The effect of new technology on the results after knee arthroplasty

Studies on robotically assisted surgery and new uni-condylar knee arthroplasty designs

Øystein Skåden

Thesis for the degree of Philosophiae Doctor (PhD)
University of Bergen, Norway
2026

UNIVERSITY OF BERGEN

The effect of new technology on the results after knee arthroplasty

Studies on robotically assisted surgery and new uni-condylar knee arthroplasty designs

Øystein Skåden

Thesis for the degree of Philosophiae Doctor (PhD)
at the University of Bergen

Date of defense: 12.06.2026

Year: 2026
Title: The effect of new technology on the results after knee arthroplasty

Name: Øystein Skåden
Print: Skipnes AS / University of Bergen

Content

Scientific environment

This work was carried out at the Norwegian Arthroplasty Register (NAR) and Haugesund Sanitetsforenings Revmatismesykehus (HSR), Haugesund, Norway between 2020 -2026.

The main supervisor was Øystein Gøthesen. Ove Nord Furnes and Geir Hallan were co-supervisors. Scientific support was also given by the staff at BioMat lab, Department of Orthopaedic Surgery, Haukeland University Hospital, Bergen, Norway and the staff at the Department of Radiology at Haugesund Hospital, Helse Fonna, Haugesund, Norway.

This thesis is part of the PhD program at the department of Clinical Medicine (K1), Faculty of Medicine and dentistry, University of Bergen.

Acknowledgements

The idea for this project was born after many interesting and motivating discussions with my main supervisor Øystein Gøthesen on robotic assisted computer navigation and introduction of a novel total knee arthroplasty. Øystein defended his thesis on the effects of computer navigation in total knee arthroplasty surgery in 2013 and has a deep understanding and vast knowledge in this field that he happily shares. Thank you for guiding me through this scientific endeavor, prioritizing our projects, always with an open door for supervision and personal support. I appreciated the many contributions to the papers in this thesis, and for the positive feedback in the process.

Co-supervisor Ove Nord Furnes: Working with you has been a pleasure. I very much appreciate your balance between giving direct feedback, when need be, and compliments. You have an in-dept knowledge of the current and past literature in the field which is impressive. The literature you provided on the way provided me with insight and was invaluable for the quality of scientific papers.

Co-author Stein Håkon Laastad Lygre: Thank you for always helping with the many important statistical analyses. I appreciated all our “teams” meetings, the scientific aspects, but also on a personal level. You managed to make a total novice in the field of statistics feel better, with kind words and support.

Co-supervisor Geir Hallan: Thank you for the invaluable insight into RSA analyses. I appreciate all the help with the articles, always kind remarks and positive feedback, which is uplifting.

Co-author Anne Marie Fenstad: You have an impressive knowledge within your field and have added valuable inputs and statistical analysis to this thesis. It is a pleasure to work with you.

Co-author Laila Moksheim: Thank you for making my life easier! You are invaluable in collecting and punching data in the NAVIO trial and having full control over the patient-lists.

Beathe Angstaur: I thank you for organizing all the out-patient controls and RSA – images. This project has been a success, and I thank you for your important contribution.

Radiological department, Haugesund Hospital, Helse Fonna with leading radiographer Ben Hassan Chedli and colleagues:
Thank you for the high-quality RSA – images you and your team produced for the study. These are the backbones of the analyses in paper II.

Randi Furnes: Thank you for the important job around the randomization process, and always making sure someone answered the phone when we called.

Haugesund Sanitetsforening: Without the financial support from the research grant, this project would not have been possible. Thank you!

Paul Johan Høl and Irene Ohlen Moldestad at BioMat lab at Haukeland University Hospital: Thank you for the contributions to the RSA-migration study. I have learned a lot from both of you.

Lars Rødeseike, Smith and Nephew. I would like to thank you for being a very knowledgeable representative. You were enthusiastic and gave important support for the technology used in this study.

Clinical staff at the orthopedic department (RKO), Haugesund sanitetsforenings revmatismesykehus: Thank you for your hard work and being

positive and understanding. This project would have been impossible without you.

Haugesund,
18.03.2026
Øystein Skåden

List of abbreviations

ADL – Activities of Daily Living
AOANJRR – the Australian Orthopedic Association National Joint Replacement Registry
ASA – American Society of Anesthesiologists physical status classification system
CAS – Computer Assisted Surgery
CI – Confidence Interval
CN – Condition Number
CORI – Core of Real Intelligence, second generation robotically assisted computer navigation system from Smith and Nephew
CPAK – Coronal Plane Alignment of the Knee
CT – Computer Tomography
EQ-5D – Health Questionnaire developed by the EuroQol group
FJS – Forgotten Joint Score
HR – Hazard Ratio
HA – Hydroxy Apatite
KM – Kaplan-Meier
KOOS – Knee Injury and Osteoarthritis Outcome Score
KSS – Knee Society Score
MCID – Minimal Clinical Important Difference
MRI – Magnetic Resonance Image
N - Number
NAR – Norwegian Arthroplasty Register
NAVIO – First generation robotically assisted computer navigation system from Smith and Nephew
OMERACT-OARSI – Outcome Measures in Rheumatology - Osteoarthritis
PROM – Patient Reported Outcome Measure
RCT – Randomized Controlled Trial
Robotic – Robotically Assisted Computer Navigation

RSA – Radio Stereometric Analysis

SD – Standard Deviation

SHR – Sub-distribution Hazard Ratio

TKA – Total Knee Arthroplasty

UKA – Uni-condylar Knee Arthroplasty

VAS – Visual Analogue Scale

WOMAC – Western Ontario and McMaster Universities Osteoarthritis Index

List of publications

1. Skaden O, Furnes ON, Lygre SHL, Badawy M, Gothesen OJ. **Did a new design of the Oxford unicompartmental knee prosthesis result in improved survival? A study from the Norwegian Arthroplasty Register 2012-2021.** Clin Orthop Relat Res 2023; 481:1703-1712. DOI: 10.1097/CORR.0000000000002671

2. Skåden O, Furnes ON, Lygre SHL, Moldestad IO, Hallan G, Fenstad AM, Høl PJ, Gøthesen ØJ. **Radiostereometric measurement of implant migration in robotically assisted vs conventional bi-cruciate stabilized cemented total knee arthroplasty: secondary analysis of a randomized controlled trial.** Acta Orthop 2025; 96: 283-289. DOI: 10.2340/17453674.2025.43081

3. Skaden O, Furnes ON, Lygre SHL, Hallan G, Fenstad AM, Moksheim L, Gothesen O. **2-year results of robotic-assisted functionally aligned vs. conventional mechanically aligned total knee arthroplasty – a randomized controlled trial.**

   Submitted 2025.

Abstract

Introduction

New implants with different designs and more advanced surgical operating tools have been developed due to a growing demand for knee arthroplasty surgery and the urge for clinical improvement. Robotically assisted computer navigation (robotic) was developed in the pursuit of more precise implant positioning and balancing, theoretically leading to better alignment accuracy and increased implant survivorship as well as patient satisfaction. The purpose of this thesis was to compare the effects of new technology and implant design on the results after knee arthroplasty. We compared robotically assisted total knee surgery with conventional surgery using a responder analysis, Patient Reported Outcome Measures (PROMs), radiological measurements and migration studies for a novel cemented bi-cruciate stabilized total knee arthroplasty. We also compared the newest Oxford uni-compartmental knee (UKA) designs to a previous design.

Methods

The thesis is based on results from a randomized controlled trial (RCT) and data from a prospective observational national register study.

In paper I, we compared the new twin-peg cemented and uncemented Oxford partial knee with the established single-peg cemented Oxford phase III knee, in a study from the Norwegian Arthroplasty Register (NAR). The overall relative risk of revision, and the risk of revision for specific causes, up to 5 years after surgery, were studied.

In paper II, the first 51 patients in a RCT were assessed with radiostereometric analysis (RSA) after randomization to either robotic or conventional technique, to compare migration patterns of the tibial component, between the groups.

In paper III, 209 patients were enrolled to compare clinical and radiological results in a randomized controlled trial after 24 months. We used PROM

responder analysis, PROMs, radiographical measurements, and physical tests to compare robotic or conventional operation techniques for a cemented total knee arthroplasty.

Results

The results in Paper I did not show any difference in the overall risk of revision between the cemented Oxford partial and cemented Oxford phase III in the 5-year period, but the uncemented Oxford partial had an increased risk of revision for infection, compared to cemented Oxford III and more periprosthetic fracture compared to cemented Oxford partial. The uncemented Oxford partial had a lower risk of revision for pain and instability compared to cemented Oxford III, and the cemented Oxford partial had a lower risk of revision for femoral component loosening compared to cemented Oxford III.

Paper II showed a higher mean migration for the robotic compared to the conventional group, but the overall migration pattern for the bi-cruciate stabilized implant was acceptable.

Paper III did not show any difference between robotic and conventional groups with respect to the PROM responder analysis, PROMs, or physical tests. The femoral components were more flexed, and tibial components more sloped in the robotic group. The operating time was 11 minutes longer.

Conclusions

The new twin-peg cemented Oxford Partial Uni appears to be an acceptable replacement for the single-peg cemented Oxford III. The cemented version should be preferred over the uncemented version.

The robotically operated bi-cruciate stabilized TKAs migrate more up to 24 months, but this study did not find any difference in the clinical results between the two techniques. The cost- and time-effective conventional technique should still be considered the “gold standard” for primary total knee arthroplast

Introduction

1. Background

Knee osteoarthritis is a degenerative disease in which the cartilage, covering the joint surfaces, degenerates. Loss of cartilage leads to narrowing of the joint space, development of osteophytes, hard sclerotic bone and-/ or erosions into the bone. The loss of cartilage and bone height can lead to loss of ligament integrity, disruption of the individual knee alignment and result in instability. Patients with end-stage osteoarthritis are good candidates for knee arthroplasty with 80-90% chance of a good or very good result(1-6).

Knee arthroplasty has been on the rise in Norway and globally for the past two decades, and this increase has been driven by an aging population, rising obesity, and an increasing prevalence of osteoarthritis. Also, a rising optimism for the results after surgery has contributed, as have new prostheses, improved conventional instrumentation and advances in computer-assisted surgery and robotics. The number of primary knee arthroplasties performed in Norway has increased steadily from around 1000 procedures in 1994 to above 9000 operations in 2024.(7) The last five years (2020-2024) the proportion of Uni-compartmental knee arthroplasty (UKA) have increased from 12.6% to 17.1%.

With a high development rate in a growing field, independent control systems are crucial for a safe introduction into market. Registry studies as well as well-designed randomized controlled trials play a major role as “gate keepers” in this field, where new technology seems to play an increasing role. Patients have good access to information and often request or even demand the newest and most accurate options available. It is our duty as surgeons to use well documented implants but also operating tools that are proven to benefit the patients, without adding unnecessary cost or operating time. In this thesis we used a register-based study to compare the risk of revision of a re-designed UKA with an established design (paper I), and a randomized controlled trial to evaluate the difference in migration pattern (paper II) and

clinical result between robotically assisted surgery and conventional technique for a novel type TKA (paper III).

2. Robotic computer navigation (robotic) and the NAVIO project

Robotically assisted computer navigation (robotic) is the latest development in technology-assisted surgery of the knee. Computer assisted surgery (CAS) was first used in neurosurgery before it got introduced into knee arthroplasty surgery a few decades ago(8-11). In robotic surgery the bone cuts or milling get executed precisely by either a robotic arm or a hand-held robotic burr, as opposed to CAS where the surgeon performs the cuts through cutting guides, aided in place by the CAS system. The robotic execution theoretically leads to more precise implant fitting and placement relative to the intraoperative plan developed on the touch screen. The core principles of computer navigation technology are the same for both robotic and CAS. The systems are developed to give the surgeon information needed to take a decision on the most optimal placement of the prosthesis components relative to bony structures, soft tissue tension and bone-specific- and overall alignment. Computer technology in knee arthroplasty surgery has evolved from a basic setup with a goal of reaching an alignment target without soft tissue considerations, to more complex robotized computer navigation systems which also aid in execution of surgery and ligament balancing of the knee. The latest CAS systems have a system for balancing the soft-tissue envelope, but no robotized execution function. There are a wide variety of systems where some are image based (CT or MRI) with the advantage of preoperative planning, potentially reducing the operating time, and some imageless (as NAVIO/ CORI used in our study) (figure 1,2). The disadvantages of image-based systems are higher costs and radiation exposure. Imageless systems make use of intraoperative mapping of the bony structures. Most systems are only open to the few implants of the company providing the system.

Robotic technology is on the rise and is presently the preferred non-conventional technique for both TKA and UKA. The Australian national register

(AOANJRR) reports that 40% of TKAs are robotically assisted(12). In Norway it was a slight decline in technology assisted procedures the last years with only 6% computer assisted TKAs reported to the Norwegian Arthroplasty Register (NAR) in 2024 and 4.7% robotic(7). In the USA the utilization of robotic assisted knee surgery grew from 0.01% in 2008 to 8.5% in 2020 and have increased rapidly since, reaching an estimated 70% by 2030(13).
The main advantage of robotic assisted technology is that one can make a precise plan of component positioning before executing the bone cuts, whereas in conventional technique the cuts are done by bony landmark guidance combined by intra- or extramedullary anatomical axes, and soft tissue guidance. Manipulation of the soft tissue envelope (ligament loosening) is more often necessary with the conventional technique, but doesn't necessarily lead to inferior results(14,15)
Robotic gives the option to use any alignment technique, but a mixed technique called functional alignment is perhaps the most popular method for achieving balanced flexion and extension gaps(16), often without soft-tissue manipulation. The functional alignment is dependent on the very precise positioning allowed by robotics and computer navigation. Restricted functional alignment uses a neutral mechanical overall alignment as default, before moving the components to match the bony structures (shape matching) of tibia and femur. Lastly, the components can be adjusted according to the ligament tension to create a natural soft tissue balance(17).
Most studies on CAS or robotic report less coronal overall alignment outliers(4,18-23), but no improvement for the clinical results or satisfaction rates(24,25). Correct alignment is crucial for function of the knee, limb and the entire locomotor system. The CPAK classification(26) shows that not all patients are constitutionally straight, so correcting all limbs to neutral mechanical alignment could be unnatural. Certain limitations for corrections in the coronal plane into varus or valgus are advised, since shear forces potentially can lead to early loosening of the components. The tibial components are designed to get implanted 90° on the axis of tibia.

Pin-site tracking related fractures(27) and infections(28) used to be downsides with robotically assisted surgery, but has largely been overcome with smaller pins (<4 mm) which are placed in the metaphysis within the skin incision rather than the diaphysis(29). The systems are associated with higher costs and increased operating time, as well as a learning curve of 15-50 cases(30-32). In the present study we used the NAVIO system from Smith and Nephew (figure 1, 2) which is an imageless closed robotically assisted system. Infrared light is reflected from discs mounted on 3 mm pins that are drilled into the proximal tibia and femur, to a camera placed about 2 meters away from the operating table. After the surgical approach is made, information on the center of tibia, femur, ankle and hip is fed into the computer by a pointer with reflector discs drawing over the bony structures (figure 2). The ligament laxity is then noted with valgus and varus stress (aided by a Z retractor) to the knee in the entire range of motion. Planning is done on the touch screen, where the prosthesis components can be moved in three dimensions. The burr is then used for milling out the distal femoral cut and holes for the femoral and tibial cutting guides. After the trial components are inserted, the ligament laxity and alignment can be assessed before cementing the final prosthesis.

A cemented bi-cruciate stabilized total knee arthroplasty (Journey II BCS) was developed to mimic the kinematic pattern of a native pre-arthritis average shaped knee(33). The prothesis` joint line obliquity is 3-degree apex distal, meaning it is 3 degrees varus relative to mechanical axis from the hip center via the knee to the ankle (HKA), and parallel to the ground, which is true for an estimated 75% of the native knee constitutionally(26,34). The prosthesis is a posterior stabilized (PS) type implant with a more kinematically similar movement from full extension to flexion, where femur rotates (pivots) outwards on tibia in the first part of the motion to roll-back of both femoral condyles toward the end of the flexion motion. The bone fitting surfaces of both the tibial and femoral components are similar previous implants (Legion/ Genesis II) from the same company (Smith and Nephew) despite internal mechanical

differences. There are strict EU regulations for the release of implants (CE-marked) into market, however no long-term clinical results are demanded. This is the reason that NAR demands ODEP classification(35) of 10A, good results after 10 years in the Norwegian Arthroplasty Register (NAR), other registries, or an acceptable 2-year migration results from RSA studies. This will classify an implant as well documented and advised used in common clinical practice. We were curious about this CE-marked, but not well documented new implant, and found it to be a suiting implant to use in a randomized controlled trial to assess if robotic computer navigation is superior to conventional instrumentation due to its potentially unforgiving and rather complex design. We wanted to evaluate whether a more complex implant needed a more precise tool of implantation to achieve a good result. To evaluate the effect and usefulness of robotic assisted surgery, and to get a wide scope of assessment, we designed a study containing a variety of outcomes. Short term implant migration as measured with RSA has been shown to predict the risk of aseptic loosening in the longer term. Therefore, we measured the migration of this novel tibial implant. We also wished to evaluate if surgical technique (robotics vs conventional) had an influence on the migration of the implant. The study would also gain insight into the midterm survivorship of the prosthesis in the present study with regards to its introduction into market. To assess the clinical results after TKA, we designed a randomized controlled trial (RCT) with a responder analysis(36) as the primary endpoint to assess the results linearly.

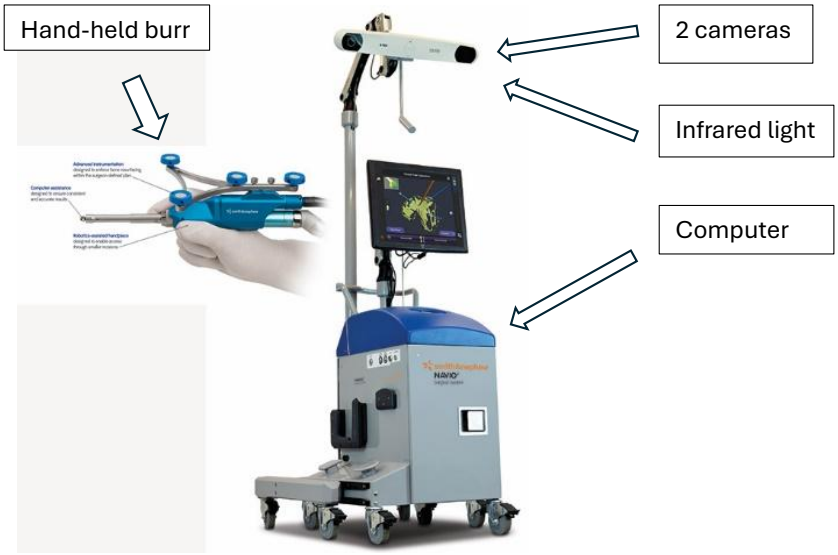


Figure 1. NAVIO robotic assisted computer navigation system from Smith and Nephew (Memphis, TN, USA)

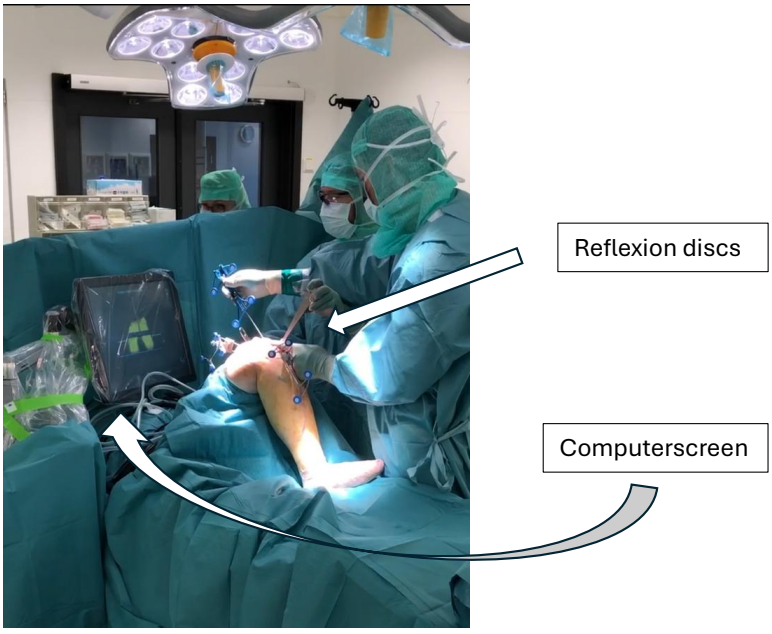


Figure 2. Image illustrating intraoperative setup for NAVIO

3. Unicompartmental Knee arthroplasty (UKA)

UKA is only used if the patient has uni-compartmental osteoarthritis. The anterior and posterior cruciate ligaments as well as the collateral ligaments must be intact, and patients should not present with a flexion contracture, as well as a valgus deformity or lateral joint space narrowing to be considered for a medial UKA. Some retro-patellar osteoarthritis is accepted. There is a higher revision rate for UKA patients(37), but lower risk of postoperative complication, higher forgotten joint score (FJS) (38-42), an accelerated recovery and better post operative range of motion (ROM) (43) than the TKA. Cemented UKA had lower pain levels than the uncemented versions in a prospective register study (44), while the results for pain score in a systematic review did not find any difference comparing UKA to TKA (39). Patient selection can be a challenge for UKA, and the operating technique is sensitive to surgical error. A low hospital volume is associated with higher revision risk (45,46). UKAs has historically shown a higher revision rate than total knee arthroplasty (TKA), especially for aseptic loosening and progression of osteoarthritis (37,47,48). Attempting to increase the implant-longevity a twin-peg femoral component (Oxford partial) replaced the single-peg version (Oxford phase III) of the widely used Oxford medial UKA. The aim of the new design was to improve the fixation of the femoral component. The new prosthesis was developed with two pegs, taking advantage of the two femoral holes for the cutting guide. The Oxford Microplasty instruments were introduced in Norway in 2012, along with this new version of the Oxford UKA, allowing for implantation in a more flexed position, which is believed to reduce shear forces and the risk of anterior impingement. These instruments were developed to make the operation easier and placement of the components more accurate.(49-53).

4. Radiostereometric analysis (RSA) and implant migration

Conventional radiostereometric analysis (RSA) with intraoperative implantation of tantalum markers into bone and poly-insert (figure 3 and 4) is still considered the gold standard for measurement of three-dimensional implant migration using radiographic images. A rigid body is defined by the markers that make up each segment, in the present study polyethylene insert and tibial bone. To be able to identify each segment the markers had different sizes. The RSA examinations were taken with the knee inside a bi-plane calibration cage with tantalum markers positioned to make a system of coordinates as a reference to the patient markers (cage 10; RSA Biomedical, Umeå, Sweden) (figure 3). Radiographs were uploaded to a software program that aided in the analysis of micromotion of the tantalum markers relative to one another (UmRSA Digital Measure version 6.0, RSA Biomedical). The rigid body movements between examinations were used to calculate translations and rotations around the x-, y- and z axis. The Maximum Total Point Motion (MPTM) represents the magnitude of motion and is the 3-D measure of the marker that moved the most. With repeated Examinations, a 3-D motion of each marker can be calculated. Migration-patterns can be used in the risk-assessment of early aseptic loosening for knee prosthesis components. The technique was first described by Selvik et al in a Swedish research group in 1974 (54). It has been shown that increased early implant migration can correspond to the risk of aseptic loosening at midterm (55). Linear motion as small as approximately 0.2 mm and rotations from 0.2°-1.2° can be detected by this method. The benefit of being able to evaluate small changes in migration is that few patients are needed to achieve high statistical power. Valstar et al published in 2005 guidelines for standardization of RSA studies (56) and these guidelines were updated through systematic reviews in 2012(57) and 2023 from the same research group (58). Downsides of conventional RSA are increased cost, difficult and labor-intensive X-ray procedure, operating time and its invasive nature.

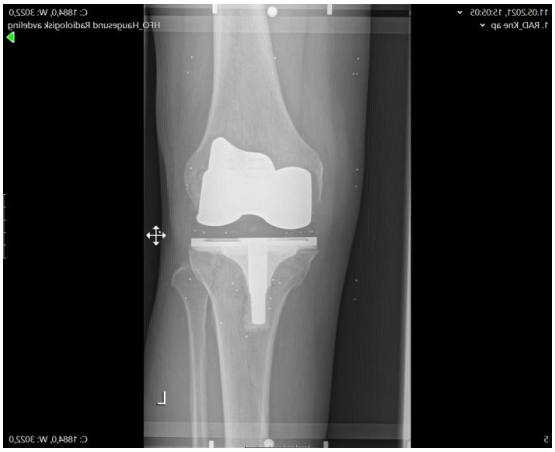


Figure 3. The knee inside a bi-plane RSA cage. One lateral- and one frontal radiograph is captured at the same time,

Figure 4. A frontal radiograph showing a knee with a total knee arthroplasty and tantalum markers implanted into the proximal tibia and polyethylene insert.

5. Responder-analysis and Patient Reported Outcomes (PROMs)

In the present study, we included a cemented bi-cruciate stabilized total knee prosthesis (Journey II BCS, Smith and Nephew), that was developed to mimic the kinematic movement of the native knee. The prosthesis was not well-documented according to what is advised from the Norwegian Arthroplasty Register (NAR) and had a ODEP rating of 3A(35). We found this implant to be optimal, with its advanced design for comparison of robotic assisted surgery to a conventional technique, asking if robotic has advantages over conventional technique for this theoretically less forgiving and more complex implant. Many often-used PROMs are riddled with the ceiling effect issue, which occurs when a high proportion of respondents (>15%) achieve the maximum score or near it. This means that the questionnaire is insufficiently sensitive to measure further improvement(59).

To avoid the ceiling-effect we used responder analysis(36,60) as the primary outcome. The individual patient longitudinal differences can be assessed with minimal clinical important change (MCID) and then the proportions that meet MCID criteria can be compared between the groups. The Western Ontario and McMaster Universities Outcome Index (WOMAC) and Knee Injury and Osteoarthritis Outcome Score (KOOS) were used to calculate responders. To get a wide scope we wanted a diversity of outcomes and included three physical tests. Two were evaluated and well documented for testing knee arthroplasty patients (walking test and chair test)(61,62). The last one is only validated for use in a rehabilitation setting for patients with osteoarthritis(63). In addition, we included radiographic measurements of the overall coronal alignment as well as the positions of the prosthesis components in the sagittal plane. Lastly, we included the most used PROMs, Knee Society Score (KSS), KOOS, EQ-5D, Visual Analogue Score (VAS) pain and the forgotten joint score (FJS), a PROM not prone to ceiling effect.

To investigate the results of the newest and re-designed Oxford UKA, we designed a register study (paper I) with no PROM scores. To compare the new robotic system (NAVIO) with conventional technique for the novel cemented

Bi-cruciate stabilized TKA (Journey II BCS) we designed a randomized controlled trial (RCT). The first 60 patients participated in a radiostereometric migration analysis (RSA) (paper II), and 209 patients were randomized to compare the groups for clinical results (paper III).

6. Radiological outcome

To assess the overall alignment and the position of the prosthesis components, long legged (Hip-Knee-Ankle (HKA)) radiographs were taken before and after surgery (figure 5). The arithmetic HKA angle was calculated using Medial Proximal Tibial Angle (MPTA)- Lateral Distal Femoral Angle (LDFA). This value represents the constitutional overall coronal alignment without taking the osteoarthritis and joint line collapse/ thinning) into account. It is not the same as the actual (osteoarthritic) overall alignment measured from the center of the hip through the middle of the knee and to the ankle. The constitutional angle plus the joint line conversion angle (JLCA) adds up to the overall actual alignment (HKA). To evaluate the position of the femoral component and the tibia in the sagittal view, we measured the femoral flexion and tibial slope as seen on figure 6a and 6b. The aims with these measurements were to assess if the position of the components were different when using robotically assisted surgery. The advantages of robotics are the unlimited adjustment opportunities for both the femoral and tibial components. The conventional instruments used in this study did not have that possibility. All patients in the conventional group were operated with an intramedullary (IM) rod for the tibia cut, with a fixed 3° slope, and the femoral component had a limited freedom of positioning in the sagittal plane depending on where the entry point of the IM rod into distal femur would be.

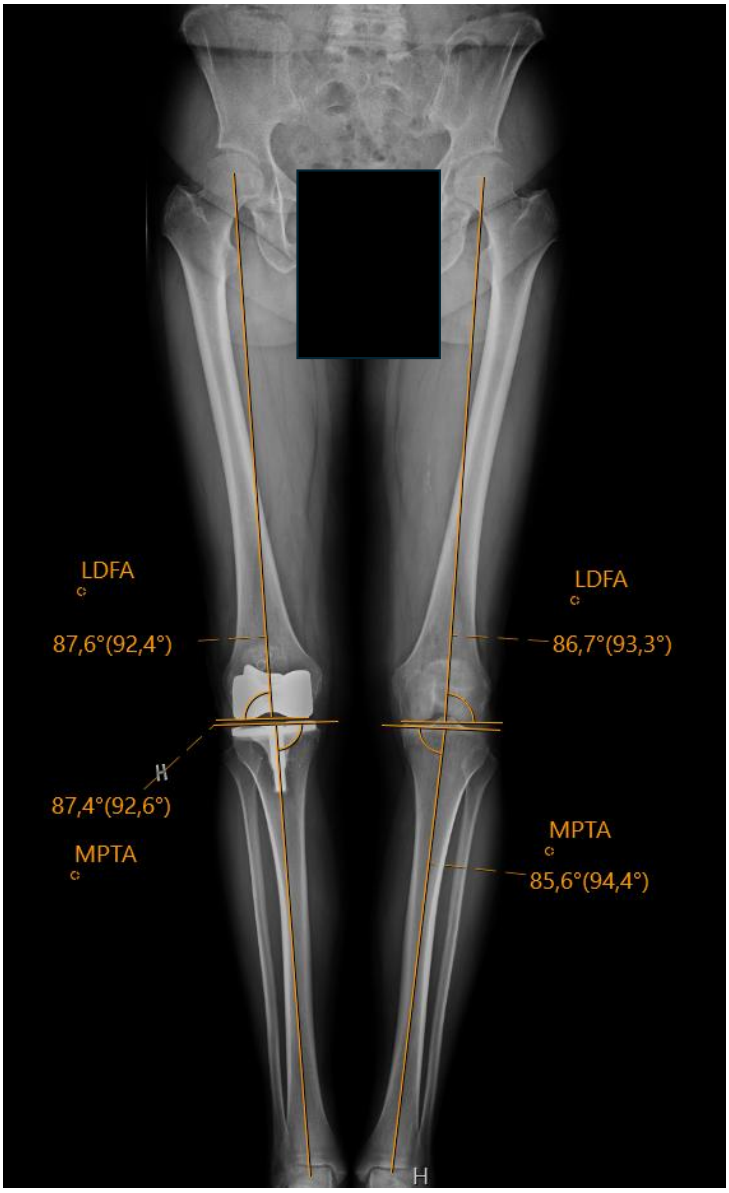


Figure 5. Hip-Knee- Ankle (HKA) radiographs with measurements for calculating constitutional arithmetic HKA and joint line obliquity angle.

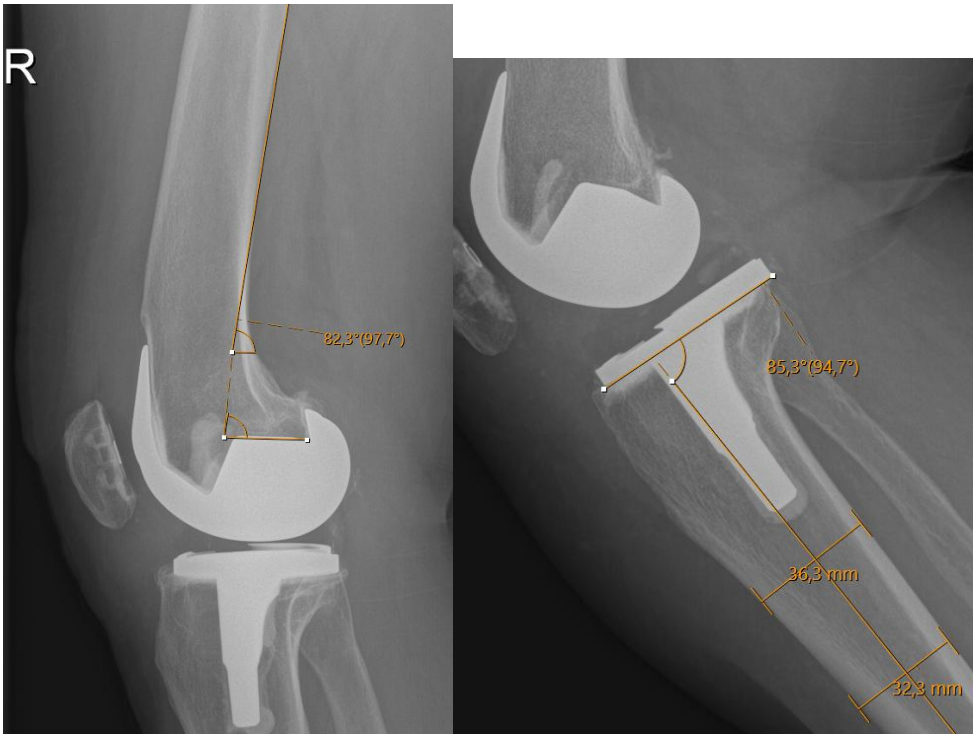


Figure 6a. Sagittal radiographic view with measurements of femoral component flexion. The horizontal line is drawn on top of the box which is 90° on the component longitudinal axis.

Figure 6b. Measurements of tibial component slope.

Aims of the studies

Study I: Using data from the Norwegian Arthroplasty Register (NAR), we asked: (1) Has the 5-year implant survival (free from revision for any cause) improved with the medial Oxford unicompartmental knee after the introduction of new designs? (2) Did the causes of revision change between the old and new designs? (3) Is there a difference in risk for specific revision causes between the uncemented and cemented versions of the new design?

Study II: Compare migration between robotically and conventional techniques in cemented bi-cruciate stabilized TKAs, using radiostereometric analysis (RSA) based on a secondary analysis of a randomized controlled trial (RCT).

Study III: Compare clinical results of a hand-held robotic-assisted functionally aligned technique (NAVIO, Smith and Nephew) to conventional technique, for a cemented bi-cruciate stabilized TKA, in a randomized controlled trial (RCT).

Method

1. Paper I

1.1 Prospective observational register study (Oxford UKA)

Oxford Uni-condylar knee replacements reported to the Norwegian Arthroplasty Register (NAR) from 2012-2021 were included in this prospective observational study. The NAR was first established for reporting hip replacements in 1987(64), and other types of joint prostheses including knee replacements followed in 1994(65). After surgery a form (electronic or on paper) is completed and sent to the register with information on gender, age, ASA-category, date of surgery, previous knee surgery, prosthesis brand/ type, antithrombotic medication, prophylactic antibiotic brand and doses, previous knee surgery, approach, surgical method, use of computer navigation or robotic surgery, fixation method (uncemented or cemented), intraoperative complications, status of the cruciate ligaments, and if the present surgery was a primary or secondary (revision) operation. Complete or partial removal of implant is defined as a revision, as is addition of a component. The unique identification number, joint and laterality of a Norwegian residents link primary surgery to any subsequent revisions.

NAR has a high completeness for reporting of both primary operations (95%) as well as revisions (93%)(37)

1.2 Inclusion (Oxford UKA)

After excluding patients with missing data, hybrid fixation, lateral Oxford UKAs and patients with a combination of the two generation Oxford implants, there were 908 medial cemented Oxford III, 4715 cemented Oxford Partial (twin-peg), and 1821 uncemented Oxford Partial UKAs eligible for inclusion. The cemented Oxford III was reported from 2012-2017, when it was replaced entirely by the cemented Oxford Partial (reported from 2012-2021) while the newest uncemented Oxford Partial was reported from its debut in 2014 until 2021. The data were censored at 5 years to avoid confounding due to different follow-up times. The median follow-up times were 5 years for cemented Oxford

Partial, 4 years for the cemented Oxford III and 3 years for the uncemented Oxford Partial.

1.3 Statistics (Oxford UKA)

To assess baseline characteristics of the three different study groups, descriptive analyses were used. Chi-square test was used to determine p-values for binary/ categorical variables, and a one-way ANOVA test was used to calculate continuous variables. Cox regression multivariate analyses were used to calculate Hazard Ratio (HR) adjusting for age, gender, ASA classification, diagnosis and time-period to compare risk of revision for all causes. We used adjusted Cox regression analyses to assess the risk for each specific revision cause. For the overall survival analysis, proportional hazards assumption was tested and found valid. Fine and Grey analysis was used for specific revision causes and checked against the Cox analysis. The Fine and Grey SHR estimates were reported if the values differed. The Kaplan-Meier method was used to measure cumulative survival, and intact implant with no part removed, added or exchanged defined a surviving prosthesis. For statistical differences, a log-rank test was used.

1.4 Ethics

Norwegian Arthroplasty Register has a concession from the Norwegian Data Inspectorate to collect and analyze data based on patient written consent. The registration of data was performed confidentially on patient consent and according to the Norwegian Data Protection Regulations (Ref. no. 03/00058-20/CGN

2. Paper II

2.1 Randomized controlled trial (RSA study)

This study is based on an analysis of RSA data from the first 60 of the 209 patients in the randomized controlled trial described in paper III. Patients were randomly assigned to robotic (NAVIO) or conventional surgery (allocation ratio 1:1). Two surgeons performed all the operations after 10 pre-study robotic cases done together. A cemented Journey II BCS total knee arthroplasty (Smith and Nephew, Memphis, TN, USA) was implanted in all patients (fig 7.), using Palacos R+G cement (Haraeus, Hanau, Germany). We chose adjusted mechanical alignment technique(17), with room to adjust the distal femur cut to preserve native deformity within a limit of -/+ 1°, for the conventional knees. A restricted functional alignment technique was used in the robotic group, where the overall coronal plane alignment was restricted to 2° valgus - 4° varus. All cases were patellar resurfaced, using the “onlay” method. The robotic system used in this study was the hand-held NAVIO robotic system (figure (Smith and Nephew, Memphis, TN, USA). The conventional operations were all performed with cutting guides on intramedullary rods for both tibia and femur. No drains were used, and a tourniquet was used for all cases.

In the robotic group a hand-held burr was used for the distal femoral cut, and a conventional cutting guide for the rest of the osteotomies. The burr was also used for making holes ventrally into tibia to support a cutting guide. The cut surfaces were verified and sometimes refined with the burr.

A 1-stage cementing technique was used after pulsed lavage and the tourniquet was deflated in all cases when the wound was closed. For skin closure we used running mattress sutures. The Knee was positioned in 90° of flexion for 2 hours postoperatively, and a compression dressing was applied to minimize bleeding. Patients were allowed full weightbearing after surgery but were advised to use crutches for 6 weeks to prevent falling.

All the patients in this study had tantalum markers inserted. Six markers were implanted into the polyethylene insert (0.8 and 1.0 mm in diameter) through small drill holes, and 9 into the proximal tibia. (1.0 mm in diameter). The index

RSA images were taken between 1 and 3 days after surgery and repeated after 3, 12 and 24 months. A double examination was performed 12 weeks after surgery, for the purpose of calculating precision values. The images were sent to BioMat lab, Orthopedic department, Haukeland University Hospital for analysis, and the evaluators were blinded to patient allocations. The RSA trial will end after reporting data at 5 years follow up.

2.2 Inclusion

Males and females from 45-85 years, with primary- or secondary osteoarthritis (OA) in the need of a total knee replacement, were eligible and invited into the study. Only patients in American Society of Anesthesiologists (ASA) category 1-3 were included.

Patients with ongoing infection, metastasizing disease, degenerative neurological disease, severe cardio-pulmonary disease, dementia, serious systemic disorders, ASA class 4 and previous fractures or deformity in the tibia or femur were excluded.

2.3 Statistics

To determine the number of patients necessary for inclusion, a power analysis from a previous similar study(66) was used, claiming 0.1 mm to be a relevant difference between groups, with an anticipated repeatability of 0.1 mm in the RSA measurements. A 2-sided, 2-sample t-test was used to calculate the group sizes necessary. To detect a difference of 0.1 mm with a standard deviation of 0.1 a group size of 17 would achieve 80% power with a significance level of 0.05. To ensure proper groups sizes up to 5 years it was decided that 60 patients (30 in each group) would be sufficient.

The difference between doble measurements was calculated at 12 months, to evaluate the measurement precision. (67). The standard deviation (SD) of the differences with respect to zero was also calculated. The Pearson and Saphiro-Wilk test showed that the migration data were not normally distributed, so both median and interquartile range (IQR) are reported in table 2. Migration

magnitude and progress were reported with mean values, and for the differences between groups, the median values were used. This is similarly reported in previous studies where the migration data were not normally distributed(66,68), and the group numbers were small. To compare robotic assisted surgery to the conventional group for migration we used Mann-Whitney test. For the differences in descriptive data like age, gender, diagnosis Pearson`s chi-square test was used.

2.4 Ethics

This study was approved by the regional committee for medical and health research ethics (REK) on March 4, 2020 (ref.no.68448 NAVIO HSR) in Bergen, Norway, and the trial was registered in the trial database at ClinicalTrials.gov (identifier: NCT04525950) on September 7, 2020.

3 Paper III

3.1 Randomized controlled trial (Clinical outcome)

This paper reports on the two-year clinical outcomes from a randomized controlled trial comparing robotically assisted surgery (NAVIO) to conventional instrumentation for a Bi-Cruciate stabilized total knee arthroplasty (Journey II BCS) (Figure 7). 209 patients were assigned randomly in a 1:1 ratio. Two experienced surgeons (ØS and ØG) from the same hospital (HSR) operated all the cases in the study, the first 60 together. Long-legged radiographs in addition to calibrated lateral views were taken preoperatively (for template planning) and after 1 year (for radiological evaluation) of all patients.

3.2 Inclusion; see paper II

3.3 Statistics

A sample size of 97 would achieve 80% power to detect a clinical important difference of 0.17 in the rate of “non-responders” and “high-responders” between the groups, with a standard deviation of 20 and a 0.05 significant level. 209 patients were included to ensure proper sample size.
To compare mean improvements of KOOS, FJS, WOMAC, KSS, EQ-5D, and mean radiograph angles we used an independent sample t-test with a 95% confidence interval (CI). All tests were two-sided and p-values above 0.05 were considered significant. IBM SPSS statistics program version 30.0 IBM Corp., Armok, NY, USA was used for the statistical analyses.

3.4 Ethics

See paper II

Figure 7. Journey II bi-cruciate stabilized (BCS) total knee arthroplasty from Smith and Nephew

Summary of papers

Paper 1

Background:

Despite of superior function and less risk of infection, uni-compartmental knee arthroplasty (UKA) has shown higher revision rates than total knee arthroplasty (TKA), especially the femoral component.

A twin-peg femoral component (Oxford Partial) has replaced the single-peg version (Oxford Phase III) of the widely used Oxford medial UKA, with the aim of improving femoral component fixation. The introduction of the Oxford Partial Knee also included a fully uncemented option. However, there has been relatively little evidence regarding the effect of these changes on implant survival and revision diagnoses from groups not associated with the implant design. Using data from the Norwegian Arthroplasty Register, we asked: (1) Has the 5-year implant survival (free from revision for any cause) improved with the medial Oxford uni-compartmental knee after the introduction of new designs? (2) Did the causes of revision change between the old and new designs? (3) Is there a difference in risk for specific revision causes between the uncemented and cemented versions of the new design?

Methods:

We performed a registry-based observational study, using data from the Norwegian Arthroplasty Registry, a nationwide, mandatory and governmental registry with a high reporting rate. Between 2012 and 2021, 7549 uni-compartmental knee arthroplasties were performed, and 105 were excluded due to combinations of the three designs, lateral compartment replacement, or hybrid fixation, leaving 908 cemented Oxford Phase III single-peg (used from 2012 to 2017), 4715 cemented Oxford Partial twin-peg (used from 2012 to 2021) and 1821 uncemented Oxford Partial twin-peg (used from 2014 to 2021) UKAs available for the analysis. The Kaplan-Meier method and Cox regression multivariate analysis were used to find the 5-year implant survival and the risk of revision (hazard ratio), when adjusting for age, gender, diagnosis, ASA

grade, and time-period. The risk of revision for any cause, and the risk of revision for specific causes were compared, first for the older with the two new designs, and second for the cemented with the uncemented version of the new design. Revision was defined as any operation exchanging or removing implant parts.

Results:

The 5-year Kaplan-Meier implant overall survival (free from revision for any cause) for the medial Oxford Partial uni-compartmental knee did not improve over the past decade. The 5-year Kaplan-Meier survival was different (p = 0.03) between the groups: it was 92% (95% confidence interval [CI] 90% to 94%) for the cemented Oxford III, 94% (95% CI 93% to 95%) for the cemented Oxford Partial, and 94% (95% CI 92% to 95%) for the uncemented Oxford Partial. However, the overall risk of revision during the first 5 years was not different between the groups (Cox regression HR 0.8 [95% CI 0.6 to 1.0]; p = 0.09 and 1.0 [95% CI 0.7 to 1.4]; p = 0.96, for the cemented Oxford Partial and the uncemented Oxford Partial, respectively, compared with cemented Oxford III [HR 1]). The uncemented Oxford Partial had a higher risk of revision for infection within the first year (HR 4.1 [95% CI 1.3 to 13.5]; p = 0.02) compared with the cemented Oxford III. The uncemented Oxford Partial had a lower risk of revision for pain (HR 0.5 [95% CI 0.2 to 1.0]; p = 0.045) and instability (HR 0.3 [95% CI 0.1 to 0.9]; p = 0.03) compared with the cemented Oxford III. The cemented Oxford Partial had a lower risk of revision for aseptic femoral loosening (HR 0.3 [95% CI 0.1 to 1.0]; p = 0.04) compared with the cemented Oxford III. When comparing the uncemented and cemented versions of the new design, the uncemented Oxford Partial had a higher risk of revision for periprosthetic fracture (HR 15 [95% CI 4 to 54]; p < 0.001) and infection within the first year (HR 2.1 [95% CI 1.2 to 3.9]; p = 0.02) than the cemented Oxford Partial.

Conclusion:

Considering that we found no difference in overall risk of revision during the first 5 years, but we found a higher risk of revision for infection, periprosthetic fracture, and higher per implant cost, we currently would recommend against the use of uncemented Oxford Partial over the cemented Oxford Partial or the cemented Oxford III.

Paper 2

Background

Robotically assisted computer navigation (robotic), has been developed to improve the positioning of total knee arthroplasties (TKAs), attempting to achieve better functional results and longevity of the prostheses. However, the benefit of robotics is still controversial. The aim of our study was to compare migration between robotic and conventional techniques in cemented bi-cruciate stabilized TKAs, using radiostereometric analysis (RSA) based on a secondary analysis of a randomized controlled trial (RCT).

Method

We enrolled 60 TKA patients from one hospital (2020-2021), with osteoarthritis and arthritic disease. The patients were examined up to 24 months after surgery, to estimate the mechanical stability of the tibial component. The maximum total point motion (MTPM) representing the magnitude of migration, the largest negative (subsidence) and positive (lift-off) value for y-translation, and prosthetic rotations were measured. The migration in the two groups was compared and the precision evaluated.

Results

51 RSA marked TKAs were available for a comparison of tibial migration between robotically assisted (n = 26) and conventional operations (n = 25). The Maximal Total Point Motion (MTPM) the first year was 0.44 mm and 0.64 mm, and at 24 months 0.46 mm and 0.75 mm, for the conventional and the robotic groups, respectively. The robotic group migrated more than the conventional group at 2 years, 0.21 mm (95% confidence interval [CI] 0.05–0.44; P = 0.01). The overall median MTPM for the investigated implants (both groups) up to 12 months was 0.54 mm (CI 0.44–0.63), and 0.19 mm between 12 and 24 months (CI 0.16–0.22). The magnitude of migration and rotation around the 3 axes was small for both groups, but flexion/extension migration of the tibial component was slightly higher in the robotic group 0.14° (CI 0.00–0.33; P = 0.049).

Conclusion

MTPM and flexion/extension migrations of the tibia component were higher for the robotic group, up to 24 months. The overall migration pattern for the bi-cruciate stabilized implant was acceptable.

Paper 3

Background

Robotic-assisted total knee arthroplasty (TKA) was developed to improve the accuracy of implant positioning and clinical function. The benefits of TKA are controversial. The aim of the present study was to compare clinical results of a hand-held robotic-assisted functionally aligned technique (NAVIO, Smith and Nephew) to a conventional technique, for a cemented bi-cruciate stabilized TKA, in a randomized controlled trial (RCT)

Method

We enrolled 209 TKA patients from one hospital (2020-2023) and compared the clinical and radiological results at 24 months. A responder analysis using OMERACT-OARSI (Outcome Measures in Rheumatology-Osteoarthritis Research Society International) criteria using WOMAC and KOOS scores was performed. In addition, Knee Society Score, Forgotten Joint Score, Visual Analogue Score pain, and EuroQol-5 Dimensions scores were evaluated. Objective measures were the walking test, chair test, climb-up test, and radiographical measurements.

Results

There were 191 patients available for comparison between conventional (n=97) and robotic (n=94). We found no difference between the techniques, with respect to proportion of high (73.2% and 73.4%), moderate (22.7% and 18.1%) and non- responders (4.1% and 8.5%) p=0.4 KOOS, KSS, FJS, EQ-5D, or objective measures. The femoral component was more flexed (4.40° (CI: 2,50) vs 2.95° (CI: 2,69)), and the tibial component was more posteriorly sloped (2.90° (CI: 2,36) vs 1,52° (CI: 1,67)) in the robotic group. The mean post-operative arithmetic Hip-Knee-Ankle (aHKA) alignment was similar.

Conclusion

The robotic-assisted functionally aligned technique did not contribute to better clinical outcome the first two years, compared to a conventional technique, for a bi-cruciate stabilized TKA.

Discussion

1. Method

1.1. Study designs

The NAVIO project paper II and III

-A randomized controlled trial

The development of new technology meant for aiding planning and more precise implant positioning is rapidly growing. There are strict regulations for the release of new prostheses into market, and equally important it is to assess the effect of new operating tools like computer assisted surgery (CAS) and robotically assisted surgery (robotic). The medical community should be concerned with the cost-effectiveness versus the improvement in results after surgery with these tools. To evaluate the effect and usefulness of robotic technology, the first challenge in the project was to select appropriate parameters and study designs. A randomized controlled trial was performed comparing robotically assisted surgery to conventional technique for a cemented bi-cruciate stabilized total knee arthroplasty. Paper II discusses the migration patterns of the tibial components operated with the two techniques to assess and compare the prospective longevity between the groups. Paper III compared clinical and radiological outcomes between the two operating techniques. In the project we included a novel total knee arthroplasty that was not considered well-documented with ODEP rating of 3A(35) at the initiation phase of the study. A RCT is a prospective study, considered the gold standard in comparing the results of two treatments/ interventions. The randomization act balances the participant characteristics and thus minimizing selection bias. In some instances, RCTs may not be applicable due to narrow patient eligibility criteria, but in the present study the inclusion criteria are made as broad as possible, and the exclusion criteria are relatively few.

Register studies

On the scope of assessing new implantation tools and prostheses changes, we designed a prospective observational study based on data from the Norwegian Arthroplasty Register (NAR) to evaluate the effect of a femoral component design development on the risk of early revision for the Oxford UKA.

Register studies are well suited for assessing weakness of implantation tools and implant designs. A register study is based on data from a wide variety of surgeons and orthopedic departments, with different experience, skills and traditions, and the results thus have good external validity for the “average” surgeon. Even though one of the groups in paper I consisted of “only” 908 patients, the numbers are higher than in any RCT reported in the field, making the statistical power high. This entails an opportunity to detect small differences, and to do sub-analyses, as we did in paper I. Implant survivorship is an important measure, but it doesn’t give information on patient function and satisfaction with the implant, so one of the weaknesses or limitations of our register study is that the endpoint is only risk of revision. A component that has not been revised does not automatically equal to good function and a satisfied patient. In paper 1, the prospective design from register data is relevant, since the changes are mostly done on the bone-implant interface of the femur (twin-peg vs mono-peg), for better fixation. A disadvantage with registry studies is that the populations from the groups compared are heterogenous adjustments for confounders are necessary. The register data include some factors but lack others. This can skew the results. Due to unmeasured confounding this weakness cannot be fully compensated. In the present study selection bias could have occurred due to incomplete follow-up of patients. Another selection problem could have happened due to selection of the cemented instead of uncemented Oxford partial in cases of extra small tibias as well as in the older patients for the few departments that have both options. An information bias can occur in register studies if there is misclassification of exposure (type of Oxford implant) or outcome (revision)(69). If misclassification of exposure is

dependent on misclassification of outcome the results may be influenced by information bias. This is not likely to have happened in the present study, since the chances are low for mis-registration of a prosthesis that does not have any options for different bearings or prosthesis components, except the sizes. The prostheses also get registered from product numbers on stickers attached with the implants and are therefore identified correctly. Register studies in Norway do not necessary give the same result or represent the same as studies from different countries due to differences in surgical traditions, demographics, indication for surgery, economic funding and the health care system. These are factors that potentially influence revision causes and implant-survival. So, a register study from Norway will give added value as opposed to studies coming from other countries registry data.

Blinding

Physiotherapists, patients, and statisticians were fully blinded to the group assignment in study II and III. The holes for the reflector-disc pin assembly in femur and tibia were all visible on the first postoperative radiographs. This could have made the radiological evaluators and the surgeons aware of method. The radiographs were all measured by the first author and to assess the accuracy of the measurements a selection of 40 images (20 HKA and 20 sagittal projections) were measured again by the main author (intra-rater reliability) as well as by a resident (inter-rater reliability). The fact that all the pin assemblies were within the primary incisions and not through stab-incisions strengthened the blinding. During the operations the robotic systems were inside the operating rooms but not switched on during all the cases. Patients were behind a curtain out of sight of the robotic system, sedated and with little chances of detecting the method used. We believe the blinding procedure was adequate, although the most scientific optimal blinding procedures would have involved the surgeon, which was of course impossible in this situation. Future studies might consider blinding the radiological evaluator by covering up the pin holes and the area which would have contained pin holes on the radiographs. Evaluating radiographs taken after 6 months or later might also be better, since signs after the pin holes are not visible on most of these radiographs.

1.2. Limitations and strengths of the prospective observational register study

The most important limitation to Study 1 is that the patients in the uncemented Oxford partial group were only followed for a median of 3 years, whereas the median follow-up time for the cemented Oxford III was 8 years. Under 200 patients were followed for the full 5 years in the uncemented group, whereas all except one patient were followed for 5 years in the Oxford III group, and thus they had more time to fail. Aseptic loosening, which is expected to increase as time passes, might have been more often reported in the latter group. Revision causes like infection and fracture are more likely to occur early in the follow-up period and would be less affected by the difference in the follow-up between the groups. We adjusted for time periods as well as censored data at 5 years, to reduce the confounding and have more similar follow-up times.

Type I error could have weakened the results of this paper, due to multiple testing for the different revision causes.

Another limitation to this register study from a population of both female and male cases, despite adjusting for gender, is that the results do not necessarily apply equally to men and women.

An advantage of the register study is the ability to detect rare events and evaluate differences in the risk of these rare events. In paper I, we found a difference in the risk of revision for rare events like fracture and infection, and surgeons are advised to take these risks into consideration, when choosing implant and fixation method. The average surgeon volume for Oxford UKA in Norway is relative low(46), so the ability to detect these events in a surgical practice is therefore limited well- designed studies of register data can give the average surgeon useful information. A randomized trial to study such rare events would be highly unpractical and costly to perform due to the large number of cases that would be needed.

For patients doing poorly, but do not wish to undergo revision surgery or are unsuited for another operation, PROM results can add valuable information on patient satisfaction and function. There is a certain level of “under-reporting” of “bad” or malfunctioning arthroplasties. This does not disqualify the results in paper I, because it is no reason to believe that this affects one group more than the other. PROM data were not available yet in the Norwegian Arthroplasty Register for these implants in this period but is available for future studies of later time-periods.

A limitation to this specific study is that the newest uncemented Oxford partial was added later in the inclusion period than the cemented implants, and with a new fixation technique, it could potentially have added a learning curve, the results from the two other implants did not suffer from. The learning curve could have spanned over some time, especially taken the relative low surgeon volume of UKAs in Norway into account. This is true for the impaction technique, that is proven to be sensitive to early periprosthetic fractures for the uncemented implant(70-72) as we found in our study. Longer follow-up as well as studies of later periods of the uncemented group will give us valuable information on this issue.

In registers, surgeons have the option to report more than one reason for revision, without ranking them in relation to which one is the most plausible root cause. This would be similar between the groups but adds more granularity to the results.

A register`s role on reporting implants is well understood, but it also has a role in assessing operating tools. In Paper I, the change from one set of implantation instrument to another happened in the inclusion period and could than have influenced the three groups differently, since the newest Oxford “Microplasty” instruments were mostly used in the cemented and uncemented Oxford partial UKA cases, but also for some cases of the cemented Oxford III. The type of instruments used is not reported to the registry, but information on which hospitals and time periods they were introduced can be obtained from

the industry. “Microplasty” have certain advantages over previous instruments, like less bone loss and more accurate placements of the components.

1.3 Limitations and strength of the RCT – Clinical results

Responder-analysis

In general, most studies comparing operating techniques or different prostheses designs measure baseline scores and scores after surgery at different time points and compare the mean scores. There are several patient reported outcome measure (PROM) forms, and most of them assess pain and function. One weakness of this type of reporting is that the patients do not get evaluated in a linear fashion where the variation of each individual case counts. Many of these PROMs are also riddled with the ceiling effect issue(59). Results are often so high on the scale (often represented as a value between 0-100), that a Minimum Clinical Important Difference (MCID) of at least 10 points, as is the reported MCID for subscales of the KOOS score, is impossible to reach, when comparing mean result after 2 years post-surgery. Another problem is that the results of mean PROM data are expressed as continuous data, which may not be useful for the surgeon, as it could be challenging to interpret changes in the follow-up period. Surgeons should know if the patients either respond (responders) or do not respond (non-responders) to a treatment/ operation. The MCID is not meant for the difference between means, but rather for one individual case` change or improvement. OMERACT-OARSI (Outcome Measures in Rheumatology-Osteoarthritis Research Society International) set of responder criteria(73) is a approach to measure patients response to a treatment, based on a combination of absolute and relative changes of pain, function and global assessment of the patients. In paper III we used the WOMAC score to calculate responders based on if they had an improvement in pain or function of ≥50% and an absolute change of ≥20. If the patients did not reach these criteria, they could still be responders or moderate responders if 2 of the 3

following criteria were met: 1. Pain ≥20% and absolute change of ≥10; 2. Function ≥20% and absolute change of ≥10. 3. KOOS QoL Pain ≥20% and absolute change of ≥10.

The responder analysis(36,60) evaluates the patients longitudinally. In this outcome, the ceiling effect is avoided in addition to the fact that the result of every patient is counted separately. The downside to this analysis, which is based on both absolute and relative changes from pre- to postoperative PROM scores, is in some (rare) instance, it is very hard or impossible to be a responder. This is if the preoperative PROM score was relatively high. One patient in this RCT did not qualify as a responder despite having the highest possible postoperative PROM scores. The reason for this was that he had a high preoperative score. The WOMAC pain-score evaluates the pain while walking but does not rate walking distance. The same is true for pain while weightbearing. WOMAC does not state the magnitude of the weight or what distance it has been carried. This same can be said about the WOMAC function score, which does not take the magnitude of activities into account. This can lead to a high preoperative score, even though the patient struggles to walk any distance. The non-responding patient had bone-on-bone osteoarthritis on preoperative radiographs and had pain while walking some distance or going up and down stairs. With a perfect postoperative score, the patient reported to be very satisfied with the operation.

The EQ-5D PROM used for paper III is a very simple but reliable short questionnaire with only 5 questions. This test also suffers from ceiling effect where patients report maximum score with substantial residual issues, but lower than the previous EQ-5D 3L(74).

The Knee Society Score (KSS) is very reliable, responsive and sensitive to clinical changes(75), but relies on the surgeon or physical therapists assessment, and have outdated alignment criteria(76).

The forgotten joint score (FJS) is reliable for tracking outcome in the long-term since it is sensitive at picking up nuances in patient satisfaction. It has less ceiling-effect than many other PROMs and can better distinguish between

good and excellent outcomes(77). The tests limitations include loss of score if 3 or more missing answers, and some patients find it difficult to understand the questions.

The KOOS score is robust and sensitive to changes in symptoms and pain as well as daily activities, making it an efficient satisfaction measuring tool, but it has ceiling-effect and high burden on the respondent due to the amount of questions(78).

The WOMAC score is widely used for assessing pain and function in total knee arthroplasty (TKA) and is sensitive to clinical changes but is also riddled with the ceiling-effect issue as well as poor sensitivity to knee stiffness. The score measures difficulty of different tasks, but not the volume or frequency of an activity (walking etc.)(79).

A limitation that could influence the results in paper III, is that the operating surgeons (ØG and ØS) had only operated 10 cases before including patients to the RCT. An initial learning-curve of 50 cases was defined in a previous study assessing the NAVIO system(80). Most papers reporting on learning curve reported on the difference in operating time and did not find changes in PROM results or radiological outcomes(81). In the present RCT, the first 30 robotic patients (paper II) had an average operating time of 103 minutes versus 90 minutes for the last 64 included robotically operated patients in paper III.

Another limitation to this study is that the exclusion or inclusion criteria lack information on limb alignment. Patients with relatively large varus preoperative deformities, defined on the long-legged radiographs (HKA) were included in the study, and might have added granularity, even though the mean preoperative HKA angles were similar between the groups. Studies show better results for knees with large deformities that are navigated or robotically assisted(82,83).

Physical tests

When designing a RCT to compare the results between two operating techniques or toolsets of implantation, in addition to different alignment philosophies, we wanted the comparison to be as broadly scoped as possible, after our primary endpoint was defined. The walking test is a validated test for functional recovery after total knee arthroplasty surgery and a good measure of function(61). We chose to report on the walking speed (m/s), which is easy to grasp and understand. For more diversity and to test different aspects of ADL functions the chair-stand test was added. This tests the ability to get up and sit back on a chair repeatedly and gives information on the knee function in this very important daily activity(84). The stability, strength and stamina of the knee are tested. Lastly, walking stairs is an important function, and is known as one of the most demanding tasks in daily activities(85,86). Osteoarthritis (OA) leads to malalignment and changed kinematic pattern in the knee motion, instability, pain and reduced strength due to sarcopenia. Stair-climbing, or descending a flight of stairs is often the first debilitating complaint of patients with OA(87). To emulate this motion, we used a test validated for evaluating patients with OA and to measure rehabilitation improvements. The test has not yet, as far as the author knows been used to evaluate the effect of arthroplasty knee surgery(63). The climb-up test set-up is a rack where the height of the step can be adjusted from 3 to 47 cm, and the patients step up without arm-support. Stability and strength of the knee, but also the entire locomotor system is tested. In regular stair climbing, the height of the step is constant, and the step is repeated several times, as opposed to the stair-climbing test where we test how high the patients can reach. The limitation is the variable patient heights and other conditions that can lead to dizziness or general walking instability and compromise the test results. Osteoarthritis in the ipsilateral knee or hips will, like the other physical tests, influence the results. Another limitation to the test is the fact that 47 cm was the maximum height available on the rack, but some patients could have climbed higher. An aspect not covered with these three tests is the fact that OA

patients, and patients with suboptimal results after knee arthroplasty surgery, have difficulties descending stairs. This is often the first sign of compromised function(88-90). Ascending and descending stairs on time is done in previous studies(90), but no test is available, for testing the height of which patients can safely descend from. Developing good tests for evaluating function for OA- and TKA patients is important and should be encouraged.

1.4 **Limitations and strength of the RCT – RSA results**

A limitation to an RCT with low number of cases is the ability to evaluate subgroups, like age, implant sizes or even alignment differences for the two different groups. In paper II we evaluated only the tibial component for migration; migration of the femoral or patellar component was not measured. The tibial component is more susceptible to midterm aseptic loosening and was therefore the chosen component to study.

The conventional and robotic groups were slightly different in the fact that the robotic patients had two drill holes in both the femur and tibia, in addition to a different cutting guide in the robotic group that made some of the tibial osteotomies slightly more distal than in the conventional group.

The alignment techniques were different. The robotic system has more options through a restricted functional alignment technique to adjust both the tibial and femoral components. The conventional mechanical alignment restricted the distal femoral cut to the 5-7° valgus range and the tibial cut was in all cases aimed at 90 degrees on the mechanical (and anatomical) axis. The groups are thus heterogeneous. This is a limitation when only comparing two operating tools. If the alignment philosophies in the two groups were identical and the femoral and tibial osteotomies had the same boundaries with regards to angulations relative to mechanical axis, the confounding would be less. On the other hand, a functional alignment strategy respect native alignment anatomy and soft-tissue balance, and minor deviations from neutral mechanical alignment have shown not to impact long-term implant survivorship

significantly(91,92). Comparing two groups with RSA measurements for migration would then potentially add an extra insight into the risk-profile for both an alignment technique as well as the robotic tool used. Conventional technique is shown in several previous studies to give more outliers than computer navigation and robotic(18-23), so using an individualized alignment strategy like kinematic or functional alignment combined with a conventional technique could potentially lead to severely mal-aligned knees. Caution is therefore advised, and in this study the well-documented, gold standard of mechanical alignment was chosen for the conventional knees.

One of the patients in the robotic group had an HKA angle of 12 ° before surgery and was revised after 2 years. The migration was 1.5 mm up to 12 months, which is an unacceptable level. Hindsight, this patient should not have been included due to an indication for a more constraint implant with fixation in Zone 2 and 3 in the tibia.

Øhrn et al showed in a randomized controlled trial that computer tomography (CT)-based migration analysis showed sufficient precision for femoral implants in total knee arthroplasty (93,94). The same group showed that a CT-based analysis can be used with low effective radiation doses to evaluate the migration pattern of the tibial component, in a comparison of marker/ model-based RSA with CT RSA. Migration values up to 12 months were lower in the CT RSA group (95). CT-based RSA is less costly, time effective and is now an alternative to conventional RSA.

2. Results

2.1 Functional outcome, operating time and complications

Functional outcome

In paper III we found no differences for any of the outcome measures, including the responder analysis of WOMAC, other PROMs and the physical tests. Like in many studies(96), robotic technology was associated with longer operating time, conventional technique is more cost effective, and there were no differences between robotic and conventional technique in clinical outcome measures. The functional outcomes were many and we attempted to avoid ceiling effect with the responder analysis, and the forgotten joint score (FJS). With addition of the physical tests, the ability to find clinically important differences between the groups should be high. All patients in this study were primary TKA cases, and very few had significant deformities. In this setting the need for robotized operating tools may be unnecessary, according to our results.

The mean range of motion (ROM) at one year was similar between the groups (125° in conventional and 126° in robotic group), despite of slightly more flexed femoral component in the robotic group (4.4° vs 3.0°). Across studies evaluated in a recent systematic review, a slight flexion of the femoral components was associated with better clinical results as well as improved ROM(97). In the present study both groups had a rather minor flexion in the component, and the difference between groups, even statistically significant, was small. The tibial components had higher tibial slope in the conventional group (3.0° vs 1.5°) This was most likely due to flexion space being adjusted with tibial slope in the robotic group whereas the conventional instruments set had a set slope of 3°.

Operating time

In the present RCT the mean operating time was 83 minutes for the conventional and 94 minutes for the robotic patients. The 11-minutes overall difference decreased after the average operating time of the first 60 patients (15 minutes difference; conventional 88 minutes and robotic 103 minutes). This presents a limitation where surgeons are still in the learning curve for robotic procedures and the implant during the study. On the other hand, the operating time on the conventional cases also reduced after the first 60 patients, most likely due to an increasing surgeon and hospital volume in that period.

Complications

There were two patients in each group that suffered from a superficial wound complication the first period after surgery due to a hard suture type used for subcutaneous closure. The suture-ends kept the skin from closing, leading to wound revision with removal of suture debris. None of these cases developed a deep periprosthetic infection.

There were no major complications in the groups, and only one patient in the robotic group was revised to a more constrained type of revision prosthesis, due to aseptic loosening of the tibial component. There are reported complications to robotically assisted surgery such as pin-hole infections and pin-hole associated fractures(28). There were no fractures in the present study in which the pins were drilled into bone relatively close to the joint. At that location the bone can handle torsional and bending stresses better than the diaphysis(29,98), making fractures less likely(99). Using smaller pins (3.0 mm) as advised in previous studies, was another preventing measure to avoid pin-site fractures(100). Pin-site infections are very rare when pins are inserted in the primary wound(99), as opposed to through stab incisions into tibia with less soft tissue between skin and bone.

2.2 Implant survivorship and revision causes

Based on data from the NAR we performed a prospective observational register study aiming to find out how new design elements of the Oxford UKA femoral component would perform with regards to survivorship, overall risk of revision and specific risks of revision. Revision for implant loosening is a well-known problem and involves both components. Previous studies showed that 25-50% of aseptic loosening involves the femoral component of the UKA. In TKAs the femoral component is less likely to loosen. The new twin-peg cemented Oxford partial did not have better survivorship nor better results for overall risk of revision for all causes compared to the mono-peg cemented Oxford III in the present study, but the risk of revision for the femoral component was reduced with the new design. Other studies showed an advantage for the twin-peg prosthesis(101-103). The uncemented Oxford partial, with the same design elements as the cemented version, except the hydroxyapatite-coated titanium mesh on the backside surface, did differ from the two other UKAs in the risk of revision for infection and peri-prosthetic fracturs up to one year. Even though the uncemented version had a higher risk of infections the first year, it is still lower than the risk for many total knee arthroplasties(104), and the uncemented performed best from 1-5 years for overall risk of revision. In paper I, we present the 5-year results for the three prostheses and based on this it is advised to use the cemented version of the twin-peg Oxford partial over the uncemented version. It is shown in previous studies that the risk of periprosthetic fracture is significantly higher in patients with small size tibias(72), making use of the cemented version a safe choice. The uncemented version is also more expensive. On the other hand, this is not reason enough to discard the uncemented version, that can be a good choice if used in high volume hospitals with a good impaction technique(70), with a cemented version for selected patients with small tibias and the osteoporotic elderly demographic. Data from 10-year follow-up is available from the NAR soon and will give us valuable information on the midterm results of the three UKAs, but mostly on the comparison of the cemented and uncemented Oxford

partial. Microplasty instrumentation was introduced in 2011 but used parallel with the older instrumentation for all three UKAs and will be less of a confounding factor when assessing the 10-year results, since Microplasty has been used for all Oxford UKA, the last 5 years.

Journey II BCS from paper II and III, has evolved from Journey I BCS, which had weaknesses in that the polyethylene insert post was too short and thick in the sagittal plane, leading the femoral component to luxate over the post, and lateral knee pain due to exaggerated rollback. The design was changed to overcome these flaws. The Journey prosthesis has a very different design philosophy and multiple new design elements compared to its predecessor, Legion or Genesis from Smith and Nephew, and it is therefore important to assess it for future introduction into market. The RSA study in paper II suggests that the risk of midterm aseptic loosening is probably not a concern with this implant. The result from paper III shows that it also performs well clinically.

It is equally important to assess prostheses that are not totally redesigned or designed from scratch but rather evolved through minor changes. This is what paper I evaluate through a register study. One study showed that a minor change to an implant can cause a large clinical difference(105). The results from Paper I show that a minor change can lead to better result for the femoral component, and that the fixation method (cemented vs uncemented) is equally important to assess.

2.3 Migration differences between robotic and conventional

In paper II we did a secondary analysis of the migration patterns of 60 patients from the RCT reported in Paper III. The 51 patients that were analyzed showed an overall acceptable migration pattern for Journey II BCS TKA. The tibial component migrated the most three first months for both the robotic and conventional groups whereafter it was minimal. The robotic group had a statistically significantly larger Maximum Total Point Motion (MTPM) migration up to 12 and 24 months, compared to the conventionally operated tibial components. Even the robotic group had acceptable migration values despite the differences reported, so the finding is not likely clinically significant. On the other hand, the findings are valuable when adapting to new systems, like robotically assisted surgery, where small adjustments to the technique can influence the result. With robotic technique the tibia was cut a bit lower meaning that the cut surface likely had less sclerotic bone than with the conventional technique. We argue that this can be the reason for more migration of the tibial component in the robotic group. The overall alignment was similar in the two groups, and the osteotomies were 90° on the tibial mechanical axis for most cases, not likely affecting the outcome. Paper II reports on the results up to 24 months, but future publication will report on the 5-year results from this study. This will give valuable information on the strict continuous migration patterns(55). The patients with alarming migration patterns can be followed individually with radiographs to see if they have developed radiolucent lines and if there are clinical signs of early aseptic loosening.

2.4 Alignment, intra-/ interobserver correlation

Coronal alignment

Both the mean preoperative arithmetic Hip Knee Ankle (aHKA) angles (1.2° varus) and the postoperative mean aHKA angles (1.5° varus) were similar between the groups. The functional alignment technique used in the robotic group focuses on ligament balance. Varus malalignment is the most common deformity in osteoarthritic knees, and accordingly adjusting the femoral component into more varus was the most frequent deviation from in the robotic group. It was rarely necessary to adjust the tibial component from its 90° cut on the mechanical axis, but some tibias were slightly less sloped to balance the flexion gap in the robotic group. Mild varus position in an aHKA varus knee is probably kinematically advantageous(106). In the conventional group, the principles of adjusted mechanical alignment were used (aMA), where the cuts were predominantly executed according to bony anatomical landmarks, and adjusted with soft tissue balancing is needed. The difference from strict mechanical alignment is the choice of 5-7 degrees valgus on the distal femoral cut, adjusting the femoral component more in varus for varus knees and perhaps less for a valgus knee. This could explain the similar results between the groups for the mean overall alignment. The tibial cuts were comparable in the groups, rarely altered from 90° on mechanical axis, even in the robotic cases. This can be done quite precisely for the conventional knees with an intramedullary (IM) rod in most instances, but with an S-shaped tibia it is advised to use an external guide for the cutting block to achieve a precise tibia cut.

Intra- and interobserver correlation for radiological measures

In paper III, twenty sets of radiographs were measured twice by the first author, and once by an orthopedic resident. The inter- and intra-observer correlation coefficient was calculated for the overall coronal alignment, and flexion of the femoral component and posterior slope of the tibial component on the lateral view. The intra-rater reliability coefficients were considered “excellent agreement” for the Medial Proximal Tibial Angle (MPTA), Lateral Distal Femoral Angle (LDFA) (preop and postop) and tibial component slope. For the femoral component flexion, the intraclass coefficient was considered within “good agreement”. The inter-class reliability scores were within “ almost perfect agreement” for all measurements, except femoral component flexion and tibial component slope, which came under “substantial agreement”(107). The differences between the coronal and sagittal view measurement accuracy are variations of how much of the femoral- and tibial length that is captured on the lateral radiographs. The longer view of the tibia or femur would probably yield higher accuracy than an image containing only small parts of the bones. The accuracy of the coronal measurements was excellent, probably because all images contained the necessary points needed for the measurements (Hip, Knee and Ankle).

Conclusions

1. The redesigned Oxford uni-compartmental knee did not show improvements over the older version for the overall revision risks up to 5 years after primary surgery. The new cemented Oxford Partial displayed a reduced risk of revision for femoral aseptic loosening compared to the older cemented Oxford III, and a lower risk of revision for periprosthetic fracture and infection than the uncemented Oxford Partial. Thus, the cemented Oxford Partial seems to be a good replacement for the older cemented Oxford III and should be preferred over the uncemented version.

2. We found more migration for the cemented bi-cruciate stabilized total knee prosthesis when operated with robotic assisted computer navigation compared to conventional technique but from 1 to 2 years, the migration patterns did not differ between the two techniques. We consider the overall migration, as well as the migration patterns for each technique to be within safe limits.

3. We did not find any advantage of robotically assisted surgery for the cemented bi-cruciate stabilized total knee arthroplasty over the conventional technique up to two years, based on the results from a responder analysis, comparison of physical tests and PROMs.

In summary: As surgeons we should evaluate all aspects of surgeries we are involved with in the pursuit of long-lasting good results for our patients. In this thesis we evaluated and compared the newest form of operating tool (Robotically assisted surgery) for total knee arthroplasty to conventional instrumentation, which we found to still be the gold standard. In this RCT we included the novel, and not previously well documented Journey II BCS TKA,

which has design elements that make it more advanced and complex. This implant was evaluated and proven with migration studies and acceptable clinical results from paper III. The prosthesis can be used safely with robotic assistance and conventional instrumentation. Furthermore, it is equally important to evaluate implants that evolve, as opposed to brand new prostheses with respect to implant-longevity, but also since even small changes can give clinical consequences. The twin-peg Oxford Partial femoral component showed acceptable results with respect to survival. The fixation method was also evaluated with the uncemented version which showed more early infections and periprosthetic fractures. These results could be taken into consideration when choosing implant.

Implications and future research

The development of new implants and specifically operating tools is going very rapidly due to new advances almost monthly. In this thesis we confirmed that using robotic assisted surgery is on par with conventional surgery but failed to show any advantages. The same has been found by others(22,108-110). With the system that we used the reflector disc assembly-pins were of a proper size (under 4 mm) and drilled into bone in an area, less prone to fracture. This probably contributed to the fact that we had no pin-hole complications. Such complications have been rather frequent in some studies.(111,112). However, robotic systems are more expensive, and operating time is usually longer compared to conventional technique(113-115). One evaluation from American College of Surgeons National Quality Improvement Program (NSQIP) based on machine learning algorithms point out that the variation in surgery duration is more attributable to the surgical team proficiency(116). Most patients with primary osteoarthritis (OA) have a mild varus deformity with joint deterioration mainly in the medial compartment. Approximately 1/3 of a population with non-osteoarthritic knees are in varus constitutionally according to the result of the study supporting the CPAK classification(26). In paper III 37,5% had varus (>2°) constitutional coronal overall alignment (arithmetic HKA angle). Only 7 patients were above 6° varus and 41% had a neutral mechanical alignment (from <2° valgus to <2° varus) preoperatively. One patient had a preoperative varus aHKA angle of 12° and had to be revised within 2 years after surgery with a more constrained prosthesis, due to aseptic loosening. The post operative coronal alignment was 3° varus after the primary surgery, as intended. This case should have been operated primarily with a more constrained and stemmed prosthesis. The patient-population in this study presented mostly with technically relatively unchallenging deformities that can be safely operated with conventional instrumentation for the novel cemented bi-cruciate stabilized total knee arthroplasty. Robotic technology may be more useful for advanced cases with large varus- or valgus- as well as extraarticular deformities, as the technology is very precise and gives less outliers from

aimed target(19-21). In cases of previous fractures or previous surgery altering the integrity of femur or tibia making use of an intramedullary rod in femur less accurate or impossible, robotic assisted surgery has an advantage. Patient specific instruments based on 3-D reconstructions from preoperative images like computer tomography or magnetic resonance imaging can also be used for these cases, but proves less accurate than robotic assisted surgery(117) and is associated with more complications(118). The challenges with designing good randomized controlled studies with a patient population with a wide variety of deformities are the heterogenicity and the fact that very few departments can include enough cases to get statistical power. So, only well-designed multi-center randomized controlled trials, and prospective observational studies on register data, can give valuable information on the effect of robotic assisted surgery compared to conventional surgery for more advanced cases. Reporting preoperative coronal alignment information to the registers could be useful. Varus, valgus or neutral overall alignment as well as the degree of malalignment, could then be linked to implant survivorship. Revision knee surgery is another field in which the technological advances of robotic are promising due to the need of precision and accuracy in assessing the joint line position, bone loss and optimal alignment(119). The valgus or varus laxity is notably higher in revision patients than the general TKA patients(120), making accurate alignment tools useful. Optimal alignment is only achievable when using short, cemented stems, which have the advantages of being adjustable. Long uncemented stems don’t have this due to their fixed position in the intramedullary canals. The malalignment seen in some revision cases could potentially have been avoided with the combination of robotic and shorter stems. Robotic also have the potential to create machine learned algorithms based on the information gained both during and after surgery with respect to clinical and radiological results, to make the planning phase more standardized and result-based(121-126). This could potentially decrease the operating time, perioperative costs and optimize the quality in both simple primary and more advanced cases(127,128). Future

studies with long term follow-up and a variety of outcome measures will give insight into potential advantages of robotic surgery in revision cases. It is a challenge that the groups are potentially even more heterogeneous than primary cases, and the volume low.

Assessing new implants with totally new design elements, and prostheses more subtly evolved through small changes, is an important task of well-established national registries. Future studies should focus on both PROM-results as well as survival analyses, and link these for a better understanding of how risk of early or mid-term revisions are linked to preoperative as well as 1 year PROM-results. PROMs have been added to the NAR and can be used in the analysis of 10-year results for Oxford UKA. PROMs in registries also enable international comparisons of patient-centered outcomes after knee arthroplasty surgery, since scores may vary between registry populations, and can thus give valuable insight(129)

1. Bourne RB, Chesworth BM, Davis AM, Mahomed NN, Charron KD. Patient satisfaction after total knee arthroplasty: who is satisfied and who is not? Clin Orthop Relat Res 2010; 468: 57-63.

2. Neuprez A, Delcour JP, Fatemi F, Gillet P, Crielaard JM, Bruyere O, Reginster JY. Patients' Expectations Impact Their Satisfaction following Total Hip or Knee Arthroplasty. PLoS One 2016; 11: e0167911.

3. Maradit Kremers H, Larson DR, Crowson CS, Kremers WK, Washington RE, Steiner CA, et al. Prevalence of Total Hip and Knee Replacement in the United States. J Bone Joint Surg Am 2015; 97: 1386-1397.

4. Gunaratne R, Pratt DN, Banda J, Fick DP, Khan RJK, Robertson BW. Patient Dissatisfaction Following Total Knee Arthroplasty: A Systematic Review of the Literature. J Arthroplasty 2017; 32: 3854-3860.

5. Hamel MB, Toth M, Legedza A, Rosen MP. Joint replacement surgery in elderly patients with severe osteoarthritis of the hip or knee: decision making, postoperative recovery, and clinical outcomes. Arch Intern Med 2008; 168: 1430-1440.

6. Skou ST, Roos EM, Laursen MB. A Randomized, Controlled Trial of Total Knee Replacement. N Engl J Med 2016; 374: 692.

7. Annual Report, Norwegian Arthroplasty Register

https://www.helse-bergen.no/4a01cd/contentassets/227cba5a5f094ba1bc08d780f667b86d/rapport-2025.pdf. 2025.

8. Grunert P, Darabi K, Espinosa J, Filippi R. Computer-aided navigation in neurosurgery. Neurosurg Rev 2003; 26: 73-99; discussion 100-101.

9. Bagga V, Bhattacharyya D. Robotics in neurosurgery. Ann R Coll Surg Engl 2018; 100: 22-26.

10. La Palombara PF, Fadda M, Martelli S, Marcacci M. Minimally invasive 3D data registration in computer and robot assisted total knee arthroplasty. Med Biol Eng Comput 1997; 35: 600-610.

11. Martelli M, Marcacci M, Nofrini L, F LAP, Malvisi A, Iacono F, et al. Computer- and robot-assisted total knee replacement: analysis of a new surgical procedure. Ann Biomed Eng 2000; 28: 1146-1153.

12. Australian Orthopaedic Association National Joint Replacement Registry. Annual Report. AOA: Adelaide; 2025, https://aoanjrr.sahmri.com/documents/d/guest/aoa-full-report-2025. 2025.

13. Khan ST, Emara AK, Zhou G, Koroukian SM, Cleveland Clinic Adult Reconstruction R, Piuzzi NS, et al. Robotic-assisted total knee arthroplasty in the USA: Nationwide adoption trends towards 70 % by 2030. J Clin Orthop Trauma 2025; 68: 103069.

14. Aunan E, Rohrl SM. No detrimental effect of ligament balancing on functional outcome after total knee arthroplasty: a prospective cohort study on 129 mechanically aligned knees with 3 years' follow-up. Acta Orthop 2018; 89: 548-554.

15. Unitt L, Sambatakakis A, Johnstone D, Briggs TW, Balancer Study G. Short-term outcome in total knee replacement after soft-tissue release and balancing. J Bone Joint Surg Br 2008; 90: 159-165.

16. Van de Graaf VA, Chen DB, Allom RJ, Wood JA, MacDessi SJ. Functional alignment in total knee arthroplasty best achieves balanced gaps and minimal bone resections: an analysis comparing mechanical, kinematic and functional alignment strategies. Knee Surg Sports Traumatol Arthrosc 2023; 31: 5118-5127.

17. Scientific Committee from the Personalized Arthroplasty S. Standardizing definitions of the total knee alignment techniques: recommendations by the Personalized Arthroplasty Society. EFORT Open Rev 2025; 10: 623-635.

18. Dyrhovden GS, Gothesen O, Lygre SH, Fenstad AM, Soras TE, Halvorsen S, et al. Is the use of computer navigation in total knee arthroplasty improving implant positioning and function? A comparative study of 198 knees operated at a Norwegian district hospital. BMC Musculoskelet Disord 2013; 14: 321.

19. Gothesen O, Espehaug B, Havelin LI, Petursson G, Hallan G, Strom E, et al. Functional outcome and alignment in computer-assisted and conventionally operated total knee replacements: a multicentre parallel-group randomised controlled trial. Bone Joint J 2014; 96-B: 609-618.

20. Shatrov J, Parker D. Computer and robotic - assisted total knee arthroplasty: a review of outcomes. J Exp Orthop 2020; 7: 70.

21. Shah SM. After 25 years of computer-navigated total knee arthroplasty, where do we stand today? Arthroplasty 2021; 3: 41.

22. Kort N, Stirling P, Pilot P, Muller JH. Robot-assisted knee arthroplasty improves component positioning and alignment, but results are inconclusive on whether it improves clinical scores or reduces complications and revisions: a systematic overview of meta-analyses. Knee Surg Sports Traumatol Arthrosc 2022; 30: 2639-2653.

23. Mert U, Khasawneh MY, Ghandour M, Al Zuabi A, Horst K, Hildebrand F, et al. Comparative Efficacy and Precision of Robot-Assisted vs. Conventional Total Knee Arthroplasty: A Systematic Review and Meta-Analysis of Randomized Controlled Trials. J Clin Med 2025; 14.

24. Hoveidaei AH, Esmaeili S, Ghaseminejad-Raeini A, Pirahesh K, Fallahi MS, Sandiford NA, Citak M. Robotic assisted Total Knee Arthroplasty (TKA) is not associated with increased patient satisfaction: a systematic review and meta-analysis. Int Orthop 2024; 48: 1771-1784.

25. Blakeney WG, Khan RJ, Palmer JL. Functional outcomes following total knee arthroplasty: a randomised trial comparing computer-assisted surgery with conventional techniques. Knee 2014; 21: 364-368.

26. MacDessi SJ, Griffiths-Jones W, Harris IA, Bellemans J, Chen DB. Coronal Plane Alignment of the Knee (CPAK) classification. Bone Joint J 2021; 103-B: 329-337.

27. Feroe AG, Chakraborty AK, Rosenthal DI, Simeone FJ. Fracture through tracking pin sites following a robotic-assisted total knee arthroplasty. Skeletal Radiol 2022; 51: 2217-2221.

28. Nogalo C, Meena A, Abermann E, Fink C. Complications and downsides of the robotic total knee arthroplasty: a systematic review. Knee Surg Sports Traumatol Arthrosc 2023; 31: 736-750.

29. Baek JH, Lee SC, Kim JH, Ahn HS, Nam CH. Distal Femoral Tracker Pin Placement Prevents Delayed Pin Tract-Induced Fracture in Robotic-Assisted Total Knee Arthroplasty: Results of Minimum 1-Year Follow-Up. J Knee Surg 2023; 36: 1102-1104.

30. Tay ML, Kawaguchi K, Bolam SM, Bayan A, Young SW. Robotic arm-assisted total knee arthroplasty is associated with improved surgical and postoperative outcomes compared with imageless computer navigation : a large single-centre study. Bone Joint J 2025; 107-B: 804-812.

31. Shatrov J, Foissey C, Batailler C, Gunst S, Servien E, Lustig S. How long does image based robotic total knee arthroplasty take during the learning phase? Analysis of the key steps from the first fifty cases. Int Orthop 2023; 47: 437-446.

32. Marchand KB, Ehiorobo J, Mathew KK, Marchand RC, Mont MA. Learning Curve of Robotic-Assisted Total Knee Arthroplasty for a High-Volume Surgeon. J Knee Surg 2022; 35: 409-415.

33. Inui H, Taketomi S, Yamagami R, Kono K, Kawaguchi K, Takagi K, et al. Comparison of intraoperative kinematics and their influence on the clinical outcomes between posterior stabilized total knee arthroplasty and bi-cruciate stabilized total knee arthroplasty. Knee 2020; 27: 1263-1270.

34. Bellemans J. Neutral mechanical alignment: a requirement for successful TKA: opposes. Orthopedics 2011; 34: e507-509.

35. Orthopaedic Data Evaluation Panel, https://www.odep.org.uk/. 2026.

36. Petursson G, Fenstad AM, Gothesen O, Dyrhovden GS, Hallan G, Rohrl SM, et al. Computer-Assisted Compared with Conventional Total Knee Replacement: A Multicenter Parallel-Group Randomized Controlled Trial. J Bone Joint Surg Am 2018; 100: 1265-1274.

37. Dyrhovden GS, Lygre SHL, Badawy M, Gothesen O, Furnes O. Have the Causes of Revision for Total and Unicompartmental Knee Arthroplasties Changed During the Past Two Decades? Clin Orthop Relat Res 2017; 475: 1874-1886.

38. Hansen EN, Ong KL, Lau E, Kurtz SM, Lonner JH. Unicondylar Knee Arthroplasty Has Fewer Complications but Higher Revision Rates Than Total Knee Arthroplasty in a Study of Large United States Databases. J Arthroplasty 2019; 34: 1617-1625.

39. Wilson HA, Middleton R, Abram SGF, Smith S, Alvand A, Jackson WF, et al. Patient relevant outcomes of unicompartmental versus total knee replacement: systematic review and meta-analysis. BMJ 2019; 364: l352.

40. Zuiderbaan HA, van der List JP, Khamaisy S, Nawabi DH, Thein R, Ishmael C, et al. Unicompartmental knee arthroplasty versus total knee arthroplasty: Which type of artificial joint do patients forget? Knee Surg Sports Traumatol Arthrosc 2017; 25: 681-686.

41. Arirachakaran A, Choowit P, Putananon C, Muangsiri S, Kongtharvonskul J. Is unicompartmental knee arthroplasty (UKA) superior to total knee arthroplasty (TKA)? A systematic review and meta-analysis of randomized controlled trial. Eur J Orthop Surg Traumatol 2015; 25: 799-806.

42. Mortensen JF, Blanche P, Blom CS, Vase M, Overgaard S, Kappel A, et al. Medial Unicompartmental Versus Total Knee Arthroplasty in the Treatment of Isolated Anteromedial Knee Osteoarthritis: Two-Year Results from a Double-Blinded, Multicenter, Randomized Trial of 350 Patients. J Bone Joint Surg Am 2026; 10.2106/JBJS.25.00612.

43. Kleeblad LJ, van der List JP, Zuiderbaan HA, Pearle AD. Larger range of motion and increased return to activity, but higher revision rates following unicompartmental versus total knee arthroplasty in patients under 65: a systematic review. Knee Surg Sports Traumatol Arthrosc 2018; 26: 1811-1822.

44. Gifstad T, Nordskar JJ, Egeberg T, Wik TS, Winther SB. Cementless unicompartmental knee arthroplasty results in higher pain levels compared to the cemented technique: a prospective register study. Knee Surg Sports Traumatol Arthrosc 2022; 30: 2738-2743.

45. Badawy M, Espehaug B, Indrekvam K, Engesaeter LB, Havelin LI, Furnes O. Influence of hospital volume on revision rate after total knee arthroplasty with cement. J Bone Joint Surg Am 2013; 95: e131.

46. Badawy M, Fenstad AM, Bartz-Johannessen CA, Indrekvam K, Havelin LI, Robertsson O, et al. Hospital volume and the risk of revision in Oxford unicompartmental knee arthroplasty in the Nordic countries -an observational study of 14,496 cases. BMC Musculoskelet Disord 2017; 18: 388.

47. Furnes O, Espehaug B, Lie SA, Vollset SE, Engesaeter LB, Havelin LI. Failure mechanisms after unicompartmental and tricompartmental primary knee replacement with cement. J Bone Joint Surg Am 2007; 89: 519-525.

48. Lygre SH, Espehaug B, Havelin LI, Furnes O, Vollset SE. Pain and function in patients after primary unicompartmental and total knee arthroplasty. J Bone Joint Surg Am 2010; 92: 2890-2897.

49. Gaba S, Wahal N, Gautam D, Pandit H, Kumar V, Malhotra R. Early Results of Oxford Mobile Bearing Medial Unicompartmental Knee Replacement (UKR) with the Microplasty Instrumentation: An Indian Experience. Arch Bone Jt Surg 2018; 6: 301-311.

50. Mohammad HR, Matharu GS, Judge A, Murray DW. New surgical instrumentation reduces the revision rate of unicompartmental knee replacement: A propensity score matched comparison of 15,906 knees from the National Joint Registry. Knee 2020; 27: 993-1002.

51. Malhotra R, Kumar V, Wahal N, Clave A, Kennedy JA, Murray DW, Pandit H. New Instrumentation Improves Patient Satisfaction and Component Positioning for Mobile-Bearing Medial Unicompartmental Knee Replacement. Indian J Orthop 2019; 53: 289-296.

52. Alvand A, Wilson HA, Sabah SA, Middleton R, Bottomley N, Jackson WFM, Price AJ. New instrumentation system for cementless mobile-bearing unicompartmental knee arthroplasty improves surgical performance particularly for trainees. Knee 2021; 31: 46-53.

53. Sun XW, Lu FF, Zou K, Hong M, Zhang QD, Guo WS. Does new instrument for Oxford unicompartmental knee arthroplasty improve short-term clinical outcome and component alignment? A meta-analysis. J Orthop Surg Res 2020; 15: 386.

54. Selvik G. Roentgen stereophotogrammetry. A method for the study of the kinematics of the skeletal system. Acta Orthop Scand Suppl 1989; 232: 1-51.

55. Ryd L, Albrektsson BE, Carlsson L, Dansgard F, Herberts P, Lindstrand A, et al. Roentgen stereophotogrammetric analysis as a predictor of mechanical loosening of knee prostheses. J Bone Joint Surg Br 1995; 77: 377-383.

56. Valstar ER, Gill R, Ryd L, Flivik G, Borlin N, Karrholm J. Guidelines for standardization of radiostereometry (RSA) of implants. Acta Orthop 2005; 76: 563-572.

57. Pijls BG, Valstar ER, Nouta KA, Plevier JW, Fiocco M, Middeldorp S, Nelissen RG. Early migration of tibial components is associated with late revision: a systematic review and meta-analysis of 21,000 knee arthroplasties. Acta Orthop 2012; 83: 614-624.

58. Puijk R, Puijk RH, Laende EK, Dunbar MJ, Plevier JWM, Nolte PA, Pijls B. 6-month migration sufficient for evaluation of total knee replacements: a systematic review and meta-analysis. Acta Orthop 2023; 94: 577-587.

59. Eckhard L, Munir S, Wood D, Talbot S, Brighton R, Walter B, Bare J. The ceiling effects of patient reported outcome measures for total knee arthroplasty. Orthop Traumatol Surg Res 2021; 107: 102758.

60. Escobar A, Gonzalez M, Quintana JM, Vrotsou K, Bilbao A, Herrera-Espineira C, et al. Patient acceptable symptom state and OMERACT-OARSI set of responder criteria in joint replacement. Identification of cut-off values. Osteoarthritis Cartilage 2012; 20: 87-92.

61. Unnanuntana A, Ruangsomboon P, Keesukpunt W. Validity and Responsiveness of the Two-Minute Walk Test for Measuring Functional Recovery After Total Knee Arthroplasty. J Arthroplasty 2018; 33: 1737-1744.

62. Ozden F, Coskun G, Bakirhan S. The test-retest reliability and concurrent validity of the five times sit to stand test and step test in older adults with total hip arthroplasty. Exp Gerontol 2020; 142: 111143.

63. Nyberg L. Primärvården har en nyckelroll för tidig diagnos och uppföljning. Läkartidningen in Sweeden 2014.

64. Havelin LI, Engesaeter LB, Espehaug B, Furnes O, Lie SA, Vollset SE. The Norwegian Arthroplasty Register: 11 years and 73,000 arthroplasties. Acta Orthop Scand 2000; 71: 337-353.

65. Furnes O, Espehaug B, Lie SA, Vollset SE, Engesaeter LB, Havelin LI. Early failures among 7,174 primary total knee replacements: a follow-up study from the Norwegian Arthroplasty Register 1994-2000. Acta Orthop Scand 2002; 73: 117-129.

66. Petursson G, Fenstad AM, Gothesen O, Haugan K, Dyrhovden GS, Hallan G, et al. Similar migration in computer-assisted and conventional total knee arthroplasty. Acta Orthop 2017; 88: 166-172.

67. Ranstam J, Ryd L, Onsten I. Accurate accuracy assessment: review of basic principles. Acta Orthop Scand 2000; 71: 106-108.

68. Van Laarhoven SN, Te Molder MEM, Van Hellemondt GG, Heesterbeek PJC. Acceptable migration of a fully cemented rotating hinge-type knee revision system measured in 20 patients with model-based RSA with a 2-year follow-up. Acta Orthop 2023; 94: 185-190.

69. Varnum C, Pedersen AB, Gundtoft PH, Overgaard S. The what, when and how of orthopaedic registers: an introduction into register-based research. EFORT Open Rev 2019; 4: 337-343.

70. Burger JA, Jager T, Dooley MS, Zuiderbaan HA, Kerkhoffs G, Pearle AD. Comparable incidence of periprosthetic tibial fractures in cementless and cemented unicompartmental knee arthroplasty: a systematic review and meta-analysis. Knee Surg Sports Traumatol Arthrosc 2022; 30: 852-874.

71. Eckert JA, Jaeger S, Klotz MC, Schwarze M, Bitsch RG. Can intraoperative measurement of bone quality help in decision making for cementless unicompartmental knee arthroplasty? Knee 2018; 25: 609-616.

72. Hiranaka T, Yoshikawa R, Yoshida K, Michishita K, Nishimura T, Nitta S, et al. Tibial shape and size predicts the risk of tibial plateau fracture after cementless unicompartmental knee arthroplasty in Japanese patients. Bone Joint J 2020; 102-B: 861-867.

73. Pham T, van der Heijde D, Altman RD, Anderson JJ, Bellamy N, Hochberg M, et al. OMERACT-OARSI initiative: Osteoarthritis Research Society International set of responder criteria for osteoarthritis clinical trials revisited. Osteoarthritis Cartilage 2004; 12: 389-399.

74. Jiang R, Rand K, Kuharic M, Pickard AS. EQ-5D-5L measurement properties are superior to EQ-5D-3L across the continuum of health using US value sets. Health Qual Life Outcomes 2022; 20: 134.

75. Culliton SE, Bryant DM, MacDonald SJ, Hibbert KM, Chesworth BM. Validity and Internal Consistency of the New Knee Society Knee Scoring System. Clin Orthop Relat Res 2018; 476: 77-84.

76. Leica A, Sava MP, Khan ZA, Hugli RW, Hirschmann MT. Limitations of the knee society score in kinematically aligned total knee arthroplasty. J Exp Orthop 2024; 11: e12054.

77. Howell SM, Zabiba A, Nedopil AJ, Hull ML. The Forgotten Joint Score after total knee arthroplasty with a kinematic alignment-optimized femoral component matches total hip arthroplasty. Knee Surg Sports Traumatol Arthrosc 2025; 33: 3646-3653.

78. Ghanem E, Pawasarat I, Lindsay A, May L, Azzam K, Joshi A, Parvizi J. Limitations of the Knee Society Score in evaluating outcomes following revision total knee arthroplasty. J Bone Joint Surg Am 2010; 92: 2445-2451.

79. Clement ND, Bardgett M, Weir D, Holland J, Gerrand C, Deehan DJ. What is the Minimum Clinically Important Difference for the WOMAC Index After TKA? Clin Orthop Relat Res 2018; 476: 2005-2014.

80. Stegelmann SD, Butler J, Eaddy SG, Davis T, Davis K, Miller R. Learning curve for imageless robotic-assisted total knee arthroplasty in non-fellowship trained joint replacement surgeons. J Orthop 2023; 45: 72-77.

81. Abdel Khalik H, Abesteh J, Aldawodi M, Khanna V, Adili A. The learning curve of robotic-assisted total knee arthroplasty: a systematic review and meta-analysis. J Robot Surg 2025; 19: 456.

82. Jenny JY, Saragaglia D, Bercovy M, Cazenave A, Gaillard T, Chatain F, et al. Navigation Improves the Survival Rate of Mobile-Bearing Total Knee Arthroplasty by Severe Preoperative Coronal Deformity: A Propensity Matched Case-Control Comparative Study. J Knee Surg 2021; 34: 1080-1084.

83. Vermorel PH, Ciccullo C, De Berardinis L, Gigante AP, Neri T, Philippot R. Does robotic arm-assisted total knee arthroplasty have a role to play in large deformities? SICOT J 2024; 10: 50.

84. Gill SD, de Morton NA, Mc Burney H. An investigation of the validity of six measures of physical function in people awaiting joint replacement surgery of the hip or knee. Clin Rehabil 2012; 26: 945-951.

85. Larsen AH, Puggaard L, Hamalainen U, Aagaard P. Comparison of ground reaction forces and antagonist muscle coactivation during stair walking with ageing. J Electromyogr Kinesiol 2008; 18: 568-580.

86. Ogawa A, Iijima H, Takahashi M. Identification of Early Knee Osteoarthritis Based on Knee Joint Trajectory during Stair Climbing. Int J Environ Res Public Health 2022; 19.

87. Iijima H, Eguchi R, Shimoura K, Aoyama T, Takahashi M. Stair climbing ability in patients with early knee osteoarthritis: Defining the clinical hallmarks of early disease. Gait Posture 2019; 72: 148-153.

88. Kline PW, Jacobs CA, Duncan ST, Noehren B. Step descent strategy is altered bilaterally despite unilateral muscle strength impairment after total knee arthroplasty. Knee Surg Sports Traumatol Arthrosc 2020; 28: 1508-1515.

89. Kakiage H, Hatayama K, Nonaka S, Terauchi M, Saito K, Takase R, et al. Stair climbing ability and postoperative activity in patient-reported outcomes after CR-TKA are more related to handgrip strength than sagittal knee stability. Arch Orthop Trauma Surg 2025; 145: 113.

90. Walsh M, Woodhouse LJ, Thomas SG, Finch E. Physical impairments and functional limitations: a comparison of individuals 1 year after total knee arthroplasty with control subjects. Phys Ther 1998; 78: 248-258.

91. Matassi F, Pettinari F, Frascona F, Innocenti M, Civinini R. Coronal alignment in total knee arthroplasty: a review. J Orthop Traumatol 2023; 24: 24.

92. Harris AB, Vigdorchik JM, Khanuja HS, Hegde V. Modern Alignment Strategies in Total Knee Arthroplasty and How to Best Achieve Them. J Bone Joint Surg Am 2025; 107: 2457-2468.

93. Ohrn FD, Engseth LHW, Pripp AH, Schulz A, Rohrl SMH. Precision of computer tomography based RSA on femoral implants in total knee arthroplasty: A porcine cadaver study. Clin Biomech (Bristol) 2025; 123: 106456.

94. Ohrn FD, Engseth LHW, Pripp AH, Rohrl SMH, Schulz A. Dose reduction does not impact the precision of CT-based RSA in tibial implants: a diagnostic accuracy study on precision in a porcine cadaver. Acta Orthop 2023; 94: 550-544.

95. Engseth LHW, Ohrn FD, Schulz A, Rohrl SM. CT-based migration analysis of a tibial component compared to radiostereometric analysis : one-year

results of a prospective single-group implant safety study. Bone Joint J 2025; 107-B: 173-180.

96. Mostafa O, Malik M, Qayum K, Ishaq U, Khan AM, Wasim AS, et al. Robotic-assisted versus conventional total knee arthroplasty: a systematic review and meta-analysis of alignment accuracy and clinical outcomes. Ann Med Surg (Lond) 2025; 87: 867-879.

97. Burbelo A, Huffman AB, Stone W, Potts CE, Darbandi A, Morgan C, et al. Femoral component sagittal alignment and its influence on short-term outcomes in total knee arthroplasty: a systematic review. BMC Musculoskelet Disord 2026; 27: 121.

98. Yun AG, Qutami M, Pasko KBD. Do bicortical diaphyseal array pins create the risk of periprosthetic fracture in robotic-assisted knee arthroplasties? Arthroplasty 2021; 3: 25.

99. Stetzer M, Bircher J, Klika AK, Rullan PJ, Bloomfield MM, Krebs VE, et al. Intraincisional Pin Placement is Safe for Robotic-Assisted Total Knee Arthroplasty. J Arthroplasty 2024; 39: 910-915 e911.

100. Vermue H, Luyckx T, Winnock de Grave P, Ryckaert A, Cools AS, Himpe N, Victor J. Robot-assisted total knee arthroplasty is associated with a learning curve for surgical time but not for component alignment, limb alignment and gap balancing. Knee Surg Sports Traumatol Arthrosc 2022; 30: 593-602.

101. White SH, Roberts S, Kuiper JH. The cemented twin-peg Oxford partial knee replacement survivorship: a cohort study. Knee 2015; 22: 333-337.

102. Mohammad HR, Matharu GS, Judge A, Murray DW. A matched comparison of revision rates of cemented Oxford Unicompartmental Knee Replacements with Single and Twin Peg femoral components, based on data from the National Joint Registry for England, Wales, Northern Ireland and the Isle of Man. Acta Orthop 2020; 91: 420-425.

103. Mohammad HR, Matharu GS, Judge A, Murray DW. Comparison of the 10-year outcomes of cemented and cementless unicompartmental knee replacements: data from the National Joint Registry for England, Wales, Northern Ireland and the Isle of Man. Acta Orthop 2020; 91: 76-81.

104. Mikkelsen M, Rasmussen LE, Price A, Pedersen AB, Gromov K, Troelsen A. Does changes in unicompartmental knee arthroplasty practice pattern influence reasons for revision? Bone Jt Open 2023; 4: 923-931.

105. Martin JR, Jennings JM, Watters TS, Levy DL, McNabb DC, Dennis DA. Femoral Implant Design Modification Decreases the Incidence of Patellar Crepitus in Total Knee Arthroplasty. J Arthroplasty 2017; 32: 1310-1313.

106. Aflatooni JO, Wininger AE, Park KJ, Incavo SJ. Alignment options and robotics in total knee arthroplasty. Front Surg 2023; 10: 1106608.

107. McHugh ML. Interrater reliability: the kappa statistic. Biochem Med (Zagreb) 2012; 22: 276-282.

108. Fozo ZA, Ghazal AH, Hesham Gamal M, Matar SG, Kamal I, Ragab KM. A Systematic Review and Meta-Analysis of Conventional Versus Robotic-Assisted Total Knee Arthroplasty. Cureus 2023; 15: e46845.

109. Sacco R, Tecame A, Lalevee M, Perrier A, Massa E, Kouyoumdjian P, Adravanti P. Robotic vs. conventional total knee arthroplasty over two decades: Evolving trends toward personalised alignment without significant clinical superiority in predominantly mild varus deformity-A systematic review of RCTs. J Exp Orthop 2025; 12: e70452.

110. Sun C, Ma Q, Zhang X, Li H, Yang X, Cai X. Improved alignment accuracy but similar early clinical outcomes with NAVIO imageless robotic-assisted vs. conventional total knee arthroplasty: a meta-analysis. J Orthop Surg Res 2025; 20: 619.

111. Beldame J, Boisrenoult P, Beaufils P. Pin track induced fractures around computer-assisted TKA. Orthop Traumatol Surg Res 2010; 96: 249-255.

112. Smith TJ, Siddiqi A, Forte SA, Judice A, Sculco PK, Vigdorchik JM, et al. Periprosthetic Fractures Through Tracking Pin Sites Following Computer Navigated and Robotic Total and Unicompartmental Knee Arthroplasty: A Systematic Review. JBJS Rev 2021; 9: e20 00091.

113. Fang CJ, Mazzocco JC, Sun DC, Shaker JM, Talmo CT, Mattingly DA, Smith EL. Total Knee Arthroplasty Hospital Costs by Time-Driven Activity-Based Costing: Robotic vs Conventional. Arthroplast Today 2022; 13: 43-47.

114. Mancino F, Jones CW, Benazzo F, Singlitico A, Giuliani A, De Martino I. Where are We Now and What are We Hoping to Achieve with Robotic Total Knee Arthroplasty? A Critical Analysis of the Current Knowledge and Future Perspectives. Orthop Res Rev 2022; 14: 339-349.

115. Garcia-Sanz F, Sosa-Reina MD, Jaen-Crespo G, Gonzalez-de-la-Flor A, Villafane JH, Romero-Morales C. Redefining Knee Arthroplasty: Does Robotic Assistance Improve Outcomes Beyond Alignment? An Evidence-Based Umbrella Review. J Clin Med 2025; 14.

116. Guo J, Jin Z, Xia M. Evaluating surgical outcomes: robotic-assisted vs. conventional total knee arthroplasty. J Orthop Surg Res 2025; 20: 166.

117. Lei K, Liu L, Chen X, Feng Q, Yang L, Guo L. Navigation and robotics improved alignment compared with PSI and conventional instrument, while clinical outcomes were similar in TKA: a network meta-analysis. Knee Surg Sports Traumatol Arthrosc 2022; 30: 721-733.

118. Tran T, McEwen P, Peng Y, Trivett A, Steele R, Donnelly W, Clark G. Kinematic alignment in total knee arthroplasty: a five-year prospective, multicentre, survivorship study. Bone Jt Open 2022; 3: 656-665.

119. Ross KA, Wiznia DH, Long WJ, Schwarzkopf R. The Use of Computer Navigation and Robotic Technology in Complex Total Knee Arthroplasty. JBJS Rev 2021; 9: e20 00200.

120. Stroobant L, Vermue H, Jacobs E, Arnout N, Sadones C, Van Onsem S, Victor J. Extension stress radiographs for coronal laxity assessment in revision TKA: high reliability and increased valgus laxity in this population. Arch Orthop Trauma Surg 2025; 145: 302.

121. Batailler C, Shatrov J, Sappey-Marinier E, Servien E, Parratte S, Lustig S. Artificial intelligence in knee arthroplasty: current concept of the available clinical applications. Arthroplasty 2022; 4: 17.

122. Helm JM, Swiergosz AM, Haeberle HS, Karnuta JM, Schaffer JL, Krebs VE, et al. Machine Learning and Artificial Intelligence: Definitions, Applications, and Future Directions. Curr Rev Musculoskelet Med 2020; 13: 69-76.

123. Mickley JP, Kaji ES, Khosravi B, Mulford KL, Taunton MJ, Wyles CC. Overview of Artificial Intelligence Research Within Hip and Knee Arthroplasty. Arthroplast Today 2024; 27: 101396.

124. Karlin EA, Lin CC, Meftah M, Slover JD, Schwarzkopf R. The Impact of Machine Learning on Total Joint Arthroplasty Patient Outcomes: A Systemic Review. J Arthroplasty 2023; 38: 2085-2095.

125. Longo UG, De Salvatore S, Valente F, Villa Corta M, Violante B, Samuelsson K. Artificial intelligence in total and unicompartmental knee arthroplasty. BMC Musculoskelet Disord 2024; 25: 571.

126. Verstraete MA, Moore RE, Roche M, Conditt MA. The application of machine learning to balance a total knee arthroplasty. Bone Jt Open 2020; 1: 236-244.

127. Salman LA, Khatkar H, Al-Ani A, Alzobi OZ, Abudalou A, Hatnouly AT, et al. Reliability of artificial intelligence in predicting total knee arthroplasty component sizes: a systematic review. Eur J Orthop Surg Traumatol 2024; 34: 747-756.

128. Lan Q, Li S, Zhang J, Guo H, Yan L, Tang F. Reliable prediction of implant size and axial alignment in AI-based 3D preoperative planning for total knee arthroplasty. Sci Rep 2024; 14: 16971.

129. Ingelsrud LH, Wilkinson JM, Overgaard S, Rolfson O, Hallstrom B, Navarro RA, et al. How do Patient-reported Outcome Scores in International Hip and Knee Arthroplasty Registries Compare? Clin Orthop Relat Res 2022; 480: 1884-1896.

Appendices

Appendix 1	NAR knee registration from
Appendix 2	Information letter paper II and III
Appendix 3	Registration of patient information paper II and III

Nasjonalt Register for Leddproteser
Helse Bergen HF, Ortopedisk klinikk
Haukeland universitetssjukehus
Møllendalsbakken 7
5021 BERGEN
Tlf: 55973742

F.nr. (11 sifre).....
Navn:.....
Sykehus:.....

Kneproteser

Innsetting, skifting eller fjerning av protese eller protesedeler, samt alle reoperasjoner relatert til proteseleddet.

Aktuell operasjon
☐Primæroperasjon ☐Reoperasjon (protese tidligere)

Aktuell side ☐Venstre ☐Høyre

Operasjonsdato (dd.mm. åå) |__|__|__|__|__|__|

ASA ☐ASA1 ☐ASA2 ☐ASA3 ☐ASA4 ☐ASA5

Vekt (kg) |__|__|__| **Høyde (cm)** |__|__|__|

Ahlbäcks gradering av artrose (angis ved primæroperasjon)
☐Grad1 ☐Grad2 ☐Grad3 ☐Grad4 ☐Grad5

Leddspalte (minste i mm) ..... mm. (angis ved primæroperasjon)

Tidligere operasjon i aktuelle ledd (angis ved primærop. Evt. flere kryss)
☐Nei ☐Ukjent ☐Ja. Spesifiser:
☐Osteotomi ☐Artrodese
☐Protese ☐Synovektomi
☐Menisk ☐Artroskopi (diagnostisk)
☐Leddbånd ☐Korsbånd
☐Menisk og leddbånd ☐Bein-og/eller brusktransplantasjon
☐Shaving/Opprensking (Debridement)
☐Osteosyntese for intraartikulær/leddnær fraktur
☐Annet.....

Årsak til aktuell primæroperasjon (evt. flere kryss)
☐Idiopatisk artrose ☐Rheumatoid artritt
☐Frakturseksvele ☐Mb. Bechterew
☐Sekvele ligamentskade ☐Sekvele meniskskade
☐Infeksjonssekvele ☐Osteochondritt sekvele
☐Akutt fraktur ☐Psoriasis artritt
☐Osteonekrose sekvele/avaskulær nekrose

☐Annen årsak .....

Årsak til aktuell reoperasjon (evt. flere kryss)
☐Løs proksimal protesedel ☐Løs distal protesedel
☐Løs patellaprotese ☐Luksasjon av patella
☐Instabilitet ☐Dyp infeksjon
☐Smerter ☐Progresjon av artrose
☐Forlenget sårsivning ☐Fibrose
☐Tidligere fjernet protese pga infeksjon ☐Aksefeil

☐Protesenær fraktur i femur. Angi klassifisering:
(se rettledning)
☐Femur I ☐Femur II ☐Femur III

☐Protesenær fraktur i tibia. Angi klassifisering:
(se rettledning)
☐Tibia I A ☐Tibia I B ☐Tibia I C
☐Tibia II A ☐Tibia II B ☐Tibia II C
☐Tibia III A ☐Tibia III B ☐Tibia III C
☐Tibia IV A ☐Tibia IV B ☐Tibia IV C

☐Protesenær fraktur i patella. Angi klassifisering:
(se rettledning)
☐Patella I ☐Patella II ☐Patella III A ☐Patella III B

☐Slitt eller defekt plastforing. Spesifiser:
☐Slitt ☐Knekt ☐Annet: ☐Tibia (Hele)
☐Tibia Medialt
☐Tibia Lateralt
☐Patella
☐Tibia & Patella

☐Annen reoperasjonsårsak .....

Reoperasjonstype (evt. flere kryss)
☐Bytte eller innsetting av distal komponent
☐Bytte eller innsetting av proksimal komponent
☐Bytte eller innsetting av hele protesen
☐Innsetting av patellakomponent
☐Bytte av patellaprotese
☐Bytte av plastforing
☐Artrodese
☐Amputasjon
☐Bløtdelsdebridement for infisert protese
☐Innsetting av sementspacer

☐Osteosyntese av protesenær fraktur. Spesifiser hvilket bein:
☐Proksimal ☐Distal ☐Patella

☐Fjernet protesedeler. Spesifiser:
☐Alle ☐Sementspacer ☐Proksimal
☐Distal ☐Patella ☐Intermediær (polyetylen)
☐Annen protesekomponent

☐Annen reoperasjonstype .....

Peroperative komplikasjoner (evt. flere kryss)
☐Blodtomhet sviktende ☐Adm.svikt (manglende komp. mm)
☐Fraktur av proksimalt bein ☐Fraktur av distalt bein
☐Ruptur skade MCL ☐Ligamentruptur/seneskade
☐Svikt av instrumenter ☐Svikt pga. anatomiske forhold
☐Sprekk i distalt bein ☐Teknisk problem med sement

☐Annet .....

Operasjonstid (min) |__|__|__|

Blodtomhet ☐Nei ☐Ja: **Blodtomhetstid (min)** |__|__|__|

Miniinvasiv Kirurgi (MIS) ☐Ja ☐Nei

Computernavigering (CAOS) ☐Nei ☐Ja: Type .....

Robotassistert ☐Nei ☐Ja: Type .....

Pasientilpassede instrumenter ☐Nei ☐Ja: Type: .....

Operasjonstilgang
☐Parapatellar medialt ☐Parapatellar lateralt ☐Subvastus

☐Annet .....

Lokal infiltrasjons analgesi ☐Ja ☐Nei

Perifer nerveblokkade ☐Ja ☐Nei

Anestesi
☐Generell ☐Epidural ☐Spinal ☐Annet .....

Lukking Huden lukket på:
☐Ekstensjon ☐Fleksjon ☐Både ekstendert og flektert

☐Annet .....

Suturteknikk (hud)
☐Fortløpende hudsutur ☐Enkeltstående hudsutur
☐Intracutan hudsutur ☐Klips ☐Lim

☐Annet .....

Dren ☐Ja ☐Nei

Korsbånd
Intakt fremre korsbånd før operasjon ☐Ja ☐Nei
Intakt fremre korsbånd etter operasjon ☐Ja ☐Nei
Intakt bakre korsbånd før operasjon ☐Ja ☐Nei
Intakt bakre korsbånd etter operasjon ☐Ja ☐Nei

Rettledning kneproteser

Registreringen gjelder innsetting, skifting eller fjerning av protesedeler, samt alle andre reoperasjoner relatert til proteseleddet.
Reoperasjoner kan for eksempel være:

- Bløtdelsdebridement pga infeksjon
- Osteosyntese av protesenær fraktur
- Lukket eller åpen reposisjon av luksert tibiaplast
- Mobilisering under anestesi (MUA)
- Artroskopisk adheransløsning
- Rekonstruksjon av strekkeapparatet

ASA klassifisering (ASA=American Society of Anesthesiologists)

ASA-klasse 1: Friske pasienter som røyker mindre enn 5 sigaretter daglig.
ASA-klasse 2: Pasienter med en asymptomatisk tilstand som behandles medikamentelt (f.eks. hypertensjon) eller med kost (f.eks. diabetes mellitus type 2) og ellers friske pasienter som røyker 5 sigaretter eller mer daglig.
ASA-klasse 3: Pasienter med en tilstand som kan gi symptomer, men som holdes under kontroll medikamentelt (f.eks. moderat angina pectoris og mild astma).
ASA-klasse 4: Pasienter med en tilstand som ikke er under kontroll (f.eks. hjertesvikt og astma).
ASA-klasse 5: Moribund/døende pasient

Ahlbäck's radiografiske gradering av artrose, med tillegg av gradering av artrosen i lateral projeksjon

Anteroposterior (AP) projeksjon (frontbilde)
Grad 1: Reduksjon av leddsplate
Grad 2: Manglende leddsplate
Grad 3: Slitasje av tibialeddflate < 5 mm
Grad 4: Slitasje 5-10 mm
Grad 5: Stor subluksasjon av tibia

Lateral projeksjon (sidebilde)
Grad 3: Inntakt bakre posterior tibialeddflate
Grad 4: Slitasje av bakre tibialeddflate
Grad 5: Fremre subluksasjon av tibia < 10 mm

Graderingen er laget for primær artrose, men fint om dere forsøker å angi graden også ved andre typer leddskade.

Leddspalte
Røntgen bilde anbefales tatt stående front med vektbelastning (antero-posterior- AP view). Begge knær i full ekstensjon. Strålegang horisontalt med leddlinjen. Medial og lateral leddspalte høyde (joint space width) måles i midten av de respektive kompartment i mm. Oppgi hele tall.

Peroperative komplikasjoner
Dersom pasienten dør under eller like etter operasjonen, ønsker vi likevel melding om operasjonen.

Miniinvasiv Kirurgi (MIS)
(MIS = Minimally Invasive Surgery) Her menes at kirurgen har brukt kort snitt og at det er brukt spesialinstrument laget for MIS.

Computernavigering (CAOS)
(CAOS = Computer Aided Orthopaedic Surgery) Angi firmanavn på computersystem

Pasientilpassede instrumenter
Her menes kutteblokker eller instrumenter som lages etter MR eller CT bilder tatt av pasienten før operasjonen. Oppgi navn på systemet.

Beintap og beintransplantasjon/beinerstatning
Påsmøring av benvev rundt protesen regnes ikke som bentransplantat.

Tromboseprofylakse
Medikament, dose og antatt varighet av profylaksen skal angis separat for operasjonsdagen og senere. Det skal også oppgis om pasienten står fast på tromboseprofylakse (AlbyIE, Marevan, Plavix ol).

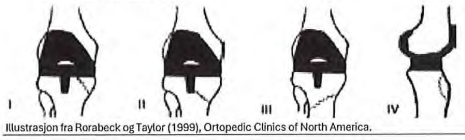
Fibrinolysehemmer
Her føres det på om en benytter blødningsreduserende legemidler i forbindelse med operasjonen (f.eks. Cyklokapron).

Protesetype
Gjelder ved revisjon
Dersom det er gjort revisjon av totalprotese uten patellakomponent og REOPERASJONSTYPE er innsetting av patellakomponent, skal 'Totalprotese m/patella' velges. Totalprotese med patellakomponent (dvs. protesen har nå blitt en totalprotese med patellakomponent).
Ved revisjon av unicondylær protese til totalprotese brukes enten 'Totaltprotese m/patella', 'Totaltprotese u/patella' eller hengslet/stabilisert.

Periprostetiske frakturer – klassifikasjon

Tibiafrakturer klassifikasjon Felix, Stuart og Hanssen (1997) Clin Orthop Relat Res.
4 typer (I-IV) etter lokalisasjon
(Felix, Stuart og Hanssen (1997) Clin Orthop Relat Res.)

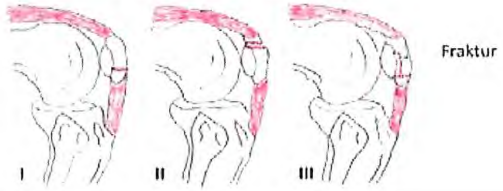
A) Fast protese
B) Løs protese
C) Intraoperativ fraktur



Illustrasjon fra Rorabeck og Taylor (1999), Ortopedic Clinics of North America.

Patellafraktur klassifikasjon Ortiguera og Berry (2002), JBJS.

Type I: Intakt strekkeapparat, fast protese
Type II: Avbrutt strekkeapparat, fast protese
Type III: Løs protese
A)OK bein
B) Kominutt fraktur eller <10mm patella



Femurfraktur klassifikasjon Rorabeck og Lewis (1997).

Type I: Udislokert fraktur, fastsittende protese
Type II: Dislokert fraktur, fastsittende protese
Type III: Udislokert eller dislokert fraktur, løs protese

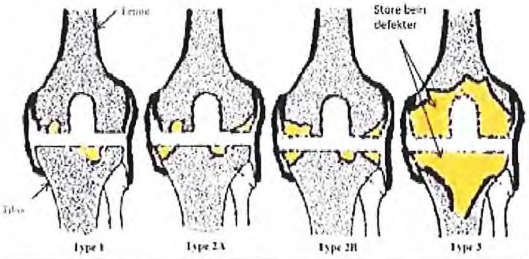
Illustrasjon fra Rorabeck og Taylor (1999), Ortopedic Clinics of North America.

Anderson beintap klassifikasjon

Type 1: Intakt metafysebein, mindre beindefekt, revisjonskomponent forventes å være stabil
Femur (F1): Normal leddlinje, kondyler intakt
Tibia (T1): Protesekomponent over fibulahode og metafyse intakt

Type 2 (2A-en kondyl 2B- begge kondyler): Skadet metafysebein, metafysert beintap
Femur (F2): Hevet leddlinje og kondyler skadet
Tibia (T2): Protesekomponent ved eller under toppen av fibula hodet og tibia bredden redusert

Type 3: Manglende metafyse, større beindefekter, kollateral eller patellar ligament muligens løsrevet
Femur (F3): Vandring av protesekomponent eller osteolyse til nivå med epikondylene
Tibia (T3): Komponent vandring eller osteolyse som har ført til tap av tibiakondyler.



Kontaktpersoner vedrørende registreringsskjema er
Seksjonsoverlege Ove Furnes, tlf. 55 97 56 90.
Ortopedisk klinikk, Haukeland universitetssjukehus. Besøksadresse: Møllendalsbakken 7.
Sekretærer i Nasjonalt Register for Leddproteser, Ortopedisk klinikk, Helse Bergen:
Randi Furnes, tlf. 55 97 37 42. Epost: nrl@helse-bergen.no Internett: https://www.helse-bergen.no/nrl

Beintap
☐Proksimalt (femur) ☐Distalt (tibia)

Beintap klassifikasjon:
(se rettledning)
☐Type 1 ☐ Proksimalt ☐ Distalt
☐Type 2A ☐ Proksimalt ☐ Distalt
☐Type 2B ☐ Proksimalt ☐ Distalt
☐Type 3 ☐ Proksimalt ☐ Distalt

Er det utført beintransplantasjon eller augmentering?
☐Beinpakking ☐Proksimalt ☐Distalt
☐Augment av metall ☐Proksimalt ☐Distalt
☐Fokal transplantasjon ☐Proksimalt ☐Distalt
☐Strukturert beingraft fiksert med skruer ☐Proksimalt ☐Distalt
☐Kon av metall ☐Proksimalt ☐Distalt

☐Annet .....

Tromboseprofylakse
☐Nei ☐Ja, 1 medikament ☐Ja, 2 medikament
Første dose ☐Preoperativt ☐Postoperativt

Medikament 1 .....

Fast medikasjon ☐Ja ☐Nei: Antall dgr planlagt .....

Medikament 2 .....

Fast medikasjon ☐Ja ☐Nei: Antall dgr planlagt .....

Fast antikoagulasjon ☐Nei ☐Ja ☐Ukjent

Angi medikament .....

Fibrinolysehemmer ☐Nei ☐Ja ☐Ukjent

Angi medikament .....
Administrering:
☐Systemisk ☐Lokalt ☐Systemisk og lokalt

Dosering ved systemisk adm. .....

Antibiotikaprofylakse
☐Nei ☐Ja,1 medikament ☐Ja,2 medikament
Pågående antibiotikabehandling ☐Nei ☐Ja
Antibiotikaprofylakse preoperativt ☐Nei ☐Ja

Medikament 1.....

Dosering ..... ☐Milligram ☐Gram

Antall doser (pr døgn) ..... Varighet (timer) .....

Medikament 2 .....

Dosering ..... ☐Milligram ☐Gram

Antall doser (pr døgn) ..... Varighet (timer) .....

Protesetype
☐Totalprot. m/patella
☐Totalprot. u/patella
☐Unicondylær protese. Spesifiser: ☐Medial ☐Lateral
☐Patellefemoral
☐Bi-compartmental
☐Hengslet protese
☐Total stabilisering (CCK)

☐Annen protesetype .....

Fest produktklistrelapper nederst, eller spesifiser nøyaktig:

Femurkomponent Navn/Type/Str / evt. katalognr.

.....

Sentral stamme ☐Nei ☐Ja, evt. lengde ..... mm
Sementert stamme ☐Nei ☐Ja
Metallforing ☐Nei ☐Ja
Stabilisering ☐Nei ☐Ja, bakre ☐Ja, annen

☐Sement m/antibiotika Navn: .....

☐Sement u/antibiotika Navn: .....

☐Usementert

Tibiakomponent (metallplatå) Navn/Type/Str / evt. katalognr.:

.....

Forlenget sentral stamme ☐Nei ☐Ja, evt. lengde ..... mm
Sementert stamme ☐Nei ☐Ja
Metallforing ☐Nei ☐Ja
Stabilisering ☐Nei ☐Ja, bakre ☐Ja, annen

☐Sement m/antibiotika Navn: .....

☐Sement u/antibiotika Navn: .....

☐Usementert

Tibiakomponent (plastkomp.) Navn/Type/Str / evt. katalognr.

.....

Tykkelse ..... mm
Stabilisering ☐Nei ☐Ja, bakre ☐Ja, annen

Patellakomponent Navn/Type/Str / evt. katalognr.

.....

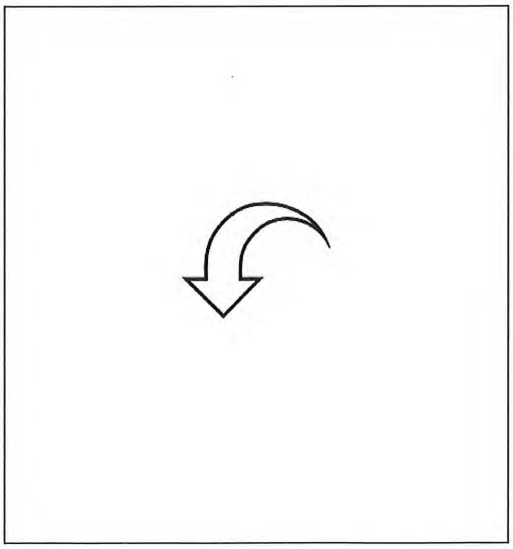
Metallforing ☐Nei ☐Ja

☐Sement m/antibiotika Navn: .....

☐Sement u/antibiotika Navn: .....

☐Usementert

Lege .....
Legen som har fylt ut skjemaet.



HAUGESUND SANITETSFORENINGS revmatismesykehus as

FORESPØRSEL OM DELTAKELSE I FORSKNINGSPROSJEKTET

JOURNEY II BCS KNEPROTESE, KONVENSJONELL OPERASJONSTEKNIKK (VANLIG) VS ROBOTISERT COMPUTER NAVIGASJON (NY)

Dette er et spørsmål til deg om å delta i et forskningsprosjekt. Du skal opereres med en kneprotese. Dette er en etablert behandling med gode resultater for de aller fleste pasienter. Operasjonen innebærer at man setter inn nye leddflater av plast og metall som festes med ben-sement. Som annen medisinsk behandling er også kneprotesekirurgien i stadig utvikling, og man forsøker hele tiden å finne løsninger som ytterligere vil bedre behandlingsresultatene. Som ledd i vår søken etter bedre løsninger vil vi nå sammenligne kneproteser operert med vanlig, standard metode og kneproteser operert ved hjelp av såkalt robotisert computernavigasjon.

Vi bruker i dag en protese som kalles «Journey II BCS», som er godkjent for bruk i både USA og Europa. «Journey II BCS» er utviklet med tanke på kneets egentlige utforming og bevegelsesmønster. Flere mindre studier viser at denne protesen fører til blant annet bedre bevegelse og styrke, og følelsen av et mer naturlig kne. En større studie på over 2000 pasienter fra USA og Europa viser at varigheten av protesen etter 5 år er like god som de beste protesene på markedet i dag. Sammen med Journey-protesen er det utviklet et robotisert navigasjonssystem (Navio), som skal sikre at protesen blir plassert nøyaktig og riktig i forhold til anatomien din. Alternativet er å bruke konvensjonell (vanlig) operasjonsteknikk.

I denne studien ønsker vi å sammenligne den nye robotiserte operasjonsteknikken (Navio) med standard (konvensjonell) operasjonsteknikk. I utgangspunktet er operasjonsteknikkene like gode. Den nye teknikken er kostbar og dersom den ikke gir bedre resultater, er det viktig at Helse-Norge ikke bruker penger på slikt utstyr. På den annen side, hvis resultatene blir bedre med den nye teknikken, vil det være mer aktuelt å investere i denne.

Ulempen ved å ta i bruk nytt utstyr er at man ikke vet om det vil oppstå nye utfordringer med denne metoden, selv om den teoretisk skal være bedre enn den vanlige metoden. Derfor anbefaler Nasjonalt register for leddproteser at pasienter som opereres med slik ny teknologi bør inngå i en studie.

Du blir herved forespurt om du vil delta i en studie som har til hensikt å sammenligne behandlingsresultatet med disse to operasjonsmetodene.

HVA INNEBÆRER PROSJEKTET?

Studien innebærer at man ved loddtrekning velger hvilken metode pasienten skal opereres med. Oppfølgingen vil også være den samme uavhengig av metoden. Pasienter som deltar i studien, vil under operasjonen få satt inn små metallmarkører (0,8-1mm) av metallet tantal i benet rundt protesen og i plastkomponenten. Disse metallmarkørene har vært benyttet til dette formålet internasjonalt i flere tiår og har ingen påviste bivirkninger. Ved hjelp av markørene og helt spesielle røntgenbilder kan man påvise mikroskopisk bevegelse av protesedelene og slitasje av plasten. Grad av bevegelse og slitasje sier noe om protesens stabilitet og derved kvalitet. Pasienter som deltar i studien vil få en ekstra nøye oppfølging med røntgenundersøkelser etter 3, 12 og 24 måneder, samt vanlig rtg. kontroll og undersøkelse etter 5 år.

I prosjektet vil vi innhente og registrere opplysninger om deg. De opplysninger og data som framkommer gjennom studien vil samles og analyseres. Dataene tas fra din vanlige pasientjournal fra opphold ved innleggelse for operasjon, påfølgende røntgen og polikliniske kontroller hos lege og fysioterapeut. Vi registrerer plassering av protesen, bevegelse av protese, grad av smerte, funksjon, andre sykdommer, eventuelle bivirkninger og bruk av medikamenter. Alle opplysningene vil bli behandlet konfidensielt og lagres elektronisk på en egen forskningsserver hos Helse Vest IKT. Opplysningene skal kun brukes slik som beskrevet i denne informasjonen. Alle opplysninger er sikret mot innsyn fra uvedkommende. Direkte identifiserbare opplysninger, herunder navn, fødselsnummer eller andre personentydige kjennetegn, lagres adskilt fra de øvrige opplysningene på den sikrede forskningsserveren hos Helse Vest IKT. En kode knytter deg til dine opplysninger gjennom en navneliste. Bare prosjektlederen og avdelingsoverlegen ved ortopedisk avdeling HSR har tilgang til navnelisten og kan finne tilbake til dine opplysninger. Resultater fra studien skal publiseres på fagmøter og i nasjonale og internasjonale medisinske tidsskrifter. Resultater basert på analyser fra studien vil ikke kunne tilbakeføres til enkeltindivider.

MULIGE FORDELER OG ULEMPER

Studien involverer bruk av et verktøy (Navio) som er relativt nytt og dermed har kort observasjonstid. Man vet ikke sikkert om dette nye verktøyet gir bedre, dårligere eller like gode resultater som med den vanlige operasjonsmetoden. På den annen side er verktøyet utviklet for å gi bedre presisjon og dermed bedre funksjon og holdbarhet av protesen, men det gjenstår å teste ut, blant annet gjennom studier som denne.

FRIVILLIG DELTAKELSE OG MULIGHET FOR Å TREKKE SITT SAMTYKKE

Det er frivillig å delta i prosjektet. Dersom du ønsker å delta, undertegner du samtykkeerklæringen på siste side. Du kan når som helst og uten å oppgi noen grunn trekke ditt samtykke. Dette vil ikke få konsekvenser for din videre behandling. Dersom du trekker deg fra prosjektet, kan du kreve å få slettet innsamlede prøver og opplysninger, med mindre opplysningene allerede er inngått i analyser eller brukt i vitenskapelige publikasjoner. Dersom du senere ønsker å trekke deg eller har spørsmål til prosjektet, kan du kontakte prosjektleder og overlege Øystein Gøthesen, Haugesund sanitetsforenings revmatismesykehus, ortopedisk avdeling. Telefon 52 80 50 00 eller e-post post@hsr.as.

HVA SKJER MED OPPLYSNINGENE OM DEG?

Opplysningene som registreres om deg skal kun brukes slik som beskrevet i hensikten med prosjektet. Du har rett til innsyn i hvilke opplysninger som er registrert om deg og rett til å få korrigert eventuelle feil i de opplysningene som er registrert. Du har også rett til å få innsyn i sikkerhetstiltakene ved behandling av opplysningene.

Alle opplysningene vil bli behandlet uten navn og fødselsnummer eller andre direkte gjenkjennende opplysninger. En kode knytter deg til dine opplysninger gjennom en navneliste. Det er kun prosjektleder Øystein Gøthesen, forsker Øystein Skåden og forskere ved nasjonalt register for leddproteser (Ove Furnes og Anne Marie Fenstad) som har tilgang til denne listen.

Prosjektet avsluttes år 2032. Alle innsamlede forskningsdata vil anonymiseres den 31.12.2036. Vanlige journalopplysninger vil ikke slettes.

FORSIKRING/ANSVAR

Du har de samme rettigheter og forsikringsordninger som du ellers ville hatt som pasient i det offentlige helsevesenet jfr pasientskadeloven.

GODKJENNING

Regional komité for medisinsk og helsefaglig forskningsetikk har vurdert prosjektet, og har gitt forhåndsgodkjenning (REK ref.nr. 68448, datert 04.03.20)

Etter ny personopplysningslov har behandlingsansvarlig Haugesund Sanitetsforenings Revmatismesykehus og prosjektleder Øystein Gøthesen et selvstendig ansvar for å sikre at behandlingen av dine opplysninger har et lovlig grunnlag. Dette prosjektet har rettslig grunnlag i EUs personvernforordning artikkel 6 nr. 1a og artikkel 9 nr. 2a og ditt samtykke.

Du har rett til å klage på behandlingen av dine opplysninger til Datatilsynet.

KONTAKTOPPLYSNINGER

Spørsmål vedrørende studien kan rettes til din behandlende lege ved HSR eller Haugesund sanitetsforenings revmatismesykehus, ortopedisk avdeling v/avdelingsoverlege Øystein Skåden. Telefon 52 80 50 00 eller e-post post@hsr.as.

Studien ledes av Øystein Gøthesen (PhD), overlege og spesialist i ortopedisk kirurgi ved Haugesund sanitetsforenings revmatismesykehus (HSR).

Personvernombud ved institusjonen er oivind.armando.reinertsen@haraldsplass.no

Feltkode

JEG SAMTYKKER TIL Å DELTA I PROSJEKTET OG TIL AT MINE PERSONOPPLYSNINGER BRUKES SLIK DET ER BESKREVET

Sted og dato

Deltakers signatur

Deltakers navn med trykte bokstaver

PASIENTSKJEMA;

Robotisert navigasjon vs konvensjonell metode v/TKA.

- **Pasientnummer:…….**
- **Fødselsdato:.....**
- **Kjønn: Mann____Kvinne___**(sett kryss)
- **Diagnose:**
  1. Primær gonartrose
  2. Sequele fraktur
  3. RA
  4. Psoriasis / Bechterev
  5. Annet. Presiser:…….
- **Side:** Hø
  Ve
- **Charnley klasse:**
  A -Unilateral knelidelse
  B -Bilateral knelidelse
  C -Multippel leddlidelse eller annen sykdom som nedsetter gangfunksjonen
- **Status i kontralaterale kne:**
  1. Normal funksjon
  2. Moderat nedsatt funksjon
  3. Alvorlig nedsatt funksjon
- **Tidligere inngrep i aktuelle kne:**
  1. Åpen/Artroskopisk meniskreseksjon/debridement
     a. 0-1 år siden
     b. >1 år siden
  2. Osteosyntese etter fraktur:
     a. Patella
     b. Femur
     c. Tibia
     d. Kombinasjon av ovennevnte
  3. Artroskopisk båndoperasjon
     a. ACL
     b. Annet (inkl pcl, mcl, lcl, menisksutur etc)
- **Tidligere sykdommer:**
  1. DVT i aktuelle underekstremitet
  2. DVT i kontralaterale underekstremitet
  3. Lungeemboli
  4. Hjerteinfarkt
  5. Atrieflimmer/flutter
  6. Annen hjerterytmeforstyrrelse
  7. Hjerteklaff-sykdom
  8. TIA
  9. Sequele etter hjerneslag/hjerneblødning
  10. Revmatoid artritt
  11. Psoriasis artritt
  12. Polyartritt

➡ **Allergier: Penicillinallergi: Ja___Nei___**

➡ **Medikamenter:**

Medikament	Dose (vedlikeholds-)	Sluttdato preop	Gjenoppstarts -dato postop	Pågående (ikke seponert preop – sett kryss)
1. Marevan	mg pr uke			
2. Albyl-E	mg pr dag			
3. Plavix	mg pr dag			
4. Pradaxa	mg pr dag			
5. Persantin	mg pr dag			
6. Eliquis	mg pr dag			
7. Annet	mg pr dag			

➡ **Høyde (cm):_____**

➡ **Vekt (kg):_____**

➡ **Blodprøver:**

Preoperativt: Hb_____

Postoperativt dag 2-3: Hb_____

➡ **Transfusjoner (totalt antall enheter SAG):_____**

➡ **Operasjonsdato:**

➡ **Operatør:**

➡ **Blodtomhetstid (min):_____**

➡ **Knivtid (min):_____**

➡ **Anestesitype/postop sm.regime:**

1. **Spinal/epidural**
2. **Narkose/annet**

➡ **Komplikasjoner/bivirkninger:**

1. Dyp infeksjon
2. DVT
3. Lungeemboli
4. Hjerteinfarkt
5. Hjerneslag
6. Fraktur
7. Utstyrssvikt (spesifiser!)
8. Annet

Signatur, ansvarlig lege……

Dato:……

Clin Orthop Relat Res (2023) 481:1703-1712
DOI 10.1097/CORR.0000000000002671

Clinical Orthopaedics and Related Research®
A Publication of The Association of Bone and Joint Surgeons®

Selected Proceedings From the 11th International Congress of Arthroplasty Registries
Guest Editor: Ola Rolfson MD, PhD

OPEN

Did a New Design of the Oxford Unicompartmental Knee Prosthesis Result in Improved Survival? A Study From the Norwegian Arthroplasty Register 2012-2021

Øystein Skåden MD[1,4], Ove Nord Furnes MD, PhD[2,4], Stein Håkon Låstad Lygre PhD[2,5], Mona Badawy MD, PhD[3], Øystein Gøthesen MD, PhD[1,4]

Received: 16 November 2022 / Accepted: 29 March 2023 / Published online: 30 May 2023

Abstract

Background Unicompartmental knee arthroplasty (UKA) has generally shown higher revision rates than TKA, and this is particularly true for the femoral component. A twin-peg femoral component (Oxford Partial) has replaced the single-peg version (Oxford Phase III) of the widely used Oxford medial UKA, with the aim of improving femoral component fixation. The introduction of the Oxford Partial Knee also included a fully uncemented option. However, there has been relatively little evidence regarding the effect of these changes on implant survival and revision diagnoses from groups not associated with the implant design.

The institution of one or more of the authors (ONF) has received, during the study period, payment from Ortomedic and Heraeus Medical for lectures on cementation technique in knee replacement.
Each author certifies that there are no funding or commercial associations (consultancies, stock ownership, equity interest, patent/licensing arrangements, etc.) that might pose a conflict of interest in connection with the submitted article related to the author or any immediate family members.
All ICMJE Conflict of Interest Forms for authors and *Clinical Orthopaedics and Related Research®* editors and board members are on file with the publication and can be viewed on request.
Clinical Orthopaedics and Related Research® neither advocates nor endorses the use of any treatment, drug, or device. Readers are encouraged to always seek additional information, including FDA approval status, of any drug or device before clinical use.
Ethical approval was not sought for the present study.
This work was performed at Haugesund Hospital for Rheumatic Diseases in Haugesund, Norway and at The Norwegian Arthroplasty Register in Bergen, Norway.

[1]Haugesund Hospital for Rheumatic Diseases, Haugesund, Norway

[2]Norwegian Arthroplasty Register, Department of Orthopaedic Surgery, Haukeland University Hospital, Helse Bergen HF, Bergen, Norway

[3]Coastal Hospital in Hagevik, Helse Bergen HF, Bergen, Norway

[4]Department of Clinical Medicine, University of Bergen, Bergen, Norway

[5]Department of Occupational Medicine, Haukeland University Hospital, Helse Bergen, Bergen, Norway

Ø. Skåden ✉, Department of Orthopaedic Surgery, Haugesund Hospital for Rheumatic Diseases, Karmsundgate 134, 5528 Haugesund, Norway, Email: oystein.skaden@hsr.as

Questions/purposes Using data from the Norwegian Arthroplasty Register, we asked: (1) Has the 5-year implant survival (free from revision for any cause) improved with the medial Oxford unicompartmental knee after the introduction of new designs? (2) Did the causes of revision change between the old and new designs? (3) Is there a difference in risk for specific revision causes between the uncemented and cemented versions of the new design?

Methods We performed a registry-based observational study using data from the Norwegian Arthroplasty Register, a nationwide, mandatory and governmental registry with a high reporting rate. Between 2012 and 2021, 7549 Oxford UKAs were performed, and 105 were excluded due to combinations of the three designs, lateral compartment replacement, or hybrid fixation, leaving 908 cemented Oxford Phase III single-peg (used from 2012 to 2017), 4715 cemented Oxford Partial twin-peg (used from 2012 to 2021), and 1821 uncemented Oxford Partial twin-peg (used from 2014 to 2021), UKAs available for the analysis. The Kaplan-Meier method and Cox regression multivariate analysis were used to find the 5-year implant survival and the risk of revision (hazard ratio), when adjusting for age, gender, diagnosis, American Society of Anesthesiologists grade, and time period. The risk of revision for any cause and the risk of revision for specific causes were compared, first for the older with the two new designs, and second for the cemented with the uncemented version of the new design. Revision was defined as any operation exchanging or removing implant parts.

Results The 5-year Kaplan-Meier overall implant survival (free from revision for any cause) for the medial Oxford Partial unicompartmental knee did not improve over the study period. The 5-year Kaplan-Meier survival was different (p = 0.03) between the groups: it was 92% (95% confidence interval [CI] 90% to 94%) for the cemented Oxford III, 94% (95% CI 93% to 95%) for the cemented Oxford Partial, and 94% (95% CI 92% to 95%) for the uncemented Oxford Partial. However, the overall risk of revision during the first 5 years was not different between the groups (Cox regression HR 0.8 [95% CI 0.6 to 1.0]; p = 0.09 and 1.0 [95% CI 0.7 to 1.4]; p = 0.89 for the cemented Oxford Partial and the uncemented Oxford Partial, respectively, compared with cemented Oxford III [HR 1]). The uncemented Oxford Partial had a higher risk of revision for infection (HR 3.6 [95% CI 1.2 to 10.5]; p = 0.02) compared with the cemented Oxford III. The uncemented Oxford Partial had a lower risk of revision for pain (HR 0.5 [95% CI 0.2 to 1.0]; p = 0.045) and instability (HR 0.3 [95% CI 0.1 to 0.9]; p = 0.03) compared with the cemented Oxford III. The cemented Oxford Partial had a lower risk of revision for aseptic femoral loosening (HR 0.3 [95% CI 0.1 to 1.0]; p = 0.04) compared with the cemented Oxford III. When comparing the uncemented and cemented versions of the new design, the uncemented Oxford Partial had a higher risk of revision for periprosthetic fracture (HR 15 [95% CI 4 to 54]; p = 0.001) and infection within the first year (HR 3.0 [95% CI 1.5 to 5.7]; p = 0.001) than the cemented Oxford Partial.

Conclusion Considering that we found no difference in overall risk of revision during the first 5 years but we found a higher risk of revision for infection, periprosthetic fracture, and higher per implant cost, we currently would recommend against the use of uncemented Oxford Partial over the cemented Oxford Partial or the cemented Oxford III.

Level of Evidence Level III, therapeutic study

Introduction

The main problem with unicompartmental knee arthroplasty (UKA) survival has been the risk of revision for aseptic loosening. Data from the Norwegian Arthroplasty Register shows that aseptic loosening was the main cause of revision for UKA (81%) at 10-year follow-up [6, 8]. Other registries, including the Australian and Swedish arthroplasty registries, have also shown that this is a global problem [2, 19]. Previous studies have shown that between 25% and 50% of aseptic loosening in UKAs involve the femoral component [8, 13]. The Oxford UKR (Zimmer Biomet) is one of the most commonly used UKA implants worldwide [2, 15, 16, 19]. To address femoral loosening and improve survival, the implant was changed. The Oxford Phase III femoral component is, like its predecessors (the Phase I and II), spherical with only one anchoring peg for insertion into the femoral condyle. The new Oxford Partial femoral component was designed with two pegs to achieve more stable fixation, taking advantage of the two femoral holes used for the cutting guide. To support an extra peg, the femoral component was advanced 15° anteriorly (of a sphere), resulting in a larger surface area for support (Fig. 1). The Oxford Microplasty instruments were introduced in Norway in 2012, along with this new version of the Oxford UKA, allowing for implantation of the femoral component in a slightly more flexed position, which is believed to reduce shear forces and the risk of anterior impingement.

The Oxford Partial UKA was introduced in some countries in 2004, but it was not widely available in Norway until 2012. In the Norwegian Arthroplasty Register, the cemented Oxford Partial has been reported since 2012, the uncemented Oxford Partial since 2014, and the Oxford Microplasty instruments have primarily been used for Oxford Partial UKAs in our registry. The difference between the cemented Oxford Partial and uncemented Oxford Partial designs is the hydroxyapatite-coated titanium mesh of the backside surfaces of the uncemented prosthesis, with the tibial components and the polyethylene bearings largely unchanged. One cohort study reported good midterm results (98% survival after 9 years) for the twin-peg cemented Oxford Partial [23]; another cohort

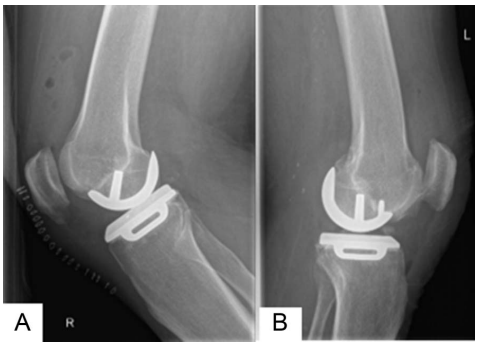


Fig. 1 **(A)** A single-peg cemented Oxford III is shown here. (**B**) This figure demonstrates a twin-peg cemented Oxford partial implant.

study [9] found 97% 5-year survival for the uncemented Oxford Partial. A study from the National Joint Registry for England, Wales, Northern Ireland, and the Isle of Man published in 2020 a matched comparison between the two cemented Oxford UKRs; the results showed an improved survival for the new twin-pegged femoral component (96.2% versus 94.8% 5-year survival) [14]. It is important that new technology and new implants are introduced to the market with care and ultimately to the benefit of our patients [1].

As the Oxford UKA is the most widely used UKA implant worldwide, improved survival would have an impact on many patients. The results with the new design have been promising in a cohort study and in the National Joint Registry (NJR) [15, 23]. However, it is uncertain whether the new design represents an improvement compared with the Oxford III because in many countries, the Oxford Partial knee was introduced with both cemented and uncemented versions along with the Oxford Microplasty instruments. Furthermore, the uncemented version of the new design may have introduced new problems and risks to be assessed, through analyses of causes for revision.

Using data from the Norwegian Arthroplasty Register, we asked: (1) Has the 5-year implant survival (free from revision for any cause) improved with the medial Oxford UKA after the introduction of the new designs? (2) Did the causes of revision change between the older and newer designs? (3) Is there a difference in revision causes between the uncemented and cemented versions of the new design?

Patients and Methods

Study Design and Setting

This study analyzed arthroplasty data from the Norwegian Arthroplasty Register, which covers a population of about 5.2 million people. Although the NJR reports have been promising for the new design, the data in that registry contains data from many high-volume surgeons involved in implant development. The results from a country like Norway, with a high reporting rate and less influence from the designing surgeons, would be valuable. Furthermore, results from different registries may vary due to different surgical traditions, indications for surgery (primary and revision), demographics, economic funding, and public health systems. All these factors will influence the survival and revision causes. If the results from the NJR can be reproduced and verified in other registries, they will be viewed as more valid for the average orthopaedic surgeon worldwide.

Improvements in surgical technique and more experience with UKAs over the years may have influenced the results. However, if the improvement was not directly related to the new design, there would be no reason to replace the Oxford III with the Oxford Partial knee. To detect what variables may have influenced survival, an analysis of the revision causes needs to be done.

Moreover, the two variants of the new design (cemented and uncemented) seem unnecessary if they have similar results. In Norway, the cost is higher for the uncemented variant, and this extra cost should be justified. If unexpected risks and challenges occur, the presumed benefit of improved fixation with cementless designs may be reduced by added complications.

Data Sources

The data from the Norwegian Arthroplasty Register included patient-, implant-, and surgery-specific information. After each surgical procedure, the surgeon completed a standard form and forwarded it to the register. The surgeon recorded the implant catalogue numbers of all implant parts on the form [8]. The registration completeness exceeds 95% for primary operations and is greater than 93% for revisions [6, 16]. We extracted anonymized data from the Norwegian Arthroplasty Register, including all primary Oxford UKAs in a 10-year period between January 2012 and December 2021 (Fig. 2). We chose 2012 as the starting year because the twin-peg Oxford femoral component UKA was first reported to the registry that year.

Patients

After excluding lateral Oxford UKAs, hybrid fixation, and combined implantations (old and new implants) and patients with missing data/lost to follow-up, we were left with 908 medial cemented Oxford III, 4715 cemented

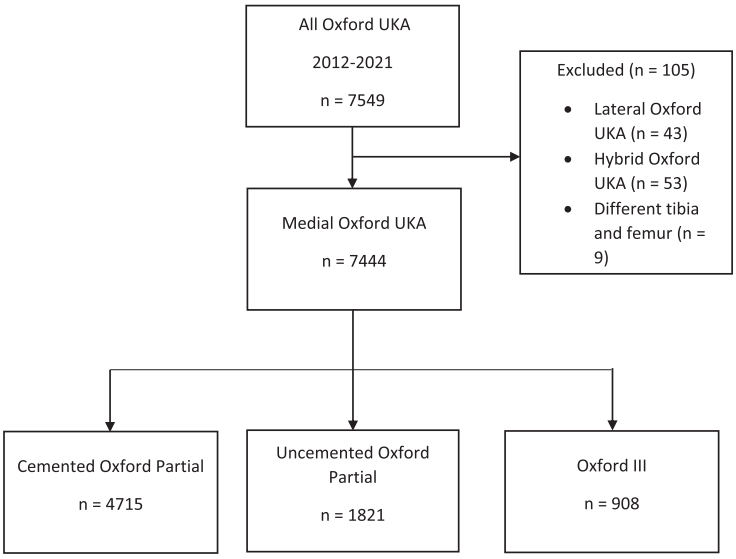


Fig. 2 After applying our exclusion criteria, 7444 Oxford UKAs performed from 2012 to 2021 were included in our analysis.

Oxford Partial (twin-peg), and 1821 uncemented Oxford Patrial UKAs eligible for study inclusion (Fig. 2). Median follow-up was 8 years for the cemented Oxford III, 4 years for the cemented Oxford Partial, and 3 years for the uncemented Oxford Partial. The longer follow-up time for the cemented Oxford III was because it was used until 2017, when it was replaced by the new Oxford Partial prostheses. Use of the cemented Oxford III and the cemented Oxford Partial implant overlapped from 2012 to 2017. Use of the uncemented Oxford partial was first reported in 2014, but in a relatively low number the first 2 years. The cemented Oxford Partial was reported during the entire study period but with lower numbers the first 3 years. To avoid confounding due to different follow-up times, the data were censored after 5 years, with 5 years of median follow-up for the cemented Oxford III, 4 years for the cemented Oxford Partial, and 3 years for the uncemented Oxford Partial.

Descriptive Data

The mean age of patients was 65 ± 9 years for the cemented Oxford III and 66 ± 9 years for both the cemented and uncemented Oxford Partial, but the gender distribution differed between the groups. There were slightly more women than men for the Oxford III, but the opposite was true for the newer cemented and uncemented Oxford Partial. The American Society of Anesthesiologists (ASA) classification also differed marginally between the groups, where the Oxford III group reported a higher percentage (89%) of ASA I classification than the two other designs (84% and 85%). These marginal differences between the groups were adjusted for in the analyses, and they were considered too small to have influenced the main results beyond the adjustments (Table 1). The primary indication for surgery was osteoarthritis (96% [7117 of 7444]).

Primary and Secondary Study Outcomes

Our primary study goal was to analyze whether the redesigned Oxford Partial prostheses (cemented and uncemented) had better overall survival compared with the older cemented Oxford phase III. To achieve this, we estimated the 5-year Kaplan-Meier survival and an adjusted Cox regression HR, comparing the older cemented Oxford III with the cemented and uncemented Oxford Partial, adjusting for age, gender, diagnosis (osteoarthritis/other joint disease), ASA grade (ASA I/ASA II/ASA III+), and time period (2012 to 2016/2017 to 2021).

Our secondary study goals were to assess (1) whether the risks of revision causes differ when moving from the old to the new designs and (2) whether the risks of revision

Table 1. Demographics

Covariate	Oxford III cemented (n = 908)	Oxford Partial cemented (n = 4715)	Oxford Partial uncemented (n =1821)	p value	p value (Oxford III excluded)
Gender				0.02	0.48
Female	52 (471)	47 (2209)	48 (871)		
Male	48 (437)	53 (2506)	52 (950)		
Age at surgery	65 ± 9	66 ± 9	66 ± 9	< 0.001	0.35
Primary diagnosis				0.001	0.007
Primary OA	93 (852)	95 (4500)	97 (1765)		
Other	6 (56)	5 (215)	3 (56)		
ASA grade				< 0.001	0.21
I	89 (795)	84 (3873)	85 (1514)		
II	11 (10)	17 (763)	15 (271)		
III or above					
Year of surgery				< 0.001	< 0.001
2012-2016	100 (907)	39 (1824)	14 (247)		
2017-2021	0 (1)	61 (2891)	86 (1574)		
Year of surgery					
2012	330	106	0		
2013	232	204	0		
2014	198	373	7		
2015	129	513	59		
2016	18	628	181		
2017	1	543	296		
2018	0	564	399		
2019	0	577	368		
2020	0	597	200		
2021	0	610	311		

Data presented as % (n) or mean ± SD. p values were determined using a chi-square test for binary/categorical variables and one-way ANOVA for continuous variables.

causes vary between the cemented Oxford Partial and uncemented Oxford Partial designs.

Variables

Revision was defined as surgery with removal, exchange, or addition of one or more prosthesis components. The surgeons could report one or more of the following reasons for revision: loose femoral component, loose tibial component, dislocation, instability, malalignment, deep infection, fracture, pain, worn or broken polyethylene, or progression of OA; surgeons were also allowed to choose their own descriptions. All reported revision causes were included in the analyses, with no censoring or hierarchical selection. If more than one cause of revision was given, they were all included in the subanalyses for specific revision causes to avoid underestimation of the individual revision causes due to a hierarchy. Confounding by competing risks was additionally tested by Fine and Gray analyses and did not alter the results.

Ethical Approval

Ethical approval was not sought since the Norwegian Arthroplasty Register has a concession from the Norwegian Data Inspectorate to collect and analyze data based on written consent from the patients. The registration of data and the study was performed confidentially on patient consent and according to the Norwegian Data Protection regulations (reference number 03/00058-20/CGN) and Norwegian and EU data protection rules. Data may be accessible upon application to the Norwegian Arthroplasty Register. The Norwegian Arthroplasty Register fully financed the study.

Statistical Analysis

For our primary outcome, we used the Kaplan-Meier method to estimate cumulative survival. Survival was defined as an implant free of any revision where parts were exchanged or removed. Statistical significance was tested with a log-rank test. Furthermore, an HR was calculated using a Cox regression multivariate analysis, adjusting for age, gender, ASA classification (ASA I/ASA II/ASA III+), diagnosis (osteoarthritis/other joint disease), and time period (2012 to 2016/2017 to 2021), to compare risk of revision for all causes. For our secondary outcomes, an adjusted Cox regression analysis for each specific revision cause was performed. Firstly, we compared the cemented Oxford Partial and uncemented Oxford Partial UKAs with the cemented Oxford III UKAs (Oxford III as reference). Secondly, we compared the uncemented Oxford Partial with the cemented Oxford Partial UKAs. Proportional hazards were tested and found valid for the overall survival analysis. For the specific revision causes, we performed a Fine and Gray analysis and checked it against the Cox regression analysis. If the results differed, the Fine and Gray estimate was reported. For demographics, p values were determined using a chi-square test for binary/categorical variables and one-way ANOVA for continuous variables.

All statistical analyses were performed using IBM SPSS version 22.0 (IBM Corp) and STATA version 17.0 (STATA Corp). All p values less than 0.05 were considered significant, with a presented 95% confidence interval (CI).

Results

Has Survival of the Medial Oxford Unicompartmental Knee Improved With the New Design?

Survivorship did not improve with the new design of the medial Oxford UKA. Overall 5-year survival for the cemented Oxford Partial was 94% (95% CI 93% to 95%) compared with 94% (95% CI 92% to 95%) for the uncemented Oxford Partial and 92% (95% CI 90% to 94%; p = 0.03) for the cemented Oxford III (Fig. 3). We found no difference for the overall risk of revision comparing the cemented and uncemented Oxford Partial with the cemented Oxford III in the reported time period, 2012 to 2021, when adjusting for age, gender, diagnosis, ASA classification, and time periods (Table 2). However, for the uncemented Oxford Partial, the overall risk of revision was lower than the older design cemented Oxford III from 1 to 5 years of follow-up (Table 2).

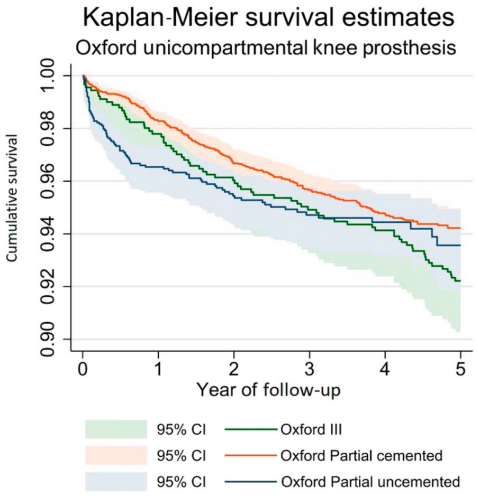


Fig. 3 Five-year survival for the cemented Oxford Partial was 94%, it was 94% for the uncemented Oxford Partial, and it was 92% for the cemented Oxford III. A color image accompanies the online version of this article.

Did the Indications for Revision Change Between the Older and Newer Design?

The main indications for revision changed with the introduction of the new design. The risk of revision for femoral loosening was lower for the cemented Oxford Partial compared with the cemented Oxford III (HR loosening 0.3 [95% CI 0.1 to 1.0]; p = 0.04). The uncemented Oxford Partial had a higher risk of revision for infection (HR 3.6 [95% CI 1.2 to 10.5]; p = 0.02) and a lower risk of revision for pain (HR 0.5 [95% CI 0.2 to 1.0]; p < 0.05) and instability (HR 0.3 [95% CI 0.1 to 0.9]; p = 0.03 (Table 2).

Did the Indications for Revision Differ Between the Uncemented and Cemented Designs?

The revision causes differed between the cemented Oxford Partial and the uncemented Oxford Partial designs. When comparing the uncemented Oxford Partial with the cemented Oxford Partial (HR 1), we found a higher risk of revision for periprosthetic fracture (HR 15 [95% CI 4 to 54]; p < 0.001) and infection up to 1 year (HR 3.0 [95% CI 1.5 to 5.7]; p = 0.001, and polyethylene wear the first 2.5 years (HR 7.8 [95% CI 1.5-40]; p = 0.02, for the uncemented version (Table 3).

Discussion

A primary issue with UKA survival has been the risk of aseptic loosening, particularly of the femoral component.

Table 2. Cox multivariate regression analysis of the three design options for the Oxford medial UKA

	Oxford III cemented (n = 908)		Oxford Partial cemented (n = 4715)			Oxford Partial uncemented (n = 1821)		
Diagnosis of revision	Number	HR	Number	HR (95% CI)	p value	Number	HR (95% CI)	p value
All diagnoses (overall)[a]	71	1	205	0.8 (0.6-1.0)	0.09	89	1.0 (0.7-1.4)	0.89
All diagnoses year 0-1	31	1	78	0.8 (0.5-1.4)	0.47	61	1.7 (0.9-3.1)	0.08
All diagnoses year 1-5	50	1	127	0.8 (0.5-1.1)	0.16	28	0.5 (0.3-0.9)	0.02
Infection[a]	5	1	30	1.6 (0.6-4.3)	0.34	20	3.6 (1.2-10.5)	0.02
Infection year 0-1	4	1	22	1.4 (0.5-4.2)	0.56	20	4.1 (1.3-13.5)	0.02
Periprosthetic fracture[b]	0		3	1		15	15 (4-54)	< 0.001
Polyethylene wear/damaged	3	1	4	0.3 (0.1-1.6)	0.17	7	1.4 (0.2-8.6)	0.69
Femoral loosening	8	1	8	0.3 (0.1-1)	0.04	1	0.2 (0.0-1.5)	0.11
Tibial loosening[a]	10	1	29	0.9 (0.4-1.9)	0.80	6	0.7 (0.2-2.2)	0.56
Tibial loosening year 0-1.5	2	1	15	2.1 (0.5-9.7)	0.34	5	2.3 (0.4-13)	0.37
Tibial loosening year 1.5-5	8	1	14	0.6 (0.2-1.6)	0.31	1	0.2 (0.0-2)	0.18
Progression of osteoarthritis	16	1	45	1.0 (0.5-1.8)	0.91	6	0.4 (0.1-1.2)	0.10
Pain	30	1	65	0.7 (0.5-1.2)	0.19	12	0.5 (0.2-1.0)	0.045
Instability	12	1	39	0.5 (0.2-1.2)	0.11	10	0.3 (0.1-0.9)	0.03
Malalignment	9	1	17	0.4 (0.2-1.1)	0.07	5	0.3 (0.1-1.2)	0.10
Luxation of polyethylene	6	1	20	0.7 (0.2-1.8)	0.41	15	1.2 (0.4-3.8)	0.79
Other	7	1	32	1.2 (0.5-3.1)	0.69	17	1.7 (0.6-4.9)	0.35

Risk of revision for specific indications for revision and overall risk of revision (Cox – adjusted for gender, age, diagnosis, ASA, and time period).
[a]Separate time periods to fulfill proportional hazards assumption.
[b]Oxford III excluded from analysis.

Table 3. Cox multivariate regression analysis of the two newer design options for the Oxford medial unicompartmental knee replacement

	Oxford Partial cemented (n = 4715)		Oxford Partial uncemented (n = 1821)		
	Number	HR	Number	HR (95% CI)	p value
Periprosthetic fracture	3	1	14	15 (4-54)	< 0.001
Polyethylene wear/damaged[a]	4	1	7	4.7 (1.3-17)	0.02
Polyethylene wear/damaged year 0-2.5	2	1	6	7.8 (1.5-40)	0.02
Infection[a]	30	1	20	2.2 (1.2-4.1)	0.01
Infection year 0-1	22	1	20	3.0 (1.5-5.7)	0.001
Loosening femur	8	1	1	0.5 (0.1-3.9)	0.47
Loosening tibia	29	1	6	0.8 (0.3-2.0)	0.59
Progression of osteoarthritis	45	1	6	0.4 (0.2-1.1)	0.07
Pain	65	1	12	0.6 (0.3-1.2)	0.15
Instability	39	1	10	0.6 (0.3-1.3)	0.20
Malalignment	17	1	5	0.8 (0.3-2.1)	0.60
Luxation of polyethylene	20	1	15	1.8 (0.9-3.7)	0.11
Other	32	1	17	1.4 (0.7-2.6)	0.32

Risk of revision for specific diagnoses of revision and overall risk of revision (Cox – adjusted for gender, age, diagnosis, ASA, and time period).
[a]Not valid due to proportional hazard assumption not fulfilled.

Data from the Norwegian Arthroplasty Register shows that aseptic loosening was the main cause of revision for UKA at 10-year follow-up [8]. One cohort study [23] and a registry study [14] have suggested that the overall survival has improved with the new design of the Oxford unicompartmental knee, and there was hope that the uncemented version of the new design had diminished the problem of radiolucencies and aseptic loosening. This study shows that the design changes of the Oxford UKA changed the causes for revision without improving the overall survival. The ability to identify the effect of changes in implant designs is an important task of well-established national registries, and data from a country with a high reporting rate and little influence from the designers/manufacturers is especially valuable when evaluating new or redesigned implants. Other registries have shown that revision for implant loosening is a global problem, and previous studies have shown that 25% to 50% of aseptic loosening in UKAs involve the femoral component [8, 13]. We analyzed data from the Norwegian Arthroplasty Register to compare the newer design cemented and uncemented Oxford partial UKA to the previous Oxford Phase III design. We found no difference in the overall revision risk between these three implants. When comparing the specific reasons for revision, we found that revisions for aseptic loosening of the femoral component were higher for the cemented single-peg Oxford III compared with the twin-peg cemented Oxford Partial. Revision risk for pain was lower for the uncemented Oxford Partial compared with the Oxford III. Periprosthetic fracture as a revision cause was higher for the uncemented Oxford Partial compared with cemented Oxford Partial. This latter finding is alarming with respect to the causes for early failure in the uncemented Oxford Partial group. The cemented Oxford Partial has replaced the older cemented Oxford III in the market. It has similar 5-year survival to the cemented Oxford III, and in this study, we found no alarming new causes of revision for the cemented Oxford Partial knee. Additionally, in Norway, the uncemented version is more expensive, and with the differing risks of revision for the uncemented implant in mind, the cemented version should be preferred.

Limitations

One important limitation to this study is the relatively short follow-up with different median follow-up times for the groups. The cemented Oxford III implants have had more time to fail, and certain causes of revision such as aseptic loosening, which are expected to increase with time, might be more often reported in this group. To minimize this confounder and achieve more similar follow-up times, the inclusion of data was stopped at 5 years of follow-up. The difference in revision causes reported, such as fracture and infection, occur early in the period, hence they will be detected despite the short follow-up. Furthermore, prostheses and surgical technique may improve with time and volume. However, this possible bias is likely to have impacted all three groups equally, and there is no reason to believe that one group would be more affected than the other.

The multiple testing for different revision causes may have introduced the risk of a statistical Type I error, weakening our results. On the other hand, the strength of registry studies is the ability to detect and analyze relatively rare events, like revisions. Due to the serious implications for patients, these rare occasions must be addressed and surgeons must be alerted that they exist. Gender must also be considered in our study results, because one cannot assume that a finding drawn from a population of men and women would apply equally for men and women separately. In this study, the only outcome measure is revision, which is a crude measure, but gender was adjusted for in the analyses to reduce this bias. PROMs could identify patients who are doing poorly but who chose not to undergo another surgery; however, PROMs were not available in the Norwegian Arthroplasty Register for these implants in this period. Revision as the only endpoint is a limitation for all registries because of the issue with patients who may have pain due to a loose implant but who are not candidates for revision surgery or who choose not to undergo revision surgery. This does not disqualify the findings here because there is no reason to think it more likely in one group than another.

We do not have any data on the potential learning curve for the newest uncemented Oxford Partial, which represents a limitation to this study. Another limitation is that surgeons can report more than one revision cause without classifying which cause is the most plausible reason for implant failure. Again, this limitation would apply equally to all groups but also allows for more granularity in reporting of the revision indications. The low number of revisions in this study may be the reason why we were not able to show statistically significant differences for the various revision causes. Furthermore, the Oxford Microplasty instrumentation became available in 2011 and was mostly used for cemented and uncemented Oxford Partial but also for some of the cemented Oxford III operations throughout the study period. This may have influenced the results in favor of the newer designs, since the new instrument set aids in more accurate placement of the components, with a modified implantation technique. Conversely, there is always a learning curve with new instrumentation.

Has Survival of the Medial Oxford Unicompartmental Knee Improved With the New Design?

We found no difference in the overall revision risk between the three Oxford UKA implants we analyzed. The

unadjusted survival estimates from the Kaplan-Meier analysis showed a statistically but not clinically significant difference. When adjusting for age, gender, diagnoses, ASA class, and time, the Cox regression hazard ratios showed no difference. A register-based study with a large number of patients that compared single-peg with twin-peg Oxford UKAs in a matched comparison similarly showed no difference in the overall revision risk at 5 years between cemented Oxford Partial and cemented Oxford III [14]. A cohort study found better survivorship for the cemented twin-peg Oxford partial when compared with the cemented single-peg Oxford [23]. Based on these findings, we recommend the use of the cemented Oxford Partial implant, which has replaced the single-peg cemented Oxford III, over the more costly uncemented Oxford Partial. For the first 1 to 5 years, however, the uncemented Oxford Partial had a lower risk of revision overall compared with the older cemented Oxford III; this result might leave some optimism and is the reason why further research with longer follow-up is needed.

Did the Indications for Revision Change Between the Older and Newer Design?

We found that the twin-peg cemented Oxford Partial had a lower risk of revision for femoral loosening compared with the single-peg Oxford III. This finding supports previous results that the combination of microplasty instruments and a new twin-peg design creates a stable situation with less chance of revision for a loose femoral component. Two cadaver studies also showed better strength of fixation for the twin-peg femoral component [17, 18]. The uncemented Oxford Partial had more revisions for periprosthetic fracture and infection but a lower risk of revision for pain than the Oxford III. All the cemented Oxford UKAs in this study utilized antibiotic bone cement (ABC), which slowly releases antibiotics in the early period after surgery. Most cemented arthroplasties in Norway use ABC. The fact that the uncemented prosthesis only get antibiotics intravenously around the surgery could perhaps explain the difference in infection rate. To elaborate this infection risk further, large registry or randomized controlled studies must be performed. The cemented technique might be preferred over the cementless because it is less traumatic to the bone. The impaction of bone and pressfit technique of the uncemented design might introduce a risk of fracture.

The new Oxford Microplasty instruments were introduced along with the cemented Oxford Partial and uncemented Oxford Partial to improve the reproducibility of implant positioning and to minimize tibial bone resection. Two studies comparing Oxford Microplasty to conventional instrumentation showed a reduced risk of malalignment of the femoral component and more accurate tibial bone resection, with less bone loss [21, 22]; another study reported reduced revision rates with the new instrumentation [20]. This new instrument set, mostly used for the newest designs, may have influenced the results in favor of the Oxford partial prostheses.

The causes for revision indicated by the surgeon may have changed over time along with the design changes. Previously, the revision indication of pain was more acceptable as a sole reason for revision. One study showed that the results after revision for pain alone had less favorable outcomes than revision for a known cause of pain [11]. Our study showed that the uncemented Oxford Partial knee had a lower risk of revision for pain. This finding might be because the uncemented Oxford Partial had been included later in the observation period.

Did the Indications for Revision Differ Between the Uncemented and Cemented Designs?

Periprosthetic fracture as a revision cause was more common in the uncemented Oxford Partial compared with the cemented Oxford Partial, which is supported by previous studies [12, 13]. Nevertheless, a recent meta-analysis concluded that good results can be achieved for uncemented UKAs, comparable to cemented prostheses, when surgeons are aware of the different risk factors of causing fracture, like excessive press fit (interference fit) and impaction technique [5]. The interference fit may introduce an additional risk and be less forgiving of surgical errors, especially for patients at higher risk of periprosthetic fracture. One small study suggested techniques for intraoperative testing of the bone quality as a tool to select fixation methods [7]. Hiranaka et al. [10] found an increased fracture risk in patients with very small tibial components; the authors recommended cemented fixation for this group. Consequently, the implantation of an uncemented tibial component may be a more challenging procedure, requiring more surgical experience and skill. The risk of fracture with uncemented implants needs to be further investigated. Badawy et al. [3, 4] showed that in general, the results for UKAs are better for hospitals with a higher patient volume. Thus, for low-volume hospitals and surgeons, the cemented implant might be the best option. However, data on surgeon case load and experience were not reported to the Norwegian Arthroplasty Register. There was a higher revision risk for polyethylene wear/damage the first 2.5 years for the uncemented Oxford Partial compared with the cemented version, and it was more common that this reason for revision was reported with polyethylene luxation. Polyethylene damage could have been a consequence of the luxation. Again, this would lead the authors here to recommend use of the cemented Oxford Partial, given that

it can be more widely used, independent of bone quality, size of bone, gender, or age of the patient.

Conclusion

This study did not find any overall differences in the revision risk at 5 years between the three Oxford unicompartmental knee designs. We found an improvement with less risk of femoral loosening for the cemented Oxford Partial compared with the older Oxford III, but we found more periprosthetic fractures and infections for the uncemented Oxford Partial knee. The cemented Oxford Partial appears to be an acceptable replacement for the previous Oxford III at 5 years and should be preferred over the uncemented version. Future studies should focus on reasons for infection and fracture associated with the use of an uncemented implant.

Acknowledgment We would like to thank the Norwegian orthopaedic surgeons for their excellent reporting to the registry.

References

1. Anand R, Graves SE, de Steiger RN, et al. What is the benefit of introducing new hip and knee prostheses? *J Bone Jt Surg*. 2011; 93(Suppl 3):51-54.
2. Australian Orthopaedic Association National Joint Replacement Registry. Hip, knee and shoulder arthroplasty 2022 annual report. Available at: https://aoanjrr.sahmri.com/documents/10180/732916/AOA+2022+AR+Digital/f63ed890-36d0-c4b3-2e0b-7b63e2071b16. Accessed March 1, 2022.
3. Badawy M, Espehaug B, Indrekvam K, et al. Influence of hospital volume on revision rate after total knee arthroplasty with cement. *J Bone Joint Surg Am*. 2013;95:e131.
4. Badawy M, Fenstad AM, Bartz-Johannessen CA, et al. Hospital volume and the risk of revision in Oxford unicompartmental knee arthroplasty in the Nordic countries - an observational study of 14,496 cases. *BMC Musculoskelet Disord*. 2017;18:388.
5. Burger JA, Jager T, Dooley MS, et al. Comparable incidence of periprosthetic tibial fractures in cementless and cemented unicompartmental knee arthroplasty: a systematic review and meta-analysis. *Knee Surg Sports Traumatol Arthrosc*. 2022;30: 852-874.
6. Dyrhovden GS, Lygre SHL, Badawy M, et al. Have the causes of revision for total and unicompartmental knee arthroplasties changed during the past two decades? *Clin Orthop Relat Res*. 2017;475:1874-1886.
7. Eckert JA, Jaeger S, Klotz MC, et al. Can intraoperative measurement of bone quality help in decision making for cementless unicompartmental knee arthroplasty? *Knee*. 2018;25:609-616.
8. Furnes O, Espehaug B, Lie SA, et al. Failure mechanisms after unicompartmental and tricompartmental primary knee replacement with cement. *J Bone Joint Surg Am*. 2007;89:519-525.
9. Hefny MH, Smith NA, Waite J. Cementless medial Oxford unicompartmental knee replacement. Five-year results from an independent series. *Knee*. 2020;27:1219-1227.
10. Hiranaka T, Yoshikawa R, Yoshida K, et al. Tibial shape and size predicts the risk of tibial plateau fracture after cementless unicompartmental knee arthroplasty in Japanese patients. *Bone Joint J*. 2020;102:861-867.
11. Kerens B, Boonen B, Schotanus MG, et al. Revision from unicompartmental to total knee replacement: the clinical outcome depends on reason for revision. *Bone Joint J*. 2013;95: 1204-1208.
12. Knifsund J, Reito A, Haapakoski J, et al. Short-term survival of cementless Oxford unicondylar knee arthroplasty based on the Finnish Arthroplasty Register. *Knee*. 2019;26:768-773.
13. Mohammad HR, Matharu GS, Judge A, et al. Comparison of the 10-year outcomes of cemented and cementless unicompartmental knee replacements: data from the National Joint Registry for England, Wales, Northern Ireland and the Isle of Man. *Acta Orthop*. 2020;91:76-81.
14. Mohammad HR, Matharu GS, Judge A, et al. A matched comparison of revision rates of cemented Oxford unicompartmental knee replacements with single and twin peg femoral components, based on data from the National Joint Registry for England, Wales, Northern Ireland and the Isle of Man. *Acta Orthop*. 2020;91:420-425.
15. National Joint Registry. 19th Annual Report. Available at: https://www.ncbi.nlm.nih.gov/books/NBK587525/pdf/Bookshelf_NBK587525.pdf. Accessed December 31, 2021.
16. Norwegian Arthroplasty Register. 2022 Annual Report. Available at: https://helse-bergen.no/seksjon/Nasjonal_kompetansetjeneste_leddproteser_hoftebrudd/Share%20point%20Documents/Rapport/Report%202022%20english.pdf. Accessed September 1, 2022.
17. Reiner T, Jaeger S, Schwarze M, et al. The stability of the femoral component in the Oxford unicompartmental knee replacement: a comparison of single and twin peg designs. *Bone Joint J*. 2014; 96:896-901.
18. Reiner T, Schwarze M, Panzram B, et al. The influence of the twin peg design on femoral interface temperature and maximum load to failure in cemented Oxford unicompartmental knee arthroplasty. *Clin Biomech (Bristol, Avon)*. 2018;55:23-27.
19. Swedish Arthroplasty Register. Annual report 2022; the Swedish Arthroplasty Register. Available at: https://registercentrum.blob.core.windows.net/sar/r/SAR-Annual-Report-2022_EN-HkgQE89Nus.pdf. Accessed October 2, 2022.
20. Sun XW, Lu FF, Zou K, et al. Does new instrument for Oxford unicompartmental knee arthroplasty improve short-term clinical outcome and component alignment? A meta-analysis. *J Orthop Surg Res*. 2020;15:386.
21. Tu Y, Xue H, Ma T, et al. Superior femoral component alignment can be achieved with Oxford microplasty instrumentation after minimally invasive unicompartmental knee arthroplasty. *Knee Surg Sports Traumatol Arthrosc*. 2017;25:729-735.
22. Walker T, Heinemann P, Bruckner T, et al. The influence of different sets of surgical instrumentation in Oxford UKA on bearing size and component position. *Arch Orthop Trauma Surg*. 2017;137:895-902.
23. White SH, Roberts S, Kuiper JH. The cemented twin-peg Oxford partial knee replacement survivorship: a cohort study. *Knee*. 2015;22:333-337.

Radiostereometric measurement of implant migration in robotically assisted vs conventional bi-cruciate stabilized cemented total knee arthroplasty: secondary analysis of a randomized controlled trial

Øystein SKÅDEN [1,2], Ove Nord FURNES [2,3], Stein Håkon Låstad LYGRE [3,5], Irene Ohlen MOLDESTAD [4], Geir HALLAN [3,6], Anne Marie FENSTAD [3], Paul Johan HØL [2,4], and Øystein Johannes GØTHESEN [1,2]

[1] Haugesund Hospital for Rheumatic Diseases, Haugesund; [2] Department of Clinical Medicine, University of Bergen, Bergen; [3] Norwegian Arthroplasty Register, Department of Orthopaedic Surgery, Haukeland University Hospital, Helse Bergen HF, Bergen; [4] Biomatlab, Department of Orthopaedic Surgery, Haukeland University Hospital, Helse Bergen HF, Bergen; [5] Department of Occupational Medicine, Haukeland University Hospital, Helse Bergen, Bergen; [6] Coastal Hospital in Hagevik, Helse Bergen, Bergen, Norway
Correspondence: oystein.skaden@hsr.as
Submitted 2024-08-19. Accepted 2025-01-23.

Background and purpose — Robotically assisted computer navigation (robotic) has been developed to improve the positioning in total knee arthroplasties (TKAs), attempting to achieve better functional results and longevity of the prostheses. However, the benefit of robotics is still controversial. The aim of our study was to compare migration between robotic and conventional techniques in cemented bi-cruciate stabilized TKAs, using radiostereometric analysis (RSA) based on a secondary analysis of a randomized controlled trial (RCT).

Methods — We enrolled 60 TKA patients from one hospital (2020–2021), with osteoarthritis or arthritic disease. The patients were examined up to 24 months after the surgery, to estimate the mechanical stability of the tibial component. The maximum total point motion (MTPM) representing the magnitude of migration, the largest negative (subsidence) and positive (lift-off) value for y-translation, and prosthetic rotations were measured. The migration in the 2 groups was compared and the precision evaluated.

Results — 51 RSA marked TKAs were available for a comparison of tibial migration between robotically assisted (n = 26) and conventional operations (n = 25). The MTPM in the first year was 0.44 mm and 0.64 mm, and at 24 months 0.46 mm and 0.75 mm, for the conventional and the robotic groups, respectively. The robotic group migrated more than the conventional group at 2 years, 0.21 mm (95% confidence interval [CI] 0.05–0.44; P = 0.01). The overall median MTPM for the investigated implants (both groups) up to 12 months was 0.54 mm (CI 0.44–0.63), and 0.19 mm between 12 and 24 months (CI 0.16–0.22). The magnitude of migration and rotation around the 3 axes was small for both groups, but flexion/extension migration of the tibial component was slightly higher in the robotic group 0.14° (CI 0.00–0.33; P = 0.049).

Conclusion — MTPM and flexion/extension migrations of the tibial component were higher for the robotic group, up to 24 months. The overall migration pattern for the bi-cruciate stabilized implant was acceptable.

Total knee arthroplasty (TKA) is an effective treatment for severe osteoarthritis (OA), with an excellent overall survival rate [1]. However, up to 20% of patients are reportedly dissatisfied due to residual pain, discomfort, and restricted knee function [2]. Computer navigation systems aid in accurate implant positioning and alignment but have not yet shown to improve clinical results and longevity of the implant [3-10]. Robotic computer navigation systems execute bone cuts/burring in the pursuit of even more precise implant fitting than regular computer navigation systems. The downsides are higher costs and increased operating time. Conventional instrumentation is cost effective, with the challenge being repeatable accuracy in component positioning and extremity alignment. Gøthesen et al. [11] showed in a study from the Norwegian Arthroplasty Register (NAR) that the short-term risk of revision was either the same or higher for computer-assisted surgery (CAS) compared with conventional surgery (CONV) and depended more on the brand of the prosthesis. A later study from Dyrhovden et al. [8] with longer follow-up showed similar results for CAS compared with conventional TKAs, but fewer revisions for malalignment for CAS. A bi-cruciate stabilized prosthesis emulating the native anatomy and kinematics of the human knee (Journey II BCS, Smith & Nephew, Memphis, TN, USA) was developed in pursuit of a better functional outcome. This implant has not yet been evaluated through a radiostereometric analysis (RSA). A

DOI 10.2340/17453674.2025.43081

10-year survivorship with ODEP (Orthopaedic Data Evaluation Panel) 10 A, or a minimum of 2 years' RSA evaluation showing safe migration patterns, is advised before use of prosthesis implants in everyday clinical practice in Norway, to avoid using implants susceptible to early aseptic loosening and revision [12]. To our knowledge this is the first RSA analysis comparing a robotic with a conventional technique for TKA.

The aim of our study was to compare migration between robotic and conventional techniques in cemented bi-cruciate stabilized TKA using radiostereometric analysis (RSA).

Methods

Study design

This is a study based on a secondary analysis of RSA data collected from the first 60 patients enrolled in a larger randomized controlled trial (RCT). The results from the primary RCT will be reported as 2-year clinical and radiological outcome of robotic versus conventionally operated total knees (214 patients) when follow-up is completed.

The trial was designed and conducted according to the CONSORT statement guidelines for reporting of parallel group randomized trials [13], and the checklist from the guideline for RSA implant migration measurements was used [14].

Patients were block-randomized (2 or 4 cases in each block) and assigned, in a 1:1 ratio, to either robotically assisted or conventional TKA, to ensure equal numbers of each method per surgeon. The randomized lists for each surgeon were created according to software randomization and kept at a separate location from the operating department. Surgeons called a research assistant before surgery and were informed of the assigned method (conventional or robotic).

The patients and observers (physiotherapist and radiologists) were blinded to which surgical method was used. 60 patients were enrolled in the RSA analysis, where 36 (18 in each arm) had complete data sets and 51 had index plus 1 or more image(s) ready for analysis.

Setting

Patients were recruited and treated at Haugesund Hospital for Rheumatic Diseases (HSR) in Norway by 2 experienced arthroplasty surgeons (22 and 29 operations each in the study). The surgeons performed 10 robotically assisted TKAs, as well as cadaver operations prior to patient inclusion in the trial.

Patients

Inclusion criteria were patients with an age from 45–85 years old, with primary or secondary osteoarthritis (OA).

Exclusion criteria included active infection, degenerative neuromuscular disease, active metastasizing cancer, severe cardio- or pulmonary disease, ASA class 4, dementia, serious systemic disease, and previous fracture or deformity making use of intramedullary rods impossible.

Intervention

The bi-cruciate stabilized Journey II BCS total knee replacement (Smith & Nephew, Memphis, TN, USA) was implanted in all knees using Palacos R+G cement (Heraeus, Hanau, Germany). The patella was resurfaced, and the lower limit for remaining patellar thickness was 12 mm. In the conventional group the measured resection technique [15] with a default of 3° tibial posterior slope, and 5–7° valgus on the distal femoral cut, aiming for a neutral mechanical alignment, was used. For the robotic group (NAVIO system, Smith & Nephew, Memphis, TN, USA) we used a functional alignment technique [16], starting with components in mechanical overall alignment (software default), then shape-matching to the bony and cartilaginous structures, and finally adjusting the gaps in flexion and extension, to comply with good ligament balance, restricted to 2° valgus and 4° varus. If ligament balance was not met within these restrictions, soft tissue release was performed. Tibial posterior slope was rarely altered from the system default of 3°. A hand-held robotic burr was used for the distal femoral cut and for holes supporting the tibia cutting guide, which was secured in place by additional speed pins. The cutting guide position was checked with the navigation system before cuts were performed. The cut surfaces were in some cases refined with a burr, for better accuracy and component fitting. Conventional operations were all performed with intramedullary rods for both tibia and femur. A torniquet was used for all procedures, as well as a 1-phase cementing technique, after pulsed lavage. Tranexamic acid i.v. injection 1.5 g was administered 10 minutes before surgery for all patients. No drains were used. Anti-thrombotic medication (Fragmin 5,000 U) was administered as a subcutaneous injection 10 hours after surgery and continued for 14 days (self-administration). Antibiotic prophylaxis (cefazoline 2 g i.v. injection) was administered 30–20 minutes before surgery, then after 4, 8, and 12 hours. The skin incision was closed with running mattress sutures. The operated knee was positioned in 90° flexion for 2 hours post-surgery to reduce hematoma. The patients were mobilized and allowed full weightbearing after surgery and trained with standardized exercises from the first postoperative day.

RSA

For the RSA analysis, 6 tantalum markers (diameter 0.8 and 1.0 mm) were inserted during surgery into the polyethylene through slightly undersized drilled tunnels. In the tibial metaphysis, 9 tantalum markers (1.0 mm) were inserted according to a defined protocol, before the tibial component was implanted. No additional incision was used in this study as the reflector disc pins were drilled bi-cortically into bone within the primary incision in both femur and tibia, extending the incision slightly in some of the robotic cases.

The index RSA radiographs were taken on day 1, 2, or 3 (conventional mean 1.7 days, SD 0.5, robotic mean 2.0 days, SD 0.5) after weightbearing, and repeated at 3, 12 (conventional

mean 386 days, SD 18, robotic mean 386 days, SD 22), and 24 months after surgery. The patients were supine with the knee positioned inside a biplane calibration cage (cage 10; RSA Biomedical, Umeå, Sweden) according to a technique described earlier [17]. 1 portable X-ray tube and 1 gantry-mounted X-ray tube were used to obtain 2 simultaneous exposures at a 90° angle. For radiographic imaging, we used high-definition digital plates (Agfa CR MD 4.0) and for plate reading we used the ADC compact digitizer (Agfa, Mortsel, Belgium).

The investigators involved in the RSA examinations and analysis were blinded to the patient allocation. However, the fixator pin holes securing the reflector discs could be seen on some of the index images from the robotic group. The RSA measurements were possible if 3 or more of the markers were visible in each segment for repeated examinations. Translation and rotation of the tibial component relative to bone was calculated using the markers in the polyethylene insert as the moving segment and tibia as the fixed reference segments (UmRSA Digital Measure version 6.0; RSA Biomedical, Chatham, Kent, UK).

The precision of the RSA measurements was calculated after double examinations at 12 months and showed a mean difference of maximum total point motion (MTPM) of 0.13 mm (CI 0.10–0.17) in the conventional group and 0.14 mm (CI 0.10–0.18) in the robotic group.

Mean and SD of number of markers, condition number, and mean error of body fitting for each rigid body at the primary follow-up timepoint were 5.72 (0.54), 25.4 (5.31), and 0.08 (0.16) respectively.

Outcomes

The movements of the implant were measured along and around a medially directed axis (x-axis, anteroposterior rotation [AP]), sagittal axis (z-axis, varus–valgus rotation), and longitudinal axis (y-axis, internal–external rotation) of the knee. The condition number was set at 150, and the upper limit for mean error of body fitting at 0.35 to ensure proper stability and distribution of the tantalum markers [17,18]. Translations were expressed as MTPM, subsidence, and lift-off. MTPM represents the 3-D vector of the prosthetic marker that moved the most and is a measure of the magnitude of migration only [19]. The largest positive Y-translation was called lift-off and the largest negative Y-translation was called subsidence. The calculations were performed according to the orthogonal right-handed coordinate system.

The primary outcome for this RSA analysis was MTPM of the tibial components at 1 and 2 years after surgery with robotic and conventional technique.

The secondary outcomes were x-, y-, and z rotation, subsidence, and lift-off of the tibial component.

Statistics

A power analysis previously used in a similar study [20] was used to determine the number of patients included in this present analysis, claiming 0.1 mm as a clinically relevant between-group difference, and with an anticipated repeatability of 0.1 mm in the RSA measurements. A group sample size of 17 would achieve 80% power to detect a difference of 0.1 between groups with an estimated standard deviation of 0.1 and with a significance level of (alfa) 0.05, using a 2-sided, 2-sample t-test. To ensure proper sample size at 2 and 5 years we chose to include 60 patients in the study, 30 in each group.

To evaluate the RSA measurement precision, the difference between double measurements was calculated after 1 year. We also calculated the standard deviation (SD) of the differences with respect to zero [21].

Magnitude and progress of migration are presented as mean values, whereas for the difference between groups the median values are used, and only absolute values were analyzed. The Mann–Whitney test was used to compare the conventional and robotic groups for migration. The Shapiro–Wilk and Pearson test showed that migration data was not normally distributed, so both median and interquartile range (IQR) are reported. Pearson's chi-square test was used to assess the differences in age, sex, and diagnosis. For statistical analysis, the median difference and the corresponding CI for the median difference for each migration and clinical parameter were calculated as described by Campbell and Gardner (1988)[22]. P value < 0.05 was considered significant. Statistical evaluation was performed using Stata version 18 (StataCorp LLC, College Station, TX, USA).

Ethics, registration, data sharing plan, funding, use of AI, and disclosures

The study was registered in the trial database at ClinicalTrials.gov (identifier: NCT04525950) on September 7, 2020. The trial was approved by the regional committee for medical and health research ethics (REK), Bergen, Norway on March 4, 2020 (ref.no.68448 NAVIO HSR). Haugesund Sanitetsforenings Forskningsfond gave financial support. AI tools were not used at any stage in this submission, and no author had any conflict of interest. Data is available by contacting the corresponding author.

Complete disclosure of interest forms according to ICMJE are available on the article page, doi: 10.2340/17453674.2025.43081

Results

We enrolled 60 patients between September 2020 and June 2021 where 55 were sufficiently tantalum marked, excluding 3 patients with no RSA cage, 1 with no image taken on day 2–3 after surgery, leaving 51 for analysis, 26 in the robotic and 25 in the conventional group. Some of the patients did not have a full data set, for various reasons, but were included if at least 2 RSA examinations, including the index examination, were performed (Figure 1) and omitted from those time points

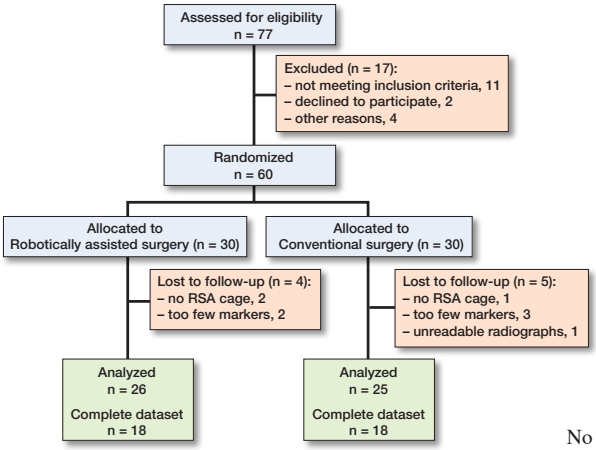


Figure 1. Flowchart of patients included in the study.

Table 1. Patient characteristics and operating time. Data presented as count or mean (SD)

Factor	Conventional n = 25	Robotic n = 26
Men	10	14
Mean age (SD)	67.7 (3.9)	65.7 (3.7)
ASA class		
1	1	4
2	20	16
3	3	6
Missing	1	–
Diagnosis		
Idiopathic osteoarthritis	18	19
Other	7	7
Mean operating time, minutes (SD)	88 (17)	103 (19)

where no images were captured. The last follow-up images were captured in June 2023.

1 of the included patients died before the 2-year examination.

The operating time was 103 minutes (SD 19) in the robotic group and 88 minutes (SD 18) minutes in the conventional group (Table 1).

Outcome

The tibial component migrated most during the first 3 months for both groups and tapered off thereafter (Figure 2). The mean MTPM up to 12 and 24 months was higher in the robotic: 0.64 mm (CI 0.49–0.78) and 0.75 mm (CI 0.57–0.92), than in the conventional group: 0.44 mm (CI 0.33–0.56) and 0.46 mm (CI 0.37–0.54), respectively (Table 2). The median difference in MTPM between the robotic and conventional group was 0.14 mm (CI 0.02–0.35; P = 0.03) and 0.21 mm (CI 0.05– 0.44; P = 0.01) at 12 and 24 months respectively (Table 3).

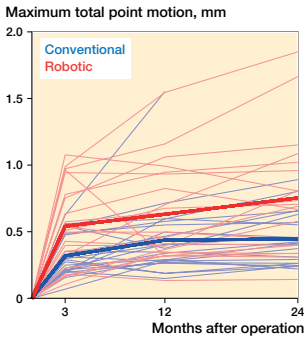


Figure 2. Spaghetti plot with individual and mean maximum total point motion.

No difference was found between the groups for the median migration between 12 and 24 months, 0.03 mm (CI –0.01 to 0.08; P = 0.1) (Table 3).

The overall mean MTPM migration up to 12 months for all patients was 0.54 mm (CI 0.44–0.63) and the overall mean MTPM migration between 12 and 24 months was 0.19 mm (CI 0.16–0.23).

The median difference between the groups for flexion/extension migration of the tibia at 24 months was 0.14° (CI 0.00–0.33), P = 0.049 (Table 3).

There were no significant differences between the groups for maximum subsidence and lift-off at 12 and 24 months.

Discussion

This is the first study to compare implant migration in a robotically assisted computer-navigated technique with conventional TKAs. The use of robotic assistance for the implantation of the bi-cruciate stabilized prosthesis was associated with an increased migration of the tibial component occurring within the observation period. However, the migration of the robotic group tapered off, and did not migrate more than the conventional group between 12 and 24 months. The overall migration for the bi-cruciate stabilized implant, regardless of operating technique, was within acceptable limits. There were 4 patients with MTPM migration at 12 months above 1.0 mm in the robotic group, the highest being 1.5 mm, whereas in the conventional group only 1 patient was above 1.0 mm (1.5 mm).

The mean MTPM migration from 12 to 24 months was not significantly different between the groups, measuring < 0.2 mm in the conventional and just above 0.2 mm in the robotic group. In a previous study by Ryd et al., the limit for strict continuous migration (SCM) was set at 0.2 mm after 12 months, above which the risk of aseptic loosening was increased [19]. The overall migration up to 12 months was 0.54 mm and 0.19 mm from 12–24 months. Pijls et al. suggested a limit

Table 2. Migration up to 24 months for the conventional and the robotic group

Factor	Conventional		Robotic	
Months FU	Median [IQR]	Mean (CI)	Median [IQR]	Mean (CI)
X-axis rotation [flexion–extension] (°, absolute value)				
3	0.09 [0.05–0.22]	0.14 (0.09–0.20)	0.12 [0.07–0.26]	0.20 (0.12–0.27)
12	0.14 [0.06–0.26]	0.21 (0.12–0.29)	0.32 [0.10–0.41]	0.30 (0.20–0.39)
24	0.15 [0.05–0.32]	0.20 (0.13–0.27)	0.36 [0.14–0.55]	0.39 (0.25–0.53)
Y-axis rotation [internal–external] (°, absolute value)				
3	0.09 [0.04–0.20]	0.13 (0.08–0.19)	0.11 [0.08–0.19]	0.14 (0.09–0.20)
12	0.13 [0.08–0.24]	0.22 (0.07–0.37)	0.23 [0.08–0.33]	0.24 (0.16–0.31)
24	0.14 [0.09–0.25]	0.19 (0.12–0.26	0.27 [0.07–0.43]	0.30 (0.19–0.42)
Z-axis rotation [varus–valgus] (°, absolute value)				
3	0.09 [0.05–0.14]	0.10 (0.07–0.13)	0.09 [0.06–0.26]	0.23 (0.10–0.35)
12	0.16 [0.06–0.26]	0.17 (0.11–0.24)	0.11 [0.06–0.27]	0.24 (0.11–0.36)
24	0.13 [0.07–0.21]	0.17 (0.09–0.24)	0.10 [0.05–0.20]	0.24 (0.10–0.37)
Maximum total point motion, mm				
3	0.29 [0.20–0.49]	0.35 (0.27–0.44)	0.47 [0.28–0.77]	0.52 (0.40–0.65)
12	0.39 [0.28–0.55]	0.44 (0.33–0.56)	0.48 [0.38–0.94]	0.64 (0.49–0.78)
24	0.42 [0.26–0.63]	0.46 (0.37–0.54)	0.70 [0.40–0.99]	0.75 (0.57–0.92)
12–24 [a]	0.16 [0.12–0.20]	0.16 (0.14–0.19)	0.19 [0.14–0.26]	0.23 (0.16–0.29)
Maximum lift-off, mm				
3	0.09 [0.05–0.13]	0.09 (0.06–0.12)	0.13 [0.04–0.24]	0.21 (0.11–0.30)
12	0.11 [0.07–0.24]	0.14 (0.09–0.19)	0.18 [0.11–0.33]	0.25 (0.15–0.36)
24	0.13 [0.05–0.22]	0.15 (0.10–0.21)	0.15 [0.10–0.42]	0.28 (0.17–0.40)
Maximum subsidence, mm				
3	0.08 [0.05–0.12]	0.10 (0.07–0.14)	0.12 [0.06–0.16]	0.14 (0.08–0.20)
12	0.09 [0.06–0.17]	0.13 (0.07–0.19)	0.13 [0.04–0.23]	0.17 (0.05–0.29)
24	0.11 [0.04–0,18]	0.13 (0.07–0.20)	0.14 [0.04–0.28]	0.21 (0.06–0.36)

[a] Migration between 12 and 24 months for conventional and robotic
IQR = Interquartile range; CI = 95% confidence interval; FU= follow-up.

Table 3. Median difference in migration between robotic and conventional cemented tibial components up to 24 months, and between 12 and 24 months

Factor	Conventional median	Robotic median	Median difference (CI)	P value
Conventional vs robotic at 12 months				
X rotation	0.14	0.32	–0.09 (–0.22 to 0.02)	0.1
Y rotation	0.13	0.23	–0.05 (–0.15 to 0.03)	0.3
Z rotation	0.16	0.11	0.01 (–0.06 to 0.09)	0.7
MTPM	0.42	0.70	–0.14 (–0.35 to –0.02)	0.03
Lift-off	0.11	0.18	–0.06 (–0.14 to 0.03)	0.1
Subsidence	0.09	0.13	0.01 (–0.06 to 0.09)	0.7
Conventional vs robotic at 24 months				
X rotation	0.15	0.36	–0.14 (–0.33 to –0.00)	0.049
Y rotation	0.14	0.27	–0.07 (–0.23 to 0.04)	0.3
Z rotation	0.13	0.11	0.00 (–0.07 to 0.06)	0.99
MTPM	0.42	0.70	–0.21 (–0.44 to –0.05)	0.01
Lift-off	0.13	0.15	–0.06 (–0.18 to 0.01)	0.1
Subsidence	0.11	0.14	0.03 (–0.06 to 0.12)	0.5
Conventional vs robotic from 12–24 months				
MTPM	0.16	0.19	–0.03 (–0.08 to 0.01)	0.1
Lift-off			–0.02 (–0.06 to 0.01)	0.3
Subsidence			0.01 (–0.04 to 0.03)	0.8

CI = 95% confidence interval; MTPM = maximum total point motion.

for unacceptable migration with a high rate of early aseptic loosening at 1.6 mm at 12 months, and under 0.5 mm was considered the limit under which all studies showed acceptable survival of the prostheses [23]. These thresholds were reaffirmed in a recent updated systematic review [24]. In the light of these previous studies, we conclude that the overall migration in the present study was within acceptable limits. A previous randomized clinical RSA study comparing conventional with navigated cemented Profix CR TKAs [20] as well as a recent cohort study with a new ball-in-socket (BS) medial conformity CR TKA [25] had lower MTPM migration values up to 24 months than the values measured in our study, while another RSA study comparing the results of a symmetrical cemented PS (NexGen, Zimmer Biomet) to an asymmetrical cemented PS (Persona, Zimmer Biomet, Warsaw, IN, USA) TKA, had higher MTPM migration values up to 24 months [26]. A recent RSA cohort study shows a higher risk of aseptic loosening for PS compared with CR TKAs [27]. The migration in the robotic group was higher than in the conventional group in our study, but lower than the migration patterns of both tibial components in the Nexgen-Persona study.

Strengths

The main strength of this analysis is the RCT design comparing migration between robotic and conventional TKA alignment techniques. The number of patients was sufficient to evaluate whether there was a statistically and clinically significant difference in implant migration between the groups [26,28]. 2 experienced arthroplasty surgeons from the same department (ØS and ØG) operated on every case together; consequently, there could be only small variations regarding the surgery.

Limitation

The main limitation was that the number of participants was too small to evaluate subgroups (age groups and implant sizes) within the study population. The study did not evaluate the migration of the femoral component. Only the tibial component migration was investigated, as aseptic loosening is more common on the tibial side.

The patients in the robotic group had bi-cortical metaphyseal pin holes in the tibia for the reflector disc assembly, more distal tibial cutting guide fixation, no opening of the tibial intramedullary canal, different alignment technique, and a higher degree of femoral component flexion (4° vs 2°). The alignment target differed between the groups and could theoretically lead to more shear forces and changes in migration.

Conclusion

The cemented bi-cruciate stabilized total knee implant migrates more in the first 2 years, when operated with robotic assistance, but after year 1 the migration pattern did not differ for the 2 techniques. However, the overall migration pattern is considered within safe limits.

ØS: designed the study, acquired data and wrote the manuscript. ØG: co-designed the study, analyzed data, and reviewed the manuscript. OF: co-designed the study and reviewed the manuscript. SHLL: analyzed the data, reviewed the manuscript, and contributed to figures and tables. IOM: produced the RSA data and reviewed the manuscript. GH, PJH: reviewed the manuscript. AMF: analyzed the data and reviewed the manuscript.

The authors would like to thank radiographers at Haugesund Hospital, Helse Fonna, for producing high-quality RSA images, and coordinator Beathe Angstaur for organizing all the patient follow-ups.

They also would like to thank the surgical team and staff at the Orthopaedic Department of Haugesund Hospital for Rheumatic diseases (RKO) for all support and help with this study, and Haugesund Sanitetsforenings Forskningsfond for the financial support.

They thank Randi Furnes for help with the randomization of patients.

Handling co-editors: Keijo Makela and Robin Christensen
Acta thanks Poul Torben Nielsen and Olof Sandberg for help with peer review of this manuscript.

1. **Hamel M B, Toth M, Legedza A, Rosen M P.** Joint replacement surgery in elderly patients with severe osteoarthritis of the hip or knee: decision making, postoperative recovery, and clinical outcomes. Arch Intern Med 2008; 168: 1430-40. doi: 10.1001/archinte.168.13.1430.
2. **Bourne R B, Chesworth B M, Davis A M, Mahomed N N, Charron K D.** Patient satisfaction after total knee arthroplasty: who is satisfied and who is not? Clin Orthop Relat Res 2010; 468: 57-63. doi: 10.1007/s11999-009-1119-9.
3. **Spencer J M, Chauhan S K, Sloan K, Taylor A, Beaver R J.** Computer navigation versus conventional total knee replacement: no difference in functional results at two years. J Bone Joint Surg Br 2007; 89: 477-80. doi: 10.1302/0301-620X.89B418094.
4. **Kim Y H, Kim J S, Choi Y, Kwon O R.** Computer-assisted surgical navigation does not improve the alignment and orientation of the components in total knee arthroplasty. J Bone Joint Surg Am 2009; 91: 14-19. doi: 10.2106/JBJS.G.01700.
5. **Longstaff L M, Sloan K, Stamp N, Scaddan M, Beaver R.** Good alignment after total knee arthroplasty leads to faster rehabilitation and better function. J Arthroplasty 2009; 24: 570-8. doi: 10.1016/j.arth.2008.03.002.
6. **Lad D G, Thilak J, Thadi M.** Component alignment and functional outcome following computer assisted and jig based total knee arthroplasty. Indian J Orthop 2013; 47: 77-82. doi: 10.4103/0019-5413.106915.
7. **Lutzner J, Dexel J, Kirschner S.** No difference between computer-assisted and conventional total knee arthroplasty: five-year results of a prospective randomised study. Knee Surg Sports Traumatol Arthrosc 2013; 21: 2241-7. doi: 10.1007/s00167-013-2608-7.
8. **Dyrhovden G S, Gothesen O, Lygre S H, Fenstad A M, Soras T E, Halvorsen S, et al.** Is the use of computer navigation in total knee arthroplasty improving implant positioning and function? A comparative study of 198 knees operated at a Norwegian district hospital. BMC Musculoskelet Disord 2013; 14: 321. doi: 10.1186/1471-2474-14-321.
9. **Blakeney W G, Khan R J, Palmer J L.** Functional outcomes following total knee arthroplasty: a randomised trial comparing computer-assisted surgery with conventional techniques. Knee 2014; 21: 364-8. doi: 10.1016/j.knee.2013.04.001.
10. **Gothesen O, Espehaug B, Havelin L I, Petursson G, Hallan G, Strom E, et al.** Functional outcome and alignment in computer-assisted and conventionally operated total knee replacements: a multicentre parallel-group randomised controlled trial. Bone Joint J 2014; 96-B: 609-18. doi: 10.1302/0301-620X.96B5.32516.
11. **Gothesen O, Espehaug B, Havelin L, Petursson G, Furnes O.** Short-term outcome of 1,465 computer-navigated primary total knee replacements 2005–2008. Acta Orthop 2011; 82: 293-300. doi: 10.3109/17453674.2011.575743.
12. **Annual Report, Norwegian Arthroplasty Register.** Available from: https://www.kvalitetsregistre.no/sites/default/files/2022-09/%C3%85rsrapport%202021%20Nasjonalt%20Leddproteseregister%202021.pdf. 2022
13. **Schulz K F, Altman D G, Moher D.** CONSORT 2010 statement: updated guidelines for reporting parallel group randomised trials. J Pharmacol Pharmacother 2010; 1: 100-7. doi: 10.4103/0976-500X.72352.
14. **Kaptein B L, Pijls B, Koster L, Kärrholm J, Hull M, Niesen A, et al.** Guideline for RSA and CT-RSA implant migration measurements: an update of standardizations and recommendations. Acta Orthop 2024; 95: 256-67. doi: 10.2340/17453674.2024.40709.
15. **Whiteside L A.** Soft tissue balancing: the knee. J Arthroplasty 2002; 17: 23-7. doi: 10.1054/arth.2002.33264.
16. **Shatrov J, Foissey C, Kafelov M, Batailler C, Gunst S, Servien E, Lustig S.** Functional alignment philosophy in total knee arthroplasty: rationale and technique for the valgus morphotype using an image based robotic platform and individualized planning. J Pers Med 2023; 13. doi: 10.3390/jpm13020212.
17. **Henricson A, Linder L, Nilsson K G.** A trabecular metal tibial component in total knee replacement in patients younger than 60 years: a two-year radiostereophotogrammetric analysis. J Bone Joint Surg Br 2008; 90: 1585-93. doi: 10.1302/0301-620X.90B12.20797.
18. **Valstar E R, Gill R, Ryd L, Flivik G, Borlin N, Kärrholm J.** Guidelines for standardization of radiostereometry (RSA) of implants. Acta Orthop 2005; 76: 563-72. doi: 10.1080/17453670510041574.
19. **Ryd L, Albrektsson B E, Carlsson L, Dansgard F, Herberts P, Lindstrand A, et al.** Roentgen stereophotogrammetric analysis as a predictor of mechanical loosening of knee prostheses. J Bone Joint Surg Br 1995; 77: 377-83.
20. **Petursson G, Fenstad A M, Gothesen O, Haugan K, Dyrhovden G S, Hallan G, et al.** Similar migration in computer-assisted and conventional total knee arthroplasty. Acta Orthop 2017; 88: 166-72. doi: 10.1080/17453674.2016.1267835.
21. **Ranstam J, Ryd L, Önsten I.** Accurate accuracy assessment: review of basic principles. Acta Orthop Scand 2000; 71: 106-8. doi: 10.1080/00016470052944017.
22. **Campbell M J, Gardner M J.** Calculating confidence intervals for some non-parametric analy-ses. Br Med J 1988; 296: 1454-6. doi: 10.1136/bmj.296.6634.1454.
23. **Pijls B G, Valstar E R, Nouta K A, Plevier J W, Fiocco M, Middeldorp S, et al.** Early migration of tibial components is associated with late revision: a systematic review and meta-analysis of 21,000 knee arthroplasties. Acta Orthop 2012; 83: 614-24. doi: 10.3109/17453674.2012.747052.
24. **Puijk R, Singh J, Puijk R H, Laende E K, Plevier J W M, Nolte P A, et al.** Evaluation and refinement of thresholds for early migration of total knee replacements as an estimator of late aseptic loosening: an updated systematic review of RSA and survival studies. Acta Orthop 2025; 96: 1-10. doi: 10.2340/17453674.2024.42574.
25. **Niesen A E, Tirumalai P A, Howell S M, Hull M L.** A new tibial insert design with ball-in-socket medial conformity and posterior cruciate ligament retention has low tibial baseplate migration after unrestricted kinematically aligned total knee arthroplasty: a cohort study using radiostereometric analysis. Acta Orthop 2024; 95: 758-64. doi: 10.2340/17453674.2024.42489.
26. **Koster L A, Meinardi J E, Kaptein B L, Van der Linden-Van der Zwaag E, Nelissen R.** Two-year RSA migration results of symmetrical and asymmetrical tibial components in total knee arthroplasty: a randomized controlled trial. Bone Joint J 2021; 103-B: 855-63. doi: 10.1302/0301-620X.103B5.BJJ-2020-1575.R2.

27. **Puijk R, Sierevelt I N, Pijls B, Spekenbrink-Spooren A, Nolte P A.** Increased risk of aseptic loosening for posterior stabilized compared with posterior cruciate-retaining uncemented total knee replacements: a cohort study of 13,667 knees from the Dutch Arthroplasty Registry. Acta Orthop 2023; 94: 600-6. doi: 10.2340/17453674.2023.33283.

28. **Kärrholm J, Gill R H, Valstar E R.** The history and future of radiostereometric analysis. Clin Orthop Relat Res 2006; 448: 10-21. doi: 10.1097/01.blo.0000224001.95141.fe.

Graphic design: Communication Division, UiB / Print: Skipnes AS

uib.no

ISBN: 9788230883372 (print)
9788230895290 (PDF)