Kinematics, tribology and safety of a dual mobility hip prosthesis

RSA analysis of the anatomic dual mobility cup

PhD thesis

Peter Bo Jørgensen

Faculty of Health Sciences
University of Aarhus
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Preface

This thesis is based on scientific work conducted during my enrolment as a PhD student at Aarhus University, Denmark and employment as a Research Assistant at Aarhus University Hospital from 2016 to 2021.

I have had the great privilege of guidance from Maiken Stilling as my main supervisor in this PhD. Maiken introduced me to RSA in 2013 and has been an outstanding supervisor, support and example through many RSA projects since then. I am sincerely grateful for Maiken's faith in my abilities to conduct research and for creating an inspiring research environment for me and my colleagues. My three other supervisors; Stig Storgaard Jakobsen, Kjeld Søballe and Inger Mechlenburg have all offered imminent support throughout this PhD. Each of you has contributed with expertise in all aspects of the PhD, for which I am very grateful.

Throughout this PhD, I have enjoyed the privilege of collaboration with and guidance from Bart L. Kaptein. Thank you for your great contribution to the scientific work in this PhD and for the many hours discussing the possibilities and challenges of RSA.

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This thesis is based on the following papers:

I. Feasibility of combined and hybrid marker models for radiostereometry assessment of polyethylene liner motion in dual mobility hip prosthesis. Peter Bo Jørgensen, Bart L. Kaptein, Kjeld Søballe, Stig S. Jakobsen and Maiken Stilling. Submitted for publication in European Radiology Experimental 2021.

II. Polyethylene liner motion in dual mobility hip prostheses measured with static and dynamic RSA one year after operation. Peter Bo Jørgensen, Bart L. Kaptein, Kjeld Søballe, Stig S. Jakobsen and Maiken Stilling. Submitted for publication in Acta Orthopaedica 2021.

III. Five-year polyethylene cup migration and PE wear of the anatomic dual mobility acetabular construct. Peter Bo Jørgensen, Bart L. Kaptein, Kjeld Søballe, Stig S. Jakobsen and Maiken Stilling. Submitted for publication in Journal of Arthroplasty 2021.

Contents

Abbreviations

2D	Two-dimensional
3D	Three-dimensional
ADM	Anatomic dual mobility
CAD	Computer assisted design
CMC	Combined markers configuration model
CN	Condition number
CR	Coefficient of repeatability
CT	Computed tomography
DM	Dual mobility
dRSA	Dynamic radiostereometric analysis
DXA	Dual x-ray absorptiometry
EGS	Elementary geometrical shape (model)
FABER	Flexion/abduction/external rotation
HAGOS	The Copenhagen Hip and Groin Score
HOOS	Hip Disability and Osteoarthritis Outcome Score
HXLPE	Highly crosslinked PE
IPD	Intra prosthetic dislocation
IPI	Iliopsoas tendinitis and impingement
MC	Marker configuration
OHS	Oxford Hip Score
PE	Polyethylene
PMMA	Polymethylmethacrylate
PROM	Patient-reported outcomes
QOL	Quality of life
RBE	Rigid body error
RSA	Radiostereometric analysis
sRSA	Static radiostereometric analysis
THA	Total hip arthroplasty
VHDD	Vertical head displacement required for dislocation
WOMAC	Western Ontario and McMaster Universities Osteoarthritis Index

Definitions

Annealing	Heat treatment just below the melting point, used for removal of free radicals from polyethylene
Aseptic loosening	Mechanical loosening of an endo-prosthesis without signs of infection
Creep	Plastic deformation of implant material, mostly present early after the operation
Frame	A set of two radiographs completing a frame
Marker configuration model	A set of coordinates defining the relative positions of a number of markers
Large articulation	The articulation between liner and metal shell in DM cups
Migration	Translation or rotation of an implant over time
RSA recording	The act or product of recording RSA. Thus, RSA recording refers to an action or one or more sets or radiographs
Small articulation	The articulation between femoral head and liner in DM cups
Wear	Removal of material from prostheses over time

1. English summary

The hip prosthesis is designed as a ball and socket joint between the femoral head on the one side and the acetabular insert on the other. This design was challenged in the seventies by the introduction of a second articulation within the same joint (dual mobility). In the late seventies, G. Bousquet and his colleagues laid the groundwork for today's dual mobility design, which has been further developed over the years. Although the dual mobility design has shown to effectively reduce the risk of hip dislocation, we still have much to learn about the kinematics, wear and implant migration of this design. Radiostereometric analysis (RSA) holds the ability to measure kinematics, wear and implant migration with high precision and accuracy, and was used as the main method in the present study.

In Study I, we developed a method for measuring polyethylene movement with dynamic RSA. Firstly, a method was developed for uniquely marking the liner for measuring liner orientation with RSA. Secondly, a method was developed for including as many markers as possible in the analysis. Lastly, the methods were tested in a clinical setup with a patient from Study II.

In Study II, 20 patients with marked anatomic dual mobility liners were analysed postoperatively and one year after surgery for liner movement, and the movements were tested for correlation with the biomechanics of the hip prosthesis and clinical outcomes. It was shown that the liners could still move 1 year after surgery and that they changed orientation over time.

In Study III, a cohort of patients with the anatomic dual mobility cup was investigated for risk factors 5 years after surgery. Due to the large joint surface of the dual mobility hip, wear is a particular concern and excessive polyethylene wear has been shown to contribute to implant loosening. Likewise, cup migration has been shown to correlate with the risk of implant loosening. Low polyethylene wear and cup migration are therefore critical to dual mobility hip implant safety. In this study, we found low polyethylene wear and acceptable cup migration in a mixed population.

In conclusion, the thesis studies show that dynamic RSA can be used to evaluate polyethylene liner movement. The dual mobility liners in ADM cups were shown to move 1 year after surgery. Liner movement may protect patients from hip dislocation and excessive polyethylene wear, especially when the cup position is suboptimal and has a high inclination. These findings may also apply to other dual mobility hip implant designs and support the general use of dual mobility prostheses.

2. Danish summary

Hofteproteser er typisk designet som et kugleled mellem lårbenets hoved og hofteskålen. Dette design fik i 70'erne konkurrence fra et andet design med to ledflader i samme led (dobbeltled). Sidst i 70'erne lagde franskmanden G. Bousquet sammen med sine kolleger grunden for den dobbeltledsprotese, som bruges i dag. Selvom det har vist sig, at dobbeltledsproteser effektivt har reduceret risikoen for at hoften går af led, er der stadig meget, vi ikke ved om protesens kinematik, slid og fiksation i knoglen.

Med radiostereometrisk analyse (RSA) har man muligheden for at måle kinematik, slid og fiksation med høj præcision og akkuratesse, og RSA er den primære undersøgelsesmetode i studierne i denne afhandling.

I studie I udvikledes en metode til kinematisk måling af polyethylenens bevægelser i dobbeltledsprotesen ved hjælp af dynamisk RSA. Første skridt var at udvikle en metode til at markere lineren, så det var muligt at måle linerens orientering med RSA. Dernæst udvikledes en metode til at inkludere så mange af disse markører som muligt i analysen. Til sidst blev metoderne testet med en patient fra studie II.

I studie II blev 20 patienter med markører i lineren analyseret postoperativt og et år efter operationen. Linerbevægelser blev registreret og korreleret med hoftebevægelser og kliniske resultater. Studie I kunne påvise, at lineren stadig kunne bevæges et år efter operation, og at den skiftede position over tid.

I studie III blev en gruppe patienter med anatomisk dobbeltledsprotese undersøgt for slid og migration af protesen op til 5 år efter operation. Med to slidflader kunne man være bekymret for øget slid af lineren, og slid har vist sig at bidrage til proteseløsning. Tilsvarende har tidlig protesemigration vist sig at korrelere med proteseløsning. Det er derfor vigtigt med begrænset slid og migration af proteser. Vi fandt begrænset slid og acceptabel migration i en blandet population af patienter.

Tilsammen viser studierne i denne afhandling, at dynamisk RSA kan bruges til at undersøge bevægelse i polyetylenlinere samt, at lineren i dobbelledsprotsen var i stand til at bevæge sig et år efter operationen. Bevægelse af lineren kan beskytte imod, at protesen går af led og mod slid af lineren, særligt når protesen ikke sidder optimalt. Resultaterne kan også gælde for andre typer af dobbeltledsproteser og understøtter brugen af dobbeltledsproteser.

3. Introduction

Total hip arthroplasty

An estimated one million total hip arthroplasty (THA) operations are performed annually on a global scale (15). In Denmark alone, more than 10 000 THA procedures are performed annually and this number has been rising in recent years due to an aging population (16). THA has proven a very effective treatment for pain mainly for patients with hip arthrosis but also for other conditions (17,18). In the Danish Hip Registry, 80% of primary THA procedures are conducted due to osteoarthritis and 10% due to femoral neck fractures. The remaining 10% of THA procedures are performed due to rheumatoid and other types of arthritis, femoral head necrosis and congenital diseases like Perthes and congenital dislocation, epiphysiolysis, fractures and traumatic dislocations, and metastasis (16).

Although THA is a very successful treatment, it is a mechanical construct and does not last forever. Revision surgery can be initiated for several reasons, the two most common of which are dislocation (24%) and aseptic loosening (23%) (16).

Some of the underlying conditions like femoral neck fractures or femoral head osteonecrosis have been associated with an increased risk of THA revision (19,20). Other patient-related factors like high Body Mass Index (BMI=, gender, comorbidities and use of pharmaceuticals also affect the risk of revision (21-24).

The THA implants used today are expected to remain in-situ in 95% of all patients after 5 years. However, only an estimated three-quarters of the hip implants last 15-25 years (16,25) .

As the need for THA is substantial and growing, it is important to develop and improve hip implants to withstand use and wear for many years in active patients – young and old.

Single and dual mobility THA

One of the first single mobility cups, the low friction THA, was introduced in the early 1960s by sir John Charnley (26). The design of the low-friction THA was quite similar to that of the single mobility THA used today; on the pelvic side, an acetabular cup articulates with the femoral head that is attached to the femoral bone via a stem fixed in the femoral canal (Figure 1). Since then, much effort has been devoted to improving the THA concept to increase its function and durability. Improvements have largely fallen into three categories: a) strengthening the fixation of the implant in bone, b) reducing polyethylene (PE) wear and c) improving joint mobility and stability.

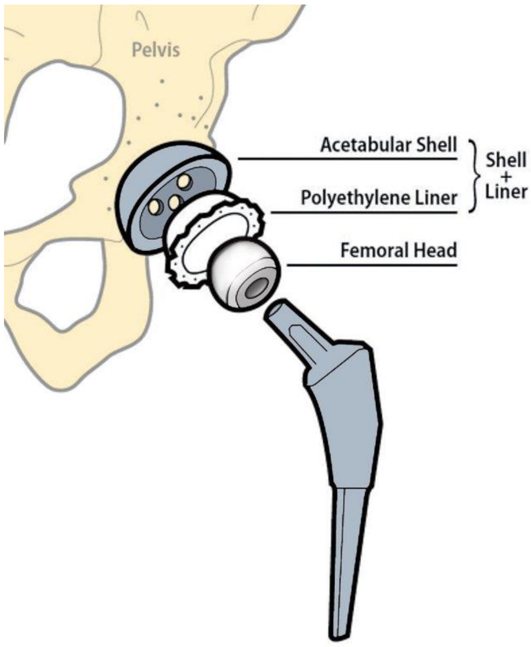

Figure 1. Schematic overview of the total hip arthroplasty (1).

One of the steps in the development of the acetabular construct was the creation of the dual mobility (DM) design presented in the 1970s by prof. Gilles Bousquet, Andrè Rambert and their colleagues. The DM design added a second articulating surface to the ball and socket joint of the standard prosthesis and provided increased range of movement in the joint while reducing the risk of dislocation (10,27,28) .

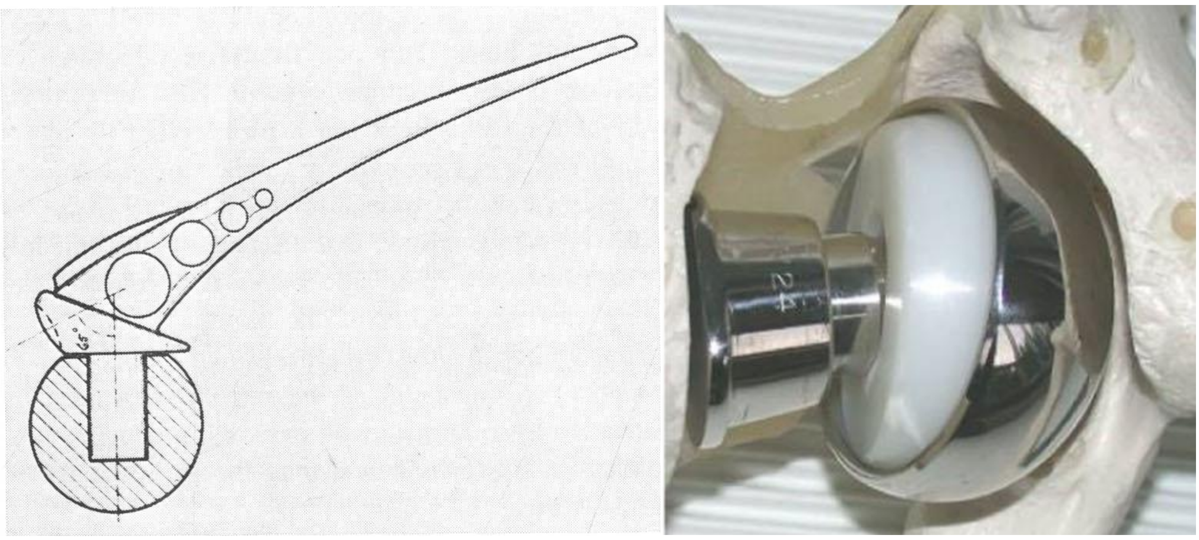

Figure 2. The trunnion bearing articulated (left) between the femoral head and stem (8) and the shielded THA with a non-fixated metal shell (right) (10).

The development of the DM cup took place in the course of several years in the 1970s. It started with the creation of the trunnion hip by Tor Christiansen, where the liner formed a cylindrical articulation with the femoral neck (trunnion) (Figure 2) (29). Later, a shell was added on the outside of the liner allowing for axial movement between liner and cup. The PE liner unfortunately quickly showed substantial wear and, a new design was warranted. The next step was the design of the non-fixated cup with a free-moving liner capturing the femoral head (Figure 2). Like the trunnion cup, this design resulted in substantial PE wear; and in 1979, it was replaced by the design that is largely used today: a fixed outer shell with a free-moving liner capturing the smaller femoral head. This was, in fact, very close to the low-friction implant presented by Charnley, but with the added benefit of a larger head represented by the head-liner construct, which markedly reduced the risk of THA dislocation.

Since 1979, numerous design changes have been made to the DM construct including the production of different cemented and cementless cups with and without flanges, screws and supports (10).

In 1990, the original patent on the DM cup was terminated and "modern" DM cups like SunFit (Serf, France) developed on the original Novae cup, the QUATTRO (Groupe Lepine, France) with optional apical and equatorial fins, the Gyros (DePuy J&J Corporation, Saint Priest, France) with obturator hook, and the MDM (Stryker, Warsaw, Mazovia, Poland) with optional screw fixation and G7 (Biomet, Warsaw, Indiana) with vitamin E infused PE (Figure 3).

Figure 3. Selection of "Modern" DM cups. Left: The Novae SunFit (3) based on the original Novae, the QUATTRO cup with optional fins (4), the Gyros with optional obturator hook (9). Right: the MDM with optional screws (12) and the G7 with vitamin E infused liner (13), the Avantage with cemented/cementless options and vitamin E infused liner (14).

Though DM cups reduced the risk of dislocation, some patients still complained of groin pain related to iliopsoas tendinitis and impingement (IPI). In resurfacing (metal-on-metal) THA an incidence of groin pain was reported in 18% of patients and suggested to be caused by large femoral heads (30,31). Since DM THA also has a large femoral head, it has been a concern that the high rate of groin pain in resurfacing THA would persist for the DM THA. Contrary, in SM THA, the incidence of groin pain has been reported to be 4% and associated with overhang of the metal shell (32).

The anatomic dual mobility (ADM) cup (Figure 4) is also a development of the DM system.

Figure 4. The anatomic dual mobility construct with a metal shell, polyethylene liner and ceramic head.

The outer shell is coated with titanium and hydroxyapatite to mediate bone ingrowth while the inside, articulating with the liner, is highly polished cobalt chrome. The cup has an anatomical shape that follows the acetabulum with a sparing for the iliopsoas tendon in the anterior part and a posterior excess to accommodate deep flexion. The liner is produced from a second-generation sequentially annealed HXLPE (X3, Stryker, Warsaw, Mazovia, Poland) and encloses the femoral head which is produced either from ceramic or metal.

Mechanical properties in the hip implant

The single mobility acetabular construct has a metal outer shell – the cup – which is fixed to the pelvic bone. In the cup lies a liner of either ceramic or, more commonly, PE (Figure 5a). The liner articulates with the femoral head which is made of a metal alloy or ceramic.

The DM acetabular construct has the same components, but the liner also articulates with the outer shell. The outer, large articulation is activated by contact with and pushing from the femoral neck (Figure 5b) (27).

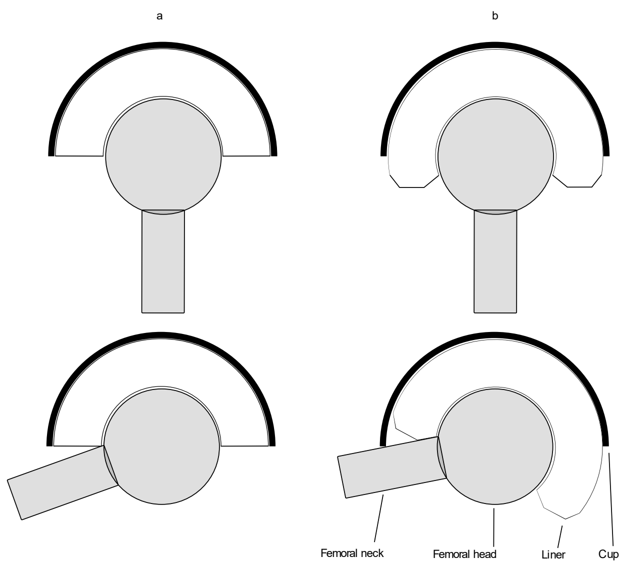

Figure 5. Schematic presentation of single and dual mobility implants.

Patient-reported outcome measures (PROM) of THA

Using scoring systems is a way of assessing functional outcome and health. One of the first such scores used for THA and still used today is the Harris Hip Score. Originally, the score was completed by the doctor assessing the patient's outcome. Although there may be concordance between doctors and patients in evaluation of physical function and pain, it is not always the case as far as the outcome of quality-of-life status is concerned (33,34). Therefore, PROMs have become a part of the assessment of THA outcome.

PROMs can be generic health scores or specific for a condition or site. Generic PROMs like the EQ5D and SF36 scores are validated for assessment of health in general and are widely used, but for THA patients, condition or site-specific PROMs are also recommended (35-37). One of the most common disease-specific PROMs for hip osteoarthritis is the Western Ontario and McMaster Universities osteoarthritis index (WOMAC) (38). WOMAC measures pain, disability and joint stiffness in knee and hip osteoarthritis. For the THA patient, there is a range of hip-specific PROMs such as the hip disability and osteoarthritis outcome score (HOOS), the Copenhagen hip and groin score (HAGOS) and the OHS. Each score has a different focus and scope. HOOS uses 40 questions in five sub-scores: pain, symptoms, activities of daily living, sport and recreation and hip-related quality-of-life and is intended for adults with hip disability with or without arthritis (39).

HAGOS is aimed at the young or middle-aged patient and contains six sub scores; Pain, symptoms, physical function in daily living, Physical function in sport and recreation, Participation in physical activities, and hip and/or groin-related quality of life (QOL) (40). OHS provides one common score for the patient's perceived hip related QOL. With 12 questions, the OHS is the shortest of the three but still has a good responsiveness to changes over time (41,42).

Some considerations must be made when choosing a PROM for a population. The choice may begin by finding the PROMs that are translatable to the language of the patients and are specific for the condition or site. It is also important to choose a PROM that is responsive within the time frame of the study. Furthermore, age, health and other parameters may create a mismatch between the population and the PROMs chosen. For example, a young population will likely score very high on a physical function PROM intended for the elderly. Any increase from a maximum score will then be obscured in the follow-up, known as ceiling. The opposite - flooring - can be seen when the condition of the population is worse than intended for the PROM. Another consideration is the length of the PROM. Extensive PROMs may negatively affect the response rate. Thus, many parameters must be considered when choosing a PROM.

Radiostereometry

Estimating the three-dimensional (3D) position of objects using stereo x-ray has been attempted since the 1890s just a few years after the discovery of roentgen. However, it was not until 1970s that Göran Selvik described radiostereometric analysis (RSA) as we know it today. In 1979, the first hip study using RSA was conducted (43,44). The RSA setup (Figure 6) requires two x-ray sources pointing at the joint from different locations. To enable spatial calculations, a calibration box with markers with known positions is placed underneath the patient, just above the detectors (11). Using this setup, the positions of the x-ray tubes and implant can be calculated.

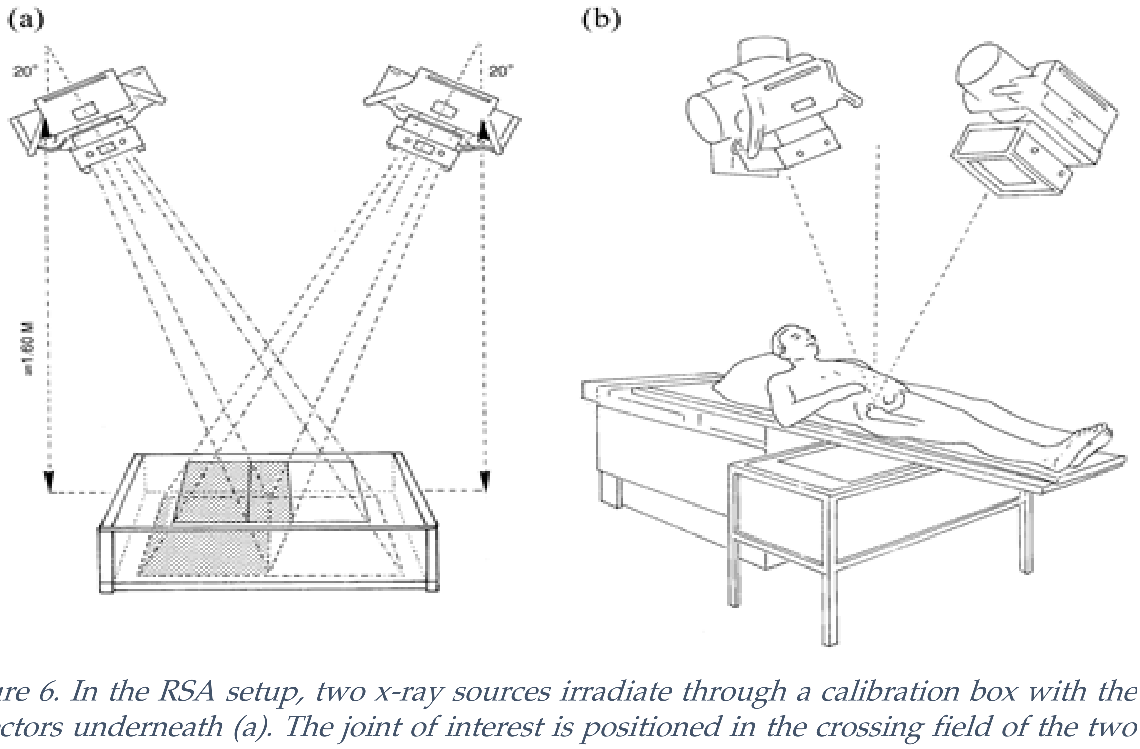

Figure 6. In the RSA setup, two x-ray sources irradiate through a calibration box with the detectors underneath (a). The joint of interest is positioned in the crossing field of the two beams (b) (11).

Markers and models in RSA

From the start, RSA was marker-based and depended on metal markers implanted in bone and attached to the investigated implants. Each marker represented a point that had a set of 3D coordinates. A rigid body is a combination of several markers and can be described in position and orientation by a minimum of three markers (Figure 7).

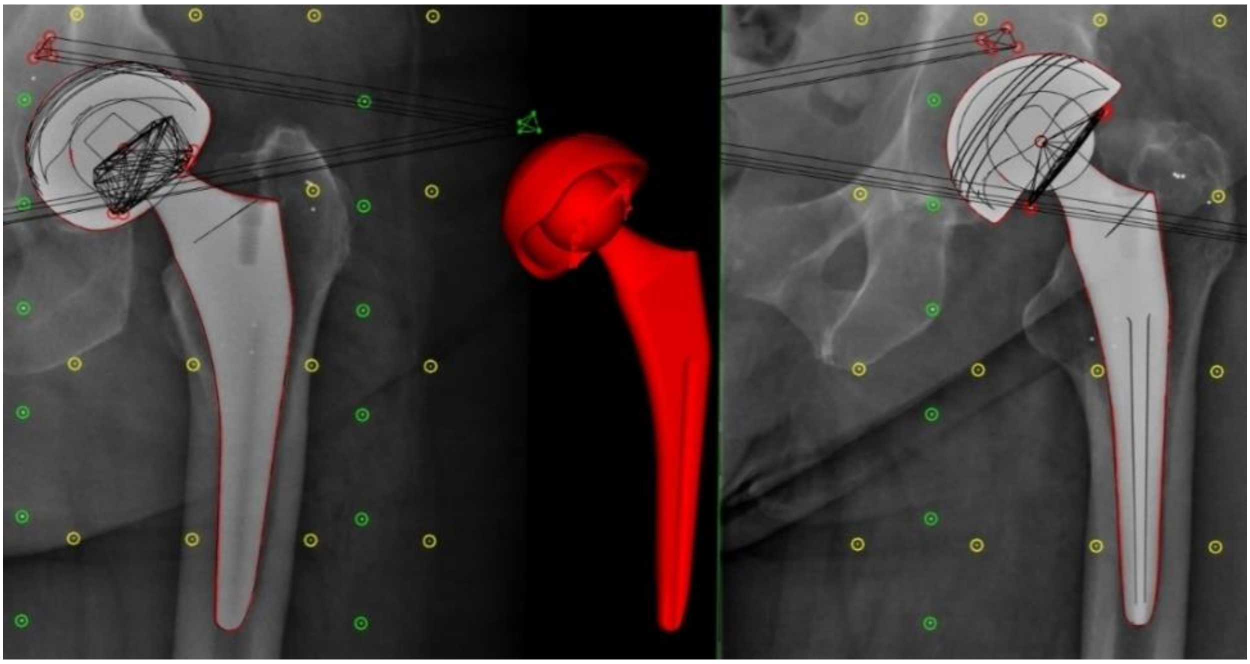

Figure 7. RSA analysis of a dual mobility THA with four reference markers in the pelvic bone. The stem and shell positions are calculated using the contour and CAD models, while the head is fitted using EGS models. Tantalum markers in the liner (left) and the pelvic bone (right) are occluded by the acetabular shell.

The marker distribution can be described using the condition number (CN). A low CN indicates that a good marker distribution. Currently, the recommended maximum threshold for CN in hip and knee arthroplasty is 150 (45). However, anatomy decides the possible marker distribution and therefore the CN will vary with joint size (46).

Later, marker-less RSA was developed and allowed for estimation of the position a CAD implant model or a geometrical shape by use of registration of contours in the RSA images (47-49). However, markers are still used as a reference of bone to enable calculation of implant migration. Patient-specific bone models derived from computed tomography (CT) scans have been used to describe joint motions and kinematics of joints experimentally and clinically (50). The use of bone models as reference for measurement of implant migration has not yet been validated.

To ensure that the reference markers do not migrate themselves, each marker position is calculated relative to that of the other markers. The resulting rigid body error (RBE)

is benchmarked against a threshold of 0.35 mm; and if the individual marker does not comply with the standard, it is excluded from the analysis.
Markers are also used for position estimation of radiolucent materials like PE. Due to its radiolucency, PE leaves virtually no contours in the RSA images, which makes model fitting impossible. Therefore, markers have been applied to PE to track PE movement and wear (Figure 7) (1,51-58).

Occluded markers and marker models

The use of markers in RSA is occasionally hampered by occlusion of one or more of the markers by implant material (Figure 7). Since marker projections are required in both RSA images for position calculation, a marker is excluded from analysis if it is occluded in one of the images. In worst case, marker occlusion can obstruct the RSA analysis completely. This problem may be solved by using a marker configuration model (MC model). The MC model describes marker positions relative to each other as measured in an RSA recording with all the markers present. Using the MC model instead of individual markers allows the use of information from the marker(s) projected in only one image (47,59). More recently, the MC model has been calculated from expected marker positions. With the use of a drill guide, PE was prepared with holes for the markers to control the position of the markers. Though successful, the method can only be used prospectively and it relies heavily on correct marker placement during surgery (54).

Migration

Migration describes the translation and rotation of an implant over time. With successive RSA exams, the positions and orientations of the implant are measured along with the positions and orientations of a reference. The relative translation and rotation of the implant can then be calculated with respect to the reference.

In the case of a hip implant, the migration of the backing shell is normally calculated with respect to tantalum markers implanted in the pelvic bone. Proximal translation and sagittal rotation dominate the early migration of the cup and can be used as a proxy for aseptic loosening of cups in THA. High cup migration as well as continuous cup migration (no stabilization after i.e., 1 year) indicates increased risk of aseptic implant loosening. Thus, implant migration can be used to identify implants at risk of loosening on a patient-individual level and aid in decision of who needs closer implant follow-up (2,60,61).

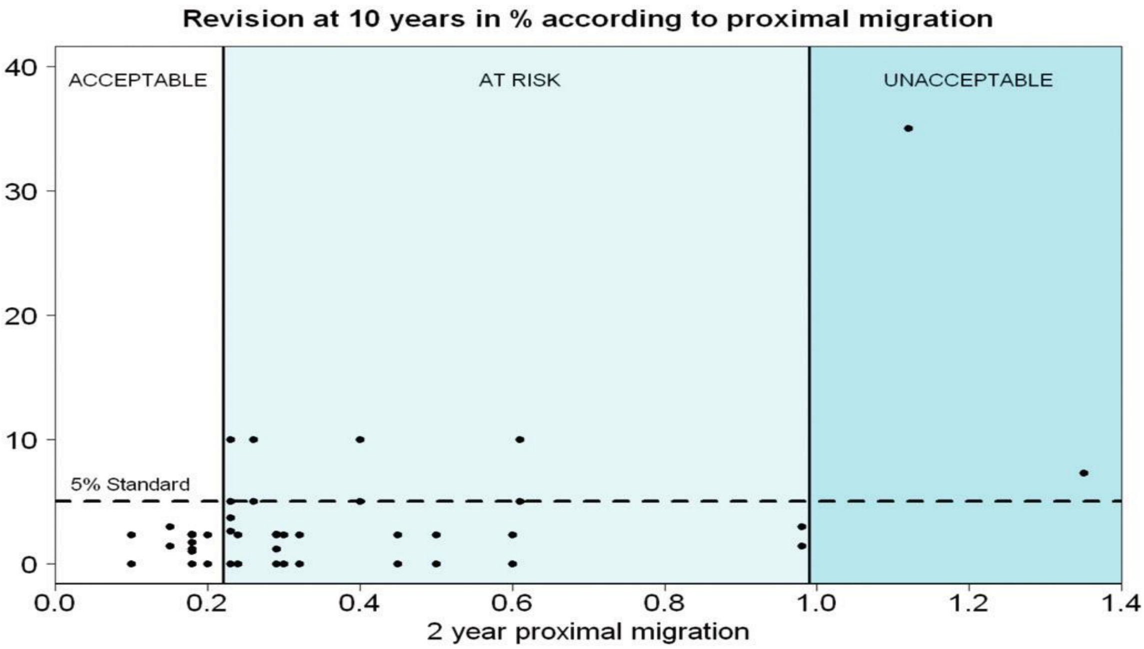

Figure 8. A study by Pijls et al. showed that cup migrating was a proxy of 10-year survival (2).

Accuracy and precision of RSA

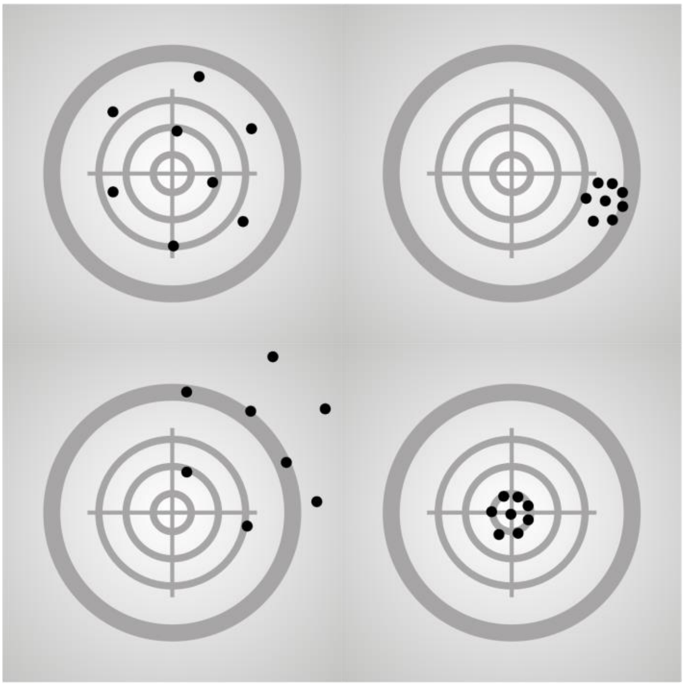

Figure 9. High accuracy and low precision, high precision and low accuracy, low precision and low accuracy, high precision and high accuracy.

When working with RSA, accuracy and precision are important factors. The precision of a method describes its ability to reproduce the same movement or migration in the same set-up. Accuracy on the other hand describes the ability to approach the true value of the measured movement or migration. Consider eight repeated measurements of the same RSA recording: With high accuracy and low precision, the results will present as a large spread around the true value. With high precision and low accuracy, the measurements will be close together, but not necessarily a good representation of the true value. Poor accuracy and precision will produce a large spread away from the true value. An optimal mix of high precision and accuracy yields convergent measurements close to the true value (Figure 9).

In clinical RSA, measurement precision should be measured for all setups, since it may be affected by parameters such as the chosen method of analysis as well as the implants measured, the radiographic settings, the detectors and the calibration boxes (62,63). Even within the same MC or model, position, orientation and occlusion of markers and models can affect RSA precision (47,63). Implant migration presumably happens very slowly over the course of several years. With two recordings obtained at short intervals (double examinations), the difference between the two should theoretically be zero. Within double examination, the mean migration difference in the cohort is an estimate of systematic error (bias), while the variation is a measure of random error (precision).

Accuracy is a more difficult factor. In order to estimate how close measurements are to the true value, the true value must be known. Therefore, implant migration or wear must be measured with other highly accurate and precise methods to establish the true value. This has been done using phantoms with known marker positions, with micrometres, and by evaluating RSA systems against each other (64-68). The accuracy of RSA has been described by Kaptein et al. for CAD- and reverse-engineered models using a micromanipulator and compared to marker-based RSA. The model-based analysis had a slightly poorer accuracy than the reverse-engineered models. Reverse-engineered models in turn showed slightly poorer accuracy than marker-based RSA. Though not as accurate as marker-based RSA, the model-based RSA was deemed useful for RSA (49). In another study, Stilling et al. validated model-based RSA for wear measurement micromanipulator and found it superior to 2D wear analysis (68).

Dynamic RSA

The transition from static RSA (sRSA) to dynamic RSA (dRSA) is demanding. The main challenges are technical, spanning from generating short rapid bursts of radiation to collect data from the detectors to analysing the enormous amount of data generated and, more practically, keeping the area of interest within the field of recording.

In dRSA, one frame consists of a set of two radiographs. The framerate has been improved from 1-2 frames/s to 5 frames/s, maintaining image full size and resolution (69,70). The current detector technology allows for up to 30 frames/s but at the expense of image resolution and size. The main reason for this is the need for transfer of the large amount of data generated. Therefore, reducing the amount of data enables a higher framerate.

Long exposure time (shutter time) may result in blurred images of moving objects (Figure 10). However, a certain amount of current is also necessary, and some time is

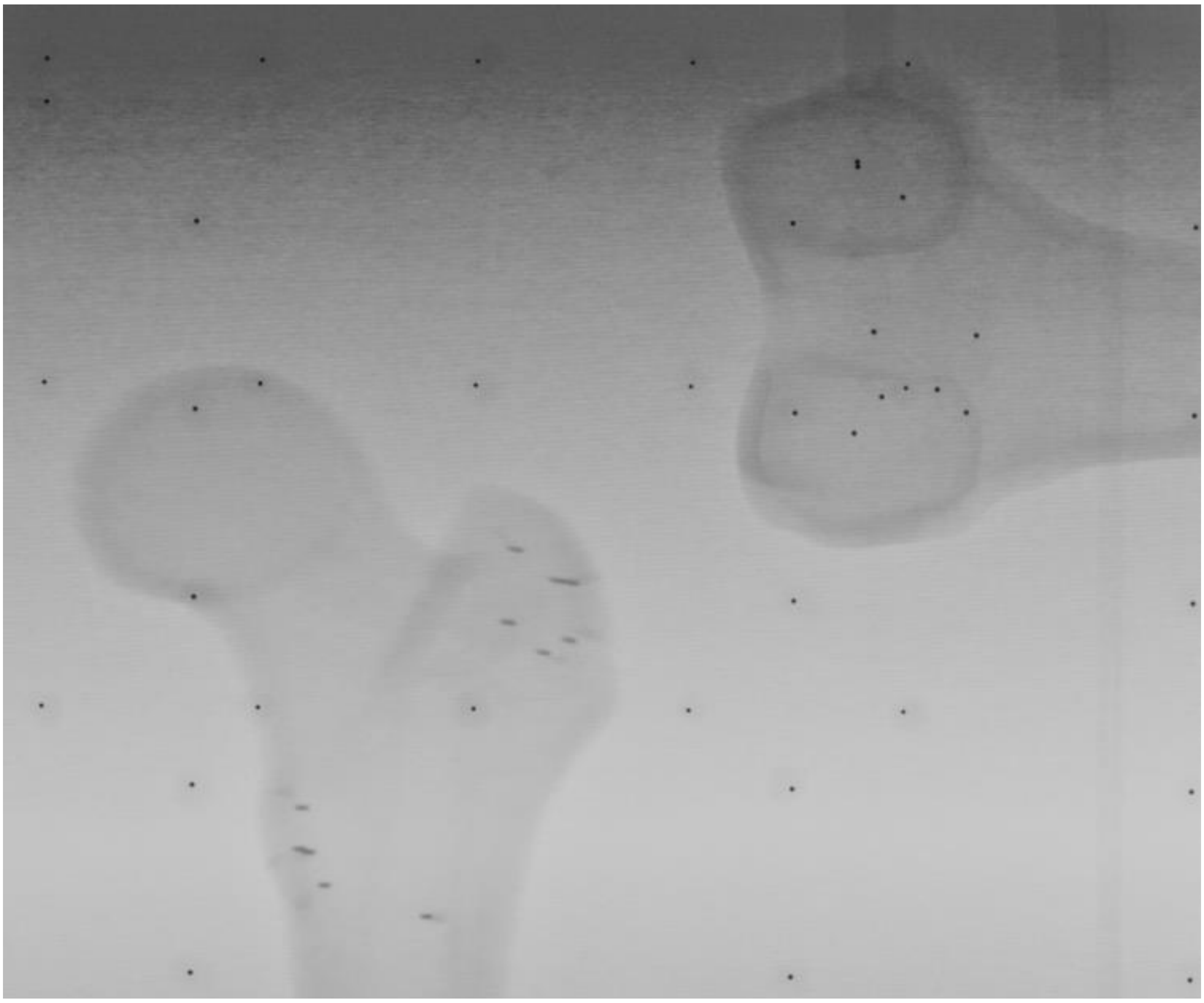

Figure 10. Phantom testing of stationary (top right) vs. 10 km/h (left). The moving phantom has blurred markers, while the stationary phantom has clear marker definition of the markers.

needed to build the current between exposures. In hip recordings, up to 8 mAs are needed (70). With the maximum current of 500 mA in the ADORA system, the minimum shutter time is 16 ms. dRSA of knees demands current less than 1.25 mAs, which can reduce the exposure time to 2.5 ms. This leaves very little time to build up the current in the generators (50).

In dRSA, the two x-ray sources need to be synchronized to avoid movement between the two images.

Studies have proven the conceptual and clinical feasibility and relevance of dRSA in small joints which are easy to isolate such as the knee (71-84). Few studies have investigated the hip joint dynamically (69,85-87).

Movements in the radiographic coordinate system

Hip movements are normally described using anatomical movement directions. The use of anatomical references has deep roots in medicine and most clinicians can therefore easily relate to hip movements such as abduction, adduction, flexion, extension and rotation. The orientation of the acetabular cup, on the other hand, is normally described as inclination and anteversion in relation to anatomical landmarks in the radiograph. The anatomical denomination is clearly not sufficient to describe the orientation of the cup, liner and femoral neck in a DM hip. Therefore, we used the radiographic coordinate system which is designed to describe movements and positions as seen on a radiograph (Figure 11) (88). The coordinate system has the rotation centre of the hip joint as its centre point and uses rotation around the acetabular axis to describe orientation. The radiographic inclination is described by the angle between the projection of the acetabulum to the frontal plane and the cranial caudal axis. The

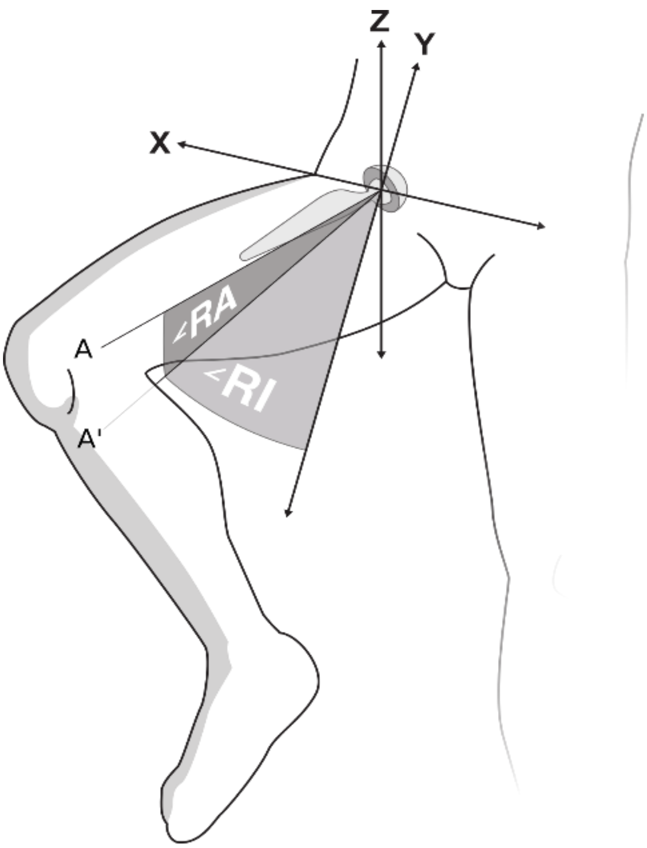

Figure 11. The radiographic coordinate system with radiographic inclination (RI) and radiographic anteversion (RA) (5).

radiographic anteversion is described by the angle between the acetabular axis and the frontal plane.

The radiographic coordinate system was adapted for the femoral neck and stem using the longitudinal axes for both. In this way, the orientations of the cup, liner, neck and stem could be described in the same coordinate system using the same denomination.

Polyethylene wear, dislocation and aseptic loosening

Polyethylene and wear

Since the very first modern THAs were developed, wear has affected implant longevity (26). Different articulation materials have been used with variable success in an attempt to reduce wear. Polytetrafluoroethylene (better known as Teflon) was used in the first low friction THA but was troubled with tissue reactions (89). In the 1960s, ultra-high molecular weight PE was produced and has remained the dominant material used for liners. Over the years, PE has been improved using various methods including radiation, remelting, vitamin E infusion and annealing (heating just below the melting point). Radiation creates crosslinking in the PE, which increases its strength but inhibits its ability to reduce free radicals by heating. Remelting effectively reduces free radicals in the PE, but has a negative effect on the mechanical properties of PE. Vitamin E enhancement of PE has successfully helped restore the mechanical properties and reduce delamination (90). Annealing reduces free radicals while preserving the mechanical properties. In 1998, the developments resulted in the successful clinical use of highly crosslinked PE (HXLPE) (91). HXLPE has continuously been developed over the past two decades and second-generation HXLPE is based on repeating radiation and annealing. With lower radiation dose as an option, annealing became more effective in removing radicals. Thus, by repeating radiation and annealing, high-level crosslinking and low-level free radicals were achieved without the negative mechanical effect of remelting. The ADM construct utilizes X3 HXLPE; a second-generation HXLPE that has shown promising results in standard THAs (92,93)

Quantification of wear

The extent of prosthesis wear can be investigated in different ways. A direct measure of wear is possible in experimental lab studies with repeated movement cycles. The strengths of this method include high accuracy, repeatability and standardisation of number of repetitions, load, materials, lubrication, etc. The weakness is that the clinical variation of gait and use of THA cannot be included in the standardised experimental setup. Wear can also be measured on retrieved implants from revision surgery and thus measures *in vivo* implant wear directly. The weakness of this methods is that the retrieved implants likely are not representative of the wear in common well-functioning THAs since they stem from revision surgery. Furthermore, the revision surgery itself may damage the implant. A third approach is indirect measurement of wear, which is commonly done with radiography. This method allows for *in vivo* estimation of wear in larger cohorts and may therefore potentially capture the effects of variation in activity, load and articulation materials. The greatest weakness of indirect wear measurement is that its accuracy and precision may vary because of diversity in radiographic material (CT, RSA and plain radiographs). Moreover, wear data may be calculated and presented in many ways, which challenges comparison across studies. Linear wear measuring femoral head penetration of the liner in two plain radiographs is a common method for indirect wear quantification. The method was first presented in 1975 as a manual wear measurement (94). The manual wear measurement requires very few instruments has been successful in follow-up with relatively large wear (95).

Computerised methods have been developed to enhance the precision of linear wear measurement on plain radiographs for 2D wear and include cross-table examination to estimate 3D linear wear (96-99).

RSA presents a very accurate measure for wear in THA and is the recommended modality for wear measurement in new materials and implants in the early follow-up or with expected low wear (1,68,100-103).

In RSA, linear wear is measured in 3D by calculating the femoral head migration into the liner. The first clinical hip wear study using PE sockets without a shell used markers in the PE as reference (44). Today markers are still used in all PE sockets to measure wear with x- and y-precision of 0.11 mm and z-precision of 0.34 mm, corresponding the expected precision of RSA (104). In cups with a metal shell, EGS or CAD models are normally used because markers in PE may be occluded. In a comparison of model-based and marker-based femoral head penetration in four cups, Sharegi et al. were unable to find precision differences in all but one design (105). Still, Nebergall et al. were able to increase the wear measurement precision with metal shells by combining information from both markers in the PE liner and model fitting of the metal shell (1).

A common weakness of the linear methods is that wear is not necessarily linear. Therefore, the linear approximations tend to underestimate wear (106-108).

While the greatest strength of RSA is the precision, the strength of using plain radiographs for wear estimation is that postoperative and follow-up radiographs are very often available, which makes retrospective wear studies and large cohorts possible.

Types of wear

In 2007, four modes of wear were suggested (109). *The first mode* was articulate wear, defined as wear between two articulating surfaces as intended by design. For the DM construct, this would mean wear either between the outer metal shell and the liner (large articulation) or between the liner and the femoral head (small articulation) (Figure 5). This mode of wear could lead to displacement of the head relative to the cup and would then be measured as femoral head penetration.

The second mode of wear was rim-contact wear defined as wear due to contact between a weight-bearing surface and a non-weight-bearing surface. For the DM prosthesis, this would happen when the femoral neck makes contact with and pushes the liner which leads to damage of the liner rim. This type of wear has been associated with intra-prosthetic dislocation in earlier DM liner designs. Rim-liner contact wear has also been identified with the second-generation X3 PE, although the reported incidence of IPD has declined (110,111).

The third mode of wear is also called third body wear. Third body wear describes the situation where a foreign body enters the articulation and accelerates wear of the articulating surfaces. An example of third body wear is delamination of the coating in cementless THA (112). The X3 PE has been reported to be robust to third body wear (113).

The fourth mode of wear is notching caused by contact of two non-weight bearing surfaces. In the DM construct, this could happen if movement continued through the full movement of both the small and large articulation. In that case, the femoral neck would contact the rim of the metal cup, potentially notching the femoral neck (114-116).

Aseptic loosening

Aseptic loosening is THA failure without infection and the second most common reason for first-time revisions in Denmark (16). The etiology of aseptic loosening is multifactorial and several pathways exists but it has not yet been fully mapped (117). During the 90s it became clear that particles of metal in general and PE in particular were associated with aseptic loosening (118,119). Small-particle debris from PE is worn off the implant and therefore has free access to the joint. Particles of 0.1 to 10 µm are thought to be the most bio-reactive. When the concentration of PE particles increases to a certain threshold, macrophages are activated, which again can lead to inflammation, osteolysis and aseptic loosening (120). Consequently, both the size and volume of particles can affect the risk of aseptic loosening.

Aseptic loosening can be evaluated in plain AP and lateral radiographs. Radiographic presentation of aseptic loosening can be divided into lytic and linear bone loss. Lytic bone loss (osteolysis) is located resorption of the periprosthetic bone in an area exceeding 3*3 mm (121). Linear bone loss is less specific and located along the prosthesis and identified as radiolucent lines. The minimum threshold for width of radiolucency for acetabular cups varies in the literature from >0.3 mm to >2 mm (121,122). Progression of radiolucent lines indicates a poor prognosis for implant loosening (123). Radiographic loosening has been defined as >5 mm translation, a circumferential radiolucency or more than 10 change in inclination (121). Radiographic loosening does not necessarily mean that the implant is clinically loose, but typically heralds future clinical loosening (124).

RSA-measured proximal translation and inclination (sagittal rotation) are proxy measures for future aseptic loosening of hip arthroplasty (2,61). On the individual level, a 2-year proximal translation in revision cups of more than 1 mm predicts an 81% risk of later clinical loosening (60).

Due to the close link between wear debris and aseptic loosening, estimates of debris concentrations are also used as a proxy for later aseptic loosening. Cobalt and chromium blood levels have commonly been used to estimate metal debris and set a threshold for needed THA revision, as PE wear rates have been used to foresee aseptic loosening due to PE debris. Early crosslinked PE materials tended to produce debris of a very bioactive size, which, although the debris volume was decreased, could lead to increased osteolysis and aseptic loosening (125). In second-generation HXLPE, exvivo analysis of debris has shown particle sizes equal to those of conventional UHMWPE (93). Though older thresholds may not hold today, wear continues to be a relevant proxy for aseptic loosening, even with the very low wear rates of HXLPE.

Dislocation

Dislocation in THA is a frequent complication and one of the most common reasons for revision surgery. Dislocation happens when the femoral head leaves the cavity of the cup. Many factors can affect the risk of dislocation, including implant design, cup orientation, surgical approach and soft tissue laxity (126-136).

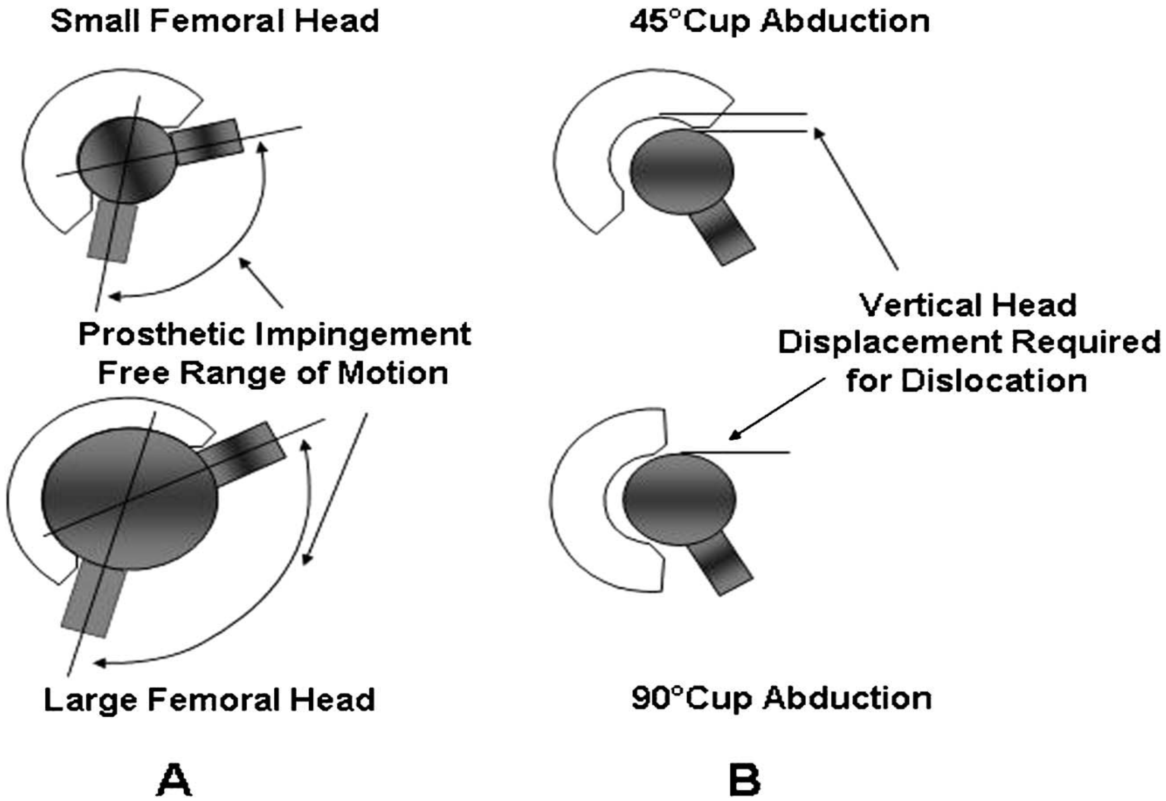

Figure 12. Impingement free movement and VHDD with large heads. (39)

The typical mechanism triggering THA dislocation is that the femoral head is levered outside the shell. This can happen when impingement occurs with the femoral neck and the acetabular cup or soft tissue (128,137). The translation of the femoral head that on the dislocation risk. The use of larger femoral heads in THAs in the past decade has reduced the dislocation rate by increasing the jump distance and increasing the free movement before impingement (Figure 12) (20,135,138,139). Unfortunately, larger femoral heads also mean increased articular sliding distance and velocity, and these factors are associated with increased wear. Furthermore, larger femoral heads result in thinner PE liners. Clinical studies have not clearly shown that the use of larger heads has succeeded in reducing revision rates despite accomplishing fewer revisions for dislocation (140).

In DM THA, the “large articulation” functions as a large femoral head (141). While most of the movement theoretically occurs in the small articulation, the large articulation takes over at the stressful end-range movement (10). An experimental study of a 46 mm ADM cup shows superior performance in terms of jump distance at varying inclination and anteversion angles when compared with hemispherical cups (Trident) with 28 and 3 mm heads and resurfacing (Cormet) THA 46 mm (131), and clinical can lead to THA dislocation is called the jump distance. The vertical head displacement required for dislocation (VHDD) is often used to describe the effect of cup orientation

studies show that the use of DM cups further reduces the risk of dislocation compared with large heads (142,143).

Intra-prosthetic dislocation

Intra-prosthetic dislocation (IPD) is a complication only seen in the DM cups. When the femoral head is not sufficiently retained in the liner in the "small articulation", the head and liner can separate within the metal cup thus causing liner dislocation where the femoral head is often contained in the metal shell (Figure 13).

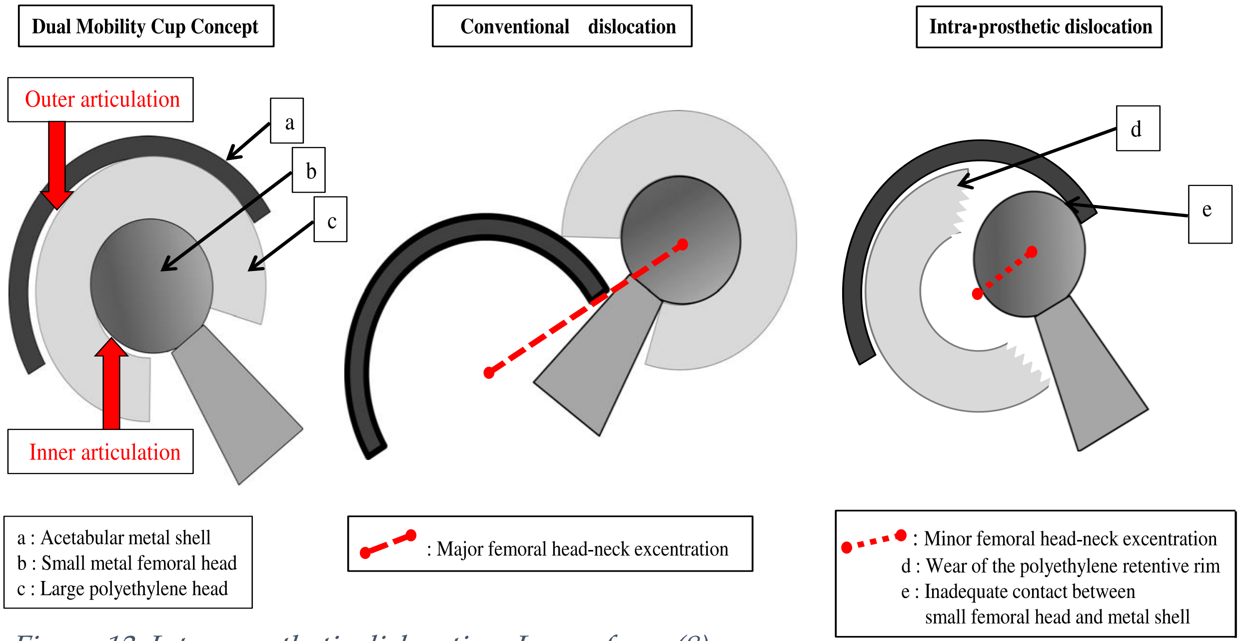

Figure 13. Intra-prosthetic dislocation. Image from (8)

Insufficient liner retainment can occur due to trauma or – more frequently - due to PE wear of the retentive rim. Clinical findings from revision surgeries for IDP show that a blockage of the larger articulation is the most likely mechanism. With liner/neck contact as the reason for rim wear, the femoral neck could have importance for the risk of IDP. Clinical findings have suggested that IDP occurred in prostheses with rough femoral stems and that thin, highly polished necks were preferable to reduce the risk of IDP (27,144). With improvements in materials and design of the neck and liner, the incidence of IPD has gone from uncommon (0.7-4%) in first-generation DM cups to very rare (0-0.1%) in the newer third-generation DM cup (8,145,146).

Motivation for the PhD thesis

Despite the findings in revision surgery of liner blockage with intra-prosthetic dislocation of DM cups supporting the importance of liner mobility in the design, no studies have evaluated liner mobility *in vivo*. Furthermore, mid-term studies of wear combined with migration of the ADM cup are absent in the literature.

4. Aim and design

The main challenges that DM THAs present today are aseptic cup loosening, PE wear and blockage of the liner movement leading to edge wear and an increase in the risk of IPD. The aim of this thesis was to evaluate aseptic loosening and wear for mid-term follow-up. Furthermore, we wanted to evaluate movements of the ADM liner *in vivo*. The latter required the development a method to quantify liner movement.

Study I

The aim of Study I was to generate and test the feasibility of a CMC model and a hybrid model for assessment of PE liner motion with dynamic and static RSA in an experimental and a clinical setting.

The study was carried out as a phantom study and clinical validation with one patient from Study II.

Study II

The aim of Study II was

(1) to evaluate if liner movement occurred in DM cups 1 year after primary operation and (2) to describe the movement pattern and range of such movement.

This study was designed as an observational study.

Study III

The aim of Study III was to evaluate five-year migration and PE wear of a DM acetabular construct in a patient cohort of 44 patients.

5. Materials & methods

Ethical issues and permissions

Study I was a phantom/method study, and ethics committee and data protection agency permissions were therefore unwarranted. The clinical example for feasibility testing of the method was from Study II for which relevant permissions were granted. Study II was registered with ClinicalTrials.gov [NCT02301182], the Danish Data Protection Agency [1-10-72-343-14] and The Central Denmark Region Committees on Health Research Ethics [1-10-72-343-14]

Study III was registered with the Danish Data Protection Agency [1-16-02-54-14], and The Central Denmark Region Committees on Health Research Ethics was approached for permission ([12/2014] dated 3. February 2014). The study was not considered notifiable according to Danish law number. 593 of June 14th 2011 on science ethics treatment of health science research projects.

Patients

Study I included only one patient. Study II included a selective cohort of young patients with a high self-perceived level of function. Study III, having no exclusion criteria, was a mixed cohort representing everyday patients receiving DM THA.

Study I

Study I included a Sawbone phantom (No 1301-165-1, Sawbones, Washington, USA) and one patient from the cohort of Study II (female, age: 65 years, BMI: 33).

Study II

Study II included a cohort of 16 patients, nested in a randomized study. Inclusion criteria were patients aged 40 - 70 years with coxarthrosis as the reason for operation. We excluded patients with osteoporosis (t-score < -2.5), ongoing metastatic cancer, metabolic disease, neuromuscular or vascular conditions that would affect daily function of the hip, and poor dental status. Also, we excluded patients with alcoholism, senile dementia, major psychiatric disease and ongoing insurance cases regarding the hip. Finally, patients who were unable to read and speak Danish and non-Danish citizens were not included.

Study III

Study III included all 44 patients receiving an ADM construct at Aarhus University Hospital during a period from 2015 to 2016. Guidelines for considering DM at Aarhus University Hospital are described in Table 1. There were no exclusion criteria, and both primary and revision surgery were accepted.

Table 1. Clinical guidelines for considering dislocation prophylaxis

Primary reasons for dislocation prophylaxis	Secondary reasons for dislocation prophylaxis
Revision due to dislocation	Rheumatoid conditions
Femoral neck fracture	Vestibular conditions
Femoral neck fracture sequalae	Age
Patients with increased risk of falling	Diabetes mellitus
Prior lumbar fusion surgery	Cardiovascular disease
Alcohol- or drug abuse	Chronic obstructive pulmonary disease
Overweight	Reduced muscle strength or coordination
Suboptimal pelvic anatomy	Reduced compliance with movement restrictions
Neurological deficits	Psychiatric conditions

Implants

All patients in the three studies of the thesis and the phantom received the ADM cup with an X3 HXLPE liner.

In Study I, the phantom was equipped with a ceramic femoral head (Biolox Delta, Stryker, Warsaw, Mazovia, Poland) combined with a Bi-Metric stem size 7 (Biomet, Warsaw, Indiana, USA). The patient underwent THA operation with the same cup and femoral head, but with an Accolade II femoral stem size 4 (Stryker, Warsaw, Mazovia, Poland).

In Study II, all patients were operated with the ADM cup, X3 HXLPE liner, ceramic femoral head (Biolox Delta, Stryker, Warsaw, Mazovia, Poland) and Accolade II stem (Stryker, Warsaw, Mazovia, Poland).

In Study III, all patients received the ADM cup and X3 HXLPE liner. The heads were either metal alloy; lfit (n=27) modular (n=2) (Stryker Orthopaedics, Warsaw, Mazovia, Poland), Versys (n=5) (ZimmerBiomet, Warzaw, IN) or Bioball (n=1) (Merete, Berlin, Germany) or ceramic; Biolox delta (=9) (Stryker Orthopaedics, Warsaw, Mazovia, Poland). The stems used were: ExeterV40 (n=30), Accolade II (n=5) and Modular Hip

System (n=3) from Stryker (Stryker Orthopaedics, Warsaw, Mazovia, Poland), CPT (n=4) and Bimetric (n=1) From ZimmerBiomet (ZimmerBiomet, Warzaw, IN), and one calcar-supported stem from Hipokrat (Hipokrat, Turkey).

In Studies I and II, the liners for the phantom and the patients had 12 1-mm tantalum markers (X-medics, Frederiksberg, Denmark) placed in the rim of the liner using a size-specific custom-made drill guide. The drill was operated at low speed to reduce friction heat and had a stop to ensure similar marker positions in every liner. The markers were positioned in four groups of three markers. Three groups had a first, second or third marker placed 1.5 mm deeper than the other markers, and the fourth group had all markers at the same depth (Figure 14). The marker pattern made it possible to identify a group of markers even if the other markers were occluded.

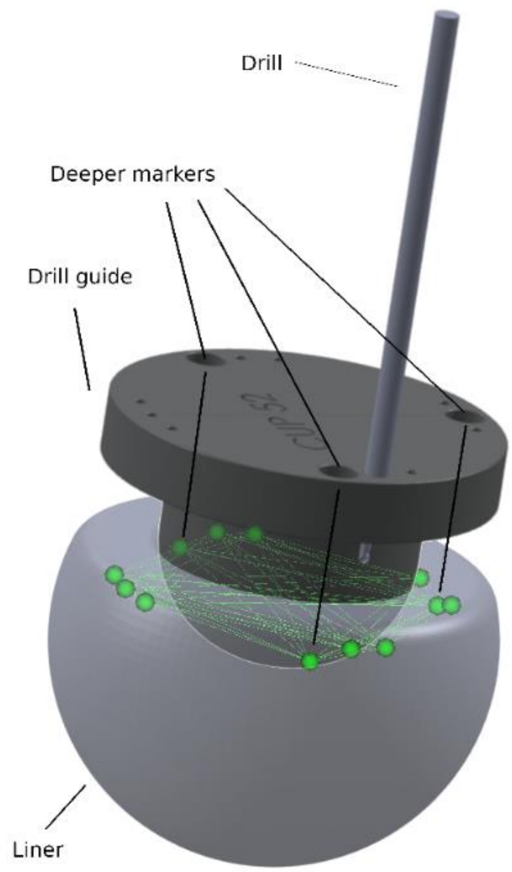

Figure 14. Markers were placed in the liner using a drill guide to ensure correct marker pattern - adapted from (6).

Dual x-ray absorptiometry (DXA)

Preoperative DXA scans were performed using a GE Lunar iDXA scanner (General Electric, Chicago, IL, USA) and analysed using the encore software (www.encore.com). Patients with a T-score < -2.5 were diagnosed with osteoporosis and referred to a specialist for further treatment. Patients with osteoporosis were excluded from Studies I and II. Patients with a T-score < -1 were diagnosed with osteopenia. These patients were informed about calcium, vitamin-D and life style changes to reduce future bone loss. Patients with osteopenia were included in all studies.

RSA setup

All studies used the same static RSA setup: the AdoraRSA Suite (Nordic X-ray Technique, Hasselager, Aarhus, Denmark) consisted of two ceiling-fixed x-ray tubes angled 40 on each other. The phantom and patients were placed in the supine position with each x-ray tube pointing anterior/posterior (at a 20 angle) to a set of cordless static detectors (CXDI-70C, Canon, Tokyo, Japan), mounted below a calibration box (cb24, Medis Specials, Leiden, Netherlands). The settings were 90 to 110 kV and 5 to 10 mAs depending on body composition. The setup used 0.1 mm copper and 1 mm aluminium as filtration.

For the dynamic recording in Studies I and II, the x-ray tubes and calibration box (cb14, Medis Specials, Leiden, Netherlands) with detectors (dynamic CXDI-50RF, Canon, Tokyo, Japan) were angled 45 relative to the frontal plane (Figure 15). Settings and filtration were equal to those of the static setup. The phantom was supplied with 10 cm

Figure 15. The dynamic RSA setup. X-ray tubes and calibration box were angled 45 for better view of implants throughout the recording (6).

polymethylmethacrylate (PMMA) as soft tissue substitute. Phantom and patients were positioned at the very bottom of the examination bed with 45 hip flexion and neutral adduction/abduction. From this position, the hip was passively moved in abduction/external rotation (FABER) and adduction/internal rotation (FADDIR), with the foot touching the examination bed at all times. Normally, FADIR/FABER uses end-range or 90 flexion, so this is a modification (147). The modified FADIR/FABER motion was continued to end-of-range for the individual patient, and for the phantom, which did not have a soft tissue stop.

RSA analysis

RSA analyses were performed by the same analysist (PBJ). The ADM shell was fitted using contours with a size-specific CAD model provided by the manufacturer. The femoral head was fitted using contour detection and an EGS sphere model. In Studies I and II, the femoral stem was fitted using contour detection and size-specific CAD models provided by the manufacturer. The femoral stem and head in Studies I and II were then fitted as a combined model. In all studies, the acetabular reference markers were detected automatically and verified manually. The rigid body error (RBE) was set to 0.35, and the marker distribution was considered adequate with CN < 150 (45). In Study III, three patients with a CN < 155 were included after examining the marker distribution. The dynamic recordings were analysed like the static recordings frame by frame, but the calibration was retrieved from an image combining all frames (Figure 16). This meant that the moving implant was blurred, while mean marker positions

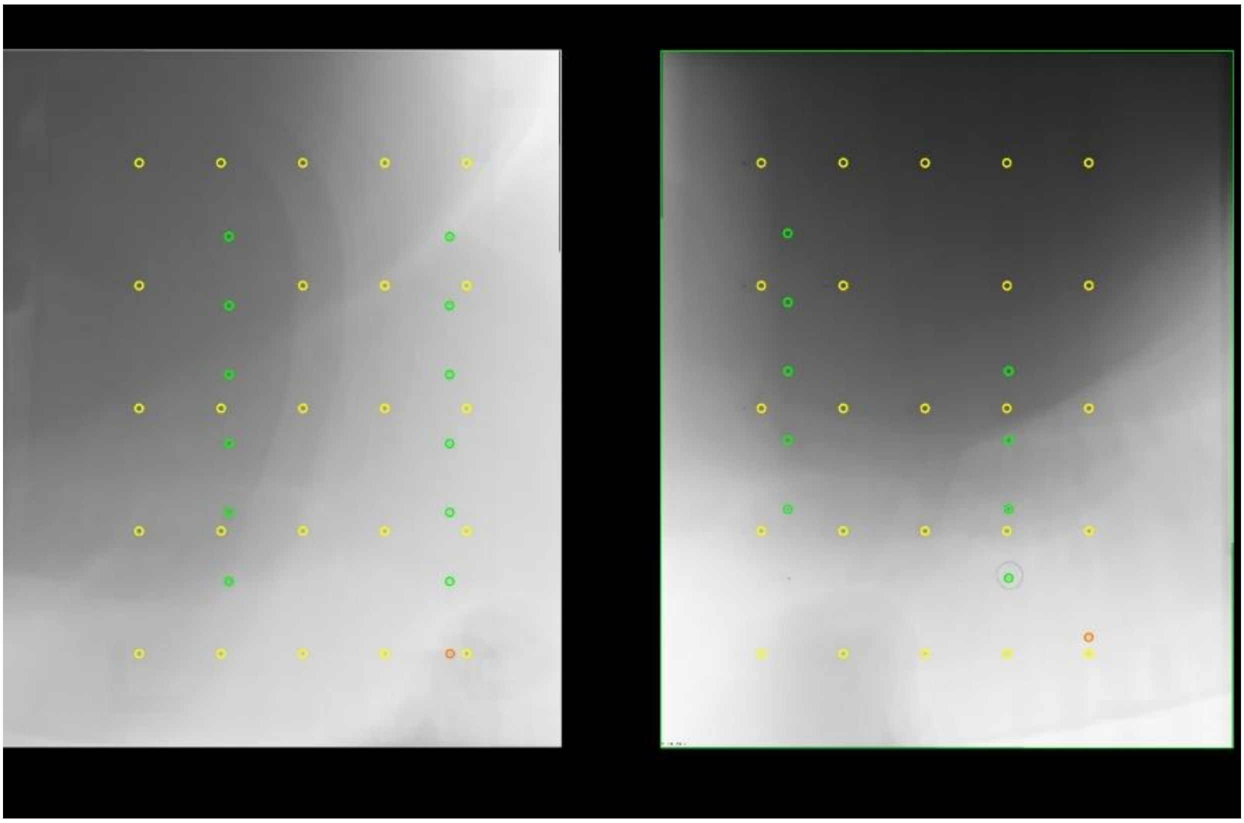

Figure 16. Calibration image for dynamic RSA analysis. The moving implant appears as a blur, and the calibration markers are clearly visible.

from the calibration box were clear. Thereby, the calibration marker occlusion was markedly reduced.

CMC model

Studies I and II aimed to measure liner movement based on tantalum markers in the PE. Most markers were occluded by either the metal shell, the ceramic femoral head or the femoral stem. This has previously been solved using a MC model of the marker positions relative to each other (47). Such a model was created from an RSA frame in which all markers are visible in both projections. The visible markers in the dynamic recording alternated and no frame presented the minimum of three markers that could be used in all frames.

The CMC model was built on the same principles as the MC model but combined the marker positions and the femoral head position from several RSA frames.

Combining two or more RSA frames would, like any rigid body, require at least three markers to create overlap between the frames (47). Since this was not possible, the femoral head was issued as a marker that was identifiable in all frames. By including the femoral head, the minimum number of overlapping markers was reduced to two (Figure 17).

The frames with two overlapping markers were aligned, and marker positions in each frame were exported. All marker positions were then combined (Figure 17a) and mean positions were used for the CMC model with the femoral head as the origin (Figure 17b). The standard deviation of the aligned marker positions was used to evaluate the dispersion of markers contributing to the CMC model.

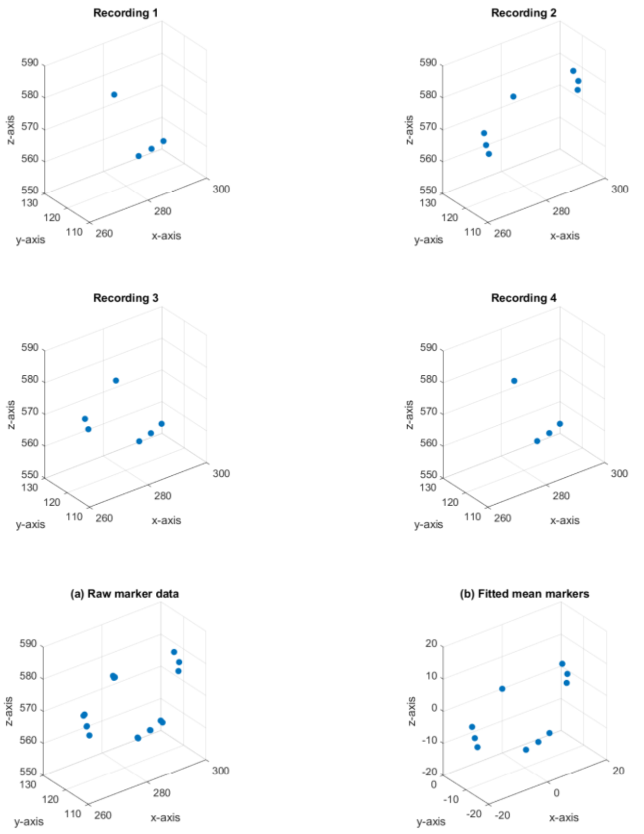

Figure 17. Multiple frames aligned using the femoral head as a common marker (top four plots). The markers were combined (bottom left plot) and a CMC model was calculated (bottom right).

For the phantom, only dynamic RSA frames were used to generate the CMC model. For the patient, dynamic hip RSA frames were combined with static hip RSA recordings to generate a CMC model with a sufficient number of representative markers.

Hybrid markers model

Liner movement between baseline and 1-year follow-up presented a large and unpredictable variation in visible markers. Therefore, a hybrid model was constructed consisting of the measured CMC model and completed with the theoretical marker positions calculated from the CAD model of the drill guide. This combination of the measured marker positions and theoretical marker positions resulted in a complete hybrid model including all 13 markers with the best possible positions (Figure 18).

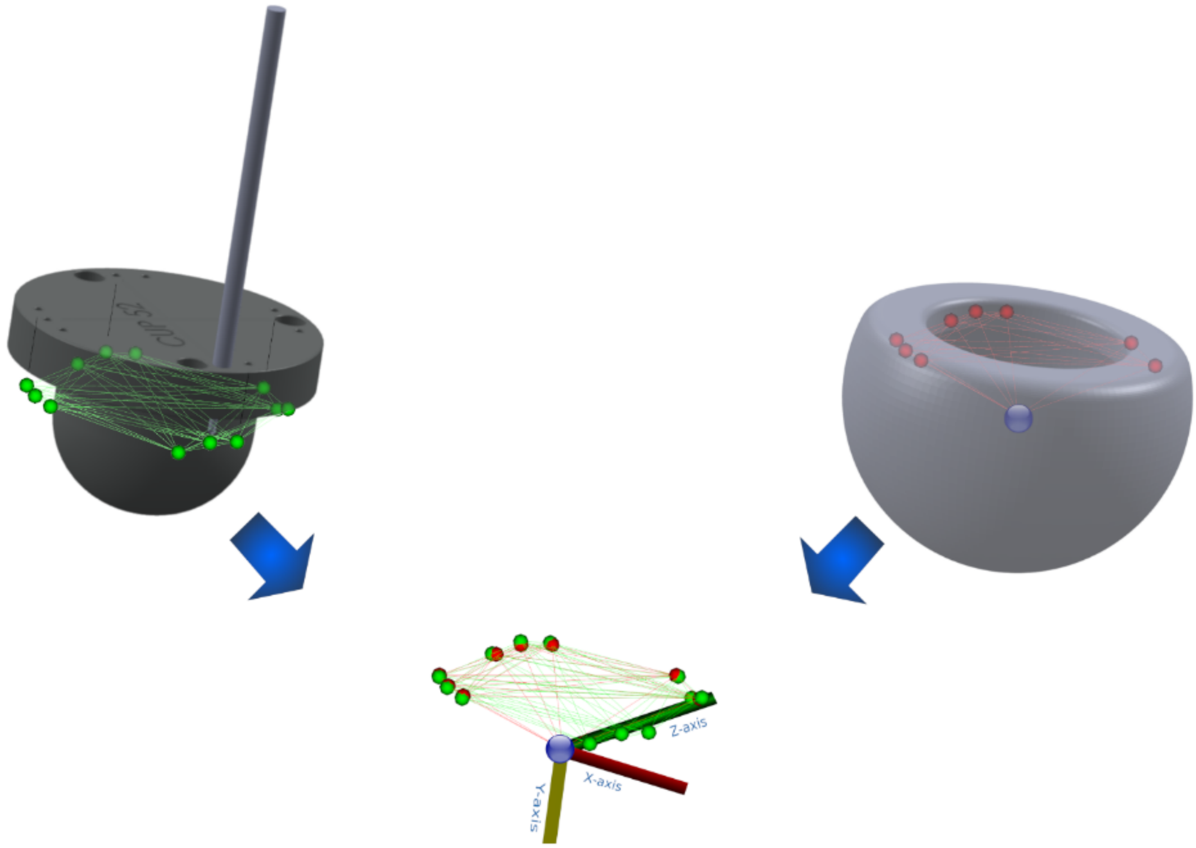

Figure 18. The hybrid model combines the measured information from the CMC model with the theoretical marker positions from the CAD model of the drill guide (6).

The hybrid model used either the measured or the theoretical model position for each marker. The theoretical marker position was used in all markers that were not represented in the CMC model. The measured marker position was used when the position difference between the theoretical and the measured marker was below 1 mm. When the position difference was above 2 mm, it was considered an error in the measured model and the theoretical marker was used for the hybrid model. When the position difference was between 1 and 2 mm, we tested the best fit for all possible combinations of markers and positions. We discarded combinations that resulted in 1) model markers missing in the radiograph in an area with good visibility, 2) single marker projections in the radiograph far from the model, 3) recordings with only one model marker (the femoral head) in one of the radiographs, or 4) recordings with poor marker representation (multiple overlapping marker projections). From the remaining combinations, the best fitting (model difference) markers were chosen for the hybrid liner model

The hybrid model was used for detecting liner movement in static RSA follow-ups over time, where the liner rotation could be very different from one RSA recording to the next.

RSA software

All RSA analyses in the three studies were performed using mbRSA (version 4.2, RSA*core*, Leiden, the Netherlands). Studies I and II further used a custom-made MatLab program (version 2019b, The MathWorks Inc, Natick, Massachusetts, USA) to calculate the CMC and hybrid model and a custom-made python program to calculate liner orientation. All analyses were performed by the same analysist (PBJ).

For creating the CMC model, the detected markers of all frames were aligned using the migration function of mbRSA software (version 4.2, RSA*core*, Leiden, the Netherlands).

RSA coordinate systems and outcomes

In Studies I and II, the coordinate system of the CMC model consisted of x- and z-axes from a base-plane fitted through the liner markers. The y-axis was perpendicular to the base-plane going through the femoral head that was used as the origin of the CMC model. The coordinate system for the theoretical markers was similarly defined, but the base plane did not include the three markers that were deeper in the liner wall.

The hybrid model used the coordinate system of the theoretical model.

The coordinate system of the metal shell was similarly defined with the origin in the centre of rotation of the cup and the y-axis (acetabular axis) perpendicular to the base-plane of the cup. Lastly, the femoral neck coordinate system was defined with the femoral head as its centre but with the y-axis aligned with the neck of the femoral stem (Figure 19).

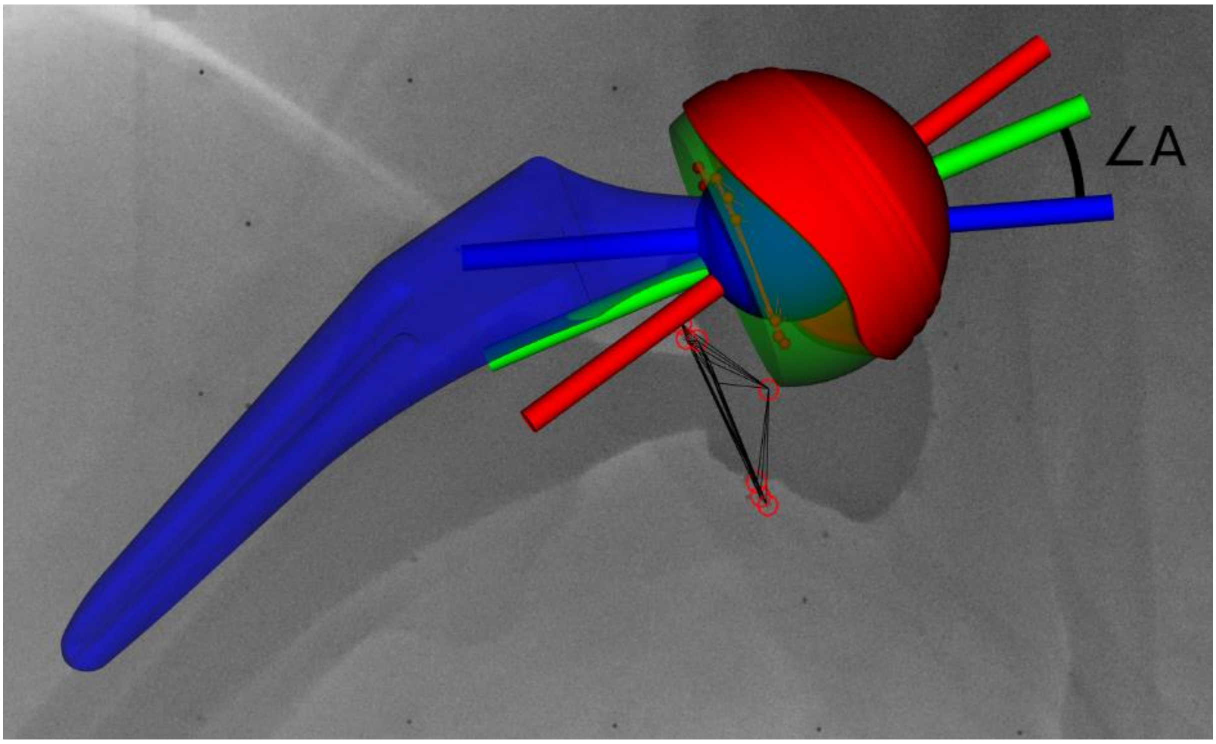

Figure 19. Y-axis of the shell, liner end neck coordinate systems with the liner/neck angle (A) (5).

Defining all coordinate systems of the ADM construct and the head with the origin in the centre of rotation meant that all movements in the cup-liner-neck complex could be expressed by uniform rotations. In the "neutral" orientation, also the main (y-) axis of all objects was aligned and the relative angles were zero.

The radiographic coordinate system was used to calculate the motions of the THA construct. Movements in the radiographic coordinate system are defined as:

- anteversion: the angle between the acetabular (y) axis of the object moving and the frontal plane and
- inclination: the angle between the longitudinal axis and the acetabular axis when projected on the frontal plane.

The angle between the neck and liner normal (y-axis) was calculated (Figure 19). This angle served as indicator of contact between the neck and the liner. With contact between neck and liner the liner should rotate relative to the cup.

The liner and stem movements were given in rotation (about the y-axis), anteversion and inclination in a radiographic coordinate system (Figure 20).

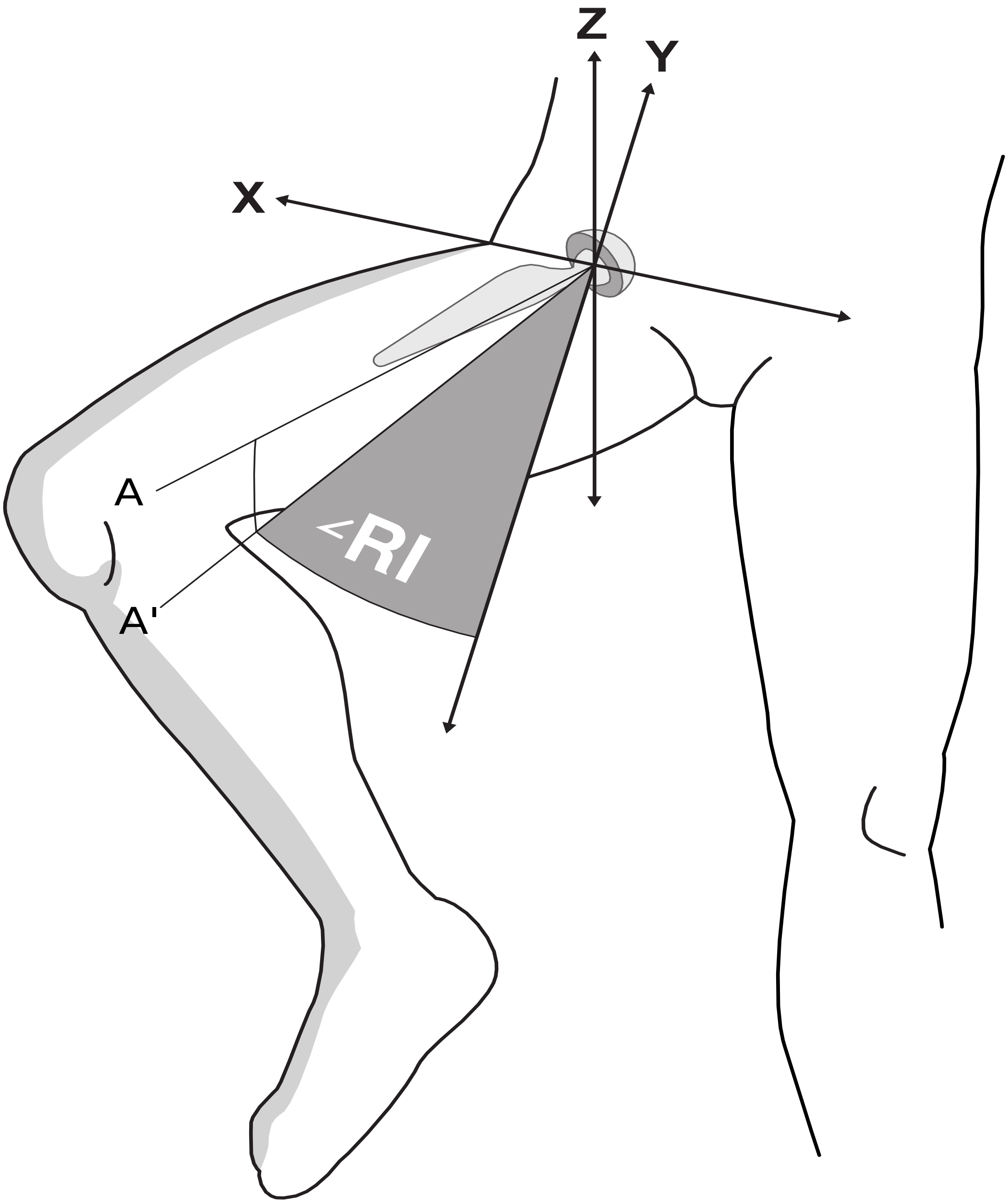

Figure 20. The radiographic coordinate system: radiographic inclination: the angle between the acetabular axis projected on the frontal plane (a') and the longitudinal axis. Radiographic anteversion: the angle between the frontal plane and the acetabular axis (5).

The effort to ensure that the hip joint reached end-range of motion caused patient movement during the dynamic RSA recording. Therefore, it was not safe to presume that the coronal plane was aligned with the calibration box at all times. Consequently, the coordinate system was aligned with the patient position in the initial image using the cup orientation.

In Studies II and III, cup orientation was given as anteversion and inclination in a radiographic coordinate system corrected to right side hip. Because of the shape of the metal shell, the cup orientation was derived from the static RSA recordings presuming optimal patient alignment with the calibration box. To reduce the risk of malalignment, the cup orientations in Study III were given as the median orientation from all accessible follow-ups. In Study III, migrations of the cup were calculated relative to the acetabulum markers in the coordinate system of the calibrations box and corrected to right side hip. Assuming patient alignment with the calibration box, the axes were positive y-translation: proximal, positive x-translation: from lateral towards medial and positive z-translation: posterior to anterior (Figure 21).

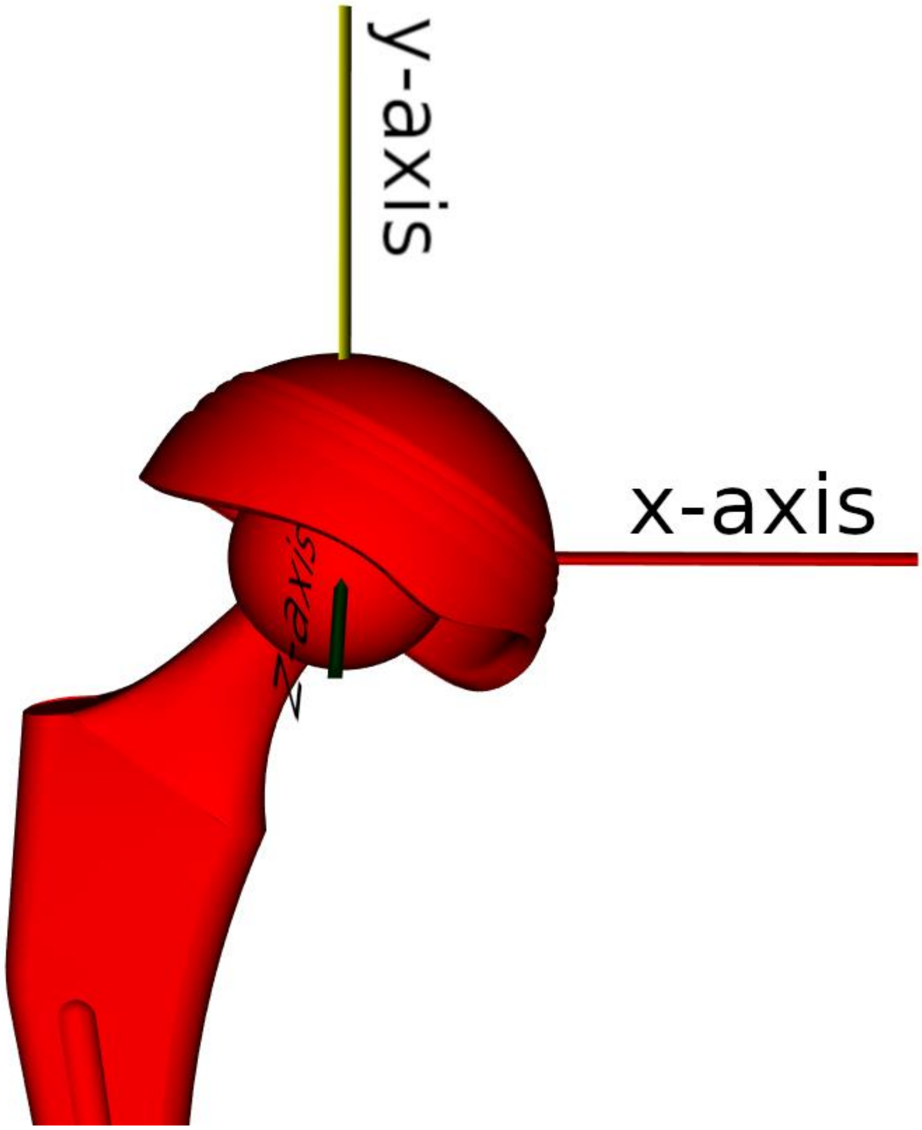

Figure 21. Coordinate system of migration and wear measures. X-translations, y- and z-rotations were corrected to a right side, right coordinate system (7).

PE wear was calculated as migrations of the femoral head relative to the metal shell. PE wear was calculated in the coordinate system of the calibration box and adjusted for side. In addition to x-, y-, and z-axis, wear was given as 2D wear defined by the vectorial sum of x- and y-wear, and 3D wear was defined as the vectorial sum of x-, y- and z-wear. Bedding-in was defined by any femoral head translation within the first year. Wear rate was calculated as the wear from 1-year follow-up to the final follow-up, and femoral head penetration was calculated as the wear from baseline to the final follow-up.

Cup orientation was given as anteversion and inclination. Cup orientation was measured using RSA because the anatomical shape of the metal shell in ADM would complicate measurement on plain radiographs. In Study II, the static 1-year recording was used. In Study III, the median cup orientation of all RSA recordings was used.

Radiolucent lines and osteolysis were evaluated on the postoperative and latest follow-up plain AP radiograph. If RSA was obtained only at the latest follow-up, the RSA images were used for evaluation of radiolucent lines and osteolysis. Radiolucent lines were measured as described by Delee and Charnley (122). Osteolysis was defined as a cystic lesion sized area sized 3 x 3 mm or more according to Hultmark et al. (121).

Patient-reported outcome (PROM)

The Oxford Hip Score (OHS) measures the patient-perceived hip pain and function validated for tracking changes over time. OHS was used in Studies II and III and filled out by the patient prior to operation and at 1-year follow-up. In Study III, OHS was also filled out at the 2- and 5-year follow-up. The minimal important change was set to 10 (41), and the accepted threshold for compliance was set to > 80% (37).

Statistics

In general, data distribution was evaluated using qq-plots, statistical significance was assumed at $p < 0.05$, and statistical computations were performed using Stata (Stata/IC 16.1, StataCorp, College Station, TX, USA).

Study I used standard deviation of the mean marker positions as calculated in MatLab (version 2019b, The MathWorks Inc, Natick, Massachusetts) and values of orientations retrieved from a custom-made Python program were visualised using Stata (Stata/IC 16.1, StataCorp, College Station, TX, USA).

In Study II, the dataset was dichotomized based on the measured neck/liner angle below/above 36.6 . Normally distributed variables were tested using Student's t-test, and variables not normally distributed were tested using Wilcoxon's rank sum test. Liner orientation and PROMs were presented using median and range. Correlations between liner movement, cup position, initial liner position and stem movement were evaluated using scatter plots. The correlations were tested using univariate linear regression, and the residuals were evaluated using scatter and qq-plots.

In Study III, migration was dichotomized to patients with osteoporosis (T-score <-2.5) and patients without osteoporosis (T-score >-2.5) and compared using multivariate repeated measurement analysis with T-score and follow-up time as factors. Equality of standard deviation and correlation was tested using multivariate tests, and residuals were examined using scatterplots. In addition, subgroup analysis on indications was performed using Student's t-test to evaluate a possible effect on migration. Correlation between wear and migration at 2- and 5-year follow-up was tested using Spearman's rank correlation. The cohort was also dichotomized on femoral head material (metal/ceramic) for evaluation of PE wear.

RSA precision was calculated on 33 double examinations (45). The baseline recording formed the reference for migration in each of the double examination RSA analyses, and both the patient and the RSA equipment were repositioned between the two RSA recordings. The mean difference from the first to the second recording was the systematic difference (bias), and the variation between the two recordings (precision) was given as coefficient of repeatability (CR) = 1.96*sd of the differences.

6. Results

Patient characteristics

All patients included in the studies are presented in Table 2. For comparison, the cohorts of Studies II and III presented obvious differences in age, BMD and OHS. The observed discrepancy arises from the strict inclusion and exclusion criteria in Study II and the complete lack of the same in Study III. No loss to follow-up was encountered in Study II since the inclusion was based on completed follow-up. On the other hand, a significant number of dropouts from Study III was observed due mainly to unrelated death and health issues, but also because some non-compliers were included in the study. Dropout could be expected due to the lack of exclusions and could be considered a necessary evil to obtain a realistic cohort for the ADM construct.

One patient received revision surgery with replacement of the acetabular construct to correct the offset. No incidences of dislocations, IDP or aseptic loosening were observed.

	Study I	Study II	Study III
Number of patients	1	16	44
Age, mean (range)	65	57 (41 - 69)	73 (41 - 94)
Gender, male/female	0 / 1	7 / 9	8 / 36
T-score, mean (95%CI)	-0.2	-0.5 (-1.1;0.0)	-1.5 (-1.9; -1.2)
BMI, mean (95%CI)	33	25 (23;27)	25 (24; 26)
Oxford Hip Score, mean (95%CI)	20	28 (25;31)	21 (18; 24)
Cup size, mean (95%CI)	50	51 (50;53)	51 (50; 51)
Side (right/left)	0 / 1	11 / 5	

Table 2. Baseline characteristics for the patients in Studies I, II and III.

Study I

In Study I, we found four common conventional markers for the phantom and two common conventional markers for the patient. All frames had additional markers that could not be used for standard analysis as they did not represent the same markers between frames. The CMC model for the phantom comprised 11 markers (including the femoral head) derived from five dRSA frames. The CMC model for the patient comprised nine markers derived from three dRSA frames and one static RSA frame. The maximum standard deviation of marker positions occurred in the out-of-plane (z) direction for both the phantom and the patient

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Table 3. Representation of markers in individual recordings. The phantom RSA frames have four common conventional markers and the patient frames have two common conventional markers. All frames have additional markers that cannot be used in standard analysis as they do not represent the same markers between frames. With a CMC model, 11 markers were utilized in the phantom and nine in the patient, and all projections of these markers were available for analysis.

		Phantom					Patient			
Recording		1	2	3	4	5	1	2	3	4
Conventional markers	All recordings	4	4	4	4	4	2	2	2	2
	Additional markers	2	3	4	3	1	4	2	5	4
Combined marker configuration model	Model Markers (n)	11	11	11	11	11	9	9	9	9
	Left	10	8	10	11	7	6	7	7	6
	Right	9	8	9	3	9	6	6	7	7

Conventional markers; the marker is clearly visible in both images of the frame. Additional markers; markers that are visible in both images in the frame but cannot be included in a standard analysis as they do not represent the same marker between frames. Combined marker configuration model; markers and marker projections used for fitting the combined marker configuration model (5).

Table 4. Markers represented in the CMC model of the phantom and the patient as specified by marker ID.

	Phantom				Patient			
Marker id	sd, x-axis	sd, y-axis	sd, z-axis	n	sd, x-axis	sd, y-axis	sd, z-axis	n
1	0.04	0.06	0.09	5				
2	0.05	0.08	0.19	5				
3	0.07	0.11	0.06	5				
4					0.25	0.19	0.11	4
5	-	-	-	1	0.13	0.14	0.28	3
6	0.12	0.11	0.01	2	0.10	0.18	0.26	3
7	0.09	0.07	0.10	3	0.03	0.35	0.16	2
8	0.12	0.02	0.29	2	0.14	0.15	0.28	2
9	-	-	-	1	0.08	0.04	0.21	2
10								
11	0.03	0.09	0.36	2	0.07	0.56	0.09	2
12	-	-	-	1	-	-	-	1
Femoral head	0.14	0.13	0.14	5	0.28	0.21	0.21	4

Marker id, id number of the marker in the model; sd, x-axis, sd, y-axis, sd, z-axis, the standard deviation of marker position per (calibration box-) axis of the RSA frame to which the markers were aligned; n, number of markers available to calculate the marker position in the CMC model (5).

Phantom

The phantom liner was positioned neutral to the cup opening, and liner motion started when the liner/neck angle approached 36.6 during the modified FABER motion, which is the angle of contact between the liner and the neck (Figure 22, 4 sec.). Conversely, at the start of the modified FADIR motion, the liner/neck angle fell below 36.6 and the liner stopped moving until about halfway through the modified FADIR motion, i.e. when the liner/neck angle again reached 36.6 , and the neck contacted the liner and initiated movement. Liner movement was primarily caused by contact with and pushing from the femoral neck at 36.6 liner/neck angle; however, some spontaneous motion also occurred at lower liner/neck angles between 32.9 -36.6 (Figure 22).

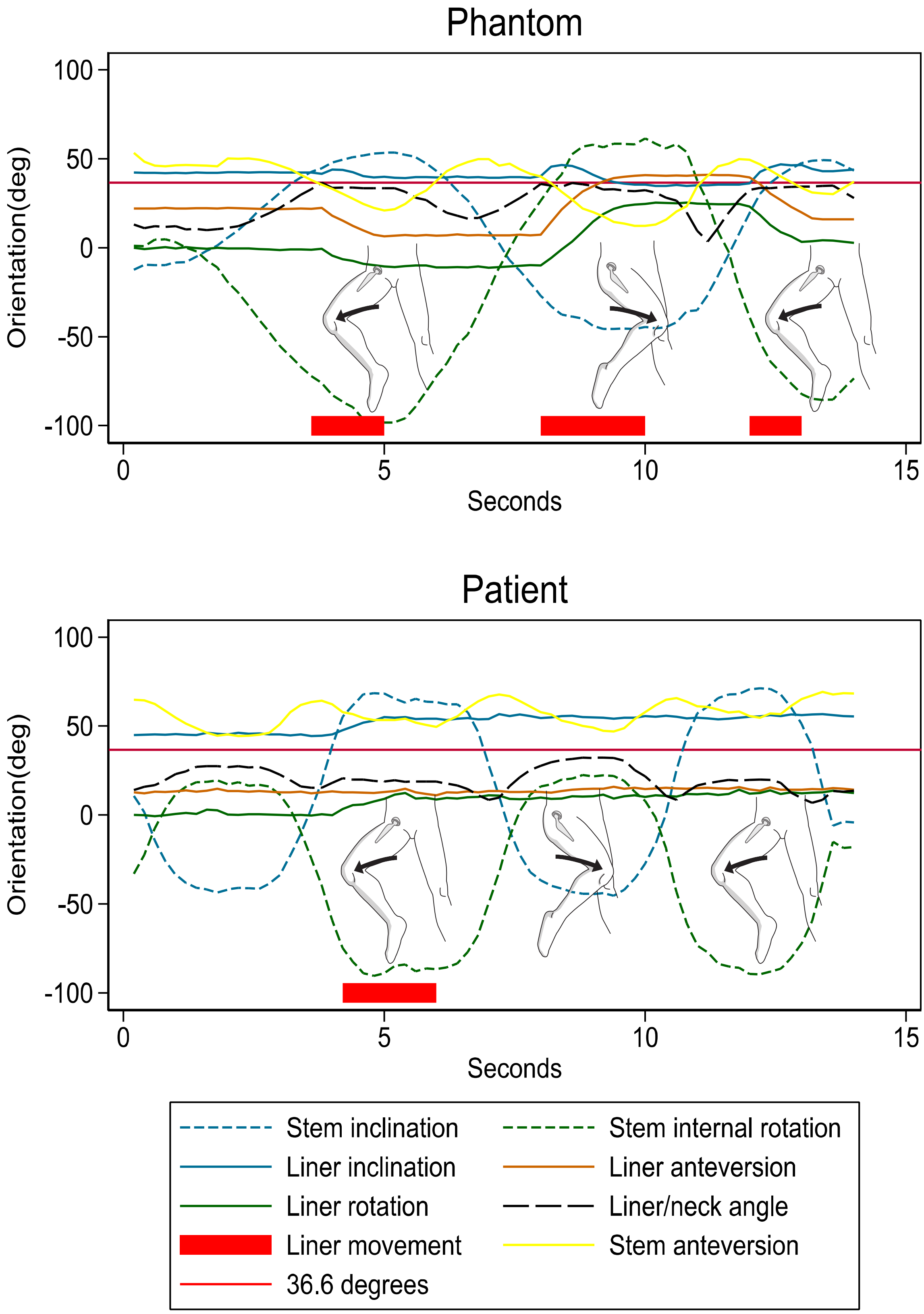


Figure 22. Liner movement in the phantom and patient (5).

The range of stem movement during recording was 99 inclination, 41 anteversion and 160 rotation. The range of liner movement was 12.2 inclination, 35 anteversion and 37 rotation. The range of liner/neck angle was 33 .

Patient

With dynamic assessment, the liner started in a position of 45 inclination and 12.8 anteversion, and began to move when the stem reached the maximum modified FABER motion for the first time (Figure 22, 4 sec.). Although a slight liner movement happened at 0 stem inclination (Figure 22, 7 sec.), the liner remained stable during the second modified FABER motion. Liner movement was not caused by contact with the femoral neck as the liner/neck angle was higher in the FADIR motion (without liner movement) than in the FABER motion (Figure 22). The ranges of hip stem movement during dynamic RSA recording were 117 inclination, 25 anteversion and 113 rotation. The ranges of liner movements were 12 inclination, 5 anteversion and -15 rotation (Figure 22). The range of liner/neck angle was 24 .

Static RSA evaluations at the postoperative and 1- and 2-year follow-up were completed with the hybrid model (all markers), which enabled registration of the liner orientation despite substantial and unpredictable liner rotation between follow-ups. Liner inclination was relatively stable from baseline to the 1- and 2-year follow-up. Anteversion decreased from 12 to 9 and 0 , and rotation was measured to -109 , -133 and -141 (Table 5).

Table 5. Static liner orientation of the patient orientation measured in the coordinate system of the calibration box at baseline, adjusted for the cup orientation in 1- and 2-year follow-up (5).

	Postop	1 year	2 years
Inclination	48	54	48
Anteversion	12	9	0
Rotation	-109	-133	-141

Study II

Dynamic RSA

The CMC models for the 16 patients consisted of mean (range) seven (5;10) markers. All six liners that reached the 36.6 threshold for liner/neck contact moved more than 5 in inclination, anteversion or rotation. Six of the ten liners that stayed below the 36.6 liner/neck angle also moved at least 5 in inclination, anteversion or rotation in the filtered data. The remaining four liners moved less than 5 in all rotations measured on filtered data.

The median (range) total liner movements were: anteversion 10 (5 ; 20), inclination 6 (2 ; 12) and rotation 11 (5 ; 48) in the non-filtered data.

The liner movement showed a clear pattern but varied much in extent between patients. Liner anteversion and inclination occurred with end-range stem inclination/rotation (at 7 and 10 seconds, Figure 23). Liner rotation occurred at end-range inclination/rotation combined with stem anteversion movement (2 seconds, Figure 23).

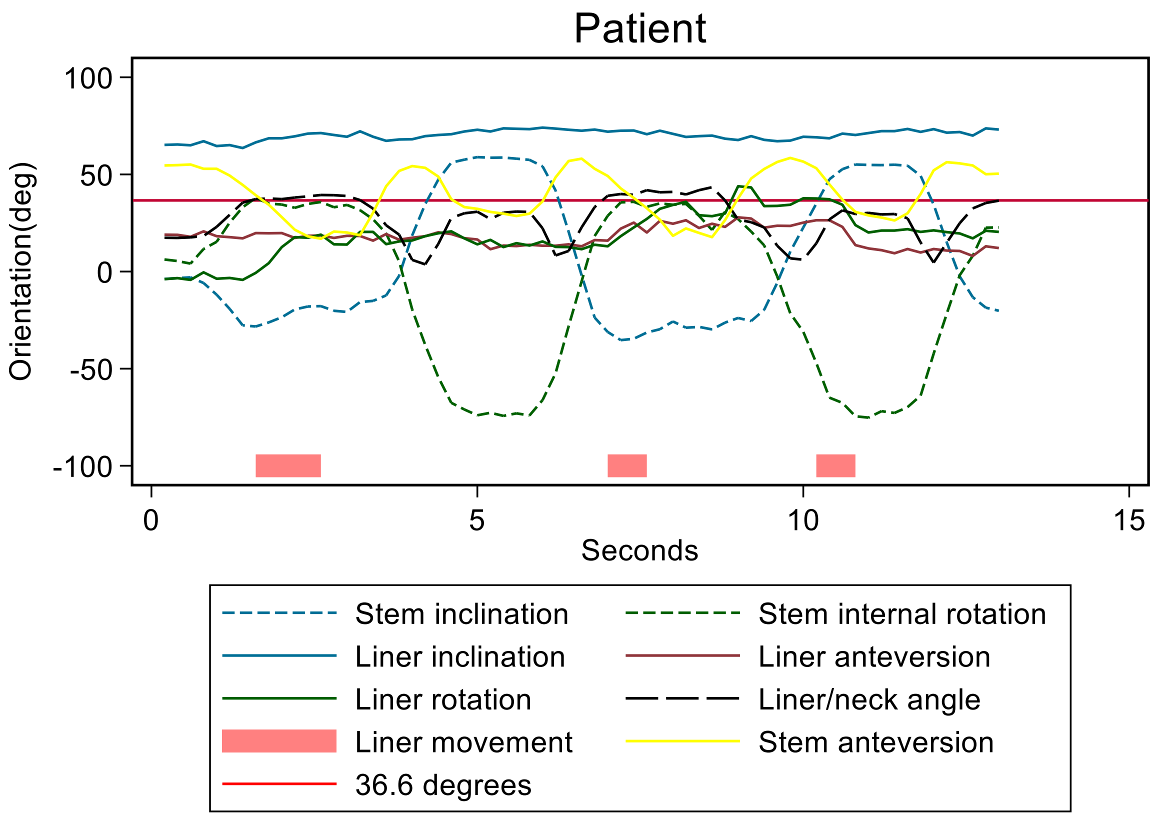


Figure 23 Example of stem- and liner movement (6).

Total liner anteversion correlated with the initial liner anteversion (slope 0.42, p=0.04), and was most pronounced in patients with liners moving beyond the liner/neck contact point (36.6 liner/neck angle) (p=0.02). Total liner inclination correlated with total stem inclination movement (slope 0.11, p=0.03) and was equally present in patients with liners moving below and beyond the liner/neck contact point. Total liner rotation was not correlated with specific stem movements and was equally distributed for liners moving beyond the liner/neck contact point.

The median (range) total change in liner/neck angle was 28 (12 ;46) and larger than the median total change in liner/cup angle of 6 (4 ;21) (p<0.001). Thus, the smaller head-liner articulation described by the liner/neck angle contributed with larger movement than the larger liner-cup articulation described by the liner/cup angle.

Static RSA

Three patients were excluded from assessment of liner movement over time due to poor model representation in the postoperative RSA recording.

At the 1-year follow-up, liner orientation showed substantial movement compared with the post-surgery baseline. The median (range) absolute change in liner movement was anteversion 11 (1 ;17), inclination 14 (1 ;42) and rotation 104 (7 ;165) (Table 6). While the median anteversion did not change statistically significantly over time, the median (range) inclination increased from 42 (35 ;66) to 59 (46 ;80) (p<0.001) (Figure 24). At the 1-year follow-up, all liners were positioned at a higher inclination angle than the cup (Figure 25, Table 7).

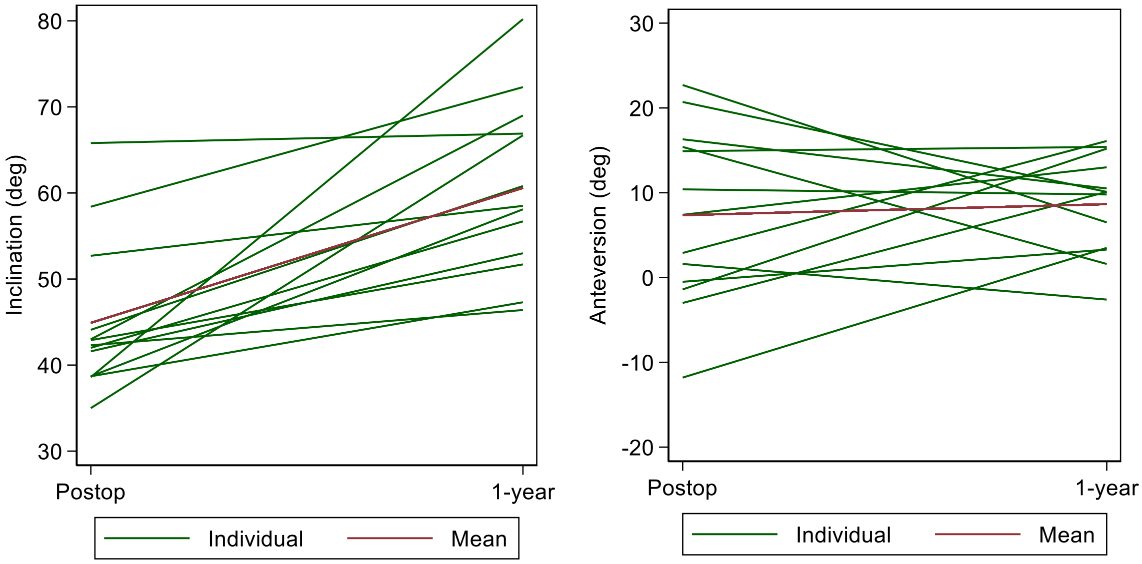


Figure 24 Line plot visualizing the change in liner orientation from postoperative static RSA recordings to follow-up after one year. There was a statistically significant increase in inclination, but no significant change in anteversion (6).

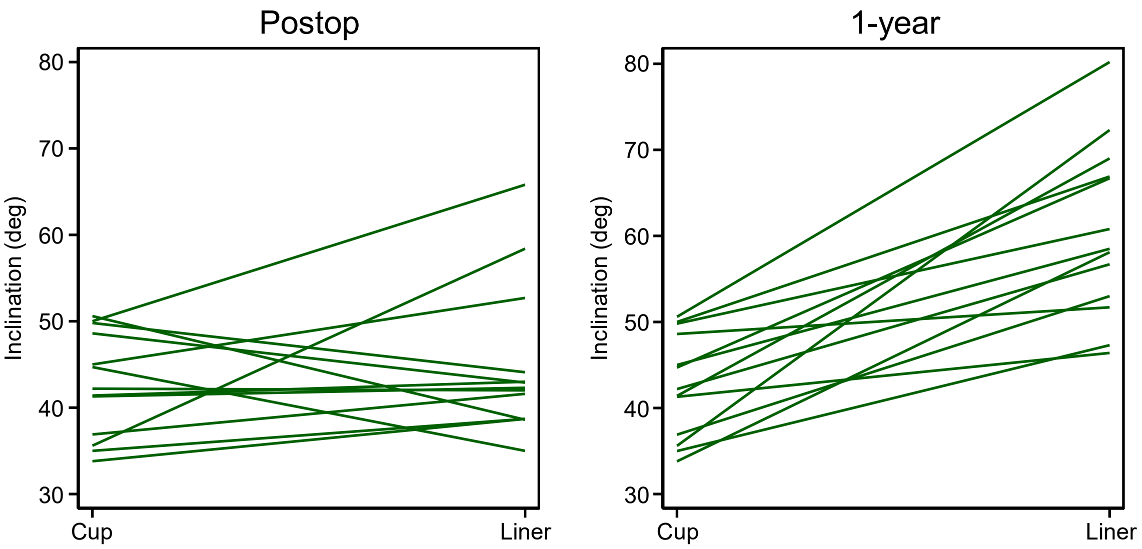


Figure 25 Parallel plot visualizing the cup/liner relationship postoperatively and at 1-year follow-up. After one year all liners showed more inclination than the cup (6).

Table 6: Biomechanical and patient reported outcome at 1-year follow-up (dynamic RSA recordings) (6).

	Total (n=16)	∠liner/neck <36.6 (n=10)	∠liner/neck >=36.6 (n=6)	P-value
Cup anteversion, mean°(95%CI)	23 (18;27)	22 (16;27)	24 (14;35)	[a] 0.62
Cup inclination, mean°(95%CI)	43 (40;46)	43 (39;46)	43 (35;50)	[a] 0.98
Initial liner anteversion, mean°(95%CI)	14 (11;18)	14 (10;19)	14 (8;20)	[a] 0.89
Initial liner inclination, mean°(95%CI)	57 (52;63)	52 (47;57)	66 (55;77)	[a] 0.01
Total liner anteversion, median°(range)	10 (5;20)	7 (5;20)	13 (10;20)	[b] 0.02
Total liner inclination, median°(range)	6 (2;12)	8 (2;12)	6 (3;11)	[b] 0.83
Total liner rotation, median°(range)	11 (5;48)	11 (6;20)	12 (5;48)	[b] 0.74
Total stem anteversion, median°(range)	25 (16;56)	24 (16;56)	27 (17;42)	[b] 0.91
Total stem inclination, median°(range)	79 (55;117)	80 (55;117)	78 (70;104)	[b] 0.91
Total stem rotation, median°(range)	97 (66;113)	92 (66;113)	100 (88;113)	[b] 0.33
Max Liner/neck∠, median°(range)	35 (25;47)	34 (25;36)	41 (38;47)	[b] 0.00
Total liner/neck ∠, median°(range)	28 (12;46)	25 (12;31)	36 (27;46)	[b] 0.01
Total neck/cup ∠, median°(range)	43 (25;70)	37 (25;70)	48 (36;68)	[b] 0.21
Total liner/cup ∠, median°(range)	6 (4;21)	5 (4;21)	9 (5;15)	[b] 0.13
Oxford hip score, median(range)	47 (18;48)	46 (32;48)	47 (18;48)	[b] 0.54
Pain decrease, rest, mean(95%CI)	23 (12;34)	26 (15;37)	18 (-11;48)	[a] 0.50
Pain decrease, active, mean(95%CI)	43 (24;63)	48 (23;73)	35 (-7;77)	[a] 0.50

a: student's t-test, b: Wilcoxon's rank sum test.

Table 7 Liner orientation (degrees) at baseline and 1-year follow-up (static RSA recordings) (6).

	Cup orientation			Liner Anteversion			Liner Inclination			Liner rotation		
id	Anteversion	Inclination	Rotation	Postop	1-year	Absolute change	Postop	1-year	Absolute change	Postop	1-year	Absolute change
1	26	41	-9	21	10	11	42	46	4	42	146	104
2	20	34	-19	7	13	6	39	58	19	-95	147	118
3	21	45	-19	2	-3	4	35	67	32	-7	-16	9
4	37	50	-25	23	7	16	44	61	17	-155	-7	148
5	12	51	-52	15	15	1	39	80	42	20	-145	165
6	35	50	-39	15	2	14	66	67	1	-27	-34	7
7	12	35	-15	3	16	13	39	47	9	178	114	64
8	20	41	-43	-1	3	4	43	69	26	-60	-171	111
9	10	42	-36	16	11	6	42	57	15	3	124	121
10	23	37	-24	-12	4	15	42	53	11	144	-116	100
11	37	36	-39	-3	10	13	58	72	14	171	156	15
14	16	45	-23	10	10	1	53	59	6	67	102	36
16	21	49	-25	-1	15	17	43	52	9	18	127	108
Median (range)	21 (10;37)	42 (34;51)	-25 (-52;-9)	7 (-12;23)	10 (-3;16)	11 (1;17)	42 (35;66)	59 (46;80)	14 (1;42)	18 (-155;178)	102 (-171;156)	104 (7;165)

Clinical outcomes

The self-perceived hip function measured as OHS increased 15 (95%CI: 10;20) points from baseline to the 1-year follow-up with no statistically significant difference between patients with and without expected liner/neck contact (p=0.6). Pain during rest and activity decreased mean 23 (95% CI: 12;34) and 43 (95%CI: 24;63) points on a 100 mm visual analogue scale with no statistically significant differences between groups (p=0.5).

Study III

Of 44 patients originally operated, 24 completed the 5-year follow-up. The reasons for loss to follow-up were mainly health issues or death for reasons unrelated to the hip arthroplasty (Figure 26). The baseline patient demographics are given in Table 1.

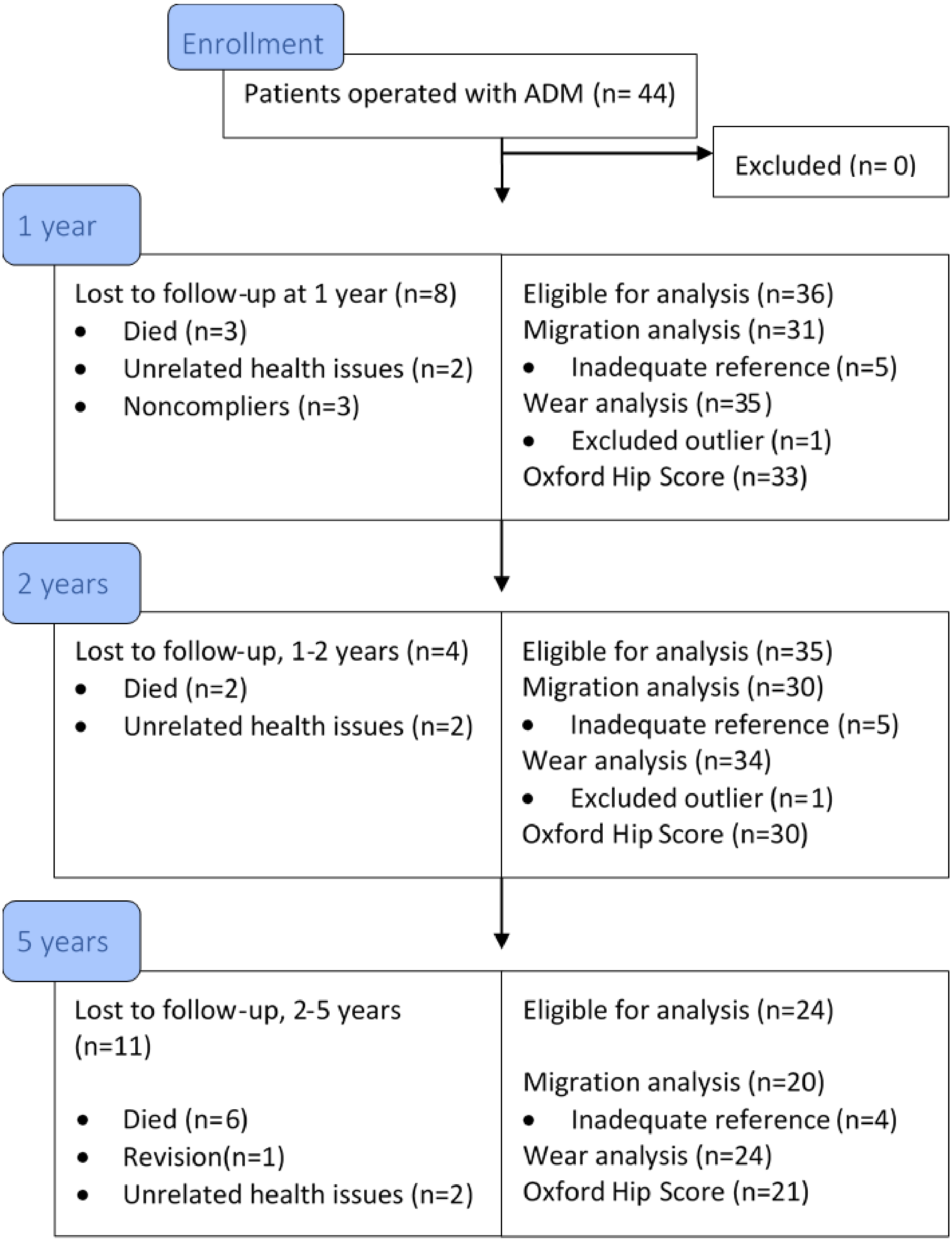


Figure 26. Flowchart of patients in Study III (7).

RSA precision

Bias was <0.01 mm for cup translations and < 0.1 for cup rotations. Precision (CR) was 0.1 mm for cup y-translations and 0.2 mm for cup x- and z-translation. CR was < 1 for cup z-rotations and < 2 for x- and y-rotations. For PE wear, the bias was <0.03 mm for all PE wear parameters (Table 8). CR was 0.1 mm for proximal and 2D wear measurements, and 0.3 mm for 3D wear measurements.

Table 8 Clinical precision of measurements (7).

Cup migration	Bias	CR	PE wear	Bias	CR
tx	0	0.17	wx	-0.02	0.13
ty	0	0.09	wy	0.01	0.13
tz	0.01	0.2	wz	-0.03	0.32
rx	-0.05	1.44			
ry	-0.09	1.51	w2D	0	0.11
rz	-0.02	0.75	w3D	-0.03	0.29

Cup migration

In the first year, the ADM cup had a proximal translation of 0.28 mm (95% CI: 0. 19; 0.38 mm) and a sagittal rotation of 0.26 (95% CI: -0.17 ; 0.68). Hereafter, the proximal translation and sagittal rotation stabilized (

Figure 27,

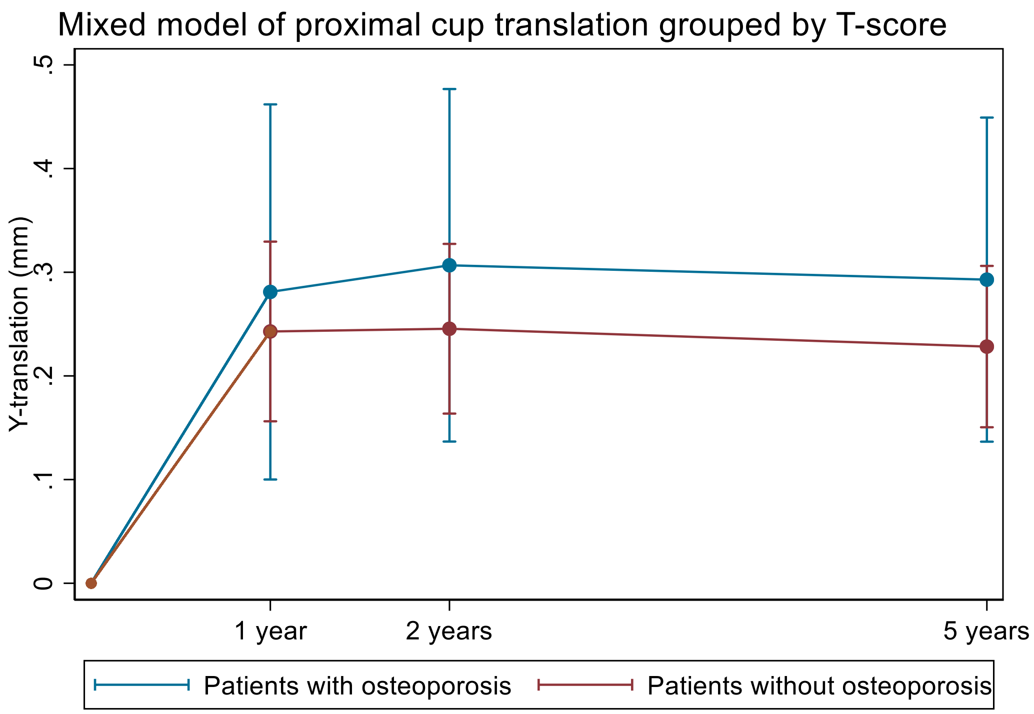
Figure 28,

Figure 29, Table 9).

Table 9 Mean (95%CI) cup migration relative to the reference markers in the acetabulum bone (7).

	1 year	2 years	5 years
x- translation (mm)	0.08 (-0.10; 0.26)	0.11 (-0.07; 0.28)	0.26 (0.05; 0.47)
y-translation (mm)	0.28 (0.19; 0.38)	0.26 (0.17; 0.36)	0.27 (0.17; 0.37)
z- translation (mm)	0.06 (-0.08; 0.20)	0.10 (-0.05; 0.25)	0.15 (-0.06; 0.36)
x-rotation ( )	0.17 (-0.32; 0.65)	0.23 (-0.13; 0.59)	0.49 (0.15; 0.84)
y-rotation ( )	0.48 (0.06; 0.90)	0.65 (0.28; 1.02)	0.49 (-0.00; 0.99)
z-rotation ( )	0.16 (-0.25; 0.58)	0.23 (-0.22; 0.68)	0.25 (-0.24; 0.75)

CR: Coefficient of repeatability



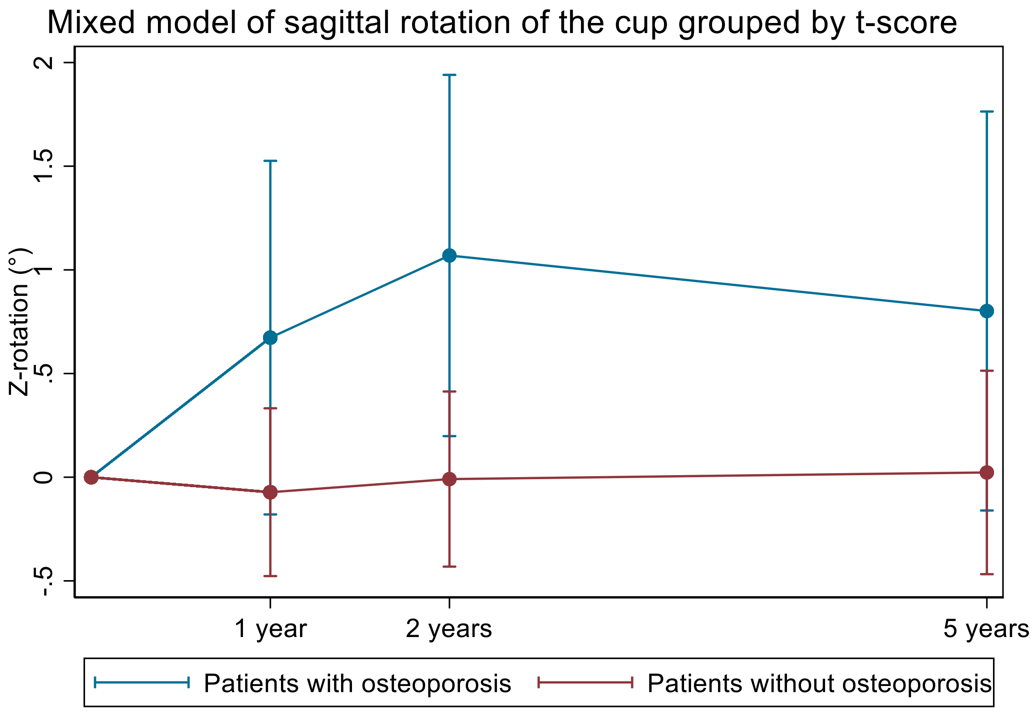


Figure 27 Multivariate repeated measures model of proximal cup migration and sagittal cup rotation grouped by T-score for each follow-up time (7).

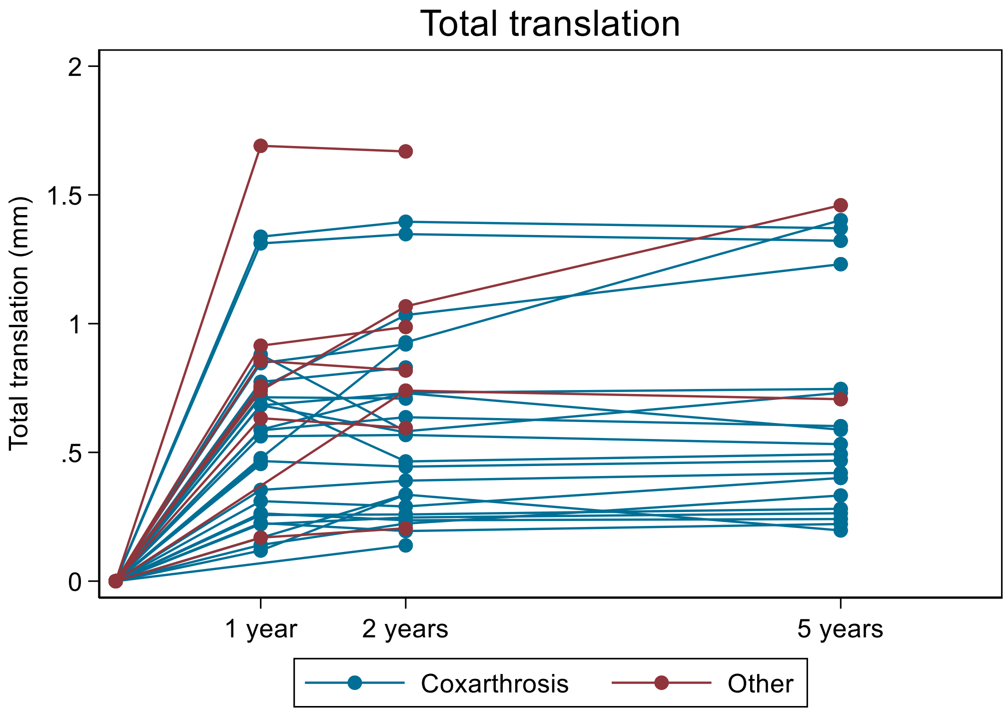


Figure 28.Total translation of the cup (vector sum of x-, y- and z-translation) (7).

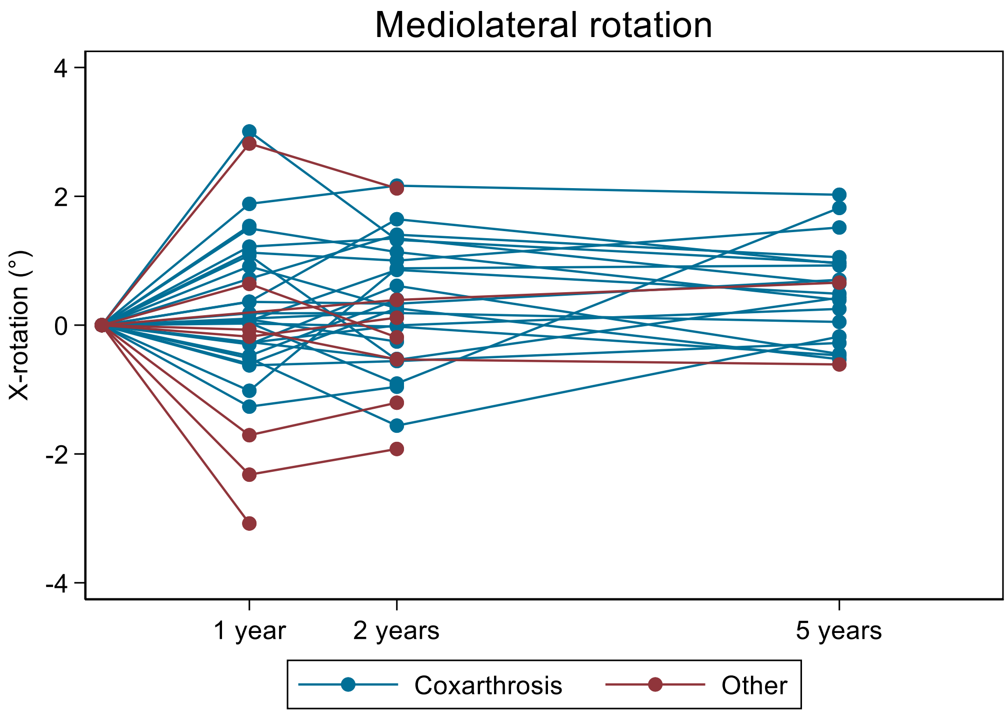


Figure 29. Mediolateral rotation (7).

At the 2-year follow-up, patients with osteoporosis (n=6) showed 0.06 mm (95% CI: -0.14; 0.25, p=0.55) more proximal migration and 1.1 (95% CI: 0.1; -2.1, p=0.04) more sagittal rotation than patients without osteoporosis (n=26) (
Figure 27). The difference in sagittal rotation was no longer statistically significantly different at the 5-year follow-up (p=0.17). Subgroup analysis of osteoarthrosis and other indications for THA showed no statistical differences in proximal migration or sagittal rotation at any time point (p>0.23).

PE wear

All wear parameters are reported in Table 10. Bedding-in was 0.3 mm (95% CI: 0.20 mm; 0.38 mm) in 3D, which also affected femoral head penetration in the PE. After 1 year, the 2D PE wear rate was 0.04 mm/year (95% CI: 0.03; 0.06) and the 3D PE wear rate was 0.07 mm/year (95% CI: 0.05; 0.09). Linear regression showed no correlation between BMI and 3D wear rate (slope 0.003, p=0.2) or age and 3D wear rate (slope 0, p=0.9). The 3D PE wear rate of 0.06 mm (95% CI: 0; 0.11) for ceramic femoral heads and of 0.08 mm (95% CI: 0.05; 0.011) for metal femoral heads was similar (p=0.38). A PE wear rate > 0.1 mm was measured in 11 metal and one ceramic femoral head. Patients operated for osteoarthrosis (n=26) had a 3D wear rate of 0.06 mm/year (95% CI:0.04; 0.09), while patients operated for other reasons (n=6) had a 3D wear rate of 0.11 mm/year (95% CI: 0.05; 0.1) with no statistically significant difference (p=0.08). Linear regression of PE wear rate neither correlated with cup proximal translation or with cup sagittal rotation at the 2- and 5-year follow-up nor with anteversion and inclination angle of the shell (slope<0.3, p>0.12).

Table 10 Mean (95%CI) wear measures in 1, 2 and 3 dimensions (7).

	Bedding-in	Femoral head penetration	Wear rate (annual)
Proximal (mm)	0.08 (0.02; 0.13)	0.08 (0.03; 0.14)	0.01 (-0.01; 0.02)
2D (mm)	0.18 (0.12; 0.25)	0.20 (0.13; 0.26)	0.05 (0.03; 0.06)
3D (mm)	0.30 (0.21; 0.38)	0.32 (0.24; 0.40)	0.07 (0.05; 0.10)

Bedding-in: postop to 1-year, femoral head penetration: postop to endpoint, and wear rate: 1-year to endpoint, CR: Coefficient of repeatability.

Radiographic evaluation of the final follow-up showed three patients with radiolucent lines > 1 mm in zone one or two. All radiolucent lines > 1 mm were reduced or unchanged compared to baseline evaluation. Two patients had radiolucent lines of 0.5 mm in zone one. One was reduced from 0.75 mm at baseline and one was not seen for baseline evaluation. No patients had sign of osteolysis at final follow-up.

Clinical outcomes

OHS increased from mean 21 (range: 4; 39) at baseline to mean 40 (range: 9; 48) at the 2-year follow-up and mean 43 (range: 25; 48) at the 5-year follow-up, which exceeded the minimal important difference of 10 points. The overall questionnaire response rate was 84 %.

One patient received revision shortly after the 2-year follow-up to correct for offset (-4 corrected to 0). During the 5-year period, there were no incidents of dislocation or aseptic implant loosening.

7. Discussion

Key findings

Study I demonstrated the feasibility of a CMC model that combined registration of the femoral head with markers inserted in the PE liner, and a hybrid markers model that combined the CMC model with the theoretical marker position in the PE.

Study II showed that the polyethylene liners in dual mobility hip prostheses move i*n vivo* at 1-year follow-up, but with great variation between patients. In the large articulation, liner anteversion was initiated by contact with the femoral neck, whereas liner rotation and inclination were not associated with liner/neck contact.

Study III showed 1) low 3D PE wear rates with no association with BMI, age, operation indication, femoral head material (ceramics/metal) and cup position and 2) higher early cup proximal translation and sagittal rotation in patients with osteoporosis with stabilization of all cups after 1 year, but no difference in cup migration for patients with osteoarthrosis versus other indications for THA.

CMC and hybrid model

Study I and II are the first studies to combine the femoral head with liner markers to construct the CMC model. Furthermore, the combination of measured and theoretical marker positions has not previously been reported in the literature. Other studies have combined models to increase precision or, like in this thesis, to make analysis possible. In a study of 52 hips, Nebergall et al. used liner markers and contour models of the metal shell to estimate the proximal migration of the PE towards the shell. Since this non-articulating connexion was stable, they found is safe to combine the shell and liner markers into one model. Like with the CMC model, they presumed that the two parts of the implant could in fact be considered as one rigid body. Nebergall et al. even had the technical opportunity to estimate the movement between the two parts. This was not possible in Studies I and II since the liner model was incomplete without the femoral head. Other model types have been improved by joining them. Prins et al. showed that a model combined of femoral head and femoral stem added a significant increase in precision of measuring the rotation of the femoral stem about the longitudinal femur axis when compared to EGS model and CAD model methods (148). In a study of femoral head penetration in particularly difficult cases, Johanson et al. combined the femoral head and the markers representing the femoral stem in one recording in order to measure the head position indirectly in another recording when in fact the head was obscured (149). In this case of combined models, the combination allowed for otherwise impossible wear analysis. Even though the technique differed from that of the CMC model, the clinical goal of measuring obscured implants by utilizing and combining the available information in the RSA recording was the same as in Study I and II.

Liner movement

Studies I and II showed liner movement in a phantom in contact with / pushed by the femoral neck. It was also evident that liners would move *in vivo* when the hip joint approached end range of movement, if the liner/neck angle was high enough. Further, the observed relationship between liner/neck and liner/cup angles supports that most movement in the ADM cup takes place in the small articulation between the femoral head and the liner, whereas movement in the large articulation between the liner and the cup is much smaller in magnitude. Together, these findings are in support of the biomechanical rationale behind the DM cup and confirm the clinical function, namely that the liner moves in end-range with contact between the femoral neck and liner (27). From baseline to the 1-year recording, the liner moved towards a position of median 59 inclination and 10 anteversion. Fabry et al. published a phantom experiment of a DM cup (Exclusif, ATF, Marignier, France) THA with continuous gait cycles and found that liners moved from a neutral position towards inclination of 60 and anteversion of 24 (150). Seemingly, they found inclination values very close to those of study II and anteversion values a bit higher. No clinical studies of DM liner movement have been published.

Cup migration

Study III showed that cup migration mainly occurred within the first year and that the migration pattern stabilised until the 5-year follow-up. The 2-year proximal cup migration of 0.28 mm was just above the 2 mm threshold for safe cups (2).

Studies on ADM cups with a similar composition in the cohort were difficult to locate in the literature, but Laende et al. reported 0.18 mm 2-year proximal migration for the same cup type (ADM) in younger patients (mean 63 years) (151). The difference is likely due to selection of the patients. Study III included the patients in the target group for dual mobility THA, older patients with osteoporosis and patients with a mix of THA indications including primary osteoarthrosis, hip fracture, osteonecrosis and revision THA, whereas Laende et al. studied patients without osteoporosis or osteopenia and accepted a range of exclusion criteria.

In another study, Tabori-Jensen et al. reported 2-year proximal migration of the cementless Avantage dual mobility cup in a cohort more similar to that of Study III. In patients with mean age of 75 year and a BMD similar to that of patients in Study III, they found proximal cup migration of 0.09 mm.

The sagittal rotation of 0.23 (95% CI: -0.22; 0.68) was similar to the 0.21 reported by Laende et al. but higher than the –0.01 reported by Tabori-Jensen et al. (151,152).

Importantly, cup migration stabilised in all patients 1 year after surgery despite the variation in BMD and indications for operation. Since dual mobility cups are used to protect against dislocation in patients with various indications for THA, it is important that the cup stabilises in these patients too.

PE wear

Linear PE wear rates have frequently been reported to be similar for both smaller and larger femoral head size, but the volumetric wear of larger heads is increased compared with that of smaller heads (153-155). In DM constructs, direct measurement and mathematical estimations of volumetric wear is challenging because the two articulations have different sizes. However, since most of the movement happens in the smaller articulation, volumetric wear of the smaller rather than the larger articulation seems most important for DM cups (6).

Study III investigated associations between PE wear and femoral head material, cup orientation, body weight and age. The femoral heads produced for ADM are either made of cobaltcobalt chromium or ceramic (biolox). In surgery, the femoral head has to be from the same manufacturer as the stem for a non-problematic trunnion assembly. Although not recommended by manufacturers, any 28 mm femoral head may fit in the same size polyethylene. The cohort of Study III included patients with different indications for DM THA (only ADMs used) wherefore femoral stems/heads were different. We made an overall comparison of PE wear with ceramic heads versus any metal head, but found no difference. Other studies have shown reduced PE wear with ceramic heads in older PE materials, but this difference seems difficult to reproduce for HXLPE (156-162).

Cup orientation has been reported to affect the PE wear in SM THA, though not consistently so (163,164). In an experimental study, Loving et al. showed that the DM cup design protected against high inclination angles (165). However, this observation lacks clinical support in the literature. The mean cup inclination of 43 presented in Study III was close to the 40 safe position suggested by Lewinneck et al. (130).

Deckard et al. showed higher linear PE wear rate of 0.27 mm/year in a clinical study of an X3 DM construct (MDM, Stryker) than the 0.05 mm/year found in with Study III (166). Deckard et al. also reported a mean cup inclination angle of 54.6 , which could indicate an association between high cup inclination angles and PE wear.

Multiple patient factors have been associated with higher PE wear. Digas et al. reported that PE wear increased with increasing body weight and with decreasing age (167). In a DM explant study, Boyer et al. showed that younger patients had more PE wear (168). In Study III, we did not find an association between BMI, age and PE wear.

Studies supporting low long-term wear rates of the X3 liner material has been presented for single mobility THA (169-171). Laende et al. studied PE wear of the X3 liner in the ADM cup until the 3-year follow-up and found a 3D wear rate of 0.09 mm/year, which is comparable to the 0.07 mm/year in the present study. They also concluded that most of the femoral head penetration took place in the bedding-in period before the 1-year follow-up, which is also supported in Study III (151).

Dislocation

Although the DM cup is known to reduce the risk of dislocation, reports of dislocations with this design do exist, with the majority in the early postoperative period (172). The studies in this thesis found no dislocations in 16 patients with a 1-year follow-up and 44 patients with up to 5 years of follow-up. Since our cohort included all patients, we would assume that the dislocation rate was comparable to those reported in arthroplasty registries. Using the Nordic Arthroplasty Register Association, Kreipke et al. investigated patients operated with THA for osteoarthritis and found a hazard ratio of 0.09 for revision due to dislocation in DM compared with SM THA in a population-based study of 2 277 hips (173). Using the same registry, Jobory et al. investigated 9 040 patients operated with THA for femoral neck fracture and found a reduced risk of revision for dislocation for DM compared with SM THA (hazard ratio: 0.45) (174). Using the Australian Orthopaedic Association National Joint Replacement Registry, Hoskins et al. investigated 16 692 patients operated with THA for femoral neck fracture and also found a lower risk of revision due to dislocation for the DM cup than for the SM THA for the first 3 months after THA surgery (hazard ratio: 0.3) although not after 3 months (175). Using the Dutch Arthroplasty Register, Bloemhuevel et al. investigated 215 953 patients operated with THA for any reason and found a 0.2% revision rate for dislocation in patients with DM THA vs. 0.5% in patients with SM THA. Thus, although DM THA protects against dislocation as compared with SM THA, the risk of dislocation and revision due to dislocation is higher in the large registry reports when the indication is hip fracture as compared to osteoarthritis. As dislocation is a rare phenomenon with DM THA, regardless of the indication for hip replacement, it is not unusual that we did not see any dislocations among the small patient cohorts in Study II and Study III on a mixed indication cohort that included patients with femoral neck fracture and THA revision.

Oxford Hip Score

In Study III, preoperative and postoperative hip status was described from the patient's perspective using the OHS. At 2-year follow-up, the mean score was 40, and at 5-year follow-up it was 43 points, which was slightly above the levels (40 points) reported for patients aged 30 to 80 years in the Danish Hip Registry (176). Hip status was also similar to the combined value of 42.5 points for Canadians and Australians aged 70 to 79 years, as reported by McLean et al. (177). The general patient accepted level for hip symptoms after THA surgery has been estimated to 42 points on OHS (178).

Indications and contraindications for DM THA

Factors outside the patient like implant, surgery technique, and cup position affect the risk of dislocation. But also factors within the patient may increase the risk of dislocation. Therefore, the indications for DM THA are many. In Study II, we included a young active cohort of patients with osteoarthritis and without osteoporosis or neuromuscular diseases. This group was contrasted with the patient cohort in Study III, which consisted of older patients in the sense that no exclusion criteria were applied at all, in accordance with the guideline for primary and secondary indications for DM THA from the Hip Section at Aarhus University Hospital, which outlines the complex aetiology of dislocation.

According to the manufacturer's manual for the ADM cup, the European and Australian indications for using ADM in THA are: noninflammatory degenerative joint disease including osteoarthritis and avascular necrosis, correction of functional deformity and dislocation risk (179). In France, DM THA has been used for all types of THA patients since year 2000. Puch et al. published a 13.9 years of follow-up study comparing patients <55 years and >55 years receiving DM THA with a, survival was 96% for failures of all causes for cup and stem in the young group, with no difference compared with patients above 55 years (180).

In New York, Rowan et al. published a 3 years follow-up of a cohort of 136 patients <55 years with the DM THA (ADM and MDM, Stryker) in comparison with a matched group of SM THA, and found no dislocations in the DM THA group, as opposed to seven dislocations and two cup revisions in the SM THA group. This is supported in the literature, where DM cups have proven successful in reducing instability and dislocation in primary and revision surgery (13,14,141-144,150,173,181-199). Femoral neck fracture has consistently been found to increase the risk of dislocation. Hailer et al. found an adjusted relative risk of 3.9 for THA dislocation in patients with femoral neck fracture (20). In the Australian Orthopaedic Association National Joint Replacement Registry, Hoskins et al. found no difference in revisions due to dislocation between DM and SM THA after 3 months. This is in contrast to findings in the Nordic Arthroplasty Register Association by Jabory et al., who found a decreased dislocation risk for the DM cup. Even after matching the groups on age, gender, fixation and year of surgery, Jabory found an unadjusted mortality hazard ratio of 1.49 for the DM cup (174). This suggests that even when matched on age and gender, DM patients are likely more fragile than SM THA patients in general. This may explain the similar dislocation rates in the Australian Orthopaedic Association National Joint Replacement Registry after 3 months.

Methodological considerations and limitations

Patient position and movement

In Studies I and II, recording of a hip movement was subject to the following considerations: it should fit in the recording area, include the end-range movement of the hip joint, be clinically relevant, be reproducible, include weight bearing and not result in compromised image quality. Studies of knee kinematics have been performed using a step-up motion (73). This was not feasible for recording of the hip joint due to large hip movements during exercise outside of the recording area. Instead, a bicycle motion was considered (75). This would be clinically relevant and would allow the hip joint to remain in the same area of recording. Unfortunately, it would not include end-range hip movement, and cycling would likely complicate RSA recording and analysis with a saddle very close to the hip joint. Gait was also considered (69). This would certainly be clinically relevant but again, it would not provide the wanted end-range movement. Inspired by another RSA hip study, a FADIR/FABER movement was considered (70). This would provide end-range movement while keeping the hip joint within the area of recording. While lacking the relevance of everyday movement, the FADIR would also be clinically relevant since combined flexion, adduction and internal rotation is thought to trigger posterior hip dislocation. Unfortunately, the FADIR/FABER movement resulted in too much soft tissue and implant overlap. To reduce this overlap, the FADIR/FABER movement was modified with a flexion stop at 45 . Although this movement was neither weight bearing nor a natural everyday movement, it was clinically relevant and reproducible, while providing the best possible image quality.

In Studies II and III, patients were placed in a supine position for sRSA. Standing recording could potentially have caused the liner to move into another position and perhaps reveal a different measure of wear. However, Madanat et al. found differences caused by patient position to be very small, and standing recordings introduce other difficulties like postoperative pain and soft tissue overlay, leading to poor image quality (52,200).

RSA setup

The dynamic RSA recordings were carried out at a 45 angle relative to the frontal plane with the patient positioned at the very edge of the examination table. This setup had some disadvantages. Firstly, the 45 angle meant that patients with excess body fat tended to have too much soft tissue overlay, which challenged image quality. The problem was somewhat minimised by using a supine patient position as opposed to a standing RSA recording which would have added more stomach tissue in the recording. Secondly, the setup needed special equipment namely footrests because of the patient's caudal position on the examination bed and furthermore a special stand for the 45 position of the calibration box was built. The advantage of the 45 setup was that an optimal angle was obtained on both the femur and the ADM construct while avoiding most soft tissue from the thigh and stomach.

Dynamic and static RSA of the dual mobility liner

dRSA was chosen to evaluate DM liner movement owing to its high precision and the dynamic nature of liner movement. From a clinical point of view, a drawback of dRSA was that patient movement was restricted to the frame of recording. From a technical perspective, the timeframe available in dRSA is also somewhat limited due to radiation dose and system overheating. Therefore, dRSA is not the best tool with which to measure the effect of a series of repeated movements over time. Also, low shutter times and current had to balance in order to obtain optimal image quality. However, the biggest obstacle was the image analysis that was both difficult and time consuming. The strength of the dynamic recordings lies in the detailed knowledge of how and when the liner moved relative to the stem and cup. On the practical side, the dynamic recording provided small steps of liner movement that allowed for easier tracking of the liner markers. Without predictable liner marker movements, generation of the CMC model would have been more difficult.

Liner movement after 1 year was investigated using sRSA. Liner movement showed a tendency towards inclination from the postoperative to the 1-year follow-up. The technical challenge was that the liner rotated freely, and the detection of the liner markers therefore needed a complete model to cover all possible rotations. The main clinical challenge was the lack of knowledge of liner movement during the year between recordings.

sRSA and dRSA provide different but valuable information about liner movement, and the challenge is to choose the modality optimally fitting the clinical goal.

Strengths and weaknesses of marker models

The MC model was developed to overcome the issue of occluded markers. The MC model has been shown to provide meaningful precision even in analysis that would normally be discarded (47). Marker placement using templates has been shown to be very good and subsequent use of the expected marker position has yielded high precision (54). The CMC model and hybrid models used in this thesis allowed us to develop the concept and expand the use of marker models; firstly, by routinely including more than one RSA frame; secondly, by issuing the femoral head as a marker; and lastly, by combining measured and theoretical marker positions.

CN and RBE

The use of MC and CMC theoretical models and hybrid models also means that RBE and CN are lost as guidelines. RBE is usually calculated for each marker in a frame to make sure that the marker position has not changed relative to that of the reference frame (45). In the mbRSA software, this is done automatically, and any marker that changes relative position over the threshold of 0.35 mm is excluded from the analysis. This is not the case for marker models. The fitting error may increase with migrating markers, but can also do so for other reasons. Therefore, the marker models may not be the best choice if marker migration (loose markers) is expected. The CN is a good measure of the distribution of markers. Normally, CN is calculated for each frame or follow-up to ensure that the same markers are present in all analyses and that they present a distribution sufficient for analysis (45). When marker models are used, CN calculation is not possible since marker models can use single projections of multiple markers. The CN of the marker model is the CN of the complete marker model and not an expression of the marker distribution in the frame. During dynamic RSA recordings, marker migration was not expected between the frames. Also, with relatively large movements, a loss of precision due to low CN can be tolerated better than in conventional migration and wear studies.

Theoretical marker positions

In some studies, the marker positions are known from the preoperative planning. The use of a drill guide has shown to be effective in placing markers in predefined positions (54). With the use of known marker positions comes the option of using the theoretical marker position for the marker model. This method provides a complete and precise model that can be directly applied to the RSA analysis. The weakness of this approach is that the theoretical marker model assumes correct marker placement and no marker migration. This is worth noting as the RBE does not apply to marker models, and migration or misplacement of markers can be detected only by visual control and model fitting. Depending on the setup, marker positions may also vary with manufacturing tolerance in the PE, which would displace the liner markers relative to the femoral head.

The CMC model

The CMC model combines marker information from multiple RSA frames and can be seen as an expanded MC model. The method presupposes no prior knowledge of the marker position and can be applied to any marker configuration in RSA. The CMC model also has weaknesses. Firstly, it includes the error of marker measurements. This error will to some extent be reduced because the method issues the mean marker positions. Furthermore, the error can be monitored using the distribution of each marker in the calculation of the final model. Secondly, the CMC model can only include markers that are projected in both radiographs of at least one of the frames of the model. This means that markers with fewer than two projections in the frames used for the model will not be represented in the final model. Lastly, each frame used for the marker needs to have three common markers. This problem was addressed using the femoral head as a marker in the CMC model.

The femoral head has previously been used to increase the precision of stem orientation, and the stem has been used to support the position of the femoral head assuming negligible micromotions in the trunnion between the two "assembled rigid bodies" (148,149). The CMC model includes the femoral head as a (large) marker. This would normally not be advisable since the liner and the femoral head do not belong to the same rigid body. The challenge in this set-up is the presence of potential micromotions and subluxation of the femoral head in the liner. The ADM construct captures the femoral head in the liner, which will normally ensure that subluxation does not take place. On the other hand, micromotion may occur between the femoral head and the liner during bedding-in and PE wear. Micromotions could result in variation of model fitting between frames, which again would lead to increased spread of the marker representations. The CMC model uses the mean marker position, which means that variation from micromotion and measurement errors will be reduced when constructing the model. The variation of marker position may be unimportant in the light of the large movements of the dynamic liner. Furthermore, the error in the distribution of each marker position can be examined. Both the phantom and the patient showed low standard deviations of the head position, indicating that femoral head micromotions were negligible.

The femoral head is usually visible in RSA with PE liners, and the inclusion of the femoral head as a known point centred in the liner provides valuable and consistent information enabling even very difficult analysis. The femoral head also provides a point of origin for the CMC model that is the centre of rotation.

Hybrid model

The hybrid model combines theoretical and measured marker positions and shares the strengths and drawbacks of both methods. The CMC model carries marker measurement error and the theoretical marker model involves marker placement and migration error. The CMC model can be applied without prior knowledge of marker positions and has the ability to include the femoral head, whereas the theoretical model is very easily obtainable. As a result, the hybrid model may be vulnerable to marker placement error and migration as well as to measurement error and femoral head micromotions. At the same time, the hybrid marker model is complete, includes the femoral head and is robust to migrating markers for the measured markers of the model.

The radiographic coordinate system

The radiographic coordinate system was chosen over other coordinate systems like the calibrations box system and an anatomical coordinate system. The limitation of the radiographic coordinate system is that it does not use the anatomical terms for movement. The calibration box coordinate system was abandoned due to its lack of clinical meaningfulness. The anatomical coordinate system was appealing owing to its clinical relevance, but it was difficult to define correct axes with the limited view. Furthermore, the anatomical coordinate system was found to be less transparent when used in complex movements. Therefore, the radiographic coordinate system was the best choice for a clinically meaningful and generic coordinate system. The radiographic coordinate system was described in 1993 by Murray and has been discussed in more than 200 scientific works on cup position (88,201).

Because of the patients' movements during the dynamic recordings, we needed a coordinate system that remained stable irrespective of patient movements. Therefore, the coordinate system was aligned with the first frame using the cup orientation as a reference point. The result was a coordinate system yielding uniform outputs based on patient-oriented coordinates.

Generalizability

Patients

The patients in Study II were selected with a view to minimise the effect of age and a range of comorbidities. Therefore, the liner may be more or less prone to movement in other populations. Patients could have increased production of scar tissue or increased risk of ossification in which case the risk of liner blockage may increase, reducing liner movement. On the other hand, patients with larger ranges of hip movement will likely stimulate more liner movement as a result of liner/neck contact.

The patients in Study III were older and unselected. This will effectively mean that they are likely representative of patients operated with DM in Denmark in daily practice. On the other hand, they will differ from French DM patients since DM is used more frequently in France, where patients undergoing this procedure may be younger and have fewer comorbidities. Whereas in Denmark the concept is primarily used for patients at risk of dislocation. This could result in a different use of the implant and a different wear response. Also, younger patients would likely have higher BMD resulting in better implant fixation.

Implants, migration and PE wear

The mechanical principles used in the DM implant are very alike between manufacturers. Therefore, other DM implants may find the same patterns of liner movement as those presented in Study II. Still, some factors must be considered: 1)

The ADM construct is a concentric design. Constructs with eccentric designs will likely have different movement patterns. 2) Designs with a higher liner wall (smaller opening angle) will produce earlier liner/neck contact resulting in more movement in the large articulation and vice versa. 3) Increased friction in the smaller articulation due to the tribology of the materials could shift the movement from the small articulation to the large articulation.

PE wear measured in Study III is likely to representative of the PE wear in other DM liners of the same type (X3) implants. Given the importance of the production methods of PE, other manufacturing and sterilization methods may yield different results regarding wear.

Migration of the cup was likely affected by the low BMD in the study population. Therefore, younger patients will likely experience have less migration with the ADM construct.

Methods

The method of combining marker positions using a series of images can be applied to any other marker configuration in which alternating markers are occluded. However, it is important to check for migrating markers and to inspect the spatial distribution of marker representation within the mean model.

The CMC model including the femoral head can be applied to other hip implants provided that the translation of the femoral head is minimal.

The hybrid model combining marker information from measured and theoretical markers can be applied in any marker configuration where prior knowledge of marker positions can be combined with measured markers to deploy all information from both images of the RSA recording.

8. Conclusion

Study I showed that PE liner motion in dual mobility hip prosthesis could be assessed using dynamic RSA recordings with CMC models reconstructed from marker positions in multiple RSA recordings. The liner movements were unpredictable from baseline to 1-year follow-up, and analysis required that all markers were included in the PE liner model. This was accomplished with a hybrid marker model that combined both the registered positions of visible markers and the theoretical positions of occluded markers. The method was developed specifically to enable analysis of a mobile PE liner in a dual mobility cup, but the concept can be applied in any static or dynamic RSA analysis complicated by altering marker visibility on successive frames.

Study II was the first clinical study to show that dual mobility liners move *in vivo*. There was a similar pattern across patients, but the extent of liner movements varied much. Liner motion was stimulated at end-range of the hip motion, with or without contact with the neck, and most of the movement occurred in the small articulation.

Study III: Despite an unselected patient group, there were no THA dislocations, no cases with clinical cup loosening and all patients had a stable 3D PE wear rate and proximal implant migration. The results support the use of this implant, also for the older and frail population.

9. Perspectives and future research

Research and technical possibilities

The development of the CMC and hybrid models as well as the generation of the patient-specific models was feasible, but also time consuming. PE manufactured with markers and fitting model could reduce the time and effort needed in future studies of liner movement. Until such PE becomes available, the CMC and hybrid markers may aid future research of PE movement in dRSA.

With the CMC and hybrid models, *in vivo* liner movements can be tracked, and the next big step in understanding the functional mechanics of the DM liner will be to solve the problem of tracking everyday movements. Developments in mobile RSA systems will likely pave the way towards such research.

Clinical perspectives

The effect of the anatomical shape of the ADM shell has not been described in this thesis. We are currently investigating this in a randomized setup comparing the ADM construct with a DM THA. In the same randomised study, objective activity data are collected to obtain a better understanding of the effects of activity in relation to wear and implant migration.

Although recent advances in THA have reduced the risk of dislocation considerably, patients are still asked to avoid adduction, internal rotation and flexion at many hospitals. It would be relevant to investigate if these restrictions are beneficial for DM patients. Maybe they should not be asked to restrict their movements, but rather seek to maintain the range of movement to avoid liner blockage and ensure free liner movement.

10. References

1. Nebergall AK, Rader K, Palm H, et al. Precision of radiostereometric analysis (RSA) of acetabular cup stability and polyethylene wear improved by adding tantalum beads to the liner. Acta Orthop 2015;86:563-568. DOI: 10.3109/17453674.2015.1054255.
2. Pijls BG, Nieuwenhuijse MJ, Fiocco M, 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;83:583-591. DOI: 10.3109/17453674.2012.745353.
3. Serf. Novae produktepalette.
4. Prudhon J-L, Ferreira A, Verdier R. Dual mobility cup: dislocation rate and survivorship at ten years of follow-up. Int Orthop 2013;37:2345-2350. DOI: 10.1007/s00264-013-2067-2.
5. Jørgensen PB, Kaptein BL, Søballe K, et al. Feasibility of combined and hybrid marker models for radiostereometry assessment of polyethylene liner motion in dual mobility hip prosthesis. Manuscript submitted for publication 2021.
6. Jørgensen PB, Kaptein BL, Søballe K, et al. Polyethylene liner motion in dual mobility hip prostheses measured with static and dynamic RSA one year after operation. Submitted for publication 2021.
7. Jørgensen PB, Kaptein BL, Søballe K, et al. Five-year polyethylene cup migration and PE wear of the anatomic dual mobility acetabular construct. Submitted for publication 2021.
8. Langlois J, El Hage S, Hamadouche M. Intraprosthetic dislocation: a potentially serious complication of dual mobility acetabular cups. Skeletal Radiol 2014;43:1013-1016. DOI: 10.1007/s00256-014-1824-7.
9. Johnson DSJ. SURGICAL TECHNIQUE of the GYROS Mobile Bearing Cup. 2010.
10. Caton JH, Ferreira A. Dual-mobility cup: a new French revolution. Int Orthop 2017;41:433-437. DOI: 10.1007/s00264-017-3420-7.
11. Valstar ER, Nelissen RGHH, Reiber JHC, et al. The use of Roentgen stereophotogrammetry to study micromotion of orthopaedic implants. ISPRS Journal of Photogrammetry and Remote Sensing 2002;56:376-389. DOI: 10.1016/s0924-2716(02)00064-3.
12. Stryker. MDM Surgical technique.
13. Young JR, O'Connor CM, Anoushiravani AA, et al. The Use of Dual Mobility Implants in Patients Who Are at High Risk for Dislocation After Primary Total Hip Arthroplasty. JBJS Reviews 2020;8.
14. Hailer NP, Weiss RJ, Stark A, et al. Dual-mobility cups for revision due to instability are associated with a low rate of re-revisions due to dislocation: 228 patients from the Swedish Hip Arthroplasty Register. Acta Orthop 2012;83:566-571. DOI: 10.3109/17453674.2012.742395.
15. Mufarrih SH, Ghani MOA, Martins RS, et al. Effect of hospital volume on outcomes of total hip arthroplasty: a systematic review and meta-analysis. J Orthop Surg Res 2019;14:468-468. DOI: 10.1186/s13018-019-1531-0.
16. DHR TDHAR. National Annual Report. 2020.
17. Wroblewski BM, Siney PD, Fleming PA. The Charnley hip replacement -- 43 years of clinical success. Acta Chir Orthop Traumatol Cech 2006;73:6-9.
18. Learmonth ID, Young C, Rorabeck C. The operation of the century: total hip replacement. The Lancet 2007;370:1508-1519. DOI: https://doi.org/10.1016/S0140-6736(07)60457-7.
19. Singh JA, Chen J, Inacio MC, et al. An underlying diagnosis of osteonecrosis of bone is associated with worse outcomes than osteoarthritis after total hip arthroplasty. BMC Musculoskelet Disord 2017;18:8. DOI: 10.1186/s12891-016-1385-0.
20. Hailer NP, Weiss RJ, Stark A, et al. The risk of revision due to dislocation after total hip arthroplasty depends on surgical approach, femoral head size, sex, and primary diagnosis. An analysis of 78,098 operations in the Swedish Hip Arthroplasty Register. Acta Orthop 2012;83:442-448. DOI: 10.3109/17453674.2012.733919.
21. Bedard NA, DeMik DE, Dowdle SB, et al. Does Preoperative Opioid Use Increase the Risk of Early Revision Total Hip Arthroplasty? J Arthroplasty 2018;33:S154-S156. DOI: 10.1016/j.arth.2018.01.018.

22. Maradit Kremers H, Schleck CD, Lewallen EA, et al. Diabetes Mellitus and Hyperglycemia and the Risk of Aseptic Loosening in Total Joint Arthroplasty. J Arthroplasty 2017;32:S251-S253. DOI: 10.1016/j.arth.2017.02.056.
23. Paxton EW, Inacio MC, Khatod M, et al. Risk calculators predict failures of knee and hip arthroplasties: findings from a large health maintenance organization. Clin Orthop Relat Res 2015;473:3965-3973. DOI: 10.1007/s11999-015-4506-4.
24. AOANJRR. Hip, Knee & Shoulder Arthroplasty: 2020 Annual Report. 2020.
25. Evans JT, Evans JP, Walker RW, et al. How long does a hip replacement last? A systematic review and meta-analysis of case series and national registry reports with more than 15 years of follow-up. The Lancet 2019;393:647-654. DOI: 10.1016/S0140-6736(18)31665-9.
26. Charnley J. ARTHROPLASTY OF THE HIP: A New Operation. The Lancet 1961;277:1129-1132. DOI: https://doi.org/10.1016/S0140-6736(61)92063-3.
27. Noyer D, Caton JH. Once upon a time.... Dual mobility: history. Int Orthop 2017;41:611-618. DOI: 10.1007/s00264-016-3361-6.
28. Guyen O, Chen QS, Bejui-Hugues J, et al. Unconstrained tripolar hip implants: effect on hip stability. Clin Orthop Relat Res 2007;455:202-208. DOI: 10.1097/01.blo.0000238796.59596.1f.
29. Christiansen T. A new hip prosthesis with trunnion-bearing. Acta Chir Scand 1969;135:43-46.
30. Bartelt RB, Yuan BJ, Trousdale RT, et al. The prevalence of groin pain after metal-on-metal total hip arthroplasty and total hip resurfacing. Clin Orthop Relat Res 2010;468:2346-2356. DOI: 10.1007/s11999-010-1356-y.
31. Bin Nasser A, Beaulé PE, O'Neill M, et al. Incidence of groin pain after metal-on-metal hip resurfacing. Clin Orthop Relat Res 2010;468:392-399. DOI: 10.1007/s11999-009-1133-y.
32. Ueno T, Kabata T, Kajino Y, et al. Risk Factors and Cup Protrusion Thresholds for Symptomatic Iliopsoas Impingement After Total Hip Arthroplasty: A Retrospective Case-Control Study. The Journal of Arthroplasty 2018;33:3288-3296.e3281. DOI: https://doi.org/10.1016/j.arth.2018.05.017.
33. Janse AJ, Gemke RJ, Uiterwaal CS, et al. Quality of life: patients and doctors don't always agree: a meta-analysis. J Clin Epidemiol 2004;57:653-661. DOI: 10.1016/j.jclinepi.2003.11.013.
34. Mahomed NN, Arndt DC, McGrory BJ, et al. The Harris hip score: comparison of patient self-report with surgeon assessment. J Arthroplasty 2001;16:575-580. DOI: 10.1054/arth.2001.23716.
35. Wittrup-Jensen KU, Lauridsen J, Gudex C, et al. Generation of a Danish TTO value set for EQ-5D health states. Scand J Public Health 2009;37:459-466. DOI: 10.1177/1403494809105287.
36. Ware JE, Jr. SF-36 health survey update. Spine (Phila Pa 1976) 2000;25:3130-3139. DOI: 10.1097/00007632-200012150-00008.
37. Rolfson O, Bohm E, Franklin P, et al. Patient-reported outcome measures in arthroplasty registries Report of the Patient-Reported Outcome Measures Working Group of the International Society of Arthroplasty Registries Part II. Recommendations for selection, administration, and analysis. Acta Orthop 2016;87 Suppl 1:9-23. DOI: 10.1080/17453674.2016.1181816.
38. Bellamy N, Buchanan WW, Goldsmith CH, et al. Validation study of WOMAC: a health status instrument for measuring clinically important patient relevant outcomes to antirheumatic drug therapy in patients with osteoarthritis of the hip or knee. J Rheumatol 1988;15:1833-1840.
39. Nilsdotter AK, Lohmander LS, Klassbo M, et al. Hip disability and osteoarthritis outcome score (HOOS)--validity and responsiveness in total hip replacement. BMC Musculoskelet Disord 2003;4:10. DOI: 10.1186/1471-2474-4-10.
40. Thorborg K, Holmich P, Christensen R, et al. The Copenhagen Hip and Groin Outcome Score (HAGOS): development and validation according to the COSMIN checklist. Br J Sports Med 2011;45:478-491. DOI: 10.1136/bjsm.2010.080937.
41. Beard DJ, Harris K, Dawson J, et al. Meaningful changes for the Oxford hip and knee scores after joint replacement surgery. J Clin Epidemiol 2015;68:73-79. DOI: 10.1016/j.jclinepi.2014.08.009.
42. Murray DW, Fitzpatrick R, Rogers K, et al. The use of the Oxford hip and knee scores. J Bone Joint Surg Br 2007;89:1010-1014. DOI: 10.1302/0301-620X.89B8.19424.
43. Selvik G. Roentgen stereophotogrammetry. A method for the study of the kinematics of the skeletal system. Acta Orthop Scand Suppl 1989;232:1-51. DOI: 10.3109/17453678909154184.
44. Baldursson H, Egund N, Hansson LI, et al. Instability and wear of total hip prostheses determined with roentgen stereophotogrammetry. Arch Orthop Trauma Surg 1979;95:257-263. DOI: 10.1007/bf00389695.

45. Valstar ER, Gill R, Ryd L, et al. Guidelines for standardization of radiostereometry (RSA) of implants. Acta Orthop 2005;76:563-572. DOI: 10.1080/17453670510041574.
46. 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;84:98-105. DOI: 10.3109/17453674.2013.765625.
47. Kaptein BL, Valstar ER, Stoel BC, et al. A new type of model-based Roentgen stereophotogrammetric analysis for solving the occluded marker problem. J Biomech 2005;38:2330-2334. DOI: 10.1016/j.jbiomech.2004.09.018.
48. Kaptein BL, Valstar ER, Spoor CW, et al. Model-based RSA of a femoral hip stem using surface and geometrical shape models. Clin Orthop Relat Res 2006;448:92-97. DOI: 10.1097/01.blo.0000224010.04551.14.
49. Kaptein BL, Valstar ER, Stoel BC, et al. A new model-based RSA method validated using CAD models and models from reversed engineering. J Biomech 2003;36:873-882. DOI: 10.1016/s0021-9290(03)00002-2.
50. Stentz-Olesen K, Nielsen ET, De Raedt S, et al. Validation of static and dynamic radiostereometric analysis of the knee joint using bone models from CT data. Bone & joint research 2017;6:376-384. DOI: 10.1302/2046-3758.66.BJR-2016-0113.R3.
51. Campbell DG, Field JR, Callary SA. Second-generation highly cross-linked X3™ polyethylene wear: a preliminary radiostereometric analysis study. Clin Orthop Relat Res 2010;468:2704-2709. DOI: 10.1007/s11999-010-1259-y.
52. Digas G, Kärrholm J, Thanner J, et al. Highly cross-linked polyethylene in cemented THA: randomized study of 61 hips. Clin Orthop Relat Res 2003:126-138. DOI: 10.1097/01.blo.0000096802.78689.45.
53. Karrholm J, Herberts P, Hultmark P, et al. Radiostereometry of hip prostheses. Review of methodology and clinical results. Clin Orthop Relat Res 1997:94-110.
54. Lam-Tin-Cheung K, Yuan X, Nikolov HN, et al. Marker-based technique for visualizing radiolucent implant components in radiographic imaging. J Orthop Res 2017;35:2017-2022. DOI: 10.1002/jor.23475.
55. Lindalen E, Nordsletten L, Rohrl 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;27:511-514. DOI: 10.1016/j.clinbiomech.2011.11.009.
56. Russo A, Bragonzoni L, Trozzi C, et al. Radiostereometric measurement of polyethylene deformation pattern in meniscal bearing TKR at 5 years follow-up. Knee Surg Sports Traumatol Arthrosc 2008;16:142-147. DOI: 10.1007/s00167-007-0429-2.
57. Ryd L, Lindstrand A, Stenstrom A, et al. Cold flow reduced by metal backing. An in vivo roentgen stereophotogrammetric analysis of unicompartmental tibial components. Acta Orthop Scand 1990;61:21-25. DOI: 10.3109/17453679008993058.
58. Zugner R, Tranberg R, Lisovskaja V, et al. Validation of gait analysis with dynamic radiostereometric analysis (RSA) in patients operated with total hip arthroplasty. J Orthop Res 2017;35:1515-1522. DOI: 10.1002/jor.23415.
59. Garling EH, Kaptein BL, Geleijns K, et al. Marker Configuration Model-Based Roentgen Fluoroscopic Analysis. J Biomech 2005;38:893-901. DOI: 10.1016/j.jbiomech.2004.04.026.
60. Kim YS, Abrahams JM, Callary SA, et al. Proximal translation of > 1 mm within the first two years of revision total hip arthroplasty correctly predicts whether or not an acetabular component is loose in 80% of cases: a case-control study with confirmed intra-operative outcomes. The bone & joint journal 2017;99-b:465-474. DOI: 10.1302/0301-620x.99b4.Bjj-2016-0805.R1.
61. Nieuwenhuijse MJ, Valstar ER, Kaptein BL, et al. 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;94:874-880. DOI: 10.2106/JBJS.K.00305.
62. Cai R, Yuan X, Rorabeck C, et al. Development of an RSA calibration system with improved accuracy and precision. J Biomech 2008;41:907-911. DOI: 10.1016/j.jbiomech.2007.11.012.
63. Lindgren L JP, Mørup RMS, Jensen M, Rømer L, Kaptein B, Stilling M. Similar patient positioning: A key factor in follow-up studies when using model-based radiostereometric analysis of the hip. Radiography 2019.

64. Bragdon CR, Estok DM, Malchau H, et al. Comparison of two digital radiostereometric analysis methods in the determination of femoral head penetration in a total hip replacement phantom. J Orthop Res 2004;22:659-664. DOI: 10.1016/j.orthres.2003.09.004.
65. Bragdon CR, Malchau H, Yuan X, et al. Experimental assessment of precision and accuracy of radiostereometric analysis for the determination of polyethylene wear in a total hip replacement model. J Orthop Res 2002;20:688-695. DOI: 10.1016/S0736-0266(01)00171-1.
66. Madanat R, Mäkinen TJ, Moritz N, et al. Accuracy and precision of radiostereometric analysis in the measurement of three-dimensional micromotion in a fracture model of the distal radius. J Orthop Res 2005;23:481-488. DOI: 10.1016/j.orthres.2004.07.002.
67. Onsten I, Berzins A, Shott S, et al. Accuracy and precision of radiostereometric analysis in the measurement of THR femoral component translations: human and canine in vitro models. J Orthop Res 2001;19:1162-1167. DOI: 10.1016/s0736-0266(01)00039-0.
68. Stilling M, Kold S, de Raedt S, et al. Superior accuracy of model-based radiostereometric analysis for measurement of polyethylene wear: A phantom study. Bone & joint research 2012;1:180-191. DOI: 10.1302/2046-3758.18.2000041.
69. Digas G, Johansson PE, Kärrholm J. Inducible displacements of the cup and the femoral head during active range of motion: dynamic RSA studies of cemented total hip replacements. J Orthop Res 2013;31:1686-1693. DOI: 10.1002/jor.22428.
70. Hansen L, de Raedt S, Jorgensen PB, et al. Dynamic radiostereometric analysis for evaluation of hip joint pathomechanics. Journal of experimental orthopaedics 2017;4:20. DOI: 10.1186/s40634-017-0096-2.
71. Bey MJ, Kline SK, Tashman S, et al. Accuracy of biplane x-ray imaging combined with model-based tracking for measuring in-vivo patellofemoral joint motion. J Orthop Surg Res 2008;3:38. DOI: 10.1186/1749-799X-3-38.
72. Tranberg R, Saari T, Zugner R, et al. Simultaneous measurements of knee motion using an optical tracking system and radiostereometric analysis (RSA). Acta Orthop 2011;82:171-176. DOI: 10.3109/17453674.2011.570675.
73. Horsager K, Kaptein BL, Romer L, et al. Dynamic RSA for the evaluation of inducible micromotion of Oxford UKA during step-up and step-down motion. Acta Orthop 2017;88:275-281. DOI: 10.1080/17453674.2016.1274592.
74. Stentz-Olesen K, Nielsen ET, De Raedt S, et al. Validation of static and dynamic radiostereometric analysis of the knee joint using bone models from CT data. Bone & joint research 2017;6:376-384. DOI: 10.1302/2046-3758.66.Bjr-2016-0113.R3.
75. Horsager K, Kaptein BL, Jorgensen PB, et al. Oxford medial unicompartmental knees display contact-loss during step-cycle motion and bicycle motion: A dynamic radiostereometric study. J Orthop Res 2018;36:357-364. DOI: 10.1002/jor.23625.
76. Nielsen ET, Stentz-Olesen K, de Raedt S, et al. Influence of the Anterolateral Ligament on Knee Laxity: A Biomechanical Cadaveric Study Measuring Knee Kinematics in 6 Degrees of Freedom Using Dynamic Radiostereometric Analysis. Orthopaedic journal of sports medicine 2018;6:2325967118789699. DOI: 10.1177/2325967118789699.
77. Bragonzoni L, Marcheggiani Muccioli GM, Bontempi M, et al. New design total knee arthroplasty shows medial pivoting movement under weight-bearing conditions. Knee Surg Sports Traumatol Arthrosc 2019;27:1049-1056. DOI: 10.1007/s00167-018-5243-5.
78. Bontempi M, Roberti di Sarsina T, Marcheggiani Muccioli GM, et al. J-curve design total knee arthroplasty: the posterior stabilized shows wider medial pivot compared to the cruciate retaining during chair raising. Knee Surg Sports Traumatol Arthrosc 2020;28:2883-2892. DOI: 10.1007/s00167-019-05645-6.
79. Cardinale U, Bragonzoni L, Bontempi M, et al. Knee kinematics after cruciate retaining highly congruent mobile bearing total knee arthroplasty: An in vivo dynamic RSA study. The Knee 2020;27:341-347. DOI: 10.1016/j.knee.2019.11.003.
80. Marcheggiani Muccioli GM, Pizza N, Di Paolo S, et al. Multi-radius posterior-stabilized mobile-bearing total knee arthroplasty partially produces in-vivo medial pivot during activity of daily living and high demanding motor task. Knee Surg Sports Traumatol Arthrosc 2020;28:3773-3779. DOI: 10.1007/s00167-020-05846-4.
81. Alesi D, Marcheggiani Muccioli GM, Roberti di Sarsina T, et al. In vivo femorotibial kinematics of medial-stabilized total knee arthroplasty correlates to post-operative clinical outcomes. Knee Surg Sports Traumatol Arthrosc 2021;29:491-497. DOI: 10.1007/s00167-020-05975-w.

82. Christensen R, Petersen ET, Jürgens-Lahnstein J, et al. Assessment of knee kinematics with dynamic radiostereometry: Validation of an automated model-based method of analysis using bone models. J Orthop Res 2021;39:597-608. DOI: 10.1002/jor.24875.
83. Pizza N, Di Paolo S, Zinno R, et al. Over-constrained kinematic of the medial compartment leads to lower clinical outcomes after total knee arthroplasty. Knee Surg Sports Traumatol Arthrosc 2021. DOI: 10.1007/s00167-020-06398-3.
84. Roberti di Sarsina T, Alesi D, Di Paolo S, et al. In vivo kinematic comparison between an ultra-congruent and a posterior-stabilized total knee arthroplasty design by RSA. Knee Surg Sports Traumatol Arthrosc 2021. DOI: 10.1007/s00167-021-06629-1.
85. Hansen L, de Raedt S, Jørgensen PB, et al. Dynamic radiostereometric analysis for evaluation of hip joint pathomechanics. Journal of experimental orthopaedics 2017;4:20. DOI: 10.1186/s40634-017-0096-2.
86. Hansen L, De Raedt S, Jørgensen PB, et al. Marker free model-based radiostereometric analysis for evaluation of hip joint kinematics: A validation study. Bone & joint research 2018;7:379-387. DOI: 10.1302/2046-3758.76.Bjr-2017-0268.R1.
87. Zügner R, Tranberg R, Lisovskaja V, et al. Validation of gait analysis with dynamic radiostereometric analysis (RSA) in patients operated with total hip arthroplasty. J Orthop Res 2017;35:1515-1522. DOI: 10.1002/jor.23415.
88. Murray DW. The definition and measurement of acetabular orientation. J Bone Joint Surg Br 1993;75:228-232. DOI: 10.1302/0301-620X.75B2.8444942.
89. Charnley J. TISSUE REACTIONS TO POLYTETRAFLUORETHYLENE. The Lancet 1963;282:1379. DOI: https://doi.org/10.1016/S0140-6736(63)90759-1.
90. Kaku N, Tagomori H, Akase H, et al. Efficacy of vitamin E for mechanical damage and oxidation of polyethylene rim by stem neck impingement. Clin Biomech (Bristol, Avon) 2019;68:8-15. DOI: 10.1016/j.clinbiomech.2019.05.024.
91. Bragdon CR, Doerner M, Martell J, et al. The 2012 John Charnley Award: Clinical multicenter studies of the wear performance of highly crosslinked remelted polyethylene in THA. Clin Orthop Relat Res 2013;471:393-402. DOI: 10.1007/s11999-012-2604-0.
92. Callary SA, Solomon LB, Holubowycz OT, et al. Wear of highly crosslinked polyethylene acetabular components. Acta Orthop 2015;86:159-168. DOI: 10.3109/17453674.2014.972890.
93. Dumbleton JH, D'Antonio JA, Manley MT, et al. The basis for a second-generation highly cross-linked UHMWPE. Clin Orthop Relat Res 2006;453:265-271. DOI: 10.1097/01.blo.0000238856.61862.7d.
94. Halley DK, Charnley J. Results of low friction arthroplasty in patients thirty years of age or younger. Clin Orthop Relat Res 1975:180-191.
95. Clarke JC, Black K, Rennie C, et al. Can wear in total hip arthroplasties be assessed from radiographs? Clin Orthop Relat Res 1976:126-142.
96. Devane PA, Bourne RB, Rorabeck CH, et al. Measurement of polyethylene wear in metal-backed acetabular cups. I. Three-dimensional technique. Clin Orthop Relat Res 1995:303-316.
97. Devane PA, Bourne RB, Rorabeck CH, et al. Measurement of polyethylene wear in metal-backed acetabular cups. II. Clinical application. Clin Orthop Relat Res 1995:317-326.
98. Martell JM, Berdia S. Determination of polyethylene wear in total hip replacements with use of digital radiographs. J Bone Joint Surg Am 1997;79:1635-1641. DOI: 10.2106/00004623-199711000-00004.
99. Hardinge K, Porter ML, Jones PR, et al. Measurement of hip prostheses using image analysis. The maxima hip technique. J Bone Joint Surg Br 1991;73:724-728. DOI: 10.1302/0301-620x.73b5.1894658.
100. Malchau H, Bragdon CR, Muratoglu OK. The stepwise introduction of innovation into orthopedic surgery: the next level of dilemmas. J Arthroplasty 2011;26:825-831. DOI: 10.1016/j.arth.2010.08.007.
101. Kärrholm J, Herberts P, Hultmark P, et al. Radiostereometry of hip prostheses. Review of methodology and clinical results. Clin Orthop Relat Res 1997:94-110.
102. Pineau V, Lebel B, Gouzy S, et al. Dual mobility hip arthroplasty wear measurement: Experimental accuracy assessment using radiostereometric analysis (RSA). Orthop Traumatol Surg Res 2010;96:609-615. DOI: 10.1016/j.otsr.2010.04.007.
103. Callary SA, Solomon LB, Holubowycz OT, et al. Accuracy of methods to measure femoral head penetration within metal-backed acetabular components. J Orthop Res 2017;35:988-996. DOI: 10.1002/jor.23356.

104. Kadar T, Hallan G, Aamodt A, et al. Wear and migration of highly cross-linked and conventional cemented polyethylene cups with cobalt chrome or Oxinium femoral heads: a randomized radiostereometric study of 150 patients. J Orthop Res 2011;29:1222-1229. DOI: 10.1002/jor.21389.
105. Shareghi B, Johanson PE, Karrholm 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;35:760-767. DOI: 10.1002/jor.23177.
106. Wroblewski BM. Direction and rate of socket wear in Charnley low-friction arthroplasty. J Bone Joint Surg Br 1985;67:757-761. DOI: 10.1302/0301-620x.67b5.4055876.
107. Yamaguchi M, Bauer TW, Hashimoto Y. Three-dimensional analysis of multiple wear vectors in retrieved acetabular cups. J Bone Joint Surg Am 1997;79:1539-1544. DOI: 10.2106/00004623-199710000-00011.
108. Yamaguchi M, Hashimoto Y, Akisue T, et al. Polyethylene wear vector in vivo: a three-dimensional analysis using retrieved acetabular components and radiographs. J Orthop Res 1999;17:695-702. DOI: 10.1002/jor.1100170511.
109. McKellop HA. The lexicon of polyethylene wear in artificial joints. Biomaterials 2007;28:5049-5057. DOI: 10.1016/j.biomaterials.2007.07.040.
110. Nebergall AK, Freiberg AA, Greene ME, et al. Analysis of Dual Mobility Liner Rim Damage Using Retrieved Components and Cadaver Models. J Arthroplasty 2016;31:1595-1602. DOI: 10.1016/j.arth.2015.12.032.
111. Hamadouche M, Arnould H, Bouxin B. Is a cementless dual mobility socket in primary THA a reasonable option? Clin Orthop Relat Res 2012;470:3048-3053. DOI: 10.1007/s11999-012-2395-3.
112. Stilling M, Rahbek O, Soballe K. Inferior survival of hydroxyapatite versus titanium-coated cups at 15 years. Clin Orthop Relat Res 2009;467:2872-2879. DOI: 10.1007/s11999-009-0796-8.
113. Netter JD, Hermida JC, Chen PC, et al. Effect of microseparation and third-body particles on dual-mobility crosslinked hip liner wear. J Arthroplasty 2014;29:1849-1853. DOI: 10.1016/j.arth.2014.04.010.
114. Vielpeau C, Lebel B, Ardouin L, et al. The dual mobility socket concept: experience with 668 cases. Int Orthop 2011;35:225-230. DOI: 10.1007/s00264-010-1156-8.
115. Matzko C, Naylor B, Cummings R, et al. Impingement Resulting in Femoral Notching and Elevated Metal-Ion Levels After Dual-Mobility Total Hip Arthroplasty. Arthroplasty today 2020;6:1045-1051. DOI: 10.1016/j.artd.2020.10.008.
116. Lygrisse KA, Matzko C, Shah RP, et al. Femoral Neck Notching in Dual Mobility Implants: Is This a Reason for Concern? J Arthroplasty 2021. DOI: 10.1016/j.arth.2021.03.043.
117. Sundfeldt M, Carlsson LV, Johansson CB, et al. Aseptic loosening, not only a question of wear: a review of different theories. Acta Orthop 2006;77:177-197. DOI: 10.1080/17453670610045902.
118. Amstutz HC, Campbell P, Kossovsky N, et al. Mechanism and clinical significance of wear debris-induced osteolysis. Clin Orthop Relat Res 1992:7-18.
119. Dumbleton JH, Manley MT, Edidin AA. A literature review of the association between wear rate and osteolysis in total hip arthroplasty. J Arthroplasty 2002;17:649-661. DOI: 10.1054/arth.2002.33664.
120. Green TR, Fisher J, Stone M, et al. Polyethylene particles of a 'critical size' are necessary for the induction of cytokines by macrophages in vitro. Biomaterials 1998;19:2297-2302. DOI: 10.1016/s0142-9612(98)00140-9.
121. Hultmark P, Höstner J, Herberts P, et al. Radiographic evaluation of Charnley cups used in first-time revision: repeated observations for 7-15 years. J Arthroplasty 2003;18:1005-1015. DOI: 10.1016/s0883-5403(03)00405-4.
122. DeLee JG, Charnley J. Radiological demarcation of cemented sockets in total hip replacement. Clin Orthop Relat Res 1976:20-32.
123. Pellicci PM, Wilson PD, Jr., Sledge CB, et al. Long-term results of revision total hip replacement. A follow-up report. J Bone Joint Surg Am 1985;67:513-516.
124. Schmalzried TP, Jasty M, Harris WH. Periprosthetic bone loss in total hip arthroplasty. Polyethylene wear debris and the concept of the effective joint space. J Bone Joint Surg Am 1992;74:849-863.
125. Fisher J, McEwen HM, Tipper JL, et al. Wear, debris, and biologic activity of cross-linked polyethylene in the knee: benefits and potential concerns. Clin Orthop Relat Res 2004:114-119. DOI: 10.1097/01.blo.0000148783.20469.4c.
126. Barrack RL. Dislocation after total hip arthroplasty: implant design and orientation. J Am Acad Orthop Surg 2003;11:89-99. DOI: 10.5435/00124635-200303000-00003.

127. von Knoch M, Berry DJ, Harmsen WS, et al. Late dislocation after total hip arthroplasty. J Bone Joint Surg Am 2002;84:1949-1953. DOI: 10.2106/00004623-200211000-00007.
128. Barrack RL, Butler RA, Laster DR, et al. Stem design and dislocation after revision total hip arthroplasty: clinical results and computer modeling. J Arthroplasty 2001;16:8-12. DOI: 10.1054/arth.2001.28359.
129. Berry DJ. Unstable total hip arthroplasty: detailed overview. Instr Course Lect 2001;50:265-274.
130. Lewinnek GE, Lewis JL, Tarr R, et al. Dislocations after total hip-replacement arthroplasties. J Bone Joint Surg Am 1978;60:217-220.
131. Nevelos J, Johnson A, Heffernan C, et al. What factors affect posterior dislocation distance in THA? Clin Orthop Relat Res 2013;471:519-526. DOI: 10.1007/s11999-012-2559-1.
132. Byström S, Espehaug B, Furnes O, et al. Femoral head size is a risk factor for total hip luxation: a study of 42,987 primary hip arthroplasties from the Norwegian Arthroplasty Register. Acta Orthop Scand 2003;74:514-524. DOI: 10.1080/00016470310017893.
133. Hedlundh U, Ahnfelt L, Hybbinette CH, et al. Dislocations and the femoral head size in primary total hip arthroplasty. Clin Orthop Relat Res 1996:226-233.
134. Kelley SS, Lachiewicz PF, Hickman JM, et al. Relationship of femoral head and acetabular size to the prevalence of dislocation. Clin Orthop Relat Res 1998:163-170. DOI: 10.1097/00003086-199810000-00017.
135. Morrey BF. Instability after total hip arthroplasty. Orthop Clin North Am 1992;23:237-248.
136. Masonis JL, Bourne RB. Surgical approach, abductor function, and total hip arthroplasty dislocation. Clin Orthop Relat Res 2002:46-53. DOI: 10.1097/00003086-200212000-00006.
137. McGrory BJ, Morrey BF, Cahalan TD, et al. Effect of femoral offset on range of motion and abductor muscle strength after total hip arthroplasty. J Bone Joint Surg Br 1995;77:865-869.
138. Kostensalo I, Junnila M, Virolainen P, et al. Effect of femoral head size on risk of revision for dislocation after total hip arthroplasty: a population-based analysis of 42,379 primary procedures from the Finnish Arthroplasty Register. Acta Orthop 2013;84:342-347. DOI: 10.3109/17453674.2013.810518.
139. McCollum DE, Gray WJ. Dislocation after total hip arthroplasty. Causes and prevention. Clin Orthop Relat Res 1990:159-170.
140. Tsikandylakis G, Kärrholm J, Hailer NP, et al. No Increase in Survival for 36-mm versus 32-mm Femoral Heads in Metal-on-polyethylene THA: A Registry Study. Clin Orthop Relat Res 2018;476:2367-2378. DOI: 10.1097/corr.0000000000000508.
141. D'Apuzzo MR, Nevelos J, Yeager A, et al. Relative head size increase using an anatomic dual mobility hip prosthesis compared to traditional hip arthroplasty: impact on hip stability. J Arthroplasty 2014;29:1854-1856. DOI: 10.1016/j.arth.2014.04.035.
142. Hoskins W, Bingham R, Dyer C, et al. A Comparison of Revision Rates for Dislocation and Aseptic Causes Between Dual Mobility and Large Femoral Head Bearings in Primary Total Hip Arthroplasty With Subanalysis by Acetabular Component Size: an Analysis of 106,163 Primary Total Hip Arthroplasties. J Arthroplasty 2021. DOI: 10.1016/j.arth.2021.05.008.
143. Hartzler MA, Abdel MP, Sculco PK, et al. Otto Aufranc Award: Dual-mobility Constructs in Revision THA Reduced Dislocation, Rerevision, and Reoperation Compared With Large Femoral Heads. Clin Orthop Relat Res 2018;476:293-301. DOI: 10.1007/s11999.0000000000000035.
144. Guyen O, Pibarot V, Vaz G, et al. Use of a dual mobility socket to manage total hip arthroplasty instability. Clin Orthop Relat Res 2009;467:465-472. DOI: 10.1007/s11999-008-0476-0.
145. Neri T, Philippot R, Klasan A, et al. Dual mobility acetabular cups for total hip arthroplasty: advantages and drawbacks. Expert Rev Med Devices 2018;15:835-845. DOI: 10.1080/17434440.2018.1538781.
146. Philippot R, Boyer B, Farizon F. Intraprosthetic Dislocation: A Specific Complication of the Dual-mobility System. Clinical Orthopaedics and Related Research® 2013;471:965-970. DOI: 10.1007/s11999-012-2639-2.
147. Martin HD, Kelly BT, Leunig M, et al. The pattern and technique in the clinical evaluation of the adult hip: the common physical examination tests of hip specialists. Arthroscopy 2010;26:161-172. DOI: 10.1016/j.arthro.2009.07.015.
148. Prins AH, Kaptein BL, Stoel BC, et al. Handling modular hip implants in model-based RSA: combined stem-head models. J Biomech 2008;41:2912-2917. DOI: 10.1016/j.jbiomech.2008.07.035.

149. Johanson P-E, Shareghi B, Eriksson M, et al. Wear measurements with use of radiostereometric analysis in total hip arthroplasty with obscured femoral head. J Orthop Res 2020;38:2040-2049. DOI: https://doi.org/10.1002/jor.24626.
150. Fabry C, Kaehler M, Herrmann S, et al. Dynamic behavior of tripolar hip endoprostheses under physiological conditions and their effect on stability. Med Eng Phys 2014;36:65-71. DOI: 10.1016/j.medengphy.2013.09.007.
151. 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;35:1109-1116. DOI: 10.1016/j.arth.2019.11.010.
152. Tabori-Jensen S, Mosegaard SB, Hansen TB, et al. 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;91:246-253. DOI: 10.1080/17453674.2020.1720978.
153. Hammerberg EM, Wan Z, Dastane M, et al. Wear and range of motion of different femoral head sizes. J Arthroplasty 2010;25:839-843. DOI: 10.1016/j.arth.2009.07.007.
154. Lachiewicz PF, Heckman DS, Soileau ES, et al. Femoral head size and wear of highly cross-linked polyethylene at 5 to 8 years. Clin Orthop Relat Res 2009;467:3290-3296. DOI: 10.1007/s11999-009-1038-9.
155. Livermore J, Ilstrup D, Morrey B. Effect of femoral head size on wear of the polyethylene acetabular component. J Bone Joint Surg Am 1990;72:518-528.
156. Stilling M, Nielsen KA, Soballe K, et al. Clinical comparison of polyethylene wear with zirconia or cobalt-chromium femoral heads. Clin Orthop Relat Res 2009;467:2644-2650. DOI: 10.1007/s11999-009-0799-5.
157. Galvin AL, Jennings LM, Tipper JL, et al. Wear and creep of highly crosslinked polyethylene against cobalt chrome and ceramic femoral heads. Proc Inst Mech Eng H 2010;224:1175-1183. DOI: 10.1243/09544119jeim741.
158. Gaudiani MA, White PB, Ghazi N, et al. Wear Rates With Large Metal and Ceramic Heads on a Second Generation Highly Cross-Linked Polyethylene at Mean 6-Year Follow-Up. J Arthroplasty 2018;33:590-594. DOI: 10.1016/j.arth.2017.09.006.
159. Meftah M, Klingenstein GG, Yun RJ, et al. Long-term performance of ceramic and metal femoral heads on conventional polyethylene in young and active patients: a matched-pair analysis. J Bone Joint Surg Am 2013;95:1193-1197. DOI: 10.2106/jbjs.L.00432.
160. Teeter MG, MacLean CJ, Somerville LE, et al. Wear performance of cobalt chromium, ceramic, and oxidized zirconium on highly crosslinked polyethylene at mid-term follow-up. Journal of orthopaedics 2018;15:620-623. DOI: 10.1016/j.jor.2018.05.018.
161. Wang S, Zhang S, Zhao Y. A comparison of polyethylene wear between cobalt-chrome ball heads and alumina ball heads after total hip arthroplasty: a 10-year follow-up. J Orthop Surg Res 2013;8:20. DOI: 10.1186/1749-799x-8-20.
162. 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;35:3769-3776. DOI: 10.1016/j.arth.2020.06.057.
163. Del Schutte H, Jr., Lipman AJ, Bannar SM, et al. Effects of acetabular abduction on cup wear rates in total hip arthroplasty. J Arthroplasty 1998;13:621-626. DOI: 10.1016/s0883-5403(98)80003-x.
164. Little NJ, Busch CA, Gallagher JA, et al. Acetabular polyethylene wear and acetabular inclination and femoral offset. Clin Orthop Relat Res 2009;467:2895-2900. DOI: 10.1007/s11999-009-0845-3.
165. Loving L, Herrera L, Banerjee S, et al. Dual mobility bearings withstand loading from steeper cup-inclinations without substantial wear. J Orthop Res 2015;33:398-404. DOI: 10.1002/jor.22774.
166. Deckard ER, Azzam KA, Meneghini RM. Contemporary Dual Mobility Head Penetration at Five Years: Concern for the Additional Convex Bearing Surface? J Arthroplasty 2018;33:S280-S284. DOI: 10.1016/j.arth.2018.02.061.
167. Digas G, Thanner J, Nivbrant B, et al. Increase in early polyethylene wear after sterilization with ethylene oxide: radiostereometric analyses of 201 total hips. Acta Orthop Scand 2003;74:531-541. DOI: 10.1080/00016470310017910.
168. Boyer B, Neri T, Geringer J, et al. Long-term wear of dual mobility total hip replacement cups: explant study. Int Orthop 2018;42:41-47. DOI: 10.1007/s00264-017-3525-z.

169. Campbell DG, Field JR, Callary SA. Second-generation highly cross-linked X3 polyethylene wear: a preliminary radiostereometric analysis study. Clin Orthop Relat Res 2010;468:2704-2709. DOI: 10.1007/s11999-010-1259-y.
170. Lindalen E, Thoen PS, Nordsletten L, et al. Low wear rate at 6-year follow-up of vitamin E-infused cross-linked polyethylene: a randomised trial using 32- and 36-mm heads. Hip Int 2019;29:355-362. DOI: 10.1177/1120700018798790.
171. Rames RD, Stambough JB, Pashos GE, et al. Fifteen-Year Results of Total Hip Arthroplasty With Cobalt-Chromium Femoral Heads on Highly Cross-Linked Polyethylene in Patients 50 Years and Less. J Arthroplasty 2019;34:1143-1149. DOI: 10.1016/j.arth.2019.01.071.
172. Tabori-Jensen S, Hansen TB, Stilling M. Low dislocation rate of Saturne(®)/Avantage(®) dual-mobility THA after displaced femoral neck fracture: a cohort study of 966 hips with a minimum 1.6-year follow-up. Arch Orthop Trauma Surg 2019;139:605-612. DOI: 10.1007/s00402-018-3093-8.
173. Kreipke R, Rogmark C, Pedersen AB, et al. Dual Mobility Cups: Effect on Risk of Revision of Primary Total Hip Arthroplasty Due to Osteoarthritis: A Matched Population-Based Study Using the Nordic Arthroplasty Register Association Database. J Bone Joint Surg Am 2019;101:169-176. DOI: 10.2106/JBJS.17.00841.
174. Jobory A, Kärrholm J, Overgaard S, et al. Reduced Revision Risk for Dual-Mobility Cup in Total Hip Replacement Due to Hip Fracture: A Matched-Pair Analysis of 9,040 Cases from the Nordic Arthroplasty Register Association (NARA). J Bone Joint Surg Am 2019;101:1278-1285. DOI: 10.2106/jbjs.18.00614.
175. Hoskins W, Griffin X, Hatton A, et al. THA for a Fractured Femoral Neck: Comparing the Revision and Dislocation Rates of Standard-head, Large-head, Dual-mobility, and Constrained Liners. Clin Orthop Relat Res 2021;479:72-81. DOI: 10.1097/corr.0000000000001447.
176. Paulsen A, Odgaard A, Overgaard S. Translation, cross-cultural adaptation and validation of the Danish version of the Oxford hip score: Assessed against generic and disease-specific questionnaires. Bone & joint research 2012;1:225-233. DOI: 10.1302/2046-3758.19.2000076.
177. McLean JM, Cappelletto J, Clarnette J, et al. Normal population reference values for the Oxford and Harris Hip Scores - electronic data collection and its implications for clinical practice. Hip Int 2017;27:389-396. DOI: 10.5301/hipint.5000465.
178. Keurentjes JC, Van Tol FR, Fiocco M, et al. Patient acceptable symptom states after totalhip or knee replacement at mid-term follow-up: Thresholds of the Oxford hip and knee scores. Bone & joint research 2014;3:7-13. DOI: 10.1302/2046-3758.31.2000141.
179. Stryker. ADM® X3® Mobile Bearing Hip® System.
180. Puch JM, Derhi G, Descamps L, et al. Dual-mobility cup in total hip arthroplasty in patients less than fifty five years and over ten years of follow-up : A prospective and comparative series. Int Orthop 2017;41:475-480. DOI: 10.1007/s00264-016-3325-x.
181. Epinette JA, Beracassat R, Tracol P, et al. Are modern dual mobility cups a valuable option in reducing instability after primary hip arthroplasty, even in younger patients? J Arthroplasty 2014;29:1323-1328. DOI: 10.1016/j.arth.2013.12.011.
182. Wegrzyn J, Tebaa E, Jacquel A, et al. Can Dual Mobility Cups prevent Dislocation in All Situations After Revision Total Hip Arthroplasty? J Arthroplasty 2015;30:631-640. DOI: 10.1016/j.arth.2014.10.034.
183. Jonker RC, van Beers L, van der Wal BCH, et al. Can dual mobility cups prevent dislocation without increasing revision rates in primary total hip arthroplasty? A systematic review. Orthop Traumatol Surg Res 2020;106:509-517. DOI: 10.1016/j.otsr.2019.12.019.
184. Gonzalez AI, Bartolone P, Lubbeke A, et al. Comparison of dual-mobility cup and unipolar cup for prevention of dislocation after revision total hip arthroplasty. Acta Orthop 2017;88:18-23. DOI: 10.1080/17453674.2016.1255482.
185. Jakobsen T, Kappel A, Hansen F, et al. The dislocating hip replacement - revision with a dual mobility cup in 56 consecutive patients. Open Orthop J 2014;8:268-271. DOI: 10.2174/1874325001408010268.
186. Heffernan C, Banerjee S, Nevelos J, et al. Does dual-mobility cup geometry affect posterior horizontal dislocation distance? Clin Orthop Relat Res 2014;472:1535-1544. DOI: 10.1007/s11999-014-3469-1.
187. van Heumen M, Heesterbeek PJ, Swierstra BA, et al. Dual mobility acetabular component in revision total hip arthroplasty for persistent dislocation: no dislocations in 50 hips after 1-5 years. J Orthop Traumatol 2015;16:15-20. DOI: 10.1007/s10195-014-0318-7.

188. Terrier A, Latypova A, Guillemin M, et al. Dual mobility cups provide biomechanical advantages in situations at risk for dislocation: a finite element analysis. Int Orthop 2017;41:551-556. DOI: 10.1007/s00264-016-3368-z.
189. Jauregui JJ, Pierce TP, Elmallah RK, et al. Dual mobility cups: an effective prosthesis in revision total hip arthroplasties for preventing dislocations. Hip Int 2016;26:57-61. DOI: 10.5301/hipint.5000295.
190. Dikmen G, Ozden VE, Karaytug K, et al. Dual-mobility cups in revision acetabular reconstructions: Short-term outcomes in high-risk patients for instability. Acta Orthop Traumatol Turc 2019;53:329-333. DOI: 10.1016/j.aott.2019.05.002.
191. Hamadouche M, Ropars M, Rodaix C, et al. Five to thirteen year results of a cemented dual mobility socket to treat recurrent dislocation. Int Orthop 2017;41:513-519. DOI: 10.1007/s00264-016-3343-8.
192. Homma Y, Baba T, Ozaki Y, et al. In total hip arthroplasty via the direct anterior approach, a dual-mobility cup prevents dislocation as effectively in hip fracture as in osteoarthritis. Int Orthop 2017;41:491-497. DOI: 10.1007/s00264-016-3332-y.
193. Iorio R, Iannotti F, Mazza D, et al. Is dual cup mobility better than hemiarthroplasty in patients with dementia and femoral neck fracture? A randomized controlled trial. Sicot-j 2019;5:38. DOI: 10.1051/sicotj/2019035.
194. Vigdorchik JM, D'Apuzzo MR, Markel DC, et al. Lack of early dislocation following total hip arthroplasty with a new dual mobility acetabular design. Hip Int 2015;25:34-38. DOI: 10.5301/hipint.5000186.
195. Saragaglia D, Ruatti S, Refaie R. Relevance of a press-fit dual mobility cup to deal with recurrent dislocation of conventional total hip arthroplasty: a 29-case series. Eur J Orthop Surg Traumatol 2013;23:431-436. DOI: 10.1007/s00590-012-1002-3.
196. Acker A, Fischer JF, Aminian K, et al. Total hip arthroplasty using a cementless dual-mobility cup provides increased stability and favorable gait parameters at five years follow-up. Orthop Traumatol Surg Res 2017;103:21-25. DOI: 10.1016/j.otsr.2016.09.020.
197. Philippot R, Camilleri JP, Boyer B, et al. The use of a dual-articulation acetabular cup system to prevent dislocation after primary total hip arthroplasty: analysis of 384 cases at a mean follow-up of 15 years. Int Orthop 2009;33:927-932. DOI: 10.1007/s00264-008-0589-9.
198. Jones CW, De Martino I, D'Apolito R, et al. The use of dual-mobility bearings in patients at high risk of dislocation. The bone & joint journal 2019;101-B:41-45. DOI: 10.1302/0301-620X.101B1.BJJ-2018-0506.R1.
199. Mohaddes M, Cnudde P, Rolfson O, et al. Use of dual-mobility cup in revision hip arthroplasty reduces the risk for further dislocation: analysis of seven hundred and ninety one first-time revisions performed due to dislocation, reported to the Swedish Hip Arthroplasty Register. Int Orthop 2017;41:583-588. DOI: 10.1007/s00264-016-3381-2.
200. von Schewelov T, Onsten I, Markusson P, et al. Weight bearing radiographs are not necessary for measurement of polyethylene penetration in total hip prostheses: a radiostereometric study of 111 patients examined in weight-bearing and supine position. Acta Orthop 2006;77:104-108. DOI: 10.1080/17453670610045768.
201. Rouzrokh P, Wyles CC, Philbrick KA, et al. A Deep Learning Tool for Automated Radiographic Measurement of Acetabular Component Inclination and Version After Total Hip Arthroplasty. J Arthroplasty 2021;36:2510-2517.e2516. DOI: 10.1016/j.arth.2021.02.026.

Paper 1

Feasibility of combined and hybrid marker models for radiostereometry assessment of polyethylene liner motion in dual mobility hip prosthesis.

Original Article

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Abstract

Background

Investigation of polyethylene liner movement in total hip arthroplasty requires bead-marking for radiographic visibility of the liner. However, occlusion of markers poses a challenge for marker registration in radiographs.

Methods

The polyethylene of a dual mobility acetabular system was marked with 12 1-mm tantalum markers (4 groups of 3 markers) using a custom-made drill guide. Liner motion in a sawbone phantom and a patient was investigated with dynamic radiostereometry (dRSA) at 1-year follow-up, and static radiostereometry (sRSA) postoperatively and at 1- and 2-year follow-up. A combined marker configuration (CMC) model was calculated from the registered positions of the liner markers and the femoral head in several RSA images. Further, the CMC model and the theoretic marker positions from CAD-models of the drill guide were combined in a hybrid model.

Results

The CMC model included 11 markers in the phantom and 9 markers in the patient, which was sufficient for dRSA analysis. Liner movement in the phantom followed liner contact with the femoral neck, while liner movement in the patient was independent. The hybrid model was necessary to determine liner orientation in sRSA recordings, which clearly changed (inclination, anteversion, rotation) from postoperative to 1- and 2-year follow-up even though the patient was positioned similarly.

Conclusion

Polyethylene liner motion in dual mobility hip prosthesis can be assessed with CMC models in dynamic RSA recordings. In static RSA, the liner position between follow-ups is unpredictable and analysis requires inclusion of all markers in the model, which can be accomplished with a hybrid marker model.

Trial registration

ClinicalTrials.gov [NCT02301182], 25. October 2015

https://clinicaltrials.gov/ct2/show/NCT02301182

Keywords

Polyethylene, Dynamic Radiostereometry, Occluded markers, Hip Prosthesis, Dual mobility, Markers model

Key points

- The occluded markers problem can be solved using a combined marker configuration model.
- Combination of marker data from multiple radiostereometry recordings improve analysis.
- Combination of measured and theoretic marker data further improves analysis.

Introduction

Recurrent dislocation is one of the most common reasons for revision of total hip replacement [1]. The dual mobility acetabular system is designed to reduce dislocation rate by providing increased jump distance, increased range of motion, and reduced risk of impingement [2]. It has a mobile polyethylene (PE) liner that articulates with respect to both the outer metal shell and the femoral head. The movements of the liner have been investigated experimentally and in a retrieval study but no clinical assessment of dual-mobility liner kinematics in patients have been performed. This is because radiographic imaging methods are challenged by PE liner radiolucency, liner symmetry, and liner occlusion by metal components, bone, and soft tissue [3; 4].

Dynamic radiostereometric analysis (dRSA) is an accurate stereo-radiography method that records several radiograph pairs (frames) per second. The method allows for kinematic analysis of joints by use of bone models, implant models, and marker-models of tantalum markers inserted in the bones [5-9]. Formerly, dRSA has been used to investigate native hip joint and total hip arthroplasty (THA) kinematics and pathomechanics, and sRSA has been used to measure polyethylene liner wear in single mobility THA by insertion of tantalum markers in the PE [10; 11].

When tantalum markers are inserted in a dual mobility PE liner, the 3D position for each marker can be calculated with RSA when the marker is visible in the radiographic image pair. This may allow for kinematic analysis of the PE liner using dRSA. However, when one of the two projections of a marker is not visible in the radiographic image pair, the 3D position of that marker cannot be calculated (Figure 1). A marker configuration model does not need all markers projected on both radiographs [8]. By combining information on marker positions from multiple RSA frames into a combined marker configuration model (CMC model), we aimed to build the most complete marker configuration model for the individual patient to solve the problem of marker occlusion and marker/liner position change during motion. By subsequently expanding the CMC- model with theoretical marker positions we aimed to create a hybrid model that included all liner markers and had the highest probability of precise assessment of PE liner kinematics.

The purpose of the study was to generate and test the feasibility of a CMC model and a hybrid model for assessment of PE liner motion with dynamic and static RSA in an experimental and a clinical setting.

Material and Methods

The study used a phantom setup for method development and evaluated the clinical feasibility of the CMC- and hybrid models in a female patient (68 years old, BMI: 31.9). The patient was recruited from a randomized clinical trial (Clinical Trial NCT02301182) and had consented orally and in writing to study participation. The Helsinki II declaration was followed [12].

Implants and surgery

The Anatomic Dual Mobility Restoration acetabular system (Stryker, Warsaw, Mazovia, Poland) with a mobile liner made of X3 highly cross-linked PE (Stryker, Warsaw, Mazovia, Poland) and a ceramic size 28 mm femoral head was used in both the phantom and the patient. The hip stems were a Bi-Metric size 7 (Biomet, Warsaw, Indiana, USA) in the phantom and Accolade II (Stryker, Warsaw, Mazovia, Poland) size 4 in the patient. Cup/liner size 56 mm was used in the phantom and size 50 mm was used in the patient. An experienced hip surgeon inserted the components into the Sawbone hip (No 1301-165-1, Sawbones, Washington, USA) and also the patient by use of a posterolateral approach.

Insertion of markers in the polyethylene

Twelve 1-mm tantalum markers (X-medics, Frederiksberg, Denmark) were placed centralized in the PE wall of the mobile liners in four groups of three markers by use of a custom-made drill guide, specific for each liner size (Figure 2). In three of the four marker groups, one specific marker was placed 1.5 mm deeper than the other two markers, which provided a recognizable and unique pattern for each marker group.

Radiostereometric recordings

The RSA recordings were obtained using the AdoraRSA Suite (Nordic X-ray Technique, Hasselager, Aarhus, Denmark) consisting of two ceiling fixed x-ray tubes angled 40° on each other. For static RSA, two static digital detectors (CXDI-70C, Canon, Tokyo, Japan) were mounted below a calibration box (cb24, Medis Specials, Leiden, Netherlands) for direct anterior/posterior recording (Figure 3a).

For dRSA, two dynamic digital detectors (CXDI-50RF, Canon, Tokyo, Japan) were mounted below a calibration box (cb14, Medis Specials, Leiden, Netherlands) and recorded five images per second. From the projection of the calibration box markers the foci position can be calculated, which enables projection of the hip implant and markers and comparison of implant component positions. The set-up allowed for a 45-degree angle on the hip joint in the cranial/caudal and anterior/posterior X-ray direction for optimal view (less marker occlusion) of the PE liner in the dual mobility cup (Figure 3b). Soft tissue equivalence in terms of a 10-cm polymethyl methacrylate (PMMA) plate was placed in the recording area of the hip phantom during dynamic RSA recordings [13]. The hip was flexed to 45° and kept there while being moved in abduction/external rotation and adduction/internal rotation. This modified FADIR/FABER movement was performed passively to end-range position (Figure **4**). The dRSA recordings were captured using 140 kV / 8 mAs for the phantom and 130 kV / 8 mAs for the patient.

Combined marker configuration model

Marker configuration model-based RSA [8] requires a marker configuration model that describes the positions of the markers in the rigid body relative to each other. By fitting this model to its projections in the RSA radiographs, the position and orientation of the model is calculated, similar to model-based RSA [8; 14]. Such a model is created from one RSA frame, in which all markers are visible in both projections, using conventional RSA [8]. The method handles the occluded marker problem, but requires that all the model markers are projected on both RSA images in one RSA frame [8]. The combined marker configuration model (CMC model) builds on the same principles, but combines the marker positions and the position of the femoral head from more than one RSA frame in the model.

Combining two or more RSA frames requires at least three overlapping markers in the image pairs. By using the femoral head as one common marker in the marker model the minimum number of overlapping markers needed for combining RSA frames is reduced to two.

For the phantom, only dynamic RSA frames were used to generate the CMC model. For the patient, dynamic hip RSA frames were combined with standard supine static hip RSA recordings to generate a CMC model with a sufficient number of representative markers.

For creating the CMC model, the detected markers of all frames were aligned using the migration function of mbRSA software (version 4.2, RSAcore, Leiden, The Netherlands). For both the phantom and the patient, the 3D marker coordinates were exported and the mean marker positions were calculated using a custom-made program in MatLab (version 2019b, The MathWorks Inc, Natick, Massachusetts). To evaluate the dispersion of markers contributing to the CMC model we used the standard deviation of the aligned marker positions [15].

Hybrid markers model

A hybrid model was created by combining the marker registrations in the mean CMC model and the theoretic marker positions known from the CAD drawings of the drill guide. The theoretic marker positions were aligned with the mean CMC model to add more information to the model and to be able to detect the specific 4 marker groups in the liner for precise registration of liner rotation. The hybrid model was used for detecting liner movement in static RSA follow-ups over time, where the liner rotation could be very different from one RSA recording to the next.

Coordinate systems

To define the local coordinate system of the CMC model, a base-plane was fitted through the markers in the liner and the local coordinate system was redefined with the femoral head as origin and the y-axis perpendicular to the base-plane of the liner. The coordinate system for the theoretic markers was created in a similar fashion, but the base plane excluded the three markers that were deeper in the liner wall. The hybrid model inherited the theoretic coordinate system. For the outer metal cup, a similar local coordinate system was defined with the origin in the center of rotation of the cup and the y-axis (acetabular axis) perpendicular to the base-plane of the cup. Lastly, the femoral neck coordinate system was defined with the femoral head as center and the y-axis aligned with the neck. This aligned the origins of the CMC model, the femoral head, and the cup coordinate systems. In the "neutral" orientation, also the main (y-) axis of all objects was aligned. Therefore, all movements in the cup-liner-neck complex could be expressed by the angle between e.g., the cup y-axis and the liner y-axis (Figure 5).

RSA Analysis and data post-processing

The CMC model was then fitted to the dRSA recording, frame by frame, using mbRSA (version 4.2, RSA*core*, Leiden, The Netherlands). The cup, liner- and femoral neck orientations were imported from mbRSA to a custom made program in Python 3 [16]. To remove the patient movements during RSA recording, the raw-data orientation was standardized using the cup orientation relative to the calibration box from the first frame. This resulted in a constant cup orientation during the whole movement. The liner rotation was set to zero for the first frame of the recording. Orientation was described as inclination, anteversion and rotation in a radiographical coordinate system as described by Murray [17]; The radiographic inclination was defined as the angle between the longitudinal axis and the acetabular axis when projected on the coronal plane. Likewise, the radiographic anteversion was defined as the angle between the acetabular axis and the coronal plane [17] (Figure 6). Stem angles were likewise calculated as standardized radiographic inclination and anteversion. Furthermore, the angle between the neck and liner normal (y-axis) was calculated (Figure 5). This angle served as indicator of contact between the neck and the liner. With contact between neck and liner the liner should rotate relative to the cup. Movements were graphically displayed using Stata/IC (version: 16.0, StataCorp, College Station, TX).

Results

The phantom RSA frames had 4 common conventional markers and the patient frames had 2 common conventional markers. All frames had additional markers that could not be used in standard analysis as they did not represent the same markers between frames. The CMC model for the phantom was derived from 5 dRSA frames and comprised of 11 markers (including the femoral head). The CMC model for the patient was derived from 3 dRSA frames and 1 static RSA frame and comprised of 9 markers. The maximum standard deviation of marker positions occurred in the out-of-plane (z)-direction for both the phantom and the patient (Table 1 and Table 2).

Phantom

The phantom-liner was positioned neutral to the cup opening, and liner motion started when the liner/neck angle approached 36.6° during the modified FABER-motion, which is the angle of contact between the liner and the neck (Figure **4** a, 4 sec.). Reversely, at the start of the modied FADIR-motion, the liner/neck angle fell below 36.6° and the liner stopped moving until about halfway through the modified FADIR-motion, when the liner/neck angle again reached 36.6°, and the neck contacted the liner and initiated movement. Liner movement was primarily caused by contact with and pushing from the femoral neck at 36.6 liner/neck angle, however; some spontaneous motion also occurred at lower liner/neck angles between 32.9°-36.6° (Figure **4** a).

The range of stem movement during recording was 99° inclination, 41° anteversion, and 160° rotation. The range of liner movement was 12.2° inclination, 35° anteversion, and 37° rotation. The range of liner/neck angle was 33°.

Patient

With dynamic assessment, the liner started in a position of 45° inclination and 12.8° anteversion, and started to move when the stem reached the maximum modified FABER motion for the first time (Figure **4** b, 4 sec.). Although a slight liner movement happened at 0° stem inclination (Figure **4** b, 7 sec.), the liner remained stable during the second modified FABER motion. Liner movement was not caused by contact with the femoral neck as the liner/neck angle was higher in the FADIR motion (without liner movement) compared to the FABER motion (Figure **4** b). The ranges of hip stem movement during dynamic RSA recording were 117° inclination, 25° anteversion, and 113° rotation. The ranges of liner movements were 12° inclination, 5° anteversion, and -15° rotation (Figure **4**b). The range of liner/neck angle was 24°.

Static RSA evaluations at postop, and at one- and two-years follow-up were completed with the hybrid model (all markers), which enabled registration of the liner orientation despite substantial and unpredictable liner rotation between follow-ups. Liner inclination was relatively stable from baseline to one- and two-years follow-up. Anteversion decreased from 12° to 9°, and 0° and rotation was measured to -109°, -133°, and -141° **(**Table **3).**

Discussion

This study is the first to quantify in-vivo PE liner motion of a dual-mobility PE in total hip arthroplasty. The study demonstrates the feasibility of a CMC model, which combines registration of the femoral head with markers inserted in the PE liner, and a hybrid markers model, which combines the CMC model with the theoretical marker position in the PE.

Utilizing the femoral head as a marker

In this study, the femoral head was utilized as a marker in the CMC model. This proved to be a great advantage since the femoral head is very likely to be detectable in RSA recordings. The theoretic disadvantage is that the femoral head and the liner are not the same rigid body. In the ADM cup, the femoral head and the liner are joined with a press fit, and very unlikely to sub-lux. Still, micro-translations are possible, and over time also PE wear may compromise the use of the femoral head in a CMC model. Nevertheless, using the femoral head in the model enabled analysis of RSA frames that would have been impossible to analyze with standard methods.

The strengths and weaknesses of the combined marker configuration model

The CMC model builds on mean marker positions from multiple RSA frames, which in theory reduces the random error in the position of the markers. However, the use of mean marker positions in the model makes it inherently sensitive to inclusion of markers with few datapoints and a large variation where one outlier can have great impact on the mean value. The standard deviation of the mean marker position is a summary measure of this variation.

The use of a CMC model enables fitting of the model with a minimum of markers in the RSA recording. This is a great advantage when image quality is compromised and marker visibility, marker detection and marker model creation by standard algorithms is not possible [8]. In fact, a marker configuration model require as little as four marker projections of the model (3 projections in one image and 1 projection in the other image) in the RSA recording to enable a clinical meaningful calculation [8]. Further, the robustness makes the marker configuration model useful for assessment of PE wear or liner motion in knee- as well as hip arthroplasty [18; 19]. The use of a CMC model solves the occluded marker problem in dynamic RSA recordings where different markers are visible in a series of RSA frames.

The strengths and weaknesses of the hybrid model

Adding theoretic marker positions to the CMC model introduce a new source of error as well as valuable information. Lam-Tin Cheung et al. [20] showed good results with theoretic markers when using a drill guide for marker placement. The disadvantage is that validity of theoretic markers relies heavily on knowledge of the initial marker position and subsequent marker migration. The great advantage of theoretic markers is that information from just a single marker projection in any of the images of the RSA-recordings can add to the analysis. The model should be used when completeness of the model outweighs the risk of misplaced markers.

Quality parameters in marker configuration models

Condition number and mean error of rigid body fitting are quality parameters, that should be used to verify standard RSA results. The condition number is a mathematical expression of how close the markers in the model are located on a line [21]. The upper acceptance limit for condition number is 150 for hip and knee RSA [22]. When using marker configuration models, the condition number indicates the marker distribution in the marker configuration model but does not describe the marker distribution in the individual frame.

The mean error of rigid body fitting indicates variation in relative position of markers between RSA frames. In a standard marker-based RSA analysis with mbRSA software, markers that cause a variation in average relative position larger than 0.35 mm are discarded [22; 23]. This is not the case with marker configuration models: Analysis of RSA recordings in mbRSA software will obtain the best possible fit of a markers model disregarding eventual changes in marker positions (e.g., migrating/loose makers). Therefore, careful manual/visual quality assurance should be performed when using marker configuration models.

Alternatives to CMC- and hybrid models

Alternative approaches for liner tracking have been described. Zaribaf et al. (2020) investigated the possibility of adding a radiopaque medium to PE, to make it visible on a standard radiograph. Although this method showed promising results as the material became radiopaque and maintained good strength, acetabular liners are symmetric and rotations are therefore difficult to visualize and quantify with RSA. Also, the technique was not tested in a clinical setting [24]. For knee implants, the PE liner motion has been tracked indirectly assuming that it fills the space between the femoral and tibial components when these are of a congruent design [25].

Feasibility and biomechanical outcome

In this study, the analysis using the CMC model was sufficient to analyze dynamic RSA recordings with only little and predictable liner motion between recorded image frames. Combining data on neck, stem and liner motion revealed the interaction of these components to initiate liner motion. The motion pattern of all components could be graphically outlined and document liner motion in-vivo. In the phantom, the measured liner motion followed an expected pattern of movement when the neck contacted the liner at the 36.5 degrees liner/neck angle [26]. In the patient, the liner/neck angle was considerably lower during liner movement, which shows that movement in the liner can also occur without liner/neck contact. Also, the total liner motion in the patient was less than in the phantom. Expectedly, the explanation for liner movement without neck contact is soft tissue contact. Thereby, soft tissue contact with the PE liner in-vivo can also be a restraint for the liner to position safely. Likely, this makes the liner motion patterns and polyethylene wear areas very heterogeneous between patients. This is the first time that liner motion of a dual-mobility PE liner has been quantified in vivo and more clinical data is necessary to further investigate liner motions in-vivo.

For analysis of liner motion in static images in-vivo the liner position was unpredictable between follow-ups. In this case, the hybrid model ensured identification of the four unique marker-groups in the liner and enabled analysis of liner position. Static analysis over time revealed large rotations and smaller changes in inclination and anteversion. Because of the large rotation of the liner, analyses were only possible due to the completeness of the hybrid model.

Conclusions

In conclusion, PE liner motion in dual mobility hip prosthesis can be assessed in dynamic RSA recordings with CMC models that are reconstructed from marker positions in multiple RSA recordings. The liner position between yearly follow-up is unpredictable and analysis requires inclusion of all markers in the PE liner model, which can be accomplished with a hybrid marker model that combines both the registered positions of visible markers and the theoretical position of occluded markers. The method was developed specifically to enable analysis of a mobile PE liner in a dual mobility cup, but the concept can be applied in any static or dynamic RSA analysis complicated with altering marker visibility on successive frames.

Declarations

Ethics approval and consent to participate

The clinical part of this study was approved by the Central Denmark Ethics committee [1-10-72-343-14]

Consent for publication

Not applicable

Availability of data and materials

The datasets generated and/or analyzed during the current study are not publicly available due to the sensitive nature of radiographic images, but are available from the corresponding author on reasonable request.

Competing interests

Neither of the authors have conflicts of interest regarding this article.

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Authors' contributions

PBJ, BK and MS designed and wrote the manuscript, BK and PBJ wrote the Python and Matlab programs, PBJ performed the image analyses. All contributed to the data interpretation, and critical revision of the manuscript.

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References

1 DHR (2019) National Report 2019, The Danish Hip Arthroplasty Register, Regionernes Kliniske Kvalitetsudviklingsprogram

2 Blakeney WG, Epinette JA, Vendittoli PA (2019) Dual mobility total hip arthroplasty: should everyone get one? EFORT Open Rev 4:541-547

3 D'Apuzzo MR, Koch CN, Esposito CI, Elpers ME, Wright TM, Westrich GH (2016) Assessment of Damage on a Dual Mobility Acetabular System. Journal of Arthroplasty 31:1828-1835

4 Grazioli A, Ek ET, Rudiger HA (2012) Biomechanical concept and clinical outcome of dual mobility cups. International Orthopaedics 36:2411-2418

5 Hansen L, De Raedt S, Jorgensen PB, Mygind-Klavsen B, Kaptein B, Stilling M (2018) Marker free model-based radiostereometric analysis for evaluation of hip joint kinematics: A validation study. Bone Joint Res 7:379-387

6 Digas G, Johansson PE, Karrholm J (2013) Inducible displacements of the cup and the femoral head during active range of motion: dynamic RSA studies of cemented total hip replacements. Journal of Orthopaedic Research 31:1686-1693

7 Zugner R, Tranberg R, Lisovskaja V, Shareghi B, Karrholm J (2017) Validation of gait analysis with dynamic radiostereometric analysis (RSA) in patients operated with total hip arthroplasty. Journal of Orthopaedic Research 35:1515-1522

8 Kaptein BL, Valstar ER, Stoel BC, Rozing PM, Reiber JH (2005) A new type of model-based Roentgen stereophotogrammetric analysis for solving the occluded marker problem. Journal of Biomechanics 38:2330-2334

9 Baad-Hansen T, Kold S, Kaptein BL, Soballe K (2007) High-precision measurements of cementless acetabular components using model-based RSA: an experimental study. Acta Orthopaedica 78:463-469

10 Borlin N, Rohrl SM, Bragdon CR (2006) RSA wear measurements with or without markers in total hip arthroplasty. Journal of Biomechanics 39:1641-1650

11 Nebergall AK, Rader K, Palm H, Malchau H, Greene ME (2015) Precision of radiostereometric analysis (RSA) of acetabular cup stability and polyethylene wear improved by adding tantalum beads to the liner. Acta Orthopaedica 86:563-568

12 World Medical A (2013) World Medical Association Declaration of Helsinki: ethical principles for medical research involving human subjects. JAMA 310:2191-2194

13 Mann KS, Kurudirek M, Sidhu GS (2012) Verification of dosimetric materials to be used as tissue-substitutes in radiological diagnosis. Applied Radiation and Isotopes 70:681-691

14 Kaptein BL, Valstar ER, Stoel BC, Rozing PM, Reiber JHC (2003) A new model-based RSA method validated using CAD models and models from reversed engineering. Journal of Biomechanics 36:873-882

15 ISO (2019) International ISO standard ISO 5725: Accuracy (trueness and precision) of measurement methods and results

16 Van Rossum GaD, Fred L. (2009) Python 3 Reference Manual. CreateSpace, Scotts Valley, CA

17 Murray DW (1993) The definition and measurement of acetabular orientation. Journal of Bone and Joint Surgery (British Volume) 75:228-232

18 Trozzi C, Kaptein BL, Garling EH et al (2008) Precision assessment of model-based RSA for a total knee prosthesis in a biplanar set-up. Knee 15:396-402

19 Garling EH, Kaptein BL, Geleijns K, Nelissen RG, Valstar ER (2005) Marker Configuration Model-Based Roentgen Fluoroscopic Analysis. Journal of Biomechanics 38:893-901
20 Lam-Tin-Cheung K, Yuan X, Nikolov HN, Lanting BA, Naudie DD, Teeter MG (2017) Marker-based technique for visualizing radiolucent implant components in radiographic imaging. Journal of Orthopaedic Research 35:2017-2022
21 Ryd L, Yuan X, Lofgren H (2000) Methods for determining the accuracy of radiostereometric analysis (RSA). Acta Orthopaedica Scandinavica 71:403-408
22 Valstar ER, Gill R, Ryd L, Flivik G, Borlin N, Karrholm J (2005) Guidelines for standardization of radiostereometry (RSA) of implants. Acta Orthopaedica 76:563-572
23 ISO (2013) International standard ISO 16087:2013. Implants for surgery — Roentgen stereophotogrammetric analysis for the assessment of migration of orthopaedic implants,
24 Zaribaf FP, Gill HS, Pegg EC (2020) Characterisation of the physical, chemical and mechanical properties of a radiopaque polyethylene. Journal of Biomaterials Applications 35:215-223
25 Horsager K, Kaptein BL, Jorgensen PB, Jepsen CF, Stilling M (2018) Oxford medial unicompartmental knees display contact-loss during step-cycle motion and bicycle motion: A dynamic radiostereometric study. Journal of Orthopaedic Research 36:357-364
26 Noyer D, Caton JH (2017) Once upon a time.... Dual mobility: history. International Orthopaedics 41:611-618

Table 1 Markers represented in the CMC model of the phantom and the patient as specified by marker ID.

	Phantom				Patient			
Marker id	sd, x-axis	sd, y-axis	sd, z-axis	n	sd, x-axis	sd, y-axis	sd, z-axis	n
1	0.04	0.06	0.09	5				
2	0.05	0.08	0.19	5				
3	0.07	0.11	0.06	5				
4					0.25	0.19	0.11	4
5	-	-	-	1	0.13	0.14	0.28	3
6	0.12	0.11	0.01	2	0.10	0.18	0.26	3
7	0.09	0.07	0.10	3	0.03	0.35	0.16	2
8	0.12	0.02	0.29	2	0.14	0.15	0.28	2
9	-	-	-	1	0.08	0.04	0.21	2
10								
11	0.03	0.09	0.36	2	0.07	0.56	0.09	2
12	-	-	-	1	-	-	-	1
Femoral head	0.14	0.13	0.14	5	0.28	0.21	0.21	4

Marker id, id number of the marker in the model; sd, x-axis, sd, y-axis, sd, z-axis, the standard deviation of marker position per (calibration box-) axis of the RSA frame to which the markers were aligned; n, number of markers available to calculate the marker position in the CMC model

Table 2: Representation of markers in individual recordings. The phantom RSA frames have 4 common conventional markers and the patient frames have 2 common conventional markers. All frames have additional markers that cannot be used in standard analysis as they do not represent the same markers between frames. With a CMC model 11 markers were utilized in the phantom and 9 in the patient and all projections of these markers were available for analysis.

		Phantom					Patient			
Recording		1	2	3	4	5	1	2	3	4
Conventional markers	All recordings	4	4	4	4	4	2	2	2	2
	Additional markers	2	3	4	3	1	4	2	5	4
Combined marker configuration model	Model Markers (n)	11	11	11	11	11	9	9	9	9
	Left	10	8	10	11	7	6	7	7	6
	Right	9	8	9	3	9	6	6	7	7

Conventional markers, the marker is clearly visible in both images of the frame; Additional markers, markers that are visible in both images in the frame but cannot be included in a standard analysis as they do not represent the same marker between frames; Combined marker configuration model, markers and marker projections used for fitting the combined marker configuration model.

Table 3 Static liner orientation of the patient at baseline, 1- and 2-year follow-up

	Postop	1 year	2 years
Inclination	48°	54°	48°
Anteversion	12°	9°	0°
Rotation	-109°	-133°	-141°

Liner orientation measured in the coordinate system of the calibration box at baseline and adjusted for the cup orientation in subsequent follow-ups.

Figure 1 Illustration of the occlusion of liner markers by the shell and the head/neck/stem (only the left RSA image frame is shown). Despite a high number of markers in the liner (n=12) (A), they tend to be occluded by the head/neck (B) and cup (C) in RSA recordings. Marker information can be used as a simple markers model (green markers) (D), a combined markers configuration model (E) that merges marker information from several recordings (blue markers), or a hybrid model (F) that adds the theoretic marker positions (red markers) from the CAD drawings of the drill-guide used to insert the tantalum markers.

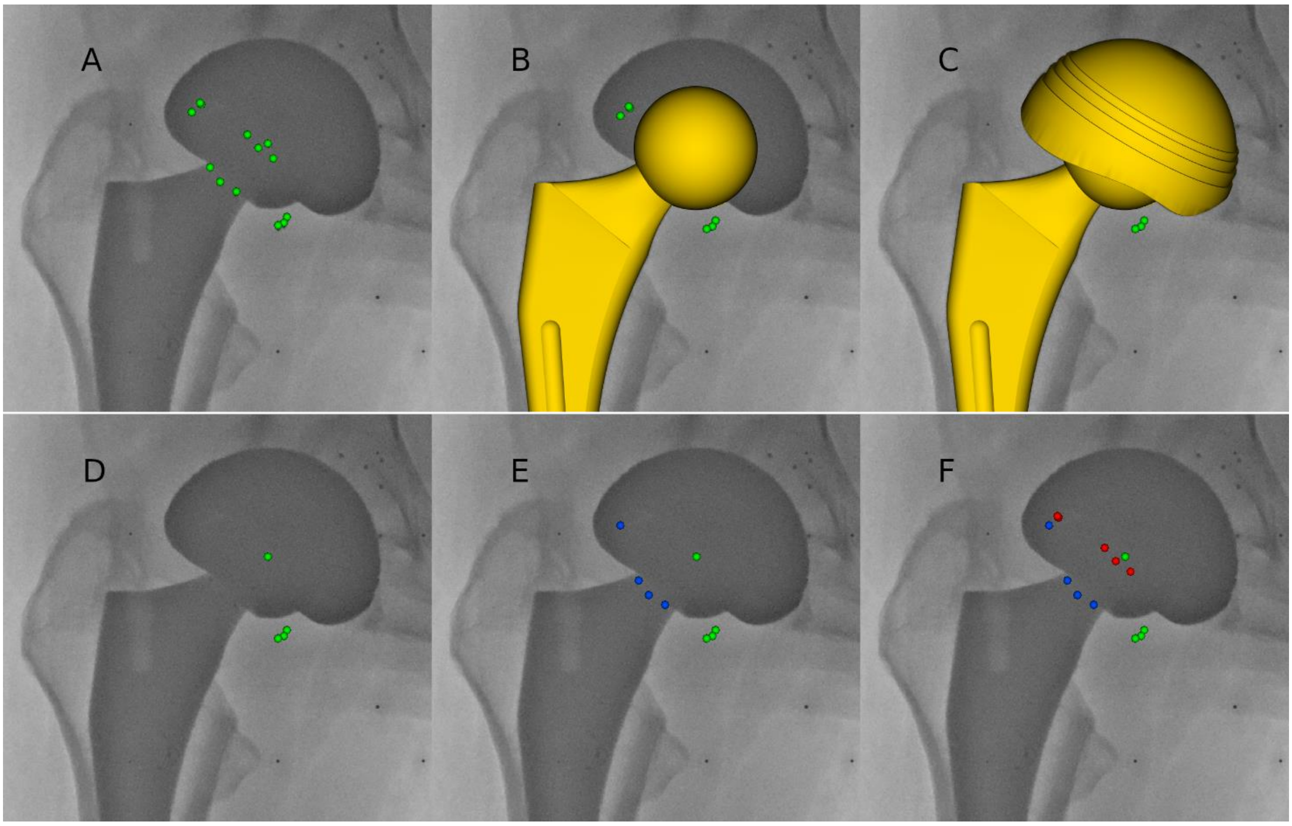


Figure 2 A customized tool with a drill guide for inserting markers in the individual liner sizes of the system was developed (left) and machined in stainless steel (right). Three markers with increased depth ensured distinctive marker groups.

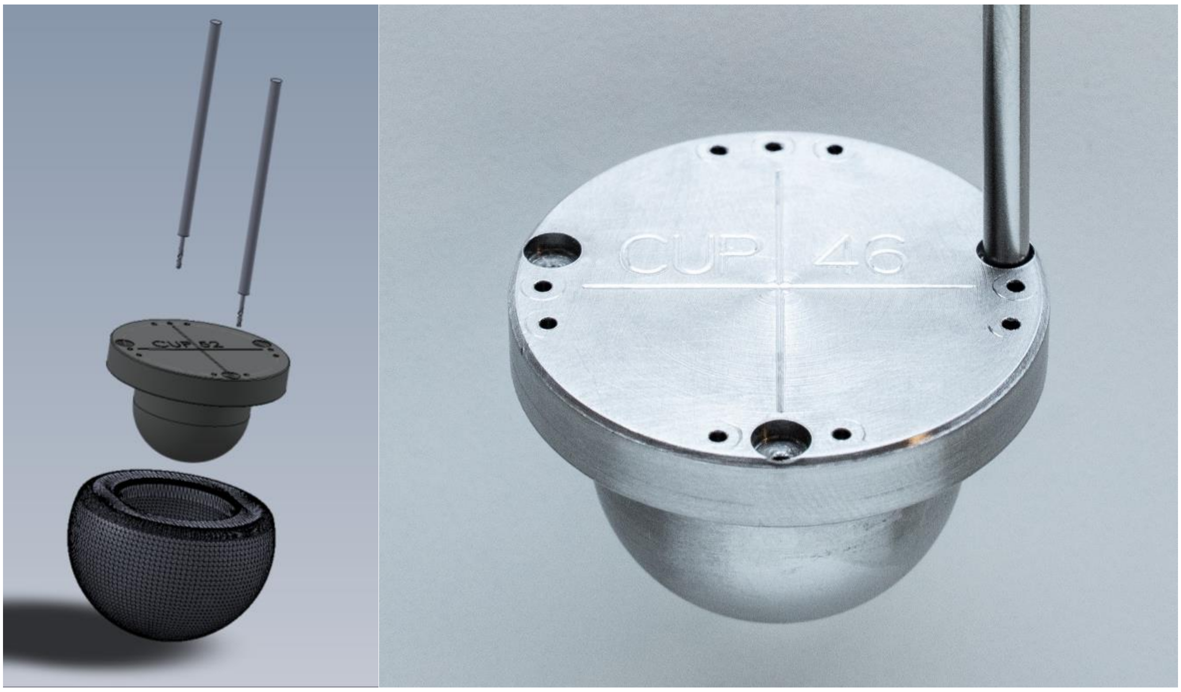


Figure 3 RSA set-up with a direct AP angle for static recordings (a) and a 45-degree recording angle (b) for dynamic recordings in order to obtain optimal view of the polyethylene liner. Image: Blue room

a

b

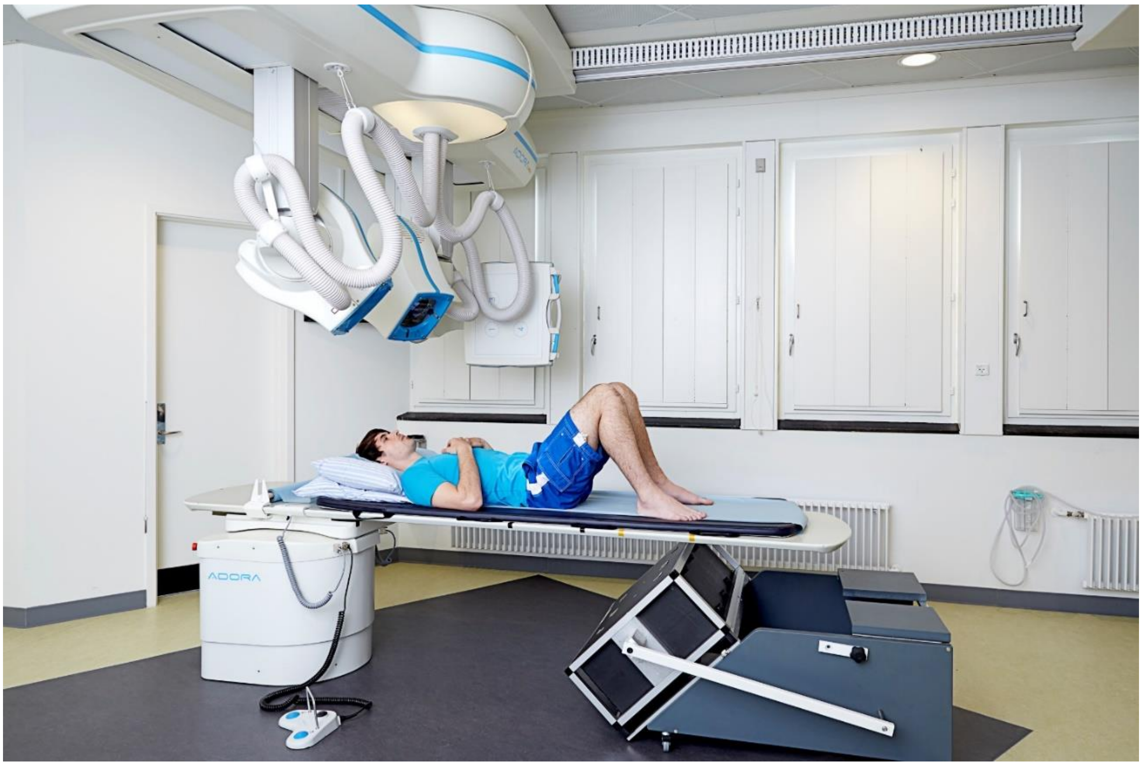


Figure 4. Liner rotation and stem rotation of the phantom (a) and patient (b). Dotted lines before movement indicates (constant) cup inclination and anteversion. Dashed lines show stem movements as indicated by the pictogram. In the phantom liner movement (solid lines) occurs in the end range of modified FABER motion (at 4 and 12 seconds) and of modified FADIF motion (at 8 seconds) when the liner/neck angle (black) approaches 36.6 degrees (solid red). In the patient liner movement occurs in end range of modified FABER motion (at 4 seconds) without the liner/neck angle approaching 36.6 degrees.

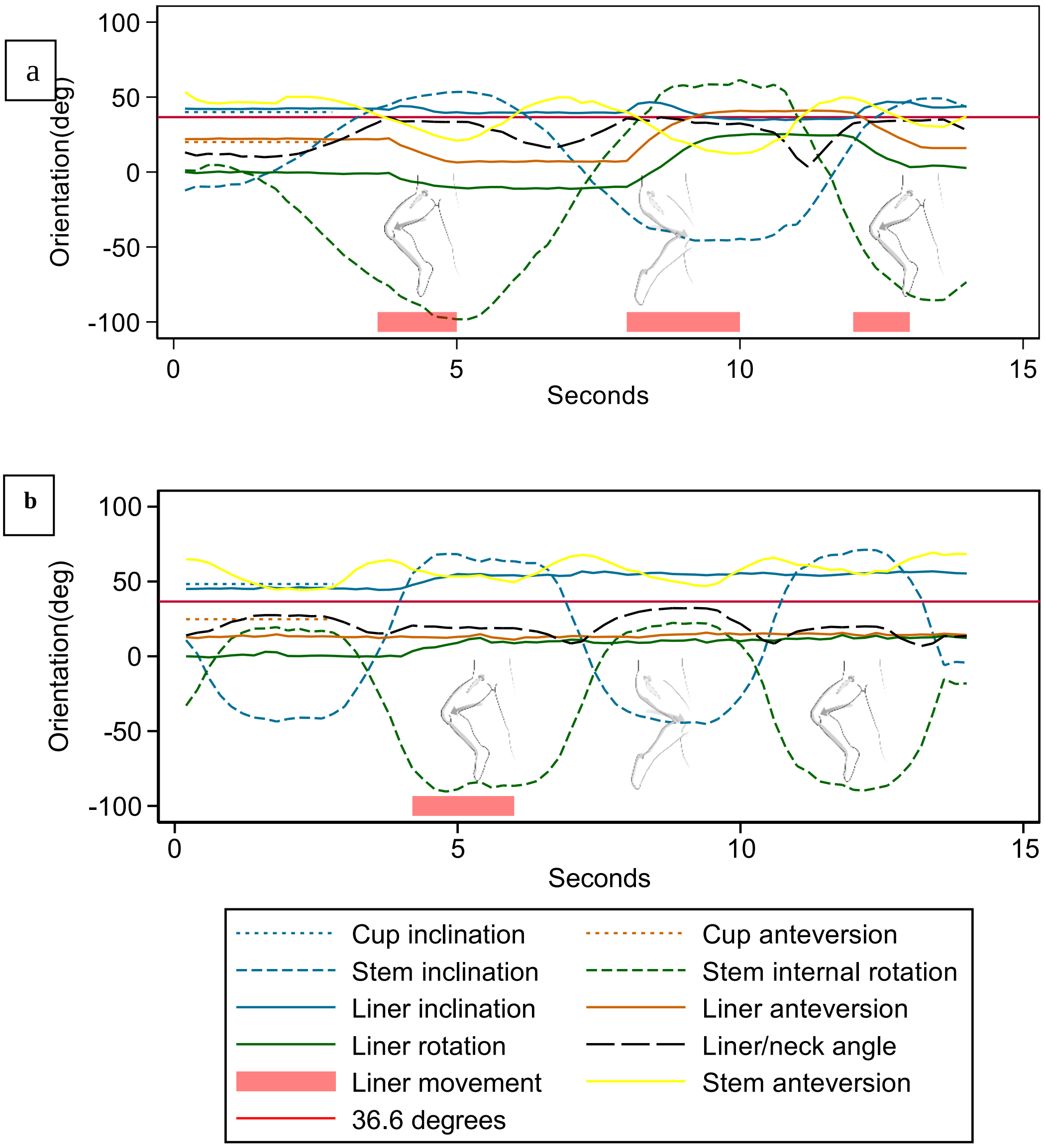


Figure 5: Example of ADM cup with a combined marker configuration model. Y-axis are shown for the femoral neck (blue), the cup (red), and the liner (green). ∠A: Liner/neck angle. The red circles indicate the detected marker projections in the image, as well as the center of the femoral head.

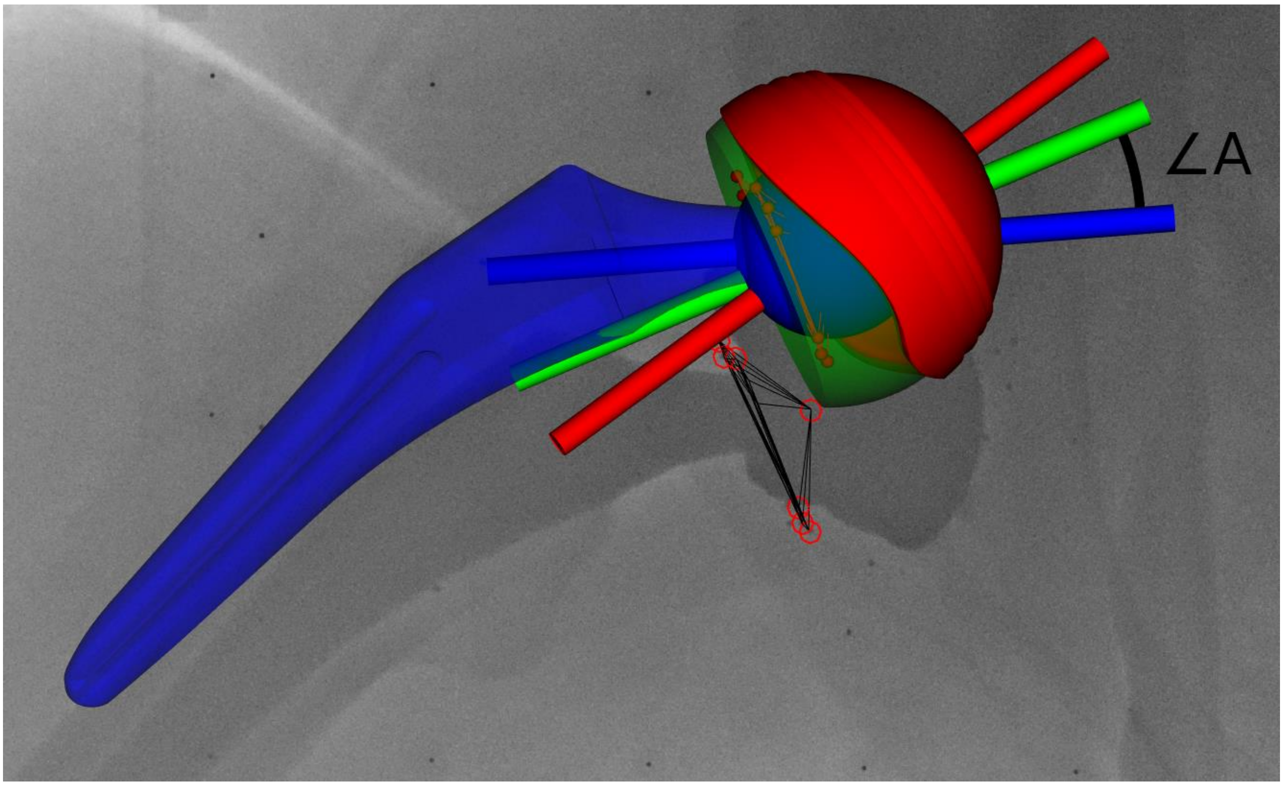
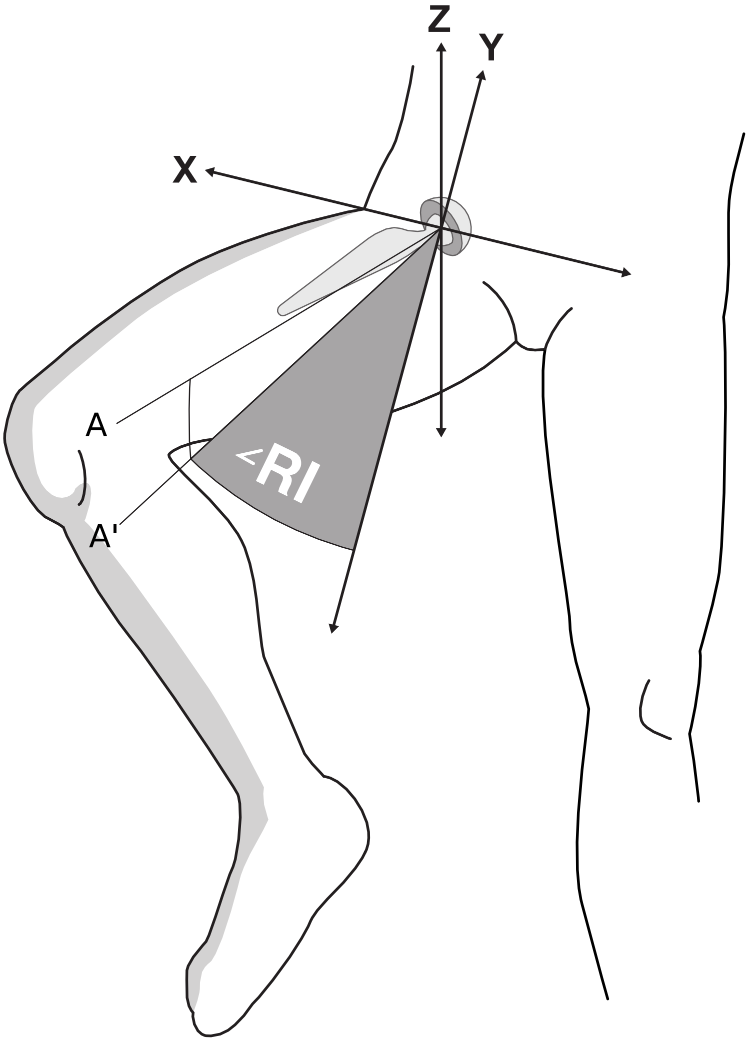


Figure 6. Radiographic anteversion and inclination of the cup. A: acetabular axis. A': projected acetabular axis. Radiographic inclination (∠RI) is defined as the angle between the longitudinal axis (y) and the acetabular axis (norm of cup) projected perpendicular on the coronal plane (A'). The radiographic anteversion (∠RA) is defined as the angle between the acetabular axis (A) and the coronal plane. X, Y, and Z represent the coordinate system of the RSA recording.



Paper 2

Polyethylene liner motion in dual mobility hip prostheses measured with static and dynamic RSA one year after operation

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Word count: 3285/3300

Abstract

Background and purpose

Dual mobility (DM) hip arthroplasty is designed with a freely moving polyethylene liner, which may protect against hip dislocation. Yet, no studies have confirmed polyethylene liner motion in vivo. We investigated the liner kinematics and factors associated with liner movement.

Patients and methods

We investigated 16 patients with Anatomical Dual Mobility acetabular components with ceramic femoral heads and HXLPE liners. Tantalum markers were implanted in the mobile liners using a drill guide to form a specific marker pattern. Static RSA recordings and patient reported outcome measures were obtained at baseline and 1-year follow-up. Dynamic RSA recordings were obtained at 1-year follow-up during a passive hip movement including 45 degrees flexion - abduction/external rotation – adduction/internal rotation (modified FABER-FADIR). Liner- and neck movements were described as anteversion, inclination and rotation.

Results

Median (range) absolute liner movements during modified FABER-FADIR were: anteversion 10° (5;20), inclination 6° (2;12), and rotation 11° (5;48) relative to the cup. Absolute changes in the resulting liner/neck angle (small articulation) was median 28° (12;46) and liner/cup angle (larger articulation) was 6° (4;21).

Static RSA showed changes in liner anteversion from median 7° (-12;23) to 10° (-3;16) and inclination from 42 (35;66) to 59 (46;80) from postop to 1-year.

Liner/neck contact was associated with high initial liner anteversion (p=0.01).

Interpretation

The polyethylene liner moves over time in most patients. One year after surgery the liner can move with or without liner/neck contact. The majority of movement is in the smaller articulation between head and liner.

Key words

Dual mobility, hip osteoarthrosis, dynamic radiostereometry, kinematics

Introduction

The dual mobility (DM) hip prosthesis is designed with a mobile polyethylene liner that acts as a spacer between the femoral head and the acetabular component. Theoretically, the DM liner moves when the neck is in contact with the liner, which increase the range of motion before impingement, but movement of the DM liner in-vivo has not previously been investigated. The DM design has been shown to reduce the postoperative dislocation rate while providing better range of hip movement compared to conventional implants (Guyen et al. 2007, McArthur et al. 2013). Further, it has been suggested that liner movement results in a more concentric polyethylene wear pattern, even with high cup inclination (Loving et al. 2013, Loving et al. 2015).

Liner movement in DM hip prostheses has only been investigated experimentally or by scratch patterns on retrieved liners (Grazioli et al. 2012, Fabry et al. 2014, Gao et al. 2018). Documentation of DM liner movement in-vivo is challenged by radiolucency of the polyethylene liner and radiopacity of the acetabular shell. Tantalum markers have previously been used to mark and visualize polyethylene liners for measurement of liner wear in single-mobility hip prostheses using marker-based radiostereometry (RSA) (Lindalen et al. 2012, Nebergall et al. 2015). However, occlusion of markers in the polyethylene by overlapping implant material poses a challenge with this method that depends on visual marker projections in both images of the RSA recording (Garling et al. 2005, Nebergall 2015). Information on marker-positions from several RSA recordings of the DM hip may be used to construct a patient-individual combined markers configuration model, which partially overcome problems with marker occlusion and make dynamic radiostereometry feasible for evaluation of DM liner mobility in-vivo (Jørgensen et al. 2021).

We hypothesized that the DM liner would be mobile 1 year after operation. Therefore, the purpose of the study was (1) to evaluate if liner movement occurred in DM cups 1 year after primary operation and (2) to describe the movement pattern and range of such movement.

Method

Patients

We included 16 patients (9 female) with DM articulations from a randomized clinical trial, which compared DM vs. ceramic/ceramic articulations (Table 1). The patients mean age was 62 years range (41;69) and the indication for surgery was primary hip osteoarthritis. Exclusion criteria were: Preoperative T-score <-1 on DXA scan of the spine and dual hip, neuromuscular or vascular disease in the affected leg, metabolic bone disease, dementia, lack of Danish citizenship or inability to comprehend the Danish language. All patients gave informed consent and the Helsinki II declaration was followed (World Medical 2013).

Implants

All patients were operated through a posterolateral access, using size 46-56 Anatomic Dual Mobility (ADM) cup, size 3-9, Accolade II stem with neck angle 127° (n=4) and 132° (n=12), and X3 HXLPE liners (Stryker, Kalamazoo, MI, USA) (Stryker, Warsaw, Mazovia, Poland). Ceramic v40 femoral heads size 28 (BIOLOX ® delta, CeramTec) was used. All polyethylene liners were prepared with 12 tantalum markers in the liner rim during surgery using a custom designed drill-guide (Figure 1). The markers were positioned in 4 groups of 3 markers, and each group had a unique pattern (Figure 1).

RSA setup

The AdoraRSA Suite (Nordic X-ray Technique, Hasselager, Aarhus, Denmark) with 2 ceiling mounted x-ray tubes angled 40° on each other was used for RSA recordings. Static RSA images were recorded post-operative and at 1-year follow-up with the patient supine, using a standard vertical tube set-up, a standard calibration box (cb24, Medis Specials, Leiden, Netherlands) and digital static detectors (CXDI-70C, Canon, Tokyo, Japan). Dynamic RSA (dRSA) images were recorded at 1-year follow-up in a 45° cranial/caudal angle tube set-up. This was a carefully chosen recording position balancing optimal radiographic views and wide range of movement (Figure 2). A standard calibration box (cb14, Medis Specials, Leiden, Netherlands) and digital dynamic detectors (CXDI-50RF, Canon, Tokyo, Japan) were used. The image resolution was 2688 x 2208 pixels with 0.16 mm pixel spacing and a framerate of 5 frames/second. The recorded hip motion was passive and applied by the same tester. The starting position was 45° hip flexion from which the hip was moved to end-range abduction/external rotation and end-range adduction/internal rotation (a modified FABER-FADIR motion) maintaining the 45° hip flexion (Figure 3).

RSA analysis

The RSA recordings were analyzed using mbRSA software (version 4.2, RSAcore, Leiden, The Netherlands). For the cup, that had a non-rotation symmetric shape, and the stem, standard projection matching techniques implemented in mbRSA were used (Kaptein et al. 2003). The markers inserted in the liner were registered in static and dynamic recordings as markers models (Kaptein et al. 2005). After aligning the models in mbRSA the marker positions from 4-7 RSA recordings were combined into a patient specific combined markers configuration (CMC) model using MatLab (version 2019b, The MathWorks Inc, Natick, Massachusetts). The femoral head was added as an extra marker. The local coordinate system of the CMC model was defined with the origin in the femoral head center and the y-axis perpendicular to the liner base plane fitted through the measured markers in the liner. Liner rotation about the y-axis was set to zero in the first dRSA recording. The measured CMC model was then applied to the dynamic recordings in mbRSA to register liner movement during hip movement. Finally, the motion patterns of the liner and stem components were extracted using a custom-made Python script (Python version 3.7, (Van Rossum 2009)).

Due to large variation in visible markers between the baseline and 1-year static recordings, a hybrid model was constructed consisting of the measured CMC model for best known marker positions and completed with the theoretical marker positions calculated from the CAD-model of the drill-guide. Combining these data sets resulted in a hybrid model including all 13 markers with the best accessible positions (Figure 1).

Liner orientation

Cup, liner and stem orientations were calculated as inclination, anteversion and rotation in a radiographic coordinate system (Murray 1993) (Figure 4). The cup inclination and anteversion was measured in the static RSA recording. To adjust for patient movements during the recording, the dynamic recordings were aligned with the first frame, using the cup position as reference. Total liner inclination / anteversion / rotation was defined as the amount of change in inclination / anteversion / rotation throughout the modified FADIR-FABER hip motion. A total of 24 dRSA frames in 2 patients (pt. 4 and 9) with missing data for the liner due to soft tissue overlay were not included in the results or analysis. Liner movement was defined as change in orientation. Total liner movement was defined as the amount of movement throughout the modified FADIR-FABER hip motion. To remove noise and identify patients with liner movement a moving average filter of 5 datapoints was applied to the measured liner angles. Liners were defined as moving if filtered movement was more than 5° in any angle. For all other measurements and graphs of liner movements, the non-filtered data was used.

The liner/cup angle was defined as the angle between liner base plane normal vector and the cup base plane normal vector. The liner/neck angle was defined as the angle between the liner normal vector and the neck axis. Increasing liner/neck angle inferred smaller distance between the rim of the liner and the neck. Based on a phantom study, contact between liner and neck was expected at liner/neck angles = 36.6°.

Clinical outcome

The Oxford hip score (OHS) was collected preoperatively and at 1-year follow-up, and was evaluated on a scale from 0 points for poor self-perceived hip function to 48 for best self-perceived hip function, as described by Murray et al (2007). Pain at rest and activity was recorded on a visual analogue scale (0-100) at baseline and 1-year follow-up.

Statistics

The dataset was dichotomized based on measured neck/liner angle below/above 36.6°. Data was evaluated for normal distribution using qq-plots. Normally distributed variables were tested using students t-test and variables not normally distributed were tested using Wilcoxon's rank sum. Liner orientation and patient reported outcomes were presented using median and range. Correlations between liner movement, cup position, initial liner position, and stem movement were evaluated using scatter plots. The correlations were tested using univariate linear regression and the residuals were evaluated using scatter and qq-plots. Statistical significance was assumed at $p<0.05$. Statistical calculations were performed using Stata (Stata/IC 16.1, StataCorp, College Station, TX, USA).

Ethics, registration, data sharing plan, funding, and potential conflicts of interest

This study was approved by the Central Denmark Ethics committee [1-10-72-343-14] and Danish Data protection Agency [1-10-72-343-14] and was registered in ClinicalTrials.gov [NCT02301182]. Stryker funded the study, but had no influence on the manuscript or publication. All authors declared no conflicts of interest.

Results

Dynamic RSA

The CMC models for the 16 patients consisted of mean (range) 7 (5;10) markers. All 6 liners that reached the 36.6° threshold for liner/neck contact moved more than 5° in inclination, anteversion or rotation. 6 of the 10 liners that stayed below the 36.6° liner/neck angle also moved at least 5° in either inclination, anteversion or rotation in the filtered data. The remaining 4 liners moved less than 5° in all rotations measured on filtered data.

The median (range) total liner movements were: anteversion 10° (5°; 20°), inclination 6° (2°; 12°), and rotation 11° (5°; 48°) in the non-filtered data.

The liner movement showed a clear pattern, but had great variation in extend between patients. Liner anteversion and inclination occurred with end-range stem inclination/rotation (at 7 and 10 seconds, Figure 5). Liner rotation occurred in end-range inclination/rotation combined with stem anteversion movement (2 seconds, Figure 5).

Total liner anteversion correlated with the initial liner anteversion (slope 0.42, p=0.04), and was most pronounced in the patients with liners moving beyond the liner/neck contact point (36.6° liner/neck angle) (p=0.02). Total liner inclination correlated with total stem inclination movement (slope 0.11, p=0.03) and was equally present in the patients with liners moving below and beyond the liner/neck contact point (36.6° liner/neck angle). Total liner rotation was not correlated with specific stem movements and was equally distributed for liners moving beyond the liner/neck contact point (36.6° liner/neck angle).

The median (range) total change in liner/neck angle was 28° (12°;46°) and larger than the median total change in liner/cup angle of 6° (4°;21°) (p=<0.001). This means that the smaller head-liner articulation described by the liner/neck angle contributed with larger movement than the larger liner-cup articulation described by the liner/cup angle.

Static RSA

For liner movement over time, 3 patients were excluded due to poor model representation in the postoperative RSA recording.

At 1-year follow-up, liner orientation showed substantial liner movement from postoperative. Median (range) absolute change in anteversion was 11° (1°;17°), inclination was 14° (1°;42°), and in rotation was 104° (7°;165°) (Table 2). While the median anteversion did not change statistically significant over time, the median (range) inclination increased from 42° (35°;66°) to 59° (46°;80°) ($p<0.001$) (Figure 6). At 1-year follow-up, all liners were positioned in higher inclination angle than the cup (Figure 7, Table 3).

Clinical outcomes

The self-perceived hip function measured as Oxford Hip Score increased 15 (95%CI: 10;20) points from baseline to 1-year follow-up with no statistically significant difference between patients with and without expected liner/neck contact ($p=0.6$). Pain during rest and activity decreased mean 23(95% CI: 12;34) and 43 (95%CI: 24;63) points on a 100 mm visual analogue scale with no statistically significant differences between groups ($p=0.5$).

Discussion

The key finding of the study was that the polyethylene liners in dual mobility hip prostheses move in vivo at 1-year follow-up, but with great variation between patients. In the large articulation, liner anteversion was initiated by contact with the neck whereas liner rotation and inclination were not associated with liner/neck contact.

Dynamic RSA

All 6 patient’s liners that reached the expected threshold for contact between liner and neck showed liner movement of more than 5° (pt. 2, 3, 5, 6, 8, 11); however, 6 liners that did not surpass the expected liner/neck contact angle also moved more than 5°. For 5 of the patients, the liner/neck angle continued to increase after the initial liner movement (pt. 4, 7, 9, 13, 14). Therefore, these liners moved without direct liner/neck contact. One patient was just above the threshold for liner motion (5.4°) and showed no sign of liner movement (pt. 16). It is therefore most likely, that the recorded movement was due to noise (figures in supplemental data).

The dual mobility hip prosthesis has a large articulation between the liner and the cup and a small articulation between the liner and the femoral head. The observed relationship between liner/neck and liner/cup angles supports that most movement in the DM hip arthroplasty takes place in the small articulation between femoral head and liner, whereas movement in the large articulation between the liner and the cup is smaller in magnitude and stimulated in end-range hip movements. These findings support the biomechanical rationale behind the dual mobility cup (Noyer et al. 2017).

During gait, the neck may come in contact with the liner as a result of the flexion/extension movement of the hip. In a phantom setup with loaded hip movements, Gao et al. (2018) found that initial liner anteversion outside the range of +/- 20° resulted in liner/neck contact and liner movement during simulated gait (Gao 2018). We found no association between initial liner anteversion and liner/neck contact. However, we did find an association between initial liner inclination and liner/neck contact. The difference in associations is likely because we studied a movement that was more inclination and less anteversion movement.

Gao et al. (2018) also found that inclination and anteversion of the cup had no influence on liner/neck contact (Gao 2018). Likewise, we found no association between cup anteversion/inclination and liner/neck contact.

Static RSA

Liner orientation changed for all patients from baseline to 1-year follow-up, with large differences in the magnitude of change of orientation between patients.

At 1-year follow-up we found a median liner inclination of 59°, which was well above the median cup inclination of 42°. If liners remain in a very high inclination, it could rise concern about uneven wear. Although, patient activities before the RSA recording were not controlled, the high inclination of the liner may be explained by patients walking prior to RSA-recording. In a phantom experiment, with continuous gait cycles Fabry et al. (2014) found that liners moved from a neutral position towards inclination of 60° and anteversion of 24° (Fabry 2014). In contrast, the median anteversion of 10° in this study was somewhat smaller.

Measured, theoretic or hybrid liner model

Measured models are constructed from actual marker projections. Actual marker projections show markers, even when the markers are misplaced. Markers can be misplaced for a number of reasons including variation in equipment (drills and guides) and variation introduced when inserting markers (e.g.: rotating the drill guide, or not obtaining the optimal depth of the marker). The greatest downside with measured models is that they require markers to be visible in both images of the RSA frame at some point. Therefore, it is very likely that some marker information never comes into play, when using this method.

Theoretic models are constructed from expected marker positions. Theoretic marker positions can provide a complete model based on the CAD-drawings of the instrument used as the guide for marker insertion. The major downside of a theoretic model is, that any deviation from the intended marker placement would result in errors and imprecision.

The hybrid model combines measured and theoretic marker positions and therefore receives strengths and weaknesses from both models. A hybrid model was chosen as the best solution for analysis of the static RSA recordings because large and unknown liner movements over time required a complete model with ID of all marker-groups. For the dynamic recordings a CMC model was chosen for its robustness, because there were smaller movements.

Liner/neck contact

The cut-off angle of 36.6° liner/neck angle appeared not to be consistent but varied between liners with a rather large range in max liner/neck angles over 36.6° (38°;47°). This could partly be explained by variation in the plane-fitting that is used to calculate the coordinate system of the CMC model and hence be a weakness due to the use of a measured model. Another liable reason could be variation of the opening angle and depth of the liners due to size differences and production tolerance.

Strengths and weaknesses

This is the first study to measure in vivo liner movement – dynamically and over time. We utilized a method for dynamic liner tracking, that modelled the markers directly. This method is robust to occluded marker projections, or markers that have changed position from the originally intended position, and enabled markers that were only visible in one of the stereo images. Further, the use of marker models has a high accuracy with a relatively small number of markers (Kaptein 2005).

The variation in maximum liner/neck angle was a drawback in this study because it indicates variation in the contact angle. Variation in contact angle could lead to misclassification of liner/neck contact for some patients and could affect the associations calculated. A better solution would have been to determine the individual contact angle. Unfortunately, this was not possible in our setup. Another weakness of the study was, that the recorded movement was not weightbearing. However, it did reflect everyday activities with risk of hip dislocation such as the patient reaching for the foot i.e., to put on shoes or socks. The set-up and hip movement were chosen after many experiments aiming to keep the hip joint/prosthesis area within the field of recording, close to the detectors, and avoiding too much soft tissue overlay.

Conclusion and interpretation

This is the first clinical study to show that dual mobility liners move in vivo and with a similar pattern between patients but to a very different extent. Liner motion was stimulated at end-range of the hip motion, with or without contact with the neck. The majority of movement occurred in the small articulation.

Author contributions

PBJ, KS, SSJ and MS designed the study, SSJ operated the patients, PBJ wrote the manuscript draft, BK and PBJ wrote the Python and Matlab programs, PBJ and BK performed the image analyses. All contributed to the data interpretation, and critical revision of the manuscript.

References

Fabry C, Kaehler M, Herrmann S, Woernle C, Bader R. Dynamic behavior of tripolar hip endoprostheses under physiological conditions and their effect on stability. Med Eng Phys. 2014;36(1):65-71. doi: 10.1016/j.medengphy.2013.09.007.

Gao Y, Chen Z, Zhang Z, Chen S, Jin Z. Effect of inclination and anteversion angles on kinematics and contact mechanics of dual mobility hip implants. Clin Biomech (Bristol, Avon). 2018;57:48-55. doi: 10.1016/j.clinbiomech.2018.06.009.

Garling EH, Kaptein BL, Geleijns K, Nelissen RG, Valstar ER. Marker Configuration Model-Based Roentgen Fluoroscopic Analysis. J Biomech. 2005;38(4):893-901. doi: 10.1016/j.jbiomech.2004.04.026.

Grazioli A, Ek ET, Rudiger HA. Biomechanical concept and clinical outcome of dual mobility cups. Int Orthop. 2012;36(12):2411-8. doi: 10.1007/s00264-012-1678-3.

Guyen O, Chen QS, Bejui-Hugues J, Berry DJ, An KN. Unconstrained tripolar hip implants: effect on hip stability. Clin Orthop Relat Res. 2007;455:202-8. doi: 10.1097/01.blo.0000238796.59596.1f.

Jørgensen PB, Kaptein BL, Søballe K, Jakobsen SS, Stilling M. Feasibility of combined and hybrid marker models for radiostereometry assessment of polyethylene liner motion in dual mobility hip prosthesis. Manuscript submitted for publication. 2021.

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. doi: 10.1016/j.jbiomech.2004.09.018.

Kaptein BL, Valstar ER, Stoel BC, Rozing PM, Reiber JHC. A new model-based RSA method validated using CAD models and models from reversed engineering. J Biomech. 2003;36(6):873-82. doi: 10.1016/s0021-9290(03)00002-2.

Lindalen E, Nordsletten L, Rohrl 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.

Loving L, Herrera L, Banerjee S, Heffernan C, Nevelos J, Markel DC, Mont MA. Dual mobility bearings withstand loading from steeper cup-inclinations without substantial wear. J Orthop Res. 2015;33(3):398-404. doi: 10.1002/jor.22774.

Loving L, Lee RK, Herrera L, Essner AP, Nevelos JE. Wear performance evaluation of a contemporary dual mobility hip bearing using multiple hip simulator testing conditions. J Arthroplasty. 2013;28(6):1041-6. doi: 10.1016/j.arth.2012.09.011.

McArthur BA, Nam D, Cross MB, Westrich GH, Sculco TP. Dual-mobility acetabular components in total hip arthroplasty. Am J Orthop (Belle Mead NJ). 2013;42(10):473-8.

Murray DW. The definition and measurement of acetabular orientation. J Bone Joint Surg Br. 1993;75(2):228-32. doi: 10.1302/0301-620X.75B2.8444942.

Murray DW, Fitzpatrick R, Rogers K, Pandit H, Beard DJ, Carr AJ, Dawson J. The use of the Oxford hip and knee scores. J Bone Joint Surg Br. 2007;89(8):1010-4. doi: 10.1302/0301-620X.89B8.19424.

Nebergall AK, Rader K, Palm H, Malchau H, Greene ME. Precision of radiostereometric analysis (RSA) of acetabular cup stability and polyethylene wear improved by adding tantalum beads to the liner. Acta Orthop. 2015;86(5):563-8. doi: 10.3109/17453674.2015.1054255.

Noyer D, Caton JH. Once upon a time.... Dual mobility: history. Int Orthop. 2017;41(3):611-8. doi: 10.1007/s00264-016-3361-6.

Van Rossum GaD, Fred L. Python 3 Reference Manual. CreateSpace: Scotts Valley, CA 2009.

World Medical A. World Medical Association Declaration of Helsinki: ethical principles for medical research involving human subjects. JAMA. 2013;310(20):2191-4. doi: 10.1001/jama.2013.281053.

Table 1: Baseline characteristics

	Total (n=16)	∠liner/neck < 36.6° (n=10)	∠liner/neck >= 36.6° (n=6)	P-value
Age, median(range)	62 (41;69)	62 (43;68)	59 (41;69)	0.48
Gender (Female/Male)	9 / 7	5 / 5	4 / 2	0.53
Body mass index	27 (18;40)	27 (18;33)	23 (21;30)	0.91
Oxford hip score (0-48), median(range)	27 (13;37)	29 (18;34)	28 (26;37)	0.79
Pain, rest (0-100), median(range) [a]	24 (0;76)	22 (0;76)	26 (16;48)	0.70
Pain, active (0-100), median(range) [a]	54 (21;93)	60 (24;86)	43 (21;74)	0.42

[a] Visual analogue scale

Table 2: Biomechanical and patient reported outcome at 1 year follow-up (dynamic RSA recordings).

	Total (n=16)	∠liner/neck <36.6° (n=10)	∠liner/neck >=36.6° (n=6)	P-value
Cup anteversion, mean°(95%CI)	23 (18;27)	22 (16;27)	24 (14;35)	[a] 0.62
Cup inclination, mean°(95%CI)	43 (40;46)	43 (39;46)	43 (35;50)	[a] 0.98
Initial liner anteversion, mean°(95%CI)	14 (11;18)	14 (10;19)	14 (8;20)	[a] 0.89
Initial liner inclination, mean°(95%CI)	57 (52;63)	52 (47;57)	66 (55;77)	[a] 0.01
Total liner anteversion, median°(range)	10 (5;20)	7 (5;20)	13 (10;20)	[b] 0.02
Total liner inclination, median°(range)	6 (2;12)	8 (2;12)	6 (3;11)	[b] 0.83
Total liner rotation, median°(range)	11 (5;48)	11 (6;20)	12 (5;48)	[b] 0.74
Total stem anteversion, median°(range)	25 (16;56)	24 (16;56)	27 (17;42)	[b] 0.91
Total stem inclination, median°(range)	79 (55;117)	80 (55;117)	78 (70;104)	[b] 0.91
Total stem rotation, median°(range)	97 (66;113)	92 (66;113)	100 (88;113)	[b] 0.33
Max Liner/neck∠, median°(range)	35 (25;47)	34 (25;36)	41 (38;47)	[b] 0.00
Total liner/neck ∠, median°(range)	28 (12;46)	25 (12;31)	36 (27;46)	[b] 0.01
Total neck/cup ∠, median°(range)	43 (25;70)	37 (25;70)	48 (36;68)	[b] 0.21
Total liner/cup ∠, median°(range)	6 (4;21)	5 (4;21)	9 (5;15)	[b] 0.13
Oxford hip score, median(range)	47 (18;48)	46 (32;48)	47 (18;48)	[b] 0.54
Pain decrease, rest, mean(95%CI)	23 (12;34)	26 (15;37)	18 (-11;48)	[a] 0.50
Pain decrease, active, mean(95%CI)	43 (24;63)	48 (23;73)	35 (-7;77)	[a] 0.50

a: students t-test, b: Wilcoxons rank sum test.

Table 3 Liner orientation (degrees) at baseline and 1-year follow-up (static RSA recordings).

	Cup orientation			**Liner Anteversion**			**Liner Inclination**			**Liner rotation**		
id	Anteversion	Inclination	Rotation	Postop	1-year	Absolute change	Postop	1-year	Absolute change	Postop	1-year	Absolute change
1	26	41	-9	21	10	11	42	46	4	42	146	104
2	20	34	-19	7	13	6	39	58	19	-95	147	118
3	21	45	-19	2	-3	4	35	67	32	-7	-16	9
4	37	50	-25	23	7	16	44	61	17	-155	-7	148
5	12	51	-52	15	15	1	39	80	42	20	-145	165
6	35	50	-39	15	2	14	66	67	1	-27	-34	7
7	12	35	-15	3	16	13	39	47	9	178	114	64
8	20	41	-43	-1	3	4	43	69	26	-60	-171	111
9	10	42	-36	16	11	6	42	57	15	3	124	121
10	23	37	-24	-12	4	15	42	53	11	144	-116	100
11	37	36	-39	-3	10	13	58	72	14	171	156	15
14	16	45	-23	10	10	1	53	59	6	67	102	36
16	21	49	-25	-1	15	17	43	52	9	18	127	108
Median	21	42	-25	7	10	11	42	59	14	18	102	104
(range)	(10;37)	(34;51)	(-52;-9)	(-12;23)	(-3;16)	(1;17)	(35;66)	(46;80)	(1;42)	(-155;178)	(-171;156)	(7;165)

Figure 1 A hybrid model was made by combining the theoretical (green) and measured (red) markers and head (blue). The 4 groups can be identified by one marker placed deeper in the PE (except for the far left group that is identified by all markers being at the same level)

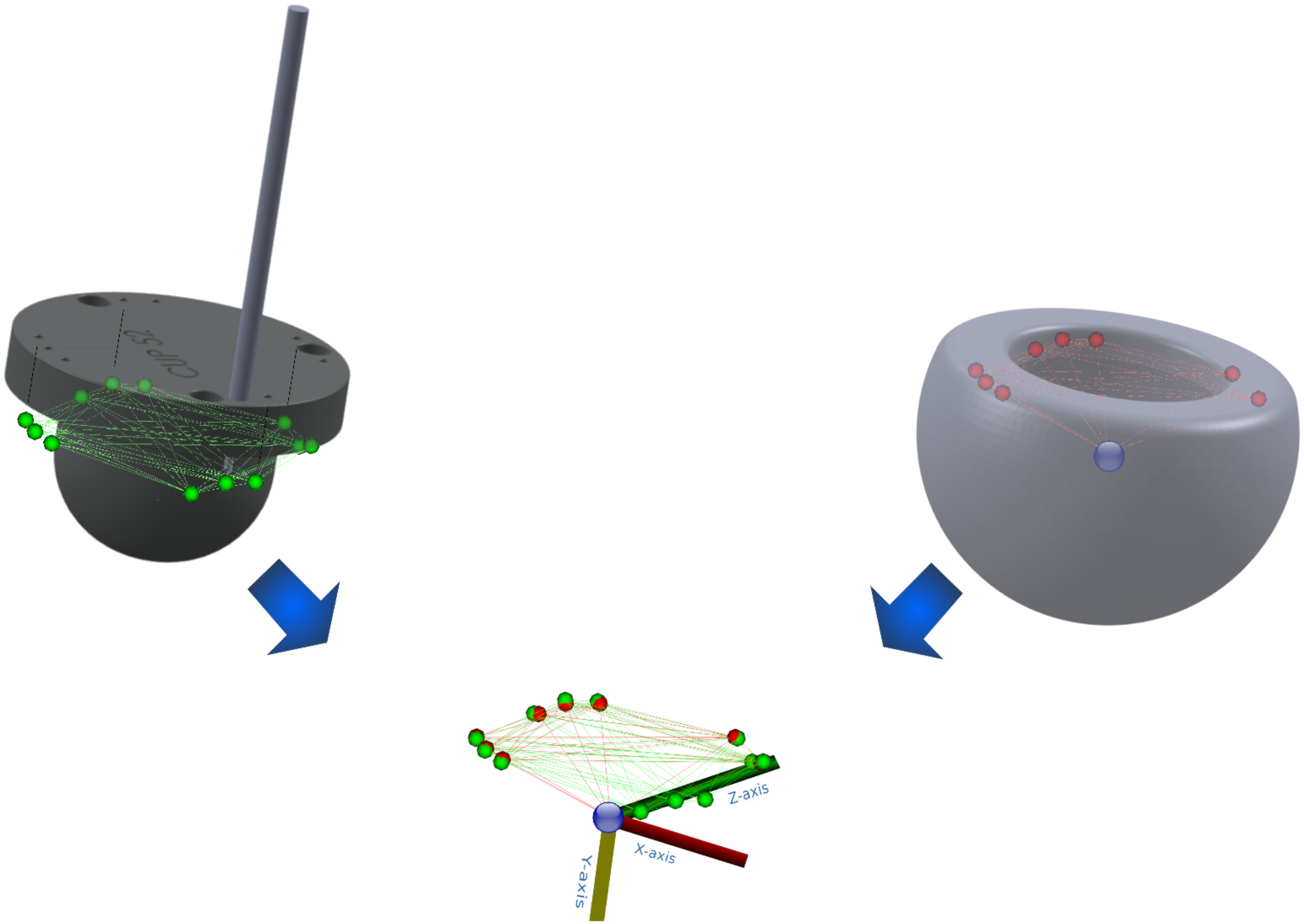


Figure 2 Dynamic radiostereometric recording. The patient was positioned at the end of the examination table with both feet at foot rests. The recorded hip was in 45 degrees flexion and the foot remained fixed in this position.

Figure 3 Hip movements during recording. From 45 degrees flexion, the hip was rotated to end-range external rotation/abduction and end-range internal rotation/adduction (model image).

Figure 4 Radiographic inclination (RI) and radiographic anteversion (RA)

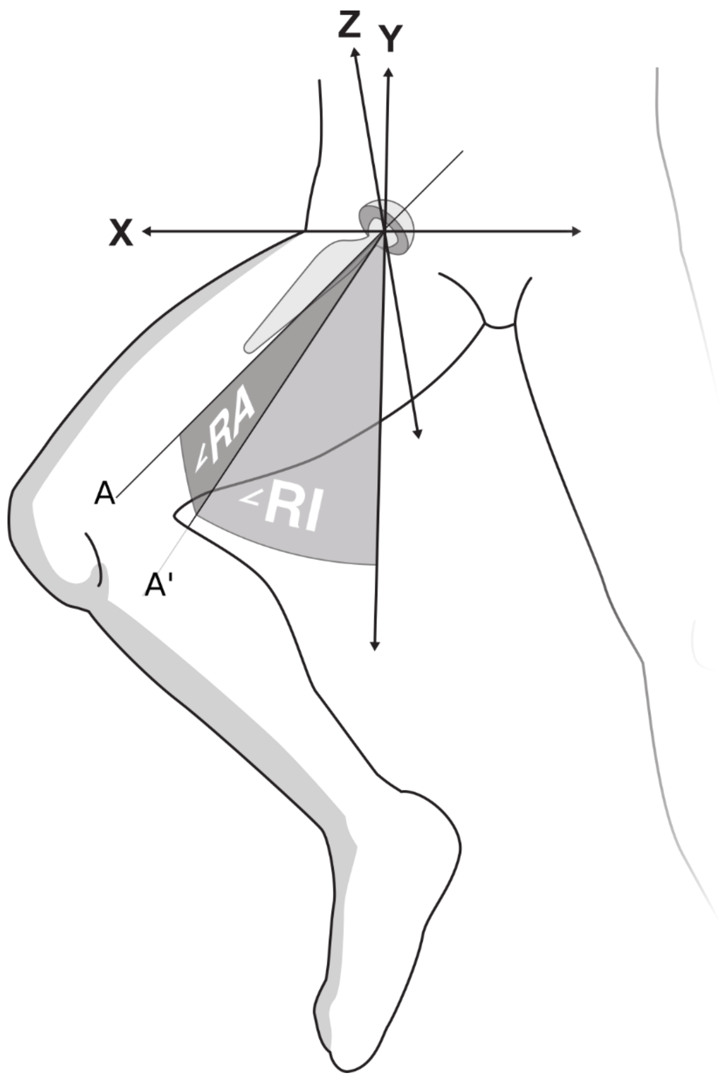


Figure 5 Example of stem- and liner movement. For complete collection of graphs see supplemental.

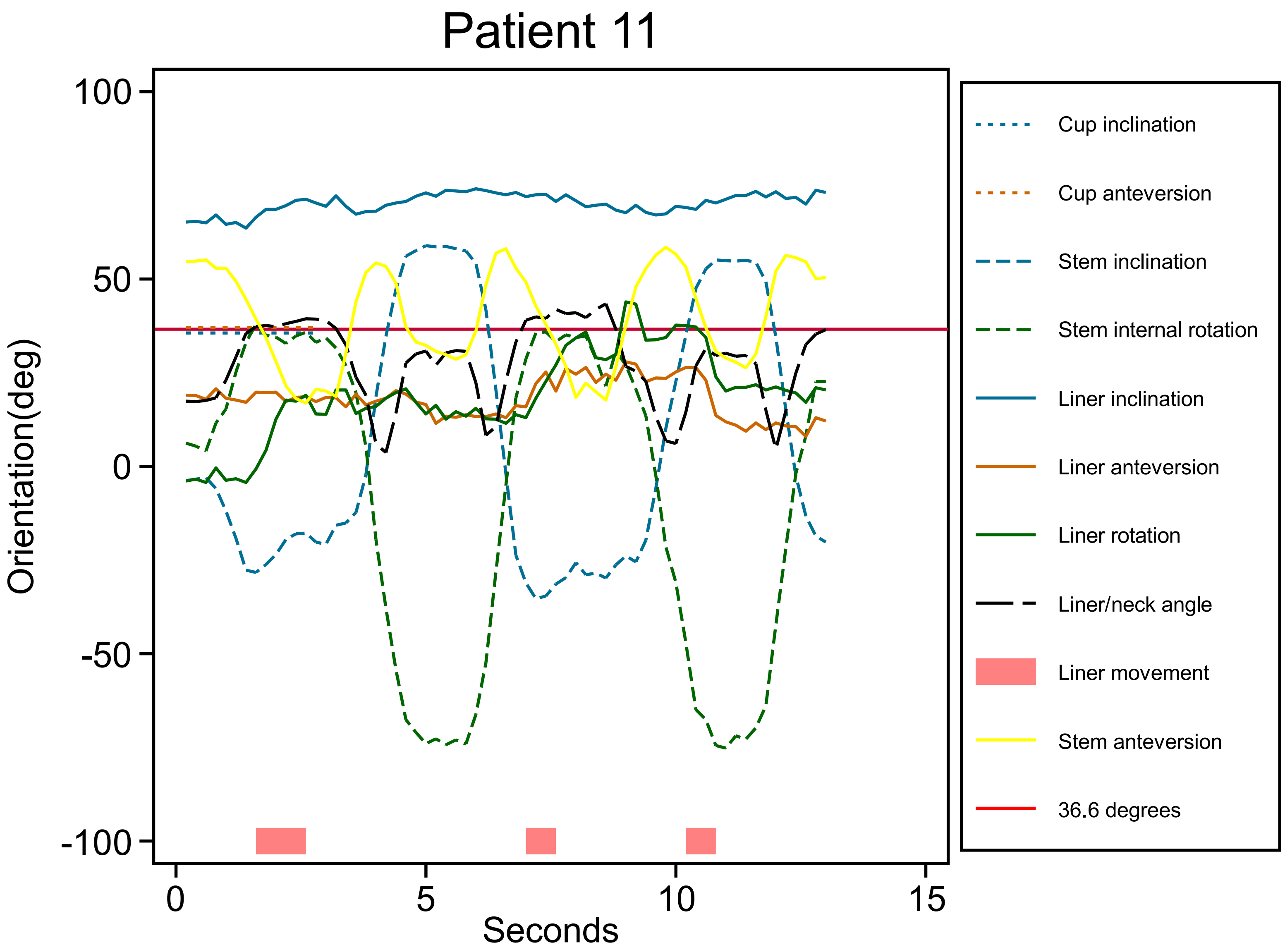


Figure 6 Line plot visualizing the change in liner orientation from postoperative static RSA recordings to follow-up after one year. There was a statistically significant increase in inclination, but no significant change in anteversion

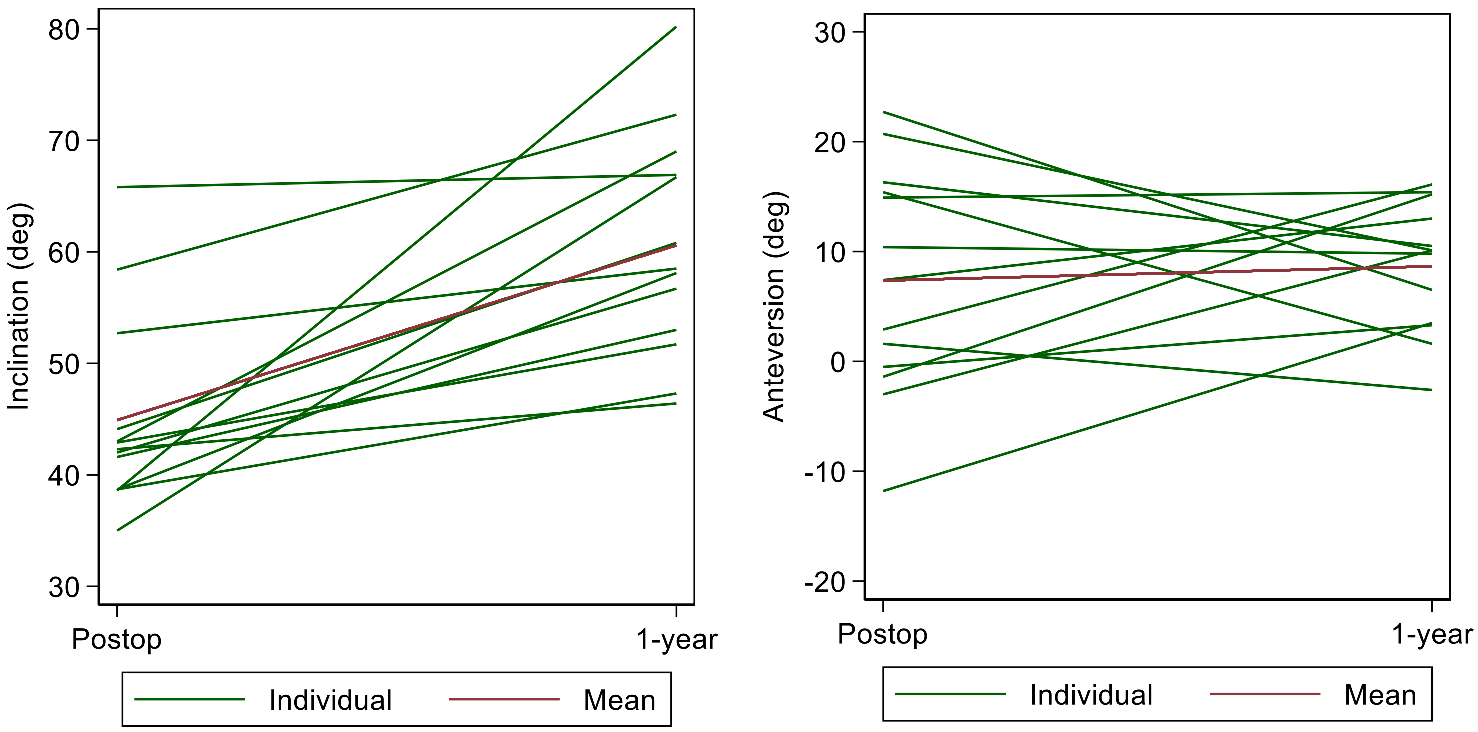
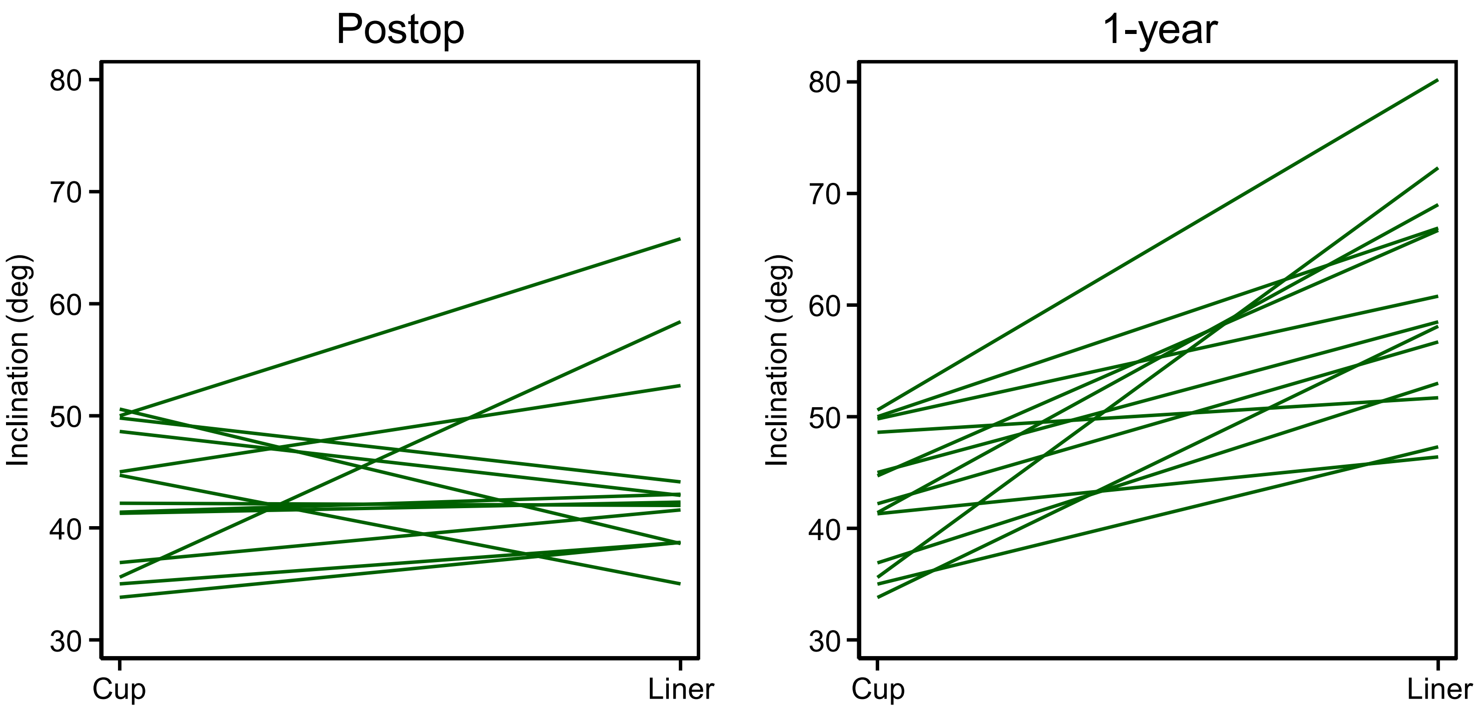
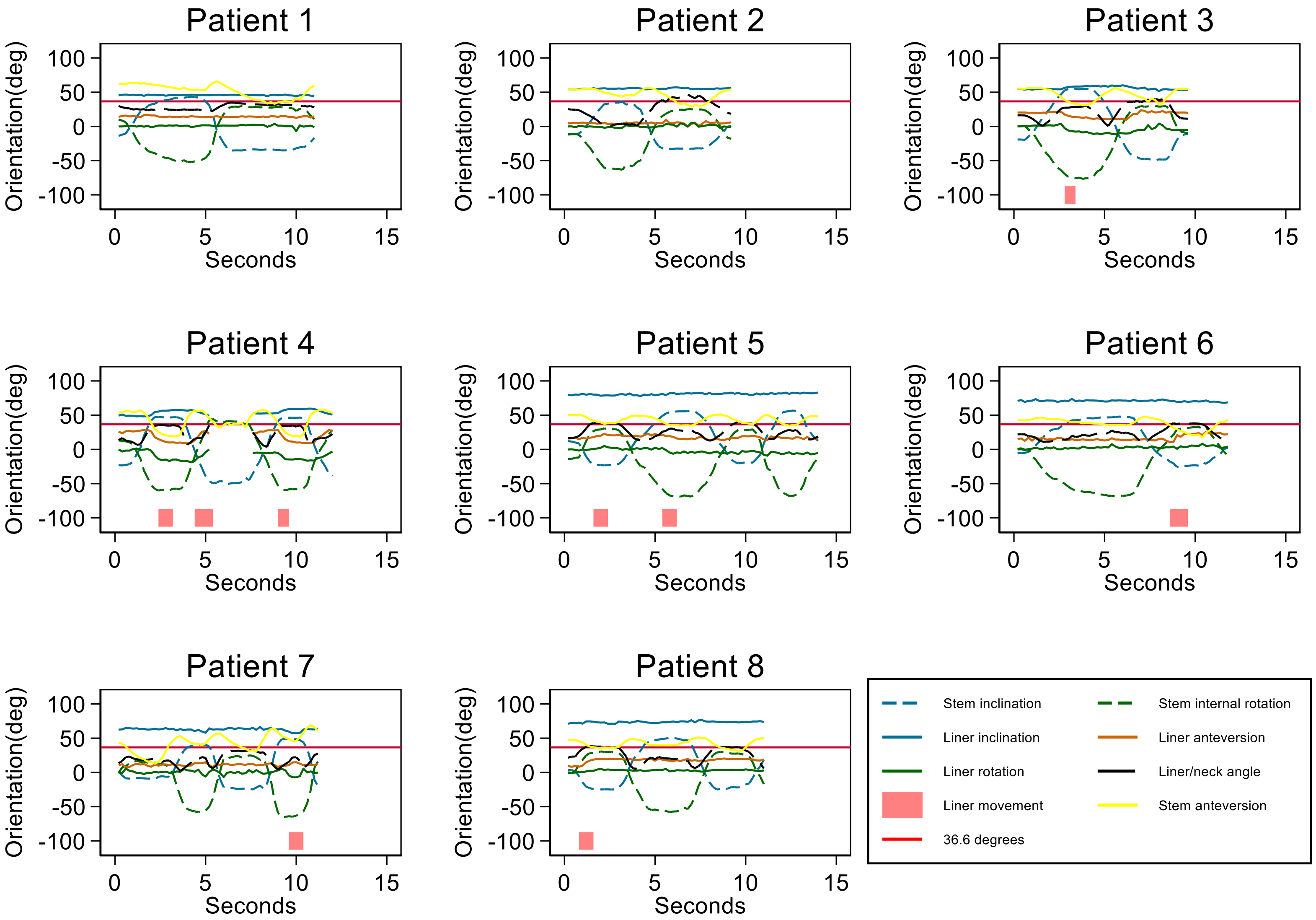
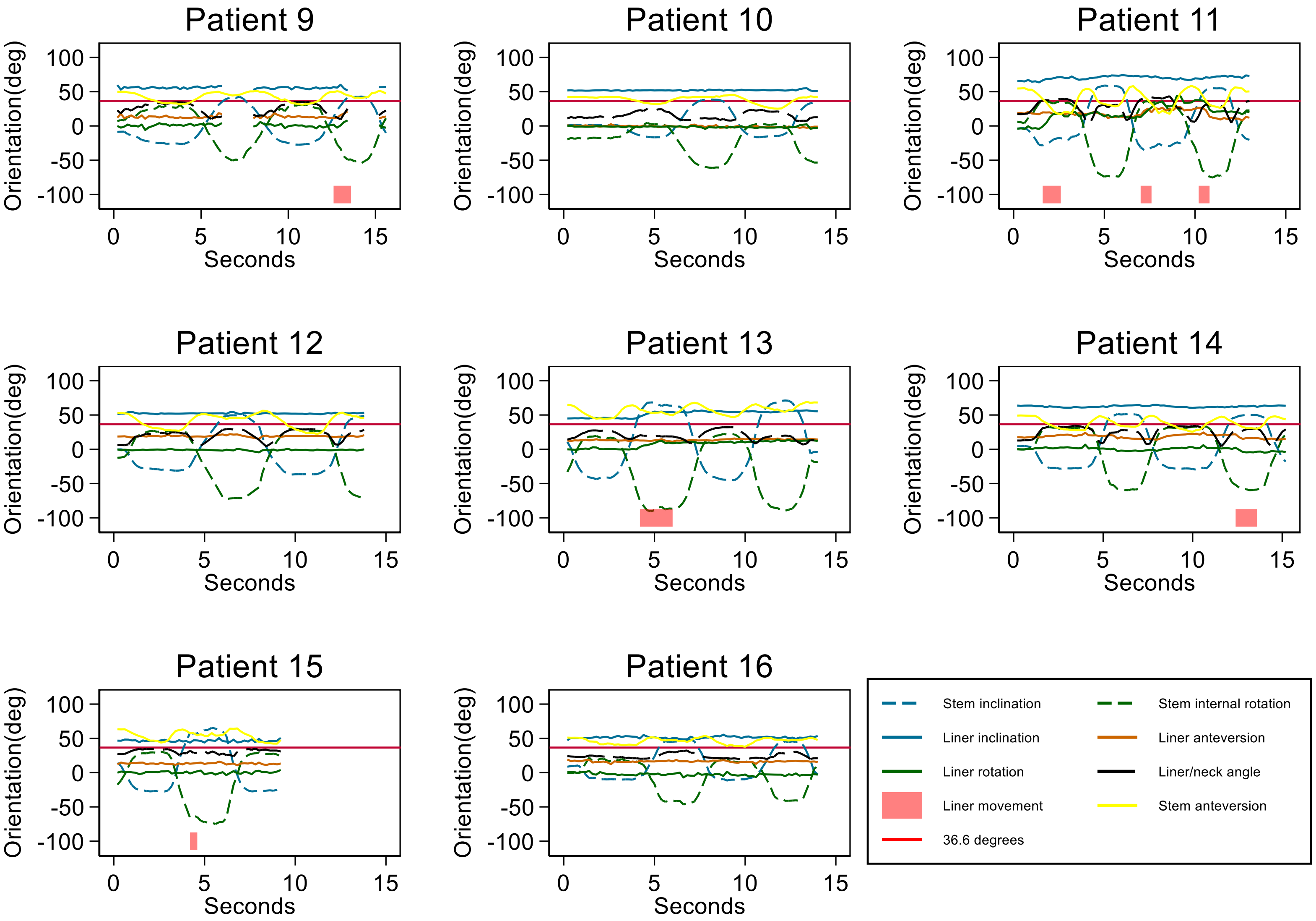


Figure 7 Parallel plot visualizing the cup/liner relationship postoperatively and at 1-year follow-up. After one year all liners showed more inclination than the cup.



Supplemental




Patient 9
Patient 10
Patient 11
Patient 12
Patient 13
Patient 14
Patient 15
Patient 16
Orientation(deg)
Seconds
100
50
0
-50
-100
0
5
10
15
Stem inclination
Stem internal rotation
Liner inclination
Liner anteversion
Liner rotation
Liner/neck angle
Liner movement
Stem anteversion
36.6 degrees

Paper 3

Five-year polyethylene cup migration and PE wear of the anatomic dual mobility acetabular construct.

Journal of Arthroplasty

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Abstract

Dual mobility implants have been successful in reducing postoperative hip dislocation but mid-term results of cup migration and polyethylene wear are missing in the literature. Therefore, we measured migration and wear at 5-year follow-up using radiostemetric analysis (RSA).

Patients and methods

The anatomic dual mobility X3 acetabular construct was utilized in total hip arthroplasty of 44 patients (mean age 73, 36 female) considered at higher risk of hip dislocation.

RSA and Oxford Hip Scores were recorded at the time of operation and 1, 2 and 5 years postoperatively. Cup migration and polyethylene wear were calculated.

Results:

Mean 2-year proximal translation was 0.3 mm (95% CI: 0.17; 0.36). Proximal translation was stable from 1- to 5-year follow-up. Mean 2-year sagittal rotation was 0.2° (95% CI: -0.22; 0.68) and was greater in patients with osteoporosis (p=0.04). From one-year recording, the annual 3D wear rate was 0.07 mm (0.05; 0.10).

Oxford hip scores improved 19 (95% CI: 14; 24) points from mean 21 (range: 4; 39) at baseline, to 40 (9; 48) 2 years postoperatively. There were no progressive radiolucent lines > 1 mm. There was 1 revision for offset correction.

Conclusions:

Despite an unselected patient group, we found no THA dislocations, no cases with clinical cup loosening and all patients had a stable 3D polyethylene wear rate and proximal implant migration. The results support the use of this implant, also for the older and frail population.

Keywords: dual mobility; hip arthroplasty; HXLPE; polyethylene wear; cup fixation; radiostereometric analysis; wear rate

Highlights (3-5 bullets)

- Low wear rate of second generation highly cross-linked polyethylene in a dual mobility acetabular construct.
- Stable migration pattern of the cementless anatomic dual mobility cup.
- No correlation of HXLPE wear and 5-year migration of an anatomical dual mobility cup.

Introduction

Dislocation, aseptic loosening, and polyethylene (PE) wear are the greatest causes for total hip arthroplasty (THA) revisions and underline the importance of a mechanically stable, well-fixed acetabular cup with low PE wear profiles (DHR 2020). Several studies have shown that dual mobility (DM) cups reduce the risk of dislocation and the associated risk of cup revision in THA (Kreipke et al. 2019, Romagnoli et al. 2019, Jonker et al. 2020). Factors that increase the risk of THA dislocation include previous THA dislocation, hip dysplasia, old age, hip fracture, high fall-risk, and dementia. Patients at greater risk of a priori THA dislocation may have a high benefit of DM THA in particular (Romagnoli 2019, Jonker 2020). In addition, frail and elderly patients often have low bone mineral density (BMD), which has been associated with increased early cup migration of cemented as well as cementless DM cups in patients with osteoarthritis (Finnila et al. 2016, Tabori-Jensen et al. 2020). Particularly, early proximal cup translation and sagittal rotation has been associated with increased risk of later aseptic implant loosening (Nieuwenhuijse et al. 2012, Pijls et al.). However, also the cup migration pattern has become increasingly important to evaluate lasting fixation and therefor mid-term and long-term studies are needed.

The use of highly cross-linked PE (HXLPE) has improved the mechanical PE wear properties in THA (Callary et al. 2015). However, the in vivo liner movements and double PE articulation in DM THA may increase PE wear (Jørgensen et al. 2021). In addition, for cementless cups, PE wear can be accelerated by third body wear from hydroxyapatite coating particles. High PE wear may result in osteolysis, cup loosening and risk of THA revision (Stilling et al. 2009).

In this study, we evaluated the five-year migration and PE wear of a DM acetabular construct in a patient cohort of 44 patients.

Material and methods

Patients

From 2015 to 2016, a consecutive cohort of 44 patients (mean age (range)73 (41 - 94), 36 female) was operated with an anatomic dual mobility (ADM) acetabular construct, in our institution. The patients were registered in the continuous clinical RSA database 2014-2017, which was registered with the Danish Data Protection Agency [1-16-02-54-14]. The Central Denmark Region Committees on Health Research Ethics did not consider the project notifiable according to Danish law number. 593 of June 14th 2011 on science ethics treatment of health science research projects.

Indications for operation were primary osteoarthrosis (n=33), hip fracture (n=5), femoral head necrosis(n=1), and revision of THA (n=5). Indication for dual mobility followed an internal algorithm in the department (Table 5). All patients consented orally to 10 years of follow-up in the clinical RSA database. Oxford hip score (OHS) and DXA-scan were completed preoperatively. RSA examinations were completed postoperatively. OHS and RSA exams continued at 1-, 2- and 5-years follow-up.

Operation and implants

All patients were operated using the posterolateral access and all cups were ADM acetabular component with a highly crosslinked X3 liner (Stryker Orthopaedics, Warsaw, Mazovia, Poland) and 28 mm heads. The ADM cup combines the DM polyethylene concept with a cementless fixation of a monoblock cobalt chrome shell with porous titanium and hydroxyapatite plasma-sprayed coating (Stryker Orthopaedics, Warsaw, Mazovia, Poland). The femoral heads were either CoCr; Ifit (n=29) modular (n=2) (Stryker Orthopaedics, Warsaw, Mazovia, Poland), Versys (n=5) (ZimmerBiomet, Warzaw, IN) or stainless steel; Bioball (n=1) (Merete, Berlin, Germany) or ceramic; Biolox delta (n=9) (Stryker Orthopaedics, Warsaw, Mazovia, Poland). The stems used were: ExeterV40 (n=30), Accolade II (n=5) and Modular Hip System (n=3) (Stryker Orthopaedics, Warsaw, Mazovia, Poland), CPT (n=4), BiMetric (n=1) (ZimmerBiomet, Warzaw, IN), and one calcar supported stem (Hipokrat, Turkey).

DXA, RSA and radiography

Preoperative DXA-scans were performed on a GE Lunar iDXA scanner (General Electric, Chicago, IL, USA), an analyzed using the encore software. Patients with a T-score < -2.5 were diagnosed with osteoporosis and referred to a specialist for further treatment.

RSA recordings with the patient in supine position were obtained using the AdoraRSA Suite (Nordic X-ray Technique, Hasselager, Aarhus, Denmark). Two ceiling mounted x-ray tubes were angled 40° on each other and we used a standard calibration box (cb24, Medis Specials, Leiden, Netherlands) and digital static detectors (CXDI-70C, Canon, Tokyo, Japan) with a resolution of 4 lp/mm. Analyses of PE wear and cup migration were performed by one investigator with Model-Based RSA 4.2 (RSAcore, Leiden, The Netherlands). We used CAD surface implant models for the cup, an elementary geometric shape model for the femoral head and bone markers as the reference.

Cup migration was calculated as the cup displacement and rotation relative to acetabulum markers in the coordinate system of the calibration box (Figure 2). Axis were adjusted to the anatomic coordinates of a right-side hip. In cases with occluded bone markers a marker configuration model was used if possible (Kaptein et al. 2005). The maximum rigid body error was set to 0.35 mm and the maximum accepted condition number was 150 (Valstar et al. 2005). Three patients had condition numbers between 150 and 155. All three were included after examining the positions for linearity of the bone markers. One was analyzed using CM-model with mean fitting error of 0,15 and the mean error of rigid body fitting for the other two were 0.16. Cup migration of the three patients did not deviate from the group migrations. Reference marker configurations with condition numbers >155 (n=4) or migration in the reference markers (n=2) were categorized as inadequate and the data excluded from the migration analysis. The average CN was 102 (95% CI: 92; 112).

Wear measurements were given in the coordinate system of the calibration box. Wear was defined as displacement of the femoral head relative to the cup which includes wear of both the small and large articulation. Wear from postop to 1-year follow-up was defined as bedding- in, femoral head penetration was defined as wear from postop to last follow-up, and wear rate was the PE wear per year from 1-year to last follow-up. All three PE wear parameters were calculated for: proximal wear defined as wear in the y-direction, 2D wear defined as the vectorial sum of x- and y-wear (frontal plane wear), and 3D wear defined by the vectorial sum of x-, y- and z-wear.

Cup orientation (anteversion and inclination) was derived from the RSA recordings. We used the median value of all accessible RSA recordings. This was because the shape of the ADM shell would expectedly affect orientation measurement on standard radiographs.

Osteolysis and radiolucent lines were investigated using the final follow-up plain AP radiographs with reference to the postoperative radiograph (DeLee et al. 1976). In cases without final follow-up plain radiograph, the RSA radiographs were used.

Patient reported outcomes

The Oxford hip score measures the patient perceived hip pain and function. It is a validated tool for tracking changes over time and was filled out by the patients prior to operation and at 1- , 2- and 5-year follow-up. The minimal important change was set to 10 (Beard et al. 2015).

Statistics

Migration, wear data and OHS were evaluated for normal distribution using qq-plots.

Migration was dichotomized on patients with osteoporosis (T-score<-2.5) and patients without osteoporosis (T-score>-2.5) and compared using multivariate repeated measurement analysis with T-score and follow-up time as factors. Equality of standard deviation and correlation was tested using multivariate test and residuals were examined using scatterplots. In addition, subgroup analysis on indications were performed using t-test to evaluate eventual effect on migration. Correlation between wear and migration at 2- and 5-year follow-up was tested using Spearman's rank correlation. The cohort was dichotomized on femoral head material (metal/ceramic) in evaluation of polyethylene wear.

RSA precision was calculated on 33 double examinations (Valstar 2005). The baseline recording formed the reference for migration in each of the double examination RSA analyses and both the patient and the RSA equipment were repositioned between the two RSA recordings. The mean difference from the first to the second recording was the systematic difference (bias) and the variation between the two recordings (precision) was given as Coefficient of repeatability (CR) = 1.96*sd of the differences.

Statistical significance was assumed at $p<0.05$. Statistical calculations were performed using Stata (Stata/IC 16.1, StataCorp, College Station, TX, USA).

Results

Of 44 patients originally operated, 24 completed the five-year follow-up. The reasons for loss to follow-up was mainly health issues or death for reasons unrelated to the hip arthroplasty (Figure 1). The baseline patient demographics are given in table 1.

RSA precision

Bias was <0.01 mm for cup translations and < 0.1° for cup rotations. Precision (CR) was 0.1 mm for cup y-translations and 0.2 mm for cup x- and z-translation. CR was < 1° for cup z-rotations and < 2° for x- and y-rotations. For PE wear, the bias was <0.03 mm for all PE wear parameters (Table 2). CR was 0.1 mm for proximal and 2D wear measurements, and 0.3 mm for 3D wear measurements.

Cup migration

In the first year, the ADM cup had proximal translation of 0.28 mm (95% CI: 0. 19; 0.38 mm) and sagittal rotation of 0.26° (95% CI: -0.17°; 0.68°). Hereafter, the proximal translation and sagittal rotation stabilized (Figure 4, Figure 5, Figure 6, Table 3).

At two years follow-up, patients with osteoporosis (n=6) showed 0.06 mm (95% CI: -0.14; 0.25, p=0.55) more proximal migration and 1.1° (95% CI: 0.1; -2.1, p=0.04) more sagittal rotation than patients without osteoporosis (n=26 (Figure 4). The difference in sagittal rotation was no longer statistically significantly different at five-year follow-up (p=0.17). Subgroup analysis of osteoarthrosis and other indications for THA showed no statistically differences in proximal migration or sagittal rotation at any timepoint (p>0.23).

PE wear

All wear parameters are reported in Table 4. Bedding-in was 0.3 mm (95% CI: 0.20 mm; 0.38 mm) in 3D, which also affected femoral head penetration in the PE (Figure 3). After one year, the 2D PE wear rate was 0.04 mm/year (95% CI: 0.03; 0.06) and the 3D PE wear rate was 0.07 mm/year (95% CI: 0.05; 0.09). Linear regression showed no correlation between BMI and 3D wear rate (slope 0.003, p=0.2) or age and 3D wear rate (slope 0, p=0.9). The 3D PE wear rate of 0.06 mm (95% CI: 0; 0.11) for ceramic femoral heads and of 0.08 mm (95% CI: 0.05; 0.011) for metal femoral heads was similar (p=0.38). PE wear rate > 0.1 mm was measured in 11 metal and 1 ceramic femoral head. Patients operated for osteoarthrosis (n=26) had a 3D wear rate of 0.06 mm/year (95% CI:0.04; 0.09), while patients operated for other reasons (n=6) had 3D wear rate of 0.11 mm/year (95% CI: 0.05; 0.1) with no statistically significant difference (p=0.08). Linear regression of PE wear rate neither correlated with cup proximal translation or cup sagittal rotation at two- or five-year follow-up nor with anteversion and inclination angle of the shell (slope<0.3, p>0.12).

Radiographic evaluation showed 3 patients with radiolucent lines in zone one or two. All of these were reduced or unchanged compared to baseline evaluation. Two patients had radiolucent lines of 0.5 mm in zone one. One was reduced from 0.75 mm at baseline and one was not seen on baseline evaluation. No patients had sign of osteolysis at final follow-up.

Clinical outcomes

OHS increased from mean 21 (range: 4; 39) at baseline to mean 40 (range: 9; 48) at two-year follow-up and mean 43 (range: 25; 48) at five-year follow-up, which exceeded the minimal important difference of 10 points. The overall questionnaire response rate was 84 %.

One patient received revision shortly after two-year follow-up to correct for offset (-4 corrected to 0). During the five-year period there were no incidents of dislocation or aseptic implant loosening.

Discussion

This is the first study to present PE wear and cup migration of the anatomic DM construct at mid-term follow-up. We found 1) low 3D PE wear rates with no association to BMI, age, operation indication, femoral head material (ceramics/metal) and cup position and 2) higher early cup proximal translation and sagittal rotation in patients with osteoporosis with stabilization of all cups after 1 year, but no difference in cup migration for patients with osteoarthrosis versus other indications for THA.

ADM cup migration

We found that cup migration mainly occurred within the first year and that the migration pattern stabilized until the five-year follow-up. The two-year proximal cup migration of 0.26 mm was higher than the 0.18 mm reported by Laende et al. for the same cup type (ADM) in younger patients (mean 63 years) (Laende et al. 2020). It was also higher than the 0.09 mm reported by Tabori-Jensen et al. for the cementless Avantage dual mobility cup in a cohort of similar age (mean 75 years) and systemic BMD as in the present study (Tabori-Jensen et al. 2018). The sagittal rotation of 0.23° (95% CI: -0.22; 0.68) was similar to the 0.21° reported by Laende et al. but higher than the –0.01° reported by Tabori-Jensen et al. (Laende 2020, Tabori-Jensen 2020). The main reason for the slightly higher proximal cup migration in the present study is likely that we studied the patients in the target group for dual mobility THA, older patients with osteoporosis and a mix of THA indications including primary osteoarthrosis, hip fracture, osteonecrosis and revision THA.

Importantly, cup migration stabilized in all patients one year after surgery despite the variation in BMD and indications for operation. This is very important since the use of dual mobility cups to protect for dislocation is preferred in patients with various indications for THA. We were unable to find migration studies on dual mobility cups with better similarity in the composition of the cohort.

PE wear of the X3 liner

Patients were positioned supine for all recordings. Standing recording could potentially have caused the liner to move into another position and perhaps reveal a different measure of wear. However, the difference caused by patient position is likely small (Digas et al. 2003, von Schewelov et al. 2006). Standing recordings introduce other difficulties like postoperative pain and soft tissue overlay, leading to poor image quality.

We found low 2D and 3D wear rates of the highly crosslinked X3 PE liner. We found a 2D wear rate of 0.05 mm/year for the X3 liner, which is lower than the 0.27 mm/year reported for the X3 HXLPE liner in another dual mobility (MDM, Stryker) cup measured with Martells method (hip analysis suite) (Deckard et al. 2018). Deckard et al. reported mean cup inclination 54.6° which is also higher than the mean inclination of 43° reported in our study. This could indicate that dual mobility constructs does not necessarily protect against exercise wear due to high cup inclination as reported by Loving et al. (Loving et al. 2015).

Low wear rates of the X3 liner material have been supported in long-term studies in single mobility THA (Campbell et al. 2010, Lindalen et al. 2019, Rames et al. 2019). Laende et al. studied PE wear of the X3 liner in the ADM cup until three-years follow-up, and found a 3D wear rate of 0.09 mm/year comparable to the 0.07 mm/year in our study, and like us concluded that most of the femoral head penetration took place in the bedding-in period before one-year follow-up (Laende 2020).

Ceramic femoral heads have been used for decades to decrease PE wear in articulation with UHMWPE (Stilling et al. 2009). However, different femoral head materials in articulation with HXLPE has not yet been shown to affect the wear rate (Teeter et al. 2018, Bergvinsson et al. 2020). The results of the present study are in line with these findings.

PE particles cause inflammation and activation of macrophages and osteoclasts, which leads to periprosthetic osteolysis. Particles from first generations of crosslinked PE has been shown to have a larger percentage of debris of bioactive size < 1 µm compared to non-crosslinked (Fisher et al. 2004). The particle size of second generation HXLPE is similar to the particle size of conventional ultra-high molecular weight polyethylene (UHMWPE) (Dumbleton et al. 2006), however the particle load is lower in HXLPE. In single mobility THA, long-term PE wear of HXLPE liners has been associated with reduced osteolysis and aseptic cup loosening (Prock-Gibbs et al. 2021). The combination of only one progressing radiolucent line and no osteolysis correlates well with the low wear found in this study.

PE wear measurement

Dual mobility PE liner wears both in the large and the small articulation. The small articulation typically has a 28mm femoral head size, which has been known to produce low wear rates in single mobility THA (Livermore et al. 1990, Tarasevicius et al. 2008). The size of the large articulation between the liner and the cup depends on the cup size. In addition, the liner moves during function in both articulations (Jørgensen 2021) Consequently, calculation of volumetric PE wear in DM THA is complicated. It has been suggested that the three-dimensional distance between the acetabular cup center and the femoral head center is the best measure for PE wear in DM constructs (Boyer et al. 2017). In this study we presented proximal- as well as 2D and 3D wear rates for comparison with the literature.

We calculated the PE wear rate using one-year follow-up RSA images as baseline for the subsequent follow-ups. Thereby we measured PE wear in any direction and the measures were not affected by PE bedding-in. We found 3D wear rates to be consistently higher than 2D wear rates using RSA for measurements. While 3D wear may be the most accurate way to measure wear, it also comes with a lower precision both in an RSA set-up and in plain radiographs (Stilling et al. 2012).

Strengths and limitations

The precision of DM cup migration and PE wear in our study of corresponds well with the precision of proximal wear (range: 0.02–0.11 mm) and 3D wear (range: 0.16–0.28 mm) reported by Callary et al (Callary 2015) but is somewhat poorer than the precision found by Laende et al. (Laende 2020). Especially, the PE wear and cup migration measured in in the z-axis have higher precision in Laende et al.'s study. The reason may be found in the angulation of the x-ray tubes where Laende at al. used 30° and our set-up used 20°. Furthermore, we accepted condition numbers for the acetabular bone reference up to 155, which may jeopardize precision. On the other hand, the anatomical cup shape improved model fitting and increased precision of the ADM cup compared to earlier findings CR of 0.35, 0.21, and 0.65 mm in x-, y- and z-translation and 1.56, 1.49 0.36° in x-, z- and y-rotation for single-mobility cup brands recorded on same equipment with the same analysist (Jorgensen et al. 2020).

We included all consecutive patients operated in our institution in the period from March 2015 to October 2016 with an ADM acetabular construct. Thereby the surgical indication for DM THA was representative of everyday life in our hip department and included patients with hip fracture, osteoporosis, and THA revision – indication that are well known to cause higher risk of THA dislocation. Due to the Covid-19 pandemic and patient fragility we only had a moderate compliance with questionnaires and follow-ups. Although, long-term implant survival may not be needed for frail elderly patients there is a continuously increasing lifetime expectancy and patients are quite active even at high-age wherefore good implant fixation, low PE wear and great function should be a priority, even for older patients, whom may not tolerate revision surgery.

Conclusions

Despite an unselected patient group, we found no THA dislocations, no cases with clinical cup loosening and all patients had a stable 3D PE wear rate and proximal implant migration. The results support the use of this implant, also for the older and frail population.

References

Beard DJ, Harris K, Dawson J, Doll H, Murray DW, Carr AJ, Price AJ. Meaningful changes for the Oxford hip and knee scores after joint replacement surgery. J Clin Epidemiol. 2015;68(1):73-9. doi: 10.1016/j.jclinepi.2014.08.009.

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.

Boyer B, Neri T, Di Iorio A, Geringer J, Philippot R, Farizon F. The linear penetration rate is not relevant for evaluating wear of dual mobility cups: an explant study. Int Orthop. 2017;41(3):599-603. doi: 10.1007/s00264-017-3406-5.

Callary SA, Solomon LB, Holubowycz OT, Campbell DG, Munn Z, Howie DW. Wear of highly crosslinked polyethylene acetabular components. Acta Orthop. 2015;86(2):159-68. doi: 10.3109/17453674.2014.972890.

Campbell DG, Field JR, Callary SA. Second-generation highly cross-linked X3 polyethylene wear: a preliminary radiostereometric analysis study. Clin Orthop Relat Res. 2010;468(10):2704-9. doi: 10.1007/s11999-010-1259-y.

Deckard ER, Azzam KA, Meneghini RM. Contemporary Dual Mobility Head Penetration at Five Years: Concern for the Additional Convex Bearing Surface? J Arthroplasty. 2018;33(7S):S280-S4. doi: 10.1016/j.arth.2018.02.061.

DeLee JG, Charnley J. Radiological demarcation of cemented sockets in total hip replacement. Clin Orthop Relat Res. 1976(121):20-32.

DHR TDHAR. National Annual Report. 2020.

Digas G, Kärrholm J, Thanner J, Malchau H, Herberts P. Highly cross-linked polyethylene in cemented THA: randomized study of 61 hips. Clin Orthop Relat Res. 2003(417):126-38. doi: 10.1097/01.blo.0000096802.78689.45.

Dumbleton JH, D'Antonio JA, Manley MT, Capello WN, Wang A. The basis for a second-generation highly cross-linked UHMWPE. Clin Orthop Relat Res. 2006;453:265-71. doi: 10.1097/01.blo.0000238856.61862.7d.

Finnila S, Moritz N, Svedstro 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.

Fisher J, McEwen HM, Tipper JL, Galvin AL, Ingram J, Kamali A, Stone MH, Ingham E. Wear, debris, and biologic activity of cross-linked polyethylene in the knee: benefits and potential concerns. Clin Orthop Relat Res. 2004(428):114-9. doi: 10.1097/01.blo.0000148783.20469.4c.

Jonker RC, van Beers L, van der Wal BCH, Vogely HC, Parratte S, Castelein RM, Poolman RW. Can dual mobility cups prevent dislocation without increasing revision rates in primary total hip arthroplasty? A systematic review. Orthop Traumatol Surg Res. 2020;106(3):509-17. doi: 10.1016/j.otsr.2019.12.019.

Jorgensen PB, Daugaard H, Jakobsen SS, Lamm M, Soballe 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.

Jørgensen PB, Kaptein BL, Søballe K, Jakobsen SS, Stilling M. Polyethylene liner motion in dual mobility hip prostheses measured with static and dynamic RSA one year after operation. Submitted for publication. 2021.

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. doi: 10.1016/j.jbiomech.2004.09.018.

Kreipke R, Rogmark C, Pedersen AB, Karrholm J, Hallan G, Havelin LI, Makela K, Overgaard S. Dual Mobility Cups: Effect on Risk of Revision of Primary Total Hip Arthroplasty Due to Osteoarthritis: A Matched Population-Based Study Using the Nordic Arthroplasty Register Association Database. J Bone Joint Surg Am. 2019;101(2):169-76. doi: 10.2106/JBJS.17.00841.

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.

Lindalen E, Thoen PS, Nordsletten L, Høvik Ø, Röhrl SM. Low wear rate at 6-year follow-up of vitamin E-infused cross-linked polyethylene: a randomised trial using 32- and 36-mm heads. Hip Int. 2019;29(4):355-62. doi: 10.1177/1120700018798790.

Livermore J, Ilstrup D, Morrey B. Effect of femoral head size on wear of the polyethylene acetabular component. J Bone Joint Surg Am. 1990;72(4):518-28.

Loving L, Herrera L, Banerjee S, Heffernan C, Nevelos J, Markel DC, Mont MA. Dual mobility bearings withstand loading from steeper cup-inclinations without substantial wear. J Orthop Res. 2015;33(3):398-404. doi: 10.1002/jor.22774.

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.

Pijls BG, Nieuwenhuijse MJ, Fiocco M, Plevier JW, Middeldorp S, Nelissen RG, Valstar ER. 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. doi: 10.3109/17453674.2012.745353.

Prock-Gibbs H, Pumilia CA, Meckmongkol T, Lovejoy J, Mumith A, Coathup M. Incidence of Osteolysis and Aseptic Loosening Following Metal-on-Highly Cross-Linked Polyethylene Hip Arthroplasty: A Systematic Review of Studies with Up to 15-Year Follow-up. J Bone Joint Surg Am. 2021;103(8):728-40. doi: 10.2106/jbjs.20.01086.

Rames RD, Stambough JB, Pashos GE, Maloney WJ, Martell JM, Clohisy JC. Fifteen-Year Results of Total Hip Arthroplasty With Cobalt-Chromium Femoral Heads on Highly Cross-Linked Polyethylene in Patients 50 Years and Less. J Arthroplasty. 2019;34(6):1143-9. doi: 10.1016/j.arth.2019.01.071.

Romagnoli M, Grassi A, Costa GG, Lazaro LE, Lo Presti M, Zaffagnini S. The efficacy of dual-mobility cup in preventing dislocation after total hip arthroplasty: a systematic review and meta-analysis of comparative studies. Int Orthop. 2019;43(5):1071-82. doi: 10.1007/s00264-018-4062-0.

Stilling M, Kold S, de Raedt S, Andersen NT, Rahbek O, Soballe K. Superior accuracy of model-based radiostereometric analysis for measurement of polyethylene wear: A phantom study. Bone & joint research. 2012;1(8):180-91. doi: 10.1302/2046-3758.18.2000041.

Stilling M, Nielsen KA, Soballe K, Rahbek O. Clinical comparison of polyethylene wear with zirconia or cobalt-chromium femoral heads. Clin Orthop Relat Res. 2009;467(10):2644-50. doi: 10.1007/s11999-009-0799-5.

Stilling M, Rahbek O, Soballe K. Inferior survival of hydroxyapatite versus titanium-coated cups at 15 years. Clin Orthop Relat Res. 2009;467(11):2872-9. doi: 10.1007/s11999-009-0796-8.

Tabori-Jensen S, Frolich C, Hansen TB, Bovling S, Homilius M, Stilling M. Higher UHMWPE wear-rate in cementless compared with cemented cups with the Saturne(R) Dual-Mobility acetabular system. Hip Int. 2018;28(2):125-32. doi: 10.1177/1120700018768615.

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.

Tarasevicius S, Robertsson O, Kesteris U, Kalesinskas RJ, Wingstrand H. Effect of femoral head size on polyethylene wear and synovitis after total hip arthroplasty: a sonographic and radiographic study of 39 patients. Acta Orthop. 2008;79(4):489-93. doi: 10.1080/17453670710015472.

Teeter MG, MacLean CJ, Somerville LE, Howard JL, McCalden RW, Lanting BA, Vasarhelyi EM. Wear performance of cobalt chromium, ceramic, and oxidized zirconium on highly crosslinked polyethylene at mid-term follow-up. Journal of orthopaedics. 2018;15(2):620-3. doi: 10.1016/j.jor.2018.05.018.

Valstar ER, Gill R, Ryd L, Flivik G, Borlin N, Karrholm J. Guidelines for standardization of radiostereometry (RSA) of implants. Acta Orthop. 2005;76(4):563-72. doi: 10.1080/17453670510041574.

von Schewelov T, Onsten I, Markusson P, Carlsson A. Weight bearing radiographs are not necessary for measurement of polyethylene penetration in total hip prostheses: a radiostereometric study of 111 patients examined in weight-bearing and supine position. Acta Orthop. 2006;77(1):104-8. doi: 10.1080/17453670610045768.

Tables and figures

Table 1 Baseline demographics

	Patients (n=44)
Age, mean (range)	73 (41 - 94)
Gender, male/female	8 / 36
T-score, mean (95%CI) (n=42)	-1.5 (-1.9; -1.2)
BMI, mean (range)	25 (16 - 39)
Oxford Hip Score, mean (95%CI) (n=33)	21 (18;24)
Cup size, mean (range)	51 (46 - 56)
Side (right/left)	26 / 18
Cup anteversion (°), mean (range)	24 (6 - 46)
Cup inclination (°), mean (range)	43 (20 - 56)

Table 2 Clinical precision of measurements

Cup migration	Bias	CR	PE wear	Bias	CR
tx	0	0.17	**wx**	-0.02	0.13
ty	0	0.09	**wy**	0.01	0.13
tz	0.01	0.2	**wz**	-0.03	0.32
rx	-0.05	1.44			
ry	-0.09	1.51	**w2D**	0	0.11
rz	-0.02	0.75	**w3D**	-0.03	0.29

Table 3 Mean (95%CI) cup migration relative to the reference markers in the acetabulum bone.

	1 year	2 years	5 years
x- translation (mm)	0.08 (-0.10; 0.26)	0.11 (-0.07; 0.28)	0.26 (0.05; 0.47)
y-translation (mm)	0.28 (0.19; 0.38)	0.26 (0.17; 0.36)	0.27 (0.17; 0.37)
z- translation (mm)	0.06 (-0.08; 0.20)	0.10 (-0.05; 0.25)	0.15 (-0.06; 0.36)
x-rotation (°)	0.17 (-0.32; 0.65)	0.23 (-0.13; 0.59)	0.49 (0.15; 0.84)
y-rotation (°)	0.48 (0.06; 0.90)	0.65 (0.28; 1.02)	0.49 (-0.00; 0.99)
z-rotation (°)	0.16 (-0.25; 0.58)	0.23 (-0.22; 0.68)	0.25 (-0.24; 0.75)

CR: Coefficient of repeatability

Table 4 Mean (95%CI) wear measures in 1, 2 and 3 dimensions.

	Bedding-in	Femoral head penetration	Wear rate (annual)
Proximal (mm)	0.08 (0.02; 0.13)	0.08 (0.03; 0.14)	0.01 (-0.01; 0.02)
2D (mm)	0.18 (0.12; 0.25)	0.20 (0.13; 0.26)	0.05 (0.03; 0.06)
3D (mm)	0.30 (0.21; 0.38)	0.32 (0.24; 0.40)	0.07 (0.05; 0.10)

Bedding-in: postop to 1-year, femoral head penetration: postop to endpoint, and wear rate: 1-year to endpoint, CR: Coefficient of repeatability.

Figure 1 Flowchart

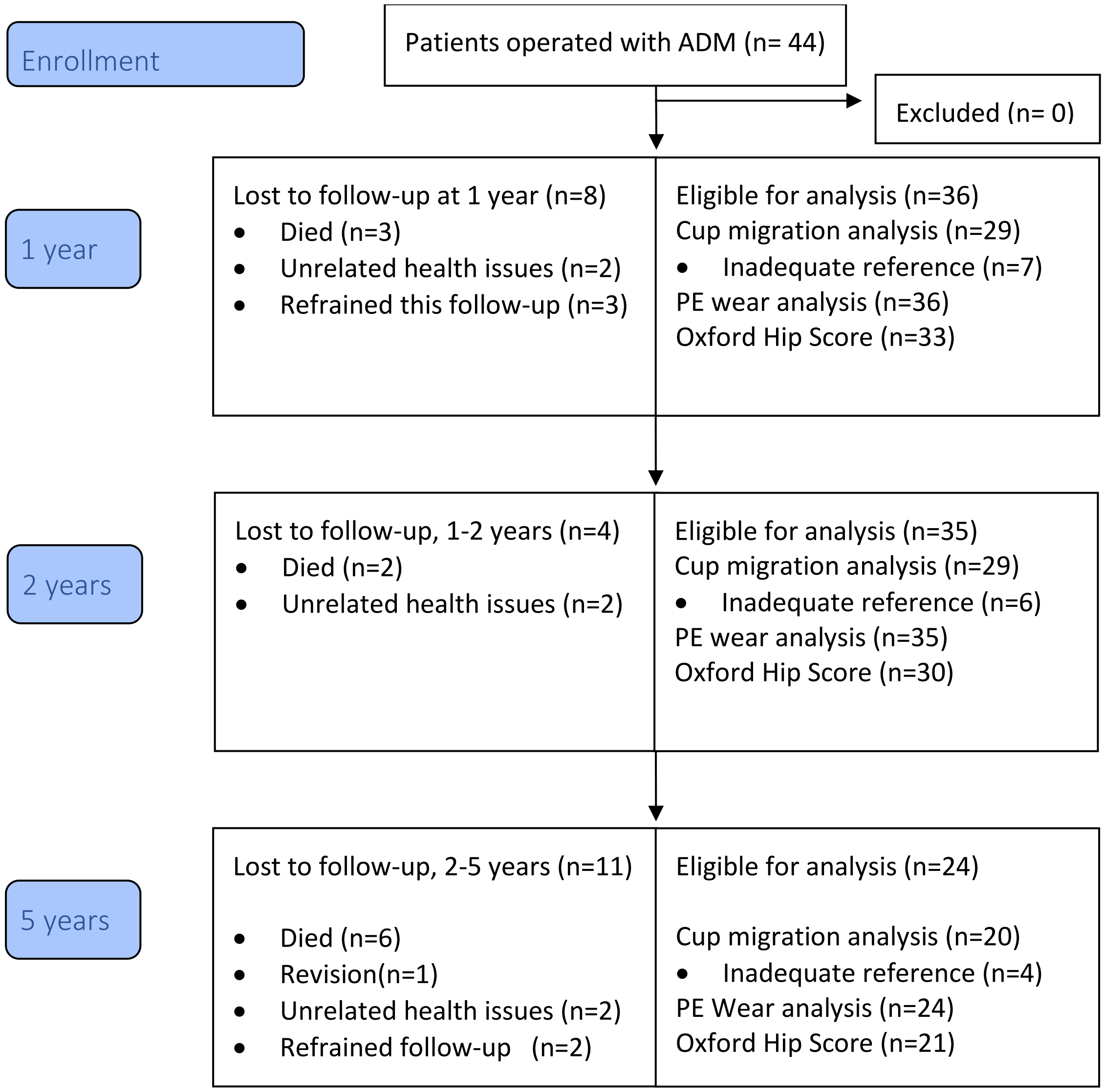


Figure 2. The axis of migration and wear was adjusted to comply with right side anatomy.

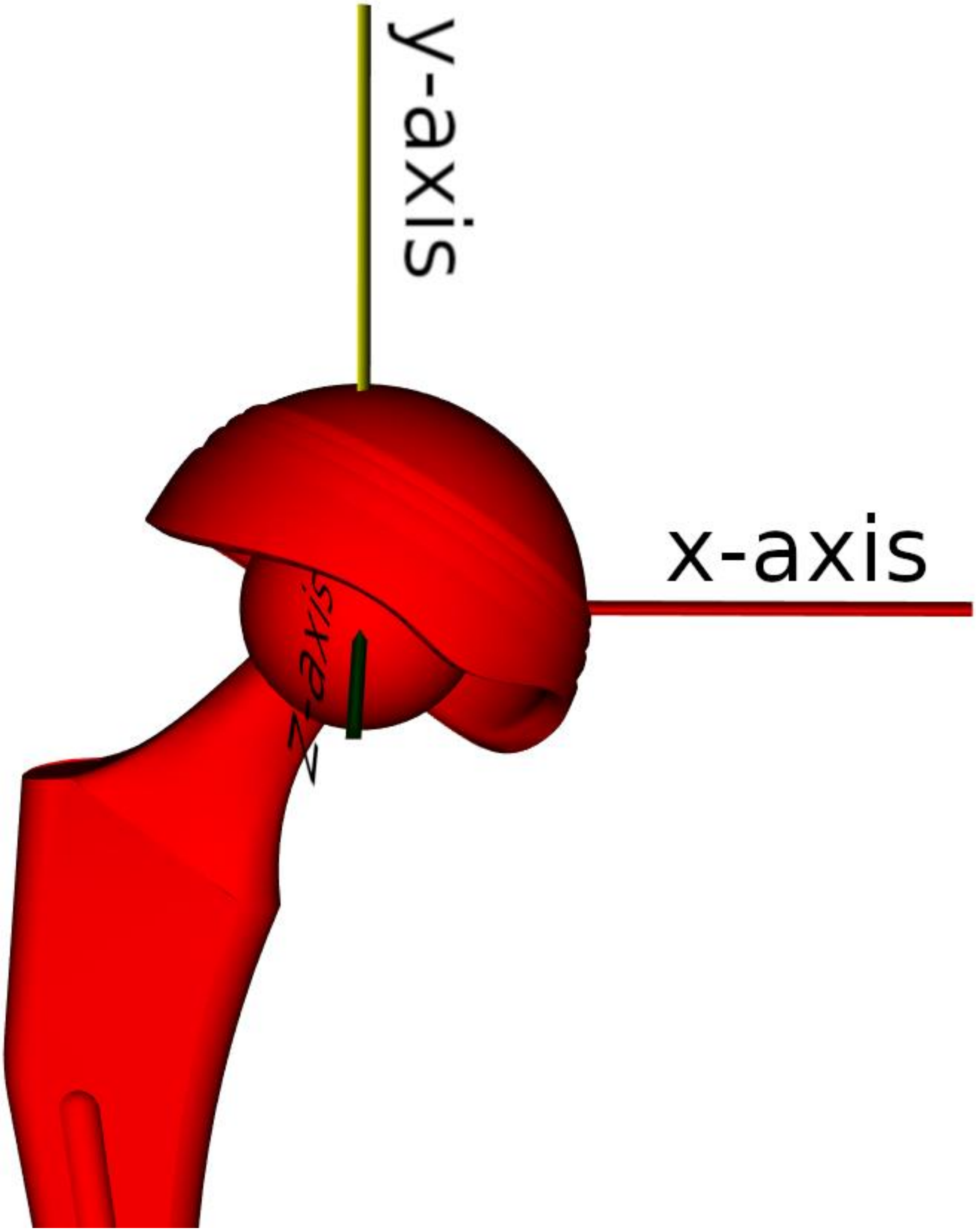


Figure 3. 3D femoral head penetration grouped by indication for operation

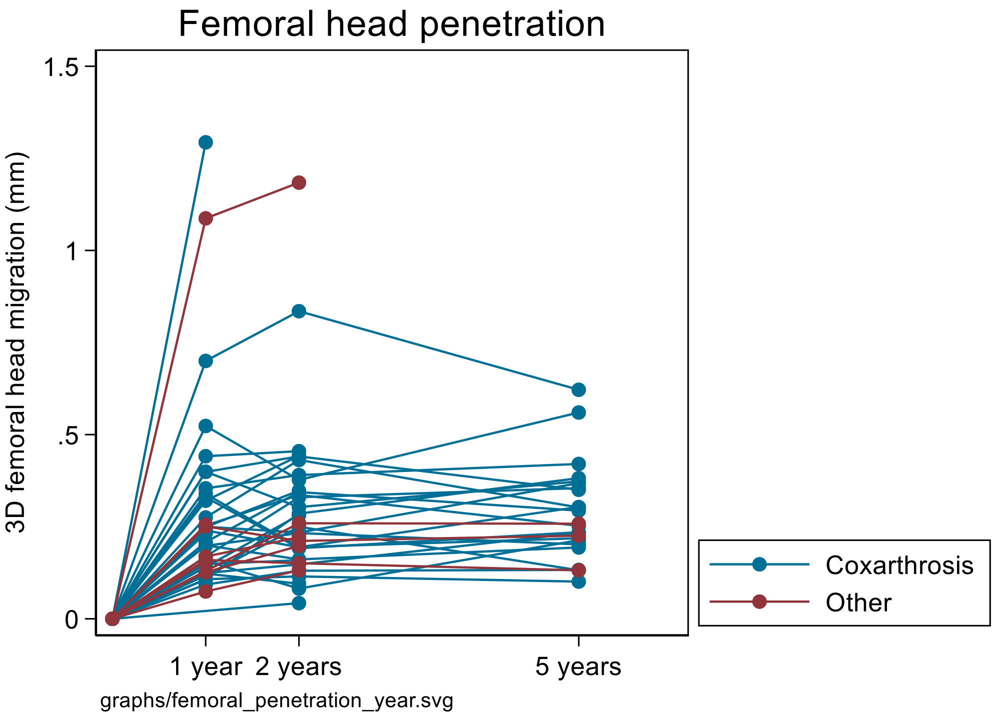
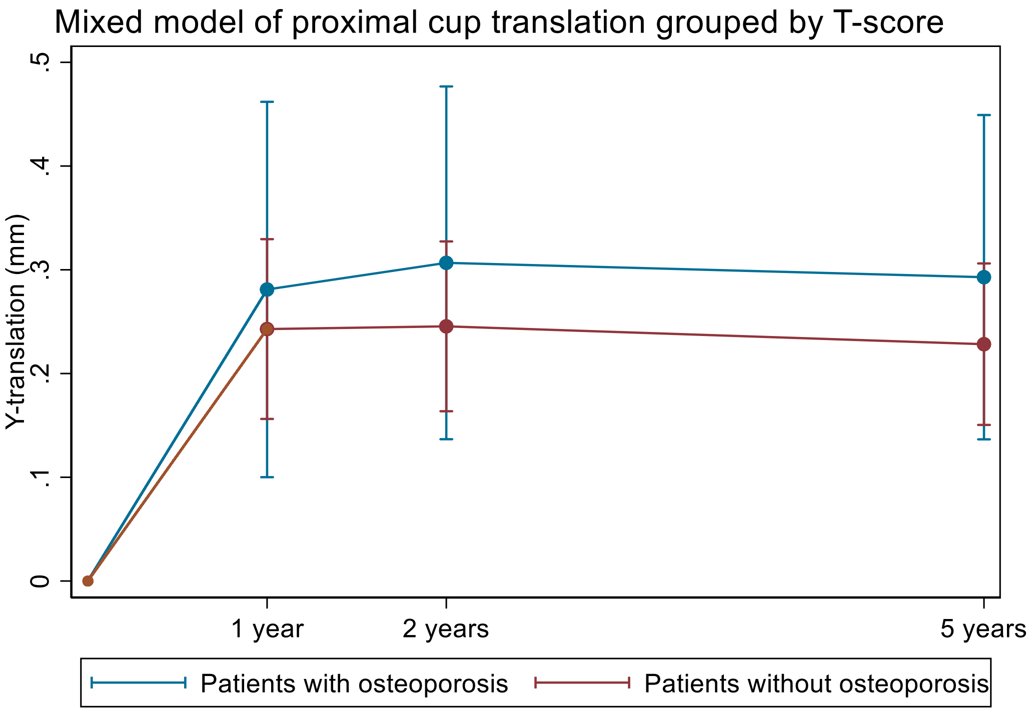


Figure 4 Multivariate repeated measures model of proximal cup migration and sagittal cup rotation grouped by T-score for each follow-up time.



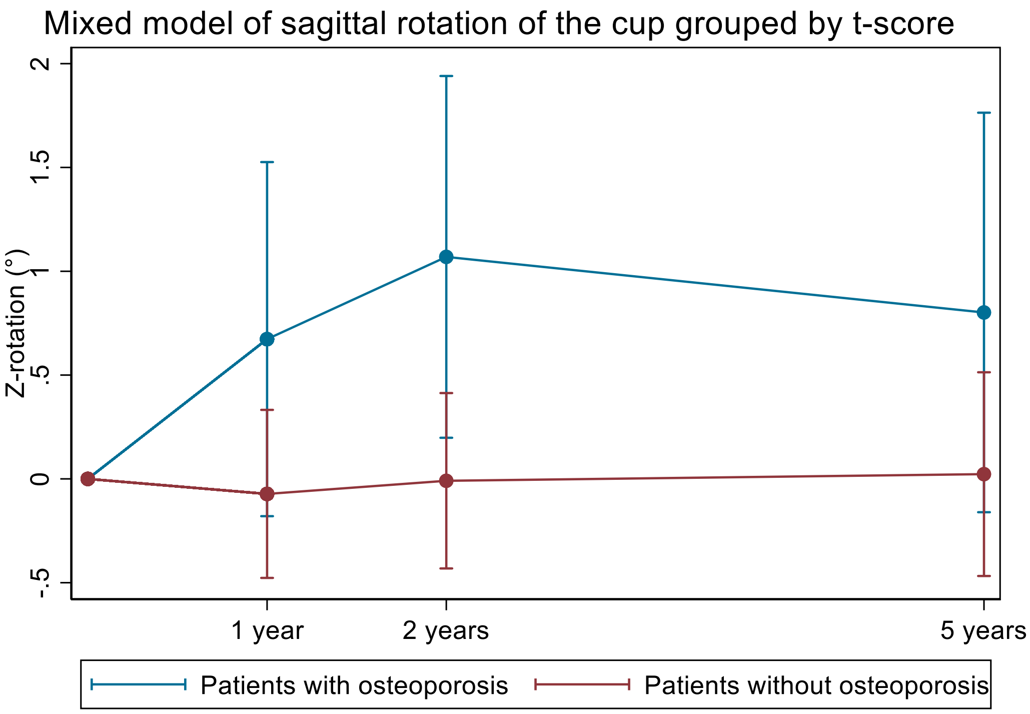


Figure 5.Total translation of the cup (vector sum of x-, y- and z-translation).

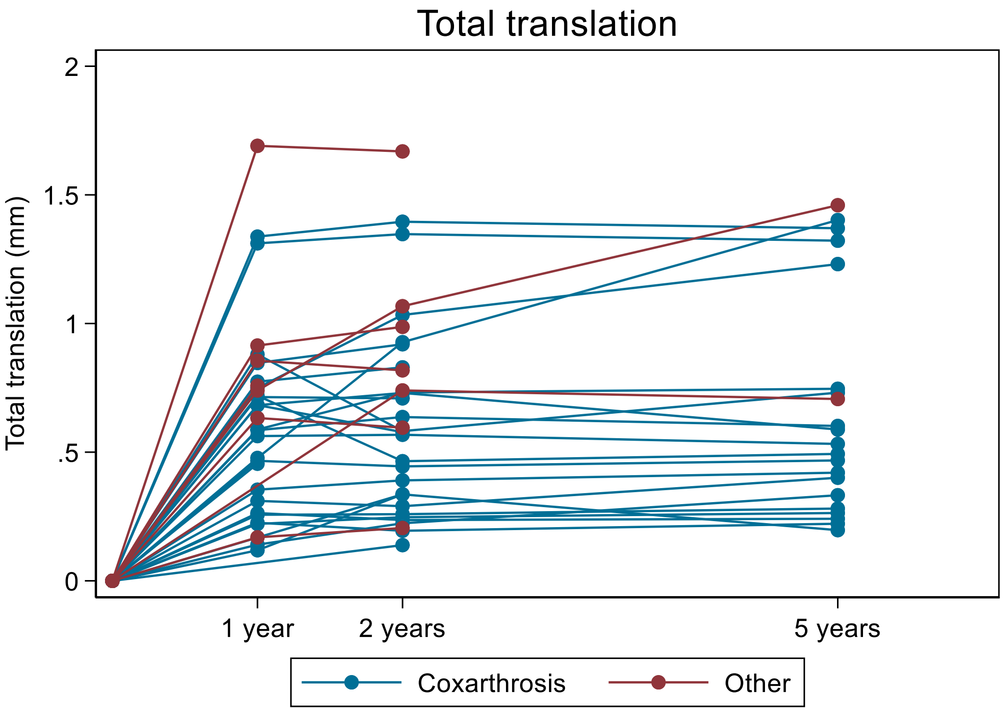
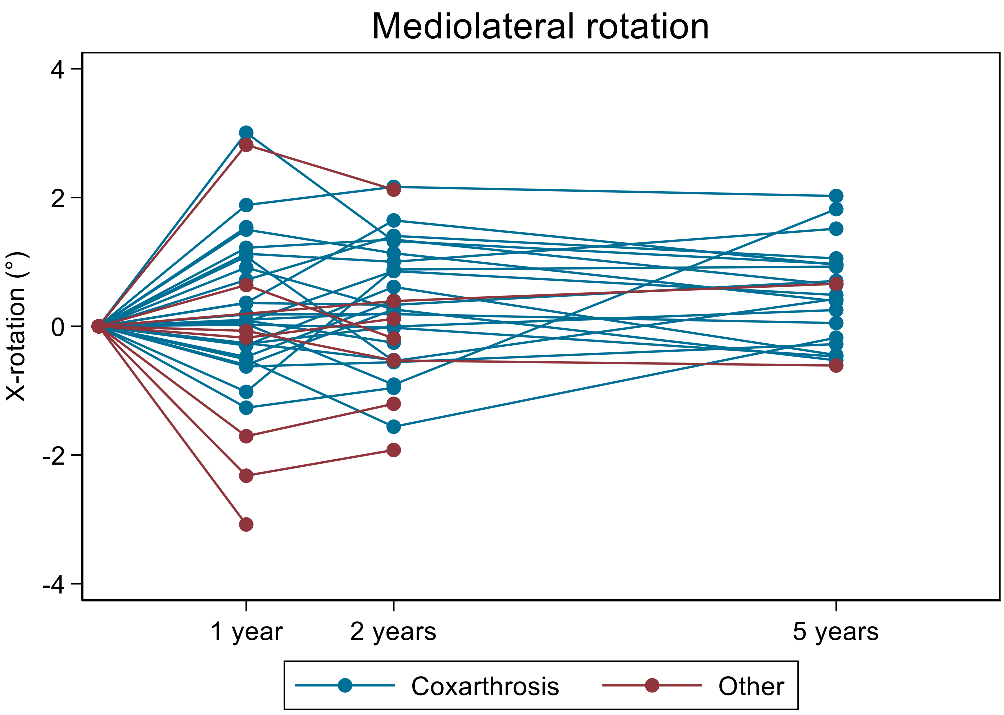


Figure 6. Mediolateral rotation



Supplemental

Table 5. Clinical guidelines for considering dislocation prophylaxis

Primary reasons for dislocation prophylaxis	**Secondary reasons for dislocation prophylaxis**
Revision due to dislocation	Rheumatoid conditions
Femoral neck fracture	Vestibular conditions
Femoral neck fracture sequalae	Age
Patients with increased risk of falling	Diabetes mellitus
Prior lumbar fusion surgery	Cardiovascular disease
Alcohol- or drug abuse	Chronic obstructive pulmonary disease
Overweight	Reduced muscle strength or coordination
Suboptimal pelvic anatomy	Reduced compliance with movement restrictions
Neurological deficits	Psychiatric conditions