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Migration- and 3D-measurements in total joint arthroplasty

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DEPARTMENT OF CLINICAL SCIENCES | FACULTY OF MEDICINE | LUND UNIVERSITY



Migration- and 3D-measurements in total joint arthroplasty

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Albin Christensson



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DOCTORAL DISSERTATION

Doctoral dissertation for the degree of Doctor of Philosophy (PhD) at the Faculty of Medicine at Lund University, to be publicly defended on the 4th of September 2026 at 13.00, Belfragesalen, BMC, Lund, Sweden

Faculty opponent

Stephan Röhrli, professor, Oslo University Hospital, Norway

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Abstract:

Background: Accurate implant positioning and stable fixation are essential for long-term success in joint arthroplasty. Conventional preoperative planning has relied on two-dimensional radiographs, while implant fixation has been evaluated using Radiostereometric analysis (RSA), the gold standard for measuring postoperative implant migration. Computed tomography (CT) enables three-dimensional (3D) planning, intraoperative navigation, and postoperative migration analysis without implanted bone markers. Combined with artificial intelligence (AI), CT-based workflows may improve automation, accessibility, and precision. The aim of this thesis was to evaluate a novel AI-based CT platform for preoperative planning, intraoperative navigation, and postoperative CT-based migration analysis, focusing on the transition from conventional RSA to AI-based CT-RSA.

Methods: Study I was a randomized controlled trial including 60 patients undergoing total knee arthroplasty (TKA) with either a medial congruent (MC) or cruciate retaining (CR) tibial insert. Implant migration was assessed with RSA over two years, and patient-reported outcome measures (PROMs) were collected. Study II included 30 total hip arthroplasty (THA) patients followed with RSA for five years and CT scans at two weeks and five years. Agreement between RSA and AI-based CT-RSA was assessed. In Study III, 26 THA patients underwent preoperative 3D planning, intraoperative navigation, and postoperative AI-based CT-RSA at 3, 12, and 24 months. Ten patients also underwent RSA, enabling direct comparison and precision assessment. Study IV evaluated navigation precision for acetabular cup placement by comparing intraoperative navigation data with postoperative CT measurements in 18 THA patients and 15 inter-rater cadaver measurements.

Results: In Study I, no significant differences in implant migration or PROMs were found between the MC and CR groups. In Study II, AI-based CT-RSA showed good agreement with RSA for both stem and cup migration, without intra- or interobserver variability. In Study III, AI-based CT-RSA migration occurred mainly during the first three months followed by stabilization. Agreement between RSA and AI-based CT-RSA was good for translations, while rotational measurements were more variable. AI-based CT-RSA showed slightly better precision than RSA. Agreement between planned and implanted component size was 25/26 for cups and 23/26 for stems. In Study IV, the CT-based navigation system showed small mean errors for cup anteversion, inclination, and depth.

Conclusion: Conventional RSA confirmed good fixation of the TKA, with no difference between MC and CR tibial designs. AI-based CT-RSA showed good agreement with RSA and demonstrated promising precision, user-independence, and clinical applicability. The same CT-based platform also provided reliable preoperative planning and precise intraoperative guidance. Together, these studies support a transition from conventional RSA toward AI-assisted CT-based planning, navigation, and migration assessment in joint arthroplasty.

Key words: THA, TKA, arthroplasty, RSA, Radiostereometric Analysis, CT-RSA, AI, Artificial Intelligence, Computer-assisted, Navigation.

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Albin Christensson



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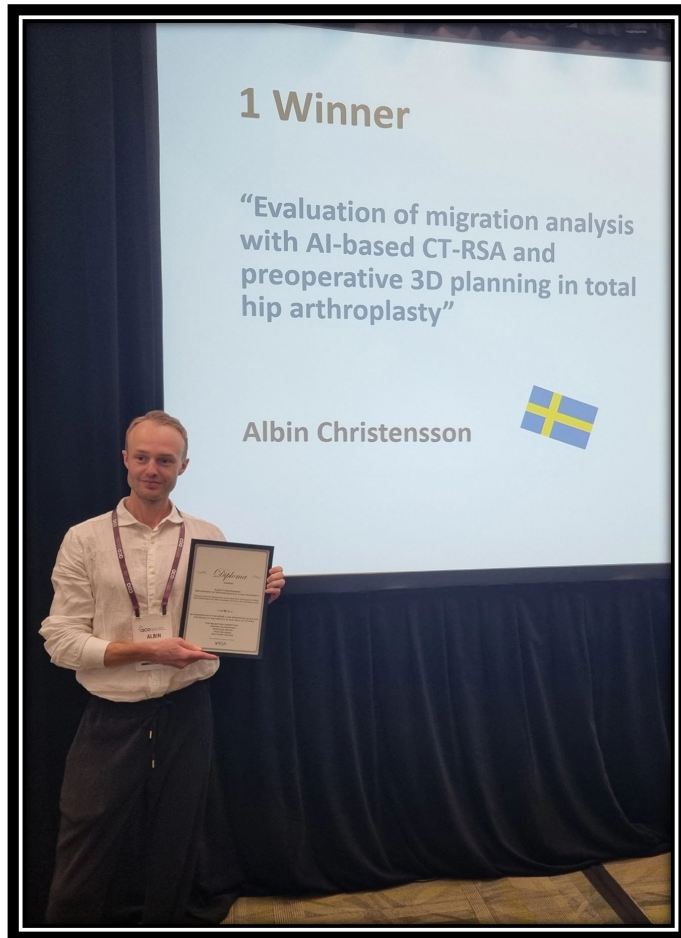
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Picture from the 9th International RSA Meeting in Vancouver, June 2025. Receiving the Best Paper Award for novelty and impact in the field of CT-RSA with our study, "Evaluation of migration analysis with AI-based CT-RSA and preoperative 3D-planning in total hip arthroplasty".

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Abstract

Background:

Accurate implant positioning and stable fixation are essential for long-term success in joint arthroplasty. Conventional preoperative planning has relied on two-dimensional radiographs, while implant fixation has been evaluated using Radiostereometric analysis (RSA), the gold standard for measuring postoperative implant migration. Computed tomography (CT) enables three-dimensional (3D) planning, intraoperative navigation, and postoperative migration analysis without implanted bone markers. Combined with artificial intelligence (AI), CT-based workflows may improve automation, accessibility, and precision. The aim of this thesis was to evaluate a novel AI-based CT platform for preoperative planning, intraoperative navigation, and postoperative CT-based migration analysis, focusing on the transition from conventional RSA to AI-based CT-RSA.

Methods:

Study I was a randomized controlled trial including 60 patients undergoing total knee arthroplasty (TKA) with either a medial congruent (MC) or cruciate retaining (CR) tibial insert. Implant migration was assessed with RSA over two years, and patient-reported outcome measures (PROMs) were collected. Study II included 30 total hip arthroplasty (THA) patients followed with RSA for five years and CT scans at two weeks and five years. Agreement between RSA and AI-based CT-RSA was assessed. In Study III, 26 THA patients underwent preoperative 3D planning, intraoperative navigation, and postoperative AI-based CT-RSA at 3, 12, and 24 months. Ten patients also underwent RSA, enabling direct comparison and precision assessment. Study IV evaluated navigation precision for acetabular cup placement by comparing intraoperative navigation data with postoperative CT measurements in 18 THA patients and 15 inter-rater cadaver measurements.

Results:

In Study I, no significant differences in implant migration or PROMs were found between the MC and CR groups. In Study II, AI-based CT-RSA showed good agreement with RSA for both stem and cup migration, without intra- or interobserver variability. In Study III, AI-based CT-RSA migration occurred mainly during the first three months followed by stabilization. Agreement between RSA and AI-based CT-RSA was good for translations, while rotational measurements were more variable. AI-based CT-RSA showed slightly better precision than RSA. Agreement between planned and implanted component size was 25/26 for cups and 23/26 for stems. In Study IV, the CT-based navigation system showed small mean errors for cup anteversion, inclination, and depth.

Conclusion:

Conventional RSA confirmed good fixation of the TKA, with no difference between MC and CR tibial designs. AI-based CT-RSA showed good agreement with RSA

and demonstrated promising precision, user-independence, and clinical applicability. The same CT-based platform also provided reliable preoperative planning and precise intraoperative guidance. Together, these studies support a transition from conventional RSA toward AI-assisted CT-based planning, navigation, and migration assessment in joint arthroplasty.

Summary in Swedish

Bakgrund:

För att en ledprotes ska fungera bra under lång tid är det viktigt att implantatet placeras korrekt och sitter stabilt i skelettet. Traditionellt har planeringen inför operationer med ledproteser gjorts med hjälp av vanliga tvådimensionella röntgenbilder. För att undersöka att ett nytt implantat är säkert för storskalig användning och sitter stabilt efter operation har man fram tills idag använt en metod som kallas radiostereometrisk analys (RSA), som är den mest tillförlitliga metoden för att mäta små rörelser mellan implantat och omgivande benvävnad över tid. RSA kräver dock att man placerar små metallkulor i benet under operationen för att kunna göra mätningen. Dessutom behövs det avancerad röntgenutrustning och utbildad personal för att göra mätningen.

Datortomografi (CT) gör det möjligt att skapa tredimensionella bilder av kroppen och borde således kunna användas både vid planering inför operation och som stöd under själva operationen. Det finns också möjlighet att använda CT efter operationen för att analysera implantatets rörelser utan att man behöver sätta in metallkulor i benet. När denna teknik kombineras med artificiell intelligens (AI) finns potential att göra arbetsprocessen mer automatiserad, tillgänglig och noggrann. Syftet med denna avhandling var att utvärdera en ny AI-baserad CT-plattform för planering inför operation, navigering under operation och analys av implantatrörelser efter operation. Särskilt fokus låg på övergången från traditionell RSA till AI-baserad CT-RSA.

Metod:

För att utvärdera detta utförde vi initialt en klassisk RSA studie. I studie I deltog 60 patienter som genomgick total knäprotesoperation. Hälften av patienterna fick en komponent i underbenet som var mer ”skålformad eller urgröpt” på insidan av knät, s.k. medialt kongruent (MC), och hälften fick en standardkomponent, cruciate retaining (CR). Tanken med MC komponenten är att efterlikna den naturliga rotationen i knäleden som sker under böj- och sträckerörelse, men hypotetiskt på bekostnad av att skapa större kraft på insidan av knät och således leda till större rörelse mellan implantat och ben? Implantatets rörelser följdes med RSA under två år och patienterna fick även besvara frågeformulär om funktion och livskvalitet.

I övergången från RSA till CT-baserad RSA inkluderas 30 patienter med total höftprotes i studie II. Dessa följdes med traditionell RSA i fem år och genomgick även CT-undersökningar efter två veckor samt fem år efter operationen. Resultaten från traditionell RSA jämfördes med den nya AI-baserade CT-RSA-metoden.

I den tredje studien (III) byggde vi vidare från studie II och inkluderade 26 patienter med total höftprotes. Dessa genomgick 3D CT baserad planering före operation, navigering baserad på 3D planeringen under operation, och uppföljning med AI-

baserad CT-RSA efter operationen, vid 3, 12 och 24 månader. Tio av patienterna undersöktes även med traditionell RSA för att möjliggöra direkt jämförelse mellan metoderna. Vi jämförde också den planerade implantatstorleken med den som faktiskt användes under operationen.

Slutligen undersökte vi precisionen hos navigeringssystemet vid placering av höftledens leddskål i studie IV. Här jämfördes data från navigeringen under operation med implantatets faktiska position på CT-bilder efter operationen hos 18 patienter, samt interbedömarreliabilitet i 15 mätningar på kadaver.

Resultat:

I studie I sågs ingen statistiskt säkerställd skillnad mellan MC- och CR-grupperna när det gällde implantatets rörelser i knäleden. Båda grupperna förbättrades dessutom när det gäller funktion och livskvalitet efter operationen.

I studie II visade AI-baserad CT-RSA god överensstämmelse med traditionell RSA vid mätning av rörelser i både höftstam och leddskål. Metoden gav också mycket liknande resultat oberoende av vem som utförde analysen.

I den tredje studien (III) kunde vi se med AI-baserad CT-RSA att de största implantatrörelserna skedde under de första tre månaderna efter operationen och att implantaten därefter stabiliserades, vilket är ett vanligt RSA mönster vid välfungerade höftimplantat. Överensstämmelsen mellan traditionell RSA och AI-baserad CT-RSA var god, framför allt vid för linjära implantatrörelser, medan mätningar av rotation varierade något mer. AI-baserad CT-RSA hade dessutom något bättre precision än traditionell RSA. När det gäller den preoperativa planeringen stämde den planerade storleken överens med den använda implantatstorleken i 25 av 26 fall för leddskålar och i 23 av 26 fall för höftstammar.

Slutligen, i studie IV, visade det CT-baserade navigeringssystemet mycket små avvikelser i visad och faktisk placering av leddskålar i patientanalyser, samt i mätningar på kadaver.

Slutsats:

Traditionell RSA bekräftade att den studerade knäprotesen hade god fixation och att det inte fanns någon skillnad mellan de två underbenskomponenterna, MC och CR. AI-baserad CT-RSA visade god överensstämmelse med traditionell RSA vid analys av rörelser mellan höftprotes och omgivande benvävnad. Dessutom hade AI-baserad CT-RSA bättre precision jämfört med RSA och hög grad av användaroberoende, vilket potentiellt ökar den kliniska användbarheten. Samma CT-baserade plattform gav även tillförlitlig planering inför operation samt noggrann vägledning under höftproteskirurgi. Sammantaget stödjer resultaten en gradvis övergång från traditionell RSA till AI-baserad CT-teknik för planering, navigering och uppföljning inom ledproteskirurgi.

List of papers

This thesis is based on the following papers, referred to in the text by their Roman numerals

- I. Christensson A, Tveit M, Kesteris U, Flivik G. **Similar migration for medial congruent and cruciate-retaining tibial components in an anatomic TKA system: a randomized controlled trial of 60 patients followed with RSA for 2 years.** Acta Orthop 2022; 93: 68-74. doi: 10.1080/17453674.2021.1983709
- II. Christensson A, Nemati HM, Flivik G. **Comparison between model-based RSA and an AI-based CT-RSA: an accuracy study of 30 patients.** Acta Orthop 2024; 95: 39-46. doi: 10.2340/17453674.2024.35749
- III. Christensson A, Nemati HM, Ydström K, Flivik G. **Evaluation of migration analysis with AI-based CT-RSA and preoperative 3D-planning in total hip arthroplasty.** Acta Orthop 2025; 96: 885-892. doi: 10.2340/17453674.2025.44948
- IV. Nemati HM, Christensson A, Pettersson A, Németh G, Flivik G. **Precision of Cup Positioning Using a Novel Computed Tomography Based Navigation System in Total Hip Arthroplasty.** Medicina 2024; 60. doi: 10.3390/medicina60101589

Abbreviations

2D	Two dimensions
3D	Three dimensions
AO	Acetabular offset
AI	Artificial intelligence
BMI	Body mass index
CAD	Computer-Aided Design
CI	Confidence intervals
CNN	Convolutional neural networks
CT	Computed tomography
CT-RSA	Computed tomography-based Radiostereometric analysis
CR	Cruciate retaining
DL	Deep learning
DICOM	Digital Imaging and Communications in Medicine
FO	Femoral offset
FJS	Forgotten Joint Score
GO	Global offset
KOOS	Knee injury and Osteoarthritis Outcome Score
LoA	Limit of agreement
MBRSA	Model-based RSA
MTPM	Maximal total point motion
MC	Medial congruent
ML	Machine learning
PCL	Posterior cruciate ligament
PROM	Patient reported outcome measures
RCT	Randomized controlled trial
ROM	Range of motion
RSA	Radiostereometric Analysis
SD	Standard deviation
THA	Total hip arthroplasty
TKA	Total knee arthroplasty

Thesis at glance

	Study I	Study II	Study III	Study IV
Type of study	TKA, RSA, clinical, prospective, single-blinded RCT	THA, RSA and CT-RSA, clinical, prospective observational, method-comparison	THA, RSA and CT-RSA, clinical, prospective observational, method-comparison	THA, Intraoperative navigation, clinical and cadaver study, technical validation
Research question	Is there a difference in implant migration between two different tibial insert designs of a TKA (CR and MC) measured with RSA? Is there a difference in PROM?	Assess the agreement between the migration results of AI-based CT-RSA and RSA between 2 weeks and 5 years	Assess the implant migration with AI-based CT-RSA (postop, 3 months, 1 and 2 years) and compare it to RSA. Evaluate AI-based CT-RSA precision	Assess precision of the OTS™ Hip Guide. Does the intraoperative information displayed in the guide tool correctly reflect the position of the cup?
Population	60 patients, 30 in CR and MC group respectively. September 2017 – August 2018	Part of an RSA project. 30 patients. March 2015 – February 2016	26 patients. November 2020 – May 2022	Clinical: 20 patients from study III. 3 cadavers. 8 May 2024
Results	RSA results indicate good fixation for both CR and MC. No difference in migration or PROM between groups	Indicating good agreement between RSA and AI-based CT-RSA	AI-based CT-RSA showed consistent migration pattern with most migration at the 3 first months. AI-based CT-RSA demonstrated accuracy comparable to RSA with slightly better precision	The OTS™ Hip Guide offered intraoperative guidance on notable precision in cup placement
Clinical perspective	The RSA results indicate that the studied TKA stabilizes as other well-performing TKAs on the market. There does not seem to be a difference in implant migration or PROM between the inserts	This first study on AI-based CT-RSA indicate that it may replace current gold standard RSA	Building upon study II, this study further supports the use of AI-based CT-RSA as a possible replacement for RSA. Better precision compared to RSA	The OTS™ Hip Guide may navigate the surgeon to intended cup position, mitigating the risk of cup position outside the safe and thus reduce the risk of dislocation

Introduction

Total joint arthroplasties are one of the most successful surgical procedures (1) and often represents the last resort for patients with advanced osteoarthritis in the lower extremities. Over recent decades, continuous advances in implant design, surgical techniques, and perioperative care have improved outcomes and prosthetic survivorship. However, still challenges remain in achieving optimal implant positioning and ensuring long-term fixation. Reoperations are often demanding surgeries for both the patient and the surgeon. It is also a cost burden for society. To optimize the chances of a successful outcome, today, surgeries are preplanned on plain X-rays taken before surgery, where the surgeon assesses size and position in two dimensions (2D). During surgery, there are often basic alignment guides attached to the surgical instruments to visually aid the surgeon to the desired implant position. The alignment guide does not, however, allow for variation in patient position with respect to the operating table, and patient orientation may vary throughout the procedure. Furthermore, it is not always easy to visualize the full bony anatomy as skin and soft tissues obstruct the view.

In recent years, Computed Tomography (CT) has emerged as a promising tool for preoperative three dimensional (3D) planning in orthopaedic surgery. At the same time, CT-based surgical navigation systems are being actively developed to help ensure that implants are positioned according to the preoperative plan. We are currently in an exploratory phase where these technologies are being refined and evaluated rather than being fully established in routine clinical practice. In parallel, the potential of using the same CT scans for postoperative follow-up and implant migration analysis, CT-RSA, is being intensively investigated. Although conventional Radiostereometric Analysis (RSA) remains the current gold standard, CT-RSA represents a frontier area of research with the potential to become a future alternative.

In this thesis, we have evaluated a novel CT-based orthopaedic surgical platform that comprises three modules: preoperative 3D planning, perioperative navigation, and postoperative implant migration analysis. The system uses integrated artificial intelligence (AI) algorithms and machine learning (ML) models to automate, assist, and simplify the procedure. For the postoperative implant migration analysis, the CT-based method was evaluated in comparison with the current gold standard, conventional RSA, in order to assess its accuracy and potential as a future alternative.

Preoperative planning with focus on the hip

With an aging population, more people expect to live longer with their prosthesis, and there are higher demands on function and thus on wear resistance of the implants. In addition, patients want to be able to maintain an active lifestyle, similar to the one they had before joint pain limited their lives. The objective in performance of a joint replacement is restoration of a pain-free and stable joint with a functional range of motion (ROM).

Careful preoperative planning is a prerequisite for successful implant positioning, and involves the selection of implant size, type and optimal positioning relative to patient specific anatomy. In this thesis we have primarily focused on the preoperative planning of total hip arthroplasty (THA). Historically, such planning relied primarily on conventional radiographs, and involves:

- Acquisition of anterior-posterior views of the hips and pelvis, and a lateral view of the affected hip.
- The radiographs need to be taken with known magnification, often with radiopaque marker of known size to allow for accurate scaling.
- The radiographic assessment includes anatomical abnormalities, leg length, centre of rotation of the hip, femoral canal shape and size, and femoral offset (FO: the horizontal distance from the centre of the femoral head to the axis of the femur (2)).
- Templating is usually done digitally using specialized software to place imported stem and cup models based on patient specific anatomy. The goal is to estimate correct size and position, and to restore biomechanics of the hip, such as, leg length, centre of rotation and offset.
- The preoperative template may be available during operation for the surgeon to look at, but there is no real-time feedback or other intraoperative guidance except for the surgical instruments with attached alignment aids.

Conventional radiographs are inherently limited by 2D projections. Factors, such as, patient position and rotation on the X-ray table, may affect cup and stem size, and position (3-6). Additionally, 2D templating of femoral component size seem to be affected by planner experience and patient body mass index (BMI) (7). This can in turn lead to an imbalance and change in the biomechanics, possibly affecting functional outcome, stability and implant longevity. During surgery, the cup position is medialized due to reaming, reducing the acetabular offset (AO: acetabular centre to centre of pelvis (2)). The mediolateral cup position determines the hip lever arm (8) and to restore the global offset ($GO = FO + AO$), FO needs to increase. Inadequate restoration of FO after THA may cause weak abductor strength and less improved functional outcome (9). Postoperative leg length difference is

debated, being one of the leading causes of litigation following the procedure (10). At the same time, perceived leg length difference is associated with worse clinical outcome scores, even though there is no radiographic difference (11). Furthermore, in a large study on biomechanics and improvements after surgery, there was an association between replicating the native centre of rotation and femoral offset and clinically relevant improvements, however, leg length inequality was not associated with these patient reported outcome measures (PROM) (12). In addition to the biomechanical impact, there is a risk that reduced femoral offset will increase acetabular polyethylene wear (13), thus jeopardizing the longevity.

There have been several approaches regarding optimal orientation of the acetabular component, and although controversial (14), Lewinnek's definition, published in 1978, of 40° inclination and 15° anteversion with a safe zone of $\pm 10^\circ$ has historically been accepted to reduce the risk of dislocation (15) (Figure 1). Even later studies have showed that, patients sustaining a dislocation following THA had acetabular components less frequently positioned within the “safe zone” compared to control patients (16). The reason for its controversiality is the increasing evidence of dislocations despite cup positioning within the Lewinnek safe zone. As a reaction, the concept of the functional safe zone has emerged as an evolution of the traditional Lewinnek “safe zone”, reflecting a more patient-specific approach to acetabular component positioning. The functional safe zone accounts for individual variations in spinopelvic mobility, pelvic tilt, lumbar spine stiffness, and sagittal balance. All of which influence the functional orientation of the acetabular component during daily activities such as sitting, standing, and bending. Interestingly, cups that are within the Lewinnek safe zone may still fall outside the patient's functional safe zone, and thus a potential reason for cup dislocation (17). In addition to the risk of dislocation, cup inclination can also affect liner wear (13), and by extension, implant durability. It is obvious that both stem and cup position are important in many aspects, including patient satisfaction, function and implant survival. In conventional templating, based on 2D radiographs, individual patient anatomy is not always illustrated reliably, and crucial parameters may differ with rotation of the hip (Figure 2).

Lewinnek's Safe Zone for Acetabular Cup Positioning in Total Hip Arthroplasty

40° inclination and 15° anteversion with a safe zone of $\pm 10^\circ$
has historically been accepted to reduce the risk of dislocation.

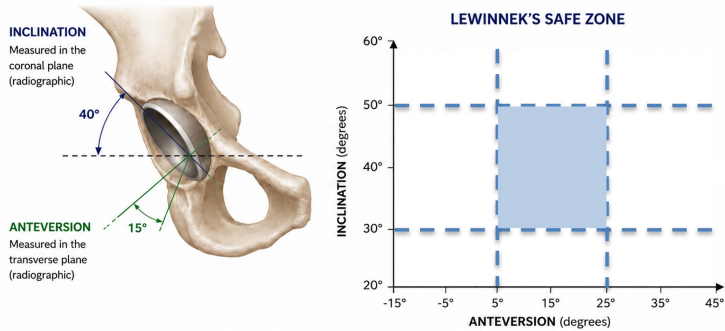


Figure 1. Lewinnek's safe zone for acetabular cup positioning in THA. Illustration of the historically accepted Lewinnek safe zone for acetabular cup positioning in THA. The target orientation is 40° of radiographic inclination and 15° of radiographic anteversion, with an accepted safe zone of $\pm 10^\circ$, corresponding to an inclination range of 30° – 50° and an anteversion range of 5° – 25°. Cup placement within this zone was originally proposed to reduce the risk of postoperative hip dislocation.

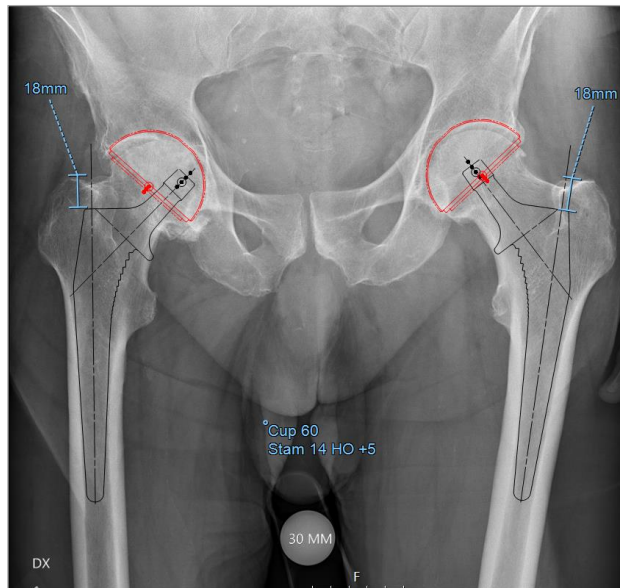


Figure 2. Effect of patient rotation on 2D preoperative templating in THA. Radiographic example illustrating the challenges of 2D templating in THA. Patient right hip (DX) rotation during image acquisition results in an apparent mismatch between the projected anatomy of the right hip and the planned implant position. Cross-comparison with the contralateral hip, left hip, confirms appropriate implant selection and alignment. The figure demonstrates the susceptibility of conventional radiographic templating to projectional and positional errors.

The introduction of CT has significantly advanced planning by allowing 3D reconstructions of the hip joint. CT-based planning provides more accurate information regarding bone morphology, alignment, and deformities, thereby enabling surgeons to tailor the procedure more precisely to the individual patient. Moreover, CT scanning can now be done with significantly lower radiation dose (18). Planning in 3D, based on CT scanning, has shown to be more accurate in predicting implant size, compared to 2D plain radiographs (19-22).

Intraoperative navigation

Translating preoperative planning into accurate intraoperative execution has historically depended on the surgeon's experience and conventional mechanical guides. However, these free hand approaches are prone to variability, which may influence implant survival.

Today, most orthopaedic surgeons rely on a combination of anatomic landmarks, mechanical guides and intraoperative assessment techniques to achieve reproducible component orientation. In THA, a neutral pelvic position is assumed; however, pelvic tilt and rotation are possible sources of errors and thus need to be considered. This, together with direct visualization of bony landmarks and ankle position after trial hip reduction constitute the cornerstones of the assessment. Real-time feedback and objective implant estimates are hence requested.

Real-time feedback using modern navigation systems, particularly those based on CT, enable intraoperative guidance using patient-specific anatomical data, allowing for more accurate component alignment and improved reproducibility (23-25). These systems typically use trackers attached to the patient and surgical instruments, which are detected by infrared camera systems to provide real-time spatial positioning during surgery. By reducing variability, navigation technology may lower the risk of malpositioning, which in turn has the potential to reduce dislocation, early implant failure and revision surgery (26). Nevertheless, the benefits of these systems must be corroborated with objective measures of implant migration and fixation, areas where RSA and CT-RSA play a central role.

RSA

Radiostereometric analysis (RSA) is an advanced, highly precise and accurate imaging technique developed to quantify 3D micromotion of orthopaedic implants. Since its introduction by Göran Selvik in the 1970s (27), RSA has become one of the most robust and validated research tools available for evaluating early implant

fixation and long-term performance in joint arthroplasty. The method has become meaningful both in pre-clinical research and in the staged introduction of new implant designs (28).

The principle of RSA relies on two radiographic projections acquired simultaneously from known geometrical positions aimed at the body part of interest (Figure 3). A calibration cage, uniplanar or biplanar, containing fiducial markers defines the 3D coordinate system (Figure 3). Tantalum markers (usually 0.8 mm), inserted into bone during surgery (Figure 4), and in some cases integrated into the prosthesis, serve as segment reference points for the migration analysis (29). With the help of computer-assisted reconstruction algorithms, the precise spatial relationship between bone and implant segment can be quantified over time. Under optimal conditions, the first RSA scan is taken as soon as possible, preferably within a couple of days after the surgery to establish a baseline and then followed by repeated measurements at subsequent intervals. Since most of the implant migration tend to occur in the period immediately after surgery, more frequent RSA follow-ups are desirable in the beginning. After about one year, stabilization should have occurred (30,31), and thus follow-ups can be done at longer intervals. The primary outcome metrics include translations and rotations along three orthogonal axes (x, y and z), as well as total translation and rotation, and maximum total point motion (MTPM). MTPM is a composite parameter reflecting overall migration behaviour. It is a 3D vector, referring to the point at every examination that has the maximum movement in relation to the bony reference segment. MTPM indicates the overall migration over time, but does not, however, specify the direction of the vector in space and can thus be different at different examination times (29). Total translation and rotation are based on the x, y and z-translation/rotation values and calculated by using the Euclidean formula $\sqrt{(x^2+y^2+z^2)}$.

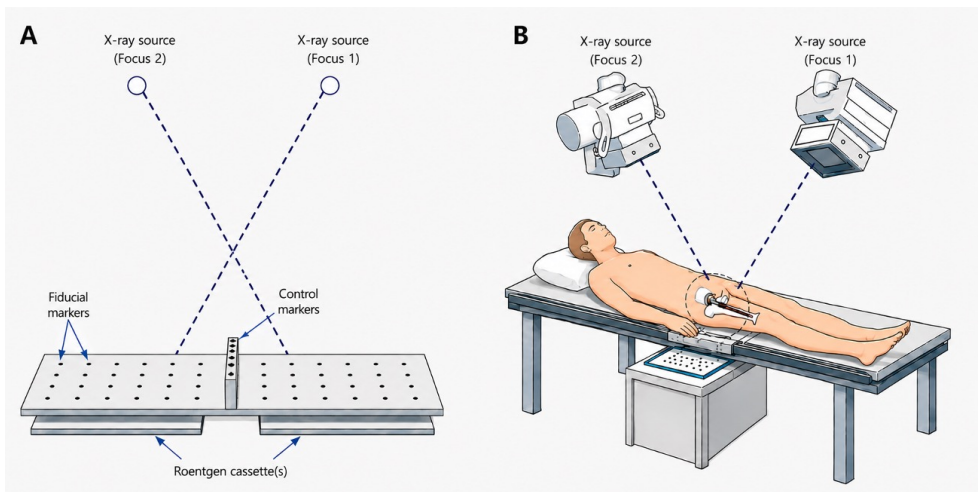


Figure 3. RSA setup and imaging geometry. (A) Schematic illustration of the RSA imaging geometry and uniplanar calibration cage. Two simultaneously acquired radiographs are obtained using two X-ray sources positioned at known angles relative to the calibration cage and region of interest. The fiducial markers are arranged in a predefined geometric pattern and serve as spatial reference points with known coordinates, enabling accurate calibration of the imaging system and precise calculation of implant migration and micromotion in 3D space. Control markers are positioned at distinct, known distances (often in a different plane), and primarily used to calculate and verify the exact position and orientation of the X-ray foci. (B) Patient positioning during THA RSA examination. The patient is positioned supine on the radiographic table with the calibration cage and cassette(s) placed beneath the anatomical region of interest. Simultaneous radiographs are acquired from two angulated X-ray sources positioned on either side of the patient (the X-ray beams intersect at the level of the implant) to generate stereoradiographic images for 3D migration analysis.

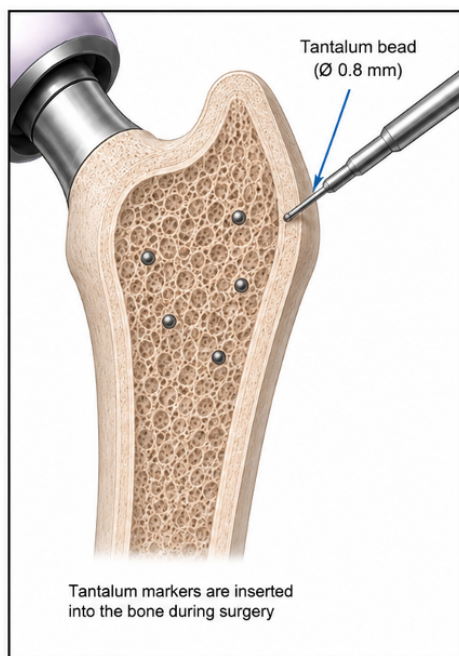


Figure 4. Intraoperative placement of tantalum markers for RSA in THA. Illustration demonstrating the intraoperative placement of tantalum markers in the proximal femur during THA for RSA. The markers serve as radiopaque markers for assessment of femoral component micromotion and implant migration over time.

A key advantage of RSA is its high accuracy and precision. Accuracy describes how close the test result is to an accepted reference (i.e. the true value). Precision is synonymous to repeatability: how close the independent test results are to each other (Figure 5). Precision is commonly reported in the range of 0.05 – 0.6mm for translations and 0.1 – 2° for rotations, depending on the type of prosthesis and clinical or non-clinical setting (32-37). This sensitivity far exceeds that of conventional radiographs. Importantly, early micromotion patterns detected by RSA have been shown to predict long-term clinical outcomes and foresee revisions.

Studies have demonstrated that implants exhibiting early stabilization are significantly less likely to undergo aseptic loosening than those that show continuous migration beyond the first postoperative years (30,31). This has positioned RSA as an essential tool for early evaluation of implant performance and has contributed to regulatory recommendations encouraging its use in the phased introduction of new arthroplasty designs.

RSA does, however, have several practical limitations. Marker insertion requires additional surgical steps, specialized instruments, and an experienced surgeon. Radiographic acquisition must follow strict protocols to be usable, and the analysis requires trained personnel and standardized quality control procedures (29). Moreover, RSA systems are not widely available due to the costs associated with equipment, maintenance, and personnel training.

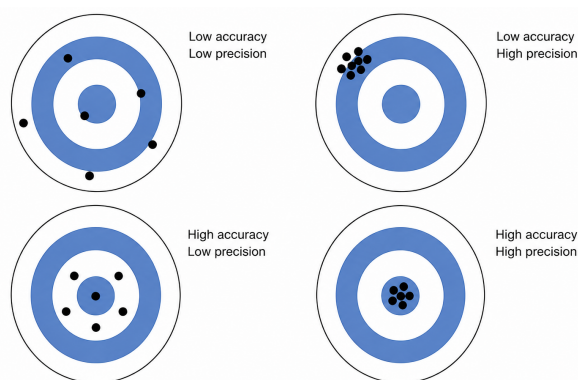


Figure 5. Illustration of accuracy and precision. This figure illustrates the conceptual difference between accuracy and precision in quantitative measurements. Accuracy refers to the closeness of repeated measurements to the true or reference value, whereas precision describes the consistency or reproducibility of repeated measurements independent of their proximity to the true value.

The development of model-based RSA (MBRSA) was a first step to simplify the procedure (38), making the prosthesis “marker-free”, and instead relying on the implant contours or 3D Computer-Aided Design (CAD) models (Figure 6). However, many of the limitations and disadvantages with RSA remained. Still, the clinical and scientific value of RSA remained indisputable. Its capacity to detect clinically relevant micromotion at an early stage enabled shorter and more efficient evaluation cycles for new orthopaedic implants, reducing the risk of widespread implant failures and improving patient safety. An active search for a worthy replacement has therefore been underway.

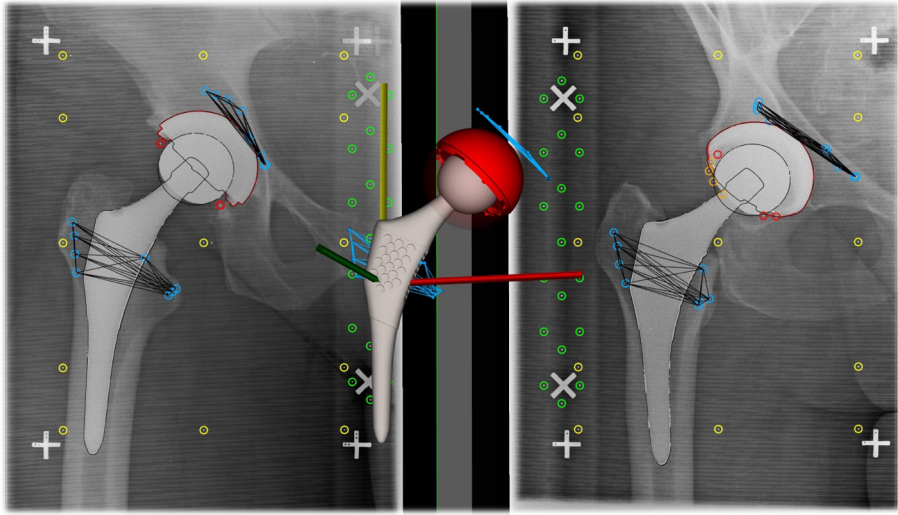


Figure 6. Model-based RSA (MBRSA). Screenshot of the MBRSA software illustrating image acquisition from two radiographic projections of the hip. The yellow circles indicate fiducial markers within the calibration cage, while the blue circles represent tantalum markers inserted into the femur and pelvis to define the corresponding bone segments. Based on the projected implant contours, a CAD model is aligned to the implant and defines the implant segment. Implant migration is subsequently calculated relative to the surrounding bone segments, using cup-to-pelvis and stem-to-femur measurements.

CT-RSA

Computed tomography-based Radiostereometric Analysis (CT-RSA) is an emerging technique that seeks to retain the high accuracy and precision of conventional RSA while overcoming many practical constraints. CT-RSA uses CT scans and advanced image registration algorithms to measure 3D implant migration without the need for inserted tantalum markers or calibration cages (39,40). Instead, data are derived directly from bone and implant surfaces (Figure 7). The main concern with CT-RSA has been the higher radiation dose (41). The development of low-dose CT protocols for imaging has, however, enabled a substantial dose reduction while maintaining a sufficient image quality (18). Optimization of scanner parameters remain important to minimize patient exposure, and standardized, quantifiable quality-control metrics and guidelines akin to those established for RSA are now developing (41,42).

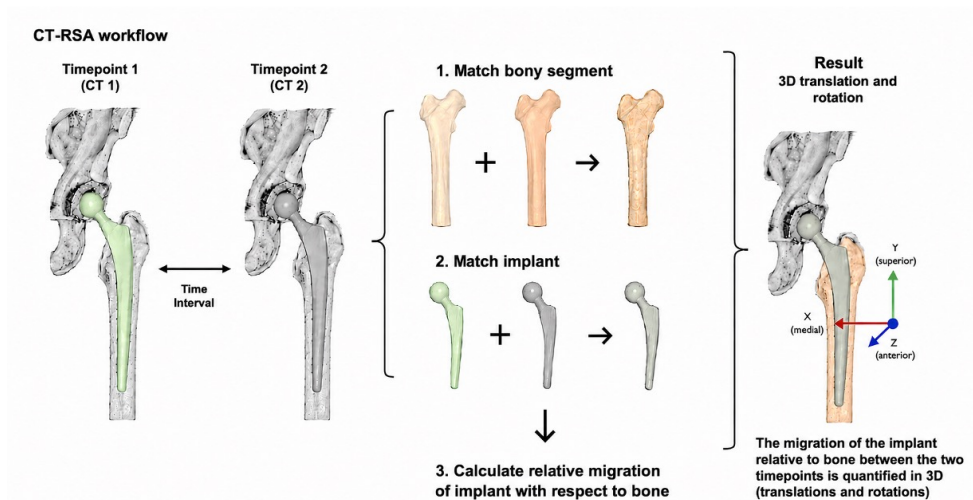


Figure 7. CT-RSA workflow. Schematic overview of the CT-RSA workflow used for assessment of implant migration. CT examinations are acquired at two different postoperative time points. 3D bone and implant models are reconstructed from the CT datasets and subsequently registered using a rigid-body matching algorithm. First, the bony anatomy is spatially aligned between the two examinations to establish a fixed anatomical reference. Thereafter, the implants are matched separately between time points. The relative change in implant position with respect to the surrounding bone is then calculated, allowing quantification of implant migration in terms of 3D translations and rotations along the orthogonal coordinate axes (x, y, and z).

CT-RSA has a broad applicability across different types of CT scanners and compatibility with multiple vendor platforms, which enhances its potential for widespread clinical implementation. In addition, current evidence suggests that its precision is not substantially compromised when using low-dose CT protocols, supporting its use while minimizing radiation exposure to patients (43).

Key advantages of CT-RSA include its marker-free surgical workflow, and it does not require modification to the implant. It allows for wider accessibility due to use of standard CT scanners, and CT-RSA can be performed with minimal specialized equipment and training. With the elimination of implanted markers, potential measurement bias due to marker obscuration is avoided. Moreover, CT-RSA facilitates retrospective analysis of routine clinical CT scans when longitudinal imaging is available.

To consider replacing today's gold standard for implant migration analysis, CT-RSA needs to perform as well as RSA. A growing body of evidence indicates that CT-RSA offers comparable or superior precision and accuracy to traditional RSA across various implant types. Recent studies have showed clinical CT-RSA precision of about 0.05 – 0.3mm in translations and 0.2 – 0.4° in rotations (34,39,40). Studies in non-clinical settings have demonstrated CT-RSA accuracy of <0.35mm and <0.85° (32,44). In a meta-analysis in different arthroplasties, the CT-RSA accuracy ranged

between $0.02 - 0.71\text{mm}$ and $0.03 - 1^\circ$, and the precision ranged between $0 - 0.47\text{mm}$ and $0 - 1.09^\circ$. The CT-RSA clinical precision ranged between $0.03 - 1.36\text{mm}$ and $0.06 - 2.25^\circ$ (45).

The transition from traditional RSA to CT-RSA has the potential to revolutionize postoperative surveillance. Unlike RSA, CT-RSA would allow for broader accessibility and could feasibly be integrated into routine clinical follow-up, enabling systematic detection of implant problems at an early stage. This could potentially improve patient safety, optimize implant design evaluation, and reduce revision burden on healthcare systems.

Artificial intelligence

Artificial intelligence (AI) refers to a wide range of computational methods that enable machines to perform tasks traditionally requiring human intelligence, including recognition, classification, prediction, and decision-making. AI systems are typically categorized into subfields such as machine learning (ML), where models learn patterns from data and deep learning (DL), which uses multilayer neural networks to process complex data representations (Figure 8). AI support automation, augmentation and optimization of human expertise. In medicine, it has enhanced diagnostic precision, guided therapeutic decisions, and improved patient outcomes (46).

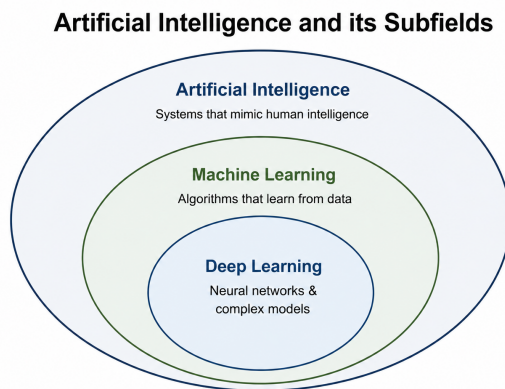


Figure 8. Artificial Intelligence (AI) and its subfields. Schematic illustration of the hierarchical relationship between AI and its major subfields. AI represents the broadest category and includes computational systems designed to perform tasks that typically require human intelligence. Machine learning (ML) is a subset of AI that enables algorithms to learn patterns and improve performance based on data without explicit programming. Deep learning (DL) is a specialized subset of machine learning that utilizes multilayered artificial neural networks capable of processing large and complex datasets.

AI has been investigated in medical imaging and radiology, where the volume, complexity, and precision demands of image data make AI particularly suited to add value. Image reconstruction, segmentation, anomaly detection, and quantification, often outperform human interpretation (47-49). These tools can augment radiologist workflows by reducing interpretation times and improving diagnostic sensitivity and specificity.

The integration of AI into orthopaedic surgery may help link imaging, preoperative planning, and intraoperative support (46). AI-based tools may enhance preoperative planning by improving the accuracy of alignment planning and implant selection or templating (50). Computer-assisted robotic systems can provide real-time intraoperative guidance, may improve procedural precision and reduce complications (51,52).

Postoperatively, commercially available CT-RSA systems require manual and time-consuming procedures, including bone segmentation and image registration similar to conventional RSA. AI-based automated image processing has the potential to substantially reduce the required processing time and thereby facilitate broader adoption of CT-RSA

OTS™

Ortoma AB, a Swedish based medical technology company that, for many years, has developed advanced digital solutions for orthopaedic surgery. Ortoma Treatment Solutions (OTS™) is a surgical system designed for CT-based 3D preoperative planning, intraoperative navigation and postoperative follow-up. The software employs AI algorithms and static ML models to automate anatomical landmark identification and bone segmentation. The ML models are developed through the use of Convolutional Neural Networks (CNNs), a specific subset of deep learning that focuses on neural networks featuring convolutional layers. More than 140.000 images from hip patients have been included for the training and test data used for developing the CNNs. The CNNs are evaluated, trained and tested thoroughly to ensure generalizability and integrity.

OTS™ uses pre-trained, static models to automatically and rapidly segment CT scans and generate editable 3D models with anatomical landmarks, accelerating planning while keeping clinicians in full control. The AI models are static; once deployed, they do not learn from individual cases. Preoperative, it suggests suitable implants and positions, and if necessary, the surgeon adjusts before approval. The plan is taken to surgery, and the system provides real-time intraoperative feedback to the surgeon, guiding the surgeon to position the implants according to plan. After surgery, AI is used to analyze the follow-up CT results. The implant and bone segment are automatically detected and verified. Implant migration can thus be

analyzed by comparing multiple CT scans taken over time, i.e. AI-based CT-RSA. We have been collaborating with Ortoma and the OTS™ has been used in this thesis.

Clinical evaluation

Patient reported outcome measures (PROM) are an integral component of outcome assessment after orthopaedic surgery. PROM capture the patient's own perspective on pain, function, symptoms, and health-related quality of life, and thereby complementing traditional clinician reported outcomes such as radiographic findings and revision rates. Their use is widespread in clinical research, national arthroplasty registries, and routine follow-up, reflecting a growing emphasis on value-based and patient-centred care.

Among the most commonly used joint-specific PROMs after knee and hip replacement are the Knee injury and Osteoarthritis Outcome Score (KOOS) (53) and its hip counterpart; the Hip disability and Osteoarthritis Outcome Score (HOOS) (54). Both instruments consist of multiple subscales addressing pain, symptoms, activities of daily living, sport and recreation, and joint-related quality of life. Their comprehensive structure allows for detailed assessment across different functional domains and disease stages.

However, the desire to cover all aspects of function and well-being may also constitute a limitation, as the questionnaires are relatively lengthy and may impose a higher response burden on patients. In addition, some PROM questionnaires have difficulty distinguishing between patients with good and excellent outcomes, i.e. ceiling effect. The Forgotten Joint Score (FJS) was developed to address some of these limitations (55). Rather than focusing on specific activities or symptoms, the FJS assesses the extent to which patients are aware of their affected joint during everyday life. This construct has been shown to be particularly sensitive in detecting differences among patients with good to very good postoperative outcomes. Nonetheless, the FJS provides less detailed information on specific functional limitations and may be less informative in the early postoperative period or in patients with poorer outcomes.

Summary

Advances in lower limb arthroplasty have been driven by continuous refinement of planning, navigation, and postoperative monitoring. CT-based planning and navigation systems have improved the accuracy of implant placement, while the emergence of CT-RSA addresses many of the accessibility limitations of

conventional RSA and holds promise for making postoperative monitoring available to more hospitals.

Together, these developments represent a potential paradigm shift toward more individualized, precise, and safer joint replacement surgery. By combining accurate planning, guided surgery, and advanced postoperative assessment, the field moves closer to achieving consistently durable outcomes for a growing and increasingly diverse patient population.

This thesis comprises four published articles. Three of these describes the journey from the current gold standard for implant migration, RSA, and the transition to CT-RSA. In the fourth study, we want to validate the software system, assessing the precision of CT as a planning and navigation tool.

Patients and methods

Patient cohorts and inclusion

In the first study (I), 60 patients with primary knee osteoarthritis were included (Table 1). The inclusion and exclusion criteria are summarized in Table 2. The inclusion process lasted between September 2017 and August 2018. Patients were all scheduled for primary total knee arthroplasty (TKA) at Skåne University Hospital, Sweden. The study was designed as a single-blinded, prospective trial. Surgeons did not know what tibial component to use before surgery. Randomization occurred in blocks to receive either a conventional cruciate retaining (CR) or a medial congruent (MC) tibial insert. The randomization forms were prepared according to software randomization and put into numbered closed envelopes, opened at surgery after all bone cuts, but before it was time to cement the components.

Patients in the second study (II) were part of an ongoing RSA study at Skåne University Hospital. Between March 2015 and February 2016, 30 patients with primary osteoarthritis underwent THA. Patient demographics and inclusion criteria are summarized in Tables 3 and 4.

The third study (III) was a prospective cohort study including 26 patients with osteoarthritis scheduled for THA. The surgeries were performed between November 2020 and May 2022. Patient demographics are summarized in Table 5. Inclusion and exclusion criteria were the same as study II and thus presented in Table 4.

The fourth (IV) study was related to the precision of the AI-based software used for navigation. Two different datasets were used. One dataset contained surgery results based on 20 patients from the third study (III) with THA. Table 6 summarizes the patients characteristics. In the second dataset, three male cadavers were operated on at Tampere Surgical Education centre, Tampere, Finland, on 8 May 2024. The mean age of the cadavers was not reported. On each cadaver, THA was performed on both left and right hip.

Table 1. Study I Patient demographics.

	CR (n = 30)	MC (n = 30)
Sex, male/female	15/15	13/17
Age, mean (SD)	67 (10)	65 (8)
BMI, mean (SD)	29 (3.9)	29 (5.3)
Side, right/left	17/13	18/12
ASA, I/II/III:	7/16/7	5/21/4
Preoperative alignment, varus/valgus	23/7	23/7
Varus: Hip knee Axis (HKA) < 180°; Valgus: HKA > 180°		

Table 2. Study I Inclusion/exclusion criteria.

Inclusion criteria:
Patients with osteoarthritis of the knee Age between 50 and 80 years at the inclusion time of the study Fit for elective surgery (ASA I – III) BMI between 18 and 35
Exclusion criteria:
A history of joint sepsis Patients who have used immunosuppressive drugs (other than inhaled corticosteroids) in the last five years Rheumatoid arthritis Severe osteoporosis and other metabolic bone diseases Personal or neuromuscular disorders Previous osteotomy to the limb or intra-articular knee fracture Per-/postoperative fracture of the knee/lower limb will be excluded from the RSA part Patients who need augmentation Severe valgus deformity (>15°) and/or contracted soft tissues laterally where one can assume sacrificing the PCL will be necessary in order to reach balance Patients with perioperative notification of a non-functional PCL and patients who perioperatively for whatever reason required a more constrained knee than what the CR insert can offer Postoperative infection of the prosthesis will be excluded from the RSA part

Table 3. Study II Patient demographics.

	(n = 30)
Sex, male/female	18/12
Age, mean (SD)	57.8 (9.3)
BMI, mean (SD)	26.3 (3.6)
Side, right/left	18/12
ASA, I/II/III:	19/11/0

Table 4. Study II and III Inclusion/exclusion criteria.

Inclusion criteria:
Primary osteoarthritis of the hip necessitating total hip replacement Male and non-pregnant female patients Hip bone quality and morphology suitable for uncemented THA Age up to 75 years old at the inclusion time of the study Patients who understand the conditions of the study and are willing to participate for the length of the prescribed follow-up Patients who are capable of, and have given informed consent for participation in the study
Exclusion criteria:
Rheumatoid arthritis Malignant disease Symptomatic arthrosis of contralateral hip Severe osteoporosis Patients with active infection Patients with malignancy Prior major surgery in the hip to be operated on Perioperative fracture Hip prosthesis or grossly distorted hip anatomy in the contralateral hip Ongoing corticosteroid (oral) or immunosuppressive medication Personal disorders affecting surgery (dementia, alcohol or drug abuse etc.) Concurrent illnesses which are likely to affect their outcome Patients suffering from deep infection or recurrent dislocation (>2) during post-operative course will be excluded from the RSA follow-up, but otherwise followed clinically, as if they were fully participating in the study Patients will be withdrawn if we are unable to get an exact fit for the stem using the preoperative templating software

Table 5. Study III Patient demographics. Demographics for all patients (CT-RSA) and subgroup (CT-RSA and RSA).

	All (n = 26)	Sub (n = 10)
Sex, male/female	20/6	6/4
Age, mean (SD)	60.2 (9.3)	66.5 (8.6)
BMI, mean (SD)	25.4 (3.2)	24.6 (3.7)
Side, right/left	12/14	4/6

Table 6. Study IV Surgery patient demographics.

	(n = 20)
Sex, male/female	16/4
Age, mean (SD)	61.5 (9.4)
Side, right/left	6/14
BMI, mean (range)	26.3 (19.6 – 32.4)
Diagnosis, primary-/dysplastic coxarthrosis	19/1

Surgical technique and implants

Three experienced arthroplasty surgeons (GF, MT, and UK), performed the TKA surgeries in the first study (I). The implant used was the Persona TKA (Zimmer Biomet, Warsaw, IN, USA). It was introduced in 2012 to be a more personalized knee system. Persona comes with side-specific tibial components, together with more implant sizes and insert heights. A new feature is also the option to choose between the CR and, a novel MC tibial insert (Figure 9). For many years, the role of the posterior cruciate ligament (PCL) and level of constraint of the polyethylene insert has been under debate, and the scientific evidence is limited (56). Both the conventional CR and the new MC inlays preserve the PCL, however, the MC is claimed to better reproduce the functional anatomy and replicate tibiofemoral kinematics. It is designed to add stability to the medial compartment while enabling the lateral condyle to roll back in flexion (57), better resembling the motion of a normal knee. The surgeons were trained in the Persona TKA system and had performed at least ten cases each before start of the study. In the study, each surgeon did ten of each design, CR and MC. A conventional preoperative templating was done on standard radiographs for component sizing and position using Sectra software in the PACS (Sectra, Linköping, Sweden). In TKA planning, long standing radiographs, covering hip, knee and ankle, and a short lateral image of the knee only were used. We aimed to achieve a neutral mechanical axis, i.e., a straight line (180°)

connecting the centre of the hip, through the knee, to the ankle (Figure 10). No 3D, CT-planning or intraoperative navigation were used in this study. Bone preparations and instrumentation followed the Persona surgical technique manual. For the RSA evaluation, at surgery, six to nine tantalum markers (0.8 mm) were positioned in the distal femur and proximal tibia, either through the cortex, or diagonally through the saw.



Figure 9. Persona TKA with CR and MC tibial components. Persona TKA with the two insert options used in study I. Left: cruciate retaining (CR) tibial insert. Right: medial congruent (MC) tibial insert. (Reproduced with permission from Zimmer Biomet, Warsaw, IN, USA).

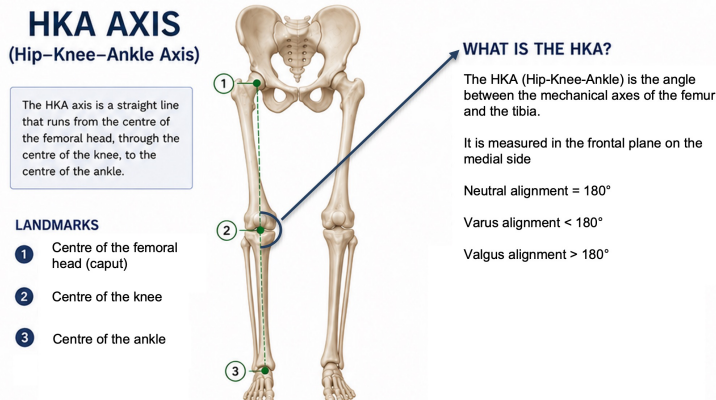


Figure 10. Hip-Knee-Ankle (HKA) axis and mechanical alignment in TKA. The Hip-Knee-Ankle (HKA) axis is defined by a line connecting the centre of the femoral head, the centre of the knee, and the centre of the ankle, measured on a standing long-leg radiograph. The HKA angle is commonly used to assess lower limb mechanical alignment and to guide preoperative planning in TKA. Neutral mechanical alignment corresponds to an HKA angle of 180° , whereas values below and above 180° represent varus and valgus alignment, respectively.

In the second study (II), three experienced surgeons (GF, SK, and MS) performed the THA operations. The implant used was the Anato stem and Trident cup (Stryker, Mahwah, NJ, USA) (Figure 11). The stem has an anatomic shape. It is based on its predecessor ABG II, and intended for cementless, press-fit application. Previously, we have published an RSA study on this THA concept (58), of which this study is a continuation. There are a neutral or anteverted neck option and eight body sizes to choose from. The Trident cup is uncemented with titanium shell and polyethylene liner. The surgeries were done in a posterior approach and instrumentation according to manufacturer's instructions. Before implant placement, the proximal femur and periacetabular bone were marked with nine to ten tantalum markers (0.8 mm) each. We aimed to achieve a maximal spread of markers in order to get as good segment for RSA analysis as possible. Templating was done preoperatively in 2D with the Sectra Orthopedic package (Sectra, Linköping, Sweden), and also in 3D using the OTS™ (Ortoma AB, Gothenburg, Sweden) Hip Plan. The contralateral hip was used for templating since it reflects the anatomy we aimed to reproduce.

Twenty-six patients underwent THA surgery in the third study (III) between November 2020 and May 2022. All surgeries were done by one experienced hip surgeon (GF). The implant used was the cementless Corail stem and Pinnacle cup (Johnson&Johnson MedTech, Warsaw, IN, USA) (Figure 11). The Corail stem is hydroxyapatite coated and comes in a variety of sizes, including a coxa vara, high offset and short neck option to restore patient specific anatomy. The stem also comes with a collared and collarless version. In this study, only the collared version was used. Surgeries were done in a posterior approach and instrumentation according to the manufacture's instruction. For preoperative templating, the OTS™ Hip Plan was used for 3D planning, and all patients were perioperatively navigated based on the CT plan with OTS™ Hip Guide. Ten out of the 26 patients got tantalum markers (0.8mm) implanted at surgery, intended for additional postoperative RSA follow-up. The proximal femur and periacetabular bone were marked with 9 – 10 tantalum markers, aiming for a maximal spread in all directions.



Figure 11. Anato stem, Corail stem and Pinnacle cup. Left: Anterior-posterior, and lateral view of the Anato stem. Right: Anterior-posterior view of the Corail stem with collar and Pinnacle cup.
(Reproduced with permission from Stryker, Mahwah, NJ, USA (Anato stem) and Johnson&Johnson MedTech, Warsaw, IN, USA (Corail stem and Pinnacle cup)).

The fourth study (IV) used surgery results from 20 patients in the third study (III) and on three cadavers. The surgical technique on live patients is described in the section before. THA surgeries performed on human cadavers on both left and right hip were the same as for the clinical cases, i.e. in a posterior approach with the cementless Corail stem and Pinnacle cup (Johnson&Johnson MedTech, Warsaw, IN, USA), and implantation technique based on the manufacturer's instruction protocol. Ten surgeons participated in the cadaver study.

RSA

In the three first studies (I-III) we used RSA for evaluating postoperative implant migration, and/or to compare it to the new, AI-based CT-RSA. The first study was RSA only, and the second and third studies had both RSA and AI-based CT-RSA follow-up (Figure 12). After perioperative tantalum marker implantation, RSA radiographs were taken according to the standard procedure in supine position with a uniplanar calibration cage for hips (Model 43, Tilly Medical, Lund, Sweden) and a biplanar cage for knees (Tilly Medical, Lund, Sweden) with two simultaneous exposed digital radiographs. All RSA data was analyzed by one experienced user with the Model-based RSA 4.1 or 4.2 (MBRSA) software (RSACore, Leiden, The

Netherlands). The implant manufacturer provided the CAD models and migration was analyzed between the implant segment and the segment consisting of the bone markers. Migration was analyzed along three axes in an orthogonal coordinate system: x, y, and z. Results were recalculated and presented as if all knees or hips were right-sided. Thus, positive directions for translations were medial, superior, and anterior translation along the x-, y-, and z-axes respectively. Positive directions for rotations were anterior tilt (x-axis), internal rotation/anteversion (y-axis), and valgus for tibial component, varus for femoral component (knee), and valgus for stem and decreased inclination for the cup (hip) (z-axis). Total translation and rotation were calculated by using the Euclidean formula ($\sqrt{x^2+y^2+z^2}$). We accepted a conditional number of <120 (indicating the spread of tantalum markers), and a mean error of rigid body fitting (stability of the markers between two examinations) of <0.35 (29). In this thesis, the term RSA (studies I-III) is used to refer to model-based RSA (MBRSA).

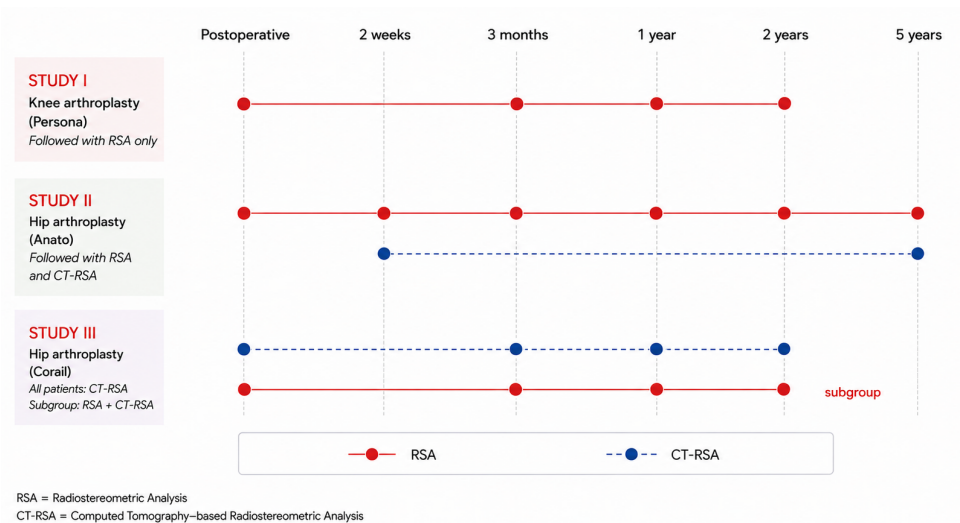


Figure 12. Postoperative follow-up schedules in Studies I-III. The figure summarizes the postoperative follow-up protocols used in studies I-III. Study I evaluated patients with the Persona knee arthroplasty using RSA postoperatively, at 3 months, 1 year, and 2 years. Study II evaluated patients with the Anato hip arthroplasty using RSA postoperatively, at 2 weeks, 3 months, 1 year, 2 years, and 5 years, while AI-based CT-RSA was performed at 2 weeks and 5 years. Study III evaluated patients with the Corail hip arthroplasty using AI-based CT-RSA postoperatively, at 3 months, 1 year, and 2 years. In addition, a subgroup of patients underwent simultaneous RSA examinations at the same follow-up time points. Solid red lines represent RSA follow-up examinations, whereas dashed blue lines represent AI-based CT-RSA examinations.

3D CT planning, navigation and follow-up

In this thesis (studies II-IV) we have evaluated a novel software using CT imaging for preoperative planning, and subsequently used intraoperatively for real-time guidance, and postoperative implant migration follow-up. The software used throughout the thesis is the orthopaedic surgical platform, Ortoma Treatment Solution, OTS™ (Ortoma AB, Gothenburg, Sweden). It contains three main modules, namely, Hip Plan, Hip Guide, and Follow-up. The OTS™ Hip Plan and Guide are released in US, EU, Japan, Australia, and UK (they have regulatory approval to be used in these regions). The OTS™ Follow-up is only released in EU, Japan, and Australia. A distinguishing feature of the OTS™ platform is its integration of AI algorithms and ML models to automate segmentation, landmark localization, and 3D reconstruction.

Throughout this thesis, preoperative 3D planning, perioperative navigation, and AI-based CT-RSA follow-up refer to the use of the corresponding modules within the OTS™ Hip Plan, Hip Guide, and Follow-up, respectively.

3D CT Planning

In the third (III) study we evaluated 3D CT planning with OTS™ Hip Plan. To perform the planning, patients undergo a preoperative low-dose CT scan of the pelvis, with complementary views of knees and ankles in order to measure leg length and neck anteversion. The pelvis section should extend from the anterior superior iliac spine to approximately 15cm distal to the lesser trochanter. This section is crucial for surgery. The knee section should include the femoral condyles and extend to 5cm distal to the tibial plateau. The ankle section is optional, but if included, it should cover the tibio-talar joint. CT scans in Digital Imaging and Communications in Medicine (DICOM) format are then imported to the server using an in-built importer tool. In the server, data is analyzed, and automatic segmentation, landmark localization, and 3D reconstruction are performed using AI-based algorithms. This is typically completed in less than one minute on a standard computer equipped with a 4 GB Nvidia graphics card. The original CT data with the analysis results from the server are then sent to the planning tool. Bone visualization is provided in three different 2D and projection views corresponding to the three primary planes of the human body. Additionally, a 3D pelvis model is displayed. Together with the 2D views, projection views, and landmarks, this shows a clear representation of human anatomy for 3D preoperative planning. The automatically localized landmarks can be adjusted based on the surgeons' preferences. The OTS™ Hip Plan provides a recommended cup and stem type and size positioned within the acetabulum and femur, based on the surgeon's prosthesis preferences. The plan is either approved or can be modified by the surgeon (Figure 13). To plan with a specific prosthesis, an implant database is used, provided by the

implant suppliers, including 3D models of acetabular and femoral components. Furthermore, patient specific range of motion can be tested by flexing-extending and adducting-abducting the hip, and collision detection algorithms identifies and simulate the risk of impingement (bone-to-implant, implant-to-implant and bone-to-bone) during activities of daily life. If necessary, implant adjustments can then be made, and anatomical variables, such as center of rotation, pelvic tilt, leg length difference, offset and femoral offsets, are restored. As the preoperative plan is completed, data required for surgery are then exported to the guide tool, facilitating surgical navigation.

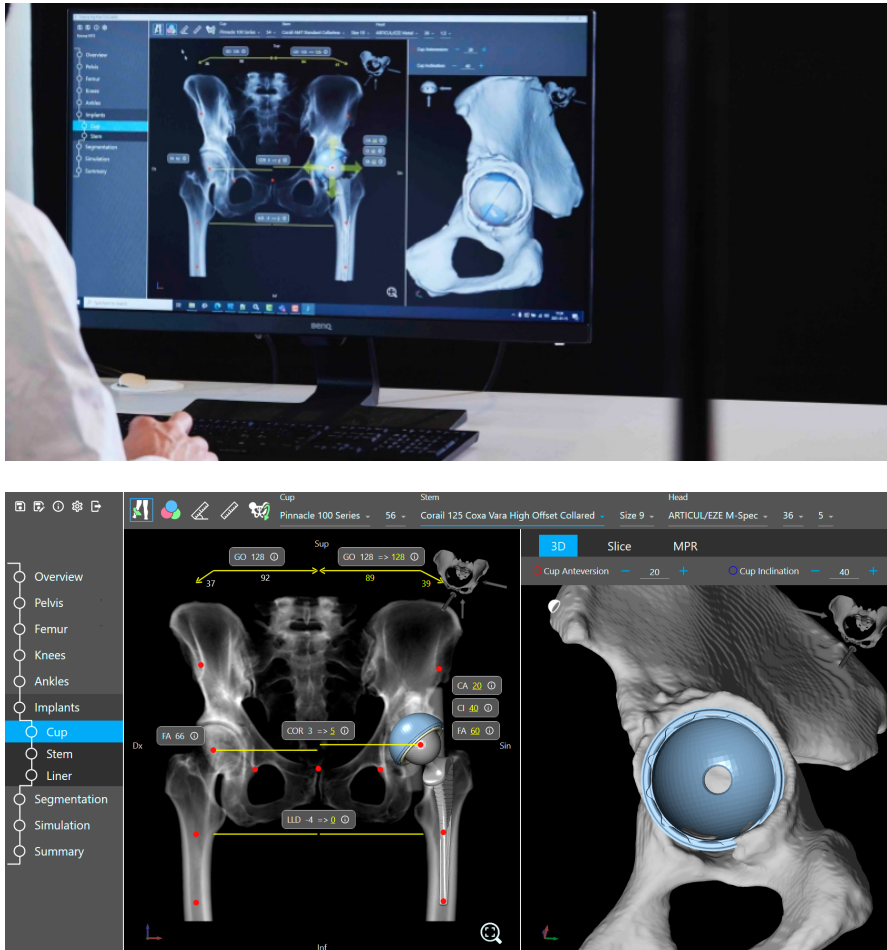


Figure 13. Preoperative planning of THA using the OTS™ Hip Plan. Top image: surgeon's view during preoperative planning. Bottom image: screenshot, illustrating preoperative acetabular cup templating and planning for THA.

Intraoperative navigation

Patients were intraoperatively navigated based on the 3D plan in the third study (III) and precision of the OTS™ Hip Guide is evaluated in the fourth study (IV). At surgery, an infrared camera, connected to a computer screen (available to the surgeon) visualizing the preoperative, patient specific plan, including bony anatomy and implant size and position, is positioned cranially, in front of the patient (Figure 14). Positions are then recorded from different reflective trackers. Dynamic trackers are attached to the surgical tools and tracks the position of the surgical instruments in relation to patient anatomy, and a reference tracker is attached to a Schanz screw that is drilled and attached bi-cortically into os ilium, cranially to the acetabulum. Each tracker consists of a rigid body on which retroreflective material that is placed in four well-defined fiducial positions. By registering reflections from the fiducials, the measurement system can track the position and rotation of the dynamic trackers. To be able to display the relative position of surgical instruments to the patient, points need to be registered from rigid bone using a pointer equipped with dynamic trackers (Figure 14). Multiple points are taken at various areas of the pelvis. The best match between the points taken and the 3D pelvis model from the CT scan is found by an AI-based search algorithm, minimizing the overall point-to-surface distance. Registration between 3D model and points is optimized so that it only takes a few seconds, minimizing the additional surgery time. The surgeon is directed to place a control screw and validate its position before and after the alignment process to ensure the quality of the alignment. The control screw can be placed in any location of the pelvis, but it needs to fulfil the following conditions: easily accessible, stay visible to the camera throughout the surgery, and allow for repeated gathering of validation measurements. The OTS™ Hip Guide navigates the surgeons during surgery. Interaction between the trackers, fixed onto the body and attached to the surgical tools, supplies real-time navigation and facilitates accurate cup placement, adjustment of leg length difference and femoral offset. Additionally, the OTS™ Hip Guide visualizes the planned anatomical targets.

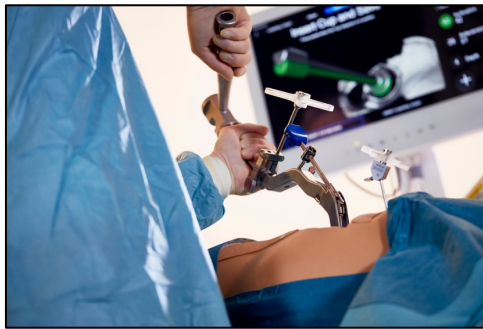


Figure 14. Perioperative navigation setup and surgical workflow during THA using the OTS™ Hip Guide. Illustration of the instrumentation and intraoperative setup used for perioperative navigation during THA with the Hip Guide. Top images: the infrared camera (positioned cranially and anterior to the patient during surgery), together with the pointer equipped with dynamic tracker and the calibration unit, and surgical instrument (impactor) fitted with an attached dynamic tracker for intraoperative navigation. Bottom images: illustration of the surgical workflow and the surgeon's intraoperative navigation view during acetabular cup implantation.

CT-RSA follow-up

In the second and third study (II and III) patients were followed with low-dose CT scans (pelvis, knees and ankles) for postoperative implant migration analysis. The data was analyzed with AI-based CT-RSA, and unlike RSA, the AI-based CT-RSA does not use tantalum markers for the migration analysis. Instead, it relies on automatically generated bone and implant segmentation, and anatomical landmarks from its integrated ML models. AI-based CT-RSA analyzes migration between two rigid bodies (bone and implant) between two CT examinations. To do so, the following steps were performed:

The postoperative CT images (e.g. postoperative day one and the later follow-up CT scans) of a specific patient were imported. AI-based CT-RSA then performed automatic segmentation and landmark localization on each CT image series, resulting in the segmentation and localization of bones (pelvis and femur) and implants (cup and stem). The femoral or pelvic bone was defined as the fixed reference. Using a rigid alignment algorithm, the software automatically aligns the reference bones in the subsequent scans as closely as possible. In the second study (II), the potentially migrating part (stem and cup) was detected and vectorized. Different parts of the implant were defined, including the tip, neck, and head of the stem as well as the center of the cup. In the third study (III) The stem and cup were detected and a prosthetic CAD model fitted to the implant (Figure 15). Cup and stem CAD models for the analysis were received from the manufacturer. In the final step, the relative migration of the implant (defined by points or CAD model) to the reference segment was obtained in six degrees of freedom (translation and rotation in x, y, and z direction). The results were calculated automatically by the software, minimizing the need for manual intervention while enabling the clinician to maintain full control over the procedure. All steps were performed in approximately five minutes. A standard computer equipped with a dedicated NVIDIA graphic processing unit (GPU) with 4 GB memory and NVIDIA GPU computing capability greater or equal to version 6.1 is required in order to run the software.

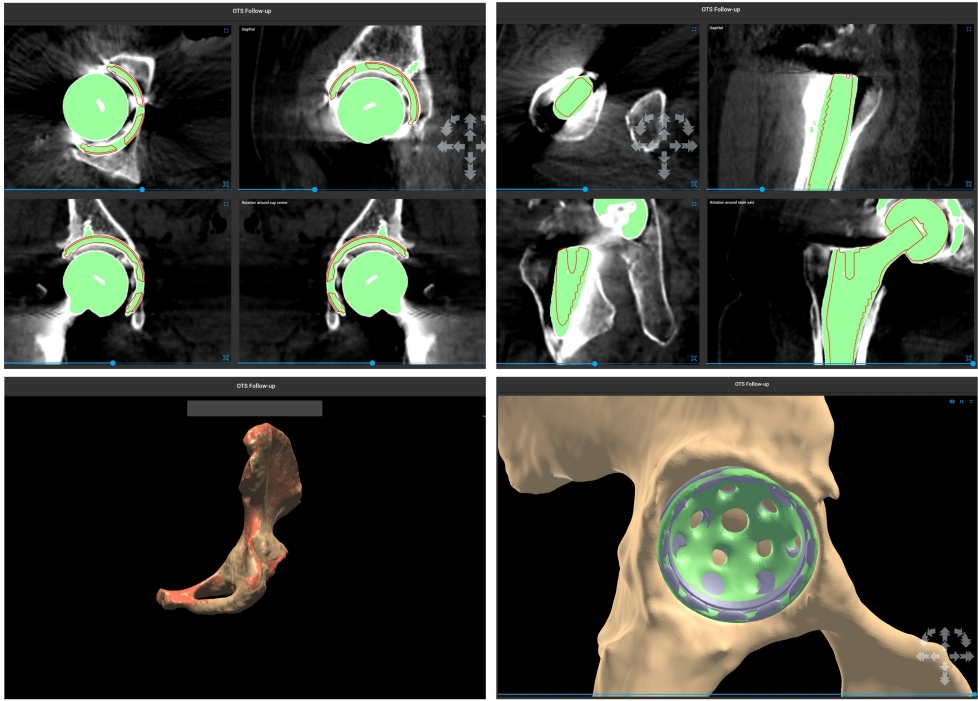


Figure 15. AI-based CT-RSA. Top figures: 2D images of the stem and cup implants, detected and segmented (in green) and fitted CAD model (red lines). Left bottom figure: 3D image of the segmented and aligned pelvic bones from two subsequent CT scans (brown and orange). Right bottom figure: 3D image of the segmented cup (green) and the fitted CAD model (grey).

The coordinate systems, used for calculating migration in RSA and CT-RSA are not the same. In RSA, translations and rotations are relative to a global coordinate system defined by the calibration cage (29). In MBRSA software there is, however, a feature using an implant-based coordinate system, with the y-axis parallel to the femoral stem and origin in the mass-center of the stem. For CT-RSA, the coordinate system can be aligned freely in 3D space. Therefore, to be able to compare the migration results between RSA and CT-RSA (study II and III), for CT-RSA, we used an implant-based coordinate system for the stem with y-axis parallel to the stem long axis, and x-axis in the same plane as the stem and neck axis, perpendicular to the y-axis. This enabled us to compare RSA and CT-RSA x-, y- and z-translations and rotations. For cup, a similar implant-based coordinate system was more difficult to achieve because of its spheric shape. For cup comparison, we used the coordinate system defined by the calibration cage for MBRSA and patient position on the CT-table for CT-RSA. Total translation and rotation were calculated in the same way for CT-RSA as RSA ($\sqrt{(x^2+y^2+z^2)}$).

CT scan settings and radiation

Different scanners and settings were used through this thesis, and there were an ongoing development and refinement of the scan protocol in order to achieve the lowest radiation dose possible without sacrificing important image quality.

In the second study (II), the CT protocol used for the Philips Brilliance 64-slice scanner (Philips Medical Systems, Eindhoven, the Netherlands) was 120kV, 30mAs, pitch 1.1, rotation time 0.4s and 64 x 0.625 matrix. Reconstruction was done in 1mm slices, with soft filter (filter B) and noise reduction iDose level 2. The calculated effective dose was 1.2mSv (SD 0.1). CT of the knees and ankles contributed comparatively little to the total CT dose (mean 0.03mSv, SD 0.01 for both knees and ankles respectively).

Patients in the third study (III) were scanned with CTs using different clinical scanner systems (Philips IQon/Siemens Somatom Flash/Siemens Somatom Edge) depending on availability. Scanning, for the majority of patients, was done with the same low dose protocol set up for the study and adopted to patient size using automatic exposure control in order to receive constant image quality (resulting in typical median radiation doses of 2.5mSv for the pelvis). Settings for pelvis was 120kV with a reference mAs of 30. For knee and foot, the mAs setting was constant set at 30mAs. In order to keep the dose lower (typical median radiation <1mSv), at some timepoints, another protocol with pelvic fixed mAs (30mAs) was used. Reconstruction of thin slices (1mm with 50% overlap) was done with soft filter and noise reduction with iterative reconstruction level 2. Metal artifact reduction (MAR-reconstruction) was applied.

Estimated effective dose (for both study II and III) was calculated using conversion factors (ICRP 103) (59).

The cadavers in study four (IV) were preoperatively CT scanned with the protocol: kVp of 120kV, tube currents of 148 effective mAs for the pelvis, 59 effective mAs for the knees and ankles, 0.625mm increments, a 0.9375 pitch for the pelvis, and a 0.5625 pitch for the knees and ankles. Slice acquisition was performed at 16 x 0.625mm. The same protocol was used for postoperative CT scans.

Validation

Precision of the OTSTM Hip Guide is validated in the fourth study, that is, the cup position values displayed on the screen intraoperatively were compared to the actual postoperative CT verified cup position (Figure 16). Evaluation was done on both patient and cadaver data. The CT scans in DICOM format were imported to the server, and the data were analyzed, and automatic segmentation, landmark

localization and 3D reconstruction were performed using AI-based algorithms. In the planning tool, the software provides recommended cup and stem type, based on the surgeons' prior preferences. The plan can then be accepted or modified by the surgeon if desired. The preoperative plan is then exported to the guide tool for surgical navigation. During the planning and surgery, cup anteversion and inclination angles were calculated, either relative to the anterior pelvic plane or the functional pelvic plane, taking preoperative pelvic tilt into account. The postoperative CT scans were then fed into the Follow-up module. It should be noted, that in this study, the Follow-up module was not used for creating postoperative examination values and possible implant migration.

Planned values		Intra-op Guide values		Post-op CT examination values		Difference between intra-op Guide values and Post-op CT examination values	
Anteversion	20	Anteversion	20.5	Anteversion	20.7	Anteversion	-0.2
Inclination	40	Inclination	38.8	Inclination	39.2	Inclination	+0.4
Cup position	X: 89.9 Y: 162.2 Z: -184.8	Cup position	X: 89 Y: 163.2 Z: -184.5	Cup position	X: 89.2 Y: 163.5 Z: -184.1	Cup position	X: -0.2 Y: -0.3 Z: -0.4



Figure 16. Validation of intraoperative navigation in Study IV. Illustration of the validation approach used in Study IV. The comparison is performed between intraoperative guide values displayed to the surgeon after acetabular cup implantation and the corresponding postoperative CT examination values. Importantly, the analysis is based on the intraoperative achieved values rather than the preoperative planned values.

On cadavers, an inter-rater assessment was performed. During navigation, precision of cup position and orientation, are highly dependent on the patient alignment accuracy. For example, the Hip Guide displays information on cup anteversion and inclination in the user interface during navigation. Parameters, such as tracking data from the camera, calibration data of the surgical instrument, and the pelvis coordinate system defined in the planning tool and specifically based on

measurement points and the patient alignment algorithm is used for calculating the before mentioned information. With the only variables being measurement points, different users can repeat the process to obtain new values for cup position and angles, given that all other factors remain the same and constant throughout the process. Inter-rater assessment was performed by letting at least three different surgeons do the patient alignment procedure per surgery/treatment side before continuing the surgical workflow and acetabular reaming. That is, after the first surgeon had performed the alignment procedure, it was reset and a new alignment procedure restarted in the Hip Guide, and another surgeon performed the same procedure. The final alignment performed by the last surgeon was then used for the remaining surgical workflow. The calculated values from inter-rater assessment were stored in log files and then extracted for analysis. Twenty-seven validation datasets were collected. Twelve out of these had to be excluded. Six datasets from one cadaver and treatment side had to be excluded because the results of patient alignment procedure were deemed as insufficient by the surgeons. Another six datasets from one cadaver and treatment side had to be excluded due to technical problems with repeated experiments in the guide tool. Accordingly, 15 datasets were available for validation.

On patients, a precision assessment with surgeries and postoperative values was done. The intraoperative displayed values for cup orientation and depth were stored in the log files and used for analysis. The planned preoperative coordinate system is used by the Hip Guide. Therefore, in order to compare postoperative CT scan values with the intraoperative values, firstly, the cup position and angles should be measured from the postoperative CT scans, and secondly, these measurements must be transformed into the preoperatively planned coordinate system. The acetabular cup position and angles were analyzed by overlaying the cup component template onto the postoperative CT image and adjusting its position manually in a slice viewer until matching the postoperative cup component. Thereafter, to align the pre- and postoperative scans and determine the rotation and transformation matrix, a volume registration algorithm was used. Finally, the extracted cup position and angles from the postoperative scan were transformed to the preoperative coordinate system and were defined as the postoperative CT examination values.

In this study (IV), we compared data on cup anteversion, inclination and depth, given by the Hip Guide to the postoperative CT scan values. For the depth, displacement of the cup component in direction of the “cup normal” was calculated in order to present the cup position difference between Hip Guide and postoperative CT scan as positive or negative values (depth inside the acetabulum). Positive and negative depth differences correspond to the cup being positioned laterally and medially, respectively, in the Hip Guide compared to data from the postoperative CT scans. The mean distance between matched point pairs after alignment was used for assessing the alignment accuracy between pre- and postoperative 3D pelvic models. The navigation error of cup depth, anteversion and inclination was defined

as the difference between values displayed intraoperatively on the Hip Guide and the postoperative CT examination values with respect to the pelvic tilt.

Clinical evaluation

In order to evaluate that patients, as expected, improve after surgery, patient-specific outcome questionnaires have been used. In the first study (I), before surgery, all patients were asked to fill in two patient reported outcome measure (PROM) questionnaires: the Knee injury and Osteoarthritis Outcome Score (KOOS) (53) and the Forgotten Joint Score (FJS) (55). The questionnaires were then collected at one and two years after surgery. The forms were posted to all patients. If there was no reply, one letter of reminder followed. The same questionnaire, the FJS, was used in the third study (III). Here, the questionnaire was collected preoperatively, at three months, one and two years postoperatively.

Statistics

In the first RCT study (I), with 30 patients in each group, and known data from the literature regarding standard deviations, the study was designed to have a power of at least 90% in detecting a minimal relevant difference of 0.5mm in MTPM at year two, having $\alpha = 0.05$. This should also allow for some dropouts.

Normality of data distribution in this thesis was assessed using histograms and Q-Q plots.

RSA and AI-based CT-RSA data over time are presented with mean values and 95% confidence intervals (CI).

In study one and three (I and III), visual analysis of the RSA data indicated that the majority of migration occurred up to three months after surgery and then levelled out (and in study III also AI-based CT-RSA). Therefore, migration over time was analyzed using a piecewise linear mixed-effect model (60) with a breaking point at three months after surgery. In the first study (I), comparing two different TKA groups, the models included three main fixed effects: group, time starting from surgery and time starting three months after surgery, and two interaction terms between the time variables and group. Adjustments were made for ASA, sex, age and BMI. In the third cohort study (III) the models included two main fixed effects: time starting from surgery, and time starting from three months after surgery. Subject was included as a random effect in both studies (I and III). This enabled us to compare the migration slopes before and after the breaking point.

In the second and third study (II and III), we graphically assessed agreement between RSA and AI-based CT-RSA with Bland Altman plots. In a Bland-Altman plot, the difference between RSA and AI-based CT-RSA ($\text{RSA} - \text{CT-RSA}$) for each patient is plotted on the y-axis, and the average of the same measurements ($(\text{RSA} + \text{CT-RSA}) / 2$) on the x-axis. Limits of agreement (LoA) were calculated around the mean on the y-axis (mean difference $\pm 1.96 \times \text{SD}$) (61). In the third study (III), since patients had multiple RSA and AI-based CT-RSA follow-ups, the baseline prosthetic postoperative position, was compared to the position at 3 months, 1 and 2 years after surgery. Each patient, thus, contributed with three migration comparisons, RSA versus AI-based CT-RSA.

To further investigate the agreement between RSA and AI-based CT-RSA, repeated measures mixed models including the ten subjects having measurements from both methods were performed in study III. Least square means and difference in least square means with corresponding 95% CI were calculated for 3 months, 1 and 2 years postoperatively.

Precision for RSA and AI-based CT-RSA were based on RSA/CT scan double examinations and presented as mean difference and standard deviation (SD). Precision was calculated as $\text{SD} \times 2$ in the first and second study (I and II), and as $\text{SD} \times \text{the critical of T for a two-tailed test, significance level of 0.05, and degrees of freedom based on the number of double examinations in the third study (III)}$.

Implant size from the planning tool, was compared to the actual implant size chosen by the surgeon during surgery in the third study (III). To calculate the binomial proportion confidence interval, the Clopper Pearson method was used.

For PROM data evaluation, we applied non-parametric tests, including Mann–Whitney U test for between-group and Wilcoxon signed-rank test for paired comparisons.

In the precision study (IV), the navigation error for cup angles and depths during patient surgeries and inter-rater cadaver study were presented as mean and SD of the difference. Graphically, the spread of difference between guide tool and the postoperative CT scan for patient surgeries was presented in a boxplot.

Statistical analyses were performed using the IBM SPSS Statistics version 26, 28 and 29.0.2.0 (IBM Corp, Armonk, NY, USA), SAS Enterprise Guide 8.1 for Windows, SAS/STAT® software version 15.2, 2020 (SAS Institute, Cary, NC, USA) and Python 3.7.

A p-value of < 0.05 was considered significant.

Ethical approval

All four studies were conducted in accordance with the principles of the Declaration of Helsinki and received approval from the appropriate ethical review authorities. Studies I and II were approved by the Regional Ethical Board at Lund University (Dnr 2017/73 and Dnr 2009/369, respectively), as well as by the local radiation committee. Studies III and IV were approved by the Swedish Ethical Review Authority (Dnr 2020-03382). All studies were registered at ClinicalTrials.gov (Studies I: NCT03494348; II: NCT01512550; III and IV: NCT05159206).

Written informed consent was obtained from all participants prior to inclusion. In Study II, additional informed consent was obtained before the 5-year CT examination, while in Study III, consent was supplemented for participants undergoing both CT and RSA follow-up. Studies I–III were reported according to relevant reporting guidelines (CONSORT for Study I and GRRAS for Studies II and III).

Use of AI

This thesis was partially produced with the assistance of the generative AI model ChatGPT (OpenAI). The tool was used to generate some images, as well as to proofread and help formulate parts of the text. I have reviewed, edited, and integrated all AI-generated text and images, and I take full responsibility for the content of this thesis.

Results

Patients

Flow charts for study one to three (I-III) show the patient flow and number of lost to follow-up (Figure 17-19).

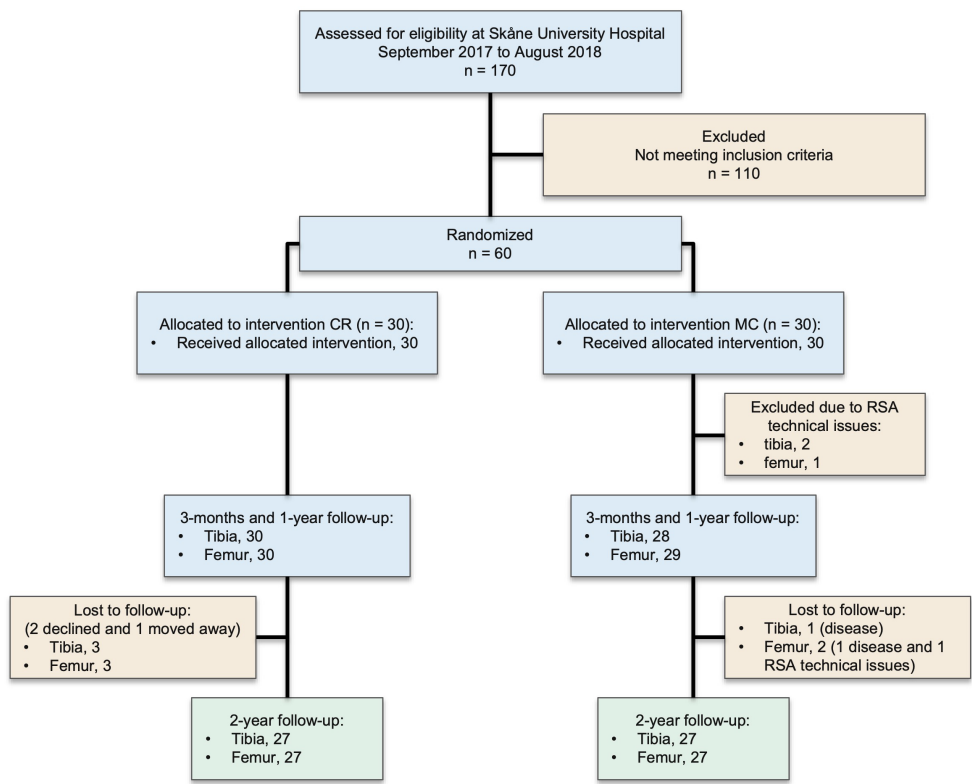


Figure 17. Study I patient flow diagram.

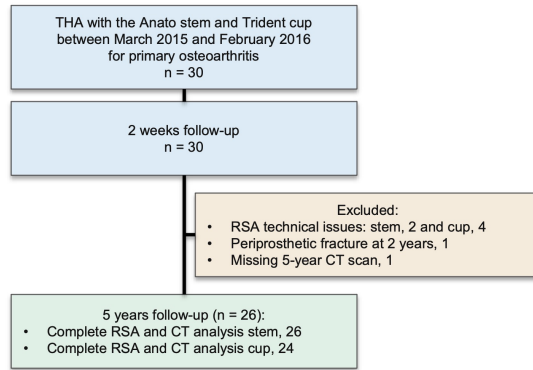


Figure 18. Study II patient flow diagram.

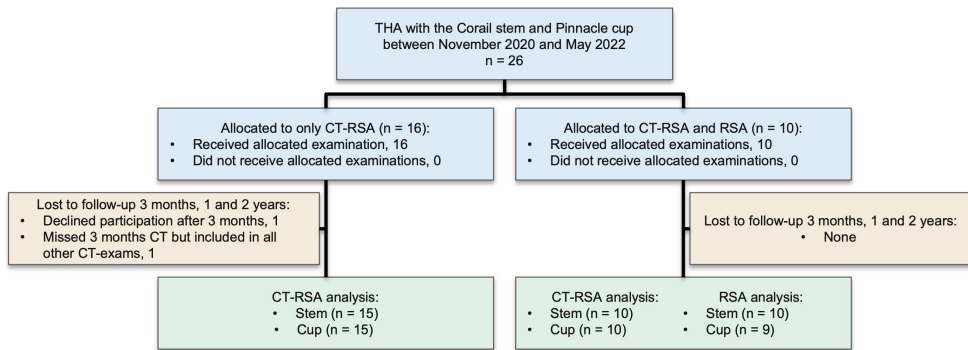


Figure 19. Study III patient flow diagram.

In the TKA RCT study (I), 27 tibias and femurs, some in different patients in the cohort, were available for RSA analysis in each group, CR and MC, at the two-year follow-up.

In the second study (II), 26 stems and 24 cups were available for the final analysis five years after surgery.

There were 26 patients included in the third study (III). All patients were scheduled to do AI-based CT-RSA. 16 out of the 26 patients were allocated to only AI-based CT-RSA, and ten were allocated to both RSA and AI-based CT-RSA. One patient declined further CT scans after three months and excluded, and one patient missed the three-month CT scan, but included in all other CT-examinations. Thus, after two years, 15 stems and cups (15 out of 16) were available for AI-based CT-RSA analysis, and in the group of ten with both RSA and AI-based CT-RSA, there were 10 stems and cups available for AI-based CT-RSA and 10 stems and 9 cups available for RSA.

In the fourth study (IV), there were 27 validation datasets collected in the cadaver cohort. Twelve had to be excluded. From one and the same cadaver and treatment side, six datasets had to be excluded because the results of the patient alignment procedure were deemed as insufficient by the surgeons. Another six sets, also from one cadaver and treatment side, had to be excluded due to technical problems with repeated experiments in the guide tool. Thus, 15 datasets were available for validation. In the patient cohort, two were excluded because of accidental movement of the attached markers during the surgeries. The remaining 18 patients were followed up and included in the evaluation.

RSA and CT-RSA migration

In the first TKA study (I), we found no statistically significant difference in RSA migration between CR and MC group at any time point or any of the measured translations, rotations nor MTPM.

In Figure 20, the MTPM for tibial and femoral components are shown for both CR and MC group. At two years, the mean tibial component MTPM were 0.62mm (CI 0.50 to 0.73) for the CR and 0.73mm (CI 0.49 to 0.96) for the MC implant. For the femoral component, corresponding mean MTPM results at two years were 0.73mm (CI 0.51 to 0.95) for CR and 0.58mm (CI 0.45 to 0.71) for MC.

One patient (#47) diverged considerably in tibial migration and did not stabilize over time. This patient was in the MC group. The MTPM after two years was 3.10mm and posterior tilt (x-rotation) -4.86° . Additionally, there were signs of radiolucency at the two-year postoperative radiographs (Figure 21). After further review, it turned out that this patient had been included despite having a BMI of 40 at the time of surgery, which was above inclusion criteria of 35, and continued to gain weight during the study period. Excluding this patient from the statistical analysis did not result in any change in significance. Figure 20 demonstrates the tibial migration with both patient #47 included and excluded.

Precision, based on RSA double examinations, was 0.20° in tibial anterior tilt (x-rotation) and 0.07mm in proximal translation (y-translation). Table 7 shows mean and SD, as basis for calculating precision.

Overall, there was a good distribution of markers with a mean condition number (SD) for tibia of 22.7 (11.2) and femur 32.6 (19.5). The mean error of rigid body fitting of 0.16 (0.08) and 0.18 (0.10) for tibia and femur, respectively, indicate that the markers were stable over time.

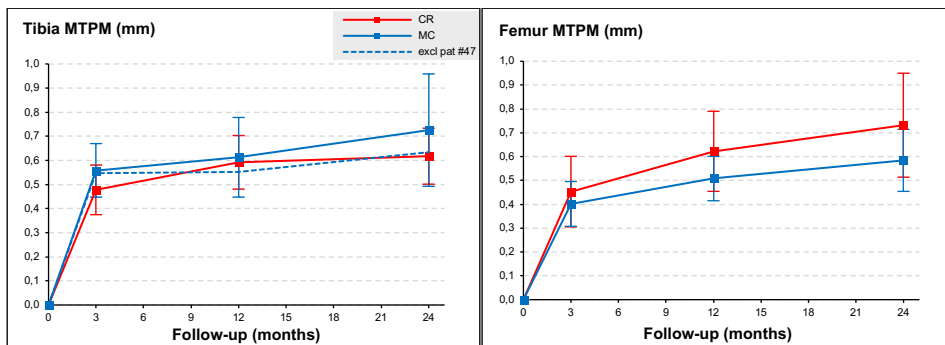


Figure 20. Study I tibia- and femur implant RSA migration. MTPM migration for the tibial and femoral component. Tibial figure with patient #47 both included (solid blue line) and excluded (dotted blue line). Error bars with 95% CI.



Figure 21. RSA radiograph of patient #47. Two year postoperative RSA radiograph of patient #47. White arrow pointing at area of radiolucent line.

Table 7. Study I Precision. Results from double examinations, as basis for calculating precision (described as 2xSD) of RSA setup, mean and SD of 72 tibias and 64 femurs.

Value	Tx	Ty	Tz	MTPM	Rx	Ry	Rz
Tibia mean	0.00	-0.01	0.00	0.22	-0.03	0.01	0.00
Tibia (SD)	0.04	0.03	0.05	0.14	0.10	0.27	0.09
Femur mean	0.00	0.01	0.00	0.15	0.01	0.01	0.01
Femur (SD)	0.06	0.03	0.09	0.10	0.08	0.08	0.09
Tx, Ty, Tz: Translations (mm), Rx, Ry, Rz: Rotations (°), MTPM: maximal total point motion							

For the THA, Anato stem and Trident cup (Stryker, Mahwah, NJ, USA), most migration occurred between the first postoperative day and second week, visualized by RSA migration values in the second study (II) (Figure 22). Between 2 weeks and 5 years after surgery, comparing RSA to AI-based CT-RSA, stem subsidence (y-translation) measured with RSA was -0.18mm (CI -0.31 to -0.05), and with AI-based CT-RSA -0.36mm (CI -0.53 to -0.19). For proximal cup translation (y-translation), the corresponding results were 0.06mm (CI 0.02 to 0.09) and 0.02mm (CI -0.01 to 0.05) respectively. Total stem translation was 0.34mm (CI 0.21 to 0.46) for RSA and 0.47mm (CI 0.33 to 0.62) for AI-based CT-RSA, and the total cup translation was 0.27mm (CI 0.21 to 0.34) and 0.16mm (CI 0.13 to 0.18), respectively.

RSA precision is shown in the RSA and AI-based CT-RSA migration graphs (Figure 22), and Table 8 summarizes the values used as basis for calculating the precision (2xSD). For stem subsidence and cup proximal migration (y-translation), the RSA precision was 0.18 and 0.06mm respectively.

The intra- and interobserver variability test of AI-based CT-RSA showed no deviation, with zero mean and SD, indicating its user-independent nature and ability to deliver consistent results.

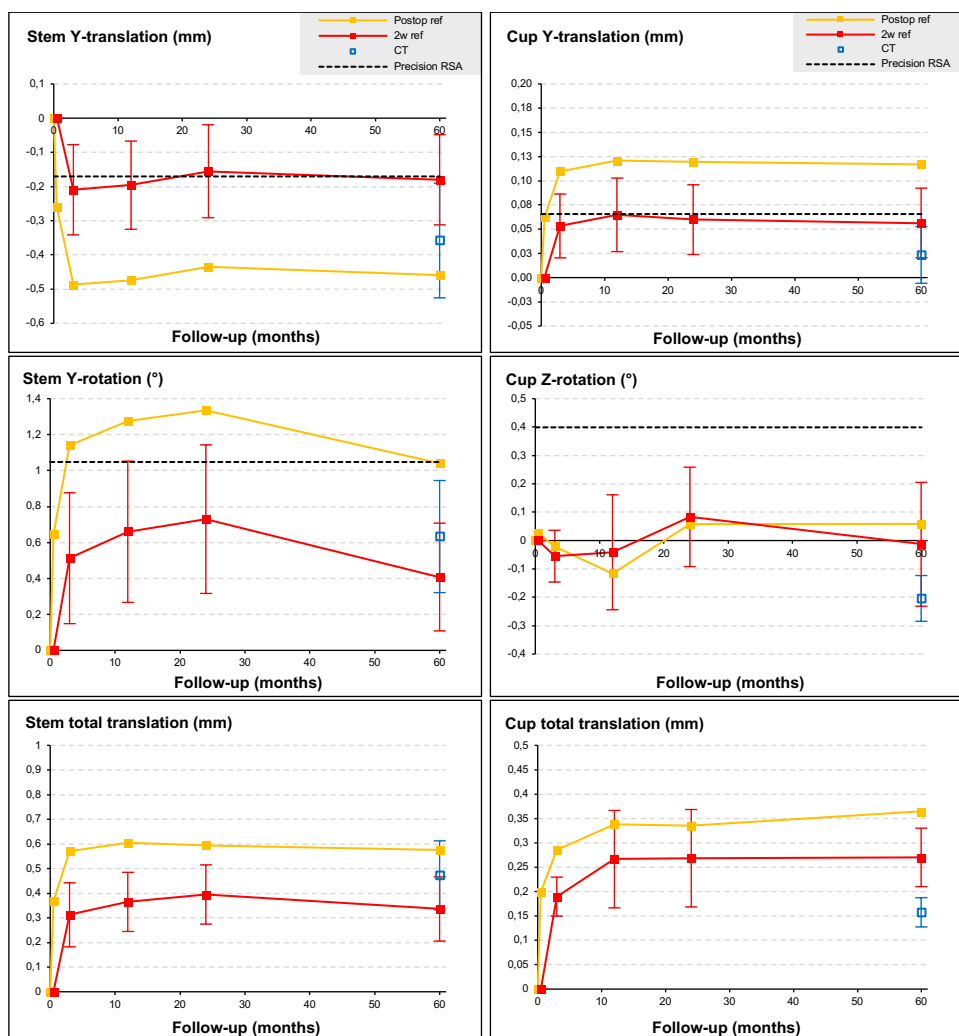


Figure 22. Study II stem and cup migration graphs. Stem (Anato) and cup (Trident) RSA and AI-based CT-RSA migration. For stem, mean y-translation (superior-inferior), y-rotation (internal-external) and total translation. For cup, mean y-translation (superior-inferior), z-rotation (decreased-increased inclination), and total translation results. RSA results with day 1 or 2 weeks as postoperative reference (yellow and red lines respectively). AI-based CT-RSA migration values from 2 weeks to 5 years represented with blue markers. Precision based on RSA double examinations (dotted black line). Error bars with 95% CI.

Table 8. Study II Precision. Results from double examinations, as basis for calculating precision (described as 2xSD) of the RSA setup, mean and SD of stem and cup.

Value	Trl X	Trl Y	Trl Z	Rot X	Rot Y	Rot Z	Tot trans
Stem, mean	-0.03	-0.02	-0.08	-0.07	-0.06	0.01	0.19
(SD)	(0.1)	(0.09)	(0.2)	(0.22)	(0.52)	(0.06)	(0.17)
Cup, mean	-0.01	0.01	-0.04	<0.01	-0.01	-0.05	0.1
(SD)	(0.05)	(0.03)	(0.11)	(0.57)	(0.6)	(0.2)	(0.08)
Trl X (medial-lateral), Y (superior-inferior), Z (anterior-posterior). Translations measured in mm. Rot X (anterior-posterior), Y (internal-external), Z (valgus-varus (stem) / decreased-increased inclination (cup). Rotations measured in degrees. Tot trans: Total translation ($\sqrt{\text{Trlx}^2 + \text{Trly}^2 + \text{Trlz}^2}$) (mm).							

Similar to the second study, demonstrating most migration taking place early after surgery measured with RSA, AI-based CT-RSA showed that the majority of migration occurred before 3 months postoperatively in the third study (III) (Figure 23). After 2 years, the results from all patients with AI-based CT-RSA showed -0.11mm in stem subsidence and 0.31mm in proximal cup migration (y-translation). Furthermore, the stem had retroverted 0.54° (y-rotation) and the cup inclination had decreased by 0.50° (z-rotation). In the comparison between RSA and AI-based CT-RSA, stem subsidence (y-translation) was slightly larger measured with AI-based CT-RSA (-0.12mm) compared with RSA (-0.03mm) and the cup had migrated cranially 0.27mm according to AI-based CT-RSA, compared with 0.44mm measured with RSA two years after surgery.

In this study we had both RSA and CT double examinations, and thus available to compare precision results. The precision for AI-based CT-RSA was superior for all migrations (Table 9). AI-based CT-RSA precision ranged from 0.06 to 0.16mm in translation, whereas RSA precision ranged from 0.17 to 0.38mm. For rotation, the precision ranged between 0.08° and 0.51° for AI-based CT-RSA and 0.24° and 0.66° for RSA, respectively.

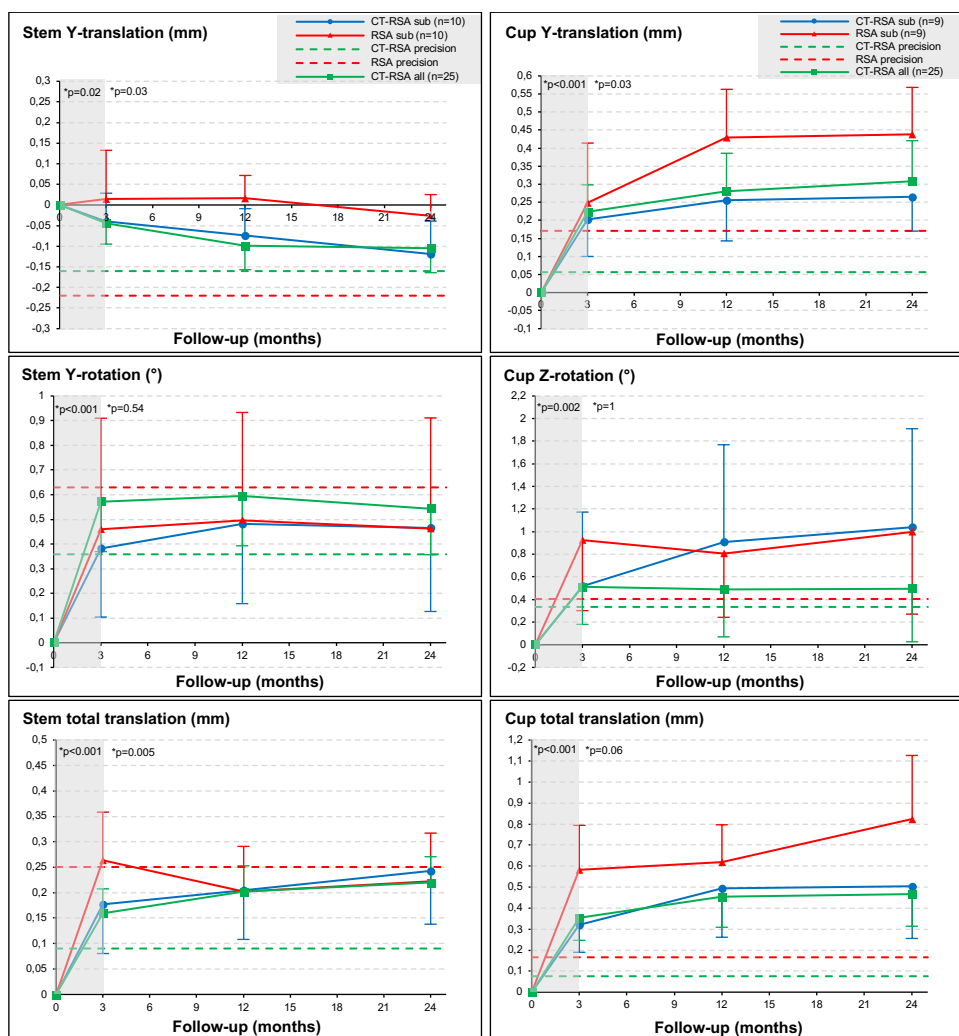


Figure 23. Study III stem and cup migration graphs. Stem (Corail) and cup (Pinnacle) RSA and AI-based CT-RSA migration. For stem, mean y-translation (superior-inferior), y-rotation (internal-external) and total translation. For cup, mean y-translation (superior-inferior), z-rotation (decreased-increased inclination), and total translation results. Blue and red lines representing AI-based CT-RSA and RSA subgroup analysis (10 and 9 patients for stem and cup respectively). Green line representing all patients in the study ($n = 25$) with exclusively AI-based CT-RSA results. Dotted green and red lines are the precision values for AI-based CT-RSA and RSA respectively. Months 0-3 highlighted in light grey. *P-values from linear mixed-effect model for all patients (green line). Slopes 0-3 months and 3-24 months. Error bars with 95% CI.

Table 9. Study III Precision. Results from double examinations, as basis for calculating precision (described as SD x the critical value of T) of RSA (n=10 cup, n=12 stem) and AI-based CT-RSA (n=14), mean and SD of stem and cup.

Value	Tx	Ty	Tz	Rx	Ry	Rz	Ttot	Rtot
RSA								
Stem, mean	0.02	-0.07	0.06	0.00	-0.03	0.03	0.19	0.34
(SD)	(0.13)	(0.10)	(0.14)	(0.22)	(0.29)	(0.11)	(0.11)	(0.13)
Precision	0.28	0.22	0.30	0.49	0.63	0.24	0.25	0.29
Cup, mean	0.03	-0.01	-0.02	-0.10	0.10	0.06	0.19	0.37
(SD)	(0.09)	(0.08)	(0.17)	(0.28)	(0.30)	(0.18)	(0.07)	(0.27)
Precision	0.19	0.17	0.38	0.62	0.66	0.41	0.17	0.60
AI-based CT-RSA								
Stem, mean	-0.01	-0.01	0.01	0.01	0.01	0.00	0.08	0.13
(SD)	(0.04)	(0.07)	(0.03)	(0.04)	(0.17)	(0.04)	(0.04)	(0.11)
Precision	0.08	0.16	0.07	0.08	0.36	0.08	0.09	0.24
Cup, mean	-0.01	0.00	0.01	-0.03	-0.06	0.02	0.06	0.29
(SD)	(0.04)	(0.03)	(0.04)	(0.19)	(0.24)	(0.16)	(0.04)	(0.18)
Precision	0.09	0.06	0.09	0.40	0.51	0.34	0.08	0.39
Tx, Ty, Tz, Ttot: Translations (mm)								
Rx, Ry, Rz, Rtot: Rotations (°)								

RSA and CT-RSA agreement

To visually compare RSA and AI-based CT-RSA, Bland-Altman plots show the difference between methods. In the second study (II), the mean difference between RSA and AI-based CT-RSA in stem subsidence was 0.18mm, and the limit of agreement (LoA) were -0.32 and 0.67mm. For proximal cup migration (y-translation) the mean difference was 0.03mm and the LoA were -0.15 and 0.22mm (Figure 24 and 25).

We compared RSA to AI-based CT-RSA with Bland-Altman plots also in the third study (III). The agreement between RSA and AI-based CT-RSA showed a mean difference of 0.08mm and LoA between -0.25 and 0.40 for stem subsidence, and mean difference of 0.13mm and LoA between -0.13 and 0.39 for proximal cup migration (y-translation) (Figure 24 and 25).

Anato stem (study II)

Corail stem (study III)

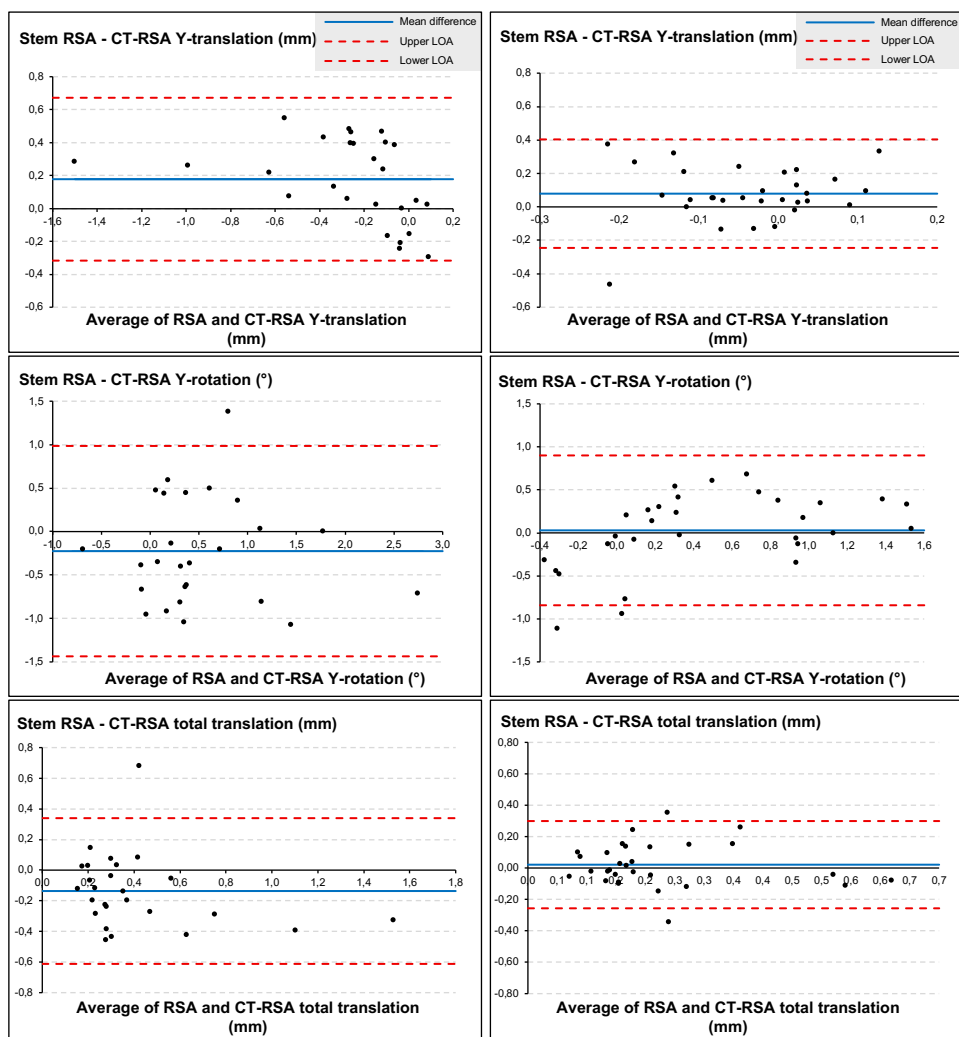


Figure 24. Bland-Altman plots for Study II and III stem. Upper left panel shows the Bland-Altman plots for the Anato stem (study II) and upper right panel the Corail stem (study III), y-translation (superior-inferior), y-rotation (internal-external) and total translation. Limits of agreement (LoA) are shown as dotted red lines. The mean difference (bias) is shown as a solid blue line.

Trident cup (study II)

Pinnacle cup (study III)

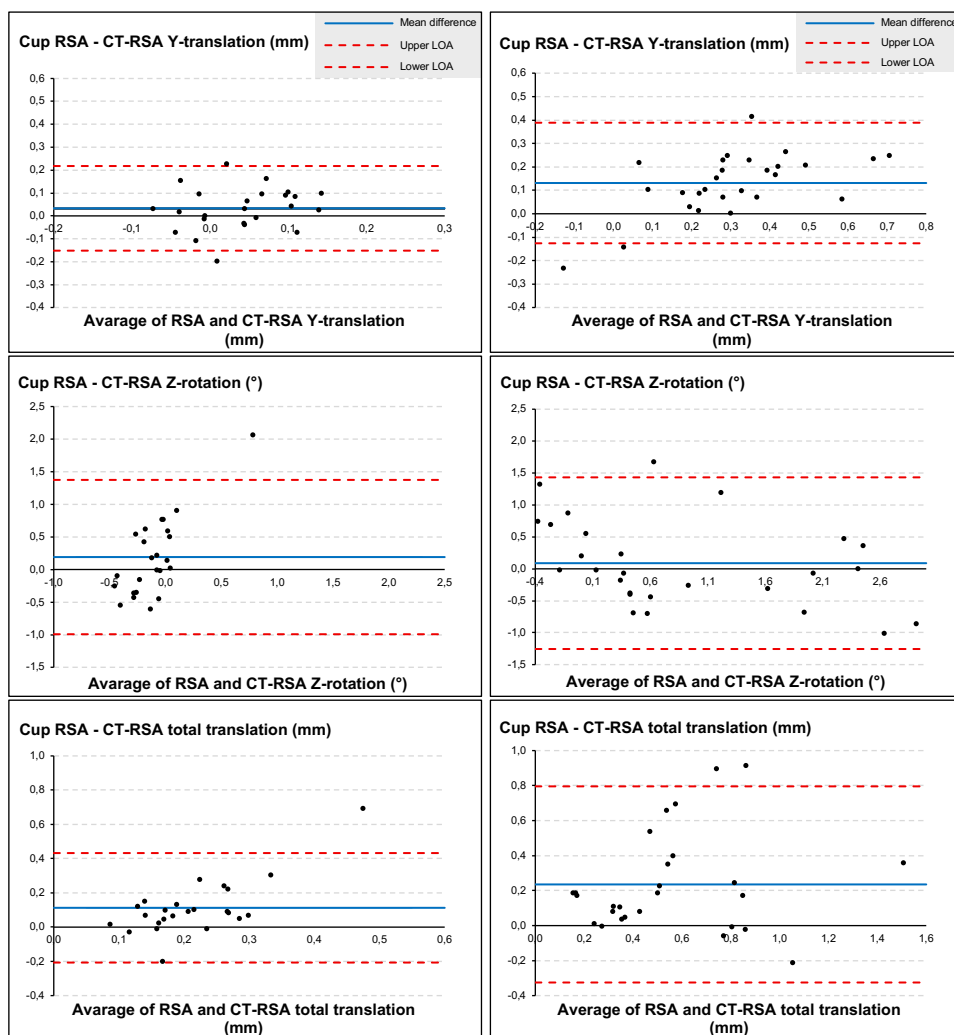


Figure 25. Bland-Altman plots for Study II and III cup. Upper left panel shows the Bland-Altman plots for the Trident cup (study II) and upper right panel the Pinnacle cup (study III), y-translation (superior-inferior), z-rotation (decreased-increased inclination) and total translation. Limits of agreement (LoA) are shown as dotted red lines. The mean difference (bias) is shown as a solid blue line.

Clinical evaluation

In the first study (I) on TKA, the response rate for the questionnaires, FJS and KOOS, was between 87% and 100% in each group at the different time points. Figure 26 shows an, as expected, clinical improvement in FJS score after surgery for both groups. In the CR group, the mean score was 13 preoperatively, and two years after surgery, the score was 61. A similar improvement was seen in the MC group, from 11 to 60. Both groups improved after the operation in all five KOOS dimensions. There was no statistically significant difference between CR and MC insert in any of the dimensions at any time point (Figure 26). None of the patients had, at the end of the study, undergone revision or had any major adverse event related to surgery, such as pulmonary emboli or deep infection. Patient #47, with radiographic signs of loosening and a BMI above the study protocol threshold, did not exhibit any clinically apparent symptoms during the study period.

Patients also reported, as expected, a clinical improvement after surgery in the third (III), THA study. Patients improved from 8 preoperatively to 66 three months after surgery in FJS score. Patient satisfaction continued to improve in the postoperative period, and two years after surgery, the FJS score was 92 (Figure 27).

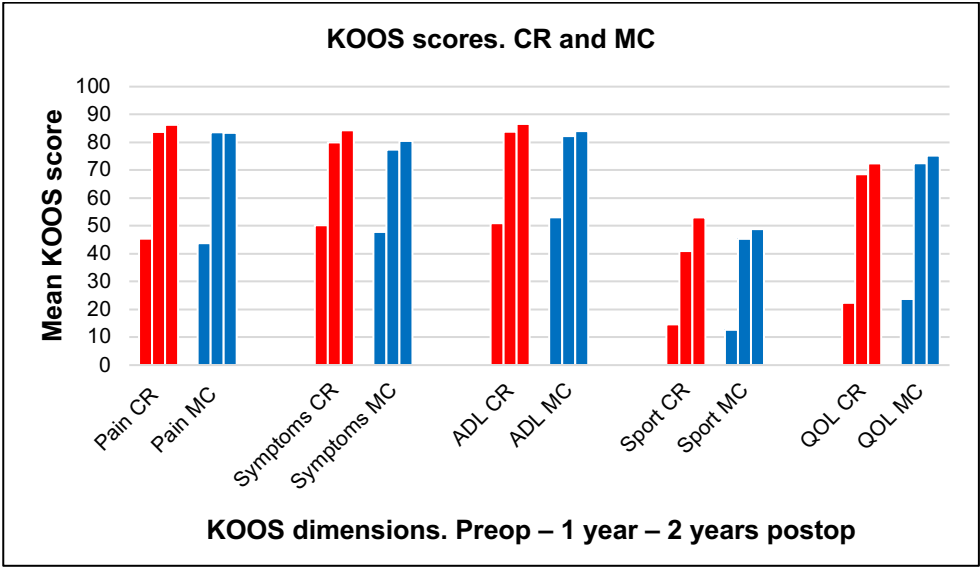
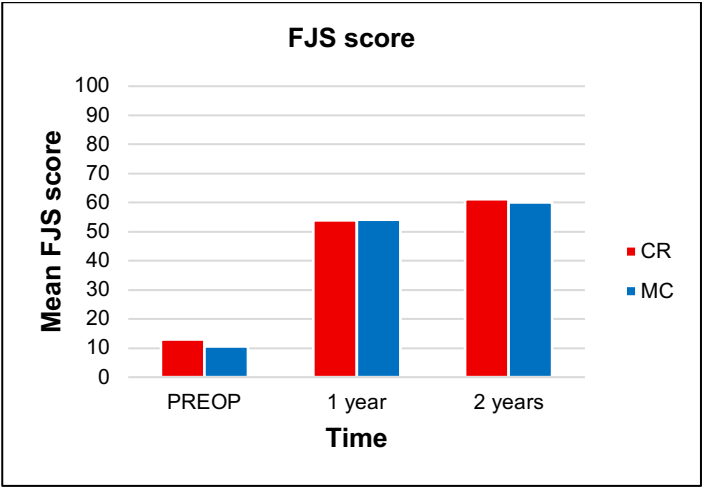


Figure 26. Patient Reported Outcome Measures (PROM) in Study I. PROM from Study I. Top figure: Forgotten Joint Score (FJS). Bottom figure: Knee injury and Osteoarthritis Outcome Score (KOOS). Both instruments are scored on a 0–100 scale, where higher scores indicate better outcomes.

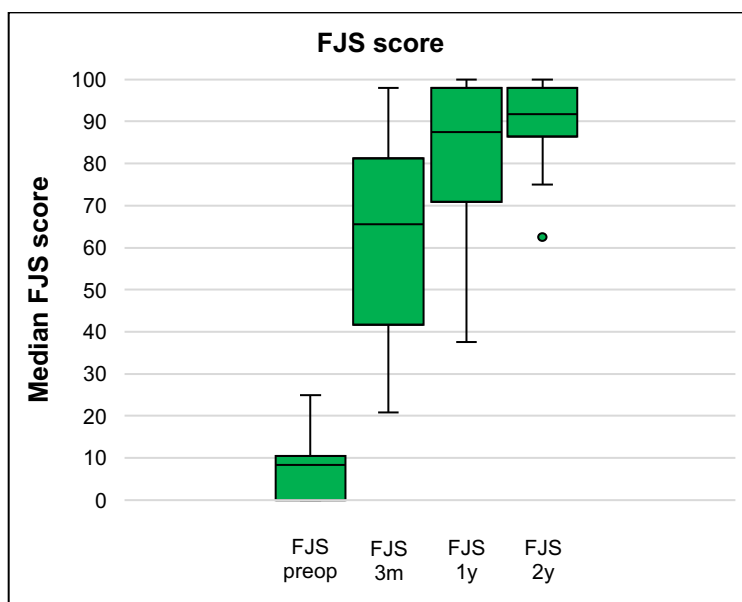


Figure 27. Patient Reported Outcome Measures (PROM) in Study III. Forgotten Joint Score (FJS). FJS is scored on a 0–100 scale, where higher scores indicate better outcomes.

Planning

In the third study (III) we compared the preoperative AI-planned implant size, but adjusted by the surgeon if required, to the one actually used. In 25 out of 26 cases (96%), the same cup size was used, and in 23 out of 26 cases (88%) the same stem size was used. There was 62% agreement in exact same stem used, including standard, varus and high-offset options.

In addition, there were no stem or cup implant size mismatches between preoperative planning and the implantation in the fourth study (IV).

Navigation

In the fourth study (IV) we looked at different aspect of precision in the OTS™ Hip Guide. During navigation, in the inter-rater assessment on cadavers, given that all other factors remain the same and constant, with the only variable being measurement points taken by different users, the difference in anteversion and inclination were $-0.31^{\circ} \pm 1.42$ (ranging from -2.63 to 2.18) and $1.06^{\circ} \pm 1.73$ (ranging

from -1.8 to 4.08), respectively. The difference in depth was $-0.94\text{mm} \pm 1.76$ (ranging from -4.86 to 1.67) (Table 10).

In the same study (IV), there were no complications reported during patient surgeries. The alignment accuracy between preoperative and postoperative 3D pelvic models (measured using the average surface distance between the two aligned pelvis bones) in all 18 patients, was mean 0.26mm and SD 0.08. For the 18 patients, the differences between the guide tool and the post-op CT examination values showed a difference in anteversion and inclination of $-0.07^\circ \pm 2.72$ (ranging from -4.68 to 5.22) and $-0.2^\circ \pm 0.86$ (ranging from -1.29 to 1.36), respectively. The difference in depth was $0.28\text{mm} \pm 0.78$ (ranging from -1.53 to 1.46) (Table 10). Thus, the spread in cup inclination was lower than the spread in cup anteversion. There were no patients with errors over 10° . One patient had an anteversion over 5° , and there were no patients with inclination errors over 5° .

Table 10. Navigation error for cup angles and depths during inter-rater cadaver, and patient surgeries

Metrics	Mean	SD
Navigation error for cup angles and depths during inter-rater cadaver study, n = 15		
Anteversion (°)	-0.31	1.42
Inclination (°)	1.06	1.73
Depht (mm)	-0.94	1.76
Navigation error for cup angles and depth during patient surgeries, n = 18		
Anteversion (°)	-0.07	2.72
Inclination (°)	-0.20	0.86
Depht (mm)	0.28	0.78

Discussion

In this thesis, we investigated how modern technology can be applied to the planning, performance, and postoperative follow-up of patients undergoing hip and knee prosthesis surgery. The overarching objective was to evaluate the progression from the established gold standard for implant migration analysis, RSA, toward CT-based methods, specifically CT-RSA, and to assess the role of AI in facilitating this transition.

The work began with the application of conventional RSA to compare migration patterns of two tibial insert designs, CR and MC, within a newly introduced total knee arthroplasty system. Building upon this foundation, we explored CT as an alternative to RSA, leveraging the availability of two CT examinations (at 2 weeks and 5 years postoperatively) in a patient cohort that had been consistently followed with RSA. Finally, a structured CT-RSA study was conducted in accordance with established RSA guidelines, including double examinations for precision analysis. In a subgroup of patients, tantalum markers were implanted intraoperatively, enabling direct comparison between CT-RSA and conventional RSA measurements. Central to this work was the implementation of an AI-based software capable of automated image analysis, i.e. AI-based CT-RSA.

In addition to evaluating migration patterns, we examined the intra- and interobserver variability of AI-based CT-RSA, compared CT-based preoperative planning with the achieved implant size, and assessed the precision of both AI-based CT-RSA and the OTS™ Hip Guide used intraoperatively.

Overall, AI-based CT-RSA demonstrated migration patterns comparable to those observed with RSA, characterized by the expected early postoperative migration followed by stabilization. The accuracy of AI-based CT-RSA was comparable to that of RSA, with good agreement between the two methods. Slightly superior clinical precision was observed with AI-based CT-RSA, and the automated software produced consistent results. Moreover, the CT-based Hip Plan provided predictable implant positioning, and the Hip Guide offered intraoperative guidance with notable precision in cup placement.

Collectively, these findings suggest that AI-based CT-RSA has the potential to serve as a clinically applicable alternative to conventional RSA, while simultaneously broadening accessibility and simplifying workflow. The implications of these

results, as well as methodological considerations and clinical relevance, are discussed in detail below.

RSA and CT-RSA

RSA has long been considered the gold standard for assessing postoperative implant migration over time due to its high precision and accuracy (35,62). However, the technique requires implantation of markers, the use of a calibration cage, facilities equipped with two X-ray units for simultaneous image acquisition, as well as specialized personnel and dedicated software for calculating the 3D positions of the markers. Furthermore, patients may be excluded due to inadequate bone marker placement or marker over-projection (29).

The introduction of MBRSA represented an important step toward addressing some of the limitations associated with conventional RSA and marker-based prostheses (38). However, this approach relies on the specific three-dimensional geometry of the implant, and its precision is highly influenced by implant design (63). In addition, markers still need to be inserted into the bone in MBRSA, and there remains a risk of patient exclusion due to obscured markers.

In our first study, we evaluated the migration pattern of two different tibial inserts, CR and MC, in a common TKA. In theory, the increased constraint on the medial side of the MC tibial component compared with the CR of the Persona TKA might be expected to influence the RSA migration pattern due to asymmetric loading. However, we concluded that both tibial designs stabilized as expected following an initial small settling phase. At 2 years, the mean tibial component MTPM was 0.62mm for the CR and 0.73mm for the MC implant. The MTPM also appears to be consistent with findings from previous studies of well-performing TKA systems currently available on the market (64-69).

MTPM is a 3D vector referring to the point that exhibits the greatest movement relative to the bony reference segment at each examination. The point of maximal motion may therefore differ between examination time points but reflects the overall migration over time (29). MTPM provides an indication of the overall magnitude of migration but does not specify the direction of the vector in space. Although the use of MTPM has been debated, we report MTPM values together with migration along the individual axes, as this approach is commonly used in RSA studies of TKA and facilitates comparison with previously published results.

In a meta-analysis of 2,470 TKA, Pijls et al. presented important threshold values for identifying patients at risk of tibial loosening. Prosthesis migration, measured as MTPM, of more than 0.5mm at 6 months indicates a prosthesis at risk, whereas migration of 1.6mm or more should be considered unacceptable. After the initial

migration phase, migration should be $<0.2\text{mm}$ between 6 months and 1 year, and between 1 and 2 years (67).

One patient in the MC group (patient #47) demonstrated a deviating tibial migration pattern. As early as 3 months postoperatively, this patient showed a tibial backward tilt (x-rotation) of -0.9° , compared with a slight forward tilt of 0.1° observed in the other patients in the MC group. At 2 years, the tibial backward tilt had increased to almost 5° and standard radiographs showed clear signs of loosening (Figure 21). Rotation around the transverse axis, as well as proximal and distal translation, has been shown by Gudnason et al. (66) to predict aseptic loosening more accurately than MTPM. In retrospect, this patient should not have been included in the study due to a BMI of 40 at the time of surgery, which is well above the inclusion limit of 35. Furthermore, the patient continued to gain weight during follow-up. We nevertheless chose to retain the patient in the study, as the case is of particular interest and therefore described separately. Both the high BMI and the relatively severe preoperative varus deformity of 13° are known risk factors for loosening (70,71) and may have contributed to the observed migration pattern. At the time of publication, the patient had reported no significant knee symptoms, and PROMs are comparable to the overall mean. However, we anticipate that revision of the tibial component may be required in the future. Retrospective exclusion of this patient would not have altered the statistical significance of the results but would have affected the graphical presentation of the data, as shown in Figure 20. We believe this case further illustrates the ability of RSA to predict later implant loosening at an early stage.

In our second study (II), we investigated whether repeated CT scans could serve as an alternative to RSA. Extending from TKA, we evaluated the agreement between RSA and AI-based CT-RSA in THA. An important feature of AI-based CT-RSA presented in this thesis, distinguishing it from other systems on the market, is its high degree of automation. Current CT-RSA systems still require manual and time-consuming procedures, including bone segmentation and image registration, similar to conventional RSA. The use of AI enables automatic image processing with high accuracy, thereby substantially reducing the time required (72).

The primary failure mechanism in THA involves proximal cup migration and stem subsidence (y-translation) (31,36), making these parameters the most important values for comparison. To determine whether the agreement between RSA and AI-based CT-RSA was sufficiently narrow for our purposes, a clinically relevant threshold needed to be defined. Proximal cup translation of $0.2\text{--}1\text{mm}$ at 2 years is considered indicative of increased risk for later revision (31) and has been used to define the limits of clinical importance (34). In the second study, we compared migration from 2 weeks to 5 years postoperatively. According to the Bland–Altman analysis, limits of agreement for proximal cup translation fall within the clinically relevant range ($0.2\text{--}1\text{mm}$). No validated thresholds exist for migration of uncemented stems; however, early subsidence of $1\text{--}2\text{mm}$, as measured by RSA, has

been associated with an increased risk of early- or intermediate-term revision (36). Furthermore, it has been demonstrated that an uncemented stem may stabilize after an initial subsidence of approximately 1.25mm within the first 3 months postoperatively (58). In our study, the LoA between RSA and AI-based CT-RSA for stem subsidence was approximately 1mm, with a mean difference (bias) of 0.18mm. Accordingly, the LoA falls within the clinically relevant range and meets the acceptance criteria defined in previous studies. Notably, the bias for all stem and cup comparisons, including x-, y-, and z-translation, as well as rotation, remained within the precision range reported for RSA.

A limitation of our second study (II), which included CT scans at only two time points, at 2 weeks and 5 years, was addressed and improved in our third study (III). To our knowledge, this was the first clinical study evaluating both THA cups and stems that compares CT-RSA with RSA, using a follow-up program in accordance with RSA guidelines, including double examinations (29). In connection with the preparation of the third study, practical guidelines were published on how to plan, conduct, and report CT-RSA research (41,42).

In the third study (III), CT examinations were taken directly postoperatively, at 3 months, 1 year and after 2 years. In addition, CT was also done before surgery for planning purposes. The AI-based CT-RSA migration pattern for this uncemented stem was as expected, with an early migration up to 3 months, which then levelled out, indicating osseointegration. The stem subsided 0.11mm after 2 years measured with AI-based CT-RSA. Previous studies on the same stem, have showed a subsidence of about 0.4 – 0.6mm after 2 years measured with RSA (73,74). The Corail stem has both a collared and collarless version, and thus, perhaps the reason to our small migration values were due to the exclusive use of collared stems. With AI-based CT-RSA, the Pinnacle cup migrated proximally similar to studies with RSA on uncemented cups (33,75).

Similar to the second study (II), we evaluated and compared AI-based CT-RSA with conventional RSA in the third study (III). However, in this study, we had access to prosthetic CAD models not only for model-based RSA but also for AI-based CT-RSA, allowing for a more balanced comparison. This approach contrasts with the second study, which relied on landmark recognition for prosthesis segmentation. For the 10 patients who were followed using both conventional RSA and AI-based CT-RSA, the Bland-Altman analysis demonstrated a smaller difference between the two methods in stem subsidence compared with our previous study (II). This suggests that incorporating prosthetic CAD models in AI-based CT-RSA yields results more comparable to model-based RSA. The mean difference in cup proximal translation remained similar to our previous findings (II) and to those reported in other studies (34). Moreover, all results were within the clinically relevant limits (34), predictive of future implant loosening (31).

In the direct comparison between conventional RSA and AI-based CT-RSA, AI-based CT-RSA results appeared stable, with narrower confidence intervals than those of conventional RSA. The precision of AI-based CT-RSA for both cup and stem measurements was consistent with previously published CT-RSA studies (34,39,40) and consistently superior to conventional RSA (Table 9).

Overall, we observed a higher correspondence between RSA and AI-based CT-RSA for translations than for rotations. It should be noted, however, that it remains unclear which method more accurately reflects true implant migration. Nonetheless, as previously discussed, AI-based CT-RSA appears to provide more stable migration measurements, with narrower confidence intervals and superior precision compared with conventional RSA. Supporting the advantages of CT-RSA, Brodén et al. reported superior rotational precision for CT-RSA relative to marker-based RSA (39). This improvement may be attributed to the benefits of 3D registration in CT-RSA and the potential impact of collinear marker distribution on rotational measurements in conventional RSA.

It should be noted that in all three of our studies (I–III) on postoperative migration analysis, the reference examination, whether RSA or AI-based CT-RSA, was performed within two days after surgery. Consequently, our migration measurements closely reflect the true total early migration. In contrast, some studies conduct the reference examination at two weeks or later, even though approximately 50% of the three-month migration has often already occurred by two weeks (76). This timing difference may introduce bias when comparing migration results across studies.

Comparing conventional RSA and AI-based CT-RSA, the measured migration values are not always identical. At present, it remains uncertain which method most accurately reflects the true implant migration, as no absolute reference standard exists for in vivo measurements. Nevertheless, there are reasons to speculate that AI-based CT-RSA may in fact provide measurements that are at least comparable to, or potentially even more accurate than, conventional RSA. The ability to evaluate implant position in 3D without reliance on marker stability or projection-dependent imaging may represent an inherent methodological advantage. As accessibility to low-dose CT protocols and dedicated software continues to improve, AI-based CT-RSA could eventually challenge, or potentially replace, conventional RSA as the future gold standard for implant migration assessment.

Radiation

CT has long been questioned due to its relatively high radiation dose. A standard CT examination of the pelvis is associated with an effective dose of approximately 6mSv, whereas the annual dose from natural background radiation is around 3mSv,

depending on geographical location (77). In recent years, however, advances in low-dose CT technology have aimed to substantially reduce radiation exposure (18) and it seems as this can be used successfully in CT-RSA (32,34,39,40,43).

In our second study (II), a mean effective radiation dose of 1.2mSv (SD 0.1) was sufficient for AI-based CT-RSA migration analysis. In the third study (III), the scan protocol was under development and optimization throughout the study period, resulting in a wider range of administered doses from the beginning to the end of the study. Factors such as increased CT slice thickness may negatively affect accuracy (44,78). We did not perform a statistical comparison between patients exposed to higher versus lower radiation doses, as such an analysis would be challenging given that the true migration is unknown. Importantly, dose reduction does not necessarily compromise precision (43). We did not observe any systematic differences when comparing pelvic segmentation and registration accuracy in a subset of cases across the higher and lower ends of the radiation spectrum. This suggests that a lower dose range (approximately 1 – 2mSv) is likely sufficient for reliable analysis. Overall, the CT radiation doses in our studies were in line with those reported in previous clinical investigations (34,40).

For RSA, the effective dose in the hip studies (II and III) was estimated at approximately 0.1 – 0.2mSv per radiographic examination. However, repeated radiographs are sometimes required to ensure visualization of all tantalum markers, which may increase the total radiation dose. In contrast, CT imaging typically does not require repeated scans, as the 3D field of view is not dependent on patient positioning in the same way as conventional radiography.

For knee examinations, the effective radiation dose is generally lower than for hip studies, due to differences in anatomical region, tissue sensitivity, and the extent of the examination.

Planning

Two-dimensional templating in THA typically involves the use of software applied to digital radiographs to estimate implant size and positioning. Although this method frequently predicts the implant size within one size, the accuracy of exact stem and cup size estimation may be below 50%, with factors such as surgeon experience and patient BMI influencing the outcome (7). Three-dimensional templating enables detailed reconstruction of the patient's anatomy and has demonstrated greater accuracy compared with 2D methods (20-22). In conventional 2D templating, it is difficult to adequately account for femoral and stem rotation, which may lead to inaccurate assessment of femoral offset and consequently suboptimal biomechanical restoration. For less experienced surgeons, AI has been shown to serve as a valuable adjunct in preoperative planning (79). In study three

(III), agreement between planned and actual implant size exceeded 85%. These findings are comparable to, or better than, those reported in previous studies on 3D-based implant size prediction (19,21,80). However, a larger cohort would be required to draw definitive conclusions.

Navigation

OTS™ Hip Guide, the surgeon-controlled guiding tool, facilitates intraoperative navigation and is used to assist in positioning the prosthetic components optimally. For component placement, surgeons are not constrained by preoperative planning values but may instead perform intraoperative modifications and final adjustments during THA. The preoperative plan therefore serves as guidance only, while the target values are those determined intraoperatively by the surgeon. Accordingly, the optimal orientation of the acetabular cup is finally established intraoperatively based on patient-specific anatomical considerations.

When considering both mean values and standard deviations (absolute value: $0.76^\circ \pm 0.40$), the precision of cup inclination measurements achieved with the guiding tool appear superior to that of comparable systems (81-87). For cup anteversion (absolute value: $2.16^\circ \pm 1.56$), the results were comparable to, or slightly better than, those reported in the previously mentioned studies, with one exception, where superior values ($1.2^\circ \pm 1.1$) were observed (81).

The inter-rater analysis conducted in this study (IV) demonstrated that the Hip Guide consistently produces accurate surgical outcomes, supporting its reliability across different users. When comparing measurement accuracy, cup inclination was more precisely assessed than cup anteversion in both inter-rater and surgical precision analyses. Although the observed absolute mean difference of approximately 2° may not be clinically significant, further investigation is warranted to determine the underlying reasons for the greater variability observed in cup anteversion measurements.

Limitations

Study I:

A possible limitation of study I is the relatively small sample size and the short follow-up period. For an RSA study, a cohort of 60 patients and a follow-up of 2 years are generally considered sufficient; however, a larger cohort would have been required for a more robust assessment of PROM data. Another limitation is that, to avoid issues related to multiplicity, the power calculation was based on MTPM rather than on translations and rotations along the individual axes, even though these measures were stated as the primary endpoint in the trial registration.

Study II:

First, ideally, postoperative CT scans and additional repeated CT examinations would have been performed concurrently with all other RSA assessments; however, the study was originally designed to include only RSA and a 2-week CT. The 5-year CT was added retrospectively. Second, we did not perform CT double examinations and are therefore unable to comment on the precision of AI-based CT-RSA. RSA calculates migration using CAD models (MBRSA), whereas the AI-based CT-RSA in this study segments the prosthesis based on landmark recognition, which may influence migration measurements. In the later study (study III), incorporation of CAD models into the AI-based CT-RSA software potentially enhances its accuracy and reliability.

Study III:

For the comparison between RSA and AI-based CT-RSA, only 10 of the 26 patients were included, in order to minimize radiation exposure. Patients in the RSA subgroup were slightly older (66.5 years) than the overall cohort (60.2 years) but were otherwise demographically similar. Another limitation was the inconsistency of low-dose CT protocols. Examinations were performed on different scanners, and protocols were under development, resulting in varying settings and radiation levels. Using CAD models for both AI-based CT-RSA and conventional RSA makes the comparison more equivalent; however, implant CAD models are not always readily provided by the manufacturer, which represents a limitation. Notably, AI-based CT-RSA can also be used without CAD models (study II). Furthermore, we anticipate that AI-based CT-RSA stem rotation measurements can be improved. Currently, the software uses only a stem CAD model for the analysis. By incorporating the stem

head, we expect that stem anteversion and retroversion (y-rotation) measurements can be enhanced.

Study IV:

Several limitations should be considered when interpreting the findings. First, patient classification based on the type of deformity was not included. Incorporating such classifications and performing subgroup error analyses could help to better define the margin of error across different deformity types. Second, the sample size was relatively small. Future studies should include a larger number of patients to ensure a more diverse study population and to improve the generalizability of the findings. In addition, appropriate statistical confidence measures should be incorporated. Despite the limited sample size, the findings indicate that the OTSTM Hip Guide performed with a high degree of accuracy in clinical settings. Furthermore, all patients were followed postoperatively, and at the time of writing the study manuscript, no complications had been reported.

Future directions

First and foremost, further research on CT-RSA is warranted, with continued validation against conventional RSA, which remains the current reference standard. While the present thesis demonstrates promising agreement between AI-based CT-RSA and RSA, commonly regarded as sufficiently close to ground truth, additional validation is necessary to fully establish the method's accuracy.

As this thesis is being written, we have recently published an evaluation of AI-based CT-RSA in a non-clinical setting (88). Specifically, looking at the accuracy to determine how closely the measurements reflect the true migration. In this thesis, we have focused on comparing AI-based CT-RSA with conventional RSA; however, true accuracy requires comparison with a known ground truth. Initially, we aimed to address this using a mechanical phantom model. However, due to the multiple sources of error associated with such setup, we instead developed a synthetic model. In this approach, a femoral stem prosthesis was digitally migrated within a computer environment, where the exact transformation parameters (i.e., the true migration) are known. These known values were then compared with the outputs generated by AI-based CT-RSA. This represents a first step toward establishing the accuracy of the method under controlled conditions.

In addition to accuracy, optimization of radiation dose remains a key area for future investigation. As discussed in the third study of this thesis, a low-dose CT protocol was developed and evaluated. Encouragingly, the findings suggest that lower radiation dose levels are sufficient for reliable migration analysis. Nevertheless, there is likely potential for further dose reduction without compromising analytical performance, which should be explored in future studies.

Furthermore, in the study comparing planned implant size with the final implanted size, future work could extend this analysis by evaluating the performance of AI-based preoperative planning tools. While we investigated how well CT-based 3D planning, sometimes adjusted preoperatively by the surgeon, corresponds to the actual implant size used intraoperatively, it would be of significant interest to assess the accuracy of fully automated AI-driven size recommendations. Such studies would shift the focus from the imaging modality itself to the performance and reliability of the software algorithms, thereby providing insight into the clinical utility of AI-assisted planning systems.

The transition from conventional 2D methods toward fully integrated 3D workflows may represent a paradigm shift in arthroplasty surgery. Preoperative CT-based planning enables a more detailed understanding of patient-specific anatomy, while intraoperative navigation allows increasingly accurate execution of the surgical plan. Postoperatively, low-dose CT and CT-RSA provide opportunities not only for highly precise assessment of implant position and migration, but also for longitudinal follow-up beyond what has traditionally been feasible in routine clinical practice.

At present, both RSA and CT-RSA remain primarily research tools, mainly used in smaller study populations for early evaluation of novel implants and fixation principles. However, if CT-based planning and postoperative low-dose CT become increasingly integrated into standard arthroplasty workflows, entirely new possibilities may emerge. A patient who undergoes preoperative CT planning and postoperative baseline CT imaging could, years later, undergo repeat CT imaging in the event of symptoms or suspected implant failure. This would make it possible to retrospectively assess implant migration and biomechanical changes over time in substantially larger and more clinically representative populations than those currently included in RSA studies.

As CT technology continues to evolve, with progressively lower radiation doses and improved image processing, it is conceivable that low-dose CT may eventually challenge not only conventional RSA, but also standard radiography in certain aspects of arthroplasty follow-up. In addition to migration analysis, CT imaging offers detailed 3D information, potentially enabling a more comprehensive understanding of implant performance throughout the lifespan of the arthroplasty.

Although many technical and logistical challenges remain, the convergence of 3D planning, navigation, artificial intelligence, and CT-based postoperative evaluation suggests a future in which arthroplasty surgery becomes increasingly personalized, data-driven, and quantitatively monitored over time.

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About the author

Albin Christensson was born and raised in Båstad, Sweden. After graduating from high school, he studied Spanish in Spain before beginning medical school at Lund University in 2012. Following graduation, he completed a research-track internship, combining clinical training with scientific work.

As an orthopedic researcher, his work focuses on the use of modern technology to improve the planning, navigation, and follow-up of patients undergoing total joint arthroplasty. This dissertation explores how digital tools and advanced imaging techniques can contribute to improved surgical outcomes, facilitate patient follow-up, and increase the accessibility of postoperative migration analysis for both clinical practice and future research.