmarketing surveillance (16, 17). Current evaluation of the 3D-printed Triathlon Tritanium TKA implant with the use of RSA remains limited to short-term follow-up, showing a higher initial migration compared with its cemented counterpart (18, 19). A recent case series documenting fatigue fractures of the 3D-printed tibial baseplate highlights possible safety concerns for this implant and underlines the importance of longer-term evaluation (20).

This paper aims to compare tibial implant migration for up to 5 years postoperatively between the cementless 3D-printed TKA implant and its cemented counterpart, with a particular focus on the progression in migration beyond 2 years. We assessed whether implant migration was progressive over time or whether continuous stabilization was achieved after the initial “settling phase.” Our hypothesis was that both the cementless and cemented tibial components have no progression in migration beyond 2 years.

Material and methods

Design and patients

This study was approved by the Regional Ethical Review Board in Lund, Sweden (entry no. 2015/8) and registered at ClinicalTrials.gov (NCT02578446). All of the patients gave informed consent prior to enrollment.

Patient selection and the surgical procedures that were used for this randomized RSA trial have been described previously (19). In short, 72 patients were randomized to a cementless Triathlon Tritanium (Stryker) cruciate-retaining (CR) fixed-bearing TKA implant or a cemented Triathlon (Stryker) CR fixed-bearing TKA implant. The prostheses were identical in geometrical shape except for the 3D-printed porous structure and 4 pegs on the undersurface of the tibial baseplate of the cementless implant. SMARTSET GHV bone cement (DePuy Synthes) was used for the cemented group, leaving the tibial keel cementless in all cases. Eight spherical tantalum beads (diameter, 0.8 mm; RSA Biomedical) were inserted into the tibia, and 5 were inserted into the polyethylene of the tibial insert. Patients remained blinded to the treatment; the surgery was performed by a single experienced surgeon (S.T.-L.). Both groups received the same intraoperative treatment and postoperative rehabilitation, including immediate full weight-bearing on the day of surgery.

Measurements

The baseline characteristics of the patients were collected, and RSA examinations were performed at baseline within 2 days after surgery as well as at 3 months and 1, 2, and 5 years postoperatively. RSA migration measurements were performed by 1 researcher (T.J.N.v.d.L.), blinded to clinical and patient-reported outcome measures. The Knee Society Score (KSS), the Knee injury and Osteoarthritis Outcome Score (KOOS), and the Forgotten Joint Score (FJS) were obtained at all of the follow-up times (21-23). All scores range from 0 to 100, with higher scores indicating better outcomes.

RSA

Radiographs were made with a biplanar technique at a 90° angle (Cage 10; RSA Biomedical) with the patient in the supine position. Analysis was performed with Model-based RSA software (version 4.2; *RSAcore*) and following RSA guidelines (24). The precision of the local RSA setup was 0.1 mm for translations and 0.1° for rotations (19). The largest set of

consistent markers was used at each follow-up to assess migration of the tibial baseplate. The amount of translation of the marker with the greatest translation (i.e., the maximum total point motion [MTPM]) was used as the primary outcome measure (25). Migration of the implant in patients who had a TKA in the left knee was transformed to match the data of those who had the TKA in the right knee. A mean error of rigid body fitting of ≤0.35 mm and a condition number of ≤120 were set as cutoff points (25). Individual implants were considered to be "continuously migrating" if the MTPM was ≥0.3 mm (i.e., ≥0.1 mm/year) between 2 and 5 years postoperatively. Implants with ≥0.2 mm of micromotion in the second postoperative year but subsequent micromotion of <0.3 mm between 2 and 5 years were considered "stabilized" (14, 26, 27).

Statistical analysis

As described previously, 23 patients were needed in each group to detect a difference between groups beyond the 0.13 mm measurement error of the MTPM with a power of 80% and an alpha of 0.05 (19). To account for possible dropouts and inadequate radiographs, 36 patients were randomized to each group.

The MTPM was compared between the TKA groups using a linear mixed-effects model (LMM), which effectively deals with missing values during follow-up or when patients withdraw from the study (e.g., due to revision); it also takes within-subject correlation into account. The model consisted of a group variable (cementless or cemented TKA implants), a time variable, and an interaction term between time and group. A random-intercept term was used, and any remaining variability was modeled with a heterogeneous autoregressive order-1 covariance structure. Given its non-normal distribution, the main outcome of MTPM was log-transformed and computed as $\log_{10}(\text{MTPM} + 1)$. The values presented in this paper were then back-transformed to the original scale (mm). The mean MTPM at the 5-year follow-up was compared between the groups, and progression in MTPM beyond 2 years was assessed for each group. We evaluated the progression in migration by estimating the change in the MTPM from the LMM, using 3 months, 1 year, and 2 years as baselines. The delta method was used for approximating the standard error of the transformed mean differences. Descriptive RSA data of translations and rotations were presented to illustrate the direction of tibial component migration. Because a normal distribution could not be obtained through transformation for the clinical scores (KSS, KOOS, and FJS), a comparable generalized estimating equation (GEE) approach was used. Means were reported with 95% confidence

intervals (CIs) or standard deviations (SDs). A p value of <0.05 was considered significant. Analysis was performed using SPSS (version 25.0; IBM) and R software (version 4.2.1; R Foundation for Statistical Computing).

Cement mantle thickness

In a post hoc analysis, we explored the effect of cement mantle thickness on the migration of cemented tibial implants. Cement mantle thickness was evaluated by a single observer (T.J.N.v.d.L) at the first postoperative radiograph: 4 zones on the anteroposterior radiograph and 2 zones on the lateral radiographs were evaluated according to The Knee Society Roentgenographic Evaluation and Scoring System (28). Measurements were performed at the tibial baseplate since the stem was not cemented. Because of random cement distribution that would have been affected by local bone architecture, cumulative measurements for the 6 zones were used (29, 30). The mean cumulative cement mantle thickness of the continuously migrating implants was compared with that of the non-continuously migrating cemented implants using an independent samples t test. An LMM, which included cement mantle thickness and time as covariates, was used to explore the association between cement mantle thickness and MTPM.

Source of funding

This investigator-initiated study was funded by Stryker, but Stryker employees had no part in the design, conduct, analysis, and interpretation of this study.

Results

All 72 patients received the allocated intervention (Figure 1). Postoperative RSA images of 2 patients in the cemented group were missing, and these patients were excluded from the analysis. In the cementless group, 1 insert was exchanged due to an infection at 3 weeks postoperatively. Because markers had been placed in the insert, this patient was excluded since RSA analysis could not be performed. Baseline characteristics of both groups are presented in Table 1. In the cemented group, 3 patients withdrew from the study and 1 patient emigrated abroad during the 5-year follow-up. In the cementless group, 1 TKA was revised at 20 months postoperatively due to pain and migration of the tibial component, 1 patient withdrew from the study, and 1 patient died. Because of COVID-19, 3 patients in the

cemented group and 1 patient in the cementless group were not able to visit the hospital for the 5-year follow-up; therefore, RSA examinations at the 5-year follow-up were performed on 27 and 30 patients in the cemented and cementless groups, respectively (Figure 1).

Table 1. Baseline characteristics.*

Characteristics	Cemented	Cementless
Patients, n	34	35
Mean age, yrs (SD)	66 (6.3)	65 (5.7)
Male sex, n (%)	18 (53)	18 (51)
Mean BMI, kg/m² (SD)	30 (3.1)	28 (3.1)
ASA classification, n (%)		
I	4 (12)	13 (37)
II	26 (77)	21 (60)
III	4 (12)	1 (3)
Ahlbäck grade, n (%)		
I	1 (3)	0 (0)
II	7 (21)	8 (23)
III	25 (74)	27 (77)
IV	1 (3)	0 (0)
Preoperative HKA angle, n (%)		
Neutral †	1 (3)	4 (11)
Varus ‡	30 (88)	23 (66)
Valgus §	3 (9)	8 (23)
Postoperative HKA angle, n (%)		
Neutral †	23 (68)	20 (57)
Varus ‡	6 (18)	9 (26)
Valgus §	5 (15)	6 (17)

* The values are given as the mean ± standard deviation or as the number with the percentages. BMI = Body mass index. ASA = American society of anesthesiologists. HKA = Hip-knee-ankle. † -3° to 3°. ‡ < -3°. § > 3°.

RSA migration measurements

The mean MTPM of the cementless and cemented groups at the 5-year follow-up was 0.66 mm (95% CI, 0.56 to 0.78 mm) and 0.53 mm (95% CI, 0.43 to 0.64 mm), respectively (p = 0.09). Between 2 and 5 years, there was no progression in mean MTPM for the cementless group (0.02 mm; 95% CI, −0.06 to 0.10 mm) versus 0.07 mm (95% CI, 0.00 to 0.14 mm) for the cemented group (Table 2). Similarly, taking 1 year as the baseline, the cementless components showed no progression in MTPM between 1 and 5 years (0.04 mm; 95% CI, −0.06 to 0.13 mm), whereas the cemented component did show progression (0.11 mm; 95% CI, 0.05 to 0.20 mm). Differences in MTPM between the cementless and cemented groups became smaller over time (Figure 2). At 3 months and at 1, 2, and 5 years of follow-up, the

difference in MTPM was 0.22 mm (95% CI, 0.09 to 0.34 mm), 0.21 mm (95% CI, 0.07 to 0.34 mm), 0.18 mm (95% CI, 0.04 to 0.32 mm), and 0.13 mm (95% CI, −0.02 to 0.28 mm), respectively.

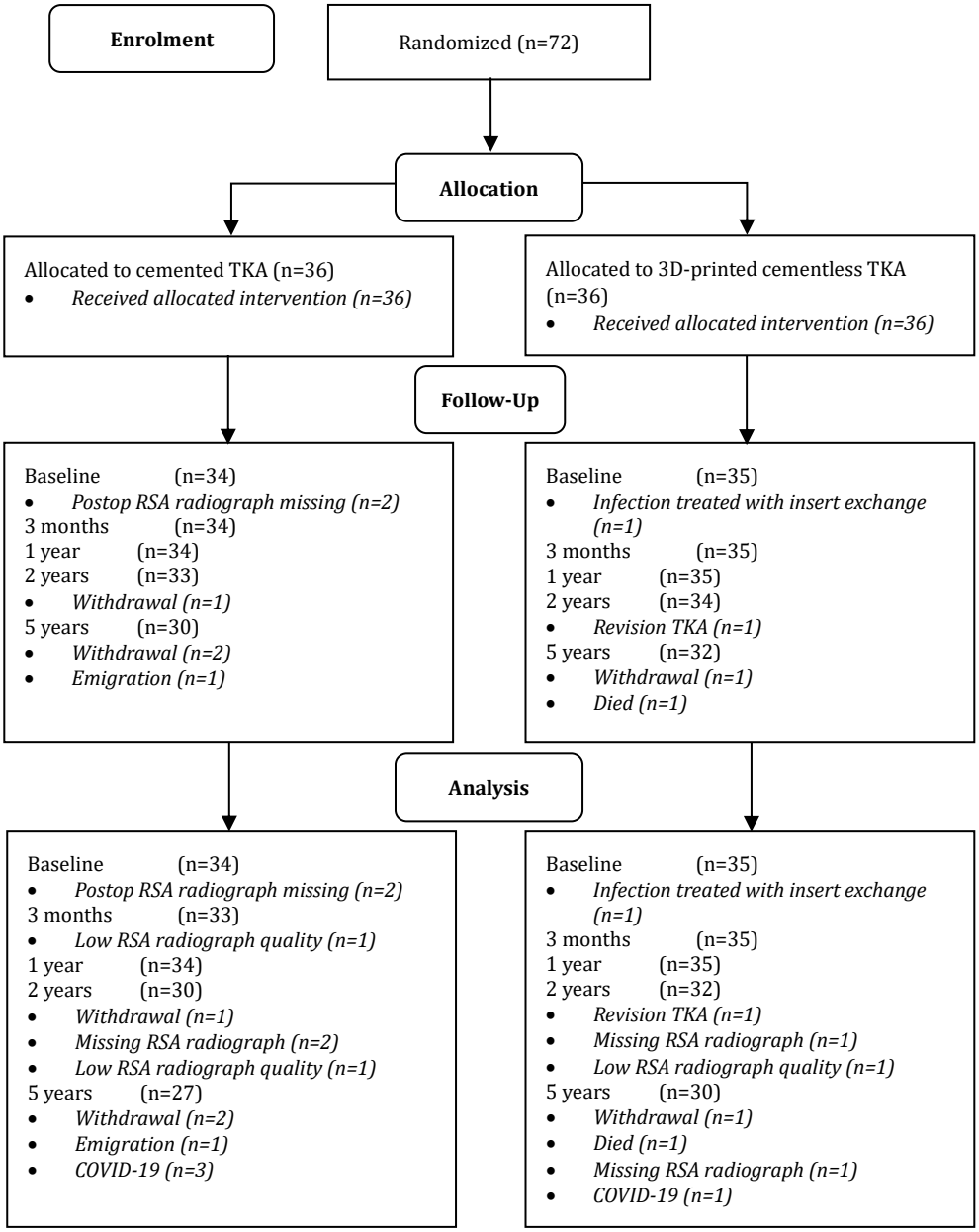


Figure 1. CONSORT flow diagram. TKA = Total knee arthroplasty.

Table 2. Progression in MTPM.*

		Cemented	Cementless
Postoperative	3 months	0.32 (0.24 to 0.41)	0.54 (0.45 to 0.64)
	1 year	0.42 (0.33 to 0.51)	0.63 (0.53 to 0.73)
	2 years	0.46 (0.37 to 0.56)	0.64 (0.54 to 0.75)
	5 years	0.53 (0.43 to 0.64)	0.66 (0.56 to 0.78)
3 months	1 year	0.10 (0.04 to 0.16)	0.09 (0.02 to 0.15)
	2 year	0.14 (0.06 to 0.22)	0.10 (0.01 to 0.19)
	5 year	0.21 (0.11 to 0.31)	0.12 (0.01 to 0.23)
1 year	2 year	0.04 (-0.02 to 0.11)	0.02 (-0.05 to 0.09)
	5 year	0.11 (0.05 to 0.20)	0.04 (-0.06 to 0.13)
2 years	5 year	0.07 (0.00 to 0.14)	0.02 (-0.06 to 0.10)

* The specific change in MTPM between the selected baseline and the specific follow-up moment was derived from the linear mixed-effects model and back-transformed to the original scale (mm).

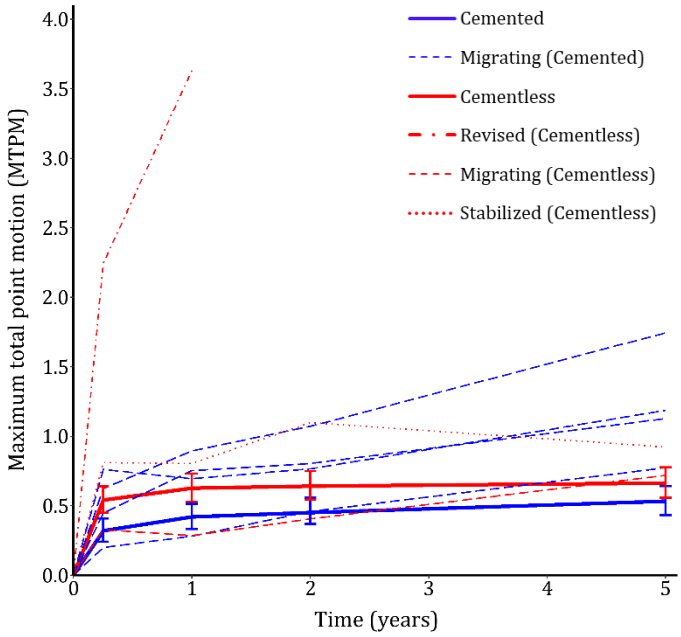


Figure 2. MTPM during the 5-year follow-up. The solid lines represent the mean MTPM of the groups, with 95% confidence intervals for all patients. Separate lines are presented for the individual revised, continuously migrating, and stabilized implants.

Translations along and rotations about each of the orthogonal axes are presented in the Appendix, showing a greater absolute initial subsidence of the cementless implant, although it remained stable beyond 2 years. Multiple cementless implants showed high initial migration in the first 3 months but stabilized before the second postoperative year (Figure 3). Nevertheless, these implants contributed to the (higher) overall mean migration of the cementless TKA group (Figure 2). One cementless and 4 cemented components showed continuous migration beyond 2 years (Figure 2 and 4). One cementless component showing ≥0.2 mm of migration in the second postoperative year showed no further progression beyond 2 years and was therefore classified as stabilized. One patient (not shown in Figure 2) with a cemented component showed ≥0.2 mm of migration in the second postoperative year but missed the 5-year follow-up visit because of COVID-19, and, therefore, the implant could not be classified as either stabilized or continuously migrating.

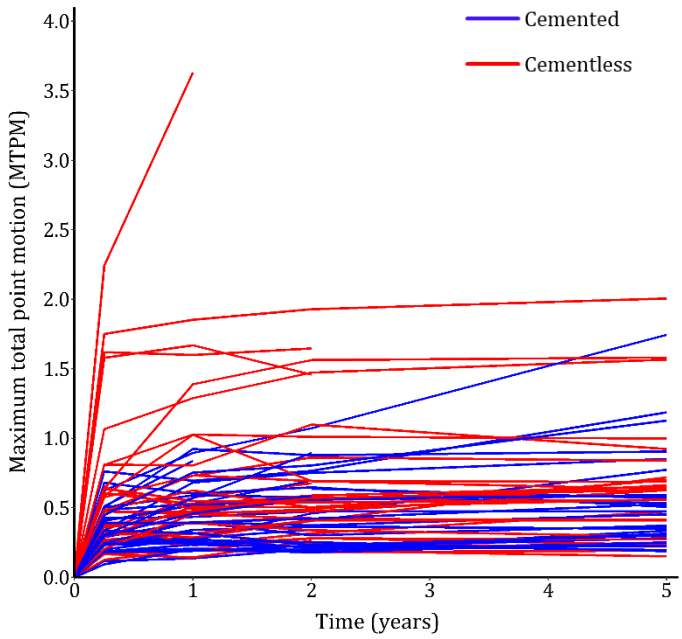


Figure 3. Spaghetti plot showing the individual implant-migration profiles.

Cement mantle thickness

Given the progression in mean MTPM for the cemented group beyond 2 years, we explored whether this could be explained by the immediate postoperative cement mantle thickness. The mean cement mantle thickness of the 4 continuously migrating implants (10.11 mm; SD, 4.1) and of the 30 non-migrating cemented implants (9.95 ± 3.5 mm) were comparable (p = 0.94). LMM analysis showed no association between cement mantle thickness and MTPM across the 5-year follow-up period (p = 0.86).

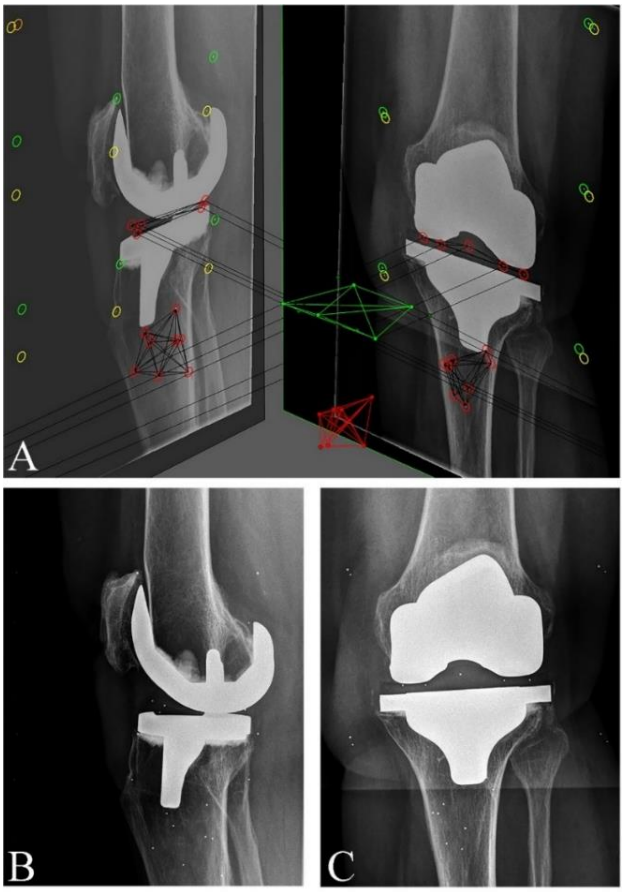


Figure 4. RSA images of a cemented TKA implant. **Figure 4-A.** Biplanar (lateral and anteroposterior) views with markers inserted in the polyethylene insert and tibial bone. **Figure 4-B.** Lateral radiograph of the same implant, which was classified as continuously migrating. **Figure 4-C.** Anteroposterior radiograph of the same implant.

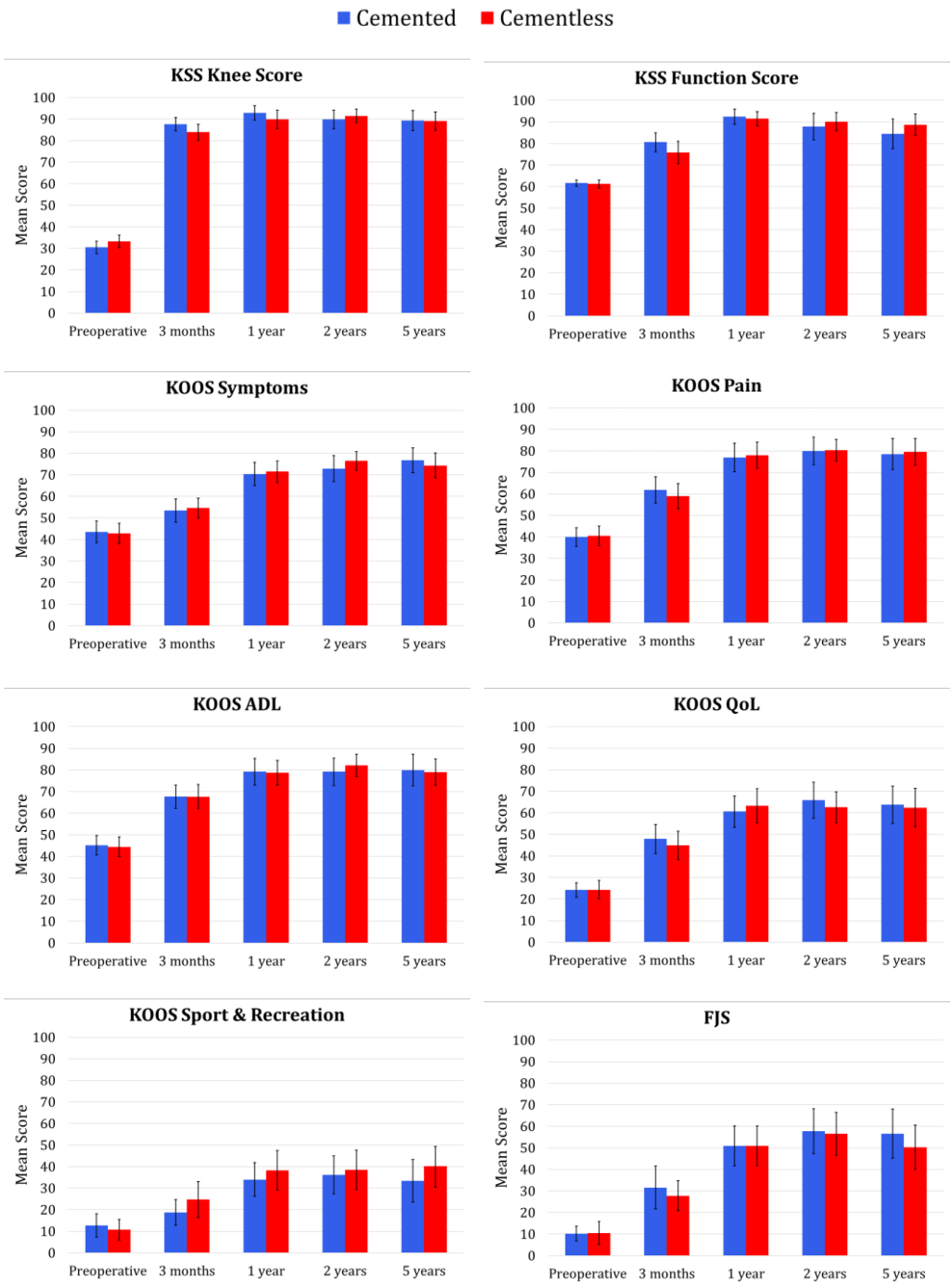


Figure 5. Mean clinical scores with 95% confidence intervals. KSS = Knee society score. KOOS = Knee injury and osteoarthritis outcome score. ADL = Activities of daily living. QoL = Quality of life. FJS = Forgotten joint score.

Clinical scores and patient reported outcome measures

No significant differences between the groups were found during the 5-year follow-up for the KSS Knee score, the KSS Function score, the KOOS subscales, and the FJS (Figure 5).

Discussion

The present study showed no difference in mean MTPM between the cementless 3D-printed and cemented tibial implants at 5 years postoperatively, despite higher initial migration of the 3D-printed implant. While the cemented implant had less migration in the early postoperative period, it showed progression of migration beyond 1 year, whereas the cementless implant remained stable. Moreover, only 1 cementless implant was continuously migrating beyond 2 years versus 4 cemented implants. This was probably related to a strong implant-bone interlock in the cementless design and a less favorable cement-bone interlock in the cemented implant.

Previous studies have reported excellent clinical outcomes of the 3D-printed implant at short-term and midterm follow-up, which was confirmed by our results (10-13). Although 2 years has generally been accepted as the benchmark for measuring migration, few data are available on this novel cementless 3D-printed implant, stressing the importance of evaluating migration over time (31). To our knowledge, this study is the first to report migration results of the Triathlon Tritanium TKA implant beyond 2 years. In a cohort study with 2 years of follow-up, Sporer et al. (18) analyzed the migration of the 3D-printed Triathlon Tritanium TKA implant in 29 patients with use of RSA; they found no significant progression in mean MTPM between 1 and 2 years. Our study found that this pattern continued to 5 years of follow-up. RSA studies investigating cementless designs typically have shown higher early migration, in the first postoperative year (the settling phase), compared with cemented implants (19, 32, 33). Cemented implants usually show little early migration since they rely on primary bone fixation through cement interdigitation (15). However, cemented implants are susceptible to cement-related complications, including concerns regarding loosening caused by tension and shear as well as third-body wear from cement debris (5). A previous study described an equivalent migration pattern for cemented and cementless tibial components between 1 and 2 years postoperatively (34). RSA studies with longer follow-up are scarce and inconclusive regarding the migration of cemented implants. For example, Nilsson et al. (35) found that cementless components stabilized after

cementless components stabilized after an initial period of early migration whereas cemented implants showed initially lower migration followed by progressive migration beyond 2 years. However, other RSA studies have rarely shown continuous migration of cemented tibial implants beyond 2 years (27, 36, 37).

Two RSA studies with at least 5 years of follow-up using the same cemented TKA design have been performed in the same hospital as the present study (Hässleholm Hospital) (26, 32). Consistent with our results, van Hamersveld et al. (32) showed progression in migration of the cemented component, with a mean MTPM of 0.58 ± 0.35 mm at 2 years to 0.68 ± 0.50 mm at 5 years. In contrast, Molt et al. (26) reported a similar mean MTPM at 2 and 5 years (0.65 ± 0.66 and 0.66 ± 0.38 mm, respectively), but did not employ an LMM to deal with missing values and repeated measurements, which may have affected their results. Both studies did not specifically report the progression in mean MTPM (and corresponding 95% CI) between 2 and 5 years. Studies focusing only on between-group comparisons may overlook significant changes in migration over time within 1 group.

Significant progression in MTPM does not directly imply a clinically relevant increase in the rate of aseptic loosening. Still, the migration of the cemented implant beyond 2 years was unexpected and warrants further research. Cement mantle thickness and proper penetration of cement into bone have been suggested to influence implant stability (38-41). However, we found no influence of cement mantle thickness on tibial implant migration. The results of that post hoc analysis, however, should be regarded as exploratory. For a definitive answer regarding whether there is an association between cement mantle thickness and implant migration, a clinical study is needed that has sufficient power and includes analysis of inter- and intraobserver variability. Additionally, it is important to note that measurements of cement mantle thickness do not represent the quantity of fixation from the cement-bone interface (3). Interestingly, all of the patients with a cemented implant that showed continuous migration were female. Female sex has been described as a risk factor for increased migration of cemented implants during the first 3 months (42). Laende et al. (43) found that larger tibial components were associated with increased migration for cemented implants in women, but this was not observed in our study.

A strength of this study was the use of RSA for a highly accurate measurement of implant migration. Besides the comparison of 2 TKA designs, RSA allows for analysis of implant migration over time within 1 group. However, some limitations should be noted. The effect of the 3D-printed cementless design cannot be separated from that of the 4 additional pegs

on the undersurface of the tibial plateau (19). To specifically assess the effect of 3D printing on implant migration, a comparison is needed with a conventionally manufactured cementless TKA implant instead of a cemented TKA implant. Also, the study was single-blinded since it is impossible to blind clinicians and researchers given the difference in radiographic appearance of the 2 types of implants.

In conclusion, there was no progression in MTPM for the cementless 3D-printed tibial components between 2 and 5 years, whereas the cemented components showed progression in migration. The early postoperative migration of the cementless 3D-printed TKA components occurred mainly during the first 3 months and can probably be considered physiological as part of the implant settling phase.

References

1. American Academy of Orthopaedic Surgeons (AAOS). American Joint Replacement Registry (AJRR): 2022 Annual Report. 2022. https://www.aaos.org/registries/publications/ajrr-annual-report/ [Accessed 18-11-2022].
2. Swedish Knee Arthroplasty Register. Annual Report 2020. 2020. https://www.myknee.se/pdf/SVK_2020_Eng_1.0.pdf [Accessed 18-11-2022].
3. Miller MA, Terbush MJ, Goodheart JR, Izant TH, Mann KA. Increased initial cement-bone interlock correlates with reduced total knee arthroplasty micro-motion following in vivo service. J Biomech. 2014;47:10:2460-6.
4. Sadauskas A, Engh Cr, Mehta M, Levine B. Implant Interface Debonding After Total Knee Arthroplasty: A New Cause for Concern? Arthroplast Today. 2020;6:4:972-5.
5. Dalury DF. Cementless total knee arthroplasty: current concepts review. Bone Joint J. 2016;98-b:7:867-73.
6. Mont MA, Pivec R, Issa K, Kapadia BH, Maheshwari A, Harwin SF. Long-term implant survivorship of cementless total knee arthroplasty: a systematic review of the literature and meta-analysis. J Knee Surg. 2014;27:5:369-76.
7. Wang X, Xu S, Zhou S, Xu W, Leary M, Choong P et al. Topological design and additive manufacturing of porous metals for bone scaffolds and orthopaedic implants: A review. Biomaterials. 2016;83:127-41.
8. Narra SP, Mittwede PN, DeVincent Wolf S, Urish KL. Additive Manufacturing in Total Joint Arthroplasty. Orthop Clin North Am. 2019;50:1:13-20.
9. Mumith A, Thomas M, Shah Z, Coathup M, Blunn G. Additive manufacturing: current concepts, future trends. Bone Joint J. 2018;100-b:4:455-60.
10. Restrepo S, Smith EB, Hozack WJ. Excellent mid-term follow-up for a new 3D-printed cementless total knee arthroplasty. Bone Joint J. 2021;103-b:6 Supple A:32-7.
11. Tarazi JM, Salem HS, Ehiorobo JO, Sodhi N, Mont MA, Harwin SF. Cementless Tritanium Baseplate Total Knee Arthroplasty: Survivorship and Outcomes at 5-Year Minimum Follow-Up. J Knee Surg. 2020;33:9:862-5.
12. Nam D, Lawrie CM, Salih R, Nahhas CR, Barrack RL, Nunley RM. Cemented Versus Cementless Total Knee Arthroplasty of the Same Modern Design: A Prospective, Randomized Trial. J Bone Joint Surg Am. 2019;101:13:1185-92.
13. Sultan AA, Mahmood B, Samuel LT, Stearns KL, Molloy RM, Moskal JT et al. Cementless 3D Printed Highly Porous Titanium-Coated Baseplate Total Knee Arthroplasty: Survivorship and Outcomes at 2-Year Minimum Follow-Up. J Knee Surg. 2020;33:3:279-83.
14. Ryd L, Albrektsson BE, Carlsson L, Dansgård F, Herberts P, Lindstrand A et al. Roentgen stereophotogrammetric analysis as a predictor of mechanical loosening of knee prostheses. J Bone Joint Surg Br. 1995;77:3:377-83.
15. Pijls BG, Valstar ER, Nouta KA, Plevier JW, Fiocco M, Middeldorp S et al. Early migration of tibial components is associated with late revision: a systematic review and meta-analysis of 21,000 knee arthroplasties. Acta Orthop. 2012;83:6:614-24.
16. Nelissen RG, Pijls BG, Kärrholm J, Malchau H, Nieuwenhuijse MJ, Valstar ER. RSA and registries: the quest for phased introduction of new implants. J Bone Joint Surg Am. 2011;93 Suppl 3:62-5.
17. Fontalis A, Haddad FS. Roentgen stereophotogrammetric analysis: still a very valuable tool in the orthopaedic research armamentarium. Bone Joint Res. 2022;11:4:210-3.
18. Sporer S, MacLean L, Burger A, Moric M. Evaluation of a 3D-printed total knee arthroplasty using radiostereometric analysis: assessment of highly porous biological fixation of the tibial baseplate and metal-backed patellar component. Bone Joint J. 2019;101-b:7_Supple_C:40-7.
19. Hasan S, van Hamersveld KT, Marang-van de Mheen PJ, Kaptein BL, Nelissen R, Toksvig-Larsen S. Migration of a novel 3D-printed cementless versus a cemented total knee arthroplasty: two-year results of a randomized controlled trial using radiostereometric analysis. Bone Joint J. 2020;102-b:8:1016-24.
20. Lam AD, Duffy GP. Early Tibial Component Fractures in a Cementless, 3D-Printed, Titanium Implant. Arthroplasty Today. 2022;18:31-8.
21. Insall JN, Dorr LD, Scott RD, Scott WN. Rationale of the Knee Society clinical rating system. Clin Orthop Relat Res. 1989:248:13-4.
22. Roos EM, Lohmander LS. The Knee injury and Osteoarthritis Outcome Score (KOOS): from joint injury to osteoarthritis. Health Qual Life Outcomes. 2003;1:64.

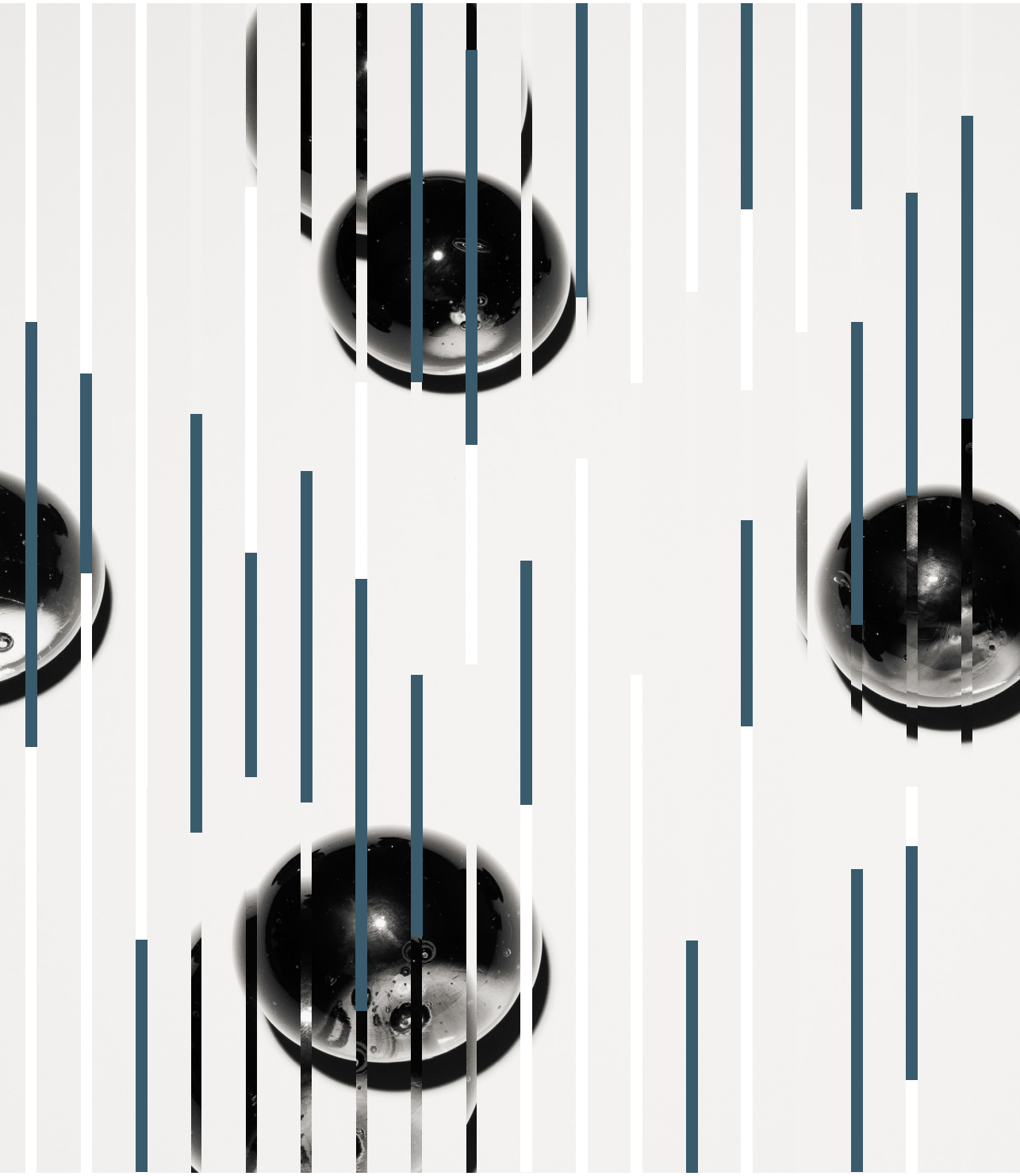
23. Behrend H, Giesinger K, Giesinger JM, Kuster MS. The "forgotten joint" as the ultimate goal in joint arthroplasty: validation of a new patient-reported outcome measure. J Arthroplasty. 2012;27:3:430-6.e1.
24. Valstar ER, Gill R, Ryd L, Flivik G, Börlin N, Kärrholm J. Guidelines for standardization of radiostereometry (RSA) of implants. Acta Orthop. 2005;76:4:563-72.
25. Implants for surgery - Roentgen stereophotogrammetric analysis for the assessment of migration of orthopaedic implants. International Organization for Standardization (ISO) 2013 (standard reviewed and confirmed in 2019).
26. Molt M, Ryd L, Toksvig-Larsen S. A randomized RSA study concentrating especially on continuous migration. Acta Orthop. 2016;87:3:262-7.
27. Wilson DA, Richardson G, Hennigar AW, Dunbar MJ. Continued stabilization of trabecular metal tibial monoblock total knee arthroplasty components at 5 years-measured with radiostereometric analysis. Acta Orthop. 2012;83:1:36-40.
28. Ewald FC. The Knee Society total knee arthroplasty roentgenographic evaluation and scoring system. Clin Orthop Relat Res. 1989:248:9-12.
29. Touzopoulos P, Ververidis A, Mpogiatzis C, Chatzigiannakis A, Drosos GI. The use of tourniquet may influence the cement mantle thickness under the tibial implant during total knee arthroplasty. European Journal of Orthopaedic Surgery & Traumatology. 2019;29:4:869-75.
30. Pfitzner T, von Roth P, Voerkelius N, Mayr H, Perka C, Hube R. Influence of the tourniquet on tibial cement mantle thickness in primary total knee arthroplasty. Knee Surgery, Sports Traumatology, Arthroscopy. 2016;24:1:96-101.
31. Pijls BG, Plevier JWM, Nelissen R. RSA migration of total knee replacements. Acta Orthop. 2018;89:3:320-8.
32. van Hamersveld KT, Marang-van de Mheen PJ, Tsonaka R, Valstar ER, Toksvig-Larsen S. Fixation and clinical outcome of uncemented peri-apatite-coated versus cemented total knee arthroplasty : five-year follow-up of a randomised controlled trial using radiostereometric analysis (RSA). Bone Joint J. 2017;99-b:11:1467-76.
33. Carlsson A, Björkman A, Besjakov J, Onsten I. Cemented tibial component fixation performs better than cementless fixation: a randomized radiostereometric study comparing porous-coated, hydroxyapatite-coated and cemented tibial components over 5 years. Acta Orthop. 2005;76:3:362-9.
34. Laende EK, Astephen Wilson JL, Mills Flemming J, Valstar ER, Richardson CG, Dunbar MJ. Equivalent 2-year stabilization of uncemented tibial component migration despite higher early migration compared with cemented fixation: an RSA study on 360 total knee arthroplasties. Acta Orthop. 2019;90:2:172-8.
35. Nilsson KG, Kärrholm J, Carlsson L, Dalén T. Hydroxyapatite coating versus cemented fixation of the tibial component in total knee arthroplasty: prospective randomized comparison of hydroxyapatite-coated and cemented tibial components with 5-year follow-up using radiostereometry. J Arthroplasty. 1999;14:1:9-20.
36. Henricson A, Nilsson KG. Trabecular metal tibial knee component still stable at 10 years. Acta Orthop. 2016;87:5:504-10.
37. Pijls BG, Valstar ER, Kaptein BL, Fiocco M, Nelissen RG. The beneficial effect of hydroxyapatite lasts: a randomized radiostereometric trial comparing hydroxyapatite-coated, uncoated, and cemented tibial components for up to 16 years. Acta Orthop. 2012;83:2:135-41.
38. Bert JM, McShane M. Is it necessary to cement the tibial stem in cemented total knee arthroplasty? Clin Orthop Relat Res. 1998:356:73-8.
39. Peters CL, Craig MA, Mohr RA, Bachus KN. Tibial component fixation with cement: full- versus surface-cementation techniques. Clin Orthop Relat Res. 2003:409:158-68.
40. Walker PS, Soudry M, Ewald FC, McVickar H. Control of cement penetration in total knee arthroplasty. Clin Orthop Relat Res. 1984:185:155-64.
41. Ritter MA, Herbst SA, Keating EM, Faris PM. Radiolucency at the bone-cement interface in total knee replacement. The effects of bone-surface preparation and cement technique. J Bone Joint Surg Am. 1994;76:1:60-5.
42. van Hamersveld KT, Marang-van de Mheen PJ, Tsonaka R, Nilsson KG, Toksvig-Larsen S, Nelissen R. Risk Factors for Tibial Component Loosening: A Meta-Analysis of Long-Term Follow-up Radiostereometric Analysis Data. J Bone Joint Surg Am. 2021;103:12:1115-24.

43. Laende EK, Mills Flemming J, Astephen Wilson JL, Cantoni E, Dunbar MJ. The associations of implant and patient factors with migration of the tibial component differ by sex : a radiostereometric study on more than 400 total knee arthroplasties. Bone Joint J. 2022;104-b:4:444-51.

Supplementary data

Table. Mean translations (mm) along and rotations (degrees) about each orthogonal axis with 95% confidence interval, as derived from the linear mixed-effects model. Post-operative RSA examination is used to calculate translations and rotations at each follow-up moment.

	Cemented	Cementless
Translation along transverse axis (mm)		
- 3 months	0.02 (-0.04 to 0.08)	-0.05 (-0.11 to 0.00)
- 1 year	0.04 (-0.02 to 0.10)	-0.06 (-0.12 to 0.00)
- 2 years	0.06 (0.00 to 0.12)	-0.07 (-0.12 to -0.01)
- 5 years	0.05 (-0.01 to 0.12)	-0.06 (-0.12 to 0.00)
Translation along longitudinal axis (mm)		
- 3 months	0.02 (-0.04 to 0.08)	-0.15 (-0.21 to -0.09)
- 1 year	0.02 (-0.04 to 0.08)	-0.12 (-0.18 to -0.06)
- 2 years	0.01 (-0.05 to 0.07)	-0.13 (-0.19 to -0.08)
- 5 years	0.03 (-0.03 to 0.10)	-0.13 (-0.19 to -0.06)
Translation along sagittal axis (mm)		
- 3 months	0.02 (-0.07 to 0.12)	0.02 (-0.08 to 0.11)
- 1 year	0.06 (-0.04 to 0.15)	0.00 (-0.10 to 0.09)
- 2 years	0.02 (-0.07 to 0.12)	-0.03 (-0.12 to 0.07)
- 5 years	0.05 (-0.05 to 0.15)	-0.01 (-0.11 to 0.08)
Rotation about transverse axis (°)		
- 3 months	0.01 (-0.23 to 0.26)	-0.25 (-0.49 to -0.01)
- 1 year	-0.02 (-0.27 to 0.22)	-0.40 (-0.64 to -0.16)
- 2 years	-0.11 (-0.35 to 0.15)	-0.44 (-0.68 to -0.20)
- 5 years	-0.10 (-0.36 to 0.16)	-0.42 (-0.67 to -0.17)
Rotation about longitudinal axis (°)		
- 3 months	-0.04 (-0.12 to 0.03)	0.01 (-0.07 to 0.08)
- 1 year	-0.03 (-0.11 to 0.04)	-0.02 (-0.10 to 0.05)
- 2 years	-0.02 (-0.09 to 0.06)	-0.02 (-0.10 to 0.05)
- 5 years	-0.05 (-0.13 to 0.03)	0.03 (-0.05 to 0.11)
Rotation about sagittal axis (°)		
- 3 months	0.02 (-0.08 to 0.12)	0.13 (0.03 to 0.23)
- 1 year	-0.02 (-0.12 to 0.08)	0.11 (0.01 to 0.20)
- 2 years	-0.04 (-0.14 to 0.06)	0.11 (0.01 to 0.21)
- 5 years	-0.08 (-0.19 to 0.02)	0.04 (-0.06 to 0.15)



Chapter 5

Influence of marker-selection method in radiostereometric analysis of total knee arthroplasty on tibial baseplate migration patterns: A secondary analysis of a randomized controlled trial with 5-year follow-up

T.J.N. van der Lelij
L.A. Koster
P.J. Marang-van de Mheen
S. Toksvig-Larsen
R.G.H.H. Nelissen
B.L. Kaptein

Acta Orthopaedica
2024 Mar 21;95:157-165

Abstract

Background and purpose

Different marker-selection methods are applied to represent implant and tibial segments in radiostereometric analysis (RSA) studies of total knee arthroplasty (TKA). Either a consistent set of markers throughout subsequent RSA examinations ("consistent-marker method") is used or all available markers at each follow-up ("all-marker method"). The aim of this secondary analysis was to compare marker-selection methods on individual and group level TKA migration results.

Methods

Data from a randomized RSA study with 72 patients was included. Tibial baseplate migration was evaluated at 3 months, 1, 2, and 5 years postoperatively with both marker-selection methods. Additionally, migration was calculated using 5 fictive points, either plotted based on the consistent set of markers or all available markers.

Results

Migration could be calculated with both marker-selection methods for 248 examinations. The same prosthesis and bone markers (n = 136), different prosthesis markers (n = 71), different bone markers (n = 21), or different prosthesis and bone markers (n = 20) were used. The mean difference in maximum total point motion (MTPM) between all examinations was 0.02 mm, 95% confidence interval -0.26 to 0.31 mm. 5 implants were classified as continuously migrating with the consistent-marker method versus 6 implants (same 5 plus one additional implant) with the all-marker method. Using fictive points, fewer implants were classified as continuously migrating in both marker-selection methods. Differences between TKA groups in mean MTPM were comparable with both marker-selection methods, also when fictive points were used.

Conclusion

Estimated group differences in mean MTPM were similar between marker-selection methods, but individual migration results differed. The latter has implications when classifying implants for estimated risk of future loosening.

Introduction

Radiostereometric analysis (RSA) is a technique to detect early implant migration, which is predictive for future loosening of tibial components in total knee arthroplasty (TKA) (1, 2).

Marker-based RSA requires the bone and prosthesis to be defined in 3 dimensions by inserting small radiopaque markers in each segment (3). However, marker projections can be superimposed by implant projection, be out of view due to incorrect patient positioning, be invisible due to poor roentgen technique, and individual markers can be unstable. An RSA analyst can choose to calculate migration using only those markers consistently visible at all RSA examinations ("consistent-marker method") or use all available markers at each follow-up examination that can be matched to the reference RSA image ("all-marker method) (Figure 1). Interestingly, most RSA studies do not specify the marker-selection method used.

For the maximum total point motion (MTPM), i.e., the length of the translation vector of the point in a rigid body that has the greatest motion, RSA guidelines and the ISO standard (ISO 16087:2013) state that if the points of measurement in a rigid body do not correspond between different implant designs, any comparison will become incorrect (4, 5). To overcome this problem, fictive points should be used to assess MTPM (4). However, in RSA studies with markers in the polyethylene (PE) liner of the tibial component fictive points are often not used (6-11). A recent review of all RSA studies on tibial component migration categorized "modular PE marker" and "fictive point" as separate marker-based RSA techniques (12). Furthermore, RSA guidelines do not provide guidance on the number and location of fictive points that should be used, or how these points should be plotted using the actual tantalum insert markers (4).

The aim of our study was to assess whether the marker-selection method affects the calculated migration of individual implants as well as the mean estimated migration results at group level. As a secondary analysis, we assessed the influence of using fictive points.

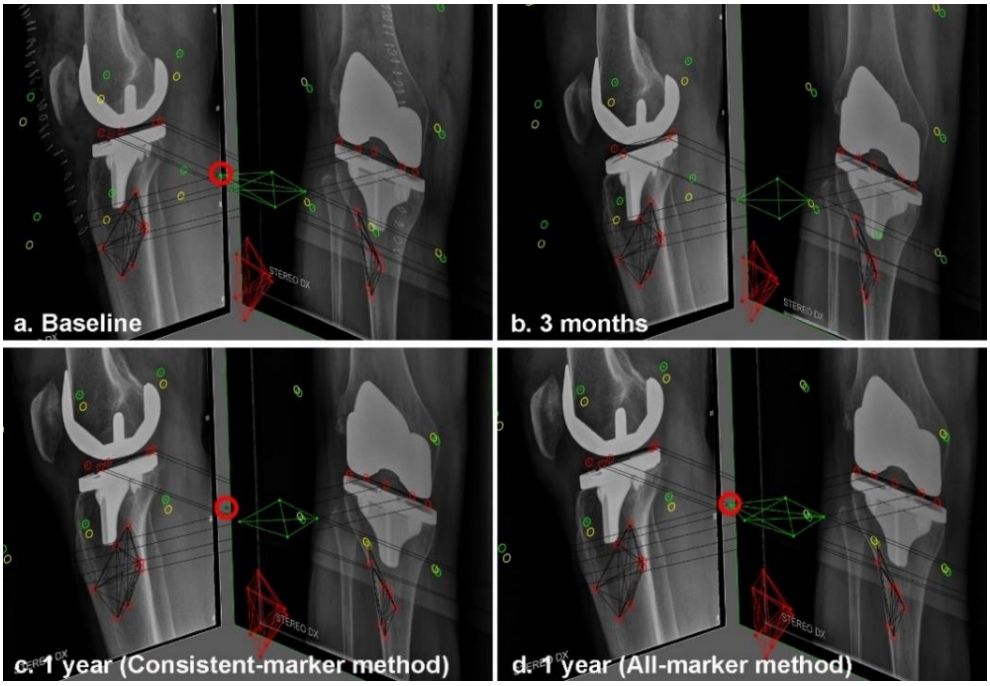


Figure 1. RSA examinations showing the baseline (a) and 3 months (b) follow-up examination of a patients. At 3 months, the anterolateral marker (red circle) in the PE insert is overprojected by the implant in the lateral radiograph. Using the consistent-marker method, only 4 of the 5 markers in the PE insert are selected at the 1-year follow-up (c) for the migration calculation (as these are the markers used at the 3 months examination). With the all-marker method, all 5 available markers that can be matched to the reference examination are used for the migration calculation at the 1-year follow-up (d).

Methods

Patient enrolment and the 2- and 5-year outcomes have been described elsewhere (13, 14). In short, 72 patients were randomized to either a cementless Tritanium Triathlon Cruciate Retaining (CR) fixed bearing TKA or a cemented Triathlon CR fixed bearing TKA (both Stryker, Mahwah, NJ, USA). All patients were operated on by a single surgeon (STL). 8 spherical tantalum markers (ø 0.8 mm, RSA Biomedical, Umeå, Sweden) were inserted into the tibia, and 5 were implanted in the PE insert at standardized positions.

Radiostereometric analysis

The first RSA examination was performed 2 days after surgery and served as the reference for the migration measurements. Subsequent examinations were performed at 3 months, 1, 2, and 5 years postoperatively. Supine RSA radiographs were taken with a biplanar calibration cage (Cage 10, RSA Biomedical, Umeå, Sweden) with a 90° angle between radiographs and analysed using model-based RSA (MBRSA) (v.4.2, *RSAcore*, Leiden, Netherlands) (4). The precision of the RSA setup was 0.1 mm for translations and 0.1° for rotations (13). The migration of the tibial baseplate relative to the tibial bone was assessed and MTPM was used as the primary outcome measure (5).

The clinical studies presenting the 2- and 5-year results used the consistent-marker method for the migration calculations (without fictive points) (13, 14). For this study, migration was recalculated based on the same RSA scenes by the same researcher (TvdL) but using the all-marker method. The only difference between the methods was therefore the set of selected markers in either the PE liner or the tibial bone. Thresholds for ME (≤ 0.35 mm) and CN (≤ 120) were used for both methods (5). Individual implants were considered continuously migrating if MTPM was ≥ 0.3 mm (i.e., ≥ 0.1 mm/year) between 2 and 5 years (1, 15-18). Implants with ≥ 0.2 mm micromotion at 2 years but micromotion of < 0.3 mm between 2 and 5 years were considered "stabilized."

Statistics

The limits of agreement between the 2 marker-selection methods, defined as the mean ± 1.96 x standard deviation (SD), should be within ± 0.5 mm of translation or ± 0.8° of rotation for the measures to be considered equivalent (19). These thresholds were chosen as these are considered the smallest clinically relevant values (4, 20, 21). There is no specific threshold described in the literature to be the smallest clinically relevant value of MTPM. However, individual implants showing ≥ 0.2 mm migration (MTPM) in year 2 are generally considered at risk of loosening (1, 22, 23). Therefore, we considered 0.2 mm a clinically relevant threshold for MTPM.

The mean difference in MTPM between marker-selection methods was calculated separately for examinations in which different prosthesis marker, bone markers, or both were used. A linear mixed-effects model (LMM), which deals effectively with missing values and takes within-subject correlation into account, was used to compare the migration of TKA groups for both marker-selection methods (24). The model consisted of a group variable, a

time variable, and an interaction term between the time and group variable. Patients were included as a random factor by using a random-intercept term and the remaining variability was modelled with a heterogeneous autoregressive order 1 covariance structure. The likelihood ratio test was used to test for a difference in mean migration, comparing this model with a model including only the time variable. Given its non-normal distribution, MTPM was log-transformed, computed as log10(MTPM+1). Presented values were back-transformed to the original scale in millimetres. The differences in mean MTPM between the TKA groups at each follow-up moment were calculated for the consistent-marker and all-marker methods, using the delta method for approximating the standard error of the transformed results. Descriptive RSA data is presented to illustrate the directions of mean translations and rotations for both marker-selection methods. Additionally, we assessed whether the classification of individual TKAs as continuously migrating or stabilized differed between the marker-selection methods. Means were reported with 95% confidence interval (CI) or with range if this was indicative for the direction of the differences. A P value < 0.05 was considered statistically significant. Analyses were performed using SPSS (v.25, IBM Corp, Armonk, New York, USA) and R software (v.4.2.1, R Foundation for Statistical Computing, Vienna, Austria).

Secondary RSA analyses using fictive points

Additional migration analyses were performed using 5 fictive points on the insert. 5 standardized points were chosen in the polyethylene insert (midpoint anteriorly, anterolateral, anteromedial, and 2 posterior points on the medial and lateral curves of the insert) and used to calculate the MTPM. The fictive points were plotted in all follow-up examinations based on either the migration of the consistent set of actual markers or all available markers. Note that the actual implant markers are still needed to plot these fictive points and need to adhere to the CN and ME thresholds.

Ethics, registration, funding, and disclosures

The original RSA study was approved by the Regional Ethical Review Board in Lund (entry no. 2015/8) and registered at clinicaltrials.gov (NCT02578446). All patients gave their informed consent prior to enrolment. The original RSA study was funded by Stryker but Stryker had no part in the design, conduct, analysis, and interpretation stated in this paper.

The authors declare no competing interests. Complete disclosure of interest forms according to ICMJE are available on the article page, doi: 10.2340/17453674.2024.40184.

Results

Of the 72 patients, 2 patients had missing baseline radiographs in the cemented group and could not be analysed (14). Because the insert of 1 patient in the cementless group was exchanged to treat an early postoperative infection, this patient was also excluded from the analysis. From 69 patients, 259 follow-up RSA examinations were performed during the 5-year follow-up. In 2 patients, 6 markers were implanted in the PE insert instead of 5. In 3 patients, 9 instead of 8 markers were placed in the tibial bone (Table 1).

Table 1. Characteristics of the marker-selection methods using the RSA examinations of a randomized controlled trial (RCT) including the 3 months, 1 year, 2 years, and 5 years follow-up examinations.

Characteristics	Consistent-marker method	All-marker method
Patients, n	69	69
RSA examinations, n	248	250
Tibial prosthesis markers, n (%)		
3	87 (35)	34 (14)
4	94 (38)	93 (37)
5	67 (27)	119 (48)
6	0 (0)	4 (2)
ME prosthesis, mean (SD)	0.09 (0.05)	0.10 (0.05)
range	0.02 – 0.34	0.02 – 0.35
CN prosthesis, mean (SD)	37.8 (13.5)	32.0 (10.9)
range	21.5 – 102.9	21.2 – 102.9
Tibial bone markers, n (%)		
3	3 (1)	1 (0)
4	6 (2)	6 (2)
5	26 (11)	18 (7)
6	27 (11)	19 (8)
7	78 (32)	74 (30)
8	97 (39)	121 (48)
9	11 (4)	11 (4)
ME tibial bone, mean (SD)	0.14 (0.06)	0.15 (0.03)
range	0.03 – 0.33	0.03 – 0.33
CN tibial bone, mean (SD)	38.2 (11.6)	36.7 (10.9)
range	24.0 – 93.2	24.1 – 93.2

ME = Mean error. CN = Condition number.

In 9 RSA examinations the migration could not be calculated with either the consistent-marker or the all-marker method, because of inferior radiograph quality, or < 3 markers were visible. Tibial baseplate migration was calculated in 248 and 250 RSA examinations for the consistent-marker and all-marker method, respectively (Table 1). This difference was caused by 2 RSA examinations in which the specific set of same markers was not available to calculate migration, but sufficient other markers could be used to calculate migration with the all-marker method. Only in 29 (42%) of the 69 patients were the same prosthesis and bone markers used during all available follow-up examinations with both methods. For 248 RSA examinations, the exact same prosthesis and bone markers were used in 136 (55%) examinations, different prosthesis markers in 71 (29%), different bone markers in 21 (8%), and different markers in both prosthesis and bone markers in 20 (8%) examinations.

Table 2. Differences in translations (mm), rotations (°), and MTPM (mm) between the consistent-marker and all-marker method and differences in migration results between the methods using 5 fictive points, matched either with a consistent set of actual markers or all available markers (secondary analysis). Mean differences are reported with the 95% confidence intervals (CI), which represent the limits of agreement between the 2 methods (n = 248 RSA examinations).

	Translation (mm)			
Method	**Transverse**	**Longitudinal**	**Sagittal**	**MTPM**
Differences between the consistent-marker and all-marker method				
mean (SD)	0.00 (0.09)	-0.01 (0.06)	0.01 (0.07)	0.02 (0.14)
CI	-0.17 to 0.17	-0.13 to 0.11	-0.14 to 0.15	-0.26 to 0.31
Differences between the consistent-marker and all-marker method using 5 fictive markers				
mean (SD)	0.00 (0.09)	0.00 (0.03)	0.01 (0.07)	0.01 (0.09)
CI	-0.17 to 0.16	-0.07 to 0.06	-0.13 to 0.15	-0.27 to 0.29

	Rotations (°)		
Method	**Transverse**	**Longitudinal**	**Sagittal**
Differences between the consistent-marker and all-marker method			
mean (SD)	0.02 (0.08)	0.00 (0.06)	0.00 (0.11)
CI	-0.14 to 0.18	-0.13 to 0.12	-0.21 to 0.22
Differences between the consistent-marker and all-marker method using 5 fictive markers			
mean (SD)	0.02 (0.08)	0.00 (0.06)	0.00 (0.11)
CI	-0.15 to 0.18	-0.12 to 0.12	-0.21 to 0.22

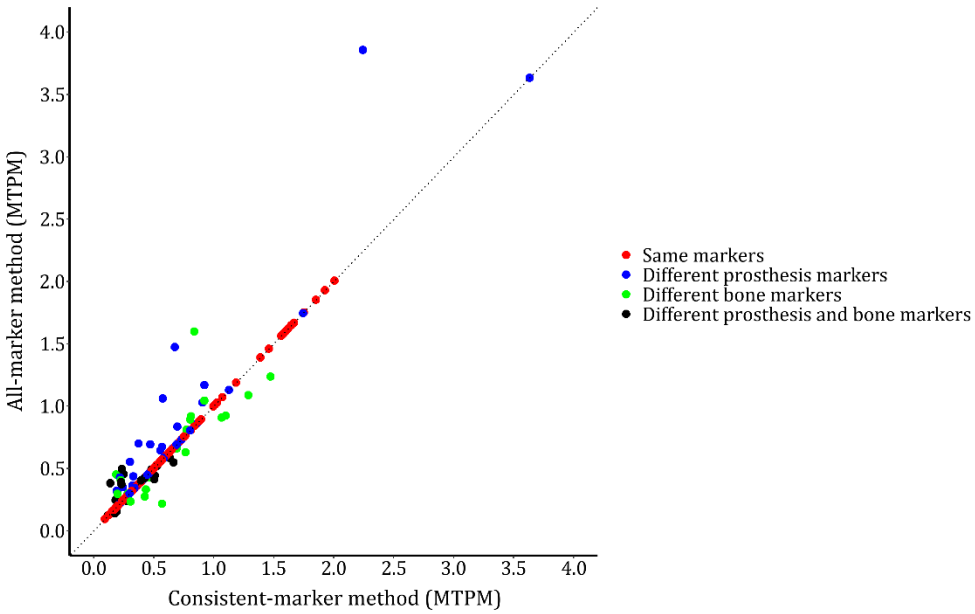


Figure 2. A scatterplot showing the MTPM of all RSA examinations calculated with both the consistent-marker and all-marker method (n = 248). The dotted line represents the line of equality. The difference in markers that have been used for the migration calculation for each examination is specified.

MTPM, translations and rotations

The mean difference in MTPM of all examinations, including examinations in which the same prothesis and bone markers were used with both methods, was 0.02 mm (CI –0.26 to 0.31). The limits of agreements of MTPM exceeded the ± 0.2 mm thresholds (Table 2). When only different prosthesis markers were used, MTPM as calculated with the all-marker method was always equal or higher compared with the consistent-marker method (Figure 2). The "different prosthesis markers" group showed a mean difference in MTPM of 0.07 (range 0.00 to 1.61) between the marker-selection methods and included the examination with the greatest difference in MTPM between methods (Figure 3, see supplementary data). In the group of examinations where only different bone markers were used, the mean difference in MTPM was 0.00 (range –0.35 to 0.76). Finally, in the subgroup of examinations where different markers in both prosthesis and bone were used, the mean difference was 0.04 (range –0.12 to 0.26). The limits of agreement for translations and rotations of all RSA examinations were within ± 0.5 mm and ± 0.8°, respectively (Table 2). The mean signed

translations and rotations along and about each orthogonal axis showed comparable results with both marker-selection methods (Table 3, see supplementary data).

Group migration patterns

The estimated MTPM across all follow-up examinations, as derived from the LMMs, was slightly higher with the all-marker than with the consistent marker method (Table 4). Only at the 1-year follow-up for the cementless group, the mean MTPM was exactly the same. Regarding the estimated difference between TKA groups, the mean migration trajectory over the entire follow-up period of the cemented group was significantly higher compared with the cementless groups using either the consistent-marker method ($P < 0.01$) or the all-marker method ($P < 0.01$) (Figure 4). The difference in MTPM between TKA groups became smaller over time with both marker-selection methods.

Table 4. RSA migration analysis of maximum total point motion (MTPM) in the cementless and cemented group using either the consistent-marker or all-marker method and using 5 standardized fictive points, matched either with a consistent set of actual insert markers or all available markers at each follow-up moment. Values are mean MTPM (mm) with the 95% confidence intervals (CI), as derived from the linear mixed-effects model.

Methods Follow-up	Cementless	Cemented	Group difference
MTPM with consistent-marker method			
3 months	0.54 (0.45 to 0.64)	0.32 (0.24 to 0.41)	0.22 (0.09 to 0.35)
1 year	0.63 (0.53 to 0.73)	0.42 (0.33 to 0.51)	0.21 (0.07 to 0.34)
2 years	0.64 (0.54 to 0.75)	0.45 (0.37 to 0.56)	0.18 (0.04 to 0.32)
5 years	0.66 (0.56 to 0.78)	0.53 (0.43 to 0.64)	0.13 (-0.02 to 0.28)
MTPM with all-marker method			
3 months	0.57 (0.47 to 0.67)	0.33 (0.25 to 0.42)	0.23 (0.10 to 0.37)
1 year	0.63 (0.52 to 0.73)	0.46 (0.36 to 0.56)	0.17 (0.03 to 0.31)
2 years	0.65 (0.54 to 0.76)	0.50 (0.40 to 0.61)	0.14 (0.00 to 0.29)
5 years	0.69 (0.57 to 0.80)	0.56 (0.45 to 0.67)	0.13 (-0.03 to 0.29)
MTPM with fictive points plotted with consistent set of markers			
3 months	0.53 (0.44 to 0.64)	0.32 (0.23 to 0.41)	0.22 (0.08 to 0.35)
1 year	0.60 (0.49 to 0.71)	0.39 (0.30 to 0.48)	0.21 (0.07 to 0.35)
2 years	0.60 (0.49 to 0.71)	0.43 (0.33 to 0.53)	0.17 (0.03 to 0.31)
5 years	0.61 (0.51 to 0.73)	0.49 (0.39 to 0.60)	0.12 (-0.03 to 0.26)
MTPM with fictive points plotted with all available markers			
3 months	0.55 (0.44 to 0.65)	0.32 (0.23 to 0.41)	0.22 (0.09 to 0.36)
1 year	0.59 (0.49 to 0.71)	0.41 (0.31 to 0.51)	0.19 (0.04 to 0.33)
2 years	0.59 (0.49 to 0.71)	0.44 (0.35 to 0.55)	0.15 (0.00 to 0.30)
5 years	0.64 (0.53 to 0.75)	0.51 (0.40 to 0.63)	0.13 (-0.03 to 0.29)

Continuously migrating implants

With the consistent-marker method, 5 implants (4 cemented and 1 cementless) were classified as continuously migrating (Table 5). Using the all-marker method, the same components and 1 additional cementless component were classified as continuously migrating. A larger increase in MTPM between 2 and 5 years with the all-marker method classified this additional implant as continuously migrating, because a different set of bone markers was used to calculate migration at 2-year follow-up, resulting in a lower MTPM. Both marker-selection methods classified 1 cementless implant as stabilized, but these were different implants (Table 5). Different bone markers were used in the migration calculation of patient 51, who was not classified as stabilized with the all-marker method as the migration in the second postoperative year was < 0.2 mm. Patient 7, where different prosthesis and bone markers were used, was not classified as stabilized with the consistent-marker method as the migration in the second postoperative year was < 0.2 mm and there were no 5-year follow-up results because the same set of markers was not available in those radiographs.

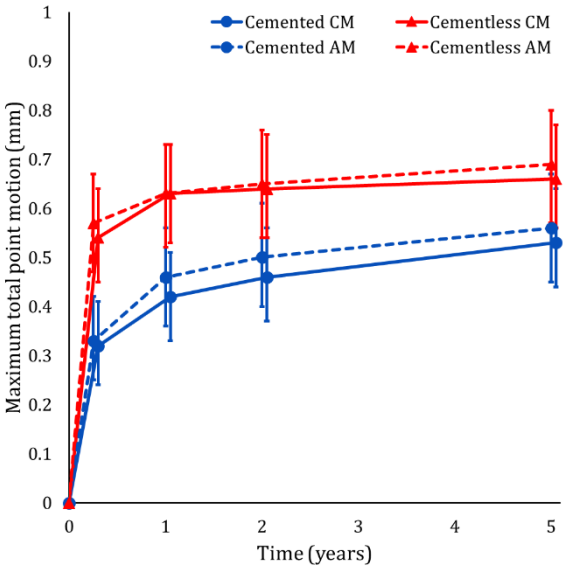


Figure 4. RSA results of maximum total point motion (MTPM). The mean and 95% confidence interval for the cemented and cementless group are shown for both the consistent-marker method and the all-marker method.

Table 5. Patients classified as stabilized or continuously migrating per group according to the marker-selection method.

Factor	Cemented (n = 34)	Cementless (n = 35)
Stabilized*		
Consistent-marker method	0	1 (# 51)
All-marker method	0	1 (# 07)
Fictive points		
Consistent marker set	0	1 (#51)
All available markers	0	0
Continuously migrating**		
Consistent-marker method	4 (# 09, 19, 40, 70)	1 (# 32)
All-marker method	4 (# 09, 19, 40, 70)	2 (# 16, 32)
Fictive points		
Consistent marker set	2 (# 40, 70)	0
All available markers	2 (# 40, 70)	1 (# 07)

* ≥ 0.2 mm MTPM in year 2 but < 3 mm between 2 and 5 years.

** ≥ 0.3 mm MTPM between 2 and 5 years.

Secondary RSA analyses using fictive points

The mean differences in MTPM, translations, and rotations between the matching methods when using fictive points were comparable with the differences between the consistent-marker and all-marker method (Table 2). Fewer patients were classified as continuously migrating when fictive points were used (Table 5). Differences in MTPM between the TKA groups remained comparable (Table 4). Mean translations and rotations of the fictive point analyses are presented in Table 6 (see supplementary data).

Discussion

We demonstrated that the mean difference in MTPM across all RSA examinations between the marker-selection methods was very small (0.02 mm, CI –0.26 to 0.31) and did not result in different conclusions regarding TKA group migration. However, the limits of agreement exceeded the clinically relevant threshold of ± 0.2 mm for individual implant migration. This implies that the two marker-selection methods cannot be used interchangeably when assessing individual migration patterns based on strict thresholds. We demonstrated that for most patients in at least one follow-up examinations a different marker-selection method resulted in different markers being used for the migration calculation.

The all-marker method resulted in equal or higher MTPM than the consistent-marker method when only prosthesis markers differed, which logically follows from the definition of MTPM. Using the all-marker method, the estimated MTPM can be determined by a marker that is not selected when using the consistent-marker method, but not vice versa. Therefore, MTPM with the consistent-marker method can never be higher than with the all-marker method if only different prosthesis markers are used. When different bone markers are used, MTPM can be either higher or lower with the all-marker method as this influences the alignment of the reference rigid body.

Mean MTPM is frequently used to assess the risk of loosening of TKA designs (2). As we found the influence of marker-selection method on mean estimated MTPM to be small, it appears justified to compare group-level migration results across RSA studies using either method. However, the number of individual implants classified as continuously migrating according to specific thresholds is also frequently reported in RSA studies (18, 22, 25). We showed that this number may depend on the marker-selection method that is used.

In routine RSA, migration is expressed in a migrating coordinate system that has its origin in the geometric center of the prosthesis markers in the reference examination, and is aligned with the global coordinate system (Figure 5 see supplementary data) (3, 4). Although MTPM and rotations are not affected by changing the origin of the migrating coordinate system, the latter does affect the calculated translations (3). RSA guidelines state that the point(s) used to calculate translation of a rigid body should be "standardized" at all follow-up occasions in all patients (4). However, this recommendation is ambiguous and does not provide clear guidance on which marker-selection method to use. Using the consistent-marker method, the origin of the implant will remain consistent between all follow-up examinations within the same patient. On the other hand, with the all-marker method, the origin differs between follow-up moments within the same patients. For both methods, the location of the origin will differ between patients, as the set of available markers differs.

Although RSA guidelines state that fictive points should be used to calculate MTPM, fictive points are not always used in clinical RSA studies. Nilsson et al. (26) described that by using the location of the actual insert markers on the radiographs, the positions of the plotted fictive points could be transformed to their corresponding position. However, it is unclear which fictive points should be used and which actual insert markers should be used to plot the position of the fictive points. The present study shows that using either a

consistent set of markers or all available markers to plot the fictive points did not result in different conclusions regarding TKA group migration. However, it did influence the classification of individual implants.

More RSA examinations were used to calculate implant migration with the all-marker (n = 250) versus the consistent-marker (n = 248) method. A disadvantage of the all-marker method is that one individual migrating marker may influence MTPM. For example, a prosthesis marker in an RSA examination might be excluded in the next examinations when it leads to an ME threshold violation. In previous examinations this unstable marker may already have migrated relative to other markers in the same rigid body without exceeding the ME threshold. The MTPM of the previous examinations may then be erroneously high because of one unstable marker. The consistent-marker method would not have this problem, because the unstable marker will not be part of the set of consistent markers. A disadvantage of the consistent-marker method is that migration results of examinations can change because of subsequent RSA examinations, when the later follow-up examination is the limiting factor in determining the consistent set of markers. It may be counterintuitive that short-term migration results are affected by later examinations.

Strengths

This was the first study to compare different marker-selection methods to calculate implant migration within a clinical RSA study. As one researcher (TvdL) performed all RSA analyses using the exact same RSA scenes for both marker-selection methods, there was no inter- or intra-observer variability that affected the calculated differences between the methods. Additionally, all patients were operated on by a single surgeon (STL) and there was no systematic difference in marker placement between patients. Moreover, the findings of our study are not restricted to marker-based RSA. Even model-based RSA still requires markers in the bone (27). Our findings are also relevant for RSA of other joints, where different sets of markers at successive follow-up moments may also be present.

Limitations

The quality of radiographs may differ between studies and it is possible that the proportion of examinations with different prosthesis and/or bone markers would be different in other studies. Note that if individual markers are excluded for specific reasons, such as overprojection or instability, results in structural differences could potentially change the

resultant shape of the rigid body systematically. Finally, although it has its own limitations, CT-based RSA avoids the issue of marker-selection method (28).

Conclusion

We showed that the estimated differences in migration at group level did not change when using either the all-marker or consistent-marker method, or when using 5 fictive points. However, individual implant migration measurements are different between marker-selection methods. In perspective, RSA studies should report the marker-selection method that is used, as part of the standardized output to facilitate comparison between clinical studies. Moreover, if fictive points are used, the location of these points and how they were plotted needs to be reported.

References

1. Ryd L, Albrektsson BE, Carlsson L, Dansgård F, Herberts P, Lindstrand A et al. Roentgen stereophotogrammetric analysis as a predictor of mechanical loosening of knee prostheses. J Bone Joint Surg Br. 1995;77:3:377-83.
2. Pijls BG, Valstar ER, Nouta KA, Plevier JW, Fiocco M, Middeldorp S et al. Early migration of tibial components is associated with late revision: a systematic review and meta-analysis of 21,000 knee arthroplasties. Acta Orthop. 2012;83:6:614-24.
3. van Hamersveld KT, Marang-van de Mheen PJ, Koster LA, Nelissen R, Toksvig-Larsen S, Kaptein BL. Marker-based versus model-based radiostereometric analysis of total knee arthroplasty migration: a reanalysis with comparable mean outcomes despite distinct types of measurement error. Acta Orthop. 2019;90:4:366-72.
4. Valstar ER, Gill R, Ryd L, Flivik G, Börlin N, Kärrholm J. Guidelines for standardization of radiostereometry (RSA) of implants. Acta Orthop. 2005;76:4:563-72.
5. Implants for surgery: Roentgen stereophotogrammetric analysis for the assessment of migration of orthopaedic implants: International Organization for Standardization (ISO). ISO16087:2013(E). 2013 (standard reviewed and confirmed in 2019).
6. Teeter MG, Thoren J, Yuan X, McCalden RW, MacDonald SJ, Lanting BA et al. Migration of a cemented fixed-bearing, polished titanium tibial baseplate (Genesis II) at ten years : a radiostereometric analysis. Bone Joint J. 2016;98-b:5:616-21.
7. Molt M, Toksvig-Larsen S. Peri-ApatiteTM Enhances Prosthetic Fixation in Tka-A Prospective Randomised RSA Study. Journal of Arthritis. 2014;3:1-6.
8. Molt M, Toksvig-Larsen S. Similar early migration when comparing CR and PS in Triathlon™ TKA: A prospective randomised RSA trial. Knee. 2014;21:5:949-54.
9. Molt M, Toksvig-Larsen S. 2-year follow-up report on micromotion of a short tibia stem. A prospective, randomized RSA study of 59 patients. Acta Orthop. 2015;86:5:594-8.
10. Hansson U, Toksvig-Larsen S, Ryd L, Aspenberg P. Once-weekly oral medication with alendronate does not prevent migration of knee prostheses: A double-blind randomized RSA study. Acta Orthop. 2009;80:1:41-5.
11. Hilding M, Aspenberg P. Local peroperative treatment with a bisphosphonate improves the fixation of total knee prostheses: a randomized, double-blind radiostereometric study of 50 patients. Acta Orthop. 2007;78:6:795-9.
12. Puijk R, Puijk RH, Laende EK, Dunbar MJ, Plevier JWM, Nolte PA et al. 6-month migration sufficient for evaluation of total knee replacements: a systematic review and meta-analysis. Acta Orthop. 2023;94:577-87.
13. Hasan S, van Hamersveld KT, Marang-van de Mheen PJ, Kaptein BL, Nelissen R, Toksvig-Larsen S. Migration of a novel 3D-printed cementless versus a cemented total knee arthroplasty: two-year results of a randomized controlled trial using radiostereometric analysis. Bone Joint J. 2020;102-b:8:1016-24.
14. van der Lelij TJN, Marang-van de Mheen PJ, Kaptein BL, Toksvig-Larsen S, Nelissen R. Continued Stabilization of a Cementless 3D-Printed Total Knee Arthroplasty: Five-Year Results of a Randomized Controlled Trial Using Radiostereometric Analysis. J Bone Joint Surg Am. 2023;105:21:1686-94.
15. Van Hamersveld KT, Marang-Van De Mheen PJ, Nelissen R, Toksvig-Larsen S. Peri-apatite coating decreases uncemented tibial component migration: long-term RSA results of a randomized controlled trial and limitations of short-term results. Acta Orthop. 2018;89:4:425-30.
16. Molt M, Ryd L, Toksvig-Larsen S. A randomized RSA study concentrating especially on continuous migration. Acta Orthop. 2016;87:3:262-7.
17. Wilson DA, Richardson G, Hennigar AW, Dunbar MJ. Continued stabilization of trabecular metal tibial monoblock total knee arthroplasty components at 5 years-measured with radiostereometric analysis. Acta Orthop. 2012;83:1:36-40.
18. Hasan S, Kaptein BL, Marang-van de Mheen PJ, Van Hamersveld KT, Nelissen R, Toksvig-Larsen S. Late stabilization after initial migration in patients undergoing cemented total knee arthroplasty: a 5-year followup of 2 randomized controlled trials using radiostereometric analysis. Acta Orthop. 2022;93:271-6.
19. Bland JM, Altman DG. Statistical methods for assessing agreement between two methods of clinical measurement. Lancet. 1986;1:8476:307-10.

20. Hurschler C, Seehaus F, Emmerich J, Kaptein BL, Windhagen H. Comparison of the model-based and marker-based roentgen stereophotogrammetry methods in a typical clinical setting. J Arthroplasty. 2009;24:4:594-606.
21. Gudnason A, Adalberth G, Nilsson KG, Hailer NP. Tibial component rotation around the transverse axis measured by radiostereometry predicts aseptic loosening better than maximal total point motion. Acta Orthop. 2017;88:3:282-7.
22. Van Hamersveld KT, Marang-Van De Mheen PJ, Nelissen R, Toksvig-Larsen S. Migration of all-polyethylene compared with metal-backed tibial components in cemented total knee arthroplasty. Acta Orthop. 2018;89:4:412-7.
23. Dunbar MJ, Wilson DA, Hennigar AW, Amirault JD, Gross M, Reardon GP. Fixation of a trabecular metal knee arthroplasty component. A prospective randomized study. J Bone Joint Surg Am. 2009;91:7:1578-86.
24. Christensen R, Ranstam J, Overgaard S, Wagner P. Guidelines for a structured manuscript: Statistical methods and reporting in biomedical research journals. Acta Orthop. 2023;94:243-9.
25. Linde KN, Rytter S, Søballe K, Madsen F, Langdahl B, Stilling M. Component migration, bone mineral density changes, and bone turnover markers in cementless and cemented total knee arthroplasty: a prospective randomized RSA study in 53 patients with 2-year follow-up. Knee Surg Sports Traumatol Arthrosc. 2022;30:9:3100-13.
26. Nilsson KG, Kärrholm J. Increased varus-valgus tilting of screw-fixated knee prostheses. Stereoradiographic study of uncemented versus cemented tibial components. J Arthroplasty. 1993;8:5:529-40.
27. Kaptein BL, Valstar ER, Stoel BC, Reiber HC, Nelissen RG. Clinical validation of model-based RSA for a total knee prosthesis. Clin Orthop Relat Res. 2007;464:205-9.
28. Sandberg OH, Kärrholm J, Olivecrona H, Röhrl SM, Sköldenberg OG, Brodén C. Computed tomography-based radiostereometric analysis in orthopedic research: practical guidelines. Acta Orthop. 2023;94:373-8.

Supplementary data

Table 3. Mean translations (mm) along and rotations (°) about each orthogonal axis with 95% confidence intervals, as derived from the linear mixed-effects model.

	Cemented (n = 34)		**Cementless (n = 35)**	
Axis	Consistent-marker	All-marker	Consistent-marker	All-marker
Follow-up	method	method	method	method
Translation along transverse axis (mm)				
3 months	0.02 (-0.04 to 0.08)	0.01 (-0.06 to 0.07)	-0.05 (-0.11 to 0.00)	-0.05 (-0.12 to 0.01)
1 year	0.04 (-0.02 to 0.10)	0.06 (0.00 to 0.12)	-0.06 (-0.12 to 0.00)	-0.06 (-0.12 to 0.01)
2 years	0.06 (0.00 to 0.12)	0.05 (-0.02 to 0.11)	-0.07 (-0.12 to -0.01)	-0.06 (-0.12 to 0.01)
5 years	0.05 (-0.01 to 0.12)	0.01 (-0.06 to 0.08)	-0.06 (-0.12 to 0.00)	-0.05 (-0.12 to 0.01)
Translation along longitudinal axis (mm)				
3 months	0.02 (-0.04 to 0.08)	0.02 (-0.06 to 0.06)	-0.15 (-0.21 to -0.09)	-0.17 (-0.23 to -0.11)
1 year	0.02 (-0.04 to 0.08)	0.01 (-0.05 to 0.07)	-0.12 (-0.18 to -0.06)	-0.11 (-0.17 to -0.06)
2 years	0.01 (-0.05 to 0.07)	0.01 (-0.05 to 0.07)	-0.13 (-0.19 to -0.08)	-0.13 (-0.19 to -0.07)
5 years	0.03 (-0.03 to 0.10)	0.02 (-0.04 to 0.09)	-0.13 (-0.19 to -0.06)	-0.13 (-0.20 to -0.07)
Translation along sagittal axis (mm)				
3 months	0.02 (-0.07 to 0.12)	0.03 (-0.09 to 0.09)	0.02 (-0.08 to 0.11)	0.01 (-0.08 to 0.10)
1 year	0.06 (-0.04 to 0.15)	0.08 (-0.02 to 0.17)	0.00 (-0.10 to 0.09)	-0.01 (-0.10 to 0.09)
2 years	0.02 (-0.07 to 0.12)	0.03 (-0.07 to 0.13)	-0.03 (-0.12 to 0.07)	-0.01 (-0.11 to 0.08)
5 years	0.05 (-0.05 to 0.15)	0.06 (-0.04 to 0.16)	-0.01 (-0.11 to 0.08)	-0.03 (-0.12 to 0.07)
Rotation about transverse axis (°)				
3 months	0.01 (-0.23 to 0.26)	0.04 (-0.20 to 0.29)	-0.25 (-0.49 to -0.01)	-0.25 (-0.49 to -0.01)
1 year	-0.02 (-0.27 to 0.22)	0.01 (-0.23 to 0.26)	-0.40 (-0.64 to -0.16)	-0.39 (-0.62 to -0.15)
2 years	-0.11 (-0.35 to 0.15)	-0.08 (-0.33 to 0.17)	-0.44 (-0.68 to -0.20)	-0.44 (-0.68 to -0.19)
5 years	-0.10 (-0.36 to 0.16)	-0.07 (-0.33 to 0.19)	-0.42 (-0.67 to -0.17)	-0.42 (-0.67 to -0.17)
Rotation about longitudinal axis (°)				
3 months	-0.04 (-0.12 to 0.03)	-0.04 (-0.12 to 0.04)	0.01 (-0.07 to 0.08)	0.02 (-0.06 to 0.09)
1 year	-0.03 (-0.11 to 0.04)	-0.03 (-0.11 to 0.05)	-0.02 (-0.10 to 0.05)	-0.03 (-0.11 to 0.04)
2 years	-0.02 (-0.09 to 0.06)	-0.02 (-0.10 to 0.06)	-0.02 (-0.10 to 0.05)	-0.02 (-0.10 to 0.06)
5 years	-0.05 (-0.13 to 0.03)	-0.07 (-0.15 to 0.02)	0.03 (-0.05 to 0.11)	0.04 (-0.04 to 0.12)
Rotation about sagittal axis (°)				
3 months	0.02 (-0.08 to 0.12)	0.03 (-0.07 to 0.14)	0.13 (0.03 to 0.23)	0.12 (0.02 to 0.23)
1 year	-0.02 (-0.12 to 0.08)	-0.04 (-0.14 to 0.07)	0.11 (0.01 to 0.20)	0.11 (0.01 to 0.21)
2 years	-0.04 (-0.14 to 0.06)	-0.03 (-0.14 to 0.07)	0.11 (0.01 to 0.21)	0.12 (0.02 to 0.22)
5 years	-0.08 (-0.19 to 0.02)	-0.04 (-0.16 to 0.07)	0.04 (-0.06 to 0.15)	0.05 (-0.05 to 0.16)

Table 6. Mean translations (mm) along and rotations (°) about each orthogonal axis with 95% confidence intervals, as derived from the linear mixed-effects model, when using 5 fictive points (FP) matched either with a consistent set of actual markers or all available markers in each follow-up.

	Cemented (n = 34)		**Cementless (n = 35)**	
Axis *Follow-up*	Consistent-marker method	All-marker method	Consistent-marker method	All-marker method
Translation along transverse axis (mm)				
3 months	0.02 (-0.04 to 0.08)	0.01 (-0.06 to 0.07)	-0.05 (-0.11 to 0.00)	-0.05 (-0.12 to 0.01)
1 year	0.04 (-0.02 to 0.10)	0.06 (-0.01 to 0.12)	-0.06 (-0.12 to 0.00)	-0.06 (-0.12 to 0.01)
2 years	0.06 (0.00 to 0.12)	0.05 (-0.02 to 0.12)	-0.06 (-0.12 to -0.01)	-0.06 (-0.12 to 0.00)
5 years	0.05 (-0.01 to 0.11)	0.02 (-0.05 to 0.08)	-0.06 (-0.12 to 0.00)	-0.05 (-0.12 to 0.01)
Translation along longitudinal axis (mm)				
3 months	0.02 (-0.03 to 0.08)	0.02 (-0.04 to 0.07)	-0.17 (-0.22 to -0.11)	-0.18 (-0.23 to -0.12)
1 year	0.02 (-0.04 to 0.07)	0.01 (-0.04 to 0.07)	-0.14 (-0.20 to -0.09)	-0.14 (-0.20 to -0.09)
2 years	0.00 (-0.06 to 0.06)	0.00 (-0.06 to 0.05)	-0.15 (-0.20 to -0.09)	-0.15 (-0.20 to -0.09)
5 years	0.02 (-0.04 to 0.08)	0.02 (-0.04 to 0.08)	-0.13 (-0.19 to -0.07)	-0.14 (-0.20 to -0.09)
Translation along sagittal axis (mm)				
3 months	0.02 (-0.07 to 0.11)	0.03 (-0.06 to 0.12)	0.01 (-0.08 to 0.10)	0.00 (-0.09 to 0.10)
1 year	0.05 (-0.04 to 0.14)	0.08 (-0.02 to 0.17)	-0.01 (-0.10 to 0.08)	-0.01 (-0.10 to 0.09)
2 years	0.01 (-0.08 to 0.11)	0.03 (-0.07 to 0.12)	-0.02 (-0.12 to 0.07)	-0.01 (-0.10 to 0.09)
5 years	0.03 (-0.06 to 0.14)	0.05 (-0.05 to 0.15)	-0.02 (-0.11 to 0.08)	-0.02 (-0.13 to 0.07)
Rotation about transverse axis (°)				
3 months	0.02 (-0.23 to 0.23)	0.04 (-0.20 to 0.24)	-0.24 (-0.48 to -0.01)	-0.25 (-0.49 to -0.01)
1 year	-0.02 (-0.26 to 0.22)	0.01 (-0.23 to 0.25)	-0.40 (-0.64 to -0.17)	-0.39 (-0.63 to -0.15)
2 years	-0.11 (-0.35 to 0.14)	-0.08 (-0.33 to 0.16)	-0.44 (-0.68 to -0.20)	-0.44 (-0.68 to -0.19)
5 years	-0.09 (-0.35 to 0.16)	-0.07 (-0.03 to 0.19)	-0.42 (-0.66 to -0.17)	-0.42 (-0.66 to -0.17)
Rotation about longitudinal axis (°)				
3 months	-0.04 (-0.12 to 0.03)	-0.04 (-0.12 to 0.03)	0.01 (-0.06 to 0.09)	0.02 (-0.06 to 0.10)
1 year	-0.04 (-0.11 to 0.04)	-0.03 (-0.10 to 0.05)	-0.02 (-0.09 to 0.05)	-0.03 (-0.10 to 0.05)
2 years	-0.02 (-0.09 to 0.06)	-0.02 (-0.10 to 0.06)	-0.02 (-0.09 to 0.05)	-0.02 (-0.10 to 0.05)
5 years	-0.05 (-0.13 to 0.03)	-0.07 (-0.15 to 0.02)	0.02 (-0.05 to 0.10)	0.04 (-0.04 to 0.12)
Rotation about sagittal axis (°)				
3 months	0.02 (-0.08 to 0.12)	0.03 (-0.07 to 0.13)	0.13 (0.04 to 0.10)	0.12 (0.02 to 0.23)
1 year	-0.02 (-0.12 to 0.08)	-0.04 (-0.14 to 0.06)	0.11 (0.01 to 0.20)	0.11 (0.01 to 0.21)
2 years	-0.04 (-0.14 to 0.06)	-0.04 (-0.14 to 0.07)	0.11 (0.02 to 0.21)	0.12 (0.02 to 0.23)
5 years	-0.08 (-0.19 to 0.02)	-0.04 (-0.16 to 0.07)	0.04 (-0.06 to 0.14)	0.05 (-0.05 to 0.16)

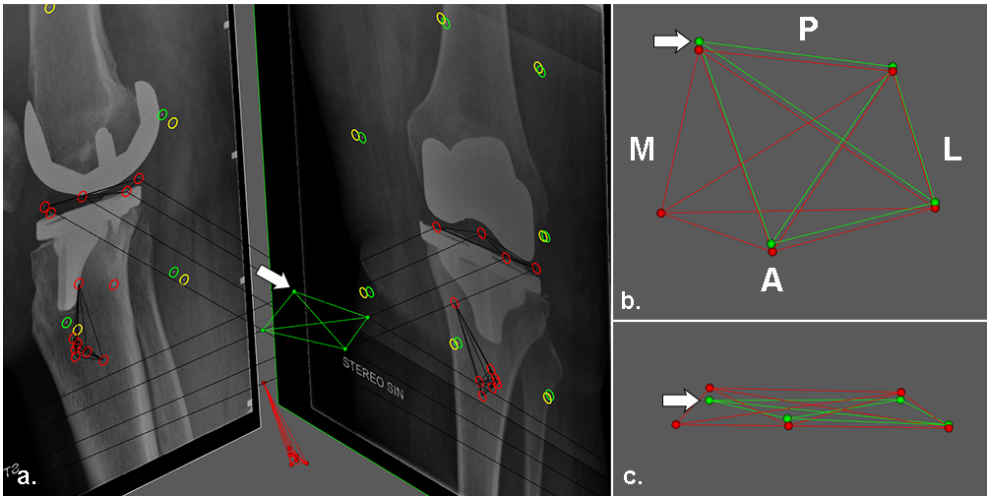


Figure 3. Figure showing the RSA examination with the greatest difference in MTPM between the consistent versus all-marker method (a). The PE markers are shown from (b) superiorly and (c) anteriorly. Markers in red represent markers from the baseline image and green markers represent the markers from the specific follow-up examination. The difference in MTPM is cause by the medio-posterior marker (arrow), which is the marker that moved the most. In the consistent-marker method, this specific marker is not used for the migration calculation, because in another RSA examination of the same patients this marker was overprojected. As a result, the MTPM with the all-marker method is higher than with the consistent-marker method. A = anterior, P = posterior, M = medial, L = lateral.

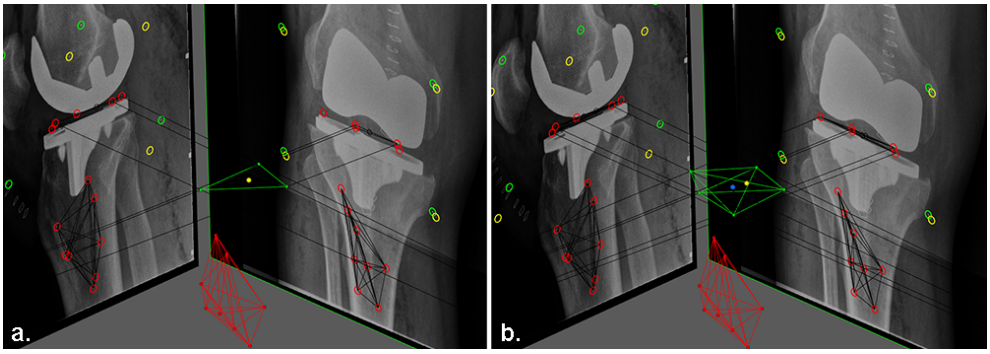
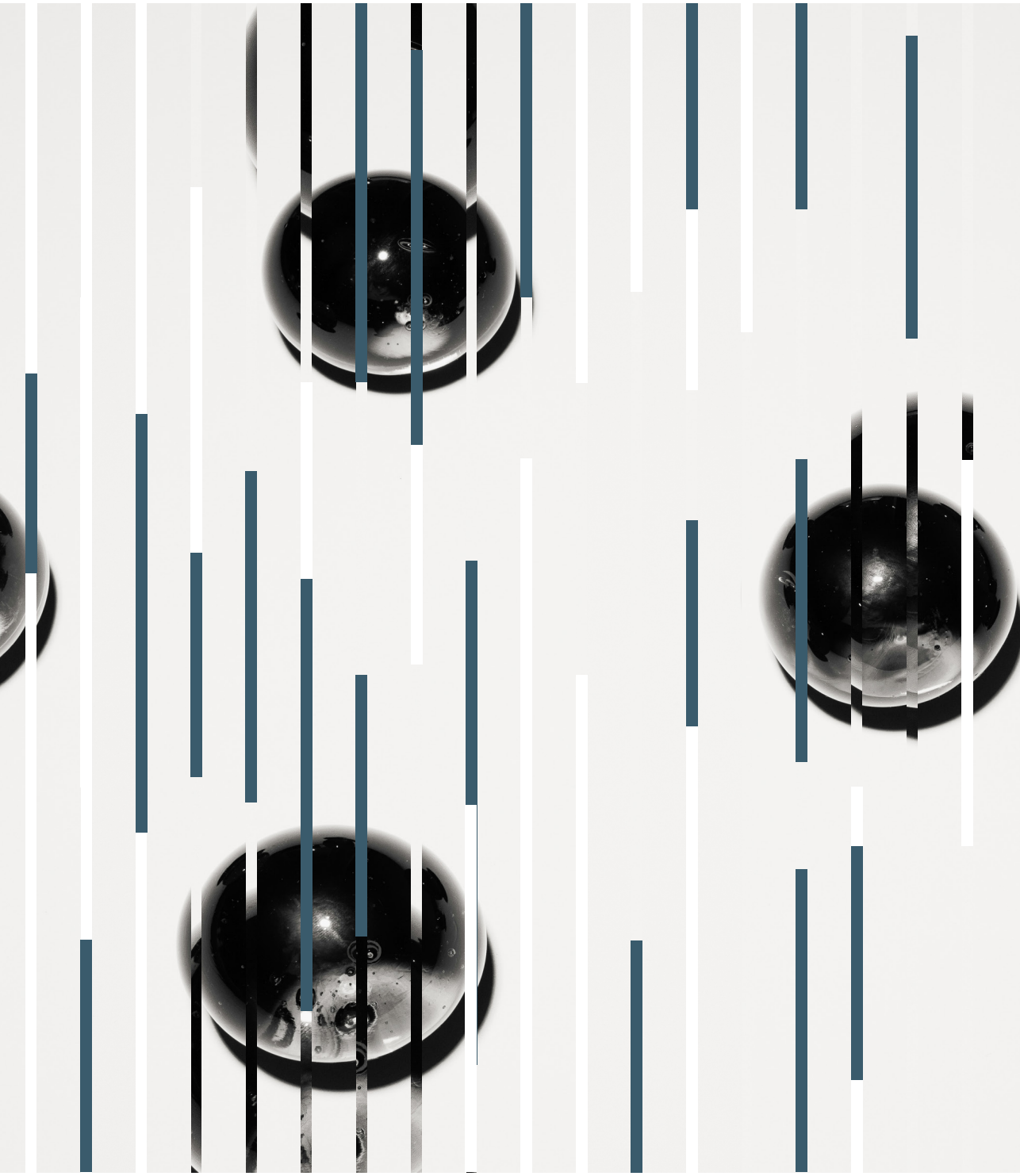


Figure 5. Figure showing the different set of makers of the migrating rigid body (prosthesis) in the reference RSA examination, as used for the migration calculations with (a) the consistent-marker method and (b) the all-marker method. The reference origin (geometrical center) for the migrating coordinate system that is used with the consistent-marker method (yellow point) differs from the reference origin that is used with the all-marker method (blue point).



Chapter 6

Adherence to the RSA and CT-RSA guideline items in clinical prosthesis migration studies: A systematic review

T.J.N. van der Lelij
L.A. Koster
B.L. Kaptein
R.G.H.H. Nelissen
P.J. Marang-van de Mheen

Acta Orthopaedica
2025 May 27;96:380-386

Abstract

Background and purpose

Standardized reporting on methodology and results in clinical RSA research papers facilitates evaluation of quality and interpretation of results. We aimed to assess the extent to which radiostereometric analysis (RSA) and computed tomography-based RSA (CTRSA) studies adhered to the items of the new RSA reporting guideline from 2024.

Methods

A systematic literature search was performed to identify all clinical RSA studies published between January 2012 and February 2024. Studies were eligible for inclusion if prosthesis migration over time was assessed. The adherence of studies to each applicable guideline item (full, partial, or no) was assessed.

Results

285 studies were included, most of which assessed prosthesis migration in the hip (n = 161) or knee (n = 99). No study reported on all guideline items. The mean (full or partial) adherence of studies to all (applicable) items was 61% (standard deviation [SD] 11). Large variation between the reporting of items was found, ranging from being reported in 1% of the studies to 100%. The least reported items in studies were the mean number and SD of days between surgery and baseline RSA examination (8% of studies), mean number and SD of days between surgery and primary endpoint RSA examination (1%), and consistent- or all-marker method for RSA analysis (3%).

Conclusion

Current studies on average reported only 61% of the items from the updated RSA guidelines. Adherence to the guidelines in clinical RSA studies on prosthesis migration should be improved, in order to improve the quality of studies and the interpretation of outcomes on implant migration.

Introduction

The reporting quality of radiostereometric analysis (RSA) studies has greatly improved after publication of the first RSA guidelines (1, 2). The guideline for standardization (2005) and the ISO standard for RSA (ISO 16087:2013) aimed to facilitate consistency in the execution, presentation, and interpretation of RSA studies (1). High reporting quality is a prerequisite for assessing methodological quality of a study. It has been shown that the proportion of RSA studies with high reporting quality increased almost 3-fold in the period 2006 to 2011 compared with the period before the 2005 guideline (2, 3). Still, the overall adherence of clinical studies to guideline items remained relatively low (2).

Recently, updated guidelines for RSA and computed tomography RSA (CT-RSA) studies were published by a group of RSA researchers from the International Radiostereometry Society (4). As migration assessment methods have been further developed and introduced in the past decade, there was a need to update the guidelines to make them better aligned with current standards (4-6). A new reporting checklist with 32 items was presented to serve as a reference for prosthesis migration studies (Table 1) (4). 10 items were already (partially) listed in standardized output for clinical RSA studies in the previous RSA guidelines (Table 2, Appendix) (1). The other 22 items, not previously included in the standardized output, are expected to be used in different RSA studies since the updated guidelines reflect the current RSA reporting standard by experts in the field.

The aim of this study was to assess to what extent RSA studies on prosthesis migration adhered to items presented in the updated RSA guidelines. Examining adherence and particularly those items frequently not reported may encourage researchers of future studies to improve the reporting quality of RSA studies and thereby their clinical value in the safe introduction of new implants.

Table 1. Checklist items for prosthesis migration studies as presented in the updated RSA and CT-RSA guidelines (adapted from Kaptein et al. 2024).

Checklist item		Studies where item was applicable (n)
Title and abstract		
1.	Identification as a radiostereometric (RSA) study or CT-based radiostereometric (CT-RSA) study in the title.	285
2.	Identification as a radiostereometric (RSA) study or CT-based radiostereometric (CT-RSA) study in the abstract and keywords.	285
Methods		
3.	Report papers/references where prior results or partial results can be found (e.g., the 2-year results have been published previously reported [REF]).	285
4.	First and last inclusion (e.g., March 1998-December 2000).	285
5.	Country and hospital(s) where surgeries were performed.	285
6.	Number of surgeons (and number of surgeries per surgeon) that performed the surgeries.	285
7.	Detailed description of prosthesis, cement/coating, and liner characteristics for each study group.	285
8.	Report whether the first postoperative examination was obtained before or after weightbearing.	285
9.	Mean number and SD of days between surgery and the baseline RSA examination.	285
10.	Mean number and SD of days between surgery and the primary endpoint RSA examination.	285
11.	Migration measurement method (marker-based RSA, model-based RSA, CT-RSA).	285
12.	Patient position (supine, weightbearing).	285
13.	Software used, including version number.	285
14.	Location and orientation of the migration coordinate system.	285
15.	Use of fictive/feature points to calculate MTPM.	150
Marker-/model-based RSA technique		
16.	Image resolution (DPI) and type (CR, DR, film) of X-ray detectors.	283
17.	Material and size of markers.	283
18.	Calibration cage used, including type (uniplanar, bi-planar).	283
19.	Cut-off values for condition number and mean error of rigid body fitting.	283
20.	Consistent- or all-marker method for RSA analysis.	283
CT-RSA technique		
21.	CT-scanner brand and model.	5
22.	Voxel size, slice thickness, kV, mAs.	5
23.	Was metal artifact reduction used.	5
24.	Effective radiation dose in mSV (for hip, spine, shoulder).	5
Results		
25.	Number of migration examinations for each study group and follow-up timepoint used in the primary analysis.	285
26.	Number and reasons why migration examinations (including double examinations) where missing or excluded; may also be reported in the methods.	285
27.	All migration data should be presented in millimeters (translations) and degrees (rotations).	285
28.	Double examinations: mean, SD, and n for all outcome variables in the study (including 3 translations, 3 rotations, MTPM, TT, and TR if relevant) should be presented in a table for each study group separately.	285

29.	Mean and SD of number of markers, condition number, and mean error of rigid-body fitting for each rigid body (bone/prosthesis) at the primary follow-up timepoint.	285
30.	Unmodelled (raw data) of translation, rotation, and MTPM results: mean, n, and one of the following [CI, SD], or median and interquartile range for non-normal data for each study group and follow-up timepoint should be presented in a table or figure or both. If this table or figure does not fit in the manuscript, then it should be placed in supplementary data, or at least be available upon request.	285
31.	Number of prosthesis revision/failures in each treatment group, including reason (e.g., revision due to aseptic loosening).	285
32.	Migration values at the last follow-up before revision or failure.	176

Methods

The present systematic review is reported in accordance with the Preferred Reporting Items for Systematic Reviews and Meta-Analyses (PRISMA) statement (see Supplementary Data) (7).

Search, screening, and selection

A systematic literature search was constructed by an experienced clinical librarian (JS). PubMed, Cochrane Library, Embase, Emcare, Academic Search Premier, and Web of Science were searched to identify all publications published between January 2012 and February 2024, as Madanat et al. (2) have already assessed adherence among studies published up to December 2011. The search was composed of the components "RSA" and "Prosthesis" (see Supplementary data). No term for specific joints (e.g. hip, knee, or shoulder) was added, as the guidelines are not specific for the type of joint or prosthesis assessed in the studies. After removal of duplicate studies, title and abstract screening was performed independently by 2 reviewers (TJNvdL and LAK). Subsequently, the full-text screening was independently performed by the same 2 reviewers and any disagreements were resolved through discussion.

Studies were eligible for inclusion if prosthesis migration relative to its surrounding bone was assessed in humans in vivo over time using RSA. There were no restrictions with regard to the RSA method used (marker-based RSA, model-based RSA, CT-RSA), study design (RCT, cohort study, case series), sample size, or follow-up time. Articles in English, Dutch, German, and French were considered and translated if necessary. Studies were excluded if only wear (of the polyethylene components) or inducible displacement (i.e., displacement

occurring instantaneously as a result of an external load such as weightbearing) was assessed.

Data extraction

Data were extracted, independently, by 2 reviewers (TJNvdL and LAK) using a prespecified SPSS file (IBM SPSS Statistics 29.0; IBM Corp). For each study, the first author's name, title, year of publication, journal, country in which the study was performed, study design, number of included patients, type of arthroplasty, type of RSA method, and duration of follow-up were extracted. We assessed if prosthesis migration was the primary or secondary outcome of the study. Additionally, it was determined whether original migration data were presented or whether a reanalysis of previously published migration data was performed. Both reviewers evaluated each study for their adherence to the reporting checklist as presented in the updated RSA guidelines. Only applicable items were evaluated for each study. For example, a study using marker-based or model-based RSA does not need to adhere to items 21 to 24, as these are only relevant for CT-RSA studies (Table 1). Also, when no maximum total point motion (MTPM) is calculated, a study will not report whether fictive/feature points are used (item 15). If there were no revisions in a study, migration values at the last follow-up before revision can also not be given (item 32). 21 items could be scored as full, partial (reporting at least 1 issue/sub-item), or no adherence. 11 items could only be scored as full or no adherence. Consensus was reached between the reviewers through discussion if different information was extracted or in case of disagreement in scoring items.

Ethics, registration, data sharing, funding, and disclosure

No ethical approval was required for this study as the data was retrieved from previously published studies. A protocol for this systematic review was registered with PROSPERO prior to screening of studies (ID:CRD42024540186). No funding was acquired for the present review and the authors declare no competing interest.

Results

Literature search and study selection

Our literature search identified 2,257 unique records that were screened for eligibility (Figure 1). After title and abstract screening, 1,859 studies were excluded. Following the exclusion of 108 studies based on the full text and 5 reports that could not be retrieved, 285 eligible studies were included (see Supplementary data).

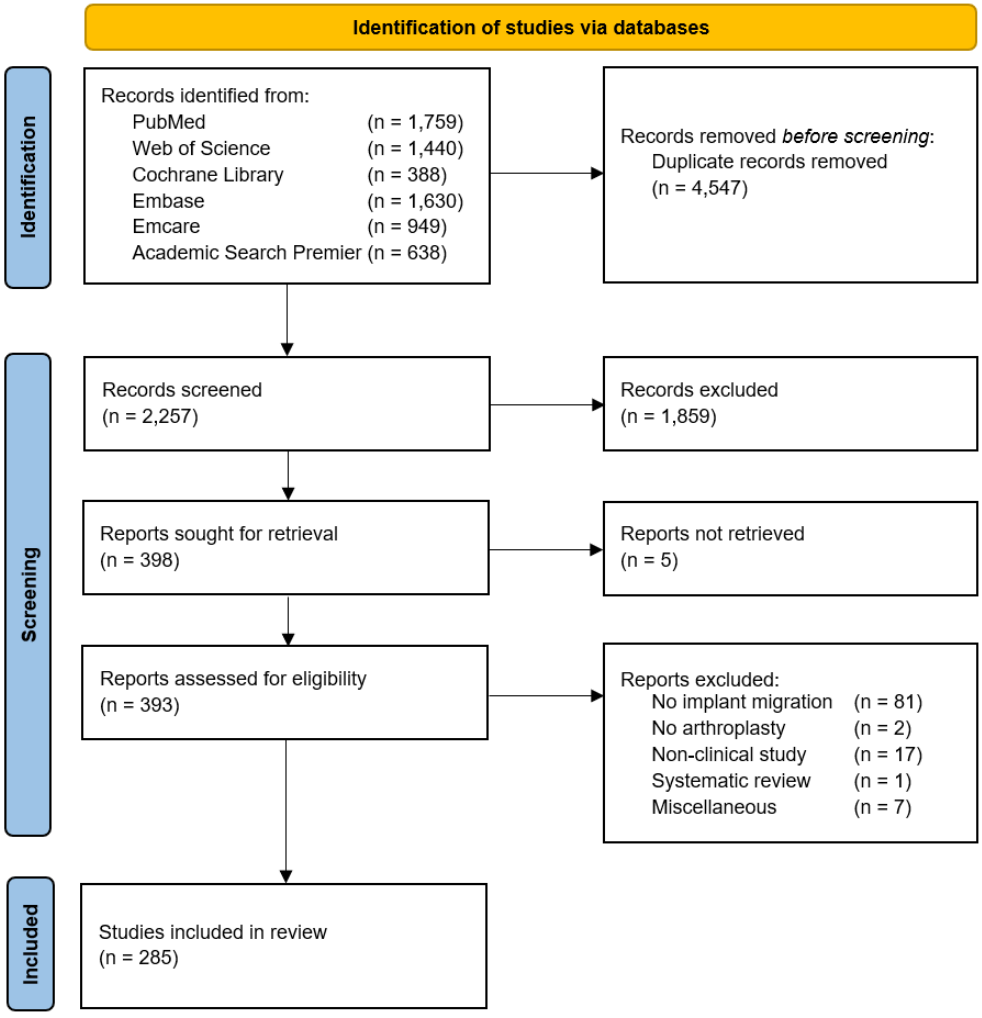


Figure 1. PRISMA flow diagram

Characteristics of included studies

The majority (n = 194) of the studies was performed in Denmark, Finland, The Netherlands, Norway, and Sweden (Table 3). Most studies were published in Acta Orthopaedica (n = 77), The Bone & Joint Journal (n = 53), and The Journal of Arthroplasty (n = 28). The annual number of published RSA studies showed an increasing trend in the last decade after a slight drop in 2013 (Figure 2).

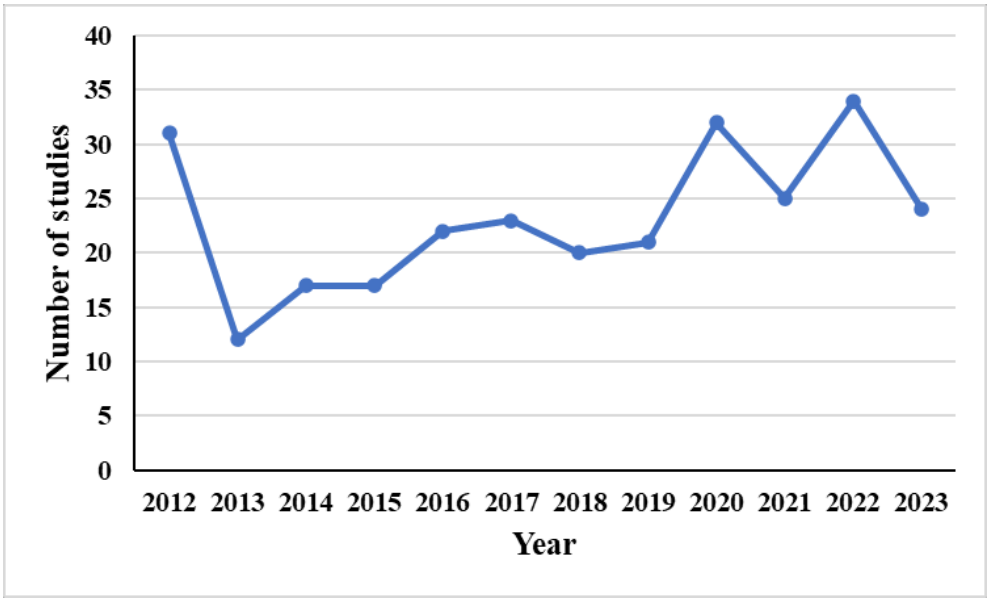


Figure 2. The annual number of clinical RSA studies on prosthesis migration.

Prosthesis migration over time was the primary outcome of 244 studies, compared with 41 studies that assessed migration as a secondary outcome. 260 studies presented original clinical migration data, whereas 25 studies performed a reanalysis of previously published implant migration data. 149 randomized controlled trials (RCTs), 135 cohort studies or case series, and 1 case report were included. Model-based RSA was applied in most studies (n = 158), followed by marker-based RSA (n = 128) (Table 3). The median sample size was 47 patients (interquartile range [IQR] 29 to 61) with a median follow-up time of 2 years (IQR 2 to 5). Various prosthesis components were assessed, including tibial (n = 96) and femoral (n =17) components in the knee, and acetabular (n = 60) and femoral (n = 106) components in the hip (Table 4).

Table 3. Characteristics of all clinical RSA studies on prosthesis migration published between 2012 and 2024.

	Number of studies
Country of study	
NOF countries *	194
Rest of Europe **	29
Northen America	44
Australia	18
Journal of publication	
Acta Orthopaedica	77
The Bone & Joint Journal	53
The Journal of Arthroplasty	28
The Journal of Bone & Joint Surgery	16
Knee Surgery, Sports Traumatology, Arthroscopy	10
Hip International	22
Other	79
Type of RSA method used * **	
Marker-based RSA	128
Model-based RSA	158
CT-based RSA	5
Non-specified	9

NOF = Nordic European Federation.
* Denmark, Finland, The Netherlands, Norway, and Sweden.
** Croatia, Germany, Italy, United Kingdom, and Switzerland.
*** Some studies applied 2 RSA methods.

Table 4. Prosthesis components of which migration was assessed in clinical RSA studies.

	Number of studies
Knee	
Tibial component	96
Femoral component	17
Hip	
Acetabular component	60
Femoral component	106
Ankle/foot	
Tibial component (Talocrural joint)	1
Talar component (Talocrural joint)	1
Proximal Phalanx Component (MTP-1 joint)	1
Shoulder	
Glenoid component	9
Humeral component	7
Elbow	
Humeral component	2
Wrist/hand	
Radial component (Radiocarpal joint)	1
Carpal component (Radiocarpal joint)	1
Trapezoid component (CMC-1 joint)	3
Spine	
Superior vertebral component (Cervical spine)	1
Inferior vertebral component (Cervical spine)	1

The total number of studies presented in this table exceeds 285, as some studies assessed the migration of multiple prosthesis components.

Adherence of studies to updated RSA guidelines

None of the studies reported all items from the updated RSA guidelines. Studies adhered (full or partial) to a mean of 61% (standard deviation [SD] 11%) of all applicable guideline items (Figure 3). The study with the highest adherence reported 92% of all applicable items (full or partial). The study with the lowest adherence reported only 22% of the applicable items. 51 studies reported 50% or less of the guideline items. When considering only full adherence (no partial) to the checklist items, the study with the greatest adherence completely reported 65% of all applicable items. The study with the lowest adherence only fully adhered to 1 item of the guideline (4%).

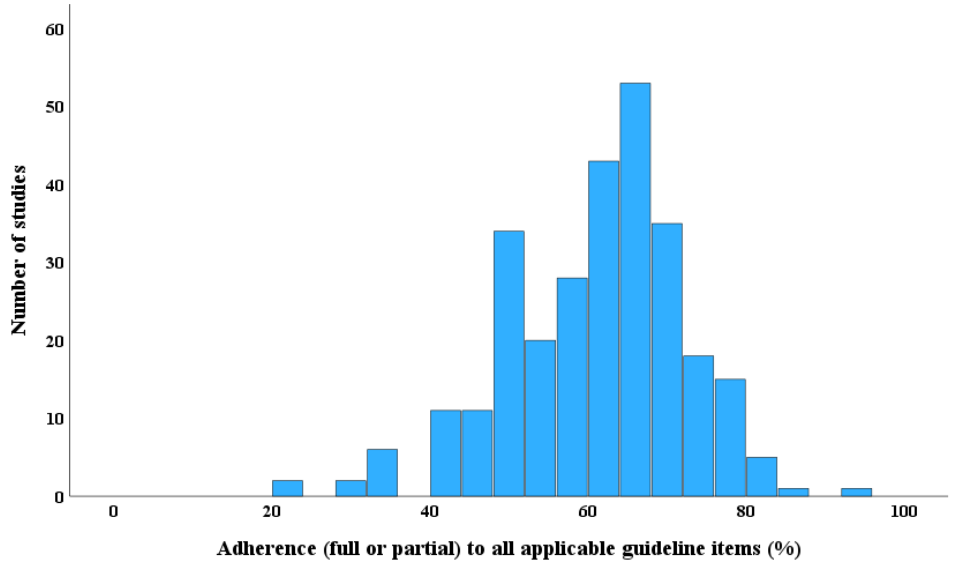


Figure 3. Adherence of RSA studies to the guidelines items (when items were applicable).

The items most frequently reported (fully or partially) were items 2 (i.e., identification RSA in abstract and keywords, reported by 100% of studies for which it was applicable), 7 (i.e., description prosthesis; 99% of studies for which it was applicable), 11 (RSA method; 93% of studies for which it was applicable), 24 (CT-scanner brand and model; 100% of studies for which it was applicable), and 27 (migration data in millimeters and degrees; 99% of studies for which it was applicable) (Figure 4). Still, a considerable number of studies did not fully adhere to these items but only partially. For example, most studies reported the type of prosthesis used but without a detailed description of all components

(e.g., liner characteristics, such as highly cross-linked polyethylene or vitamin E infused) (item 7). Also, most studies could not fully adhere to item 2 (identification RSA in abstract and keywords), as some journals do not present keywords in the full text paper.

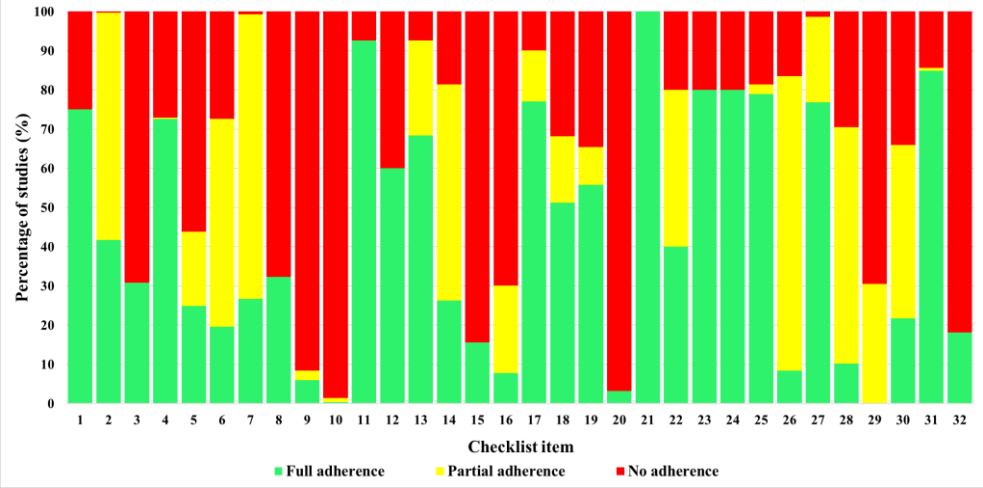


Figure 4. Adherence of RSA studies to the guidelines items (when items were applicable).

Items 9 (i.e., days to baseline RSA), 10 (i.e., days to primary endpoint RSA), and 20 (i.e., consistent-or all-marker method) were only reported (fully or partially) in, respectively, 8%, 1%, and 3% of the studies. There was one item (item 29; markers, condition number, and mean error) that no study fully adhered to (Figure 4). To fully adhere to item 29, the mean and SD of both the number of markers, condition number, and mean error of rigid-body fitting for each rigid body (bone/prosthesis) at the primary follow-up timepoints needs to be reported.

Discussion

We aimed to assess the extent to which RSA and CT-RSA studies adhered to the items of the new RSA reporting guideline from 2024. During the last decade, RSA studies on prosthesis migration reported only 61% of the recently published RSA guideline checklist items. Moreover, large variation between studies existed and some items were rarely reported. The present review provides an overview of current practice and offers directions on where the reporting quality of RSA can be improved. Although all studies were published before

publication of the new guideline (May 2024), the guidelines can be considered to reflect the current reporting standard in the field of RSA, based on the opinion of expert swho may also have acted as reviewers for RSA studies and thereby signaled missing information, so we may expect that studies included in this review would adhere to (most of) the items. Moreover, the items presented in the RSA guideline should be viewed as a minimum and authors are encouraged to provide additional information when deemed necessary (4).

Nevertheless, not all guideline items can be applied in every study; however, this is not always clear for specific items. For example, when a study does not report where prior or partial results can be found (item 3), the reader may be left uncertain as to whether such results do not exist or whether the authors simply failed to report their location. To enhance the utility and practical implantation of the RSA guideline in future clinical studies, we propose some clarifications of the RSA guideline checklist (Table 5). In this respect, item 32 states that migration values at the last follow-up before revision or failure need to be reported, but does not specify whether this should be the mean migration of the revised implants or the complete study group or individual implant migration of the revised implants. For clarity, mean migration of the revised and non-revised group as well as individual implant migration of revised implants should be given. As for the last 2 checklist items (31 and 32), the definition of "failure" of a prosthesis is ambiguous and may differ between studies. Thus, a clear definition of "failure" should be given in the text. As for item 29, which is only relevant when marker- or model-based RSA is used, this should be part of the "methods RSA technique" section (see Tables 1 and 5)

Item 25 states that the number of migration examinations for each study group and follow-up timepoint used in the primary analysis should be presented. However, in clinical RSA studies it is often unclear what constitutes the "primary analysis." In the context of clinical trials, the primary analysis refers to the analysis prespecified in the protocol that will answer the main research question, mostly using an intention-to-treat approach, whilst a secondary analysis can use an as-treated approach. When the migration up to 2-year follow-up is reported as the primary outcome, this means that the migration results of all previous follow-up moments are also included in the analysis and therefore that it holds merit to report the included examinations at all timepoints included in the analysis. Using a complete study flow diagram would solve this problem by showing both the number of patients and included examinations for each group at all different follow-up timepoints. Such a flow

diagram can also be used to adequately report the number of and reason why migration examinations were missing (item 26).

Table 5. Proposal for updated checklist for prosthesis migration studies.

Checklist item
Title and abstract
- Identification as a radiostereometric (RSA) study or CT-based radiostereometric (CT-RSA) study in the title.
- Identification as a radiostereometric (RSA) study or CT-based radiostereometric (CT-RSA) study in the abstract **(**and keywords **if available)**.
Methods
- Report papers/references where prior results or partial results can be found (e.g., the 2-year results have been published previously reported [REF]) **(if applicable)**.
- First and last ~~inclusion~~ **date of surgery of included patients** (e.g., March 1998-December 2000).
- Country and hospital(s) where surgeries were performed.
- Number of surgeons (and number of surgeries per surgeon **in each study group**) that performed the surgeries.
- Detailed description of **all components of the** prosthesis, **including** cement/coating, and liner characteristics for each study group.
- Report whether the first postoperative examination was obtained before or after weightbearing **(for joints of the lower extremities or spine)**.
- Mean number and SD**, or median and IQR,** of days**, weeks, months, or years** between surgery and the baseline RSA examination.
- Mean number and SD**, or median and IQR,** of days between surgery and the primary endpoint RSA examination.
- Migration measurement method (marker-based RSA, model-based RSA, CT-RSA).
- Patient position (supine, weightbearing) **during all follow-up examinations**.
- Software used, including version number.
- Location and orientation of the migration coordinate system.
- Use of fictive/feature points to calculate MTPM **(if applicable)**.
Marker-/model-based RSA technique
- Image resolution (DPI) and type (CR, DR, film) of X-ray detectors.
- Material and size of markers.
- Calibration cage used, including type (uniplanar, bi-planar).
- Cut-off values for condition number and mean error of rigid body fitting.
- **Mean and SD of number of markers, condition number, and mean error of rigid-body fitting for each rigid body (bone/prosthesis) at the primary follow-up timepoint.**
- Consistent- or all-marker method for RSA analysis.
CT-RSA technique
- CT-scanner brand and model.
- Voxel size, slice thickness, kV, mAs.
- Was metal artifact reduction used.
- Effective radiation dose in mSV (for hip, spine, shoulder).
Results
- Number of migration examinations for each study group and follow-up timepoint used in the primary analysis.
- Number and reasons why migration examinations (including double examinations) where missing or excluded **at each timepoint for each study group**; may also be reported in the methods.
- All migration data should be presented in millimeters (translations) and degrees (rotations).
- Double examinations: mean, SD, and n for all outcome variables in the study (including 3 translations, 3 rotations, MTPM, TT, and TR if relevant) should be presented in a table for each study group separately.
~~- Mean and SD of number of markers, condition number, and mean error of rigid-body fitting for each rigid body (bone/prosthesis) at the primary follow-up timepoint.~~

- Unmodelled (raw data) of translation, rotation, and MTPM results: mean, n, and one of the following [CI, SD], or median and interquartile range for non-normal data for each study group and **all** follow-up timepoint should be presented in a table or figure or both. If this table or figure does not fit in the manuscript, then it should be placed in supplementary data, or at least be available upon request.
- Number of prosthesis revision~~/failures~~ in each treatment group, including reason (e.g., revision due to aseptic loosening).
- **If revisions occurred, provide** migration values at the last follow-up before revision ~~or failure~~ **for each revised prosthesis individually.**

Proposed changes to the checklist are in bold (addition) or as strikethrough (removal)

An explanation for the moderate adherence of clinical RSA studies to the checklist items could be the strict formulation and interpretation of listed items. For example, 2 of the least reported items (9 and 10) state that the mean and SD of days between surgery and both baseline RSA examination and primary RSA endpoint need to be reported. Some studies provided the median and IQR as alternative measures of the variation, which provides relevant information on the distribution, and are preferred for data with a non-normal distribution (see Figure 4).

Authors may miss some of the recommendations that were described in the text of the guideline paper if they focus only on the checklist of the new RSA guideline. For example, in the text of the updated guidelines it is described that a consistent set of fictive points to report MTPM is advised for marker-based RSA and CT-RSA, but not for model-based RSA (even though the reason for this remains unclear considering the fact that both CT-RSA and model-based RSA use prosthesis models with a large number of points on the outer surface). However, the reporting checklist does not restrict the use of fictive/feature points to calculate MTPM to specific RSA methods. According to the checklist, all studies should report the use of fictive/feature points to calculate MTPM, regardless of RSA method, which may explain the relatively low adherence to item 15. As for item 30, the checklist states that unmodelled (raw) data of translation, rotation, and MTPM results should be presented. However, in the text of the guidelines it is advised to use suitable statistical analysis techniques such as (generalized) linear mixed models (LMM) to analyze the results. When only unmodeled data has to be presented, this may give biased mean results for each study group as missing data and correlations between measurements of the same patients are not accounted for.

The least reported item was the use of the consistent- or all-marker method (item 20). A recent paper drew attention to the issue of different marker-selection methods and their influence on migration results, so that reporting of this item may improve in future

studies (8). Finally, although the migration measurement method (item 11) was frequently reported in studies, we wish to draw attention to some of the implicit assumptions being made (see Figure 4). If a study merely describes that markers were attached to the prosthesis, this does not automatically indicate that marker-based RSA was used for the migration analysis, as it is still possible to perform migration analysis with model-based RSA. Furthermore, the name of the software "Model-Based RSA (RSAcore, Leiden, The Netherlands)" may be confusing for readers not familiar with RSA, as both marker- and model-based RSA analysis can be performed with this software. Therefore, the RSA method used for analysis should be explicitly reported.

Madanat et al. (2) previously reported that nearly half of the studies published between 2006 and 2011 adhered at least partially to 10 of the 13 old RSA guideline items published in 2005, whereas this was less than one-fifth of the studies published between 2000 and 2005. Therefore, it might be expected that adherence to the updated guideline items will also increase following publication of the new guideline in 2024. However, Madanat et al. (2) also found that even after publication of the old RSA guidelines in 2005, none of the studies fully met all guideline items. The latter underlines the importance of the present review, as we highlight topics that are frequently missing to promote their reporting in future studies.

Limitations

First, we searched only for clinical studies using RSA to assess implant migration. However, studies using other methods to assess implant migration exist, such as Ein Bild Roentgen Analysis (EBRA) and CT-based implant migration analysis without the term RSA, which may have been missed by our literature search (9-11). For implant migration studies that do not include the term RSA, we expect that these authors are not aware of the RSA method and guidelines. Second, we assessed the reporting quality of studies performed between 2012 and 2024, before publication of the updated RSA guidelines in 2024. However, as the updated RSA guidelines represent current practice, we expected the papers to generally adhere to the items. Third, follow-up studies may reference papers with prior results, which may give a more detailed description of the methods, but items from these previous studies were not accounted for in the evaluation of the follow-up studies. However, in the opening remarks of the updated RSA guideline it is stated that deviations from these guidelines should have the

underlying rationale stated. This provides researchers with the flexibility to not report all items and assists in the practical implementation of the updated guidelines.

Conclusion

Clinical RSA studies on prosthesis migration on average reported only 61% of the items presented in the recently published RSA guidelines. In perspective, our results can be used by RSA researchers and clinicians to guide interpretation of items and highlight the importance of complete reporting to improve the reporting quality for future studies. Furthermore, we argue that rewording of specific checklist items may also contribute to increased adherence of clinical RSA studies to the updated RSA guidelines. Further, we urge the reviewers of RSA manuscripts to ask for the reporting checklist and that this should be available as supplementary material as for any other reporting guideline.

Acknowledgements

The authors would like to thank Jan Schoones (JS), clinical librarian, for his help with performing the literature search.

Appendix

Table 2. Standardized output for clinical RSA studies from the old RSA guidelines.

Adapted from: Valstar et al. Guidelines for standardization of radiostereometry (RSA) of implants. Acta Orthopaedica. 2005;76(4):563-572.

1.	The units used for translation should always be millimetres and the units used for rotations should be degrees.
2.	The accuracy and precision of the arrangement used should be presented. Measurement interval and window tolerance should be quoted.
3.	Type of calibration cage (object) and use of reference plates should be given.
4.	It should be stated whether fixed or portable X-ray sources were used.
5.	Positioning of subject, calibration cage (object), X-ray tubes and X-ray cassettes should be standardized or described in detail. Orientation of the global coordinate system should be presented.
6.	Method of image acquisition should be stated, e.g. whether scanned (then scanner details should to be given) or whether digital radiographs have been used (then system details should be given).
7.	Software used should be stated, and if appropriate which version.
8.	Size of marker beads used should be given (and validation results should be reported for the sizes used in the study).
9.	The method of determining the position of the implant, whether based on attached beads, geometrically or model-based should be stated. If appropriate, reference to any new/novel technique should be given.
10.	The following should be stated: cut-off level for condition number and rigid body fitting error for exclusion of subjects from study.
11.	Rigid body fixed coordinate frames and angular rotation sequence should be defined.
12.	The precision of the measurements assessed by double examinations of all patients enrolled in the study should be stated.
13.	Migration/motion data should be given in terms of translations and angular rotations. All 6 degrees of freedom should be reported. If not, these data should be available from the authors on request. The point(s) used to measure translations should be indicated (either a single point of a rigid body or the center of gravity of a rigid body), standardized, and its (their) location(s) on the implant (or in the bone) should always be presented.

References

1. Valstar ER, Gill R, Ryd L, Flivik G, Börlin N, Kärrholm J. Guidelines for standardization of radiostereometry (RSA) of implants. Acta Orthop. 2005;76:4:563-72.
2. Madanat R, Mäkinen TJ, Aro HT, Bragdon C, Malchau H. Adherence of hip and knee arthroplasty studies to RSA standardization guidelines. A systematic review. Acta Orthop. 2014;85:5:447-55.
3. Pijls BG. Reflections on the RSA guidelines. Acta Orthop. 2020;91:3:232-3.
4. Kaptein BL, Pijls B, Koster L, Kärrholm J, Hull M, Niesen A et al. Guideline for RSA and CT-RSA implant migration measurements: an update of standardizations and recommendations. Acta Orthop. 2024;95:256-67.
5. Röhrl SM. "Great balls on fire:" known algorithm with a new instrument? Acta Orthop. 2020;91:6:621-3.
6. Fontalis A, Haddad FS. Roentgen stereophotogrammetric analysis: still a very valuable tool in the orthopaedic research armamentarium. Bone Joint Res. 2022;11:4:210-3.
7. Page MJ, McKenzie JE, Bossuyt PM, Boutron I, Hoffmann TC, Mulrow CD et al. The PRISMA 2020 statement: an updated guideline for reporting systematic reviews. BMJ. 2021;372:n71.
8. Van der Lelij TJN, Koster LA, Marang-van de Mheen PJ, Toksvig-Larsen S, Nelissen R, Kaptein BL. Influence of marker-selection method in radiostereometric analysis of total knee arthroplasty on tibial baseplate migration patterns: a secondary analysis of a randomized controlled trial with 5-year follow-up. Acta Orthop. 2024;95:157-65.
9. Ishaque BA, Wieczorek J, Fonseca Ulloa CA, Seeger JB, Ahmed GA, Rickert M et al. Clinical evaluation of a novel press-fit acetabular cup using “Ein-Bild-Roentgen-Analysis” (EBRA): A positive short-term prognosis. Journal of Orthopaedics. 2020;22:33-7.
10. Mittelstaedt H, Anderl C, Ortmaier R, Johl C, Krüger T, Wallroth K et al. Subsidence analysis of a cementless short stem THA using EBRA-FCA - A seven-year prospective multicentre study. J Orthop. 2023;43:93-100.
11. Clement ND, Bardgett M, Merrie K, Furtado S, Bowman R, Langton DJ et al. Cemented Exeter total hip arthroplasty with a 32 mm head on highly crosslinked polyethylene: Does age influence functional outcome, satisfaction, activity, stem migration, and periprosthetic bone mineral density? Bone Joint Res. 2019;8:6:275-87.

Supplementary data

I. PRISMA Checklist

From: Page MJ, McKenzie JE, Bossuyt PM, Boutron I, Hoffmann TC, Mulrow CD, et al. The PRISMA 2020 statement: an updated guideline for reporting systematic reviews. BMJ 2021;372:n71.

Section and Topic	Item #	Checklist item	Location where item is reported (Page #)
Title			
Title	1	Identify the report as a systematic review	113
Abstract			
Abstract	2	See the PRISMA 2020 for Abstract checklist	114
Introduction			
Rationale	3	Describe the rationale for the review in the context of existing knowledge.	115
Objectives	4	Provide an explicit statement of the objective(s) or question(s) the review addresses.	115
Methods			
Eligibility criteria	5	Specify the inclusion and exclusion criteria for the review and how studies were grouped for the syntheses.	115,116
Information sources	6	Specify all databases, registers, websites, organisations, reference lists and other sources searched or consulted to identify studies. Specify the date when each source was last searched or consulted.	116
Search strategy	7	Present the full search strategies for all databases, registers and websites, including any filters and limits used.	Supplement
Selection process	8	Specify the methods used to decide whether a study met the inclusion criteria of the review, including how many reviewers screened each record and each report retrieved, whether they worked independently, and if applicable, details of automation tools used in the process.	117,118
Data collection process	9	Specify the methods used to collect data from reports, including how many reviewers collected data from each report, whether they worked independently, any processes for obtaining or confirming data from study investigators, and if applicable, details of automation tools used in the process.	118
Data items	10a	List and define all outcomes for which data were sought. Specify whether all results that were compatible with each outcome domain in each study were sought (e.g. for all measures, time points, analyses), and if not, the methods used to decide which results to collect.	118
	10b	List and define all other variables for which data were sought (e.g. participant and intervention characteristics, funding sources). Describe any assumptions made about any missing or unclear information.	118
Study risk of bias assessment	11	Specify the methods used to assess risk of bias in the included studies, including details of the tool(s) used, how many reviewers assessed each study and whether they worked independently, and if applicable, details of automation tools used in the process.	N.a.
Effect measures	12	Specify for each outcome the effect measure(s) (e.g. risk ratio, mean difference) used in the synthesis or presentation of results.	N.a.

Synthesis methods	13a	Describe the processes used to decide which studies were eligible for each synthesis (e.g. tabulating the study intervention characteristics and comparing against the planned groups for each synthesis (item #5)).	N.a.
	13b	Describe any methods required to prepare the data for presentation or synthesis, such as handling of missing summary statistics, or data conversions.	N.a.
	13c	Describe any methods used to tabulate or visually display results of individual studies and syntheses.	N.a.
	13d	Describe any methods used to synthesize results and provide a rationale for the choice(s). If meta-analysis was performed, describe the model(s), method(s) to identify the presence and extent of statistical heterogeneity, and software package(s) used.	N.a.
	13e	Describe any methods used to explore possible causes of heterogeneity among study results (e.g. subgroup analysis, meta-regression).	N.a.
	13f	Describe any sensitivity analyses conducted to assess robustness of the synthesized results.	N.a.
Reporting bias assessment	14	Describe any methods used to assess risk of bias due to missing results in a synthesis (arising from reporting biases).	N.a.
Certainty assessment	15	Describe any methods used to assess certainty (or confidence) in the body of evidence for an outcome.	N.a.
Study selection	16a	Describe the results of the search and selection process, from the number of records identified in the search to the number of studies included in the review, ideally using a flow diagram.	119
	16b	Cite studies that might appear to meet the inclusion criteria, but which were excluded, and explain why they were excluded.	N.a.
Study characteristics	17	Cite each included study and present its characteristics.	Supplement
Risk of bias in studies	18	Present assessments of risk of bias for each included study.	N.a.
Results of individual studies	19	For all outcomes, present, for each study: (a) summary statistics for each group (where appropriate) and (b) an effect estimate and its precision (e.g. confidence/credible interval), ideally using structured tables or plots.	122
Results of syntheses	20a	For each synthesis, briefly summarise the characteristics and risk of bias among contributing studies.	N.a.
	20b	Present results of all statistical syntheses conducted. If meta-analysis was done, present for each the summary estimate and its precision (e.g. confidence/credible interval) and measures of statistical heterogeneity. If comparing groups, describe the direction of the effect.	N.a.
	20c	Present results of all investigations of possible causes of heterogeneity among study results.	N.a.
	20d	Present results of all sensitivity analyses conducted to assess the robustness of the synthesized results.	N.a.
Reporting biases	21	Present assessments of risk of bias due to missing results (arising from reporting biases) for each synthesis assessed.	N.a.
Certainty of evidence	22	Present assessments of certainty (or confidence) in the body of evidence for each outcome assessed.	N.a.

Discussion			
	23a	Provide a general interpretation of the results in the context of other evidence.	123-127
	23b	Discuss any limitations of the evidence included in the review.	123-127
	23c	Discuss any limitations of the review processes used.	123-127
	23d	Discuss implications of the results for practice, policy, and future research.	123-127
Other information			
Registration and protocol	24a	Provide registration information for the review, including register name and registration number, or state that the review was not registered.	118
	24b	Indicate where the review protocol can be accessed, or state that a protocol was not prepared.	118
	24c	Describe and explain any amendments to information provided at registration or in the protocol.	118
Support	25	Describe sources of financial or non-financial support for the review, and the role of the funders or sponsors in the review.	118
Competing interests	26	Declare any competing interests of review authors.	118
Availability of data, code and other materials	27	Report which of the following are publicly available and where they can be found: template data collection forms; data extracted from included studies; data used for all analyses; analytic code; any other materials used in the review.	N.a.

II. Search strategy

PubMed
(("Radiostereometric Analysis"[Mesh] OR "Photogrammetry"[mesh] OR "RSA"[tiab] OR "Radiostereometric Analysis"[tw] OR "Radiostereometry"[tw] OR "Radiostereometric"[tw] OR "Radiostereometr*"[tw] OR "Radio stereometry"[tw] OR "Radio stereometr*"[tw] OR "roentgen stereophotogrammetric analysis"[tw] OR "Stereophotogrammetry"[tw] OR "Stereophotogrammetric"[tw] OR "Stereophotogrammetr*"[tw] OR "Stereo photogrammetry"[tw] OR "Stereo photogrammetric"[tw] OR "Stereo photogrammetr*"[tw] OR "Rontgen Stereophotogrammetr*"[tw] OR "Roentgen Stereometry"[tw] OR "Roentgen Stereometr*"[tw] OR "Photofluorography"[tw] OR "roentgen fluoroscopic"[tw] OR "roentgen fluoroscopy"[tw] OR "roentgen fluoroscop*"[tw]) AND ("Arthroplasty, replacement"[Mesh] OR "Joint Prosthesis"[Mesh] OR "Arthroplast*"[tw] OR "Hemiarthroplast*"[tw] OR "Hemi-arthroplast*"[tw] OR "Prosthesis"[tw] OR "Prostheses"[tw] OR "endoprosthesis"[tw] OR "endoprostheses"[tw] OR "Replacement"[tw] OR "reconstruction"[tw] OR "resurfacing"[tw] OR "resurfaced"[tw] OR "Implant"[tw] OR "Implants"[tw]) AND ("2012/01/01"[PDAT] : "3000/12/31"[PDAT]))

Embase
((exp *"Radiostereometric Analysis"/ OR exp *"Photogrammetry"/ OR "RSA".ti,ab OR "Radiostereometric Analysis".ti,ab OR "Radiostereometry".ti,ab OR "Radiostereometric".ti,ab OR "Radiostereometr*".ti,ab OR "Radio stereometry".ti,ab OR "Radio stereometr*".ti,ab OR "roentgen stereophotogrammetric analysis".ti,ab OR "Stereophotogrammetry".ti,ab OR "Stereophotogrammetric".ti,ab OR "Stereophotogrammetr*".ti,ab OR "Stereo photogrammetry".ti,ab OR "Stereo photogrammetric".ti,ab OR "Stereo photogrammetr*".ti,ab OR "Rontgen Stereophotogrammetr*".ti,ab OR "Roentgen Stereometry".ti,ab OR "Roentgen Stereometr*".ti,ab OR "Photofluorography".ti,ab OR "roentgen fluoroscopic".ti,ab OR "roentgen fluoroscopy".ti,ab OR "roentgen fluoroscop*".ti,ab) AND (exp *"orthopedic prostheses, orthoses and implants"/ OR exp *"Arthroplasty"/ OR "Arthroplast*".ti,ab OR "Hemiarthroplast*".ti,ab OR "Hemi-arthroplast*".ti,ab OR "Prosthesis".ti,ab OR "Prostheses".ti,ab OR "endoprosthesis".ti,ab OR "endoprostheses".ti,ab OR "Replacement".ti,ab OR "reconstruction".ti,ab OR "resurfacing".ti,ab OR "resurfaced".ti,ab OR "Implant".ti,ab OR "Implants".ti,ab) AND 2012:2024.(sa_year) NOT (conference review or conference abstract).pt)

Web of Science
((TI=("Radiostereometric Analysis" OR "Photogrammetry" OR "RSA" OR "Radiostereometric Analysis" OR "Radiostereometry" OR "Radiostereometric" OR "Radiostereometr*" OR "Radio stereometry" OR "Radio stereometr*" OR "roentgen stereophotogrammetric analysis" OR "Stereophotogrammetry" OR "Stereophotogrammetric" OR "Stereophotogrammetr*" OR "Stereo photogrammetry" OR "Stereo photogrammetric" OR "Stereo photogrammetr*" OR "Rontgen Stereophotogrammetr*" OR "Roentgen Stereometry" OR "Roentgen Stereometr*" OR "Photofluorography" OR "roentgen fluoroscopic" OR "roentgen fluoroscopy" OR "roentgen fluoroscop*") OR AK=("Radiostereometric Analysis" OR "Photogrammetry" OR "RSA" OR "Radiostereometric Analysis" OR "Radiostereometry" OR "Radiostereometric" OR "Radiostereometr*" OR "Radio stereometry" OR "Radio stereometr*" OR "roentgen stereophotogrammetric analysis" OR "Stereophotogrammetry" OR "Stereophotogrammetric" OR "Stereophotogrammetr*" OR "Stereo photogrammetry" OR "Stereo photogrammetric" OR "Stereo photogrammetr*" OR "Rontgen Stereophotogrammetr*" OR "Roentgen Stereometry" OR "Roentgen Stereometr*" OR "Photofluorography" OR "roentgen fluoroscopic" OR "roentgen fluoroscopy" OR "roentgen fluoroscop*") OR AB=("Radiostereometric Analysis" OR "Photogrammetry" OR "RSA" OR "Radiostereometric Analysis" OR "Radiostereometry" OR "Radiostereometric" OR "Radiostereometr*" OR "Radio stereometry" OR "Radio stereometr*" OR "roentgen stereophotogrammetric analysis" OR "Stereophotogrammetry" OR "Stereophotogrammetric" OR "Stereophotogrammetr*" OR "Stereo photogrammetry" OR "Stereo photogrammetric" OR "Stereo photogrammetr*" OR "Rontgen Stereophotogrammetr*" OR "Roentgen Stereometry" OR "Roentgen Stereometr*" OR "Photofluorography" OR "roentgen fluoroscopic" OR "roentgen fluoroscopy" OR "roentgen fluoroscop*")) AND (TI=("Arthroplasty" OR "Arthroplast*" OR "Hemiarthroplast*" OR "Hemi-arthroplast*" OR "Prosthesis" OR "Prostheses" OR "endoprosthesis" OR "endoprostheses" OR "Replacement" OR "resurfacing" OR "resurfaced" OR "Implant" OR "Implants") OR AK=("Arthroplasty" OR "Arthroplast*" OR "Hemiarthroplast*" OR "Hemi-arthroplast*" OR "Prosthesis" OR "Prostheses" OR "endoprosthesis" OR "endoprostheses" OR "Replacement" OR "resurfacing" OR "resurfaced" OR "Implant" OR "Implants") OR AB=("Arthroplasty" OR "Arthroplast*" OR "Hemiarthroplast*" OR "Hemi-arthroplast*" OR "Prosthesis" OR "Prostheses" OR "endoprosthesis" OR "endoprostheses" OR "Replacement" OR "resurfacing" OR "resurfaced"

OR "Implant" OR "Implants")) AND PY=(2012 OR 2013 OR 2014 OR 2015 OR 2016 OR 2017 OR 2018 OR 2019 OR 2020 OR 2021 OR 2022 OR 2023 OR 2024) NOT DT=("meeting abstract"))

Cochrane
(("Radiostereometric Analysis" OR "Photogrammetry" OR "RSA" OR "Radiostereometric Analysis" OR "Radiostereometry" OR "Radiostereometric" OR "Radiostereometr*" OR "Radio stereometry" OR "Radio stereometr*" OR "roentgen stereophotogrammetric analysis" OR "Stereophotogrammetry" OR "Stereophotogrammetric" OR "Stereophotogrammetr*" OR "Stereo photogrammetry" OR "Stereo photogrammetric" OR "Stereo photogrammetr*" OR "Rontgen Stereophotogrammetr*" OR "Roentgen Stereometry" OR "Roentgen Stereometr*" OR "Photofluorography" OR "roentgen fluoroscopic" OR "roentgen fluoroscopy" OR "roentgen fluoroscop*"):ti,ab,kw AND ("Arthroplasty" OR "Arthroplast*" OR "Hemiarthroplast*" OR "Hemi-arthroplast*" OR "Prosthesis" OR "Prostheses" OR "endoprosthesis" OR "endoprostheses" OR "Replacement" OR "reconstruction" OR "resurfacing" OR "resurfaced" OR "Implant" OR "Implants"):ti,ab,kw) NOT DT=("meeting abstract") AND PY=(2012 OR 2013 OR 2014 OR 2015 OR 2016 OR 2017 OR 2018 OR 2019 OR 2020 OR 2021 OR 2022 OR 2023 OR 2024)

Emcare
((exp *"Radiostereometric Analysis"/ OR exp *"Photogrammetry"/ OR "RSA".ti,ab OR "Radiostereometric Analysis".ti,ab OR "Radiostereometry".ti,ab OR "Radiostereometric".ti,ab OR "Radiostereometr*".ti,ab OR "Radio stereometry".ti,ab OR "Radio stereometr*".ti,ab OR "roentgen stereophotogrammetric analysis".ti,ab OR "Stereophotogrammetry".ti,ab OR "Stereophotogrammetric".ti,ab OR "Stereophotogrammetr*".ti,ab OR "Stereo photogrammetry".ti,ab OR "Stereo photogrammetric".ti,ab OR "Stereo photogrammetr*".ti,ab OR "Rontgen Stereophotogrammetr*".ti,ab OR "Roentgen Stereometry".ti,ab OR "Roentgen Stereometr*".ti,ab OR "Photofluorography".ti,ab OR "roentgen fluoroscopic".ti,ab OR "roentgen fluoroscopy".ti,ab OR "roentgen fluoroscop*".ti,ab) AND (exp *"orthopedic prostheses, orthoses and implants"/ OR exp *"Arthroplasty"/ OR "Arthroplast*".ti,ab OR "Hemiarthroplast*".ti,ab OR "Hemi-arthroplast*".ti,ab OR "Prosthesis".ti,ab OR "Prostheses".ti,ab OR "endoprosthesis".ti,ab OR "endoprostheses".ti,ab OR "Replacement".ti,ab OR "reconstruction".ti,ab OR "resurfacing".ti,ab OR "resurfaced".ti,ab OR "Implant".ti,ab OR "Implants".ti,ab) AND 2012:2024.(sa_year))

Academic Search Premier
((TI("Radiostereometric Analysis" OR "Photogrammetry" OR "RSA" OR "Radiostereometric Analysis" OR "Radiostereometry" OR "Radiostereometric" OR "Radiostereometr*" OR "Radio stereometry" OR "Radio stereometr*" OR "roentgen stereophotogrammetric analysis" OR "Stereophotogrammetry" OR "Stereophotogrammetric" OR "Stereophotogrammetr*" OR "Stereo photogrammetry" OR "Stereo photogrammetric" OR "Stereo photogrammetr*" OR "Rontgen Stereophotogrammetr*" OR "Roentgen Stereometry" OR "Roentgen Stereometr*" OR "Photofluorography" OR "roentgen fluoroscopic" OR "roentgen fluoroscopy" OR "roentgen fluoroscop*") OR KW("Radiostereometric Analysis" OR "Photogrammetry" OR "RSA" OR "Radiostereometric Analysis" OR "Radiostereometry" OR "Radiostereometric" OR "Radiostereometr*" OR "Radio stereometry" OR "Radio stereometr*" OR "roentgen stereophotogrammetric analysis" OR "Stereophotogrammetry" OR "Stereophotogrammetric" OR "Stereophotogrammetr*" OR "Stereo photogrammetry" OR "Stereo photogrammetric" OR "Stereo photogrammetr*" OR "Rontgen Stereophotogrammetr*" OR "Roentgen Stereometry" OR "Roentgen Stereometr*" OR "Photofluorography" OR "roentgen fluoroscopic" OR "roentgen fluoroscopy" OR "roentgen fluoroscop*") OR AB("Radiostereometric Analysis" OR "Photogrammetry" OR "RSA" OR "Radiostereometric Analysis" OR "Radiostereometry" OR "Radiostereometric" OR "Radiostereometr*" OR "Radio stereometry" OR "Radio stereometr*" OR "roentgen stereophotogrammetric analysis" OR "Stereophotogrammetry" OR "Stereophotogrammetric" OR "Stereophotogrammetr*" OR "Stereo photogrammetry" OR "Stereo photogrammetric" OR "Stereo photogrammetr*" OR "Rontgen Stereophotogrammetr*" OR "Roentgen Stereometry" OR "Roentgen Stereometr*" OR "Photofluorography" OR "roentgen fluoroscopic" OR "roentgen fluoroscopy" OR "roentgen fluoroscop*")) AND (TI("Arthroplasty" OR "Arthroplast*" OR "Hemiarthroplast*" OR "Hemi-arthroplast*" OR "Prosthesis" OR "Prostheses" OR "endoprosthesis" OR "endoprostheses" OR "Replacement" OR "resurfacing" OR "resurfaced" OR "Implant" OR "Implants") OR KW("Arthroplasty" OR "Arthroplast*" OR "Hemiarthroplast*" OR "Hemi-arthroplast*" OR "Prosthesis" OR "Prostheses" OR "endoprosthesis" OR "endoprostheses" OR "Replacement" OR "resurfacing" OR "resurfaced" OR "Implant" OR "Implants") OR AB("Arthroplasty" OR "Arthroplast*" OR "Hemiarthroplast*" OR "Hemi-arthroplast*" OR "Prosthesis" OR "Prostheses" OR "endoprosthesis" OR "endoprostheses" OR "Replacement" OR "resurfacing" OR "resurfaced"

OR "Implant" OR "Implants")) AND PY=(2012 OR 2013 OR 2014 OR 2015 OR 2016 OR 2017 OR 2018 OR 2019 OR 2020 OR 2021 OR 2022 OR 2023 OR 2024 NOT DT=("meeting abstract"))

III. References included studies (N = 285)

1. Abrahams JM, Callary SA, Jang SW, Hewitt J, Howie DW, Solomon LB. Accuracy of EBRA-cup measurements after reconstruction of severe acetabular defects at revision THR. J Orthop Res. 2020;38(7):1497-505. doi: 10.1002/jor.24623.
2. Acklin YP, Jenni R, Bereiter H, Thalmann C, Stoffel K. Prospective clinical and radiostereometric analysis of the Fitmore short-stem total hip arthroplasty. Arch Orthop Trauma Surg. 2016;136(2):277-84. doi: 10.1007/s00402-015-2401-9.
3. Akhtar A, Ricks M, Cunningham L, Moffatt M, Bale S, Walton M, et al. A randomized prospective study comparing migration of hydroxyapatite and non-hydroxyapatite coated glenoid components using radiostereometric analysis. Seminars in Arthroplasty JSES. 2021;31(4):635-43. doi: https://dx.doi.org/10.1053/j.sart.2021.04.001.
4. Alsousou J, Oragui E, Martin A, Strickland L, Newman S, Kendrick B, et al. Primary stability of a proximally coated and tapered stem. Bone Joint J. 2021;103-b(4):644-9. doi: 10.1302/0301-620x.103b4.Bjj-2020-1648.R1.
5. Andersen MR, Winther N, Lind T, SchrøDer H, Flivik G, Petersen MM. Monoblock versus modular polyethylene insert in uncemented total knee arthroplasty. Acta Orthop. 2016;87(6):607-14. doi: 10.1080/17453674.2016.1233654.
6. Andersen MR, Winther N, Lind T, Schrøder H, Flivik G, Petersen MM. Tibial Component Undersizing Is Related to High Degrees of Implant Migration Following Cementless Total Knee Arthroplasty: A Study of Radiostereometric Analysis Data for 111 Patients with 2-Year Follow-up. JB JS Open Access. 2023;8(3). doi: 10.2106/jbjs.Oa.23.00032.
7. Andersen MR, Winther NS, Lind T, Schrøder HM, Flivik G, Petersen MM. Low Preoperative BMD Is Related to High Migration of Tibia Components in Uncemented TKA-92 Patients in a Combined DEXA and RSA Study With 2-Year Follow-Up. J Arthroplasty. 2017;32(7):2141-6. doi: 10.1016/j.arth.2017.02.032.
8. Angelomenos V, Mohaddes M, Itayem R, Shareghi B. Precision of low-dose CT-based micromotion analysis technique for the assessment of early acetabular cup migration compared with gold standard RSA: a prospective study of 30 patients up to 1 year. Acta Orthop. 2022;93:459-65. doi: 10.2340/17453674.2022.2528.
9. Aro E, Alm JJ, Moritz N, Mattila K, Aro HT. Good stability of a cementless, anatomically designed femoral stem in aging women: a 9-year RSA study of 32 patients. Acta Orthop. 2018;89(5):490-5. doi: 10.1080/17453674.2018.1490985.
10. Aro E, Moritz N, Mattila K, Aro HT. A long-lasting bisphosphonate partially protects periprosthetic bone, but does not enhance initial stability of uncemented femoral stems: A randomized placebo-controlled trial of women undergoing total hip arthroplasty. J Biomech. 2018;75:35-45. doi: 10.1016/j.jbiomech.2018.04.041.
11. Aro HT, Alm JJ, Moritz N, Mäkinen TJ, Lankinen P. Low BMD affects initial stability and delays stem osseointegration in cementless total hip arthroplasty in women: a 2-year RSA study of 39 patients. Acta Orthop. 2012;83(2):107-14. doi: 10.3109/17453674.2012.678798.
12. Aro HT, Engelke K, Mattila K, Löyttyniemi E. Volumetric Bone Mineral Density in Cementless Total Hip Arthroplasty in Postmenopausal Women: Effects on Primary Femoral Stem Stability and Clinical Recovery. J Bone Joint Surg Am. 2021;103(12):1072-82. doi: 10.2106/jbjs.20.01614.
13. Aro HT, Nazari-Farsani S, Vuopio M, Löyttyniemi E, Mattila K. Effect of Denosumab on Femoral Periprosthetic BMD and Early Femoral Stem Subsidence in Postmenopausal Women Undergoing Cementless Total Hip Arthroplasty. JBMR Plus. 2019;3(10):e10217. doi: 10.1002/jbm4.10217.
14. Ayers DC, Greene M, Snyder B, Aubin M, Drew J, Bragdon C. Radiostereometric analysis study of tantalum compared with titanium acetabular cups and highly cross-linked compared with conventional liners in young patients undergoing total hip replacement. J Bone Joint Surg Am. 2015;97(8):627-34. doi: 10.2106/jbjs.N.00605.
15. Balesar VV, Koster LA, Kaptein BL, Keizer SB. Five-Year Prospective Roentgen Stereophotogrammetric and Clinical Outcomes of the BioPro MTP-1 Hemiarthroplasty. Foot Ankle Int. 2022;43(5):637-45. doi: 10.1177/10711007211061366.
16. Barbadoro P, Ensini A, Leardini A, d'Amato M, Feliciangeli A, Timoncini A, et al. Tibial component alignment and risk of loosening in unicompartmental knee arthroplasty: a radiographic and radiostereometric study. Knee Surg Sports Traumatol Arthrosc. 2014;22(12):3157-62. doi: 10.1007/s00167-014-3147-6.

17. Belfrage O, Tägil M, Sundberg M, Kesteris U, Flivik G. Locally administered bisphosphonate in hip stem revisions using the bone impaction grafting technique: a randomised, placebo-controlled study with DXA and five-year RSA follow-up. Hip Int. 2019;29(1):26-34. doi: 10.1177/1120700018781809.
18. Bergvinsson H, Sundberg M, Flivik G. Polyethylene Wear With Ceramic and Metal Femoral Heads at 5 Years: A Randomized Controlled Trial With Radiostereometric Analysis. J Arthroplasty. 2020;35(12):3769-76. doi: 10.1016/j.arth.2020.06.057.
19. Bergvinsson H, Zampelis V, Sundberg M, Flivik G. Highly cross-linked polyethylene still outperforms conventional polyethylene in THA: 10-year RSA results. Acta Orthop. 2021;92(5):568-74. doi: 10.1080/17453674.2021.1932140.
20. Bergvinsson H, Zampelis V, Sundberg M, Tjörnstrand J, Flivik G. Vitamin E infused highly cross-linked cemented cups in total hip arthroplasty show good wear pattern and stabilize satisfactorily: a randomized, controlled RSA trial with 5-year follow-up. Acta Orthop. 2022;93:249-55. doi: 10.2340/17453674.2022.1517.
21. Bohm E, Petrak M, Gascoyne T, Turgeon T. The effect of adding tobramycin to Simplex P cement on femoral stem micromotion as measured by radiostereometric analysis: a 2-year randomized controlled trial. Acta Orthop. 2012;83(2):115-20. doi: 10.3109/17453674.2011.652885.
22. Breddam Mosegaard S, Jørgensen PB, Storgaard Jakobsen S, Daugaard H, Søballe K, Stilling M. Larger 5-year migration but similar polyethylene wear of cementless hemispherical cups with electrochemically applied hydroxyapatite (BoneMaster) coating compared with porous plasma-spray titanium: a randomized 5-year RSA study. Acta Orthop. 2022;93:658-64. doi: 10.2340/17453674.2022.3976.
23. Breddam Mosegaard S, Rytter S, Madsen F, Odgaard A, Søballe K, Stilling M. Two-year fixation and ten-year clinical outcomes of total knee arthroplasty inserted with normal-curing bone cement and slow-curing bone cement: A randomized controlled trial in 54 patients. Knee. 2021;33:110-24. doi: 10.1016/j.knee.2021.08.027.
24. Brinke BT, Kosse NM, Flikweert PE, van der Pluijm M, Eygendaal D. Long-term outcomes after Instrumented Bone Preserving total elbow arthroplasty: a radiostereometric study with a minimum follow-up of 10 years. J Shoulder Elbow Surg. 2020;29(1):126-31. doi: 10.1016/j.jse.2019.07.023.
25. Broberg JS, Koff MF, Howard JL, Lanting BA, Potter HG, Teeter MG. A multimodal assessment of cementless tibial baseplate fixation using radiography, radiostereometric analysis, and magnetic resonance imaging. J Orthop Res. 2024;42(1):100-8. doi: 10.1002/jor.25662.
26. Broberg JS, Naudie DDR, Howard JL, Lanting BA, Vasarhelyi EM, Teeter MG. Correlating Contact Kinematics to Tibial Component Migration Following Cemented Bicruciate Stabilized Total Knee Arthroplasty. J Arthroplasty. 2023;38(6s):S355-s62. doi: 10.1016/j.arth.2023.01.051.
27. Broberg JS, Naudie DDR, Lanting BA, Howard JL, Vasarhelyi EM, Teeter MG. Patient and Implant Performance of Satisfied and Dissatisfied Total Knee Arthroplasty Patients. J Arthroplasty. 2022;37(6s):S98-s104. doi: 10.1016/j.arth.2021.10.024.
28. Broberg JS, Vasarhelyi EM, Lanting BA, Howard JL, Teeter MG, Naudie DDR. Migration and Inducible Displacement of the Bicruciate-Stabilized Total Knee Arthroplasty: A Randomized Controlled Trial of Gap Balancing and Measured Resection Techniques. J Arthroplasty. 2022;37(2):252-8. doi: 10.1016/j.arth.2021.10.010.
29. Brodén C, Reilly P, Khanna M, Popat R, Olivecrona H, Griffiths D, et al. CT-based micromotion analysis method can assess early implant migration and development of radiolucent lines in cemented glenoid components: a clinical feasibility study. Acta Orthop. 2022;93:277-83. doi: 10.2340/17453674.2022.1976.
30. Bruni D, Bragonzoni L, Gagliardi M, Bontempi M, Akkawi I, Raspugli GF, et al. Roentgen stereophotogrammetric analysis: an effective tool to predict implant survival after an all-poly unicompartmental knee arthroplasty-a 10 year follow-up study. Knee Surg Sports Traumatol Arthrosc. 2015;23(11):3273-80. doi: 10.1007/s00167-014-3106-2.
31. Budde S, Derksen A, Hurschler C, Fennema P, Windhagen H, Plagge J, et al. Very early migration of a calcar-guided short stem: a randomized study of early mobilization and the influence of a calcium phosphate coating with 60 patients. Sci Rep. 2024;14(1):3837. doi: 10.1038/s41598-023-50829-3.
32. Budde S, Seehaus F, Schwarze M, Hurschler C, Floerkemeier T, Windhagen H, et al. Analysis of migration of the Nanos® short-stem hip implant within two years after surgery. Int Orthop. 2016;40(8):1607-14. doi: 10.1007/s00264-015-2999-9.

33. Bunting AC, Costi K, Chimutengwende-Gordon M, Callary SA, Pannach S, Nelson R, et al. Staged Revision Hip Arthroplasty With Femoral Impaction Bone Grafting for Prosthetic Joint Infections: Radiostereometric Analyses and Clinical Outcomes at Minimum 5-Year Follow-Up. J Arthroplasty. 2023;38(12):2716-23.e1. doi: 10.1016/j.arth.2023.06.003.
34. Callary SA, Campbell DG, Mercer GE, Nilsson KG, Field JR. The 6-year migration characteristics of a hydroxyapatite-coated femoral stem: a radiostereometric analysis study. J Arthroplasty. 2012;27(7):1344-8.e1. doi: 10.1016/j.arth.2011.12.002.
35. Campbell D, Callary S, Field J, Nilsson KG. All-polyethylene tibial components in young patients have stable fixation; a comparison RSA study. Knee. 2019;26(2):392-9. doi: 10.1016/j.knee.2018.12.003.
36. Campi S, Kendrick BJL, Kaptein BL, Valstar ER, Jackson WFM, Dodd CAF, et al. Five-year results of a randomised controlled trial comparing cemented and cementless Oxford unicompartmental knee replacement using radiostereometric analysis. Knee. 2021;28:383-90. doi: 10.1016/j.knee.2020.09.003.
37. Christensson A, Nemati HM, Flivik G. Comparison between model-based RSA and an AI-based CT-RSA: an accuracy study of 30 patients. Acta Orthop. 2024;95:39-46. doi: 10.2340/17453674.2024.35749.
38. Christensson A, Tveit M, Kesteris U, Flivik G. Similar migration for medial congruent and cruciate-retaining tibial components in an anatomic TKA system: a randomized controlled trial of 60 patients followed with RSA for 2 years. Acta Orthop. 2022;93:68-74. doi: 10.1080/17453674.2021.1983709.
39. Christiansen JD, Ejaz A, Nielsen PT, Laursen M. An Ultra-Short Femoral Neck-Preserving Hip Prosthesis: A 2-Year Follow-up Study with Radiostereometric Analysis and Dual X-Ray Absorptiometry in a Stepwise Introduction. J Bone Joint Surg Am. 2020;102(2):128-36. doi: 10.2106/jbjs.19.00104.
40. Coffey SP, Sorial RM, Sharma R, Field JR. Two-year migration characteristics of a novel cementless femoral stem: a radiostereometric analysis and clinical outcomes study. ANZ J Surg. 2021;91(3):398-403. doi: 10.1111/ans.16616.
41. Critchley O, Callary S, Mercer G, Campbell D, Wilson C. Long-term migration characteristics of the Corail hydroxyapatite-coated femoral stem: a 14-year radiostereometric analysis follow-up study. Arch Orthop Trauma Surg. 2020;140(1):121-7. doi: 10.1007/s00402-019-03291-8.
42. Cunningham LJ, Walton M, Bale S, Trail IA. A prospective radiostereometric analysis of the stability of a metal-backed glenoid component/autograft composite in reverse shoulder arthroplasty. Bone Joint J. 2023;105-b(8):912-9. doi: 10.1302/0301-620x.105b8.Bjj-2022-1280.R2.
43. Dahl J, Snorrason F, Nordsletten L, Röhrl SM. More than 50% reduction of wear in polyethylene liners with alumina heads compared to cobalt-chrome heads in hip replacements: a 10-year follow-up with radiostereometry in 43 hips. Acta Orthop. 2013;84(4):360-4. doi: 10.3109/17453674.2013.810516.
44. Dahl J, Söderlund P, Nivbrant B, Nordsletten L, Röhrl SM. Less wear with aluminium-oxide heads than cobalt-chrome heads with ultra high molecular weight cemented polyethylene cups: a ten-year follow-up with radiostereometry. Int Orthop. 2012;36(3):485-90. doi: 10.1007/s00264-011-1334-3.
45. de Ridder R, Kaptein BL, Pijls BG, Nelissen R, Kaptijn HH. Five-year migration and insert wear of uncemented tibial components with either conventional polyethylene or sequentially annealed highly crosslinked polyethylene inserts: a blinded randomized controlled trial using radiostereometric analysis. Bone Joint J. 2023;105-b(5):518-25. doi: 10.1302/0301-620x.105b5.Bjj-2022-0986.R1.
46. de Waard S, Sierevelt IN, Jonker R, Hoornenborg D, van der Vis HM, Kerkhoffs G, et al. The migration pattern and initial stability of the Optimys short stem in total hip arthroplasty: a prospective 2-year follow-up study of 33 patients with RSA. Hip Int. 2021;31(4):507-15. doi: 10.1177/1120700020901844.
47. deVos MJ, Verdonschot N, Luites JW, Anderson PG, Eygendaal D. Stable fixation of the IBP humeral component implanted without cement in total elbow replacement: a radiostereometric analysis study of 16 elbows at two-year follow-up. Bone Joint J. 2014;96-b(2):229-36. doi: 10.1302/0301-620x.96b2.29050.

48. Dunbar MJ, Fong JW, Wilson DA, Hennigar AW, Francis PA, Glazebrook MA. Longitudinal migration and inducible displacement of the Mobility Total Ankle System. Acta Orthop. 2012;83(4):394-400. doi: 10.3109/17453674.2012.712890.
49. Dunbar MJ, Laende EK, Collopy D, Richardson CG. Stable migration of peri-apatite-coated uncemented tibial components in a multicentre study. Bone Joint J. 2017;99-b(12):1596-602. doi: 10.1302/0301-620x.99b12.Bjj-2016-1118.R2.
50. Dyreborg K, Andersen MR, Winther N, Solgaard S, Flivik G, Petersen MM. Migration of the uncemented Echo Bi-Metric and Bi-Metric THA stems: a randomized controlled RSA study involving 62 patients with 24-month follow-up. Acta Orthop. 2020;91(6):693-8. doi: 10.1080/17453674.2020.1802682.
51. Dyreborg K, Sørensen MS, Flivik G, Solgaard S, Petersen MM. Preoperative BMD does not influence femoral stem subsidence of uncemented THA when the femoral T-score is > -2.5. Acta Orthop. 2021;92(5):538-43. doi: 10.1080/17453674.2021.1920163.
52. Dyreborg K, Winther N, Lind T, Flivik G, Mørk Petersen M. Evaluation of different coatings of the tibial tray in uncemented total knee arthroplasty. A randomized controlled trial with 5 years follow-up with RSA and DEXA. Knee. 2021;29:208-15. doi: 10.1016/j.knee.2021.02.002.
53. Ebert JR, Nivbrant NO, Petrov V, Yates P, Wood DJ. A 2-year prospective clinical and bone density evaluation, with a subset undergoing radiostereometric analysis, using the Absolut cemented stem. ANZ J Surg. 2022;92(4):830-6. doi: 10.1111/ans.17519.
54. Edmondson M, Ebert J, Nivbrant O, Wood D. Prospective randomised clinical trial assessing subsidence and rotation, using radiostereometric analysis, of two modular cementless femoral stems (Global K2 and Apex). Journal of Orthopaedics. 2014;11(2):96-102. doi: https://dx.doi.org/10.1016/j.jor.2014.02.001.
55. Ejaz A, Laursen AC, Jakobsen T, Rasmussen S, Nielsen PT, Laursen MB. Absence of a Tourniquet Does Not Affect Fixation of Cemented TKA: A Randomized RSA Study of 70 Patients. J Arthroplasty. 2015;30(12):2128-32. doi: 10.1016/j.arth.2015.05.058.
56. El-Sahoury JAN, Kjærgaard K, Ovesen O, Hofbauer C, Overgaard S, Ding M. Vitamin E-diffused liners show less head penetration than cross-linked polyethylene liners in total hip arthroplasty: a ten-year multi-arm randomized trial. Bone Joint J. 2023;105-b(10):1052-9. doi: 10.1302/0301-620x.105b10.Bjj-2023-0115.R1.
57. Ensini A, Barbadoro P, Leardini A, Catani F, Giannini S. Early migration of the cemented tibial component of unicompartmental knee arthroplasty: a radiostereometry study. Knee Surg Sports Traumatol Arthrosc. 2013;21(11):2474-9. doi: 10.1007/s00167-012-2068-5.
58. Fallahnezhad K, Callary SA, O'Rourke D, Bahl JS, Thewlis D, Solomon LB, et al. Corroboration of coupled musculoskeletal model and finite element predictions with in vivo RSA migration of an uncemented acetabular component. J Orthop Res. 2024;42(2):373-84. doi: 10.1002/jor.25671.
59. Ferguson RJ, Broomfield JA, Malak TT, Palmer AJR, Whitwell D, Kendrick B, et al. Primary stability of a short bone-conserving femoral stem: a two-year randomized controlled trial using radiostereometric analysis. Bone Joint J. 2018;100-b(9):1148-56. doi: 10.1302/0301-620x.100b9.Bjj-2017-1403.R1.
60. Finnilä S, Löyttyniemi E, Aro HT. Denosumab in Cementless Total Hip Arthroplasty: Multivariate Reanalysis of 3D Femoral Stem Migration and the Influence on Outliers. JBMR Plus. 2022;6(2):e10588. doi: 10.1002/jbm4.10588.
61. Finnilä S, Moritz N, Svedström ME, Alm JJ, Aro HT. Increased migration of uncemented acetabular cups in female total hip arthroplasty patients with low systemic bone mineral density. A 2-year RSA and 8-year radiographic follow-up study of 34 patients. Acta Orthop. 2016;87(1):48-54. doi: 10.3109/17453674.2015.1115312.
62. Flatøy B, Dahl J, Röhrl SM, Nordsletten L. Does radiopaque cement conceal periprosthetic bone loss around femoral stems? Hip Int. 2020;30(6):731-8. doi: 10.1177/1120700019863352.
63. Flatøy B, Röhrl SM, Bøe B, Nordsletten L. No medium-term advantage of electrochemical deposition of hydroxyapatite in cementless femoral stems. 5-year RSA and DXA results from a randomized controlled trial. Acta Orthop. 2016;87(1):42-7. doi: 10.3109/17453674.2015.1084768.
64. Flatøy B, Röhrl SM, Rydinge J, Dahl J, Diep LM, Nordsletten L. Triple taper stem design shows promising fixation and bone remodelling characteristics: radiostereometric analysis in a randomised controlled trial. Bone Joint J. 2015;97-b(6):755-61. doi: 10.1302/0301-620x.97b6.34736.

65. Flatøy B, Rydinge J, Dahl J, Röhrl SM, Nordsletten L. Low wear, high stability - promises of success in a moderately cross-linked cup? Hip Int. 2015;25(3):199-203. doi: 10.5301/hipint.5000230.
66. Flivik G, Kristiansson I, Ryd L. Positive effect of removal of subchondral bone plate for cemented acetabular component fixation in total hip arthroplasty: a randomised RSA study with ten-year follow-up. Bone Joint J. 2015;97-b(1):35-44. doi: 10.1302/0301-620x.97b1.34391.
67. Floerkemeier T, Budde S, Lewinski GV, Windhagen H, HurSchler C, Schwarze M. Greater early migration of a short-stem total hip arthroplasty is not associated with an increased risk of osseointegration failure: 5th-year results from a prospective RSA study with 39 patients, a follow-up study. Acta Orthop. 2020;91(3):266-71. doi: 10.1080/17453674.2020.1732749.
68. Fontalis A, Kayani B, Vanhegan I, Tahmassebi J, Haddad IC, Giebaly DE, et al. 2-Year Radiostereometric Analysis Evaluation of a Short, Proximally Coated, Triple-Taper Blade Femoral Stem Versus a Quadrangular-Taper Stem With Reinforced Proximal Body: A Randomized Controlled Trial. J Arthroplasty. 2023;38(7s):S152-s61. doi: 10.1016/j.arth.2023.03.030.
69. Fraser AN, Bøe B, Fjalestad T, Madsen JE, Röhrl SM. Stable glenoid component of reverse total shoulder arthroplasty at 2 years as measured with model-based radiostereometric analysis (RSA). Acta Orthop. 2021;92(6):644-50. doi: 10.1080/17453674.2021.1943932.
70. Galea VP, Rojanasopondist P, Laursen M, Muratoglu OK, Malchau H, Bragdon C. Evaluation of vitamin E-diffused highly crosslinked polyethylene wear and porous titanium-coated shell stability: a seven-year randomized control trial using radiostereometric analysis. Bone Joint J. 2019;101-b(7):760-7. doi: 10.1302/0301-620x.101b7.Bjj-2019-0268.R1.
71. Gascoyne TC, McRae SMB, Parashin SL, Leiter JRS, Petrak MJ, Bohm ER, et al. Radiostereometric analysis of keeled versus pegged glenoid components in total shoulder arthroplasty: a randomized feasibility study. Can J Surg. 2017;60(4):273-9. doi: 10.1503/cjs.001817.
72. Gudnason A, Adalberth G, Nilsson KG, Hailer NP. Tibial component rotation around the transverse axis measured by radiostereometry predicts aseptic loosening better than maximal total point motion. Acta Orthop. 2017;88(3):282-7. doi: 10.1080/17453674.2017.1297001.
73. Hansen TB, Stilling M. Equally good fixation of cemented and uncemented cups in total trapeziometacarpal joint prostheses. A randomized clinical RSA study with 2-year follow-up. Acta Orthop. 2013;84(1):98-105. doi: 10.3109/17453674.2013.765625.
74. Hasan S, Kaptein BL, Marang-van de Mheen PJ, Van Hamersveld KT, Nelissen R, Toksvig-Larsen S. Late stabilization after initial migration in patients undergoing cemented total knee arthroplasty: a 5-year follow up of 2 randomized controlled trials using radiostereometric analysis. Acta Orthop. 2022;93:271-6. doi: 10.2340/17453674.2022.1381.
75. Hasan S, Kaptein BL, Nelissen R, van Hamersveld KT, Toksvig-Larsen S, Marang-van de Mheen PJ. The Influence of Postoperative Coronal Alignment on Tibial Migration After Total Knee Arthroplasty in Preoperative Varus and Valgus Knees: A Secondary Analysis of 10 Randomized Controlled Trials Using Radiostereometric Analysis. J Bone Joint Surg Am. 2021;103(24):2281-90. doi: 10.2106/jbjs.20.01659.
76. Hasan S, Marang-Van De Mheen PJ, Kaptein BL, Nelissen R, Toksvig-Larsen S. All-polyethylene versus metal-backed posterior stabilized total knee arthroplasty: similar 2-year results of a randomized radiostereometric analysis study. Acta Orthop. 2019;90(6):590-5. doi: 10.1080/17453674.2019.1668602.
77. Hasan S, van Hamersveld KT, Marang-van de Mheen PJ, Kaptein BL, Nelissen R, Toksvig-Larsen S. Migration of a novel 3D-printed cementless versus a cemented total knee arthroplasty: two-year results of a randomized controlled trial using radiostereometric analysis. Bone Joint J. 2020;102-b(8):1016-24. doi: 10.1302/0301-620x.102b8.Bjj-2020-0054.R1.
78. Haugan K, Foss OA, Husby OS, Husby VS, Svenningsen S, Winther SB. Surgical approach had minor association with femoral stem migration in total hip arthroplasty: radiostereometric analysis of 61 patients after 5-year follow-up. Acta Orthop. 2023;94:410-5. doi: 10.2340/17453674.2023.18264.
79. Haugan K, Husby OS, Klaksvik J, Foss OA. The migration pattern of the Charnley femoral stem: a five-year follow-up RSA study in a well-functioning patient group. J Orthop Traumatol. 2012;13(3):137-43. doi: 10.1007/s10195-012-0187-x.
80. Heesterbeek PJ, Wymenga AB, van Hellemondt GG. No Difference in Implant Micromotion Between Hybrid Fixation and Fully Cemented Revision Total Knee Arthroplasty: A Randomized Controlled Trial with Radiostereometric Analysis of Patients with Mild-to-Moderate Bone Loss. J Bone Joint Surg Am. 2016;98(16):1359-69. doi: 10.2106/jbjs.15.00909.

81. Henricson A, Nilsson KG. Trabecular metal tibial knee component still stable at 10 years. Acta Orthop. 2016;87(5):504-10. doi: 10.1080/17453674.2016.1205169.
82. Henricson A, Rösmark D, Nilsson KG. Trabecular metal tibia still stable at 5 years: an RSA study of 36 patients aged less than 60 years. Acta Orthop. 2013;84(4):398-405. doi: 10.3109/17453674.2013.799418.
83. Henricson A, Wojtowicz R, Nilsson KG, Crnalic S. Uncemented or cemented femoral components work equally well in total knee arthroplasty. Knee Surg Sports Traumatol Arthrosc. 2019;27(4):1251-8. doi: 10.1007/s00167-018-5227-5.
84. Hjorth MH, Kold S, Søballe K, Langdahl BL, Nielsen PT, Christensen PH, et al. Preparation of the Femoral Bone Cavity for Cementless Stems: Broaching vs Compaction. A Five-Year Randomized Radiostereometric Analysis and Dual Energy X-Ray Absorption Study. J Arthroplasty. 2017;32(6):1894-901. doi: 10.1016/j.arth.2016.12.029.
85. Hjorth MH, Lorenzen ND, Søballe K, Jakobsen SS, Stilling M. Equal Primary Fixation of Resurfacing Stem, but Inferior Cup Fixation With Anterolateral vs Posterior Surgical Approach. A 2-Year Blinded Randomized Radiostereometric and Dual-energy X-Ray Absorptiometry Study of Metal-on-Metal Hip Resurfacing Arthroplasty. J Arthroplasty. 2017;32(11):3412-20. doi: 10.1016/j.arth.2017.05.034.
86. Hjorth MH, Søballe K, Jakobsen SS, Lorenzen ND, Mechlenburg I, Stilling M. No association between serum metal ions and implant fixation in large-head metal-on-metal total hip arthroplasty. Acta Orthop. 2014;85(4):355-62. doi: 10.3109/17453674.2014.922731.
87. Hjorth MH, Stilling M, Søballe K, Nielsen PT, Christensen PH, Kold S. Preparation of the femoral bone cavity in cementless stems: broaching versus compaction. Acta Orthop. 2016;87(6):575-82. doi: 10.1080/17453674.2016.1244958.
88. Holm-Glad T, Røkkum M, Röhrl SM, Roness S, Godang K, Reigstad O. A randomized controlled trial comparing two modern total wrist arthroplasties : improved function with stable implants, but high complication rates in non-rheumatoid wrists at two years. Bone Joint J. 2022;104-b(10):1132-41. doi: 10.1302/0301-620x.104b10.Bjj-2022-0201.R2.
89. Hoornenborg D, Schweden AMC, Sierevelt IN, van der Vis HM, Kerkhoffs G, Haverkamp D. The influence of hydroxyapatite coating on continuous migration of a Zweymuller-type hip stem: a double-blinded randomised RSA trial with 5-year follow-up. Hip Int. 2023;33(1):73-80. doi: 10.1177/11207000211006782.
90. Hoornenborg D, Sierevelt IN, Spuijbroek JA, Cheung J, van der Vis HM, Beimers L, et al. Does hydroxyapatite coating enhance ingrowth and improve longevity of a Zweymuller type stem? A double-blinded randomised RSA trial. Hip Int. 2018;28(2):115-21. doi: 10.5301/hipint.5000549.
91. Howie DW, Holubowycz OT, Callary SA, Robertson TS, Solomon LB. Highly Porous Tantalum Acetabular Components Without Ancillary Screws Have Similar Migration to Porous Titanium Acetabular Components With Screws at 2 Years: A Randomized Controlled Trial. J Arthroplasty. 2020;35(10):2931-7. doi: 10.1016/j.arth.2020.05.049.
92. Itayem R, Arndt A, Daniel J, McMinn DJ, Lundberg A. A two-year radiostereometric follow-up of the first generation Birmingham mid head resection arthroplasty. Hip Int. 2014;24(4):355-62. doi: 10.5301/hipint.5000136.
93. Jacobsen A, Seehaus F, Hong Y, Cao H, Schuh A, Forst R, et al. Model-based roentgen stereophotogrammetric analysis using elementary geometrical shape models: 10 years results of an uncemented acetabular cup component. BMC Musculoskelet Disord. 2018;19(1):335. doi: 10.1186/s12891-018-2259-4.
94. Jensen CL, Petersen MM, Schrøder HM, Flivik G, Lund B. Revision total knee arthroplasty with the use of trabecular metal cones: a randomized radiostereometric analysis with 2 years of follow-up. J Arthroplasty. 2012;27(10):1820-6.e2. doi: 10.1016/j.arth.2012.04.036.
95. Johanson PE, Antonsson M, Shareghi B, Kärrholm J. Early Subsidence Predicts Failure of a Cemented Femoral Stem With Minor Design Changes. Clin Orthop Relat Res. 2016;474(10):2221-9. doi: 10.1007/s11999-016-4884-2.
96. Johanson PE, Digas G, Herberts P, Thanner J, Kärrholm J. Highly crosslinked polyethylene does not reduce aseptic loosening in cemented THA 10-year findings of a randomized study. Clin Orthop Relat Res. 2012;470(11):3083-93. doi: 10.1007/s11999-012-2400-x.
97. Jørgensen PB, Daugaard H, Jakobsen SS, Lamm M, Søballe K, Stilling M. Higher early proximal migration of hemispherical cups with electrochemically applied hydroxyapatite (BoneMaster) on a porous surface compared with porous surface alone: a randomized RSA study with 53 patients. Acta Orthop. 2020;91(1):26-32. doi: 10.1080/17453674.2019.1687860.

98. Jørgensen PB, Kaptein BL, Søballe K, Jakobsen SS, Stilling M. Five-year polyethylene cup migration and PE wear of the Anatomic Dual Mobility acetabular construct. Arch Orthop Trauma Surg. 2023;143(9):5957-65. doi: 10.1007/s00402-023-04774-5.
99. Jørgensen PB, Lamm M, Søballe K, Stilling M. Equivalent hip stem fixation by Hi-Fatigue G and Palacos R + G bone cement: a randomized radiostereometric controlled trial of 52 patients with 2 years' follow-up. Acta Orthop. 2019;90(3):237-42. doi: 10.1080/17453674.2019.1595390.
100. Jørgensen PB, Tabori-Jensen S, Mechlenburg I, Homilius M, Hansen TB, Stilling M. Cemented and cementless dual mobility cups show similar fixation, low polyethylene wear, and low serum cobalt-chromium in elderly patients: a randomized radiostereometry study with 6 years' follow-up. Acta Orthop. 2022;93:906-13. doi: 10.2340/17453674.2022.5761.
101. Jun BJ, Ricchetti ET, Haladik J, Bey MJ, Patterson TE, Subhas N, et al. Validation of a 3D CT imaging method for quantifying implant migration following anatomic total shoulder arthroplasty. J Orthop Res. 2022;40(6):1270-80. doi: 10.1002/jor.25170.
102. Kadar T, Furnes O, Aamodt A, Indrekvam K, Havelin LI, Haugan K, et al. The influence of acetabular inclination angle on the penetration of polyethylene and migration of the acetabular component: a prospective, radiostereometric study on cemented acetabular components. J Bone Joint Surg Br. 2012;94(3):302-7. doi: 10.1302/0301-620x.94b3.27460.
103. Kaptein BL, den Hollander P, Thomassen B, Fiocco M, Nelissen R. A randomized controlled trial comparing tibial migration of the ATTUNE cemented cruciate-retaining knee prosthesis with the PFC-sigma design. Bone Joint J. 2020;102-b(9):1158-66. doi: 10.1302/0301-620x.102b9.Bjj-2020-0096.R1.
104. Keiller T, Saari T, Sharegi B, Kärrholm J. No difference in clinical outcome but in RSA in total knee arthroplasty with the ATTUNE vs. the PFC Sigma: a randomized trial with 2-year follow-up. Acta Orthop. 2023;94:560-9. doi: 10.2340/17453674.2023.24577.
105. Kendrick BJ, Kaptein BL, Valstar ER, Gill HS, Jackson WF, Dodd CA, et al. Cemented versus cementless Oxford unicompartmental knee arthroplasty using radiostereometric analysis: a randomised controlled trial. Bone Joint J. 2015;97-b(2):185-91. doi: 10.1302/0301-620x.97b2.34331.
106. Kent M, Edmondson M, Ebert J, Nivbrant N, Kop A, Wood D, et al. Stem Migration and Fretting Corrosion of the Antirotation Pin in the K2/Apex Hip System. J Arthroplasty. 2016;31(3):727-34. doi: 10.1016/j.arth.2015.10.004.
107. Kiernan S, Geijer M, Sundberg M, Flivik G. Effect of symmetrical restoration for the migration of uncemented total hip arthroplasty: a randomized RSA study with 75 patients and 5-year follow-up. J Orthop Surg Res. 2020;15(1):225. doi: 10.1186/s13018-020-01736-0.
108. Kiernan S, Hermann KL, Wagner P, Ryd L, Flivik G. The importance of adequate stem anteversion for rotational stability in cemented total hip replacement: a radiostereometric study with ten-year follow-up. Bone Joint J. 2013;95-b(1):23-30. doi: 10.1302/0301-620x.95b1.30055.
109. Kjærgaard K, Ding M, Jensen C, Bragdon C, Malchau H, Andreasen CM, et al. Vitamin E-doped total hip arthroplasty liners show similar head penetration to highly cross-linked polyethylene at five years: a multi-arm randomized controlled trial. Bone Joint J. 2020;102-b(10):1303-10. doi: 10.1302/0301-620x.102b10.Bjj-2020-0138.R1.
110. Klaassen AD, Schäffer EA, Willigenburg NW, Van Beers L, Scholtes VAB, Van der Hulst VPM, et al. Comparison of early migration patterns between a ceramic and polyethylene liner in uncemented Trabecular Titanium cups: a 2-year randomized controlled trial of 52 hips using radiostereometric analysis. Acta Orthop. 2022;93:451-8. doi: 10.2340/17453674.2022.2267.
111. Klein LJ, Puretic G, Mohaddes M, Kärrholm J. Similar clinical results and early subsidence between the Collum Femoris Preserving and the Corail stem: a randomized radiostereometric study of 77 hips with 2 years' follow-up. Acta Orthop. 2019;90(3):202-8. doi: 10.1080/17453674.2019.1577344.
112. Klerken T, Mohaddes M, Nemes S, Kärrholm J. High early migration of the revised acetabular component is a predictor of late cup loosening: 312 cup revisions followed with radiostereometric analysis for 2-20 years. Hip Int. 2015;25(5):471-6. doi: 10.5301/hipint.5000246.
113. Knudsen MB, Thillemann JK, Jørgensen PB, Jakobsen SS, Daugaard H, Søballe K, et al. Electrochemically applied hydroxyapatite on the cementless porous surface of Bi-Metric stems reduces early migration and has a lasting effect : an efficacy trial of a randomized five-year follow-up radiostereometric study. Bone Joint J. 2022;104-b(6):647-56. doi: 10.1302/0301-620x.104b6.Bjj-2021-1545.R1.

114. Kok RY, Koster LA, Kaptein BL, Fiocco M, Keizer SB. A model-based radiostereometric analysis (RSA) randomized control trial evaluating the stability of the cementless Taperloc hip stem: the TapHip study. Acta Orthop. 2022;93:212-21. doi: 10.2340/17453674.2021.1127.
115. Koppens D, Rytter S, Dalsgaard J, Sørensen OG, Hansen TB, Stilling M. The Effect of Bone Quality on Tibial Component Migration in Medial Cemented Unicompartmental Knee Arthroplasty. A Prospective Cohort Study Using Dual X-Ray Absorptiometry and Radiostereometric Analysis. J Arthroplasty. 2020;35(3):675-82.e2. doi: 10.1016/j.arth.2019.10.027.
116. Koppens D, Rytter S, Munk S, Dalsgaard J, Sørensen OG, Hansen TB, et al. Equal tibial component fixation of a mobile-bearing and fixed-bearing medial unicompartmental knee arthroplasty: a randomized controlled RSA study with 2-year follow-up. Acta Orthop. 2019;90(6):575-81. doi: 10.1080/17453674.2019.1639965.
117. Koppens D, Stilling M, Munk S, Dalsgaard J, Rytter S, Sørensen OG, et al. Low implant migration of the SIGMA(®) medial unicompartmental knee arthroplasty. Knee Surg Sports Traumatol Arthrosc. 2018;26(6):1776-85. doi: 10.1007/s00167-017-4782-5.
118. Kosse NM, van Hellemondt GG, Wymenga AB, Heesterbeek PJ. Comparable Stability of Cemented vs Press-Fit Placed Stems in Revision Total Knee Arthroplasty With Mild to Moderate Bone Loss: 6.5-Year Results From a Randomized Controlled Trial With Radiostereometric Analysis. J Arthroplasty. 2017;32(1):197-201. doi: 10.1016/j.arth.2016.06.003.
119. Koster LA, Meinardi JE, Kaptein BL, Van der Linden-Van der Zwaag E, Nelissen R. Two-year RSA migration results of symmetrical and asymmetrical tibial components in total knee arthroplasty: a randomized controlled trial. Bone Joint J. 2021;103-b(5):855-63. doi: 10.1302/0301-620x.103b5.Bjj-2020-1575.R2.
120. Koster LA, Rassir R, Kaptein BL, Sierevelt IN, Schager M, Nelissen R, et al. A randomized controlled trial comparing two-year postoperative femoral and tibial migration of a new and an established cementless rotating platform total knee arthroplasty. Bone Joint J. 2023;105-b(2):148-57. doi: 10.1302/0301-620x.105b2.Bjj-2022-0414.R1.
121. Kruijntjens D, Koster L, Kaptein BL, Jutten LMC, Arts JJ, Ten Broeke RHM. Early stabilization of the uncemented Symax hip stem in a 2-year RSA study. Acta Orthop. 2020;91(2):159-64. doi: 10.1080/17453674.2019.1709956.
122. Laende EK, Astephen Wilson JL, Mills Flemming J, Valstar ER, Richardson CG, Dunbar MJ. Equivalent 2-year stabilization of uncemented tibial component migration despite higher early migration compared with cemented fixation: an RSA study on 360 total knee arthroplasties. Acta Orthop. 2019;90(2):172-8. doi: 10.1080/17453674.2018.1562633.
123. Laende EK, Mills Flemming J, Astephen Wilson JL, Cantoni E, Dunbar MJ. The associations of implant and patient factors with migration of the tibial component differ by sex : a radiostereometric study on more than 400 total knee arthroplasties. Bone Joint J. 2022;104-b(4):444-51. doi: 10.1302/0301-620x.104b4.Bjj-2021-1247.R1.
124. Laende EK, Richardson CG, Dunbar MJ. A randomized controlled trial of tibial component migration with kinematic alignment using patient-specific instrumentation versus mechanical alignment using computer-assisted surgery in total knee arthroplasty. Bone Joint J. 2019;101-b(8):929-40. doi: 10.1302/0301-620x.101b8.Bjj-2018-0755.R3.
125. Laende EK, Richardson CG, Dunbar MJ. Predictive value of short-term migration in determining long-term stable fixation in cemented and cementless total knee arthroplasties. Bone Joint J. 2019;101-b(7_Supple_C):55-60. doi: 10.1302/0301-620x.101b7.Bjj-2018-1493.R1.
126. Laende EK, Richardson CG, Dunbar MJ. Migration and Wear of a Dual Mobility Acetabular Construct at 3 Years Measured by Radiostereometric Analysis. J Arthroplasty. 2020;35(4):1109-16. doi: 10.1016/j.arth.2019.11.010.
127. Laende EK, Richardson CG, Meldrum AR, Dunbar MJ. Tibial Component Migration After Total Knee Arthroplasty With High-Viscosity Bone Cement. J Arthroplasty. 2021;36(6):2000-5. doi: 10.1016/j.arth.2021.01.081.
128. Lam Tin Cheung K, Lanting BA, McCalden RW, Yuan X, MacDonald SJ, Naudie DD, et al. Inducible displacement of cemented tibial components ten years after total knee arthroplasty. Bone Joint J. 2018;100-b(2):170-5. doi: 10.1302/0301-620x.100b2.Bjj-2017-0428.R2.
129. Lazarinis S, Mattsson P, Milbrink J, Mallmin H, Hailer NP. A prospective cohort study on the short collum femoris-preserving (CFP) stem using RSA and DXA. Primary stability but no prevention of proximal bone loss in 27 patients followed for 2 years. Acta Orthop. 2013;84(1):32-9. doi: 10.3109/17453674.2013.765623.

130. Lazarinis S, Milbrink J, Mattsson P, Mallmin H, Hailer NP. Bone loss around a stable, partly threaded hydroxyapatite-coated cup: a prospective cohort study using RSA and DXA. Hip Int. 2014;24(2):155-66. doi: 10.5301/hipint.5000104.
131. Ledin H, Aspenberg P, Good L. Tourniquet use in total knee replacement does not improve fixation, but appears to reduce final range of motion. Acta Orthop. 2012;83(5):499-503. doi: 10.3109/17453674.2012.727078.
132. Ledin H, Good L, Aspenberg P. Denosumab reduces early migration in total knee replacement. Acta Orthop. 2017;88(3):255-8. doi: 10.1080/17453674.2017.1300746.
133. Ledin H, Good L, Johansson T, Aspenberg P. No effect of teriparatide on migration in total knee replacement. Acta Orthop. 2017;88(3):259-62. doi: 10.1080/17453674.2017.1300745.
134. Li Y, Röhrl SM, Bøe B, Nordsletten L. Comparison of two different Radiostereometric analysis (RSA) systems with markerless elementary geometrical shape modeling for the measurement of stem migration. Clin Biomech (Bristol, Avon). 2014;29(8):950-5. doi: 10.1016/j.clinbiomech.2014.06.007.
135. Lindalen E, Dahl J, Nordsletten L, Snorrason F, Høvik Ø, Röhrl S. Reverse hybrid and cemented hip replacement compared using radiostereometry and dual-energy X-ray absorptiometry: 43 hips followed for 2 years in a prospective trial. Acta Orthop. 2012;83(6):592-8. doi: 10.3109/17453674.2012.742393.
136. Lindalen E, Nordsletten L, Röhrl SM. Segment choice and cup stability influence wear measurements using radiostereometric analysis: a radiostereometric study comparing wear measured by markers in the polyethylene with markers in the periacetabular bone. Clin Biomech (Bristol, Avon). 2012;27(5):511-4. doi: 10.1016/j.clinbiomech.2011.11.009.
137. Linde KN, Madsen F, Puhakka KB, Langdahl BL, Søballe K, Krog-Mikkelsen I, et al. Preoperative Systemic Bone Quality Does Not Affect Tibial Component Migration in Knee Arthroplasty: A 2-Year Radiostereometric Analysis of a Hundred Consecutive Patients. J Arthroplasty. 2019;34(10):2351-9. doi: 10.1016/j.arth.2019.05.019.
138. Linde KN, Rytter S, Søballe K, Madsen F, Langdahl B, Stilling M. Component migration, bone mineral density changes, and bone turnover markers in cementless and cemented total knee arthroplasty: a prospective randomized RSA study in 53 patients with 2-year follow-up. Knee Surg Sports Traumatol Arthrosc. 2022;30(9):3100-13. doi: 10.1007/s00167-022-06860-4.
139. Lorenzen ND, Stilling M, Jakobsen SS, Gustafson K, Søballe K, Baad-Hansen T. Marker-based or model-based RSA for evaluation of hip resurfacing arthroplasty? A clinical validation and 5-year follow-up. Arch Orthop Trauma Surg. 2013;133(11):1613-21. doi: 10.1007/s00402-013-1850-2.
140. Mahmoud AN, Kesteris U, Flivik G. Stable migration pattern of an ultra-short anatomical uncemented hip stem: a prospective study with 2 years radiostereometric analysis follow-up. Hip Int. 2017;27(3):259-66. doi: 10.5301/hipint.5000458.
141. Matejcic A, Vidovic D, Nebergall A, Greene M, Bresina S, Tepic S, et al. New cementless fixation in hip arthroplasty: a radiostereometric analysis. Hip Int. 2015;25(5):477-83. doi: 10.5301/hipint.5000254.
142. McCalden RW, Korczak A, Somerville L, Yuan X, Naudie DD. A randomised trial comparing a short and a standard-length metaphyseal engaging cementless femoral stem using radiostereometric analysis. Bone Joint J. 2015;97-b(5):595-602. doi: 10.1302/0301-620x.97b5.34994.
143. Mechlenburg I, Klebe TM, Døssing KV, Amstrup A, Søballe K, Stilling M. Evaluation of periprosthetic bone mineral density and postoperative migration of humeral head resurfacing implants: two-year results of a randomized controlled clinical trial. J Shoulder Elbow Surg. 2014;23(10):1427-36. doi: 10.1016/j.jse.2014.05.012.
144. Meinardi JE, Valstar ER, Van Der Voort P, Kaptein BL, Fiocco M, Nelissen RG. Palacos compared to Palamed bone cement in total hip replacement: a randomized controlled trial. Acta Orthop. 2016;87(5):473-8. doi: 10.1080/17453674.2016.1199146.
145. Mills K, Wymenga AB, Bénard MR, Kaptein BL, Defoort KC, van Hellemondt GG, et al. Fluoroscopic and radiostereometric analysis of a bicruciate-retaining versus a posterior cruciate-retaining total knee arthroplasty: a randomized controlled trial. Bone Joint J. 2023;105-b(1):35-46. doi: 10.1302/0301-620x.105b1.Bjj-2022-0465.R2.
146. Mills K, Wymenga AB, van Hellemondt GG, Heesterbeek PJC. No difference in long-term micromotion between fully cemented and hybrid fixation in revision total knee arthroplasty: a randomized controlled trial. Bone Joint J. 2022;104-b(7):875-83. doi: 10.1302/0301-620x.104b7.Bjj-2021-1600.R1.

147. Minten MJ, Heesterbeek PJ, Spruit M. No effect of additional screw fixation of a cementless, all-polyethylene press-fit socket on migration, wear, and clinical outcome. Acta Orthop. 2016;87(4):363-7. doi: 10.1080/17453674.2016.1190244.
148. Mohaddes M, Herberts P, Malchau H, Johanson PE, Kärrholm J. High proximal migration in cemented acetabular revisions operated with bone impaction grafting; 47 revision cups followed with RSA for 17 years. Hip Int. 2017;27(3):251-8. doi: 10.5301/hipint.5000452.
149. Mohaddes M, Shareghi B, Kärrholm J. Promising early results for trabecular metal acetabular components used at revision total hip arthroplasty: 42 acetabular revisions followed with radiostereometry In a prospective randomised trial. Bone Joint J. 2017;99-b(7):880-6. doi: 10.1302/0301-620x.99b7.Bjj-2016-1241.R1.
150. Molt M, Harsten A, Toksvig-Larsen S. The effect of tourniquet use on fixation quality in cemented total knee arthroplasty a prospective randomized clinical controlled RSA trial. Knee. 2014;21(2):396-401. doi: 10.1016/j.knee.2013.10.008.
151. Molt M, Ljung P, Toksvig-Larsen S. Does a new knee design perform as well as the design it replaces? Bone Joint Res. 2012;1(12):315-23. doi: 10.1302/2046-3758.112.2000064.
152. Molt M, Ryd L, Toksvig-Larsen S. A randomized RSA study concentrating especially on continuous migration. Acta Orthop. 2016;87(3):262-7. doi: 10.3109/17453674.2016.1166876.
153. Molt M, Toksvig-Larsen S. Similar early migration when comparing CR and PS in Triathlon™ TKA: A prospective randomised RSA trial. Knee. 2014;21(5):949-54. doi: 10.1016/j.knee.2014.05.012.
154. Molt M, Toksvig-Larsen S. 2-year follow-up report on micromotion of a short tibia stem. A prospective, randomized RSA study of 59 patients. Acta Orthop. 2015;86(5):594-8. doi: 10.3109/17453674.2015.1033303.
155. Mosegaard SB, Odgaard A, Madsen F, Rømer L, Kristensen PW, Vind TD, et al. Comparison of cementless twin-peg, cemented twin-peg and cemented single-peg femoral component migration after medial unicompartmental knee replacement: a 5-year randomized RSA study. Arch Orthop Trauma Surg. 2023;143(12):7169-83. doi: 10.1007/s00402-023-04991-y.
156. Munir S, Suzuki L, Dixon M. Migration Characteristics of a Proximally Coated Collarless Femoral Stem: A Prospective 2-Year Radiostereometric Analysis Study. Arthroplast Today. 2023;22:101157. doi: 10.1016/j.artd.2023.101157.
157. Munzinger U, Guggi T, Kaptein B, Persoon M, Valstar E, Doets HC. A titanium plasma-sprayed cup with and without hydroxyapatite-coating: a randomised radiostereometric study of stability and osseointegration. Hip Int. 2013;23(1):33-9. doi: 10.5301/hip.2013.10598.
158. Murray DW, Gulati A, Gill HS. Ten-year RSA-measured migration of the Exeter femoral stem. Bone Joint J. 2013;95-b(5):605-8. doi: 10.1302/0301-620x.95b5.31330.
159. Naudie DD, Somerville L, Korczak A, Yuan X, McCalden RW, Holdsworth D, et al. A randomized trial comparing acetabular component fixation of two porous ingrowth surfaces using RSA. J Arthroplasty. 2013;28(8 Suppl):48-52. doi: 10.1016/j.arth.2013.06.041.
160. Nazari-Farsani S, Vuopio M, Löyttyniemi E, Aro HT. Contributing factors to the initial femoral stem migration in cementless total hip arthroplasty of postmenopausal women. J Biomech. 2021;117:110262. doi: 10.1016/j.jbiomech.2021.110262.
161. Nazari-Farsani S, Vuopio ME, Aro HT. Bone Mineral Density and Cortical-Bone Thickness of the Distal Radius Predict Femoral Stem Subsidence in Postmenopausal Women. J Arthroplasty. 2020;35(7):1877-84.e1. doi: 10.1016/j.arth.2020.02.062.
162. Nebergall A, Bragdon C, Antonellis A, Kärrholm J, Brånemark R, Malchau H. Stable fixation of an osseointegated implant system for above-the-knee amputees: titel RSA and radiographic evaluation of migration and bone remodeling in 55 cases. Acta Orthop. 2012;83(2):121-8. doi: 10.3109/17453674.2012.678799.
163. Niesen AE, Garverick AL, Howell SM, Hull ML. Low tibial baseplate migration 1 year after unrestricted kinematically aligned total knee arthroplasty using a medial conforming implant design. Knee Surg Sports Traumatol Arthrosc. 2023;31(4):1433-42. doi: 10.1007/s00167-022-07171-4.
164. Nieuwenhuijse MJ, Valstar ER, Kaptein BL, Nelissen RG. Good diagnostic performance of early migration as a predictor of late aseptic loosening of acetabular cups: results from ten years of follow-up with Roentgen stereophotogrammetric analysis (RSA). J Bone Joint Surg Am. 2012;94(10):874-80. doi: 10.2106/jbjs.K.00305.
165. Nieuwenhuijse MJ, Valstar ER, Kaptein BL, Nelissen RG. The Exeter femoral stem continues to migrate during its first decade after implantation: 10-12 years of follow-up with

radiostereometric analysis (RSA). Acta Orthop. 2012;83(2):129-34. doi: 10.3109/17453674.2012.672093.
166. Nieuwenhuijse MJ, Valstar ER, Nelissen RG. 5-year clinical and radiostereometric analysis (RSA) follow-up of 39 CUT femoral neck total hip prostheses in young osteoarthritis patients. Acta Orthop. 2012;83(4):334-41. doi: 10.3109/17453674.2012.702392.
167. Nieuwenhuijse MJ, van der Voort P, Kaptein BL, van der Linden-van der Zwaag HM, Valstar ER, Nelissen RG. Fixation of high-flexion total knee prostheses: five-year follow-up results of a four-arm randomized controlled clinical and roentgen stereophotogrammetric analysis study. J Bone Joint Surg Am. 2013;95(19):e1411-11. doi: 10.2106/jbjs.L.01523.
168. Nieuwenhuijse MJ, Vehmeijer SBW, Mathijsen NMC, Keizer SB. Fixation of the short global tissue-sparing hip stem. Bone Joint J. 2020;102-b(6):699-708. doi: 10.1302/0301-620x.102b6.Bjj-2019-1026.R2.
169. Nilsson KG, Theodoulou A, Mercer G, Quinn SJ, Krishnan J. Mid-term migration of a cementless, porous acetabular cup: A 5 year Radiostereometric analysis. J Orthop. 2017;14(4):454-60. doi: 10.1016/j.jor.2017.07.004.
170. Nivbrant NO, Khan RJK, Fick DP, Haebich S, Smith E. Cementless Versus Cemented Tibial Fixation in Posterior Stabilized Total Knee Replacement: A Randomized Trial. J Bone Joint Surg Am. 2020;102(12):1075-82. doi: 10.2106/jbjs.19.01010.
171. Nuttall D, Birch A, Haines JF, Trail IA. Radiostereographic analysis of a shoulder surface replacement: does hydroxyapatite have a place? Bone Joint J. 2014;96-b(8):1077-81. doi: 10.1302/0301-620x.96b8.30534.
172. Nuttall D, Birch A, Haines JF, Watts AC, Trail IA. Early migration of a partially cemented fluted glenoid component inserted using a cannulated preparation system. Bone Joint J. 2017;99-b(5):674-9. doi: 10.1302/0301-620x.99b5.Bjj-2016-0745.R1.
173. Nuttall D, Haines JF, Trail IA. The early migration of a partially cemented fluted pegged glenoid component using radiostereometric analysis. J Shoulder Elbow Surg. 2012;21(9):1191-6. doi: 10.1016/j.jse.2011.07.028.
174. Nysted M, Foss OA, Klaksvik J, Benum P, Haugan K, Husby OS, et al. Small and similar amounts of micromotion in an anatomical stem and a customized cementless femoral stem in regular-shaped femurs. A 5-year follow-up randomized RSA study. Acta Orthop. 2014;85(2):152-8. doi: 10.3109/17453674.2014.899846.
175. Nyström A, Kiritopoulos D, Mallmin H, Lazarinis S. Continuous periprosthetic bone loss but preserved stability for a collum femoris-preserving stem: follow-up of a prospective cohort study of 21 patients with dualenergy X-ray absorptiometry and radiostereometric analysis with minimum 8 years of follow-up. Acta Orthop. 2022;93:206-11. doi: 10.2340/17453674.2021.1080.
176. Øhrn FD, Lian Ø B, Tsukanaka M, Röhrl SM. Early migration of a medially stabilized total knee arthroplasty : a radiostereometric analysis study up to two years. Bone Jt Open. 2021;2(9):737-44. doi: 10.1302/2633-1462.29.Bjo-2021-0115.R1.
177. Øhrn FD, Van Leeuwen J, Tsukanaka M, Röhrl SM. A 2-year RSA study of the Vanguard CR total knee system: A randomized controlled trial comparing patient-specific positioning guides with conventional technique. Acta Orthop. 2018;89(4):418-24. doi: 10.1080/17453674.2018.1470866.
178. Okowinski M, Hjorth MH, Mosegaard SB, Jürgens-Lahnstein JH, Storgaard Jakobsen S, Hedevang Christensen P, et al. Ten-year comparison of two different techniques for femoral bone cavity preparation-broaching versus compaction in patients with cementless total hip arthroplasty : a randomized radiostereometric study of 30 total hip arthroplasties in 15 patients operated bilaterally. Bone Jt Open. 2021;2(12):1035-42. doi: 10.1302/2633-1462.212.Bjo-2021-0152.R1.
179. Olerud F, Olsson C, Flivik G. Comparison of Refobacin bone cement and palacos with gentamicin in total hip arthroplasty: an RSA study with two years follow-up. Hip Int. 2014;24(1):56-62. doi: 10.5301/hipint.5000088.
180. Otten V, Wästerlund D, Lindbjörn J, Mertens C, Mukka S, Crnalic S, et al. Evaluation of a new cemented highly cross-linked all-polyethylene cup: a prospective and randomised study assessing wear and fixation characteristics using radiostereometric analysis. Hip Int. 2022;32(6):779-86. doi: 10.1177/1120700021989991.
181. Otten VT, Crnalic S, Röhrl SM, Nivbrant B, Nilsson KG. Stability of Uncemented Cups - Long-Term Effect of Screws, Pegs and HA Coating: A 14-Year RSA Follow-Up of Total Hip Arthroplasty. J Arthroplasty. 2016;31(1):156-61. doi: 10.1016/j.arth.2015.07.012.

182. Pakvis D, Luites J, van Hellemondt G, Spruit M. A cementless, elastic press-fit socket with and without screws. Acta Orthop. 2012;83(5):481-7. doi: 10.3109/17453674.2012.720116.
183. Pasma JH, Hesseling B, De Esch N, Verburg H, Niesten DD, Mathijssen NMC. Early migration in unicompartmental knee arthroplasty: a radiostereometric study of 26 patients with 24 months of follow-up. Acta Orthop. 2022;93:914-21. doi: 10.2340/17453674.2022.5672.
184. Penny JO, Ding M, Varmarken JE, Ovesen O, Overgaard S. Early micromovement of the Articular Surface Replacement (ASR) femoral component: two-year radiostereometry results. J Bone Joint Surg Br. 2012;94(10):1344-50. doi: 10.1302/0301-620x.94b10.29030.
185. Perelgut ME, Polus JS, Lanting BA, Teeter MG. The effect of femoral stem collar on implant migration and clinical outcomes following direct anterior approach total hip arthroplasty. Bone Joint J. 2020;102-b(12):1654-61. doi: 10.1302/0301-620x.102b12.Bjj-2019-1428.R1.
186. Petursson G, Fenstad AM, Gøthesen Ø, Haugan K, Dyrhovden GS, Hallan G, et al. Similar migration in computer-assisted and conventional total knee arthroplasty. Acta Orthop. 2017;88(2):166-72. doi: 10.1080/17453674.2016.1267835.
187. Pijls BG, Valstar ER, Kaptein BL, Fiocco M, Nelissen RG. The beneficial effect of hydroxyapatite lasts: a randomized radiostereometric trial comparing hydroxyapatite-coated, uncoated, and cemented tibial components for up to 16 years. Acta Orthop. 2012;83(2):135-41. doi: 10.3109/17453674.2012.665330.
188. Pijls BG, Valstar ER, Kaptein BL, Nelissen RG. Differences in long-term fixation between mobile-bearing and fixed-bearing knee prostheses at ten to 12 years' follow-up: a single-blinded randomised controlled radiostereometric trial. J Bone Joint Surg Br. 2012;94(10):1366-71. doi: 10.1302/0301-620x.94b10.28858.
189. Polus JS, Perelgut ME, Vasarhelyi EM, Teeter MG, Lanting BA. Femoral stem migration after direct lateral and direct anterior total hip arthroplasty: a prospective cohort study. Can J Surg. 2022;65(4):E487-e95. doi: 10.1503/cjs.013221.
190. Polus JS, Vasarhelyi EM, Lanting BA, Teeter MG. Acetabular cup fixation with and without screws following primary total hip arthroplasty: migration evaluated by radiostereometric analysis. Hip Int. 2024;34(1):42-8. doi: 10.1177/11207000231164711.
191. Ramasamy B, Abrahams JM, Clothier RJ, Solomon LB, Callary SA. RSA Measurements of Implant Instability in a Paprosky III Pelvic Defect with Discontinuity: A Case Report. JBJS Case Connect. 2022;12(4). doi: e22.0029610.2106/jbjs.Cc.22.00296.
192. Reiner T, Sonntag R, Kretzer JP, Clarius M, Jakubowitz E, Weiss S, et al. The Migration Pattern of a Cementless Hydroxyapatite-Coated Titanium Stem under Immediate Full Weight-Bearing-A Randomized Controlled Trial Using Model-Based RSA. J Clin Med. 2020;9(7). doi: 10.3390/jcm9072077.
193. Richardson CG, Laende EK, Gross M, Dunbar MJ. Prospective clinical study using radiostereometric analysis (RSA) to evaluate fixation of a modular cemented polished femoral stem. Hip Int. 2021;31(2):191-5. doi: 10.1177/1120700019881429.
194. Rilby K, Mohaddes M, Kärrholm J. Similar results after five years with the use of the Fitmore or the CLS femoral components. Bone Jt Open. 2023;4(5):306-14. doi: 10.1302/2633-1462.45.Bjo-2023-0007.R1.
195. Rilby K, Mohaddes M, Nauclér E, Kärrholm J. Similar outcome with a new anteverted or a straight standard stem: a randomized study of 72 total hip arthroplasties evaluated with clinical variables, radiostereometry, and DXA up to 2 years. Acta Orthop. 2022;93:59-67. doi: 10.1080/17453674.2021.1993606.
196. Rilby K, Nauclér E, Mohaddes M, Kärrholm J. No difference in outcome or migration but greater loss of bone mineral density with the Collum Femoris Preserving stem compared with the Corail stem: a randomized controlled trial with five-year follow-up. Bone Joint J. 2022;104-b(5):581-8. doi: 10.1302/0301-620x.104b5.Bjj-2021-1539.R1.
197. Röhrl SM, Nivbrant B, Nilsson KG. No adverse effects of submelt-annealed highly crosslinked polyethylene in cemented cups: an RSA study of 8 patients 10 yaers after surgery. Acta Orthop. 2012;83(2):148-52. doi: 10.3109/17453674.2011.652889.
198. Rutherford M, Khan RJK, Fick DP, Haebich S, Nivbrant O, Kozak T. Randomised clinical trial assessing migration of uncemented primary total hip replacement stems, with and without autologous impaction bone grafting. Int Orthop. 2019;43(12):2715-23. doi: 10.1007/s00264-019-04290-5.

199. Saari TM, Digas G, Kärrholm JN. Risedronate does not enhance fixation or BMD in revision cups: randomised study with three years follow-up. Hip Int. 2014;24(1):49-55. doi: 10.5301/hipint.5000081.
200. Salemyr M, Muren O, Ahl T, Bodén H, Eisler T, Stark A, et al. Lower periprosthetic bone loss and good fixation of an ultra-short stem compared to a conventional stem in uncemented total hip arthroplasty. Acta Orthop. 2015;86(6):659-66. doi: 10.3109/17453674.2015.1067087.
201. Salemyr M, Muren O, Eisler T, Bodén H, Chammout G, Stark A, et al. Porous titanium construct cup compared to porous coated titanium cup in total hip arthroplasty. A randomised controlled trial. Int Orthop. 2015;39(5):823-32. doi: 10.1007/s00264-014-2571-z.
202. Sandberg O, Tholén S, Carlsson S, Wretenberg P. The anatomical SP-CL stem demonstrates a non-progressing migration pattern in the first year: a low dose CT-based migration study in 20 patients. Acta Orthop. 2020;91(6):654-9. doi: 10.1080/17453674.2020.1832294.
203. Schewelov T, Ahlborg H, Sanzén L, Besjakov J, Carlsson A. Fixation of the fully hydroxyapatite-coated Corail stem implanted due to femoral neck fracture: 38 patients followed for 2 years with RSA and DEXA. Acta Orthop. 2012;83(2):153-8. doi: 10.3109/17453674.2011.641107.
204. Schilcher J, Ivarsson I, Perlbach R, Palm L. No Difference in Periprosthetic Bone Loss and Fixation Between a Standard-Length Stem and a Shorter Version in Cementless Total Hip Arthroplasty. A Randomized Controlled Trial. J Arthroplasty. 2017;32(4):1220-6. doi: 10.1016/j.arth.2016.11.015.
205. Schilcher J, Palm L, Ivarsson I, Aspenberg P. Local bisphosphonate reduces migration and formation of radiolucent lines adjacent to cemented acetabular components. Bone Joint J. 2017;99-b(3):317-24. doi: 10.1302/0301-620x.99b3.Bjj-2016-0531.R1.
206. Schoeman MA, Pijls BG, Oostlander AE, Keurentjes JC, Valstar ER, Nelissen RG, et al. Innate immune response and implant loosening: Interferon gamma is inversely associated with early migration of total knee prostheses. J Orthop Res. 2016;34(1):121-6. doi: 10.1002/jor.22988.
207. Schotanus MGM, Pilot P, Kaptein BL, Draijer WF, Tilman PBJ, Vos R, et al. No difference in terms of radiostereometric analysis between fixed- and mobile-bearing total knee arthroplasty: a randomized, single-blind, controlled trial. Knee Surg Sports Traumatol Arthrosc. 2017;25(9):2978-85. doi: 10.1007/s00167-016-4138-6.
208. Schwarze M, Budde S, von Lewinski G, Windhagen H, Keller MC, Seehaus F, et al. No effect of conventional vs. minimally invasive surgical approach on clinical outcome and migration of a short stem total hip prosthesis at 2-year follow-up: A randomized controlled study. Clin Biomech (Bristol, Avon). 2018;51:105-12. doi: 10.1016/j.clinbiomech.2017.12.004.
209. Sesselmann S, Hong Y, Schlemmer F, Hussnaetter I, Mueller LA, Forst R, et al. Radiostereometric migration measurement of an uncemented Cerafit® femoral stem: 26 patients followed for 10 years. Biomed Tech (Berl). 2018;63(6):657-63. doi: 10.1515/bmt-2016-0251.
210. Sesselmann S, Hong Y, Schlemmer F, Wiendieck K, Söder S, Hussnaetter I, et al. Migration measurement of the cemented Lubinus SP II hip stem - a 10-year follow-up using radiostereometric analysis. Biomed Tech (Berl). 2017;62(3):271-8. doi: 10.1515/bmt-2015-0172.
211. Sevaldsen K, Schnell Husby O, Lian Ø B, Farran KM, Schnell Husby V. Is the French Paradox cementing philosophy superior to the standard cementing? A randomized controlled radiostereometric trial and comparative analysis. Bone Joint J. 2022;104-b(1):19-26. doi: 10.1302/0301-620x.104b1.Bjj-2021-0325.R2.
212. Shareghi B, Johanson PE, Kärrholm J. Femoral Head Penetration of Vitamin E-Infused Highly Cross-Linked Polyethylene Liners: A Randomized Radiostereometric Study of Seventy Hips Followed for Two Years. J Bone Joint Surg Am. 2015;97(16):1366-71. doi: 10.2106/jbjs.N.00595.
213. Shareghi B, Johanson PE, Kärrholm J. Wear of Vitamin E-Infused Highly Cross-Linked Polyethylene at Five Years. J Bone Joint Surg Am. 2017;99(17):1447-52. doi: 10.2106/jbjs.16.00691.
214. Shareghi B, Johanson PE, Kärrholm J. Clinical evaluation of model-based radiostereometric analysis to measure femoral head penetration and cup migration in four different cup designs. J Orthop Res. 2017;35(4):760-7. doi: 10.1002/jor.23177.
215. Sillesen NH, Greene ME, Nebergall AK, Nielsen PT, Laursen MB, Troelsen A, et al. Three Year RSA Evaluation of Vitamin E Diffused Highly Cross-linked Polyethylene Liners and Cup Stability. J Arthroplasty. 2015;30(7):1260-4. doi: 10.1016/j.arth.2015.02.018.
216. Sköldenberg OG, Rysinska AD, Chammout G, Salemyr M, Mukka SS, Bodén H, et al. A randomized double-blind noninferiority trial, evaluating migration of a cemented vitamin E-stabilized highly crosslinked component compared with a standard polyethylene component in reverse hybrid

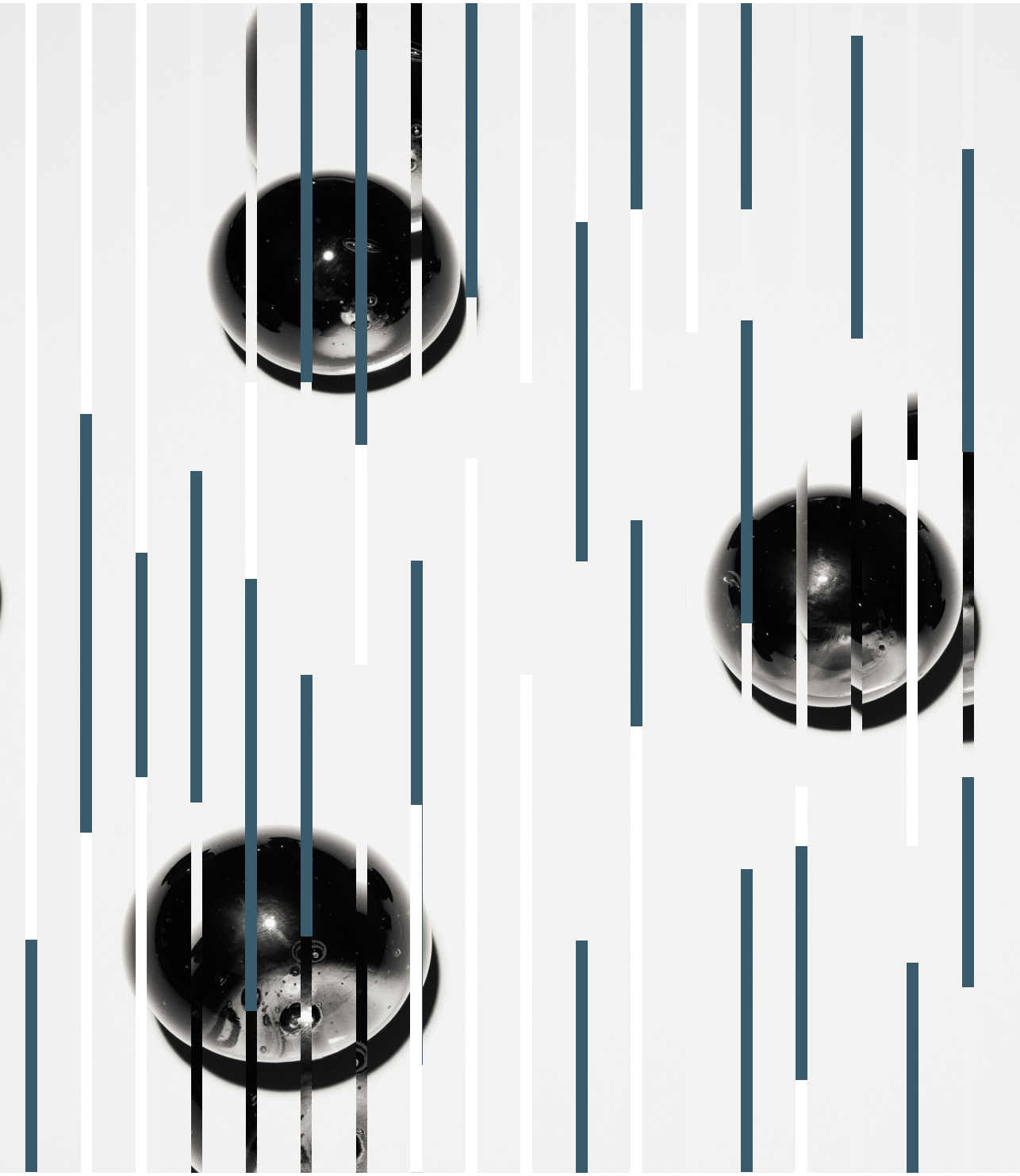
total hip arthroplasty. Bone Joint J. 2019;101-b(10):1192-8. doi: 10.1302/0301-620x.101b10.Bjj-2019-0456.R2.
217. Sköldenberg OG, Sjöö H, Kelly-Pettersson P, Bodén H, Eisler T, Stark A, et al. Good stability but high periprosthetic bone mineral loss and late-occurring periprosthetic fractures with use of uncemented tapered femoral stems in patients with a femoral neck fracture. Acta Orthop. 2014;85(4):396-402. doi: 10.3109/17453674.2014.931195.
218. Söderlund P, Dahl J, Röhrl S, Nivbrant B, Nilsson KG. 10-year results of a new low-monomer cement: follow-up of a randomized RSA study. Acta Orthop. 2012;83(6):604-8. doi: 10.3109/17453674.2012.742392.
219. Solomon LB, Abrahams JM, Callary SA, Howie DW. The Stability of the Porous Tantalum Components Used in Revision THA to Treat Severe Acetabular Defects: A Radiostereometric Analysis Study. J Bone Joint Surg Am. 2018;100(22):1926-33. doi: 10.2106/jbjs.18.00127.
220. Solomon LB, Studer P, Abrahams JM, Callary SA, Moran CR, Stamenkov RB, et al. Does cup-cage reconstruction with oversized cups provide initial stability in THA for osteoporotic acetabular fractures? Clin Orthop Relat Res. 2015;473(12):3811-9. doi: 10.1007/s11999-015-4460-1.
221. Sporer S, MacLean L, Burger A, Moric M. Evaluation of a 3D-printed total knee arthroplasty using radiostereometric analysis: assessment of highly porous biological fixation of the tibial baseplate and metal-backed patellar component. Bone Joint J. 2019;101-b(7_Supple_C):40-7. doi: 10.1302/0301-620x.101b7.Bjj-2018-1466.R1.
222. Stålman A, Sköldenberg O, Martinez-Carranza N, Roberts D, Högström M, Ryd L. No implant migration and good subjective outcome of a novel customized femoral resurfacing metal implant for focal chondral lesions. Knee Surg Sports Traumatol Arthrosc. 2018;26(7):2196-204. doi: 10.1007/s00167-017-4805-2.
223. Steiner DK, Drivsholm NS, Buchardt STE, Laursen M. The influence of migration of the exeter V40 stem on patient reported outcome measures: a 2-year follow-up of 112 total hip arthroplasties using radiostereometric analysis. Eur J Orthop Surg Traumatol. 2022;32(1):167-74. doi: 10.1007/s00590-021-02937-x.
224. Stilling M, Mechlenburg I, Amstrup A, Soballe K, Klebe T. Precision of novel radiological methods in relation to resurfacing humeral head implants: assessment by radiostereometric analysis, DXA, and geometrical analysis. Arch Orthop Trauma Surg. 2012;132(11):1521-30. doi: 10.1007/s00402-012-1580-x.
225. Stilling M, Mechlenburg I, Jepsen CF, Rømer L, Rahbek O, Søballe K, et al. Superior fixation and less periprosthetic stress-shielding of tibial components with a finned stem versus an I-beam block stem: a randomized RSA and DXA study with minimum 5 years' follow-up. Acta Orthop. 2019;90(2):165-71. doi: 10.1080/17453674.2019.1566510.
226. Szerlip B, Muh S, Streit JJ, Gobezie R. Humeral Fixation in Shoulder Arthroplasty: Does Stem Geometry Matter? Seminars in Arthroplasty JSES. 2012;23(2):103-5. doi: https://dx.doi.org/10.1053/j.sart.2012.03.008.
227. Tabori-Jensen S, Mosegaard SB, Hansen TB, Stilling M. Inferior stabilization of cementless compared with cemented dual-mobility cups in elderly osteoarthrosis patients: a randomized controlled radiostereometry study on 60 patients with 2 years' follow-up. Acta Orthop. 2020;91(3):246-53. doi: 10.1080/17453674.2020.1720978.
228. Teeter MG, Broberg JS, Howard JL, Lanting BA. Axial and Sagittal Rotation of Cementless Tibial Baseplates Occurs in Bone Under Joint Loading. J Arthroplasty. 2023;38(6):1166-71. doi: 10.1016/j.arth.2023.03.002.
229. Teeter MG, Marsh JD, Howard JL, Yuan X, Vasarhelyi EM, McCalden RW, et al. A randomized controlled trial investigating the value of patient-specific instrumentation for total knee arthroplasty in the Canadian healthcare system. Bone Joint J. 2019;101-b(5):565-72. doi: 10.1302/0301-620x.101b5.Bjj-2018-1323.R1.
230. Teeter MG, McCalden RW, Yuan X, MacDonald SJ, Naudie DD. Predictive accuracy of RSA migration thresholds for cemented total hip arthroplasty stem designs. Hip Int. 2018;28(4):363-8. doi: 10.1177/1120700018762179.
231. Teeter MG, Naudie DD, McCalden RW, Yuan X, Holdsworth DW, MacDonald SJ, et al. Varus tibial alignment is associated with greater tibial baseplate migration at 10 years following total knee arthroplasty. Knee Surg Sports Traumatol Arthrosc. 2018;26(6):1610-7. doi: 10.1007/s00167-017-4765-6.

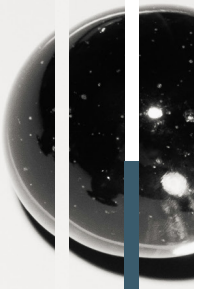
232. Teeter MG, Perry K, Yuan X, Howard JL, Lanting BA. The Effects of Resection Technique on Implant Migration in Single Radius Posterior-Stabilized Total Knee Replacement. J Knee Surg. 2020;33(1):78-83. doi: 10.1055/s-0038-1676462.
233. Teeter MG, Perry KI, Yuan X, Howard JL, Lanting BA. Contact Kinematics Correlates to Tibial Component Migration Following Single Radius Posterior Stabilized Knee Replacement. J Arthroplasty. 2018;33(3):740-5. doi: 10.1016/j.arth.2017.09.064.
234. Teeter MG, Thoren J, Yuan X, McCalden RW, MacDonald SJ, Lanting BA, et al. Migration of a cemented fixed-bearing, polished titanium tibial baseplate (Genesis II) at ten years : a radiostereometric analysis. Bone Joint J. 2016;98-b(5):616-21. doi: 10.1302/0301-620x.98b5.36865.
235. Ten Brinke B, Hesseling B, Eygendaal D, Hoelen MA, Mathijssen NMC. Early fixation of the humeral component in stemless total shoulder arthroplasty : a radiostereometric and clinical study with 24-month follow-up. Bone Joint J. 2022;104-b(1):76-82. doi: 10.1302/0301-620x.104b1.Bjj-2021-0945.R1.
236. Ten Brinke B, Mathijssen NM, Blom I, Deijkers RL, Ooms EM, Kraan GA. Model-based roentgen stereophotogrammetric analysis of the surface replacement trapeziometacarpal total joint arthroplasty. J Hand Surg Eur Vol. 2016;41(9):925-9. doi: 10.1177/1753193416629070.
237. Ten Brinke B, Mathijssen NMC, Blom IF, Koster LA, Kraan GA. A radiostereometric and clinical long-term follow-up study of the surface replacement trapeziometacarpal joint prosthesis. BMC Musculoskelet Disord. 2021;22(1):148. doi: 10.1186/s12891-021-03957-8.
238. Thien TM, Thanner J, Kärrholm J. Fixation and bone remodeling around a low-modulus stem seven-year follow-up of a randomized study with use of radiostereometry and dual-energy x-ray absorptiometer. J Arthroplasty. 2012;27(1):134-42.e1. doi: 10.1016/j.arth.2011.03.029.
239. Thoen PS, Nordsletten L, Pripp AH, Röhrl SM. Results of a randomized controlled trial with five-year radiostereometric analysis results of vitamin E-infused highly crosslinked versus moderately crosslinked polyethylene in reverse total hip arthroplasty. Bone Joint J. 2020;102-b(12):1646-53. doi: 10.1302/0301-620x.102b12.Bjj-2020-0721.R1.
240. Tjørnild M, Søballe K, Hansen PM, Holm C, Stilling M. Mobile- vs. fixed-bearing total knee replacement. Acta Orthop. 2015;86(2):208-14. doi: 10.3109/17453674.2014.968476.
241. Torle J, Thillemann JK, Petersen ET, Madsen F, Søballe K, Stilling M. Less polyethylene wear in monobloc compared to modular ultra-high-molecular-weight-polyethylene inlays in hybrid total knee arthroplasty: A 5-year randomized radiostereometry study. Knee. 2021;29:486-99. doi: 10.1016/j.knee.2021.02.033.
242. Tøttrup M, Thillemann JK, Thillemann TM, Mechlenburg I, Klebe T, Søballe K, et al. Early offset-increasing migration predicts later revision for humeral head resurfacing implants. A randomized controlled radiostereometry trial with 10-year clinical follow-up. J Orthop Res. 2022;40(11):2688-97. doi: 10.1002/jor.25298.
243. Troelsen A, Ingelsrud LH, Thomsen MG, Muharemovic O, Otte KS, Husted H. Are There Differences in Micromotion on Radiostereometric Analysis Between Bicruciate and Cruciate-retaining Designs in TKA? A Randomized Controlled Trial. Clin Orthop Relat Res. 2020;478(9):2045-53. doi: 10.1097/corr.0000000000001077.
244. Tschunko F, Wagner B, Hong Y, Söder S, Wölfel R, Müller LA, et al. Radiostereometric migration analysis of the Cerafit femoral stem: 28 patients followed for 2 years. Biomed Tech (Berl). 2016;61(3):291-8. doi: 10.1515/bmt-2015-0004.
245. Tsikandylakis G, Mortensen KRL, Gromov K, Troelsen A, Malchau H, Mohaddes M. The Use of Porous Titanium Coating and the Largest Possible Head Do Not Affect Early Cup Fixation: A 2-Year Report from a Randomized Controlled Trial. JB JS Open Access. 2020;5(4). doi: 10.2106/jbjs.Oa.20.00107.
246. Tsukanaka M, Röhrl SM, von Schewelov T, Nordsletten L. Identification of femoral head center of bipolar hemiarthroplasy in radiostereometric analysis with elementary geometrical shape models. J Biomech. 2016;49(3):469-73. doi: 10.1016/j.jbiomech.2015.11.054.
247. Turgeon TR, Gascoyne TC, Laende EK, Dunbar MJ, Bohm ER, Richardson CG. The assessment of the stability of the tibial component of a novel knee arthroplasty system using radiostereometric analysis. Bone Joint J. 2018;100-b(12):1579-84. doi: 10.1302/0301-620x.100b12.Bjj-2018-0566.R1.
248. Turgeon TR, Hedden DR, Bohm ER, Burnell CD. Radiostereometric analysis and clinical outcomes of a novel reverse total hip system at two years. Bone Jt Open. 2023;4(5):385-92. doi: 10.1302/2633-1462.45.Bjo-2023-0018.R1.

249. Turgeon TR, Righolt CH, Burnell CD, Gascoyne TC, Hedden DR, Bohm ER. Comparison of two hydroxyapatite-coated femoral components: a randomized clinical trial using radiostereometric analysis. Bone Joint J. 2023;105-b(10):1045-51. doi: 10.1302/0301-620x.105b10.Bjj-2023-0427.R1.
250. Turgeon TR, Vasarhelyi E, Howard J, Teeter M, Righolt CH, Gascoyne T, et al. Randomized controlled trial comparing traditional versus enhanced-fixation designs of a novel cemented total knee arthroplasty tibial component. Bone Jt Open. 2024;5(1):20-7. doi: 10.1302/2633-1462.51.Bjo-2023-0121.
251. Van de Kleut ML, Yuan X, Athwal GS, Teeter MG. Are short press-fit stems comparable to standard-length cemented stems in reverse shoulder arthroplasty? A prospective, randomized clinical trial. J Shoulder Elbow Surg. 2022;31(3):580-90. doi: 10.1016/j.jse.2021.11.005.
252. Van de Kleut ML, Yuan X, Teeter MG, Athwal GS. Bony increased-offset reverse shoulder arthroplasty vs. metal augments in reverse shoulder arthroplasty: a prospective, randomized clinical trial with 2-year follow-up. J Shoulder Elbow Surg. 2022;31(3):591-600. doi: 10.1016/j.jse.2021.11.007.
253. van der Lelij TJN, Marang-van de Mheen PJ, Kaptein BL, Koster LA, Ljung P, Nelissen R, et al. Migration and clinical outcomes of a novel cementless hydroxyapatite-coated titanium acetabular shell: two-year follow-up of a randomized controlled trial using radiostereometric analysis. Bone Joint J. 2024;106-b(2):136-43. doi: 10.1302/0301-620x.106b2.Bjj-2023-0862.R1.
254. van der Lelij TJN, Marang-van de Mheen PJ, Kaptein BL, Toksvig-Larsen S, Nelissen R. Continued Stabilization of a Cementless 3D-Printed Total Knee Arthroplasty: Five-Year Results of a Randomized Controlled Trial Using Radiostereometric Analysis. J Bone Joint Surg Am. 2023;105(21):1686-94. doi: 10.2106/jbjs.23.00221.
255. Van Der Voort P, ML DKN, Valstar ER, Kaptein BL, Fiocco M, R GHHN. Long-term migration of a cementless stem with different bioactive coatings. Data from a "prime" RSA study: lessons learned. Acta Orthop. 2020;91(6):660-8. doi: 10.1080/17453674.2020.1840021.
256. van der Voort P, Valstar ER, Kaptein BL, Fiocco M, van der Heide HJ, Nelissen RG. Comparison of femoral component migration between Refobacin bone cement R and Palacos R + G in cemented total hip arthroplasty: A randomised controlled roentgen stereophotogrammetric analysis and clinical study. Bone Joint J. 2016;98-b(10):1333-41. doi: 10.1302/0301-620x.98b10.37116.
257. van der Voort P, van Delft D, Valstar ER, Kaptein BL, Fiocco M, Nelissen RG. Migration behaviour of 2 clinically excellent cementless stems with different design rationales: 5-year follow-up of a randomised RSA-study. Hip Int. 2022;32(6):747-58. doi: 10.1177/1120700021995482.
258. van Hamersveld KT, Marang-van de Mheen PJ, Koster LA, Nelissen R, Toksvig-Larsen S, Kaptein BL. Marker-based versus model-based radiostereometric analysis of total knee arthroplasty migration: a reanalysis with comparable mean outcomes despite distinct types of measurement error. Acta Orthop. 2019;90(4):366-72. doi: 10.1080/17453674.2019.1605692.
259. van Hamersveld KT, Marang-van de Mheen PJ, Nelissen R. The Effect of Coronal Alignment on Tibial Component Migration Following Total Knee Arthroplasty: A Cohort Study with Long-Term Radiostereometric Analysis Results. J Bone Joint Surg Am. 2019;101(13):1203-12. doi: 10.2106/jbjs.18.00691.
260. Van Hamersveld KT, Marang-Van De Mheen PJ, Nelissen R, Toksvig-Larsen S. Migration of all-polyethylene compared with metal-backed tibial components in cemented total knee arthroplasty. Acta Orthop. 2018;89(4):412-7. doi: 10.1080/17453674.2018.1464317.
261. Van Hamersveld KT, Marang-Van De Mheen PJ, Nelissen R, Toksvig-Larsen S. Peri-apatite coating decreases uncemented tibial component migration: long-term RSA results of a randomized controlled trial and limitations of short-term results. Acta Orthop. 2018;89(4):425-30. doi: 10.1080/17453674.2018.1469223.
262. van Hamersveld KT, Marang-van de Mheen PJ, Tsonaka R, Nilsson KG, Toksvig-Larsen S, Nelissen R. Risk Factors for Tibial Component Loosening: A Meta-Analysis of Long-Term Follow-up Radiostereometric Analysis Data. J Bone Joint Surg Am. 2021;103(12):1115-24. doi: 10.2106/jbjs.20.01454.
263. van Hamersveld KT, Marang-van de Mheen PJ, Tsonaka R, Valstar ER, Toksvig-Larsen S. Fixation and clinical outcome of uncemented peri-apatite-coated versus cemented total knee arthroplasty : five-year follow-up of a randomised controlled trial using radiostereometric analysis (RSA). Bone Joint J. 2017;99-b(11):1467-76. doi: 10.1302/0301-620x.99b11.Bjj-2016-1347.R3.
264. Van Hamersveld KT, Marang-Van De Mheen PJ, Van Der Heide HJL, Van Der Linden-Van Der Zwaag HMJ, Valstar ER, Nelissen R. Migration and clinical outcome of mobile-bearing versus fixed-

bearing single-radius total knee arthroplasty. Acta Orthop. 2018;89(2):190-6. doi: 10.1080/17453674.2018.1429108.
265. van Hooff ML, Heesterbeek PJC, Spruit M. Mechanical Stability of the Prodisc-C Vivo Cervical Disc Arthroplasty: A Preliminary, Observational Study Using Radiostereometric Analysis. Global Spine J. 2020;10(3):294-302. doi: 10.1177/2192568219850763.
266. Van Laarhoven SN, Te Molder MEM, Van Hellemondt GG, Heesterbeek PJC. Acceptable migration of a fully cemented rotating hinge-type knee revision system measured in 20 patients with model-based RSA with a 2-year follow-up. Acta Orthop. 2023;94:185-90. doi: 10.2340/17453674.2023.12305.
267. van Ooij B, Sierevelt IN, van der Vis HM, Hoornenborg D, Haverkamp D. What is the role of cemented fixation in total knee arthroplasty? The two-year results of a randomized RSA controlled trial. Bone Joint J. 2021;103-b(1):98-104. doi: 10.1302/0301-620x.103b1.Bjj-2020-0788.R1.
268. Vind TD, Jørgensen PB, Vainorius D, Jakobsen SS, Søballe K, Stilling M. Migration pattern of cemented Exeter short stem in Dorr type A femurs. A prospective radiostereometry study with 2-year follow-up. Arch Orthop Trauma Surg. 2023;143(2):1071-80. doi: 10.1007/s00402-021-04307-y.
269. von Schewelov T, Carlsson A, Sanzén L, Besjakov J. Continuous distal migration and internal rotation of the C-stem prosthesis without any adverse clinical effects: an RSA study of 33 primary total hip arthroplasties followed for up to ten years. Bone Joint J. 2014;96-b(5):604-8. doi: 10.1302/0301-620x.96b5.33580.
270. Weber E, Flivik C, Sundberg M, Flivik G. Migration pattern of a short uncemented stem with or without collar: a randomised RSA-study with 2 years follow-up. Hip Int. 2021;31(4):500-6. doi: 10.1177/1120700019888471.
271. Weber E, Olsson C, Kesteris U, Flivik G. Is a hollow centralizer necessary when using a polished, tapered, cemented femoral stem? Acta Orthop. 2017;88(4):377-82. doi: 10.1080/17453674.2017.1315553.
272. Weber E, Sundberg M, Flivik G. Design modifications of the uncemented Furlong hip stem result in minor early subsidence but do not affect further stability: a randomized controlled RSA study with 5-year follow-up. Acta Orthop. 2014;85(6):556-61. doi: 10.3109/17453674.2014.958810.
273. Wierer T, Forst R, Mueller LA, Sesselmann S. Radiostereometric migration analysis of the Lubinus SP II hip stem: 59 hips followed for 2 years. Biomed Tech (Berl). 2013;58(4):333-41. doi: 10.1515/bmt-2012-0038.
274. Williams HA, Broberg JS, Howard JL, Lanting BA, Teeter MG. Effect of gap balancing and measured resection techniques on implant migration and contact kinematics of a cementless total knee arthroplasty. Knee. 2021;31:86-96. doi: 10.1016/j.knee.2021.05.011.
275. Wilson DA, Hubley-Kozey CL, Astephen Wilson JL, Dunbar MJ. Pre-operative muscle activation patterns during walking are associated with TKA tibial implant migration. Clin Biomech (Bristol, Avon). 2012;27(9):936-42. doi: 10.1016/j.clinbiomech.2012.06.012.
276. Wilson DA, Richardson G, Hennigar AW, Dunbar MJ. Continued stabilization of trabecular metal tibial monoblock total knee arthroplasty components at 5 years-measured with radiostereometric analysis. Acta Orthop. 2012;83(1):36-40. doi: 10.3109/17453674.2011.645196.
277. Winther NS, Jensen CL, Jensen CM, Lind T, Schrøder HM, Flivik G, et al. Comparison of a novel porous titanium construct (Regenerex®) to a well proven porous coated tibial surface in cementless total knee arthroplasty - A prospective randomized RSA study with two-year follow-up. Knee. 2016;23(6):1002-11. doi: 10.1016/j.knee.2016.09.010.
278. Wojtowicz R, Henricson A, Nilsson KG, Crnalic S. Uncemented monoblock trabecular metal posterior stabilized high-flex total knee arthroplasty: similar pattern of migration to the cruciate-retaining design - a prospective radiostereometric analysis (RSA) and clinical evaluation of 40 patients (49 knees) 60 years or younger with 9 years' follow-up. Acta Orthop. 2019;90(5):460-6. doi: 10.1080/17453674.2019.1626097.
279. Wolf O, Mattsson P, Milbrink J, Larsson S, Mallmin H. The effects of different weight-bearing regimes on press-fit cup stability: a randomised study with five years of follow-up using radiostereometry. Int Orthop. 2012;36(4):735-40. doi: 10.1007/s00264-011-1413-5.
280. Wolterbeek N, Garling EH, Mertens BJ, Nelissen RG, Valstar ER. Kinematics and early migration in single-radius mobile- and fixed-bearing total knee prostheses. Clin Biomech (Bristol, Avon). 2012;27(4):398-402. doi: 10.1016/j.clinbiomech.2011.10.013.

281. Xu J, Cao H, Sesselmann S, Taylor D, Forst R, Seehaus F. Article. Model-Based Roentgen Stereophotogrammetric Analysis Using Elementary Geometrical Shape Models: Reliability of Migration Measurements for an Anatomically Shaped Femoral Stem Component. Appl Sci-Basel. 2020;10(23):13. doi: 10.3390/app10238507.
282. Yilmaz M, Holm CE, Lind T, Flivik G, Odgaard A, Petersen MM. Bone remodeling and implant migration of uncemented femoral and cemented asymmetrical tibial components in total knee arthroplasty - DXA and RSA evaluation with 2-year follow up. Knee Surg Relat Res. 2021;33(1):25. doi: 10.1186/s43019-021-00111-5.
283. Yüksel Y, Koster LA, Kaptein BL, Nelissen R, den Hollander P. No difference in component migration at five years between the cemented cruciate-retaining ATTUNE and PFC-Sigma knee prosthesis: an update of a randomized clinical radiostereometry trial. Bone Joint J. 2023;105-b(11):1168-76. doi: 10.1302/0301-620x.105b11.Bjj-2022-0839.R4.
284. Zampelis V, Belfrage O, Tägil M, Sundberg M, Flivik G. Decreased migration with locally administered bisphosphonate in cemented cup revisions using impaction bone grafting technique. Acta Orthop. 2018;89(1):17-22. doi: 10.1080/17453674.2017.1371468.
285. Zampelis V, Flivik G, Kesteris U. No effect of femoral canal jet-lavage on the stability of cementless stems in primary hip arthroplasty: a randomised RSA study with 6 years follow-up. Hip Int. 2020;30(4):417-22. doi: 10.1177/1120700019843123.





Chapter 7

Does RSA testing of TKA implants result in lower long-term revision risk? A Dutch arthroplasty register study

T.J.N. van der Lelij
B.G. Pijls
B.L. Kaptein
L.N. van Steenbergen
R.G.H.H. Nelissen
P.J. Marang-van de Mheen

Submitted

Abstract

Background and purpose

Radiostereometric analysis (RSA) of total knee arthroplasty (TKA) is used as an early safeguard during the phased evidence-based introduction of new implants. The goal of this study was to compare the long-term revision risk between RSA-tested implant and non-RSA-tested implant in the Netherlands using patient-level data.

Methods

All primary TKAs between 2007 and 2016 from the Dutch Arthroplasty Register were included and procedures with an RSA-tested implant were identified. Both all-cause major revision risk and revision risk because of loosening were calculated at 5 and 10 years postoperatively using Kaplan-Meier analyses. Sensitivity analyses were performed with more stricter definitions to classify procedures as RSA-tested, to avoid camouflage of different subdesigns within the same brand implant portfolio.

Results

83,638 RSA-tested and 104,105 non-RSA-tested TKAs were included. Cumulative all-cause major revision percentages for the RSA-tested group at 5 and 10 years were 2.2% (95% confidence interval [CI] 2.1-2.3) and 3.6% (CI 3.4-3.7), respectively, compared with 2.5% (CI 2.4-2.6) and 3.3% (CI 3.2-3.4) for the non-RSA-tested group. RSA-tested TKAs showed higher 10-year revision risks because of loosening than non-RSA-tested procedures (1.8% (CI 1.7-1.9) versus 1.4% (CI 1.3-1.4) respectively). Comparable results were found after stratification by various patient characteristics and with stricter classification approaches.

Conclusion

RSA-tested TKAs did not have lower long-term revision risks than non-RSA-tested TKAs in the Netherlands. Further research should assess if comparable results are found in other countries and determine the clinical benefit of RSA-testing of new TKA implants that are released to the market.

Introduction

Radiostereometric analysis (RSA) is a valuable tool in the phased evidence-based introduction of arthroplasty implants (1-3). Early implant migration results, obtained with RSA, can warn clinicians about implants that have an increased long-term risk of revision due to loosening. However, only a limited number of implants has been studied with RSA. If TKAs with an RSA-tested implant actually show a lower long-term revision risk compared with TKAs using a non-RSA-tested implant, RSA testing of all implants introduced to the market could be advocated.

Hasan et al. (4) recently reported that "RSA-tested" TKAs on average have a lower 10-year revision risk than "non-RSA-tested" TKAs (4). However, they only used the aggregate-level mean all-cause revision risk of TKAs from annual reports of national arthroplasty registries. Therefore, they could not assess whether the patient populations receiving RSA-tested and non-RSA-tested implants were comparable. Moreover, early migration as measured with RSA is used as a proxy for the risk of revision due to loosening, not for all-cause revision. Furthermore, Hasan et al. (4) did not take the differences between subtypes within the same implant brand portfolio into account (5, 6). We know that good results from a (sub)design may camouflage the actual clinical performance of another (sub)design within the same brand implant portfolio that performs worse (5). This suggests that more detailed patient-level analyses are warranted.

The aim of this study was to compare both the long-term all-cause major revision risk and revision risk due to loosening between RSA-tested and non-RSA-tested TKAs using patient-level data. The latter allows for more accurate classification of TKAs in which an RSA-tested implant was used, thereby taking into account possible camouflage within the same implant brand portfolio. We hypothesized that TKAs with an RSA-tested implant had a lower long-term risk for all-cause revision as well as revision because of loosening.

Material and Methods

Study Design

Patient-level data for this observational study were obtained from the Dutch Arthroplasty Register (LROI), to avoid spurious associations due to the ecological fallacy when using aggregate-level data (i.e., the erroneous inference about individuals based on findings for the group to which these individuals belong) (7). This nationwide population-based register started in 2007 and achieved 100% coverage of all Dutch hospitals in 2012, and 96% completeness for primary TKAs in 2012 (8). The LROI database contains patient, procedure and implant characteristics. For each component, specific characteristics can be identified by its product number (9). In the LROI, the product number of all prosthetic components and cement (if used) are registered. This allows the opportunity to extend the information about specific prosthesis, e.g. the specific surface bone coating of the implant. To receive informed consent of patients, the LROI uses an opt-out system. The study is reported in accordance with the Strengthening the Reporting of Observational Studies in Epidemiology (STROBE) guidelines (10).

Patient Selection and Classification

All primary TKAs performed between 2007 and 2016 registered in the LROI were included. To identify whether an implant was tested with RSA, the results of a previous meta-analysis on tibial baseplate migration were used (3). In short, Pijls et al (2, 3). conducted a literature search to identify all clinical RSA studies on tibial component migration in TKA that were published up to 2016. The results of this search were used to classify procedures as “RSA-tested” (i.e., when an implant was used in a clinical RSA study) or “non-RSA-tested” (i.e., when an implant was not tested with RSA). Procedures up to 2016 were included in this study, which ensured that patients had at least 5-years of follow-up. The same database of RSA-tested implants was used by Hasan et al. (4).

The classification of TKAs was performed at 3 levels of specificity. For the primary analyses, implants were coded at the level of implant (brand) and fixation method (cemented/uncemented) (level 1). If a brand/fixation combination was described in an RSA study, the procedure in the LROI was coded as “RSA-tested”. Otherwise, the procedure was coded as “non-RSA-tested”. This level of coding was chosen for the primary analyses to align with previous research, but also because this level of information is mostly reported in RSA

studies and revision risks in annual arthroplasty registry reports are reported on this level (1,4). Moreover, we explored possible variation in revision risks between implants within the RSA-tested and non-RSA-tested group.

Furthermore, two additional, more stricter definitions were used to classify implants as RSA-tested (level 2 and 3). Besides the brand/fixation method, level 2 also included insert type (fixed/mobile bearing, cruciate retaining (CR)/posterior stabilized (PS)). To be classified as RSA-tested at level 3, implants had to match exactly with an RSA study at the subtype level within the implant brand portfolio, fixation method, fixation method specified (e.g., implant coating or type of cement), and insert type. If the implant that was used during TKA did not exactly match the implant described in an RSA study, based on the level criteria, the procedure was coded as non-RSA-tested at that level (Table II).

We only classified TKAs as RSA-tested after publication of an RSA study in which the implant was studied. Only after implant migration results have been published it is possible for clinicians to estimate the risk of late revision due to loosening. Subsequently, clinicians may decide to continue or discontinue using a specific implant (based on its expected risk of late revision) resulting in a selection of best performing implants and thereby lower revision risks for RSA-tested implants. When no RSA migration results of an implant are available at the time of surgery, it is not possible to estimate the risk of future long-term loosening. In this way, some TKAs may be classified as non-RSA-tested if the surgery was performed before publication of the RSA study and other TKAs using the exact same implant as RSA-tested if the surgery was performed after publication of the RSA study.

Statistical Analysis

All-cause major revision risks (i.e., revision of the femoral and/or tibial component) were calculated at 5 and 10 years for the RSA-tested and non-RSA-tested group (level 1) using Kaplan-Meier analyses. Minor revisions (i.e. change of polyethylene insert, insertion/change of patella component, and DAIR without implant change) were not used in our analysis. Survival time was calculated as the time from primary TKA surgery to the first major revision, death of the patient, or end of follow-up (01-01-2022). After visual inspection of the Kaplan-Meier plots and testing of scaled Schoenfeld residuals, the proportional hazards assumption was shown to be violated. Therefore, Cox proportional hazard analyses were not used. To evaluate possible confounders, and take these into account, we compared the all-cause major revision risks for both groups stratified by age

group, sex, diagnose, and American Society of Anesthesiologist (ASA)-classification. We did not stratify by Body Mass Index (BMI), Charnley score, and smoking status as these have only been registered in the LROI since 2014 (percentages of missing data in Table I). Revision risks of individual brand/fixation combinations included in the RSA-tested and non-RSA-tested groups were calculated to assess possible heterogeneity within the groups. In addition to all-cause major revision, the (major) revision risk because of loosening at 5 and 10 years were calculated for the RSA-tested and non-RSA-tested group. Finally, we performed sensitivity analyses with the more stricter matching definitions (level 2 and 3). Means were reported with 95% confidence intervals (CIs), as the latter allows a more easy and direct evaluation of clinical significance compared with the p-value (11). Analyses were performed using SPSS (version 29.0; IBM Corp) and R software (version 4.2.1; R Foundation for Statistical Computing).

Disclosures
This investigator-initiated study was supported by a grant from Stryker. The sponsor did not take part in the design, conduct, analyses, or interpretations in the present study.

Results

In total, 190,525 primary TKAs between 2007 and 2016 were registered in the LROI. Procedures with an unknown implant design (n=2,782) were excluded, leaving 187,743 procedures included in this study. Based on the classification for the primary analyses (level 1), 83,638 RSA-tested and 104,105 non-RSA-tested TKAs were included. Patient demographics were comparable between the groups (Table I). As expected, most missing data were found for the variables BMI (RSA-tested 51.2%; non-RSA-tested 63.1%), Charnley score (RSA-tested 48.8%; non-RSA-tested 60.1%), and smoking (RSA-tested 53.1%; non-RSA-tested 67.2%), because they were not registered before 2014.

All-cause Major Revision

Cumulative all-cause major revision risks for the RSA-tested group at 5 and 10 years were 2.2% (CI 2.1-2.3) and 3.6% (CI 3.4-3.7), respectively, compared with 2.5% (CI 2.4-2.6) and 3.3% (CI 3.2-3.4) for non-RSA-tested procedures (Figure 1). Revision risks in patients < 60 years were greater compared with patients > 60 years in both the RSA-tested and non-

RSA-tested group (Figure 2). Still, after stratification by age, sex, diagnose, and ASA classification, TKA procedures with an RSA-tested implant did not have lower long-term all-cause major revision risks. Within the RSA-tested group, revision risks at 10 years ranged from 1.8% (CI 0.2-3.4) (Duracon uncemented) to 9.1% (CI 8.0-10.2) (Optetrak cemented) with less variation in the non-RSA-tested group (ranging from 2.4% (CI 1.8-3.1) to 4.3% (CI 4.0-4.7)) (Figure 3).

Table I Baseline Demographic Characteristics

	RSA-tested TKAs (n = 83,638)	**non-RSA-tested TKAs (n = 104,105)**
Age in years, mean (SD) (RSA-tested, n = 83,521 (99.9%)) (non-RSA-tested, n = 104,001 (99.9%))	68.8 (9.2)	68.2 (9.6)
BMI, mean (SD) (RSA-tested, n = 40,814 (48.8%)) (non-RSA-tested, n = 38.368 (36.9%))	29.7 (5.0)	29.8 (5.1)
Sex, n (%)		
Men	28,230 (33.8)	35,579 (34.2)
Women	55,270 (66.1)	68,236 (65.5)
Missing	138 (0.2)	290 (0.3)
Diagnosis, n (%)		
Osteoarthritis	79,806 (95.4)	98,366 (94.5)
Rheumatoid arthritis	1,253 (1.5)	1,721 (1.7)
Inflammatory arthritis	45 (0.1)	48 (0.0)
Late post-traumatic	1,069 (1.3)	1,621 (1.6)
Osteonecrosis	380 (0.5)	393 (0.4)
Tumor	7 (0.0)	70 (0.1)
Other	167 (0.2)	462 (0.4)
Missing	911 (1.1)	1,424 (1.4)
ASA, n (%)		
ASA I	14,424 (17.2)	19,585 (18.8)
ASA II	54,929 (65.7)	64,969 (62.4)
ASA III-IV	11,061 (13.2)	13,833 (13.3)
Missing	3,224 (3.9)	5,718 (5.5)
Charnley score, n (%)		
A	17,691 (21.2)	17,518 (16.8)
B1	14,045 (16.8)	12,600 (12.1)
B2	8,099 (9.7)	7,173 (6.9)
C	1,247 (1.5)	1,126 (1.1)
N/A (no osteoarthritis)	1,724 (2.1)	3,139 (3.0)
Missing	40,832 (48.8)	62,549 (60.1)
Smoking, n (%)		
Yes	3,780 (4.5)	3,447 (3.3)
No	35,461 (42.4)	30,744 (29.5)
Missing	44,397 (53.1)	69,914 (67.2)
Previous surgery, n (%)		
Yes	25,721 (30.8)	31,282 (30.0)
No	53,967 (64.5)	63,909 (61.4)
Missing	3,950 (4.7)	8,914 (8.6)

TKA = Total Knee Arthroplasty, BMI = Body Mass Index, ASA = American Society of Anesthesiologists.

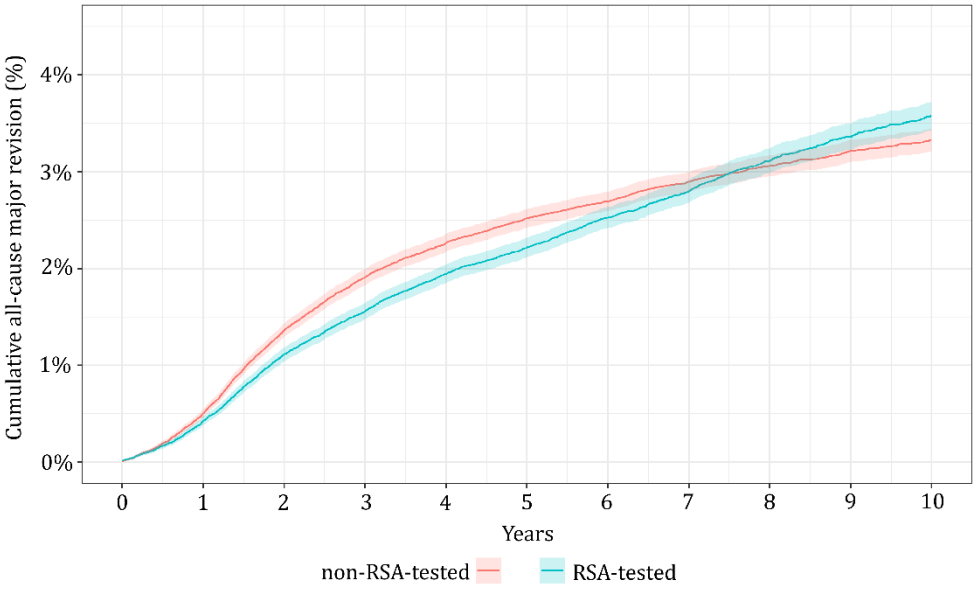


Figure 1. Cumulative all-cause major revision risk (Kaplan-Meier) through 10 years of follow up for RSA-tested and non-RSA-tested implants

Major Revision Because of Loosening

Cumulative major revision risks because of loosening for RSA-tested procedures at 5 and 10 years were 1.0% (CI 0.9-1.0) and 1.8% (CI 1.7-1.9), respectively, compared with 1.0% (CI 0.9-1.1) and 1.4% (CI 1.3-1.4) for non-RSA-tested procedures (Figure 4).

Stricter Classification of RSA-tested Procedures

When using stricter definitions to match implants with clinical RSA studies, less TKAs were classified as RSA-tested (Table II). Of the 187,734 primary TKAs included in the study, 68,634 were classified as RSA-tested at level 2. Using the latter classification, the cumulative all-cause major revision risks for the RSA-tested group at 10 years was 3.7% (CI 3.5-3.9) compared with 3.3% (CI 3.2-3.4) for non-RSA-tested procedures. For major revision due to loosening, the 10 year revision risk was 2.0% (CI 1.8-2.1), and 1.3% (CI 1.3-1.4) for the RSA-tested and non-RSA-tested group, respectively.

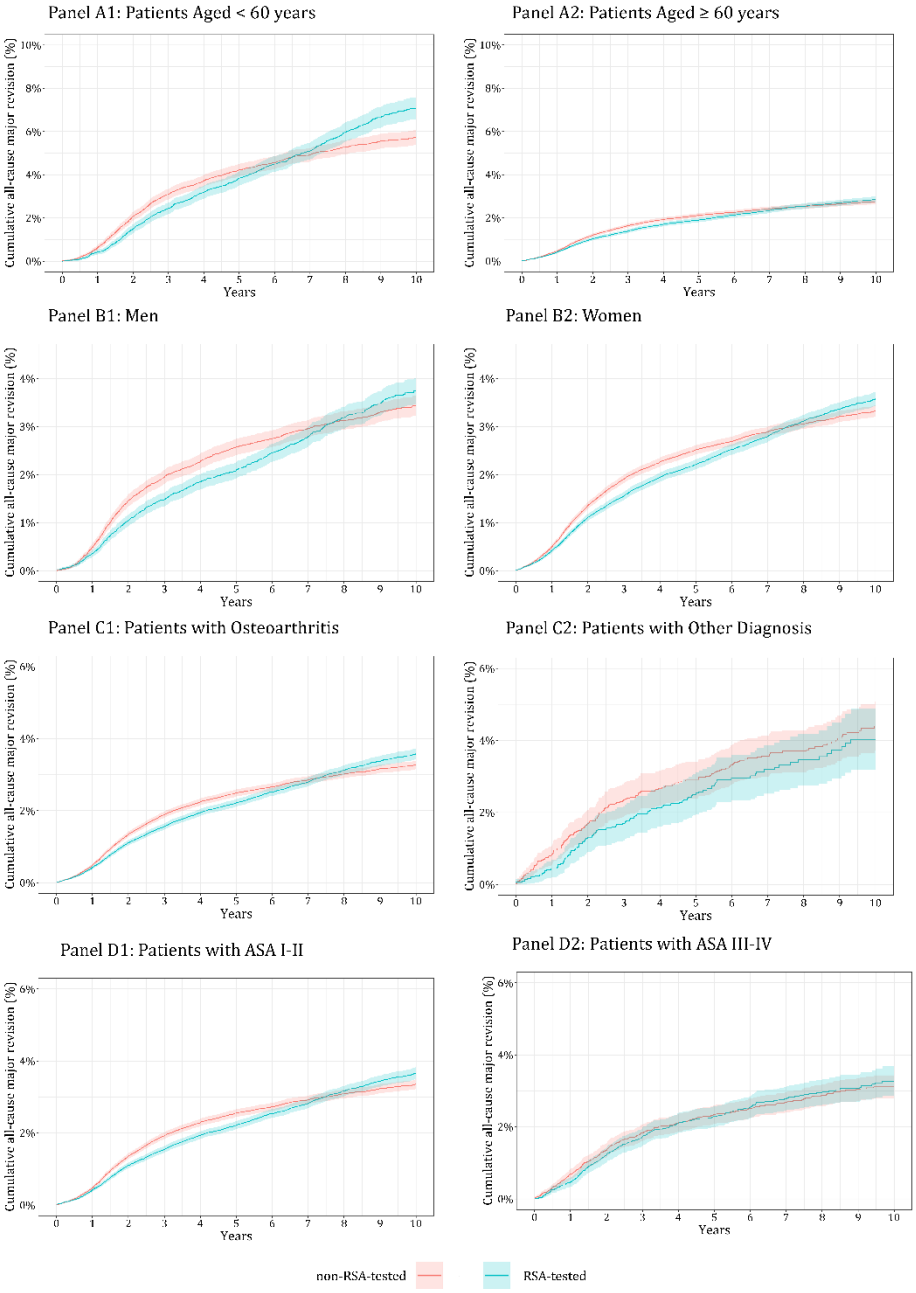


Figure 2. Cumulative all-cause major revision risk (Kaplan-Meier) plots through 10 years of follow-up for RSA-tested and non-RSA-tested procedures stratified by (A) age, (B) sex, (C) diagnosis, and (D) American Society of Anesthesiologists (ASA) classification.

Table 2. Number of procedures classified as "RSA-tested" and "non-RSA-tested" based on 3 different levels of matching.

	RSA-tested	non-RSA-tested
Level 1 (brand/fixation)	83,638	104,105
Level 2 (brand/fixation/insert)	68,634	119,109
Level 3 (brand/subtype/fixation/fixation specified/insert)	37,788	149,955

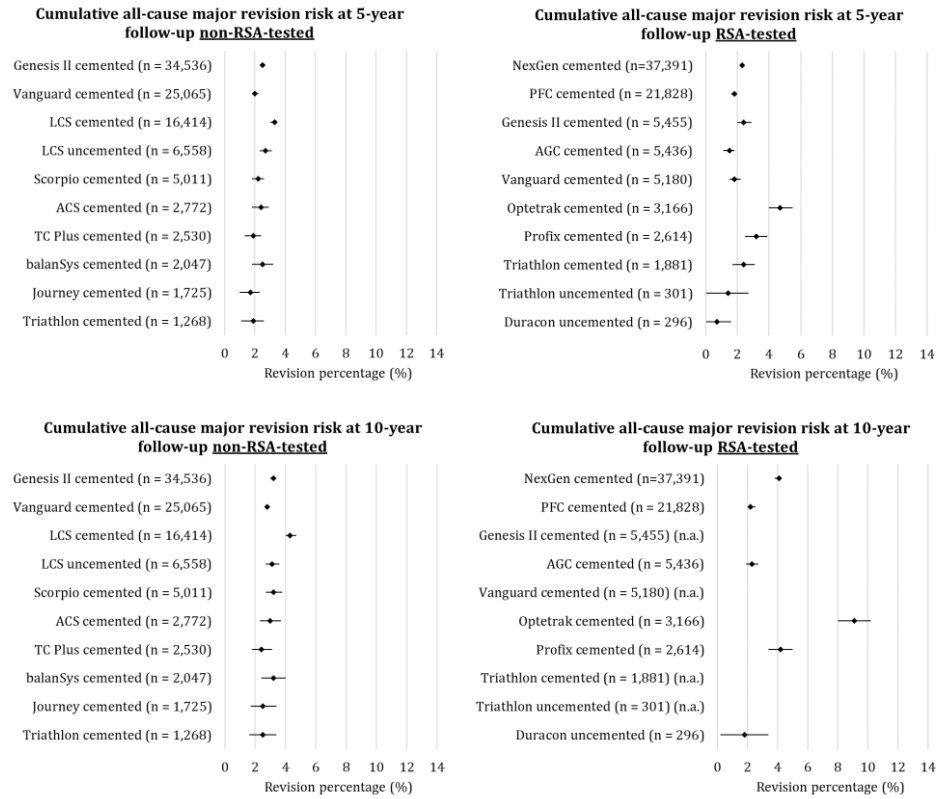


Figure 3. Forest plots showing the cumulative all-cause major revision risk (with 95% confidence intervals) of individual implant/fixation combinations within the RSA-tested and non-RSA-tested TKA group at 5 and 10 years postoperatively. For both groups, the 10 implant/fixation combinations with the greatest number of procedures is shown. Note: n.a. if < 50 cases were at risk.

At the most strict level of classifying the implants (level 3), 37,788 procedures were classified as RSA-tested. With this classification, the cumulative all-cause major revision risk for the RSA-tested group at 10 years was 4.0% (CI 3.7-4.2) compared with 3.3% (CI 3.2-3.4)

for non-RSA-tested TKAs. The mean 10 year revision risk due to loosening was 2.1% (CI 1.9-2.3) for the RSA-tested and 1.4% (CI 1.4-1.5) for non-RSA-tested group.

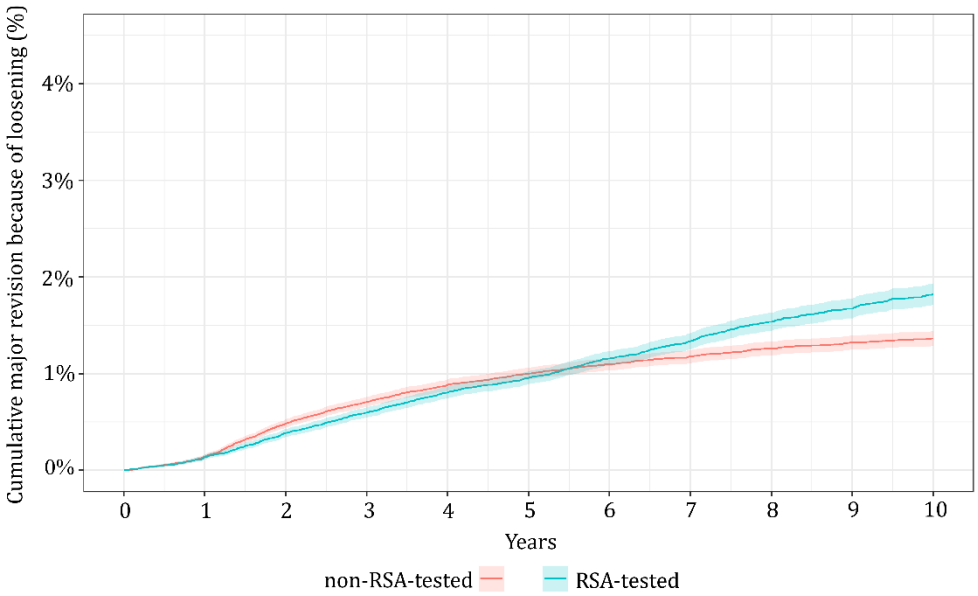


Figure 4. Cumulative major revision risk because of loosening (Kaplan-Meier) through 10 years of follow-up for RSA-tested and non-RSA-tested implants.

Discussion

Our hypothesis that TKAs using an RSA-tested implant would show lower long-term revision risks was not confirmed. At 10 years follow-up, the cumulative all-cause major revision risk in the RSA-tested group was not lower than in the non-RSA-tested group. Also, the risk of revision because of loosening was greater in the RSA-tested group than in the non-RSA-tested group. These findings remained consistent after stratification by demographic characteristics and using more stricter definitions for the classification of TKAs as RSA-tested.

After publication of an RSA study, surgeons or hospitals may use the early implant migration data as evidence for their decision to continue or discontinue using a specific implant. If RSA studies show unacceptable high early migration, indicating a high risk of long-term revision because of loosening, this could prevent the widespread use of underperforming implants if clinicians would not use these implants anymore. Interestingly,

within the RSA-tested group, revision risks between individual brand/fixation combinations varied considerably. The highest revision risk was observed in TKAs using the Optetrak cemented implant (10 year cumulative all-cause major revision risk 9.1% (CI 8.0-10.2)). Because an RSA study of the Optetrak implant was published in 2004, all procedures in the LROI with this implant were classified as RSA-tested (12). However, this RSA study does not explicitly conclude that there is an increased risk of long-term revision for this specific implant based on the early migration data. This may be due to the fact that mean implant migration thresholds predictive for late loosening to enable classification of acceptable and unacceptable migration were only proposed in 2012 (2, 12). Based on these thresholds, both the cemented Optetrak CR and PS implants would be considered to be "at risk" of revision risks higher than 5% at 10 years. Another possible explanation for high revision risks despite RSA testing may be that (seemingly) small changes to an implant design, its manufacturing process, or packaging method have been made, which may influence the clinical performance of an implant and increase the revision risk. For the Optetrak knee system, TKA polyethylene inserts manufactured since 2004 have been recalled because they were packaged in bags that did not contain a secondary barrier layer with ethylene viny alcohol to augment oxygen resistance. The use of these non-conforming bags increased oxygen diffusion to the ultra-high molecular weight polyethylene (UHMWPE) inserts, which can severely damage its mechanical properties and lead to accelerated wear debris and subsequently bone loss and loosening of the TKA implant (13). Therefore, one could argue that the Optetrak implants included in the RSA study are essentially different implants compared with the Optetrak implants used later and registered in the LROI. It has been shown previously that (accidental) changes in the manufacturing process of orthopaedic implants may significantly affect their clinical performance and that the type of PE insert material may influence the revision risk after TKA (14, 15). On the other hand, other designs may also have changed after the RSA study was published, influencing their performance, which could be explored in future studies.

RSA assess implant migration, which has been associated with long term revision risk because of loosening (2). However, early implant migration as measured with RSA has not been associated with revision because of other reasons, such as infection or implant/liner wear. Furthermore, besides revision rates, patient-reported outcome measures (PROMs) are increasingly employed in orthopaedic practice to assess clinical outcome after TKA. We have previously shown that TKA migration, as measured with RSA, is not associated with post-

operative changes in PROMs or clinical scores (16). Therefore, the performance and safety of novel TKA implant designs cannot solely be assessed on RSA alone.

We found that the mean revision risk at 10 years follow-up of non-RSA-tested TKAs in the Netherlands was very low. This is consistent with the results from Hasan et al., who showed that the revision risk of non-RSA-tested TKAs in the Netherlands was lower compared with non-RSA-tested TKAs in other countries (4). This may be due to the fact that the Netherlands has a long-tradition of ensuring the quality of orthopaedic implants used. First through a national framework established by the Dutch Orthopaedic Society (NOV) that critically evaluated clinical data and performance of implants during annual meetings, later followed by the use of the Orthopaedic Data Evaluation Panel (ODEP) ratings (17). In other countries, with less market regulation and no systems in place to ensure the quality of new implants, long-term revision risks of non-RSA-tested implants may be higher and RSA-testing may have larger impact to ensure good quality implants so that procedures with an RSA-tested implant would show lower long term-revision risks consistent with our hypothesis.

We have shown that the 10-year revision risks because of loosening of both RSA-tested and non-RSA-tested implants is low. Therefore, one may argue that fixation is not the big problem anymore in contemporary TKA. While mean revision percentages are small, the absolute number of patients requiring revision surgery because of loosening remains large; given the large amount of primary arthroplasty procedures performed each year.

The results of our study confirm the findings from Hasan et al. (4) , who have also shown higher revision rates for RSA-tested TKA in the Netherlands. This validation reinforces the observation form Hasan et al. (4) that RSA-tested TKA have a lower revision rate outside the Netherlands. However, studies on individual patient data are required to confirm or refute this hypothesis. Although there was no beneficial effect of RSA in the Netherlands, we caution against interpreting the results of our study as suggesting that RSA studies are unnecessary or should no longer be conducted for different countries.

A strength of the present study is that it is based on a large real-world population-based cohort (registry) with very high completeness. Utilizing patient-level data obtained from the LROI allowed to gauge the impact of baseline characteristics by making stratified comparisons between groups. Furthermore, it was possible to take into account the time of surgery and year of publication of RSA studies when classifying TKAs as RSA-tested or non-RSA-tested, to mimic the mechanism through which RSA-testing might have an effect.

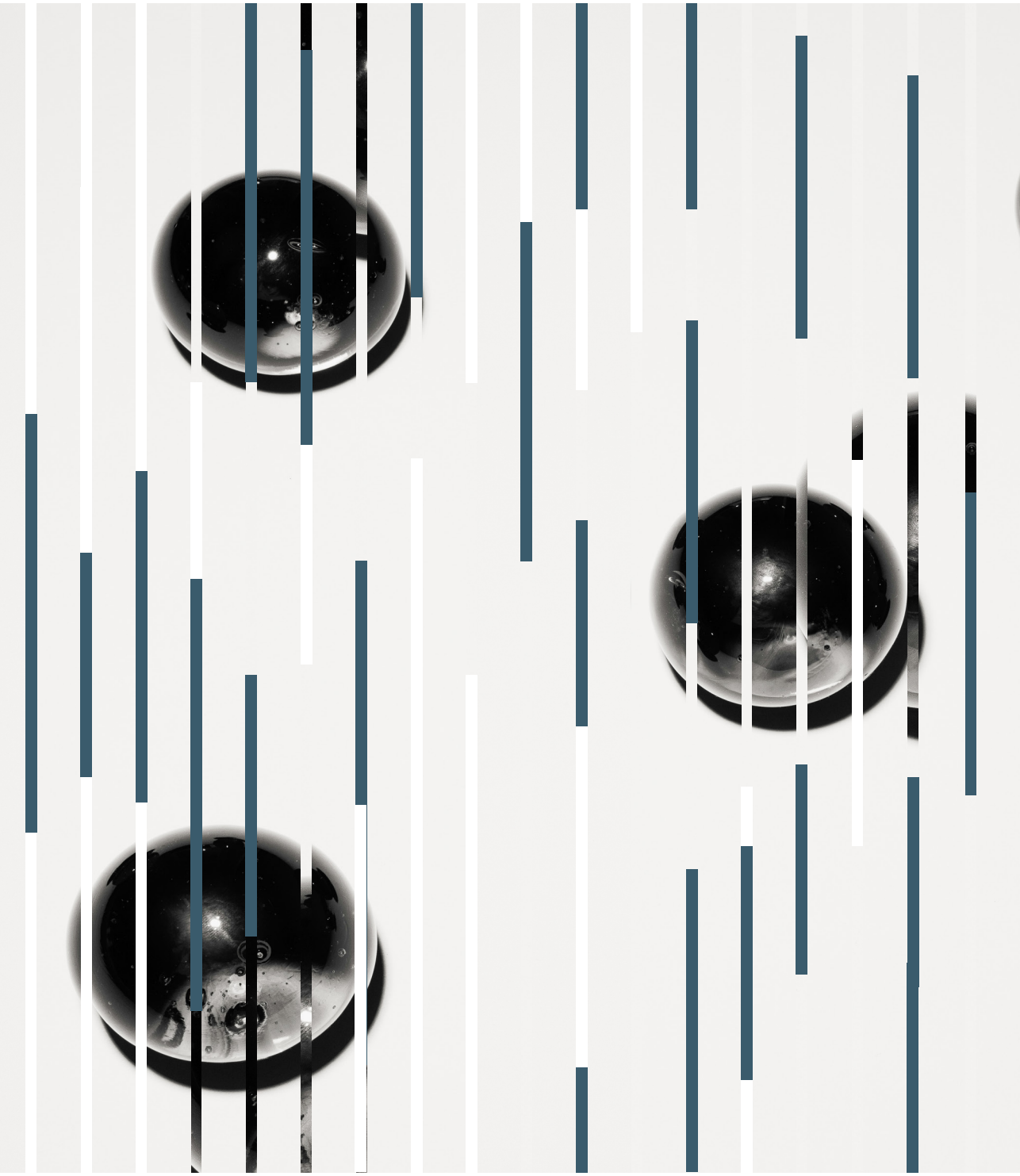
Besides addressing the possible camouflage effect by using more stricter definitions for the classification of implants, we also looked specifically at the revision risks because of loosening rather than all-cause revision, as early migration measured with RSA is associated with revision due to loosening.

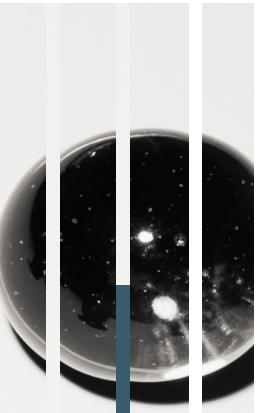
Some limitations should be acknowledged. The study was observational and therefore subject to confounding. Since only a limited number of variables is collected in the LROI, it is not possible to adjust for all potential confounders. However, we found that the RSA-tested and non-RSA-tested group were comparable regarding most of the observed patient demographics. Also, one could argue that additional time restrictions should be applied for the classification of implants as RSA-tested, because small changes to an implant design, after publication of an RSA study, may affect its clinical performance. For that matter, only procedures performed within < 10 years after publication of an RSA study on the specific implant that was used may be assumed to be the same implant and therefore classified as RSA-tested. However, such a time restriction would be arbitrary, as it is often unknown if and when such changes are made to an existing implant that is already on the market. Also, we used data from a previous meta-analyses on clinical RSA studies, in accordance with the previous study by Hasan et al. (4) However, this database only includes all published studies on tibial component migration in TKA and might miss potential clinical RSA studies that only reported femoral component migration. Finally, we compared the risk of revision because of loosening between the RSA-tested and non-RSA-tested group and intentionally did not use the terminology "aseptic" loosening. The reason for revision in the LROI is classified by the surgeon at the time of (revision) surgery and multiple reasons can be given (e.g. both infection and loosening). There is no feedback mechanism to capture cases that were initially not classified as infection, but with intra-operative cultures later showing that a (low-virulent) microbe may have led to the revision. On the other hand, a surgeon may intra-operatively suspect an infection as reason for the revision, but with intra-operative cultures remaining negative. This is common practice in multiple arthroplasty registries and is usually considered as non-differential misclassification leading to bias towards the null (18). For our study the consequence may be that we may have missed a small effect, if this exists in The Netherlands.

In conclusion, TKAs using an RSA-tested implant did not show lower revision risks at 10 years follow-up compared with TKAs using a non-RSA-tested implant in the Netherlands. Further research is needed to assess if comparable results are found in other countries.

References

1. Nelissen RG, Pijls BG, Kärrholm J, Malchau H, Nieuwenhuijse MJ, Valstar ER. RSA and registries: the quest for phased introduction of new implants. J Bone Joint Surg Am. 2011;93 Suppl 3:62-5.
2. Pijls BG, Valstar ER, Nouta KA, Plevier JW, Fiocco M, Middeldorp S et al. Early migration of tibial components is associated with late revision: a systematic review and meta-analysis of 21,000 knee arthroplasties. Acta Orthop. 2012;83:6:614-24.
3. Pijls BG, Plevier JWM, Nelissen R. RSA migration of total knee replacements. Acta Orthop. 2018;89:3:320-8.
4. Hasan S, Marang-van de Mheen PJ, Kaptein BL, Nelissen R, Pijls BG. RSA-tested TKA Implants on Average Have Lower Mean 10-year Revision Rates Than Non-RSA-tested Designs. Clin Orthop Relat Res. 2020;478:6:1232-41.
5. Wilton T, Skinner JA, Haddad FS. Camouflage uncovered: what should happen next? Bone Joint J. 2023;105-b:3:221-6.
6. Phillips JRA, Tucker K. Implant brand portfolios, the potential for camouflage of data, and the role of the Orthopaedic Data Evaluation Panel in total knee arthroplasty. Bone Joint J. 2021;103-b:10:1555-60.
7. Marang-van de Mheen PJ, Nallamothu BK. Exclusions in the denominators of process-based quality measures: the missing link in understanding performance or ecological fallacy? BMJ Qual Saf. 2017;26:3:169-73.
8. van Steenbergen LN, Denissen GA, Spooren A, van Rooden SM, van Oosterhout FJ, Morrenhof JW et al. More than 95% completeness of reported procedures in the population-based Dutch Arthroplasty Register. Acta Orthop. 2015;86:4:498-505.
9. Denissen GAW, van Steenbergen LN, Lollinga WT, Verdonschot NJJ, Schreurs BW, Nelissen R. Generic implant classification enables comparison across implant designs: the Dutch Arthroplasty Register implant library. EFORT Open Rev. 2019;4:6:344-50.
10. von Elm E, Altman DG, Egger M, Pocock SJ, Gøtzsche PC, Vandenbroucke JP. The Strengthening the Reporting of Observational Studies in Epidemiology (STROBE) statement: guidelines for reporting observational studies. Lancet. 2007;370:9596:1453-7.
11. Ranstam J. Why the P-value culture is bad and confidence intervals a better alternative. Osteoarthritis and Cartilage. 2012;20:8:805-8.
12. Catani F, Leardini A, Ensini A, Cucca G, Bragonzoni L, Toksvig-Larsen S et al. The stability of the cemented tibial component of total knee arthroplasty: posterior cruciate-retaining versus posterior-stabilized design. J Arthroplasty. 2004;19:6:775-82.
13. Exactech. US Exactech Recall Information. Knee and Ankle Polyethylene. 2022. https://www.exac.com/recall-information/ [Accessed 13 Aug 2024].
14. Gkiatas I, Karasavvidis T, Sharma AK, Xiang W, Malahias MA, Chalmers BP et al. Highly cross-linked polyethylene in primary total knee arthroplasty is associated with a lower rate of revision for aseptic loosening: a meta-analysis of 962,467 cases. Arch Orthop Trauma Surg. 2022;142:6:1177-84.
15. Bonsignore LA, Goldberg VM, Greenfield EM. Machine oil inhibits the osseointegration of orthopaedic implants by impairing osteoblast attachment and spreading. J Orthop Res. 2015;33:7:979-87.
16. van der Lelij TJN, Kaptein BL, Tsonaka R, Nelissen R, Toksvig-Larsen S, Marang-van de Mheen PJ. Tibial Baseplate Migration Is Not Associated with Change in Patient-Reported Outcome Measures and Clinical Scores After TKA: A Secondary Analysis of 5 Radiostereometric Analysis Studies with 10-Year Follow-up. J Bone Joint Surg Am. 2024;106:16:1479-85.
17. Orthopaedic Data Evaluation Panel (ODEP). https://www.odep.org.uk/ [Accessed 13 Aug 2024].
18. Roerink AMC, Nelissen R, Holder C, Graves SE, Dunbar M, Bohm E et al. Sex-based differences in risk of revision for infection after hip, knee, shoulder, and ankle arthroplasty in osteoarthritis patients: a multinational registry study of 4,800,000 implants. Acta Orthop. 2024;95:730-6.





Chapter 8

Summary, general discussion, and future perspectives

The aim of this thesis was to contribute to patient safety for patient in need for arthroplasty surgery by better understanding the value of implant migration analysis in providing clinical evidence on the performance of novel arthroplasty implants. This chapter starts with a summary of the main findings of the previous chapters. Subsequently, these findings and their clinical implications are discussed in the context of other literature and recommendations for future practice and research are given.

Summary

The clinical outcome after total knee arthroplasty (TKA) can be measured by different methods, including objective measures of implant migration with RSA (stereometry) as well as subjective measures like patient reported outcome measures (PROMs). To understand the value of these outcome measures during follow-up of patients after arthroplasty, it is important to assess whether they measure the same or a different aspect of the care delivered. In **chapter 2**, we studied the extent to which tibial component migration, as measured with RSA, was associated with postoperative changes in PROMs and clinical scores. Individual implant migration data was obtained from 5 randomized RSA studies, including a total of 300 patients with 6 distinct TKA implant designs. TKA migration was evaluated at 3 months, 1, 2, 5, 7, and 10 years postoperatively. At the same follow-up moments, the knee society score (KSS)-Knee, KSS-Function, knee injury and osteoarthritis outcome score (KOOS) subscales were collected in all studies. We found that tibial baseplate migration was not associated with postoperative worsening in PROMs or clinical scores in patients who underwent TKA across the entire follow-up. These findings suggest that implant migration, as measured with RSA, measures a different aspect of implant performance (i.e. implant bone-fixation) than PROMs (i.e. patient perceived performance) and clinical scores. Thus, TKA outcomes during follow-up cannot be evaluated solely through PROMs.

Randomized controlled trials (RCTs) are important to provide high-quality clinical evidence on the performance and safety of novel implants and guide decision making in clinical practice. By using RSA as a highly accurate measure of implant performance, only a limited number of patients need to be included in each group in randomized studies. This thesis contributes to the clinical evidence of novel arthroplasty implants by conducting two RCTs using RSA. In **chapter 3**, we compared the early migration pattern of a novel

cementless hydroxyapatite (HA)-coated titanium acetabular shell with its predecessor in patients undergoing total hip arthroplasty (THA). Eighty-seven patients were randomized to either a Trident II HA or Trident HA shell, each cementless with clusterholes and HA coating. Implant migration was evaluated with RSA, with radiographs taken at baseline, 3, 12, and 24 months postoperatively. PROMs and clinical scores were collected at each follow-up as secondary outcome measures. Over the 2 year follow-up period, clinical scores and PROMs were comparable between the groups. The novel Trident II HA shell showed comparable migration with its predecessor, the Trident HA shell. These findings suggest a similar risk of long-term aseptic loosening. In **chapter 4**, we compared the medium term migration of a new cementless three-dimensional (3D)-printed TKA with a conventionally manufactured cemented TKA of an otherwise similar design. For this study, 72 patients were randomized to either the cementless or cemented TKA. RSA radiographs were taken within 2 days after surgery as well as at 3 months, 1, 2, and 5 years postoperatively. Secondary outcomes were the KSS, KOOS, and forgotten joint score (FJS). We showed that there was no significant difference in mean migration at 5 years postoperatively between the cementless and cemented TKA implant. However, progression of the cemented TKA was present beyond 2 years, whereas the cementless 3D-printed implant remained stable after initial early migration. No significant differences between both implant designs were found during the 5 year follow-up period for the KSS, KOOS, and FJS.

To ensure that RSA studies provide reliable evidence on the clinical performance of arthroplasty implants, consistency in the execution and reporting of clinical RSA studies is essential. This thesis contributes to both the methodology as well as reporting quality of clinical implant migration studies using RSA. In **chapter 5**, the impact of using different marker-selection methods during RSA analysis on TKA migration results was assessed by reanalyzing all RSA radiographs from the RCT presented in **chapter 4.** All (marker-based) RSA examinations were analyzed using both a consistent set of markers over the complete follow-up period (consistent-marker method) and all-available markers at each follow-up that could be matched to the reference examination (all-marker method). Additionally, migration was calculated using 5 fictive points on the prosthesis, either plotted based on the consistent set of markers or all available markers. We showed that the estimated differences in migration at group level did not change when using either the consistent-marker or all-marker method, or when using 5 fictive points. However, individual implant migration measurements are different between marker-selection methods. In **chapter 5** we

recommended that RSA studies should report the marker-selection method that was used as part of the standardized output, to facilitate comparison between clinical studies. This recommendation has been incorporated in the new RSA guidelines for RSA and CT-RSA implant migration measurements (1). In **chapter 6**, we investigated the extent to which published clinical RSA studies on prosthesis migration from the past decade adhered to the RSA guideline items. A total of 285 RSA studies were included in our systematic review, with most studies reporting prosthesis migration in the hip or knee joint. We found that RSA studies adhered only moderately to the RSA guideline items. As adequate reporting is a prerequisite to adequately judge the methodological quality of a study, clinical RSA studies need to report all checklist items in the RSA guidelines as much as possible. To improve the reporting quality of future studies, RSA researchers need to be aware of all the (commonly unaddressed) items. At the end of **chapter 6** we have proposed several clarifications for the RSA guideline checklist, to enhance their utility in future clinical RSA studies.

If publication of early implant migration results, as measured with RSA, of novel implants with an expected high long-term revision risk would result in less frequent use of these implants in clinical practice, fewer patients will be exposed to underperforming implants and only well-performing implants would remain. This thesis evaluates the actual clinical performance of implants that have been tested in studies using RSA compared with implants not tested with RSA. **Chapter 7** studied the effect of RSA tested TKA implants on long-term revision risk in the Netherlands by utilizing patient-level data from the Dutch Arthroplasty Register (LROI). For this study, all primary TKA procedures between 2007 and 2016 from the LROI were included. A total of 83,836 RSA-tested and 104,105 non-RSA-tested TKAs were included. We found that the cumulative all-cause major revision risks for the RSA-tested group at 5 and 10 years were 2.2% and 3.6%, respectively, compared with 2.5% and 3.3% for the non-RSA-tested group. Looking specifically at revision risks due to aseptic loosening, RSA-tested TKAs also showed higher 10-year revision risks than non-RSA tested procedures (1.8% versus 1.4% respectively). Our findings showed that RSA-tested TKA implants did not have lower long-term revision risk than non-RSA-tested TKA implants in the Netherlands. The latter is most probably due to the modifying effect of a quality evaluation system advising to use only high quality (i.e. low revision rates at 5 and 10 years) orthopaedic implants in the Netherlands (Netherlands Orthopaedic Association (NOV) quality system, later ODEP) (2).

General discussion

THA and TKA have shown to be successful and cost-effective surgical treatments for end-stage osteoarthritis and, in the early 2000s, THA has been described as the "operation of the century" and TKA as "joint of the decade" (3, 4). However, around 10% to 20% of patients remain dissatisfied after TKA because of persistent pain or insufficient pain relief, unmet expectations, functional limitation, diminished health-related quality of life, and complications (5-10). For THA, dissatisfaction rates of around 10% have been reported (11-13). These numbers of dissatisfied TKA and THA patients may be due to progressive osteoarthritis in other joints or long-term preoperative use of opioids, which is shown to be related to pain sensitization (14-16). To address these problems new surgical techniques (e.g. navigation and robotic surgery) and a multitude of new implant designs have been introduced to the market, but some of these novelties performed worse compared with previous well-established implants thus also exposing patients to the risks of implant failure and revision surgery (17-20). The latter underscores that novel designs are not always beneficial for patients, supporting that better clinical evidence for new implants and rigorous monitoring of implant performance and early detection of safety concerns is needed, as has been endorsed earlier and enforced by the Medical Device Regulation (MDR) (21, 22).

As introduced in **chapter 1**, the European Commission has introduced the MDR in 2021 (22, 23). The MDR aims to ensure the safety and effectiveness of medical devices, including arthroplasty implants, while striving to prevent unfavorable outcomes for patients. Compared with the medical devices directive (MDD), which was the first legal basis for an EU system of evaluating medical devices and approving their market access in the 1990s, the MDR includes stricter requirements for clinical evidence of medical devices to obtain access to the market, as well as provide post-market clinical follow-up (PMCF). Although the MDR provides general principles for clinical investigations but few methodological details, the latter was addressed in the European funded CORE-MD (coordinating research and methodology for medical devices) project (22).

The goal of innovation of arthroplasty implants should be to improve patient care, with improved benefit/risk ratio for patients compared with existing implants. The introduction of new implants without clinical evidence and analysis of the benefit/risk ratio for patients, but merely the promise of theoretically superior clinical performance compared

with other implants should be avoided (24, 25). Even though pre-clinical testing methodologies of implants according to ISO standards, such as mechanical testing and finite element analysis, have further improved in the recent years, a new implant can only really be tested when it is used in patients (26). This thesis directly contributes to this evidence based introduction of two novel arthroplasty implants. **Chapter 3** showed that a new acetabular shell with a plasma-sprayed, rather than an arc-deposited, commercially pure titanium (CPTi) surface, has a low risk of future long-term mechanical loosening, based on short-term RSA migration results. Additionally, we showed that the use of metallic 3D printing of off-the-shelf tibial baseplates may contribute to enhanced bone-implant fixation in **chapter 4**. Thus, we have shown that these novel implants have an estimated low risk of revision because of loosening in the long term, without exposing a large group of patients to this new implant.

Measuring the clinical performance of arthroplasty implants

A successful outcome according to the physician is not a guarantee for treatment success perceived by the patient (27, 28). This underlines the importance of careful consideration of the outcome parameter that is used to assess the clinical performance of an implant.

We have shown that RSA measures a different aspect of performance (i.e. implant-bone fixation) than PROMs (i.e. patient perception) (**chapter 2**). In a commentary on our study, Hernandez and Chang (29) agreed that arthroplasty outcome cannot be solely evaluated through PROMs. Whereas RSA provides objective, quantitative measurements of implant performance, patient perceived performance and satisfaction is multifactorial and involves factors such as age, gender, weight, socioeconomic status, mental health, social support, education, and race (29). Furthermore, PROMs are affected by the preoperative expectations of patients, as well as the overall experience of patients on the overall per-, intra-, and postoperative period about the (surgical) procedure (9, 30). Also, about one-third of patients receive a second arthroplasty approximately 2 years after the first arthroplasty, with the majority in the contralateral cognate joint (31). A second arthroplasty of the contralateral cognate joint will also affect the generic health-related quality of life and functioning of that patient, thereby blurring the effect of the initial arthroplasty treatment. Finally, other variables such as comorbidities will likely influence the PROMs particularly at longer duration of follow-up rather than solely reflecting the implant performance (32, 33).

Postoperative (change in) PROMs are not able to detect potential implant related problems after arthroplasty. At patient-level, for example, early identification of liner wear in THA may will prevent the need for major revision surgery. Radiographic imaging studies allow for the early detection of liner wear before symptoms occur that would translate into changes in PROMs. If liner wear is detected early, a simple liner exchange can be performed, without revising also a damaged metal acetabular shell. Even more, failure to detect linear wear early can lead to serious consequences (e.g. periprosthetic osteolysis) that often require major revision surgery, resulting in an increased burden to patients overall quality of life. At population-level, solely assessing the clinical outcome of arthroplasty patients treated with a new implant is also insufficient. Clinically relevant improvements in hip and knee scores after THA and TKA are likely overestimated on a group-level, as non-respondents to questionnaires (to calculate PROMs) have higher adverse event rates (34). Higher adverse event rates are associated with a lower likelihood to achieve clinically relevant improvements in hip disability and osteoarthritis outcome scores (HOOS) and KOOS (34). Furthermore, whereas early RSA migration results of a new implant at group level can be used to estimate the probability of patients being exposed to potential disasters, early postoperative PROMs cannot (35-37).

Implant survival as outcome parameter

Traditionally, the longevity of implants before revision surgery is used as the main outcome parameter (i.e. end-point in survival analysis) to assess the clinical performance of implants, although different end-points, like clinical performance, can be defined as well (38). Such revision surgery and end-points are reported by arthroplasty registries for individual brands of implants. These registry data are not only important for surgeons in their clinical decision making but are also used by implant manufacturers for benchmarking accreditation like ODEP, and by healthcare insurance companies, and policymakers to adapt their policies (39). In **chapter 7** we compared the clinical performance of RSA-tested with non-RSA-tested implants with data obtained from the LROI, using revision surgery as the endpoint. We specifically studied all-cause major revision, defined as revision of at least the femoral or tibial component, and major revision because of aseptic loosening. However, revision surgery as outcome parameter after arthroplasty has its limitations. In clinical practice, revision surgery is a decision that is made by the surgeon together with the patient taking benefit (e.g. less pain) and risk (e.g. complications, like worse outcome) into account, but

these arguments are subjective to competing risk factors. Even if clear implant loosening is observed on radiographic examination, but the patient has little complaints or the patient's surgical risk is deemed high because of comorbidities, a surgeon will be reluctant to perform revision surgery. Additionally, in some countries revision rates of one's primary cases are used to assess hospital performance, such a system may make surgeons reluctant to revise a failed implant (40). Therefore registries should also collect revision data irrespective of the place where the primary surgery was performed, as is done in the Netherlands (LROI) and in all well-established registries. Another limitation of using revision surgery as the endpoint for the clinical evaluation of novel implants is that the (all-cause) revision risk after modern TKA and THA in the first 10 years is low (<5%), whilst its impact on patients is huge. The latter implicates that if revision surgery would be used to proof non-inferiority of a new implant designs thousands of patients with long-term follow-up are needed.

Implant migration as outcome parameter

Rather than waiting for at least 10 years and expose thousands of patients to a potential beneficial or even worse implant design, an intermediate outcome or surrogate endpoint can be used to evaluate the performance of new implants. To be considered useful in clinical evaluations, a surrogate endpoint must demonstrate a clear and strong correlation with the clinical outcome of interest and is expected to predict clinical benefit (or harm) of an intervention based on other scientific evidence (41). Implant migration as measured with RSA can be used as surrogate marker in the evaluation of new implants, as it has shown that there is a clinically relevant association between early implant migration within the bone and the long-term risk of revision surgery due to implant loosening (i.e. the clinical outcome of interest) (1, 36, 42). Because of the high accuracy of RSA, a relative small number of patients is needed to proof non-inferiority of a new implant design compared to a golden standard implant (1, 43).

RSA is generally used for implant-bone fixation safety studies, as early migration at a group level can be used to estimate the long-term revision risk in the future (**chapter 3 and 4**). However, we caution against categorizing individual implants as "migrating" or "stable" based on strict migration thresholds values. We showed that the marker-selection method that is used to analyze RSA radiographs affects individual implant migration results (but estimated group differences remained similar) (**chapter 5**). Furthermore, the proportion of patients with continuous migration (> 0.2 mm) may be reported for each

group, but this should not be used in the interpretation of implant (patient) safety as the a priori risk of the implant revision rate in each study group is unknown (1).

In **chapter 2** we showed that implant migration, as measured with RSA, measures a different aspect of performance than PROMs. Recently, Broberg et al. (44) reported that there was no difference in tibial baseplate migration between "satisfied" and "dissatisfied" patients. Their findings therefore point in the same direction as our conclusion: that PROMs after TKA cannot be used as a substitute of RSA to estimate the long-term risk of revision. However, Broberg et al. (44) only studied tibial component migration up to 2 years postoperatively in 50 patients and dichotomized individual patients based on specific migration (and PROMs) thresholds.

Camouflage of true clinical performance

To guide clinical practice, it is essential to assess and report the performance of specific implant designs. For that matter, classifying specific implants can be very complex since various implant (sub)types within the same implant brand portfolio exist (45, 46). This is particularly relevant when clinical outcomes (i.e. revision risks) of a specific implant brand are only presented at an aggregate implant brand level, for example in registry reports. This phenomenon, referred to as "camouflage", occurs when the worse performance of a specific implant design variant is concealed due to the presence of other good performing variants under the same implant name within datasets of THA and TKA implants (45-47). When a poorly performing implant is masked by other (sub)types within the same implant brand portfolio, surgeons, implant manufacturers, and policymakers may mistakenly decide to continue using such an implant, thereby exposing patients to associated risks.

This camouflage phenomenon was also highlighted in **chapter 3**, as the Trident II acetabular system (Stryker, USA) includes different subtypes, referred to as Trident II Tritanium and Trident II HA shells. Where the Trident II Tritanium shells are 3D printed, the Trident II HA shells are manufactured by a different process of forging and machine finishing (48). The latter is important, as we know that (small) changes in the manufacturing process and implant surfaces have been associated with unacceptable long-term failure rates (49-53). Regarding the Trident II acetabular system that we studied, Ulrich et al. (54) recently (incorrectly) assumed that all Trident II shells are produced with 3D printing in a case series of 2 patients with failure of screw/shell interface, whereas the reported failure concerned a specific subtype. Not recognizing differences between subtypes within the same general

brand name may lead to an incorrect hypothesis of the underlying failure mechanism. This underlines the importance of improving awareness about differences between implant subtypes within the same implant brand portfolio (55).

Potential camouflage of true clinical outcomes after TKA also needs to be considered for the implants studied in **chapter 4**. In the latter study, the Triathlon Tritanium TKA was compared with its predecessor: the Triathlon TKA. The slight difference in name may not be noticed by clinicians unfamiliar with the different (sub)types within the Triathlon implant brand portfolio, and what distinguishes these (sub)types as well as the impact on patient outcomes. As these are different implants, the cumulative revision percentages in annual reports of arthroplasty registries is reported separately for TKAs performed with Triathlon Tritanium implants and TKAs with Triathlon implants (56, 57). However, to complicate this issue even further, different subdesigns of the Triathlon TKA implant also exists. For example, uncemented Triathlon baseplates can either be porous-coated (i.e. uncoated) or coated with peri-apatite (PA) (58, 59). Van Hamersveld et al. (58) have shown that the type of coating affects implant migration and clinical performance. Therefore, these implants need to be considered as distinct implants, but annual reports of arthroplasty registries mostly only report cumulative revision rates for the entire group of Triathlon implants (56).

In **chapter 7** we tried to take potential camouflage of true clinical outcomes of implant designs into account by performing patient-level analyses using data obtained from the LROI. In **chapter 1 and 7** we already touched upon the study by Hasan et al. (60). As Hasan et al. (60) obtained the revision risks from annual reports of arthroplasty registers where survival data is only provided on aggregate implant brand level, these will suffer from camouflage. In **chapter 7** we were able to adjust for different (sub)designs within the same implant brand portfolio because all product and batch numbers of prosthetic components and cement are registered in the LROI (61). Thereby, we were able to perform a patient-level analysis with a more specific and accurate assessment of the performance of distinct TKA implants. In both **chapter 7** and the study by Hasan et al. (60), the same data from a previously published meta-analysis were used to identify RSA-tested implants. However, camouflage may also be present there in published RSA studies which frequently report only a limited description of the prosthesis that was investigated. The latter was confirmed by our systematic literature search described in **chapter 6**, where we found that only few RSA studies on prosthesis migration from the last decade provided a complete detailed

description of all prosthesis components (i.e., not only the component that was studied), type of cement/coating, and liner characteristics for each study group. To avoid potential camouflage of true clinical outcomes, both arthroplasty registries and clinical RSA studies need to improve the reporting of implants' performance on a more detailed level to enable assessment of clinical performance of relevant (sub)designs. Furthermore, this thesis underlines the importance of transparency when (small) changes to an implant design, its manufacturing process, or packaging method have been made. Different manufacturing processes or packaging methods of specific implant (sub)designs may influence its clinical performance (62, 63). The latter is particularly dangerous when the clinical performance of an implant is affected, but the implant's name remains exactly the same and the change is unknown to surgeons using that specific implant (sub)design.

Future perspectives

When acceptable early RSA migration results of a specific implant have been reported, indicating a low risk of long-term revision because of loosening, this does not exempt clinicians from continuous careful evaluation of that implant. For that matter, specific changes to an implant can occur after an RSA study has been performed, influencing its clinical performance (i.e. camouflage effect). In clinical practice it is often unclear if an implant is still exactly the same (same manufacturing method, same packing method of all components, etc.) as a few years ago. Perhaps it would be reasonable in the future to periodically (i.e. after 10 years) reassess the migration pattern of a subset of all arthroplasty implants on the market. This thesis highlights the need for more research into the societal impact of RSA testing of new arthroplasty implants.

Besides clinical evaluation of (new) implant designs, RSA can also be utilized to assess the influence of other factors on implant fixation like surgical technique (e.g. implant position, like the constitutional varus position leads to higher tibial component migration) (64). In **chapter 3** we evaluated another aspect like cement mantle thickness, but found no influence of cement mantle thickness on tibial implant migration. In recent years, the influence of various other factors on implant fixation has been studied with RSA, including the influence of patient characteristics, different TKA alignment strategies, and the use of a tourniquet (64-67). In the future, RSA research may further contribute to optimal patient specific alignment strategies for arthroplasty components. For example, RSA studies can be

used to identify the optimal tibial slope for each individual patient undergoing TKA. Such data could be used in conjunction with robotic-assisted TKA. Although it is yet to be determined whether robotic-assisted TKA results clinical relevant improved clinical outcomes, although it does allow for more predictable placement of TKA components (68). The missing link is obvious which is the optimal component position for which patients. Robotic surgery combined with data driven healthcare (i.e. kinematic data as well as morphology of specific patients) will be helpful to optimise outcome, although indication for arthroplasty and patient expectations are most probably still key for success (9, 30, 69).

Data of specific implant (e.g. total knee) migration may be used as a benchmark which is publicly available, adding to transparency of objective outcome of specific implants, comparable to an ODEP classification, or it may be part of such a classification. In the end, no innovation without evaluation (70).

References

1. Kaptein BL, Pijls B, Koster L, Kärrholm J, Hull M, Niesen A et al. Guideline for RSA and CT-RSA implant migration measurements: an update of standardizations and recommendations. Acta Orthop. 2024;95:256-67.
2. Denissen GA, van Steenbergen LN, Burgers AM, Nelissen RG. [Evidence-based hip prostheses: more high-quality prostheses used after introduction of a classification system]. Ned Tijdschr Geneeskd. 2015;160:A9532.
3. Moran CG, Horton TC. Total knee replacement: the joint of the decade. A successful operation, for which there's a large unmet need. Bmj. 2000;320:7238:820.
4. Learmonth ID, Young C, Rorabeck C. The operation of the century: total hip replacement. Lancet. 2007;370:9597:1508-19.
5. DeFrance MJ, Scuderi GR. Are 20% of Patients Actually Dissatisfied Following Total Knee Arthroplasty? A Systematic Review of the Literature. J Arthroplasty. 2023;38:3:594-9.
6. Gunaratne R, Pratt DN, Banda J, Fick DP, Khan RJK, Robertson BW. Patient Dissatisfaction Following Total Knee Arthroplasty: A Systematic Review of the Literature. J Arthroplasty. 2017;32:12:3854-60.
7. Baker PN, van der Meulen JH, Lewsey J, Gregg PJ. The role of pain and function in determining patient satisfaction after total knee replacement. Data from the National Joint Registry for England and Wales. J Bone Joint Surg Br. 2007;89:7:893-900.
8. Bourne RB, Chesworth BM, Davis AM, Mahomed NN, Charron KD. Patient satisfaction after total knee arthroplasty: who is satisfied and who is not? Clin Orthop Relat Res. 2010;468:1:57-63.
9. Tilbury C, Haanstra TM, Leichtenberg CS, Verdegaal SH, Ostelo RW, de Vet HC et al. Unfulfilled Expectations After Total Hip and Knee Arthroplasty Surgery: There Is a Need for Better Preoperative Patient Information and Education. J Arthroplasty. 2016;31:10:2139-45.
10. Latijnhouwers D, Vlieland T, Marijnissen WJ, Damen PJ, Nelissen R, Gademan MGJ. Sex differences in perceived expectations of the outcome of total hip and knee arthroplasties and their fulfillment: an observational cohort study. Rheumatol Int. 2023;43:5:911-22.
11. Anakwe RE, Jenkins PJ, Moran M. Predicting dissatisfaction after total hip arthroplasty: a study of 850 patients. J Arthroplasty. 2011;26:2:209-13.
12. Orr MN, Klika AK, Emara AK, Piuzzi NS. Dissatisfaction After Total Hip Arthroplasty Associated With Preoperative Patient-Reported Outcome Phenotypes. J Arthroplasty. 2022;37:7s:S498-s509.
13. Halawi MJ, Jongbloed W, Baron S, Savoy L, Williams VJ, Cote MP. Patient Dissatisfaction After Primary Total Joint Arthroplasty: The Patient Perspective. J Arthroplasty. 2019;34:6:1093-6.
14. Latijnhouwers D, van Gils JA, Vliet Vlieland TPM, van Steenbergen LN, Marang-van de Mheen PJ, Cannegieter SC et al. Multiple Joint Arthroplasty in Hip and Knee Osteoarthritis Patients: A National Longitudinal Cohort Study. J Arthroplasty. 2024;39:11:2661-8.e1.
15. van Brug HE, Nelissen R, Rosendaal FR, van Steenbergen LN, van Dorp ELA, Bouvy ML et al. Out-of-hospital opioid prescriptions after knee and hip arthroplasty: prescribers and the first prescribed opioid. Br J Anaesth. 2023;130:4:459-67.
16. van Brug HE, Nelissen R, Rosendaal FR, van Dorp ELA, Bouvy ML, Dahan A et al. What Changes Have Occurred in Opioid Prescriptions and the Prescribers of Opioids Before TKA and THA? A Large National Registry Study. Clin Orthop Relat Res. 2023;481:9:1716-28.
17. Langton DJ, Jameson SS, Joyce TJ, Hallab NJ, Natu S, Nargol AV. Early failure of metal-on-metal bearings in hip resurfacing and large-diameter total hip replacement: A consequence of excess wear. J Bone Joint Surg Br. 2010;92:1:38-46.
18. Luites JW, Spruit M, Hellemondt GG, Horstmann WG, Valstar ER. Failure of the uncoated titanium ProxiLock femoral hip prosthesis. Clin Orthop Relat Res. 2006;448:79-86.
19. Norton MR, Vhadra RK, Timperley AJ. The Johnson-Elloy (Accord) total knee replacement. Poor results at 8 to 12 years. J Bone Joint Surg Br. 2002;84:6:852-5.
20. Gilbert RE, Carrothers AD, Gregory JJ, Oakley MJ. The St. Leger total knee replacement: a 10-year clinical and radiological assessment. Knee. 2009;16:5:322-5.
21. Overgaard S, Grupp TM, Nelissen RG, Cristofolini L, Lübbeke A, Jäger M et al. Introduction of innovations in joint arthroplasty: Recommendations from the 'EFORT implant and patient safety initiative'. EFORT Open Rev. 2023;8:7:509-21.

22. Fraser AG, Nelissen R, Kjærsgaard-Andersen P, Szymański P, Melvin T, Piscoi P. Improved clinical investigation and evaluation of high-risk medical devices: the rationale and objectives of CORE-MD (Coordinating Research and Evidence for Medical Devices). EFORT Open Rev. 2021;6:10:839-49.
23. European Union. Regulation (EU) 2017/745 of the European Parliament and of the Council of 5 April 2017 on medical devices, amending Directive 2001/83/EC, Regulation (EC) No 178/2002 and Regulation (EC) No 1223/2009 and repealing Council Directives 90/385/EEC and 93/42/EEC. https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=uriserv:OJ.L_.2017.117.01.0001.01.ENG&toc=OJ:L:2017:117:TOC [Accessed 09-08-2024].
24. Nelissen RG, Pijls BG, Kärrholm J, Malchau H, Nieuwenhuijse MJ, Valstar ER. RSA and registries: the quest for phased introduction of new implants. J Bone Joint Surg Am. 2011;93 Suppl 3:62-5.
25. Muirhead-Allwood SK. Lessons of a hip failure. Bmj. 1998;316:7132:644.
26. Cheng C-K, Wang X-H, Luan Y-C, Zhang N-Z, Liu B-L, Ma X-Y et al. Challenges of pre-clinical testing in orthopedic implant development. Medical Engineering & Physics. 2019;72:49-54.
27. Janse AJ, Gemke RJ, Uiterwaal CS, van der Tweel I, Kimpen JL, Sinnema G. Quality of life: patients and doctors don't always agree: a meta-analysis. J Clin Epidemiol. 2004;57:7:653-61.
28. Noble PC, Fuller-Lafreniere S, Meftah M, Dwyer MK. Challenges in outcome measurement: discrepancies between patient and provider definitions of success. Clin Orthop Relat Res. 2013;471:11:3437-45.
29. Hernandez NM, Chang HY. If the Patient-Reported Outcome Measures After Total Knee Arthroplasty Are Good, Do Any Other Measurements Really Matter?: Commentary on an article by Thies J.N. van der Lelij, MD, et al.: "Tibial Baseplate Migration Is Not Associated with Change in Patient-Reported Outcome Measures and Clinical Scores After Total Knee Arthroplasty. A Secondary Analysis of 5 Radiostereometric Analysis Studies with 10-Year Follow-up". J Bone Joint Surg Am. 2024;106:16:e35.
30. Tilbury C, Haanstra TM, Verdegaal SHM, Nelissen R, de Vet HCW, Vliet Vlieland TPM et al. Patients' pre-operative general and specific outcome expectations predict postoperative pain and function after total knee and total hip arthroplasties. Scand J Pain. 2018;18:3:457-66.
31. Latijnhouwers D, van Gils JA, Vliet Vlieland TPM, van Steenbergen LN, Marang-van de Mheen PJ, Cannegieter SC et al. Multiple Joint Arthroplasty in Hip and Knee Osteoarthritis Patients: A National Longitudinal Cohort Study. J Arthroplasty. 2024.
32. Hofstede SN, Gademan MG, Vliet Vlieland TP, Nelissen RG, Marang-van de Mheen PJ. Preoperative predictors for outcomes after total hip replacement in patients with osteoarthritis: a systematic review. BMC Musculoskelet Disord. 2016;17:212.
33. Hilton ME, Gioe T, Noorbaloochi S, Singh JA. Increasing comorbidity is associated with worsening physical function and pain after primary total knee arthroplasty. BMC Musculoskelet Disord. 2016;17:1:421.
34. van Schie P, van Bodegom-Vos L, Zijdeman TM, Gosens T, Nelissen R, Marang-van de Mheen PJ. Linking Patient-Reported Outcome Measure Scores to Adverse Event Data to Gain Insight into Overestimation of Postoperative Patient-Reported Outcome Measure Improvement After Total Hip Arthroplasty and Total Knee Arthroplasty Due to Selective Nonresponse. J Arthroplasty. 2024.
35. Pijls BG, Valstar ER, Nouta KA, Plevier JW, Fiocco M, Middeldorp S et al. Early migration of tibial components is associated with late revision: a systematic review and meta-analysis of 21,000 knee arthroplasties. Acta Orthop. 2012;83:6:614-24.
36. Pijls BG, Nieuwenhuijse MJ, Fiocco M, Plevier JW, Middeldorp S, Nelissen RG et al. Early proximal migration of cups is associated with late revision in THA: a systematic review and meta-analysis of 26 RSA studies and 49 survivalstudies. Acta Orthop. 2012;83:6:583-91.
37. Pijls BG, Nelissen RGHH. Strategy for RSA migration thresholds. Acta Orthop. 2016;87:4:432-3.
38. Nelissen RG, Brand R, Rozing PM. Survivorship analysis in total condylar knee arthroplasty. A statistical review. J Bone Joint Surg Am. 1992;74:3:383-9.
39. Varnum C, Pedersen AB, Rolfson O, Rogmark C, Furnes O, Hallan G et al. Impact of hip arthroplasty registers on orthopaedic practice and perspectives for the future. EFORT Open Rev. 2019;4:6:368-76.
40. van Schie P, van Bodegom-Vos L, van Steenbergen LN, Nelissen R, Marang-van de Mheen PJ. Monitoring Hospital Performance with Statistical Process Control After Total Hip and Knee Arthroplasty: A Study to Determine How Much Earlier Worsening Performance Can Be Detected. J Bone Joint Surg Am. 2020;102:23:2087-94.

41. Ciani O, Manyara AM, Davies P, Stewart D, Weir CJ, Young AE et al. A framework for the definition and interpretation of the use of surrogate endpoints in interventional trials. EClinicalMedicine. 2023;65:102283.
42. Pijls BG, Plevier JWM, Nelissen R. RSA migration of total knee replacements. Acta Orthop. 2018;89:3:320-8.
43. Valstar ER, Gill R, Ryd L, Flivik G, Börlin N, Kärrholm J. Guidelines for standardization of radiostereometry (RSA) of implants. Acta Orthop. 2005;76:4:563-72.
44. Broberg JS, Naudie DDR, Lanting BA, Howard JL, Vasarhelyi EM, Teeter MG. Patient and Implant Performance of Satisfied and Dissatisfied Total Knee Arthroplasty Patients. J Arthroplasty. 2022;37:6s:S98-s104.
45. Phillips JRA, Tucker K. Implant brand portfolios, the potential for camouflage of data, and the role of the Orthopaedic Data Evaluation Panel in total knee arthroplasty. Bone Joint J. 2021;103-b:10:1555-60.
46. Wilton T, Skinner JA, Haddad FS. Camouflage uncovered: what should happen next? The Bone & Joint Journal. 2023;105-B:3:221-6.
47. Hoogervorst LA, van Tilburg MM, Lübbeke A, Wilton T, Nelissen R, Marang-van de Mheen PJ. Validating Orthopaedic Data Evaluation Panel (ODEP) Ratings Across 9 Orthopaedic Registries: Total Hip Implants with an ODEP Rating Perform Better Than Those without an ODEP Rating. J Bone Joint Surg Am. 2024.
48. Stryker. Trident II acetabular system. 2022. https://www.stryker.com/at/en/joint-replacement/products/trident-ii/index-eu.html [Accessed 30-08-2024].
49. Johanson PE, Antonsson M, Shareghi B, Kärrholm J. Early Subsidence Predicts Failure of a Cemented Femoral Stem With Minor Design Changes. Clin Orthop Relat Res. 2016;474:10:2221-9.
50. Hauptfleisch J, Glyn-Jones S, Beard DJ, Gill HS, Murray DW. The premature failure of the Charnley Elite-Plus stem: a confirmation of RSA predictions. J Bone Joint Surg Br. 2006;88:2:179-83.
51. Howie DW, Middleton RG, Costi K. Loosening of matt and polished cemented femoral stems. J Bone Joint Surg Br. 1998;80:4:573-6.
52. Petheram TG, Bone M, Joyce TJ, Serrano-Pedraza I, Reed MR, Partington PF. Surface finish of the Exeter Trauma Stem: a cause for concern? Bone Joint J. 2013;95-b:2:173-6.
53. Hutt J, Hazlerigg A, Aneel A, Epie G, Dabis H, Twyman R et al. The effect of a collar and surface finish on cemented femoral stems: a prospective randomised trial of four stem designs. Int Orthop. 2014;38:6:1131-7.
54. Ulrich PA, Zondervan RL, Cochran JM. Failure of Screw/Shell Interface in the Trident II Acetabular System in Total Hip Arthroplasty. Arthroplast Today. 2022;17:80-6.
55. van der Lelij TJN, Marang-van de Mheen PJ, Kaptein BL, Nelissen R. Letter to the Editor: Failure of Screw/Shell Interface in Trident II Acetabular System in Total Hip Arthroplasty. Arthroplast Today. 2024;27:101358.
56. Dutch Arthroplasty Register (LROI). Annual Report 2023. 2023. https://www.lroi-report.nl/app/uploads/2023/10/PDF-LROI-annual-report-2023-1.pdf [Accessed 09-07-2024].
57. National Joint Registry (NJR). 20th Annual report 2023. 2023. https://reports.njrcentre.org.uk/ [Accessed 09-07-2024].
58. Van Hamersveld KT, Marang-Van De Mheen PJ, Nelissen R, Toksvig-Larsen S. Peri-apatite coating decreases uncemented tibial component migration: long-term RSA results of a randomized controlled trial and limitations of short-term results. Acta Orthop. 2018;89:4:425-30.
59. Molt M, Toksvig-Larsen S. Peri-Apatite™ enhances prosthetic fixation in Tka-A prospective randomised RSA study. J Arthritis. 2014;3:3:134.
60. Hasan S, Marang-van de Mheen PJ, Kaptein BL, Nelissen R, Pijls BG. RSA-tested TKA Implants on Average Have Lower Mean 10-year Revision Rates Than Non-RSA-tested Designs. Clin Orthop Relat Res. 2020;478:6:1232-41.
61. Denissen GAW, van Steenbergen LN, Lollinga WT, Verdonschot NJJ, Schreurs BW, Nelissen R. Generic implant classification enables comparison across implant designs: the Dutch Arthroplasty Register implant library. EFORT Open Rev. 2019;4:6:344-50.
62. Exactech. US Exactech Recall Information. Knee and Ankle Polyethylene. 2022. https://www.exac.com/recall-information/ [Accessed 02-09-2024].
63. Bonsignore LA, Goldberg VM, Greenfield EM. Machine oil inhibits the osseointegration of orthopaedic implants by impairing osteoblast attachment and spreading. J Orthop Res. 2015;33:7:979-87.

64. van Hamersveld KT, Marang-van de Mheen PJ, Nelissen R. The Effect of Coronal Alignment on Tibial Component Migration Following Total Knee Arthroplasty: A Cohort Study with Long-Term Radiostereometric Analysis Results. J Bone Joint Surg Am. 2019;101:13:1203-12.
65. Laende EK, Mills Flemming J, Astephen Wilson JL, Cantoni E, Dunbar MJ. The associations of implant and patient factors with migration of the tibial component differ by sex : a radiostereometric study on more than 400 total knee arthroplasties. Bone Joint J. 2022;104-b:4:444-51.
66. Hasan S, Kaptein BL, Nelissen R, van Hamersveld KT, Toksvig-Larsen S, Marang-van de Mheen PJ. The Influence of Postoperative Coronal Alignment on Tibial Migration After Total Knee Arthroplasty in Preoperative Varus and Valgus Knees: A Secondary Analysis of 10 Randomized Controlled Trials Using Radiostereometric Analysis. J Bone Joint Surg Am. 2021;103:24:2281-90.
67. Molt M, Harsten A, Toksvig-Larsen S. The effect of tourniquet use on fixation quality in cemented total knee arthroplasty a prospective randomized clinical controlled RSA trial. Knee. 2014;21:2:396-401.
68. Siddiqi A, Horan T, Molloy RM, Bloomfield MR, Patel PD, Piuzzi NS. A clinical review of robotic navigation in total knee arthroplasty: historical systems to modern design. EFORT Open Rev. 2021;6:4:252-69.
69. Verra WC, Witteveen KQ, Maier AB, Gademan MG, van der Linden HM, Nelissen RG. The reason why orthopaedic surgeons perform total knee replacement: results of a randomised study using case vignettes. Knee Surg Sports Traumatol Arthrosc. 2016;24:8:2697-703.
70. McCulloch P, Altman DG, Campbell WB, Flum DR, Glasziou P, Marshall JC et al. No surgical innovation without evaluation: the IDEAL recommendations. Lancet. 2009;374:9695:1105-12.

Chapter 9

Appendices

Summary in Dutch (Nederlandse samenvatting)

Het doel van dit proefschrift was om een bijdrage te leveren aan de veiligheid van patiënten die een arthroplastiek van de knie of heup ondergaan. Naast het evalueren van nieuwe protheses die recent op de markt zijn verschenen, onderzoekt dit proefschrift de klinische waarde van migratieanalyse van totale knieprotheses (TKP) en totale heupprotheses (THP).

De klinische uitkomst na een TKP operatie kan op verschillende manieren worden gemeten, onder andere door objectieve metingen van implantaatmigratie middels RSA, maar ook door subjectieve uitkomstmaten zoals patiënt gerapporteerde uitkomstmaten (PROM's). Om de waarde van deze verschillende uitkomstmaten tijdens de follow-up van patiënten na een TKP operatie beter te begrijpen, is het belangrijk om te weten of deze uitkomstmaten hetzelfde, of een ander aspect, van de geleverde zorg meten. In **hoofdstuk 2** hebben we onderzocht in hoeverre migratie van TKP implantaten geassocieerd is met postoperatieve veranderingen in PROM's. Voor deze studie werden individuele implantaatmigratie resultaten uit 5 gerandomiseerde radiostereometrische analyse (RSA)-onderzoeken gebruikt, met in totaal 300 patiënten met 6 verschillende TKP implantaten. TKP migratie werd geëvalueerd 3 maanden, 1, 2, 5, 7 en 10 jaar na de operatie. Op dezelfde follow-up momenten werden de Knee Society Score (KSS)-Knee, KSS-Function, Knee injury en Osteoarthritis Outcome Score (KOOS) verzameld. De studie liet zien dat migratie van de tibia component van de TKP niet geassocieerd was met postoperatieve verandering in PROMs gedurende de gehele follow-up. Onze bevindingen suggereren dat implantaatmigratie, gemeten met RSA, een andere aspect van de klinische prestatie van een TKP implantaat meet (d.w.z. implantaat-botfixatie) dan PROM's (d.w.z. door de patiënt waargenomen subjectieve uitkomst). Daarom is het onvoldoende om de klinische uitkomst na een TKP operatie alleen met PROM's te evalueren.

Gerandomiseerde klinische studies (RCT's) zijn belangrijk om bewijs van hoge kwaliteit te leveren over de prestaties en veiligheid van nieuwe implantaten en om besluitvorming in de klinische praktijk te ondersteunen. Door RSA te gebruiken in RCT's, hoeft er slechts een beperkt aantal patiënten te worden geïncludeerd omdat RSA een zeer nauwkeurige meetmethode is. Dit proefschrift draagt bij aan het klinische bewijs van nieuwe implantaten door twee RCT's uit te voeren en daarbij RSA te gebruiken. In **hoofdstuk 3** analyseerden wij

het migratiepatroon van een nieuw cementloze hydroxyapatiet (HA)-gecoate titanium acetabulum cup in patiënten die een THP kregen. Zevenentachtig patiënten werden gerandomiseerd naar een Trident II HA of een Trident HA cup, allebei cementloze, clusterhole en HA-gecoate cups. Implantaatmigratie werd geëvalueerd met RSA op 3, 12 en 24 maanden na de operatie. PROM's en klinische scores werden verzameld bij elke follow-up als secundaire uitkomstmaten. Gedurende de 2 jaar durende follow-up periode waren klinische scores en PROM's vergelijkbaar tussen de groepen. De nieuwe Trident II HA cup liet vergelijkbare migratie met zijn voorganger, de Trident HA cup, zien. Deze bevindingen suggereren een vergelijkbaar risico op aseptische loslating op de lange termijn. In **hoofdstuk 4** vergeleken we de middellange termijn migratie van een nieuwe cementloze driedimensionale (3D)-geprinte TKP met een conventioneel geproduceerde gecementeerde TKP. Voor deze studie werden 72 patiënten gerandomiseerd naar de cementloze of gecementeerde TKP. RSA-röntgenfoto's werden gemaakt 3 maanden, 1, 2 en 5 jaar na de operatie. Secundaire uitkomsten waren de KSS, KOOS en de Forgotten Joint Sore (FJS). We toonden aan dat er geen significant verschil was in implantaatmigratie 5 jaar na de operatie tussen het cementloze en gecementeerde TKP. Enige toename van migratie van de gecementeerde TKA was echter wel aanwezig na 2 jaar, terwijl de cementloze 3D-geprinte TKP stabiel bleef. Er werden geen significante verschillen gevonden tussen beide protheses gedurende de gehele follow-up periode voor de KSS, KOOS en FJS.

Om ervoor te zorgen dat RSA studies betrouwbaar bewijs leveren over de klinische prestaties van implantaten, is consistentie in de uitvoering en rapportage van klinische RSA studies essentieel. Dit proefschrift draagt bij aan de methodologie en de kwaliteit van rapportage van klinische RSA studies. In **hoofdstuk 5** werd de impact van het gebruik van verschillende marker-selectiemethoden tijdens RSA-analyses op TKP migratieresultaten bepaald door alle RSA röntgenfoto's van de RCT die in **hoofdstuk 4** werd gepresenteerd opnieuw te analyseren. Alle RSA röntgenfoto's werden geanalyseerd met zowel een consistente set markers tijdens de volledige follow-up periode (consistent-markermethode) en met alle beschikbare markers bij elke follow-up die konden worden gekoppeld aan de referentie röntgenfoto (all-markermethode). Tevens werd de migratie berekend met behulp van 5 fictieve punten op de prothese, welke werden geplaatst op basis van de consistent-markermethode of all-markermethode. Wij lieten zien dat de geschatte verschillen in migratie op groepsniveau niet veranderden bij het gebruik van de consistent-

markermethode of all-markermethode, of bij gebruik van 5 fictieve punten. Individuele implantaatmigratiemetingen waren echter wel verschillend tussen de methoden.

Aan het einde van **hoofdstuk 5** adviseerden wij dat RSA studies de markerselectiemethode (die is gebruikt) moet rapporteren als onderdeel van de gestandaardiseerde output, om vergelijking tussen klinische studies mogelijk te maken. Onze aanbeveling is recent opgenomen in de nieuwe richtlijn voor RSA en CT-RSA implantaatmigratie studies. In **hoofdstuk 6** onderzochten wij in hoeverre gepubliceerde klinische RSA-studies van het afgelopen decennium zich aan de RSA richtlijn houden. In totaal werden 285 RSA-studies opgenomen in onze systematische review, waarbij de meeste studies de prothesemigratie in het heup- of kniegewricht hadden onderzocht. Wij lieten zien dat RSA studies zich slechts beperkt hielden aan de RSA richtlijn checklist items. Omdat adequate rapportage een voorwaarde is om de methodologische kwaliteit van een onderzoek te kunnen beoordelen, moeten klinische RSA studies zoveel mogelijk van de checklistitems uit de RSA richtlijn rapporteren. Om de kwaliteit van rapportage van toekomstige onderzoeken te verbeteren, moeten RSA onderzoekers op de hoogte zijn van alle checklist items uit de richtlijn. Aan het einde van **hoofdstuk 6** hebben wij verschillende verduidelijkingen voorgesteld voor de RSA richtlijn checklist, om de bruikbaarheid hiervan in toekomstige klinische RSA studies te verbeteren. Als vroege implantaatmigratieresultaten, gemeten met RSA, van nieuwe implantaten met een verwacht hoog revisierisico op de lange termijn resulteren in minder frequent gebruik van deze implantaten in de klinische praktijk, zullen minder patiënten worden blootgesteld aan slecht presterende implantaten. Theoretisch zouden hierdoor alleen goed presterende implantaten op de markt overblijven. Dit proefschrift evalueert de klinische prestaties van implantaten die zijn getest in onderzoeken met RSA en vergeleken deze prestatie met implantaten die niet zijn getest met RSA.

Hoofdstuk 7 onderzocht het effect van RSA metingen van TKP implantaten op het revisierisico op de lange termijn in Nederland, door gebruik te maken van data uit het Landelijke Registratie Orthopedische Interventies (LROI). Voor deze studie werden alle primaire TKP procedures tussen 2007 en 2016 uit de LROI geïncludeerd. In totaal werden 83,836 RSA-geteste en 104,105 niet-RSA-geteste TKP's geïncludeerd. Wij ontdekten dat het cumulatieve risico op TKP revisie voor de RSA-geteste groep na 5 en 10 jaar, respectievelijk, 2.2% en 3.6% waren, vergeleken met 2.5% en 3.3% voor de niet-RSA-geteste groep. Als wij

specifiek kijken naar het revisierisico als gevolg van aseptische loslating, lieten de RSA-geteste TKP implantaten ook een hogere revisierisico op 10 jaar zien dan de niet-RSA-geteste implantaten (respectievelijk 1.8% versus 1.4%). Onze bevindingen lieten zien dat RSA-geteste TKP implantaten geen lager revisierisico op de lange termijn hadden dan niet-RSA-geteste TKP implantaten in Nederland. Dit laatste is hoogstwaarschijnlijk te wijten aan het modificerende effect van een kwaliteitsbeoordelingssysteem dat adviseert om alleen hoogwaardige (d.w.z. lage revisiepercentages na 5 en 10 jaar) orthopedische implantaten in Nederland te gebruiken (Nederlandse Orthopedische Vereniging (NOV) kwaliteitssysteem, later ODEP).

Author affiliations

Affiliations of contributing authors in order of appearance in this thesis.

Thies J.N. van der Lelij, MD, PhD candidate [1]

Perla J. Marang-van de Mheen, PhD, Associate Professor, Epidemiologist [1, 2]

Bart L. Kaptein, PhD, Senior researcher, Biomechanical engineer, RSA specialist [1]

Lennard A. Koster, PhD candidate, RSA specialist [1]

Peter Ljung, MD, PhD, Orthopaedic surgeon [3]

Rob G.H.H. Nelissen, MD, PhD, Professor, Head of Department, Orthopaedic surgeon [1]

Sören Toksvig-Larsen, MD, PhD, Associate Professor, Orthopaedic surgeon [3, 4]

Bart G. Pijls, MD, PhD, Assistant Professor, Epidemiologist, Orthopaedic surgeon [1, 5]

Liza N. van Steenbergen, PhD, Epidemiologist [5]

Roula Tsonaka, PhD, Assistant Professor, Biostatistician [6]

1.	Department of Orthopaedics, Leiden University Medical Center, Leiden, The Netherlands.
2.	Safety & Security Science and Centre for Safety in Healthcare, Delft University of Technology, Delft, The Netherlands.
3.	Department of Orthopaedics, Hässleholm Hospital, Hässleholm, Sweden.
4.	Department of Clinical Sciences, Lund University, Lund, Sweden.
5.	Landelijke Registratie Orthopedische Interventies (LROI: Dutch Arthroplasty Register), 's Hertogenbosch, The Netherland
6.	Department of Biomedical Data Sciences, Medical Statistics, Leiden University Medical Center, Leiden, The Netherlands.

Acknowledgments (Dankwoord)

Geachte prof. dr. R.G.H.H. Nelissen, beste Rob, bedankt dat jij mij de kans gaf om aan dit promotietraject te beginnen. Afgelopen jaren heb jij richting gegeven aan het grotere geheel van dit proefschrift, maar daarnaast heb jij mij de ruimte gegeven om zelf invulling te geven aan de inhoud; Jouw ervaring, creativiteit, en enthousiasme zijn een grote bron van inspiratie.

Geachte dr. P.J. Marang-van de Mheen, beste Perla, jouw begeleiding is van onschatbare waarde geweest voor het tot stand komen van dit proefschrift. Jouw enthousiasme, kennis, en visie op onderzoek hebben mij zeer gemotiveerd en onze wekelijkse meetings, eerst in het LUMC en later op de TU Delft, waren iedere keer weer bijzonder waardevol en erg gezellig.

Geachte dr. ir. B.L. Kaptein, beste Bart, bedankt dat jij altijd beschikbaar was om mij te helpen met alle studies uit dit proefschrift. Jouw technische blik en oog voor detail hebben mij geholpen met de vele analyses en het schrijven van de artikelen.

Dear dr. S. Toksvig-Larsen, dear Sören, from the moment I arrived in Hässleholm you gave me your full support. Your extensive knowledge, sincere interest in people, and way of thinking about even the smallest details that may benefit patients are truly exceptional. I am grateful to have met you and privileged to have had the opportunity to work with you.

Dear colleagues in Sweden, dear Håkan, Ingela, Jannice, Jessica, and Tobbe, thank you for all your help with the RSA studies over the past few years.

Beste Lennard en Bart (Pijls), dank voor alle gesprekken en discussies over verschillende studies uit dit proefschrift. Jullie kennis en visie op onderzoek binnen de RSA wereld is van zeer grote waarde geweest.

Collega's van de D1 (voorheen C3, daarvoor C2), met in het bijzonder Zeger, Richard, Timon, Geert, Anouk, Lotje, Hilde, bedankt voor alle gezelligheid de afgelopen jaren. Alle koffietjes,

borrels, congressen en feestjes hebben het doen van onderzoek nog een stuk leuker gemaakt.

Medewerkers van de afdeling Orthopedie in het LUMC, in het bijzonder Anika, Eveline en Marisa, bedankt voor alle praktische ondersteuning tijdens mijn promotietraject.

Pieter en Peter, tijdens mijn coschappen gaven jullie mij de kans om onderzoek te doen binnen de Orthopedie. Dank voor jullie begeleiding en enthousiasme afgelopen jaren.

Max en Jaap, beste paranimfen, bedankt dat jullie mij willen bijstaan tijdens de verdediging van dit proefschrift. Max, vanaf het moment dat ik nisje 1 in Leiden betrad is onze vriendschap ontstaan en sindsdien heb ik ontelbare keren heb kunnen genieten van jouw humor en relativeringsvermogen. Jaap, afgelopen decennium heb ik genoten van alle avonturen die wij hebben beleefd. Het is erg mooi dat zowel het vele lachen als de openhartige gesprekken onze vriendschap kenmerken.

Cedric en Tom, wat begon als een noodzakelijke vakantie naar Torremolinos, is uitgegroeid tot een mooie traditie van trips naar Malaga tot aan Edinburgh. Dank voor alle MDO's afgelopen jaren in het LUMC en mooie borrels in Leiden en Den Haag.

Mannen van Horus, tijdens mijn promotietraject waren alle vakanties, feestjes, en gesprekken voor mij een zeer belangrijke vorm van plezier en ontspanning, bedankt hiervoor.

Vrienden van Noordeinde, Maestro's, bedankt voor alle prachtige jaren op de Villa, waar ik met veel plezier op terugkijk.

Vrienden uit Delft, vanaf de middelbare school hebben wij een hechte vriendschap opgebouwd waar ik veel waarde aan hecht. Ik ben dankbaar dat het nog altijd een groot feest is wanneer wij elkaar weer zien.

Lieve ouders, zonder de kansen die jullie voor mij hebben gecreëerd had ik dit proefschrift niet kunnen schrijven. Jullie zorgzaamheid, onvoorwaardelijke liefde, en interesse zijn van onschatbare waarde en hebben mij gevormd tot de persoon die ik nu ben. Bedankt voor alle steun en het vertrouwen dat jullie mij hebben gegeven door de jaren heen.

Lieve zussen, Marlotte en Jitske, ook afgelopen jaren heb ik mogen genieten van al jullie gezelligheid, onvoorwaardelijke steun, en eindeloze verhalen. Ik ben ontzettend trots op hoe jullie je eigen pad bewandelen.

Liefste Syb, bedankt voor jouw geduld, steun, en liefde. Jij geeft mij de ruimte om mijzelf te ontwikkelen en kan mij laten zien wat echt belangrijk is. Ik ben ongelofelijk trots op hoe jij in het leven staat en het is inspirerend om te zien hoe hard jij werkt om jouw eigen dromen te verwezenlijken. Ik ben ontzettend gelukkig en dankbaar dat ik jou heb ontmoet en hoop nog lang met jou te genieten van alles in het leven.

Bibliography

Publications in this thesis

T.J.N. van der Lelij, B.G. Pijls, B.L. Kaptein, L.N. Steenbergen, R.G.H.H. Nelissen, P.J. Marang-van de Mheen. Does RSA testing of TKA implants result in lower long-term revision risk? A Dutch Arthroplasty Register study. *Submitted.*

T.J.N. van der Lelij, L.A. Koster, P.J. Marang-van de Mheen, R.G.H.H. Nelissen, B.L. Kaptein. Adherence to the RSA and CT-RSA guideline items in clinical prosthesis migration studies: a systematic review. *Acta Orthop. 2025 May 27;96:380-386.*

T.J.N. van der Lelij, B.L. Kaptein, R. Tsonaka, R.G.H.H. Nelissen, S. Toksvig-Larsen, P.J. Marang-van de Mheen. Tibial Baseplate Migration is not Associated with Change in Patient Reported Outcome Measures and Clinical Scores after Total Knee Arthroplasty: A Secondary Analysis of 5 Radiostereometric Analysis Studies with 10-year Follow-up. *J Bone Joint Surg Am.* 2024 Aug 21;106(16):1479-1485.

T.J.N. van der Lelij, L.A. Koster, P.J. Marang-van de Mheen, S. Toksvig-Larsen, R.G.H.H. Nelissen, B.L. Kaptein. Influence of marker-selection method in radiostereometric analysis of total knee arthroplasty on tibial baseplate migration patterns: a secondary analysis of a randomized controlled trial with 5-year follow-up. *Acta Orthop*. 2024 Mar 21;95:157-165.

T.J.N. van der Lelij, P.J. Marang-van de Mheen, B.L. Kaptein, L.A. Koster, P. Ljung, R.G.H.H. Nelissen, S. Toksvig-Larsen. Migration and clinical outcomes of a novel cementless hydroxyapatite-coated titanium acetabular shell: two-year follow-up of a randomized controlled trial using radiostereometric analysis. *Bone Joint J.* 2024 Feb 1;106-B(2):136-143.

T.J.N. van der Lelij, P.J. Marang-van de Mheen, B.L. Kaptein, S. Toksvig-Larsen, R.G.H.H. Nelissen. Continued Stabilization of a Cementless 3D-Printed Total Knee Arthroplasty: Five-Year Results of a Randomized Controlled Trial Using Radiostereometric Analysis. *J Bone Joint Surg Am.* 2023 Nov 1;105(21):1686-1694.

Publications outside this thesis

T.J.N. van der Lelij, P. van Schie, A. Weekhout, M. Fiocco, S. Keereweer, H.M. Hazelbag, E.R.A. van Arkel, P.B.A.A. van Driel. No Association Between Patient Characteristics and Depth of Microvascular Penetration into the Human Adult Meniscus. *Am J Sports Med. 2025 Jan 27:3635465241307216.*

T.J.N. van der Lelij, W. Grootjans, K.J. Braamhaar, P.B. de Witte. Automated Measurements of Long Leg Radiographs in Pediatric Patients: A Pilot Study to Evaluate an Artificial Intelligence-Based Algorithm. *Children (Basel).* 2024 Sep 27;11(10):1182.

T.J.N. van der Lelij, P.J. Marang-van de Mheen, B.L. Kaptein, R.G.H.H. Nelissen. Letter to the Editor: Failure of Screw/Shell Interface in Trident II Acetabular System in Total Hip Arthroplasty. *Arthroplasty Today.* 2024 Apr 24;27:101358.

T.J.N. van der Lelij, L.M. Gerritsen, E.R.A. van Arkel, R. Munnik-Hagewoud, R.G. Zuurmond, S. Keereweer, P. van Schie, P.B.A.A. van Driel. The role of patient characteristics and the effects of angiogenic therapies on the microvasculature of the meniscus: A systematic review. *Knee.* 2022 Aug 11;38:91-106.

L.M. Gerritsen & **T.J.N. van der Lelij***, P. van Schie, M. Fiocco, E.R.A. van Arkel, R.G. Zuurmond, S. Keereweer, P.B.A.A. van Driel. Higher healing rate after meniscal repair with concomitant ACL reconstruction for tears located in vascular zone 1 compared to zone 2: a systematic review and meta-analysis. *Knee Surg Sports Traumatol Arthrosc.* 2022 Jun;30(6):1976-1989. **(*Shared first authorship)**

P. van Schie, **T.J.N. van der Lelij**, L.M. Gerritsen, R.P.J. Meijer, E.R.A. van Arkel, M. Fiocco, J.A. Swen, A.L. Vahrmeijer, H.M. Hazelbag, S. Keereweer, P.B.A.A. van Driel. Intraoperative near-infrared fluorescence imaging of the vascularization of the meniscus: A pilot study. *Knee Surg Sports Traumatol Arthrosc.* 2022 May;30(5):1629-1638.

Presentations

T.J.N. van der Lelij, P. van Schie, A. Weekhout, M. Fiocco, S. Keereweer, H.M. Hazelbag, E.R.A. van Arkel, P.B.A.A. van Driel. Patiënt specifieke microvasculaire anatomie van de meniscus: Is de diepte van vasculaire ingroei geassocieerd met patiëntkarakteristieken? *HMC Wetenschapsmiddag, The Hague, The Netherlands, November 2024.* (oral presentation, **awarded with the HMC research award 2024**)

T.J.N. van der Lelij, P. van Schie, A. Weekhout, M. Fiocco, S. Keereweer, H.M. Hazelbag, E.R.A. van Arkel, P.B.A.A. van Driel. Patient specific microvascularization of the human adult meniscus: Is the depth of microvascular penetration correlated with patient characteristics? *Nederlandse Vereniging voor Arthroscopie (NVA) congress, Amsterdam, The Netherlands, June 2024.* (oral presentation, **awarded with the dr. Eikelaar award 2024**)

T.J.N. van der Lelij, B.G. Pijls, B.L. Kaptein, L.N. van Steenbergen, R.G.H.H. Nelissen, P.J. Marang-van de Mheen. Does RSA testing of TKA implants result in lower revision rates? An analysis from the Dutch Arthroplasty Register. *61st Nordic Orthopaedic Federation (NOF) congress, Rotterdam, The Netherlands, June 2024.* (oral presentation)

T.J.N. van der Lelij, P.J. Marang-van de Mheen, B.L. Kaptein, R.G.H.H. Nelissen, S. Toksvig-Larsen. All-polyethylene compared with metal-backed tibial components in cemented cruciate-retaining and posterior-stabilized total knee arthroplasty: 7-year follow-up results of 2 randomized RSA studies. *61st Nordic Orthopaedic Federation (NOF) congress, Rotterdam, The Netherlands, June 2024.* (oral presentation)

T.J.N. van der Lelij, P.J. Marang-van de Mheen, B.L. Kaptein, L.A. Koster, P. Ljung, R.G.H.H. Nelissen, S. Toksvig-Larsen. Geen verschil in migratie in de eerste twee jaar postoperatief tussen de Trident II en Trident acetabulum cup: Resultaten van een RSA studie. *Nederlandse Orthopaedische Vereniging (NOV) congress, Rotterdam, The Netherlands, October 2023.* (oral presentation)

T.J.N. van der Lelij, L.A. Koster, P.J. Marang-van de Mheen, B.L. Kaptein, R.G.H.H. Nelissen, S. Toksvig-Larsen. Medium-term migration of a cementless 3D-printed TKA: 5-year results of a randomized controlled RSA study. *European Federation of National Associations of Orthopaedics and Traumatology (EFORT) congress, Vienna, Austria, May 2023.* (oral presentation)

T.J.N. van der Lelij, L.A. Koster, P.J. Marang-van de Mheen, S. Toksvig-Larsen, R.G.H.H. Nelissen, B.L. Kaptein. Influence of marker-selection method on mean tibial baseplate migration and individual migration patterns in TKA using marker-based RSA. *A re-analysis of an RCT with 5-year follow-up. 8th International RSA meeting, Nijmegen, The Netherlands, April 2023.* (oral presentation)

T.J.N. van der Lelij, P.J. Marang-van de Mheen, B.L. Kaptein, S. Toksvig-Larsen, R.G.H.H. Nelissen. Comparing long-term migration of the same TKA design in different RSA studies. 10-year follow-up of 5 randomized controlled trials using RSA. *8th International RSA meeting, Nijmegen, The Netherlands, April 2023.* (oral presentation)

T.J.N. van der Lelij, S. Hasan, B.L. Kaptein, P.J. Marang-van de Mheen, P. Ljung, R.G.H.H. Nelissen, S. Toksvig-Larsen. Comparable migration of two uncemented acetabular cups in primary THA: One-year follow-up results of a RCT study using radiostereometric analysis. *European Federation of National Associations of Orthopaedics and Traumatology (EFORT) congress, Lisbon, Portugal, June 2022.* (oral presentation)

P. van Schie, **T.J.N. van der Lelij**, L.M. Gerritsen, R.P.J. Meijer, E.R.A. van Arkel, M. Fiocco, J.W. Swen, A.L. Vahrmeijer, H.M. Hazelbag, S. Keereweer, P.B.A.A. van Driel. Intraoperative near-infrared fluorescence imaging of the vascularization of the meniscus: A pilot study. *Nederlandse Vereniging voor Arthroscopie (NVA) lustrum congress, Noordwijk, The Netherlands, September 2021.* (poster presentation)

P. van Schie, **T.J.N. van der Lelij**, L.M. Gerritsen, R.P.J. Meijer, E.R.A. van Arkel, M. Fiocco, J.W. Swen, A.L. Vahrmeijer, H.M. Hazelbag, S. Keereweer, P.B.A.A. van Driel. De toepasbaarheid van nabij-infrarode fluorescentie voor het visualiseren van de vascularisatie van de meniscus: Een pilot studie. *Nederlandse Orthopaedische Vereniging (NOV) congres, online / virtual congress, May 2021.* (oral presentation)

Curriculum vitae

Thies van der Lelij was born on June 3, 1996, in Woeden, the Netherlands. He grew up in Delfgauw with his parents (Nico and Mirjam) and two sisters (Marlotte and Jitske). After graduating from the Christelijk Lyceum Delft (Gymnasium) in 2014, he started to study medicine at the Leiden University. During his undergraduate years, he worked part-time on the medical students' team at two private orthopaedic hospitals in Delft and Rotterdam.

Upon earning his bachelor's degree in 2017, Thies went to study philosophy at the University of Richmond (Virginia, United States of America). After delving into modern western philosophy, bioethics, and academic writing, he finished his semester in Richmond as an A-list student (GPA above 3.7 and no grades below A-). During his master's degree, he commenced his orthopaedic research activities with a project on the vascularization of the meniscus under supervision of dr. P.B.A.A. van Driel and dr. P. van Schie. This project evolved into a research internship at the orthopaedics departments of the Leiden University Medical Center (LUMC), Haaglanden Medical Center (HMC), and Isala Hospital. Thies completed his final year of medical school with elective internships in general surgery (HagaZiekenhuis) and orthopaedic surgery (HMC).

After obtaining his medical degree (cum laude), he started to work on his PhD research project on January 1, 2022, at the department of orthopaedics at the LUMC under the supervision of prof. dr. R.G.H.H. Nelissen, dr. P.J. Marang-van de Mheen, and dr. ir. B.L. Kaptein. Most studies that were part of his PhD project were conducted in close collaboration with Hässleholm hospital (Sweden), under the supervision of dr. S. Toksvig-Larsen. During his PhD, Thies was active in training medical students and guiding them with research within the field of orthopaedics. He completed various statistical and epidemiological courses, presented his work at multiple (inter)national congresses, and acted as a moderator for the RSA methods session during the 8th international RSA meeting. Besides his research on implant migration and radiostereometric analysis, he continued his research on the vascularization of the meniscus, which was awarded with the dr. Eikelaar prize at the Dutch Arthroscopy Society congress in 2024. Thies continued his career at the department of orthopaedics at the Alrijne Hospital as a resident (not in training) on October 1, 2024. He has since been accepted into the orthopaedic surgery residency program in Leiden, which he will start in April 2026.