Mobile or Fixed Bearing Articulation in TKA? A Randomized Evaluation of Gait Analysis, Implant Migration, and Bone Mineral Density

PhD thesis

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Preface

The research for this thesis was conducted from 2007 to 2011 as a collaboration between the Center for Planned Surgery at Silkeborg Regional Hospital, the Gaitlab at Hammel Neurocenter and Professor Kjeld Søballe's Orthopaedic Research group at Aarhus University Hospital.

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Abbreviations

AKSS	American knee society score
AP	Anterior/posterior
ASIS	Anterior superior iliac spine
BMD	Bone mineral density
CAD	Computer-aided design
CV	Coefficient of variation
DXA	Dual-energy x-ray absorptiometry
EMG	Electromyography
FB	Fixed bearing
GC	Gait cycle
LA	Lateral
LCS	Low contact stress
MB	Mobile bearing (= rotating platform)
OA	Osteoarthritis
OKS	Oxford knee score
PA	Posterior/anterior
PCL	Posterior cruciate ligament
PE	Polyethylene
P.F.C.	Press fit condylar
PS	Posterior stabilized
PSIS	Posterior superior iliac spine
RCT	Randomized, controlled clinical trial
RE	Reverse engineering
ROI	Region of interest
ROM	Range of motion
RP	Rotating platform (= mobile bearing)
RSA	Radiostereometric analysis
SD	Standard deviation
TKA	Total knee arthroplasty
TR	Total rotation (in degrees)
TT	Total translation (in mm)
3D	Three dimensional

List of papers

I. Reproducibility of BMD Measurements in the Prosthetic Knee Comparing Knee-Specific Software to Traditional DXA Software: A Clinical Validation. Michael Tjørnild, Kjeld Søballe, Thomas Bender and Maiken Stilling. Journal of Clinical Densitometry: Assessment of Skeletal Health, vol. 14, no. 2, 138-148, 2011

II. Gait Function Before and After Total Knee Arthroplasty. A Randomized Study of Fixed Bearing versus Mobile Bearing Articulation. Michael Tjørnild, Maiken Stilling, Uwe Kersting, Poul Mogensen, and Kjeld Søballe. Manuscript submitted to Journal of Arthroplasty.

III. Migration and Bone Mineral Density in Total Knee Arthroplasty. A Randomized Study Comparing Fixed Bearing to Mobile Bearing Articulation. Michael Tjørnild, Maiken Stilling, Per Møller-Hansen, Carsten Holm, Herluf Kristensen and Kjeld Søballe. Manuscript submitted to Journal of Arthroplasty.

English summary

Total knee arthroplasty (TKA) is the standard treatment of the terminal stadium of osteoarthritis in the knee joint. The good results achieved with from TKA are based on lasting pain relief, misalignment correction and improved function. For more than 30 years, orthopaedic surgeons have had the choice between a traditional fixed bearing tibial polyethylene (PE) insert design and various designs with mobile bearing tibial PE. Several gait analysis studies show the good functional results of TKA with improvements in temporospatial, kinematic, and kinetic measurements. In spite of these improvements, TKA patients still show gait abnormalities. The majority of clinical studies in this field showed no major differences between fixed bearing and mobile bearing articulation designs. The longevity of fixed and mobile bearing articulation designs has been found to be comparable.

The central study aim was to compare a fixed bearing (FB) versus a mobile bearing (MB) articulation (P.F.C. Sigma, Depuy Int., Leeds, UK) to determine which showed the better performance. This central question was attacked from different angles in the 3 studies included in this thesis with the following focus points and results in summary.

Study I validated a new knee-specific software for Dual-energy X-ray Absorptiometry (DXA) scans prior to use in the randomized, clinical trial (Study III). We found cementation to increase the measured bone mineral density (BMD) without negative influence on the reproducibility. Leg rotation around a vertical axis changed the measured BMD; hence careful placement of the leg at follow-up examination was shown to be crucial for good reproducibility. We also compared the knee-specific software to traditional DXA software and found similar performances of the 2 softwares with regard to point typing the implant and the bone edges correctly on DXA scans.

Study II was based on a randomized clinical trial which focused on a comparison of the patients' gait function, surface electromyography, and knee scores between the 2 articulations groups before and afther 6 and 12 months' follow-up. Further, we compared the patients' gait function to that of a height/weight, gender and age matched control group. Fifty-one patients underwent gait analysis 12-months after surgery (26 FB/25 MB). The gait analysis showed normalized cadence for the MB group only. Both the FB and the MB groups improved their gait towards a more asymptomatic gait pattern, but neither the FB nor the MB group achieved a totally asymptomatic gait pattern. Results pointing towards a normalized gait pattern in both groups were the kinematic values, the minimal valgus moment and the decreased co-contraction measured by EMG.

For the FB group, additional improvements were seen in knee extension and maximal extension moment in mid stance.

Study III was based on a randomized clinical trial in which the focus points were a comparison of 1) the migration pattern of the 2 tibial articulation types from baseline and up to 12 months' follow-up assessed by model-based radiostereometric analysis and 2) the BMD in proximity of the tibial implants assessed by DXA scans using the knee-specific DXA software, which was validated in study I. In study III, 50 patients attended a 12 months follow-up (26 FB/24 MB). The FB implants migrated significantly more than the MB implants after 3, 6 and 12 months' follow-up, but the expected decrease in periprosthetic BMD was similar for both implants.

Normalized kinematics and better kinetic results towards a more asymptomatic gait pattern than with the MB articulation count in favor of the FB articulation. The normalized cadence and significantly lower migration at all follow-ups count in favor of the MB articulation. The choice between the two articulation designs is not made crystal clear from this work; both the FB and the MB articulation have their advantages. Future research regarding migration and wear assessment could provide valuable information that will aid the surgeons and patients in making a decision.

Danish summary

Total knæalloplastik (TKA) er den gængse behandling i det terminale stadium af slidgigt i knæleddet. De gode resultater fra TKA er baseret på vedvarende smertelindring, korrektion af fejlstilling og forbedret knæ funktion. I mere end 30 år har ortopædkirurger haft valget mellem en traditionel knæprotese med fastsiddende polyethylen (PE) på tibiaplateauet og forskellige designs med mobile PE indsatser. Flere ganganalyse studier har vist gode funktionelle resultater af TKA med forbedringer i temporospatiale, kinematiske og kinetiske målinger. På trods af disse forbedringer har TKA patienter fortsat vist abnormiteter i ganganalyse. De fleste kliniske undersøgelser på dette område har ikke vist større forskelle mellem de to PE ledtyper. Holdbarheden af kunstige knæled med henholdsvis faste og mobile ledtyper har vist sig at være sammenlignelige.
Det centrale formål med studiet var at undersøge om en fikseret (FB) eller en mobil (MB) ledtype (P.F.C. Sigma, Depuy Int., Leeds, UK) klarede sig bedst. Det centrale spørgsmål blev belyst med forskellige undersøgelsesmetoder i de tre forskningsprojekter, der indgår i denne afhandling med nedenstående fokuspunkter og resultater i resumé.

Studie I validerede en ny knæ-specifik software til Dual-energy X-ray absorptiometry (DXA) scanninger før brug i det kliniske lodtrækningsforsøg (studie III). Vi fandt at brug af knoglecement øgede den målte knoglemineraltæthed (BMD), dog uden negativ indflydelse på reproducerbarheden af målingerne. Rotation af det opererede knæ omkring en lodret akse påvirkede den målte BMD. En omhyggelig placering af benet i en skumpude ved senere scanningsopfølgninger viste sig at være afgørende for at sikre en god reproducerbarhed af scanningerne. Vi sammenlignede også knæ-specifik software med traditionel DXA software og fandt en sammenlignelig præstation af de 2 softwares med hensyn til korrekt idendifikation af protese og knoglekanter på DXA scanningerne.

Studie II blev baseret på et klinisk lodtrækningsstudie, hvor fokuspunkterne var en sammenligning af patienternes gangfunktion, overflade elektromyografi og funktion bedømt ud fra spøgeskemaer før og efter seks og tolv måneders opfølgning mellem de to ledtyper. Som noget nyt sammenlignede vi patienternes gangfunktion med en kontrolgruppe, der var matchet på højde/vægt, køn og alder. 51 patienter deltog i tolv-måneders ganganalyse (26 FB/25 MB). Ganganalysen viste normaliseret kadence for MB gruppen. Både FB og MB-grupperne forbedrede deres gangfunktion i retning af et mere normalt gangmønster, men hverken FB eller MB ledtypen opnåede et helt normalt gangmønster. Resultaterne, der peger på et normaliseret gangmønster i begge grupper var de kinematiske værdier, det minimale valgus moment, og den nedsatte co-kontraktion målt ved elektromyografi. For FB gruppen så vi yderligere forbedringer i knæ ekstension og maksimal knæ ekstensions moment midten af gangcyklus.

Studie III blev baseret på et klinisk lodtrækningsstudie, hvor fokuspunkterne var en sammenligning af 1) migrationen af tibiakomponenten i de to typer artikulation fra baseline og op til 12 måneders opfølgning vurderet ved modelbased radiostereometric analyse og 2) BMD omkring af skinnebensproteserne vurderet ved DXA-scanninger med den knæ-specifikke software, der blev valideret i studie I. I studie III indgik 50 patienter (26 FB/24 MB).
FB proteserne bevægede sig på mikrometerplant signifikant mere end MB proteserne efter tre, seks og tolv måneders opfølgning, men det forventede tab af knogle omkring proteserne i de to ledtyper var sammenligneligt.

En fordel ved FB artikulationen var normaliseret kinematik og bedre kinetiske resultater i retning af et mere asymptomatisk gangmønster end med MB implantat.
Til fordel for MB implantatet tæller den normaliserede kadence og færre mikrobevægelser af protesen i forhold til knoglen ved alle follow-ups.
Valget mellem de to ledtyper er ikke afgjort endeligt med vores resultater. Både FB og MB knæled har sine fordele. Fremtidig forskning vedrørende protesebevægelser og vurdering af slid kan give kirurger og patienter værdifulde oplysninger før beslutningen om operation med enten FB eller MB TKA.

Background

Total knee replacement

Over the past decades TKA surgery has become more common for patients with chronic pain and disability due to impaired knee function. TKA is a final treatment option for these patients, and today this solution is offered to still younger patients because of increased implant longevity and very good functional and clinical results.

Charnley's invention of bone cement revolutionized the procedures with total knee (and hip) replacement [1], and in 1971, Gunston introduced a cemented knee arthroplasty. In his study 22 patients with rheumatoid arthritis were give surface replacement both at the femoral and tibial joint surfaces. All patients had achieved pain relief at up to 2½ years follow-up, but only 13/22 had a post-operative range of motion (ROM) beyond 90 degrees. Other side effects, also known in today's surgery, were peroneal nerve palsy and arthrodesis in 1 patient due to insufficient functional improvement [2]. The achievements were a landslide with great importance to surgical TKA treatment and are still after more than 40 years! With surgery comes the risk of wound infections, which today are better prevented with the regular use of antibiotic containing bone cement, peri-operative antibiotic treatment, and antiseptic procedures around the surgical procedure [3].

The evolution of TKA followed 2 different approaches [4]. The anatomical approach involved implants that preserved most or all of the soft tissue constraints of the physiological knee and aimed to design fixed implants with surfaces that avoided inconsistency with these constraints. The other approach was the functional one, which attempted to simplify knee mechanics by resecting the cruciate ligaments or to design movable joint surfaces to avoid inconsistency with the kinematics that was dictated by soft tissues. The functional approaches allowed geometries not identical to the anatomic human knee surface to maximize the implant surface area and to reduce polyethylene (PE) stress [4]. With both the anatomical and the functional approaches fixed bearing and mobile bearing articulation TKAs have been designed.

Having improved the instant fixation challenge with bone cement and with the ability to prevent infections better, the non-infectious loosening of TKA appeared as a distinct challenge for the years to come [5;6]. According to the Danish Knee Arthroplasty Registry, the prevalence of knee arthroplasty has increased from 98 per 100,000 inhabitants in 1998 to 163 knee arthroplasties per 100,000 inhabitants in 2009. In 2009 87% of TKA patients had primary osteoarthritis (OA) as diagnosis, 10% secondary OA (i.e. after meniscus surgery), and 2% had rheumatoid arthritis. Ninety-seven percent of knee arthroplasties in Denmark were TKAs in 1997–2000 and 90% in 2009 indicating increased use of uni-compartmental arthroplasties over time. The average age at surgery decreased from 68.9 years in 1998 to 67.9 years in 2009. The use of bone

cement as a fixation method increased from 74% in 1997–2000 to 81% in 2009. Survival of cemented implants is superior compared to non-cemented implants, and survival of posterior cruciate ligament retaining implants is superior to posterior stabilized versions according to the Danish Knee Arthroplasty Registry [7].

Mobile bearing TKA

Noiles obtained a patent in 1976 for the Noiles PS Rotating Platform Knee and Revision System, which used metaphyseal sleeves and stems on the tibia and femoral sides. The Oxford mobile bearing TKA concept was introduced by Goodfellow and O'Connor in 1978 to mimic a more physiologic knee articulation than what was possible with the simple hinge principle known thus far. The Oxford meniscal knee system included unconstrained "meniscal" washers between the articulating surfaces of the femur and tibia [8]. This freely mobile bearing was criticized for the relatively frequent dislocations of washers, aseptic loosening, and a high wear rate [9]. The principle was further developed for continuous use in the Oxford uni-compartmental knee arthroplasty that is still used today [10]. As a parallel to the Oxford implant, Buechel and Pappas designed the New Jersey Low-Contact Stress (LCS) TKA with meniscus-bearing and thereafter the LCS rotating platform: a system that proved very durable, with excellent survival and clinical performance [11].

The Press Fit Condylar (P.F.C.) Sigma system was introduced in 1997 as a modification of the earlier P.F.C. system [12]. In 2000, the P.F.C. Sigma rotating platform (RP) was introduced. Common to both the LCS and P.F.C. Sigma mobile bearings is the unrestricted PE rotation ability around a central vertical axis without further sliding features. MB TKA was designed to minimize contact stress on the bearing surface and also to minimize the stresses at the interface of the implant complex to bone. However, a potential complication was dislocation of the polyethylene bearing elements. For the LCS MB system, dislocations was reported in less than 3.5% of cases [13-15]. The current status based on previous publications for the P.F.C. Sigma RP contains both in vitro results and medium-term clinical follow-up. In an in vitro study, Luring et al. showed significantly increased migration of the P.F.C. Sigma RP baseplate when only cementing under the tibial baseplate compared to cementing around the entire tibial tray including the stem; hence they advocated full cementation to prevent migration and early loosening [16]. In a randomized, prospective, clinical study involving bilateral surgery, a P.F.C. Sigma PCL retaining FB articulation was implanted on one side and the MB articulation on the other side. No difference between the FB and the MB articulations was reported regarding complications or clinical outcome. Knee scores (AKSS and Hospital for Special Surgery Score) were both good and so were radiographic results at 5-year follow-up. The radiographic assessment included knee joint alignment, position of the femoral and tibial components in the frontal and sagital planes, patellar angles, and pre- and post-operative joint angles [17]. Another randomized, clinical trial (RCT) with the P.F.C. Sigma FB vs. MB (using both PS and PCL retaining models) showed no significant differences at 2-year follow-up regarding clinical evaluation (AKSS, SF-36 and WOMAC knee scores) or radiographic analysis. The radiographic assessment included knee joint alignment, position of the femoral and tibial components in the

frontal and sagital planes, patellar angles, and a cumulative lucency score [18]. Similarly, in an RCT with the P.F.C. Sigma FB vs. MB (using only PS models), Rahman et al. found no difference regarding knee scores (OKS, SF-12 and WOMAC), ROM, or radiographic analysis including radiolucency scoring [19].
The P.F.C. Sigma MB (using both PS and PCL retaining models) has been tested against the Medial Pivot FB in an RCT with bilateral surgery. The P.F.C. Sigma MB optimistically showed higher ROM, better patient satisfaction, and a lower complication rate [20].

The P.F.C. Sigma implant system was further developed in a MB hyperflex version aiming at further improvement of knee joint flexion. Futai et al. showed that the new hyperflex variant potentially reduces articular contact stress in vivo due to a large contact area between the femoral component and the PE insert because the rotation of the femoral component on the tibial component was predominantly caused by rotation of the PE insert on the tibial tray. In a study with 2 consecutive non-randomized groups, Massin et al. compared the new hyperflex version with the conventional MB articulation and found increased active flexion a 1-year follow-up in a patient subgroup with the hyperflex articulation group [21]. In summary, the history of the P.F.C. Sigma MB began in the year 2000; hence long-term results are still not available, but short-term and medium-term results have been promising [17-20].

Dual-energy X-ray Absorptiometry

The clinical survival of orthopedic implants is related to the periprosthetic bone quality [22-26]. Periprosthetic BMD can be quantified precisely by DXA [27]. DXA scanners are widely used for BMD measurements in the hip, spine, and forearm to diagnose osteoporosis. Some manufacturers have improved the software of the scanners with customized packages intended for orthopedic use, especially for periprosthetic BMD measurements in proximity of total hip implants. Software specifically designed for measurements of BMD around the knee is less common and not yet validated for clinical use. Plain radiographs were unreliable for assessment of bone loss [28-31]. Bone loss of less than 25% is difficult to detect visually [29], whereas DXA can quantify the bone density precisely, with a low coefficient of variation (0.41-0.63%) [27]. BMD measurement in the proximity of orthopedic implants is interesting as a follow-up parameter because BMD measurements may correlate with implant fixation [32-34]. The precision of repetitive scans relies on the scanner's hardware and software and the homogenous position of patients at follow-up [30;35-37]. Previous methodological studies have described the effect of rotation of the femoral bone on the repeatability of BMD at follow-up [30;37;38], but to our knowledge, no previous studies have evaluated the importance of rotation of the proximal tibia for changes in the measured BMD around total knee arthroplasty (TKA) with the use of a knee-specific DXA software. Reduced proximal tibial BMD could complicate revision surgery [39], and several studies have validated DXA as a suitable method to monitor bone remodeling in the post-operative period [23;36;40]. The cohesion of poor bone quantity and implant loosening is theoretically obvious but clinically not well documented. Li et al. that there is no correlation between a decrease in periprosthetic BMD and increased tibial component migration [41;42]. They found

BMD to reach baseline level after 24 months and early migration to be more related to interface issues, such as the general trabecular bone condition, than to BMD changes below the implant. Likewise, in total hip arthroplasty, a correlation between implant migration and change in BMD has not been directly documented [43;44].

Radio Stereometric Analysis

The history of RSA reaches far as back in the medical history as the discovery of roentgen rays. From the beginning, the basic aim of RSA is to determine positions in space in radiograms. With the ability to establish rigid bodies using radio-opaque tantalum beads attached to implants, PE inserts, and inserted into patients' bones, the RSA technique can be used for early evaluation of implant fixation [45].

The first description of RSA as a method for accurate measurement of skeletal and implant micro-movements was in Göran Selvik's 1974 thesis [46]. The generally reported high accuracy of RSA ranges between 0.05mm and 0.5mm for translations and between 0.15° and 1.15° for rotations (95% confidence intervals). RSA studies can be conducted with a low number of enrolled patients [46-48]. Marker-based RSA is based on tantalum beads attached to the implant of interest, thus forming a rigid grid of the implant, and migration is calculated in 3 dimensions between the implant grid and the tantalum beads inserted into the bone adjacent to the implant, forming a rigid grid. To calculate migration, a minimum of 3 non-colinear beads in each grid is needed.

Model-based RSA was described by Kaptein et al. [49-51] as a method of implant migration analysis without tantalum beads attached to the implants of interest. Instead, a digital 3-dimensional computer image of the implant is used for migration calculation. This digital model can be provided from the implant manufacturer as computer-assisted drawing files (CAD files) or created with so-called reverse engineering (RE) in which laser scanning of implants provides very detailed digital models [49]. Because implants with tantalum beads attached are considered new products from a FDA point of view the, approval of the implant with tantalum beads attached could be a costly affaire. When supplied by the implant manufacturer, the CAD model-based RSA is easy accessible and can be converted into triangulated surface models. Using CAD models is not as accurate as the RE-model-based RSA, because some dimensional differences exist between the CAD model of the implant and the actual implant tolerance; hence before applying CAD model-based RSA in a study, the accuracy of zero motion (=precision) should first be tested in a phantom study [49]. The technique with 3D surface models (CAD- or RE-derived) is based on minimizing the differences between the virtual projections of the model and the actual implant projection in the radiograph. With symmetric implants this is difficult because the appearance of the implant in the radiograph cannot be left/right differentiated. Therefore implant orientation is estimated more easily using an asymmetric implant with features such as flanges or pegs attached. The surface model is repeatedly moved until the surface model outline fits the projection from the stereo-radiographs with minimal difference [49;52].

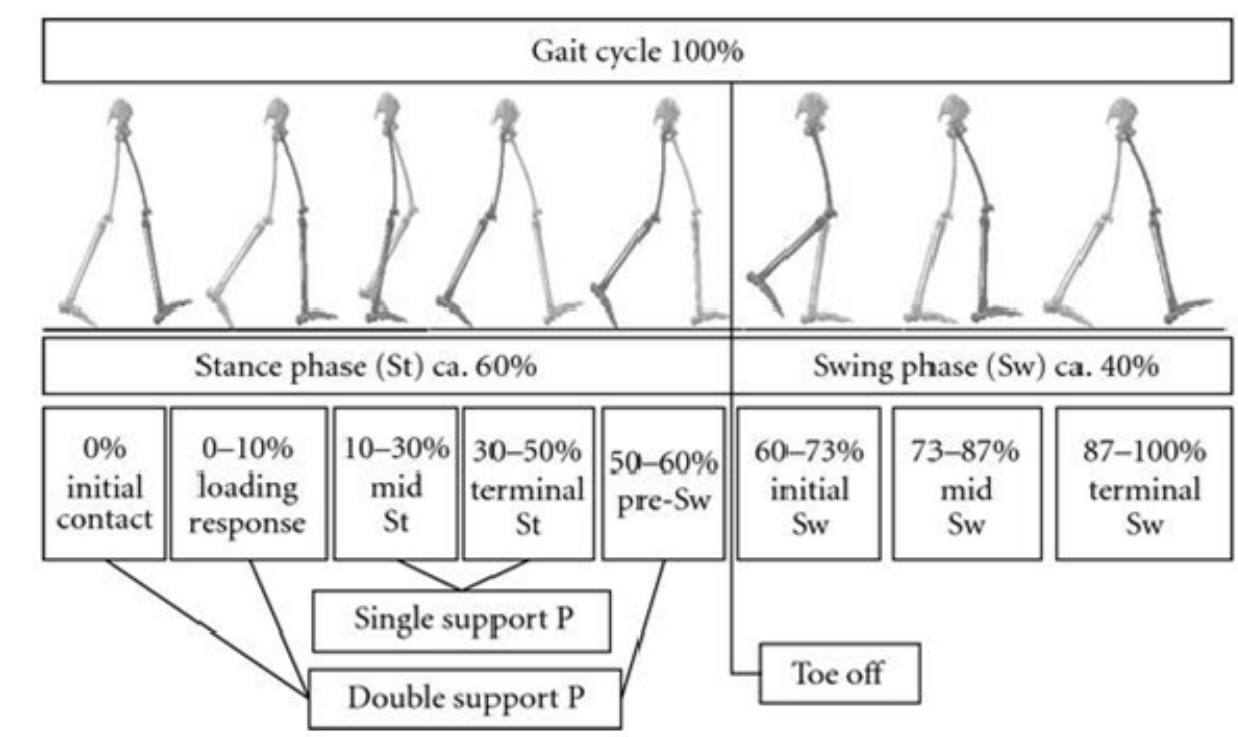
Consensus has hot been reached regarding how the RSA technique should be performed and how the results should be consistently presented [53]. The translation values from RSA are distributed in a 3-dimensional space in which the x-axis describes medial/lateral migration, the y-axis proximal/distal migration and, the z-axis describes anterior/posterior migration. The right side is used as the reference side, hence positive x-translation is medial, positive y-translation proximal and positive z-translation is anterior [48]. Regarding rotation values the x-plane describes flexion/extension, the y-plane external/internal rotation and the z-plane adduction/abduction. To ensure correct comparison of the corresponding translations in the right and left extremities, the x-axis should be reversed in translations on the left side. For correct rotation comparison between right and left extremities, the y and z-axes were reversed in the left extremities [48]. Ryd et al. reported a predictive power of 85% for identifying TKA implants at risk of mechanical loosening and found mechanical loosening only in the implants with a continuous migration pattern after 1-2 years' follow-up [54]. In an earlier publication Ryd showed the "cut off" between stable implants and continuously migrating implants to be at 2 mm after 1-2 years [55]. Ryd et al. found that the mechanical loosening process was initiated shortly after the surgical procedure, hence RSA was found appropriate to evaluate both total hip arthroplasties and TKAs at risk of mechanical loosening shortly after surgery compared to long-term follow-up with the use of plain radiographs [54].

Gait analysis basics

Walking or bipedal gait in the human being is the mechanism by which the human body is transported by the use of coordinated movements of the major lower limb joints. This locomotion requires the coordination of the neurological and the musculoskeletal systems to convert the essentially vertical movement of the lower limbs into a smooth forward movement of the head and trunk, which allows the eyes to remain relatively steady throughout the motional process. Many disorders of the musculoskeletal and nervous systems result in significant interference with gait which makes it difficult to participate in normal human activities. One of the basic purposes of clinical gait analysis is to define these difficulties and to suggest counteractive intervention [56;57]. Walking involves repetitious patterns of movement resulting in each foot periodically moving from one position of support to the next. These movements are cyclical in nature and take place step after step. This cyclical quality of walking enables researchers to focus on different parts of this cycle for the purposes of describing gait. Hence, when describing human gait, it is conventional to do so in the terms of the gait cycle (GC). A complete GC begins with the heel strike of one foot and ends when the same heel strikes the ground again. The GC is conventionally normalized to 100%. The GC is divided into a stance phase and a swing phase. The stance phase is defined as the period of time when the foot is in contact with the ground, that is, from heel strike to toe off. The swing phase is defined as the period of time when the foot is not in contact with the ground, that is, from toe off to heel strike. The *stance* and *swing phases* can be divided in 3 periods during gait: 1) *weight acceptance*, 2) *single limb support,* and 3) *limb advancement*. The stance phase accounts for approximately 60% of the total GC, and accordingly, the swing

phase accounts for approximately 40% during the preferred walking speed. Additionally, gait can be separated into 7 phases. Stance consists of the initial double support in which the *initial contact (touch down) and loading response* (1:7) are present from heel strike in the ipsilateral limb to toe off in the contralateral limb. Single support includes *mid stance* (2:7) and *terminal stance* (3:7) from toe off in the contralateral limb to heel strike in the contralateral limb. At the end of the stance phase is the *pre-swing* (4:7) from heel strike in the contralateral limb to toe off in the ipsilateral limb. The last 40% of the GC are divided into *initial swing* (5:7), *midswing* (6:7), and *terminal swing* (7:7) (Figure 1). These gait characteristics are present in both lower extremities; hence the normal gait pattern is symmetrical in healthy subjects. In pathological gait, an asymmetrical pattern very often exists. For example in a patient with unilateral knee joint osteoarthritis, pain is likely to cause the single support time to be reduced in the painful limb, which would also be reflected in a reduced swing time of the normal limb because a person prefers to spend as little time as possible with all of the body weight being supported by only the painful limb [56].

Figure 1 – Gait cycle phases



In addition to the gait phases, gait is described by *temporospatial parameters, kinematics, and kinetics*. Temporospatial parameters are cadence (steps/min), speed (m/s), gait cycle length (m), step length (m), single support (% of GC), and double support (% of GC). Self-selected gait speed is approximately 1.29 m/s (SD 0.15) in healthy elderly and depends upon step length and cadence [58]. Males tend to walk with longer steps than females due to taller body height and longer lower extremity bones [59]. When adjusted for body height, females have a longer stride length than males [59]. Natural walking velocity is the velocity of

walking which is voluntarily assumed and is generally the most efficient in terms of energy consumption for that particular person [56].

Kinematics is the branch of classical mechanics that describes the motion of bodies (objects) and systems (groups of objects) without consideration of the forces that cause the motion [60]. In gait analysis, kinematics describe the range of motion (ROM) and the motion angles in the joints of interest. Kinetics or dynamics are based on Newton's second law. (Force = mass x acceleration). The cause of motion or the change in motion is kinetics (in Newton meters; nm), and in gait analysis, kinetics is used to describe the force acting on the different motions in the joints of interest.

Segments, movement planes and joint angle definitions [56]

Segments are parts of the body that stay rigid during capture of motion in gait analysis. The lower limbs move as 7 segments in the model used for understanding the human lower limb movement: the pelvis, two thighs, 2 shanks and 2 feet. Visualizing a segment can be made by a triangle (1 point and a line) to define the plane in which the segment lies. The lower limb segments used in this dissertation are defined as follows:

- Pelvis segment
  - Point – midpoint of 2 posterior superior iliac spinae (PSIS)
  - Line – from left anterior superior iliac spinae (ASIS) to right ASIS
- Thigh segment
  - Point – hip joint center
  - Line – knee joint axis
- Shank segment
  - Point – knee joint center
  - Line – ankle joint center
- Foot segment
  - Point – ankle joint center
  - Line – lateral foot border

Movement planes

Motion of the limbs is generally described using reference planes.

1) The *sagital plane* divides the segment into left and right.
2) The *coronal/frontal plane* divides the segment into front and back.
3) The *transverse plane* divides the segment into upper and lower.

Sagital plane movements of the lower limbs involve (anterior or posterior) tilting of the pelvis, flexion/extension movements at the hip and knee, and plantar/dorsiflexion movements at the ankle joint.

Frontal plane movements involve obliquity up or down (wiggling), adduction/abduction at the hip, and varus/valgus at the knee and ankle joint.
Transverse plane movements involves protraction or forward rotation and retraction or posterior rotation at the pelvis, internal/external rotation of the hip joint, internal/external rotation of the tibia, and in-turning or out-turning of the foot.

Joint angle definitions
Segments are linked together at the joints: the hip joint between pelvis and thigh segments, the knee joint between thigh and shank segments, and ankle joint between foot and shank segments. Joint movement is defined as the movement of one segment relative to another. Movements of the pelvic segment are defined relative to the surrounding gait lab.

Sagital plane joint angle definitions

- Pelvic tilt

  The inclination of the pelvic plane relative to the horizontal plane along a line joining the right and left ASISs.
- Hip flexion/extension

  The relative angle between the long axis of the thigh and perpendicular to a line connecting the right and left ASISs.
- Knee flexion/extension

  The relative angle between the long axis of the thigh and the shank segments along the knee flexion/extension axis.
- Ankle dorsi-/plantarflexion

  The relative angle between the long axis of the shank and the long axis of the foot along the ankle flexion/extension axis.

Frontal plane joint angle definitions

- Pelvic obliquity up/down

  Angle of inclination between the ASIS line and the horizontal.
- Hip abduction/adduction

  The relative angle between the long axis of the thigh and a perpendicular to the pelvic plane.
- Knee varus/valgus

  The relative angle between the long axis of the shank and the long axis of the thigh.

Transverse plane joint angle definitions

- Pelvic protraction/retraction

  The motion of the ASIS to ASIS line relative to a line perpendicular to the direction of progression.
- Hip internal/external rotation

  The motion of the thigh relative to the ASIS to ASIS line.
- Knee internal/external rotation

  The motion of the shank relative to the knee flexion/extension axis line.
- Foot internal/external rotation

  The motion of the foot relative to a perpendicular to the plane of the shank.

Gait characteristics of normal walking

Gage presented the 5 major features of normal walking; attributes that are frequently lost in pathological gait [61]. It can be difficult to identify each feature, but when motion is slowed down, the identification is made substantially easier. These 5 features or attributes are:

1) Stability in stance
2) Foot clearance in swing
3) Pre-positioning of the foot for initial contact
4) Adequate step length
5) Energy conservation

Stability in stance requires adequate muscle strength, coordination, and control of the lower limbs as well as a suitable foot structure to provide the stable base over which the body moves during the stance phase. This forward progression of the body is provided by a combination of push-off by the ankle plantarflexors and the hip flexors of one limb and pull-forward by the hip extensors of the opposite limb. Foot clearance in swing requires adequate hip flexors to lift the thigh and adequate foot dorsiflexors to lift the foot as well as appropriate control by the femoral rectus muscle to control the swift knee flexion occurring in terminal swing/early swing. Sufficient stance control by the standing limb is of importance too. Pre-positioning of the foot for initial contact and shock absorption at terminal swing requires adequate control by the shank hamstring and femoral quadriceps muscles in coordination with the ankle dorsiflexors. Adequate step length enables distance gain with each step and progress of the body: a combination of forces propelling the limb and forces slowing up and controlling the limb. Energy conservation is important for an efficient gait. An intact neuromuscular system controls all of the elements allowing a person to walk at a self-selected pace, thereby facilitating a smooth and efficient forward progression of the body's center of gravity in terms of energy required for walking.

Awareness of possible deficits in these five attributes may provide a good functional assessment of the walking pattern.

Gait in knee osteoarthritis patients

Osteoarthritis (OA) is a degenerative joint disease affecting an increasing part of the population [62]. The exact etiology for the development of OA is unknown, but risk factors include age, female gender, high body mass index, and genetic disposition. Elderly women (>65 years) suffer from symptomatic knee arthritis twice as often as do men [63]. The knee joint is frequently affected by OA, and cartilage and subchondral bone changes related to OA are more often observed in the medial knee compartment than in the lateral knee compartment [62]. The severity of OA is an important determinant to the extent of changes in gait away from the normal gait pattern seen in healthy patients [64]. The development of knee OA is followed by changes in level walking, stair climbing, and stair descending [59;62;64-67]. During level walking, patients with OA walk with decreased velocity and cadence. They have reduced stride length and an increased double support time and total stance phase. They show higher extension at first foot contact and have less peak motion (flexion/extension) in stance and in swing as well as a reduced knee peak extension moment and knee adduction moment than do normal objects [64;67;68]. OA is often related to pain, and OA patients tend to compensate for the motion-related pain by minimizing the knee joint loading and thereby reducing knee extensor moment [67]. For patients with moderate OA, this pain avoiding strategy is effective, because the patients have sufficient hip abductor muscle strength to keep the trunk and pelvis balanced. In patients with more severe OA, a pathologic gait pattern can be seen with lateral movement of the trunk away from the supporting limb and drop of the contralateral hip through the entire swing phase. This pathologic gait pattern is known as "Trendelenburg's gait" [64]. The loads transferred through the medical compartment are higher than loads transferred through the lateral compartment. These loads and their distributions through the medial and lateral compartments may be estimated by the external knee adduction moment: a higher external knee adduction moment indicates greater loads in the medial compartment than in the lateral compartment [64]. Astephen et al. found the mid-stance knee adduction moment to be a more important parameter for distinguishing between asymptomatic and more severe OA gait patterns than the peak knee addduction value [66].

Gait in total knee arthroplasty patients

Previous studies characterized level walking patterns in TKA patients [69-72]. Two recent reviews concluded in agreement that TKA patients walk with a characteristic pattern that is not the same as in asymptomatic healthy controls [73;74]. When walking at a self-selected speed, TKA patients walk with decreased speed, with shorter stride length, and with decreased single support compared with controls. Kinematic abnormalities are characterized by decreased flexion in both stance and swing. A proper and dynamic knee flexion in weight acceptance (early stance) and before lift-off (late stance) is important to ensure a smooth forward movement of the entire body in the changes of balance between stance and swing phases [71]. The

reduced knee flexion ROM may be a consequence of a quadriceps avoidance gait, which is common in individuals with knee pain. The consequently reduced knee flexion moment reduces the eccentric load on the quadriceps femoral muscle and thereby the patient's knee joint pain [73]. The kinetic values for TKA patients in the sagital plane show decreased peak values in flexion and extension moments throughout the stance phase [66]. For frontal plane kinematics, Saari et al. [75] showed no difference between controls and TKA patients. Hatfield et al. showed that both sagital and frontal plane moments change after TKA towards a more normal gait pattern with a biphasic flexion/extension moment curve and an adduction moment curve with peaks at both weight acceptance and in late stance [76]. Achieving correct limb alignment with surgery is crucial if the TKA is to sustain the load asymmetry that occurs during gait, in which the medial compartment is stressed to a higher extent than the lateral compartment [77;78].

It has been suggested that TKA patients might retain abnormal residual characteristics from their pre-operative gait pattern [79-81] that would be difficult to change post-surgically even with a dedicated exercise program [82;83]. These patterned gait characteristics include decreased loading response flexion (stiff-knee pattern) and decreased single support (limping) and could be explained by OA patients' many years of knee joint pain and gait pattern deterioration prior to receiving a TKA [79]. Another explanation for difficulties in achieving a gait function equal to normal gait could be that patients might be somewhat reluctant to perform daily home exercises in the years after surgery when finally free from pain after many years of OA [82]. Prolonged activity in knee muscles found by means of dynamic EMG has been described and might be an abnormal feature of TKR gait function that does not reach an asymptomatic pattern throughout post-operative rehabilitation. Prolonged muscular co-contractions around the knee might relate to a compensatory mechanism aimed at providing better control of knee kinematics during stance [84] to avoid the sense of instability that might be a side effect from surgery and a TKA as well as the age related decline of proprioception [82]. Other authors have presented EMG results as mean and peak values that show decreased mean and peak EMG values throughout the gait cycle [70;72].

Aim of thesis

The central study aim was to compare a fixed bearing (FB) versus a mobile bearing (MB) articulation to determine which shows the better performance. This central question was attacked from different points in the 3 studies described below with the following focus points:

Study I

Validation of a new (non-FDA approved) knee-specific software prior to clinical use in the RCT. The focus points were 1) to examine the effect of cementation on the measured BMD and evaluate the reproducibility and consequences of leg-rotation around a vertical axis in a phantom study, and further, in a clinical set-up, 2) to compare the clinical reproducibility in double examination scans performed with the new knee-specific DXA software and with traditional spine-mode DXA software and 3) to assess the ability of the 2 softwares to point type the implant and the bone edges correctly.

Study II

Investigation of post-operative gait function with the following focus points: 1) to compare the patients' pre-surgical level walking and surface electromyography (EMG) at 6- and 12-month post-surgery follow-up; 2) to compare the patients' level walking and EMG to a healthy and BMI-, gender- and age-matched control group; and 3) to analyze if the 2 articulation designs both achieved a gait function equal to that of the healthy control group. Finally, complemented the objective gait analysis with 4) subjective patient satisfaction scores; American Knee Society Score (AKSS) and Oxford Knee Score (OKS).

Study III

Evaluation of the tibial implant migration and the peri-prosthetic BMD in the tibia with reference to a post-operative baseline.

Materials and methods

Ethical issues

The procedures in the 3 studies were in accordance with the ethical standards of the Helsinki Declaration and approval was granted by the Central Denmark Region Committees on Biomedical Research Ethics (Registration: 20050031, issue date: June24th 2005). Informed consent was obtained from all participants. The study was registered with the Danish Data Protection Agency and with www.clinicaltrials.gov (NCT01150929).

Patients and randomization

Study I

The patient material consisted of 43 patients already included in the RCT done in studies II and III. These 43 patients were invited for an additional clinical examination outside the RCT follow-up programme with 2 double DXA-scans; 42 patients agreed to participate. The preoperative diagnosis and inclusion criterion was osteoarthritis in all cases, and all patients had a fixed bearing or a mobile articulation tibial component P.F.C. Sigma knee prosthesis owing to participation in the RCT. Mean age was 68 years (range 55–77), male/female ratio was 19/23, and the implant ratio was 22 fixed bearing to 20 mobile articulation.

Studies II and III

From March 2007 to June 2010, 63 patients were included for pre-operative gait analysis by 1 senior consultant. Furthermore 30 healthy objects without gait disorders or arthroplasties implanted were recruited among the employees and community volunteers around the Regional Hospital Hammel Neurocenter. From an available subject number of 51 (aged 55-75) we used 30 subjects based on their BMI, age and gender being comparable to the included patients (Table 1). Gait analysis of the healthy controls did not include EMG measurements.

Inclusion demographics for the participants and healthy controls in study II are shown in Table 1 and for study III in Table 2. Inclusion criteria were age 50 to 75 years and uni- or bilateral knee OA. Exclusion criteria were any neurological disorder affecting patient gait pattern; concomitant orthopedic disease of ipsilateral hip joint, but not disease of contra-lateral knee or hip joint; senile demented patients; absence of written consent; patients with peri-operatively weakened PCL; and patients who postoperatively developed deep infection or abnormal scaring in the knee joint.

Table 1 – Baseline demographics for study II including the healthy controls

	Fixed bearing (n=26)		Mobile bearing (n=25)		Controls (n=30)	
	Mean	Range	Mean	Range	Mean	Range
Weight (kg)	88	(67-119)	80	(60-104)	81	(61-109)
Height (cm)	171	(155-183)	171	(160-185)	170	(153-184)
BMI (kg/m2)	30	(23-39)	27	(23-34)	28	(24-34)
Age (years)	66	(56-73)	66	(54-74)	64	(55-75)
Gender (male/female)	(14/14)		(10/14)		(17/13)	
OP side (right/left)	(14/14)		(14/10)			
Implant size	3.5	(2.5-5)	3.3	(2.5-5)		
Knee flexion (degrees)	120	(77-144)	117	(77-144)		
Extension defect (degrees)	3	(0-11)	5	(0-11)		
ROM (degrees)	117	(66-144)	113	(66-144)		

Eight patients were excluded intra-operatively after randomization due to weakening of the PCL. One patient was excluded after housecleaning and PE exchange due to early knee joint infection. One patient had her 6-month gait analysis cancelled due to a labor conflict in 2008, but was tested after 12 months. One patient was excluded after re-operation before 6 months. One patient was excluded from further tests after 8 months owing to a fall accident leaving him with deep skin bruises and later deep infection. Accordingly, 51 patients attended 6 and 12 months' 3D gait analysis. Figure 2 shows the flow chart for study II.

Table 2 – Inclusion demographics for study III

	Fixed bearing (n=26)			Mobile bearing (n=25)		
	Mean	Min	Max	Mean	Min	Max
Weight (kg)	87	67	119	80	60	104
Height (cm)	171	155	183	170	160	185
BMI (kg/m^2)	30	23	39	27	23	34
Age (years)	66	56	73	66	54	75
Gender (male/female)	(14/12)			(9/15)		
OP side (right/left)	(12/14)			(14/10)		
Implant size	4	2.5	5	3	2.5	5
Knee flexion (degrees)	119	77	144	117	77	144
Extension defect (degrees)	3	0	11	5	0	11
ROM (degrees)	116	66	144	112	66	144

In study III, 3 patients were excluded at the first post-operative RSA visit owing to an unacceptable position of the tantalum beads that were occluded by the implant. Two patients had their 3-month RSA follow-up cancelled due to a labor conflict, and 1 patient was ill at her 6-month RSA follow-up. Figure 3 shows the flow chart for study III. In summary: of 63 randomized patients, 3 patients participated in study II only and 2 patients participated in study III only.

Figure 2 – Study II CONSORT flow diagram

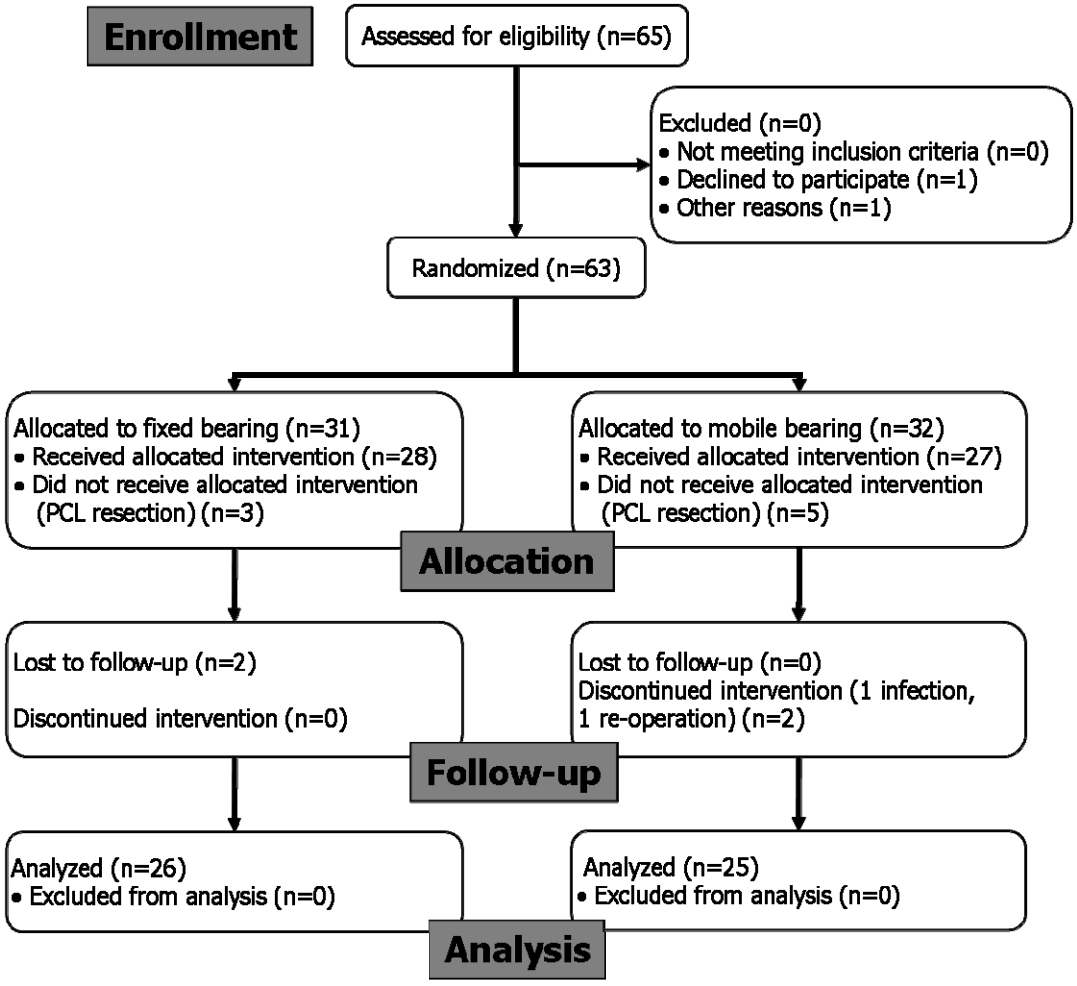
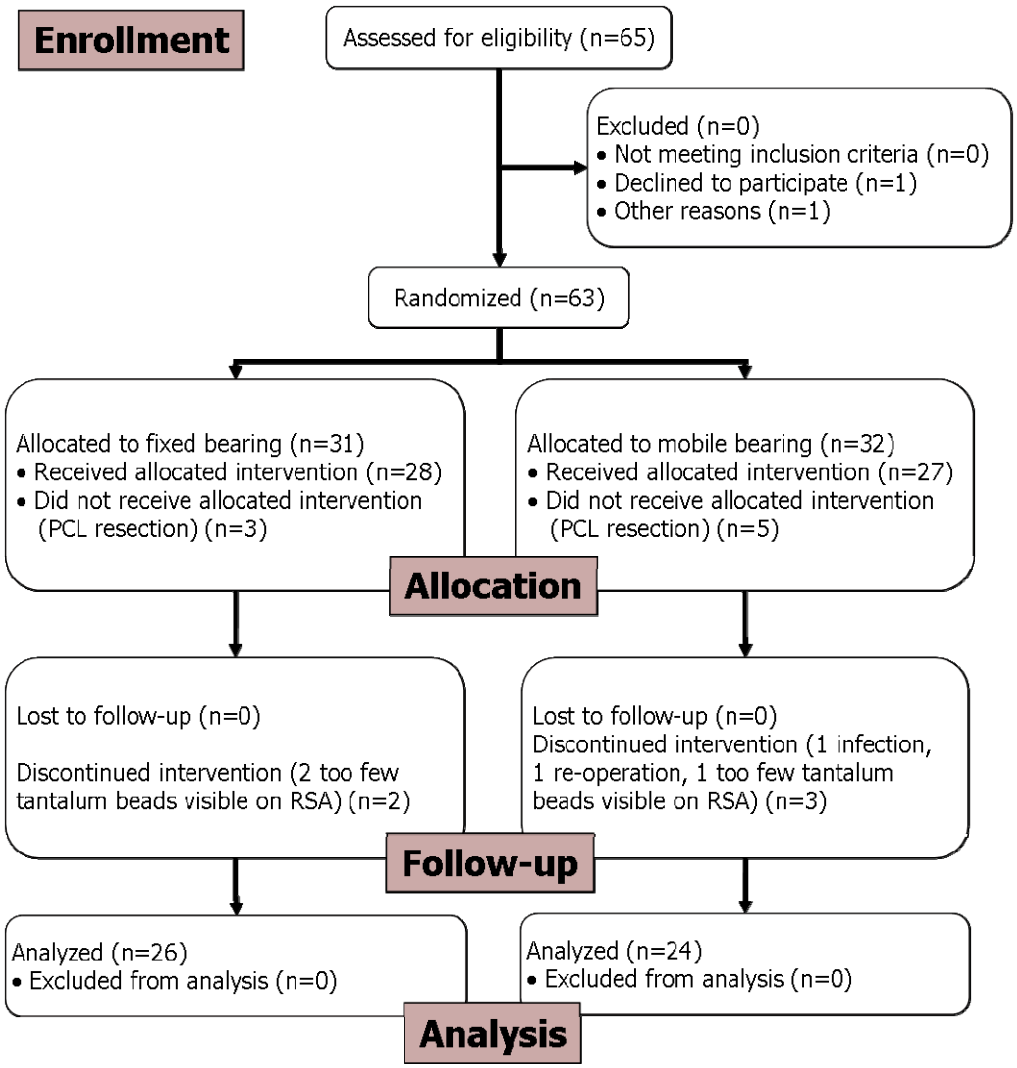


Figure 3 – Study III CONSORT flow diagram

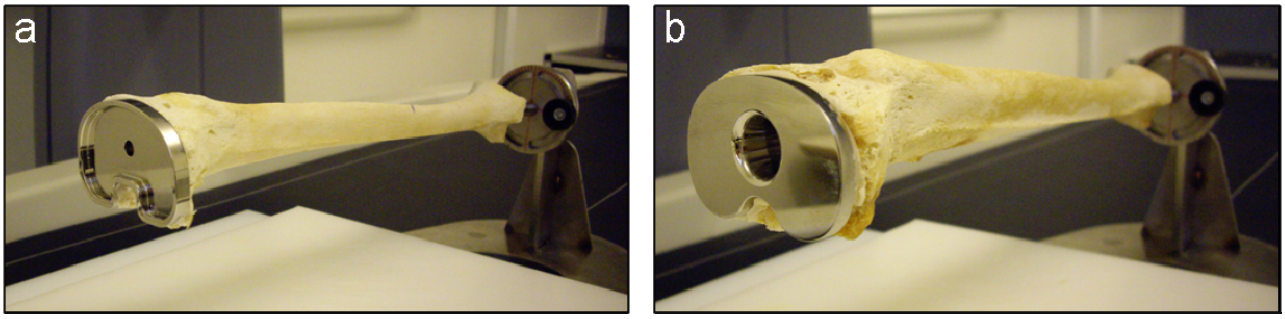


Interventions and outcomes

Study I – in vitro/phantom study

We used 2 human cadaver tibial bones and prepared them surgically for 2 different tibial components with different stem designs; P.F.C. Sigma FB and MB (Figures 4a and 4b).

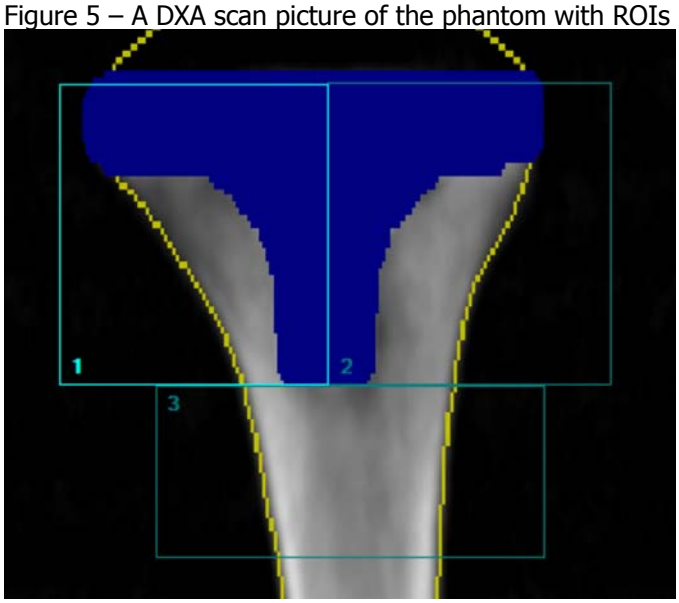
Figure 4 – The DXA scan set-up for in vitro scans



The preparation was done with the original instruments, thereby creating 2 phantoms. The phantoms were fixed tightly in a clamp allowing axial rotation intervals of one degree (Figures 4a and 4b). We measured BMD (g/cm^2) in the 2 phantoms according to a specified protocol; first with the implants press-fit (non-cemented) and secondly with the implants cemented into the bones (Simplex Bone Cement, Stryker, MI, USA). The scan window was 21.3 cm long and 12 cm wide. Tissue equivalent material in the form of nylon boards (4 cm thickness) were placed under the phantom (Figures 4a and 4b), resulting in an average tissue thickness of 9.5 cm. We used the default scan mode "thin" (average tissue thickness <13 cm). According to a pre-defined protocol we performed five scans for every five degrees of axial rotation from a neutral position (true postero-anterior view = PA; the x-ray source is beneath the scan table) to 25 degrees of internal and external rotation (Figures 4a and 4b). Mean BMD (g/cm^2) was compared between PA and each rotational position. To imitate clinical lateral scans of the tibia we performed 5 scans for every 5 degrees rotation increment from a true LA position until 25 degrees of internal rotation. Mean BMD was compared between LA and each rotational position. We did not perform scans with the phantom in external rotation from LA, because such a position was considered clinically irrelevant. (Not possible to externally rotate the foot against the bed).

We designed a template with 3 ROIs under the tibial plateau and used automatic pointtyping with detection and subtraction of metal and cement from the bone (Figure 5). The shift from ROIs 1 and 2 to ROI 3 was at the end of the stem. Thus there was no metal in ROI 3. Only the bone that is marked by the yellow edges counts in the measurement of bone mineral density. To quantify a change in BMD due to cementation, we calculated the difference in mean BMD before and after cementation for the above described phantom positions. The CVs were calculated from the 5 measurements of each rotational position to determine the scanner's repeatability.

Figure 5 – A DXA scan picture of the phantom with ROIs



Study I – in vivo/clinical assessment

All clinical DXA scans were performed using a GE Lunar Prodigy Advance 2005 DXA scanner. We used enCORE 11.40.004 software, scan mode "knee" and "spine". All DXA-scans were performed at a single out-patient visit by 1 of 3 trained technicians. With knee software we used the default scan mode "thin", meaning that the expected average tissue thickness automatically was less than 13 cm. The scan window was 20.8 cm long and 18 cm wide per default. Knee mode scans were initiated approximately 12cm below the proximal patellar pole (measured by cm ruler) and terminated automatically after the preset scan length. This was done according to the manufacturer's advice to ensure a sufficient amount of soft tissue and bone for correct dynamic tissue labeling (pointtyping). The knee software was designed to recognize right and left knees by the position of fibula; hence we consciously used the opposite side specification on the LA scans, because fibula anatomically alters its position with respect to tibia in LA position.

With the spine software we also used the option "thin" (average tissue thickness <13cm). The scan window was 23.5 cm long and 18 cm wide, which is the expected window-size for a spine scan in osteoporosis assessment. Spine mode scans were initiated approximately 19 cm below the proximal patellar pole. Spine mode scans were terminated 1 to 2 scan sweeps proximal to the tibial implant. Scan time for both programs was 56 seconds on average, with a radiation dose of 9 µGy. Scan resolution was 0.60 x 1.05 mm.

In PA scans patients were placed with their operated knee in a soft foam cast developed to avoid changes in rotation and flexion (Figure 6a). For LA scans, the patients were placed with the side on which surgery had been done towards the scan bed and the contra-lateral leg flexed in front (Figure 6b). In all spine-mode scans, the foam cast was filled with rice and the leg covered with rice bags to imitate the expected tissue volume around a spine and to avoid air in the scan field. In every scan we checked that the average tissue

thickness did not exceed 13 cm ("thin"). Patients were repositioned (left the scanner bed and walked around) between double examination scans.

Figure 6 – In vivo DXA set-up for PA scans (a) and LA scans (b).

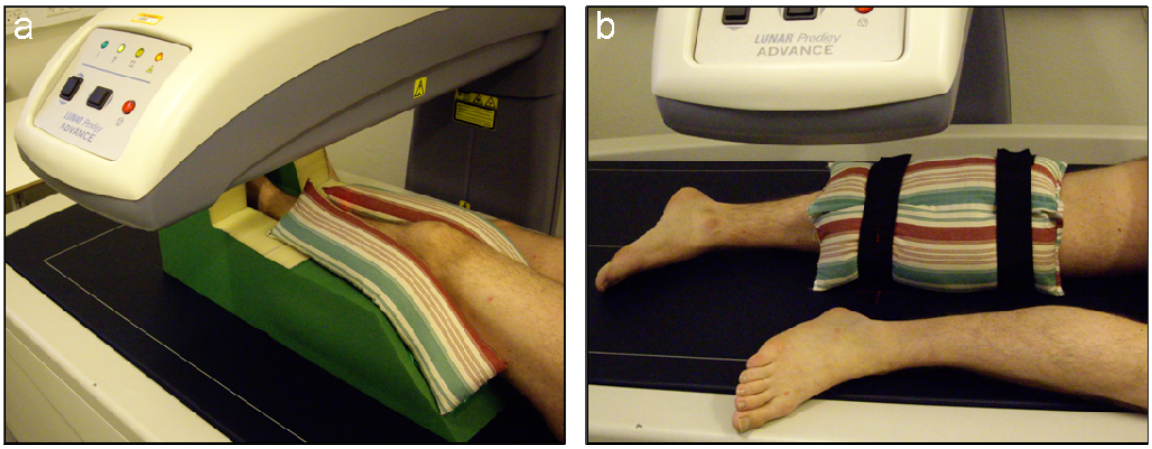
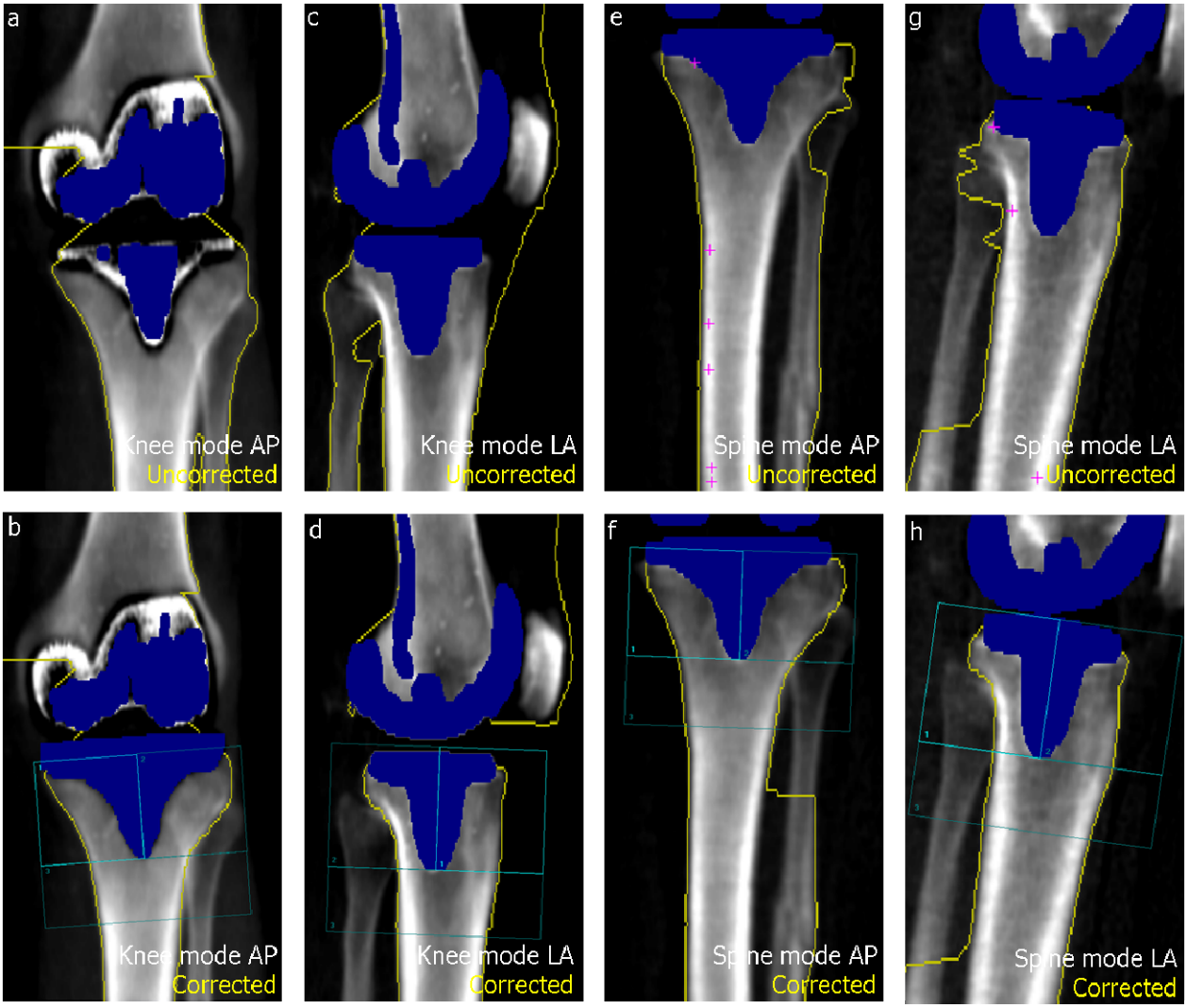


Figure 7 – Uncorrected and manually corrected point typing with the knee mode (a-d) and the spine mode (e-h) software.



Study I – analysis of DXA scans

Both in vitro and in vivo scans were analyzed using a dynamic tissue detection algorithm in the software: where scan components were typed as bone, tissue, air, artifact (implant + most of the cement), or neutral. Thereby the tibial implant was subtracted automatically in the BMD calculation. The in vitro scans were all point typed satisfactory; hence no manual corrections had to be made. For in vivo scans manual corrections had to be made in some instances to ensure correct point typing of the implant and the bone edges (Figure 7). When manual correction was indicated, we scored the extent separately to compare the 2 softwares. No attempts were made to change the typing around the cement mantle to avoid manual inaccuracies. The fibula was excluded manually where it was not over-projected by the tibia (Figure 7). We used a template of 3 ROIs (Figures 5 and 7b, 7d, 7f, and 7h). After positioning the ROI template on the baseline scan, the template was fixed to the tibial bone edges and afterwards copied to the subsequent scans in the same position, thereby ensuring comparable ROI placement. Where the individual anatomy required adjustment of ROI width, this was made without changing the ROI height to make all individual BMD measurements comparable. Because the spine mode software contained no default distinction between left and right, ROI 1 and ROI 2 were switched in the analysis of PA spine mode scans of right knees, thereby ensuring that ROI 1 was always placed medially and ROI 2 always placed laterally containing the fibula. For LA scans we switched ROI 1 and ROI 2 in spine mode scans of left knees, thereby ensuring that ROI 1 always contained the anterior tibia and ROI 2 always contained the posterior tibia. The knee-specific software had a side-recognition feature and swopped the ROI template accordingly.

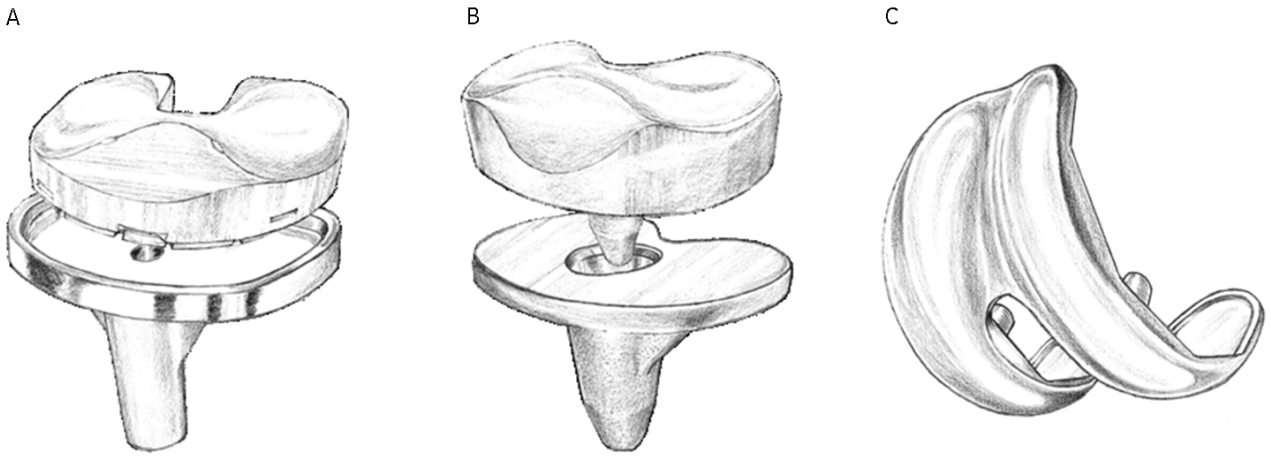
Studies II and III – surgery

Randomization followed a procedure with 98 envelopes built on groups of 4, 6 or 8 numbers to ensure a regular inclusion of both the articulation types during the inclusion period. The uneven group numbers ensured that no randomization had a predictable result.

A P.F.C. Sigma TKA was implanted into all patients. This knee system is available with both FB PE (Figure 8A) and MB PE (Figure 8B) on the tibial plateau as well as PCL retaining and posterior stabilized PE designs. We used the PCL retaining PE for all patients. There was no difference in design regarding the femoral components (Figure 8C). All metal components were made from a cobalt-chrome alloy.

Surgery was performed by 3 senior consultant surgeons who were specialized in total knee surgery and who had been using the P.F.C. Sigma TKA for a long period before the study started (no learning curve in the study). The procedure included a midline skin incision followed by a medial para-patellar incision through the quadriceps tendon. The anterior cruciate ligament was excised and the PCL was sought retained. The proximal tibia was resected to obtain an implant bearing surface that was perpendicular to the tibial shaft in the coronal plan, but had a 3° posterior slope in the sagital plane. The distal femoral condyles were resected

Figure 8



to attempt an alignment of 6° valgus in the coronal plane. The patellar thickness was measured and a resection and an implantation preparation made for the patellar PE component. The tibial, the femoral and the patellar components were fixed by bone cement (Simplex Bone Cement, Stryker, MI, USA) with pressurizing technique. For study III, 6-8 tantalum beads were randomly inserted in the proximity of the tibial implants.

All patients followed the same standardized post-operative rehabilitation program, allowing full weight bearing immediately after surgery. At discharge, the patients were instructed in a home training program followed by an instruction brush-up with a physiotherapist 14 days postoperatively. All patients were seen at an out-patient visit with a physiotherapist and the surgeon 4 months after their operation.

Study II – gait analysis and EMG

Follow-up with 3D gait analyses were performed in the Gait Laboratory at Hammel Neurocenter 6 and 12 months post-operatively. The gait analysis was conducted with a Vicon 612 8-camera system (Vicon, Oxford, UK) at 100Hz using a Helen Hayes marker set-up [63;85]. An AMTI force plate (Advanced Medical Technology Inc., Watertown, MA, USA) placed in the middle of a 10-meter walking isle recorded ground reaction forces at a sample rate of 2000Hz**.** Force plate data and camera data were captured and synchronized in a Vicon Workstation. Static and dynamic calibrations were performed before each measurement session. Reconstruction of a 3D body model and calculations of angles between each segment in the lower limb as well as the moment of force in each joint were computed with Vicon clinical manager software. Three of 5 trials of each leg were selected as data source for further analysis using Vicon PlugInGait software; selection criteria were speed similarities as recommended by Vardaxis et al. [86]. We defined the beginning of each gait cycle as heel strike (touchdown) and the end of the same cycle to be at next heel strike of the same leg. The gait cycle was normalized to 100% time basis. EMG skin electrodes were placed in accordance with a predefined protocol. Four electrodes were placed on each leg to record

EMG signals from the vastus lateralis, the biceps femoris, the tibitalis anterior, and the gastrocnemius muscles (Motion Lab MA-300.10, MotionLab Systems Inc., Los Angeles, USA). EMG signals were filtered through a 20–500 Hz band pass filter, thereafter unidirected and finally 10 Hz low pass filtered. Both filters used were 2nd order Butterworth filters. EMG output was in analog digital (AD) units; we used baseline signals as index 100 and the signals from the 6- and 12-month follow-up were related to the baseline measurement as a percentage value.

Study II – healthy controls

The subjects making up the normal material were collected from employees and community volunteers around the Regional Hospital Hammel Neurocenter and were not collected for use in the present study exclusively. From an available subject number of 51 (within the range of 55 to 75 years) we selected 30 subjects based on their BMI, age, and gender being comparable to the included patients. The demographic data for the healthy controls are shown in Table 1. Collection of normal material gait data followed the exact same set-up as for the patients included in study II. No EMG values were collected for the normal material, though.

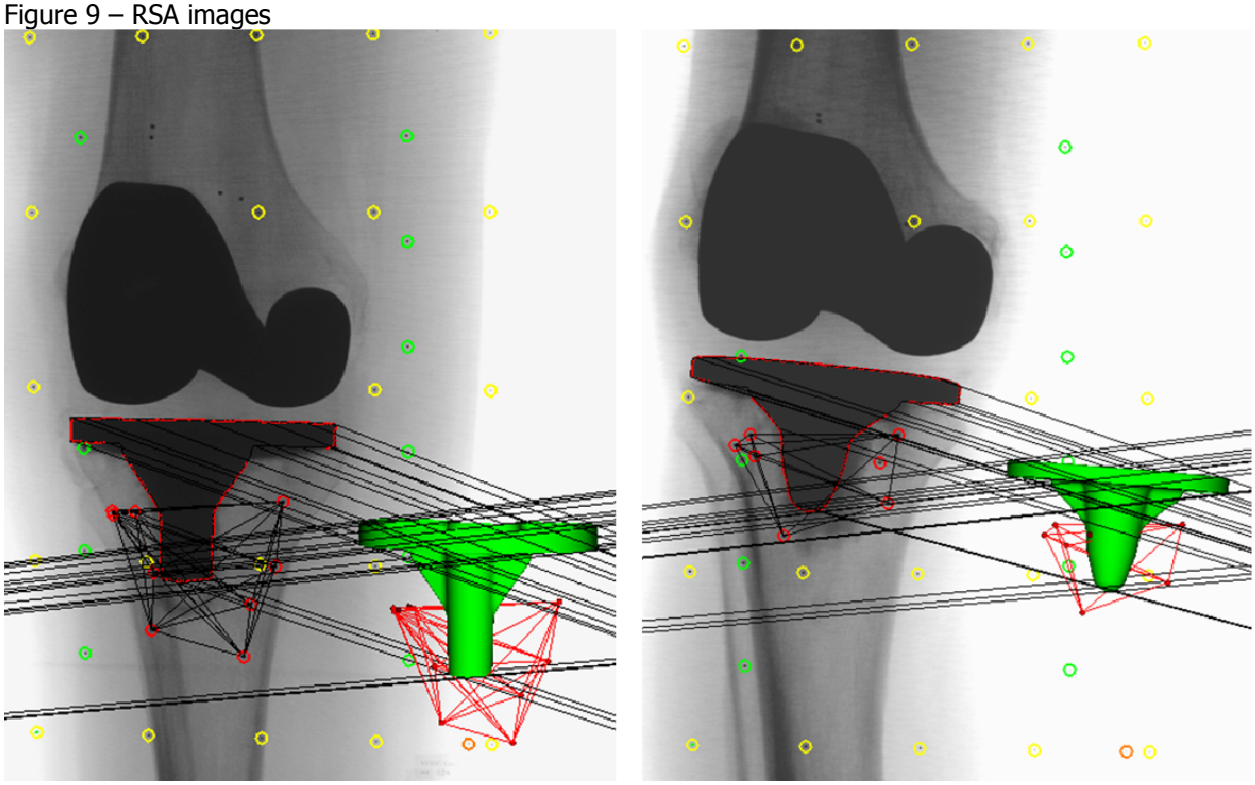
Study III – RSA

Stereoradiographs were obtained 3 days (range 2 to 7 days) after surgery and served as the baseline stereoradiographs for the follow-up visits at 3, 6, and 12 months. The patients were placed in a supine position with the operated knee parallel to the calibration box so that the anatomical axis of the leg was parallel with the y-axis of the calibration box. We used a standard RSA setup with 2 synchronized ceiling-fixed roentgen tubes (Arco-Ceil/Medira, Santax Medico, Aarhus, Denmark) with an unfocussed uniplanar carbon calibration box (Medis Specials, Leiden, The Netherlands). All stereoradiographs were digital (Dicom CR) and were re-scaled to 1,760 x 2,140 pixels, grey colors, BMP-file format. The upper limit for mean error rigid body fitting (stable markers used for migration analysis) was 0.5 mm. The mean condition number (dispersion of the bone markers in the tibia) was 17.29 (SD: 4.62; range 9.70-30.10).

Analyses of all stereoradiographs were performed by one observer with Model-Based RSA (MB-RSA) version 3.31 (Medis Specials, Leiden, The Netherlands). The observer used 3D implant computer-aided design (CAD) models that were provided by the implant manufacturer and were subsequently implemented in the MB-RSA software. Implant migration was calculated using the 3 follow-up radiographs with the postoperative radiograph as the reference [49]. The point of measurement was the center of gravity of the CAD-model in relation to the center of gravity of the tibial bone markers as the fixed rigid body reference (Figure 9). Implant translations (implant micromotion along the axes) were expressed as x-translation (medial and lateral), y-translation (proximal and distal), z-translation (anterior and posterior), and maximal total point motion [48;54]. Rotations (implant movement around the axes) were expressed as x-rotation (anterior and posterior tilt), y-rotation (internal and external rotation), and z-rotation (varus and valgus tilt). Total

translation (TT) and total rotation (TR) were calculated using the 3D Pythagorean Theorem ($TT=\sqrt{(a^2+b^2+c^2)}$) [51]. Maximal Total Point Movement (MTPM) [48;54] was calculated with the MB-RSA software as an unspecified point among the 5000 points from which the implant CAD models were constructed that had moved the farthest (vector).

Figure 9 – RSA images



Shows one half of a model-based RSA image for the fixed bearing tibial implant (left image) and for the mobile bearing tibial implant (right image) with the 3D implant models (green), the software detected tibial implants (red shape), and the tibial tantalum beads (red circles). The green and yellow circles are tantalum beads from the calibration box.

Study III – DXA

BMD was determined 3 days (range 2 to 7) postoperatively and at 12-month follow-up. All scans were performed using a GE Lunar Prodigy Advance 2005 DXA scanner. The observers used enCORE 11.40.004 software's scan mode "knee" for research purposes. This knee software is investigational and has not yet been approved by the FDA.

In study I this software was shown to be an effective tool in the research of periprosthetic bone loss [87]. The same set-up and scan protocol as described and validated for the knee-specific software in study I was used (Figure 6). After positioning the ROI template on the baseline scan, the template was fixed to the tibial bone edges and afterwards copied to the successive scans in the same position, thereby ensuring comparable ROI placement on the follow-up scans. No attempts were made to exclude the fibula, because the fibula partly overlap the tibia in all scans and are not entirely and equally removable.

Studies II and III – knee scores

The Oxford Knee Score (OKS) Questionnaire was filled out by the patients themselves before surgery and after 6 and 12 months' follow-up. OKS consists of 12 questions regarding the patient's experienced pain, function, and performance. A maximum of 48 points can be obtained [88]. The American Knee Society Score (AKSS) Questionnaire was filled out by the patient (pain score) and a physiotherapist (clinical score) preoperatively and after 6 and 12 months' follow-up. AKSS contains a patient reported pain score of 3 questions and a 7-part hospital staff assessment of function, stability, and range of motion. The pain score as well as the clinical score can result in 50 points each, so the maximum total point number is 100 [89].

Model based RSA precision

In an in vitro study we obtained 9 stereo radiographs of 2 phantoms made from tibial saw-bones with the FB and MB implants inserted press-fit. Tantalum beads of 1 mm in diameter as were inserted randomly into the peri-prostetic bone aiming at the same dispersion and number as in the clinical RSA study III. We used the exact same setting as stated for the stereo radiographs in study III. The phantoms were fixed in the clamp used in study I (Figures 4a+b). According to the recommendations from Kaptein et al. [49], we altered the position of the phantom between each stereoradiograph both in rotation around a vertical axis (0–20 degrees) and in a movement similar to knee flexion (0–20 degrees). The implants used in this in vitro study had attached 3 tantalum beads in small towers enabling us to perform both marker-based and model-based migration calculations for a precision comparison.

Sample size

Sample size was not calculated in study I due to the study design. For study II the study power was based on pilot gait analyses that pointed at a minimal relevant difference of 10 steps/minute (gait cadence) (power 90%, alpha 0.05, SD 10 steps/minute). The power calculations required 22 patients in each group. The aim was a total of 50 patients with an analyzable baseline gait analysis to compensate for eventual dropouts during follow-up. For study III the minimal relevant difference was expected to be 0.6 mm total translation (power 90%, alpha 0.05, SD 0.6mm) [47], hence study III was powered for 22 patients in each group. To allow for incomplete data collection and the dropouts that we observed through the inclusion period, we conservatively continued inclusions to 63 patients in total to maintain power.

Statistics

In study I, analyses were performed using STATA IC10 software (StataCorp., Texas, USA)
In studies II and III, analyses were performed using STATA SE11 software (StataCorp., Texas, USA)
Statistical significance was assumed at $p < 0.05$.

Study I – in vitro / phantoms

Mean BMD (g/cm^2) and SD in all 3 ROIs were calculated for the 5 consecutive PA and LA scans of the phantoms first under non-cemented fixation (press fit) and thereafter cemented implant fixation. Mean BMD differences (normal distribution by Shapiro-Wilk test) were tested by a paired t-test. The coefficient of variation (CV% = SD/mean x 100%) was calculated separately for PA and LA scans with implants non-cemented and cemented in the phantoms. The impact of rotation on mean BMD (normal distribution by Shapiro-Wilk test) was evaluated by an un-paired t-test.

Study I – in vivo / clinical scans

Visual scoring of implant-detection and bone edge-detection was noted for scans made with knee-mode versus spine-mode and comparison was made by Chi-Squared test (and with Fisher's exact test, when $n<5$ in on of the table cells). CV was calculated to describe the clinical repeatability of mean BMD from all 3 ROIs (knee scans and spine scans), because CV is widely used for comparison in the literature. Furthermore we used the standards of ASTM2008 for assessment of precision [90], where S_r is the standard deviation of a single measurement. The 95% repeatability limit (random variation) was calculated as $S_r \times \sqrt{2} \times 1.96$. Bias equals the systematic variation between double measurements and is estimated as mean difference between double measurements. Bias followed a normal distribution and was tested by a paired t-test. Bias ± the 95% repeatability limit equals the 95% limits of agreement (LOAs) as described by Bland and Altman [91].

Study II

The temporospatial and the kinematic parameters were normally distributed (judged by a Shapiro-Wilk test) with unequal variances (F-test). The change in values after 6 and 12 months' follow-up was tested by a paired t-test for unequal variances. The kinetic and the EMG values showed normal distribution (EMG when log-transformed) with equal variances for the FB and the MB group; hence ANOVA was used to test for change in values over time and between the FB and the MB groups. The knee score data were not normally distributed and were accordingly tested with Wilcoxon ranksum test. At 12 months' follow-up, the difference in temporospatial, kinematic, and kinetic values was calculated between the normal material and the FB as well as the MB group. These differences were normally distributed (Shapiro-Wilk test) with similar variances (F-test). With a 1-sample t-test, the hypothesis of no difference between patients and normal subjects was tested. Thus a p-value >0.05 indicated normalization (no difference) of gait parameters compared with the control group.

Study III

We compared the FB and MB groups regarding migration, change in BMD, and in knee scores by using the non-parametric Wilcoxon ranksum test owing to the absence of normal data distribution. The primary endpoints were the total translation and total rotations values. The correlation between implant migration and change in BMD was investigated with Spearman's rho test.

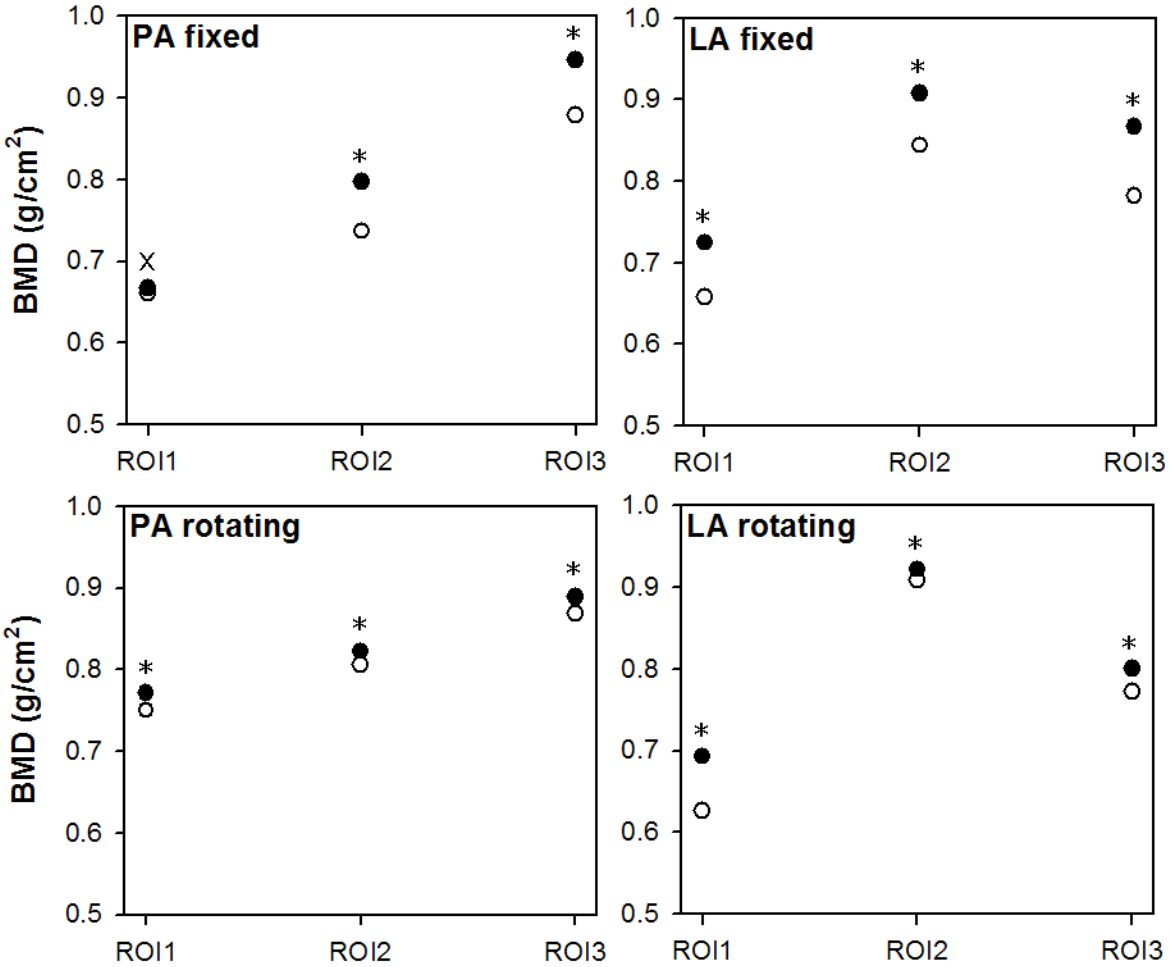
Results

Study I

In vitro – phantom study

The measured BMD was influenced by cementation in both implant groups. In the phantom with the FB implant, BMD increased 0.06g/cm^2 on average and in the phantom with the MB component the average increase in BMD was 0.03g/cm^2 (Figure 10). The increase in mean BMD after cementation was statistically significant ($p<0.01$), except in ROI1 for the FB implant in PA position (medially to the implant stem). BMD increase after cementation was similar in both implant groups ($p=0.11$).

Figure10 – Impact of cementation of the tibial component on the measured BMD in DXA scans

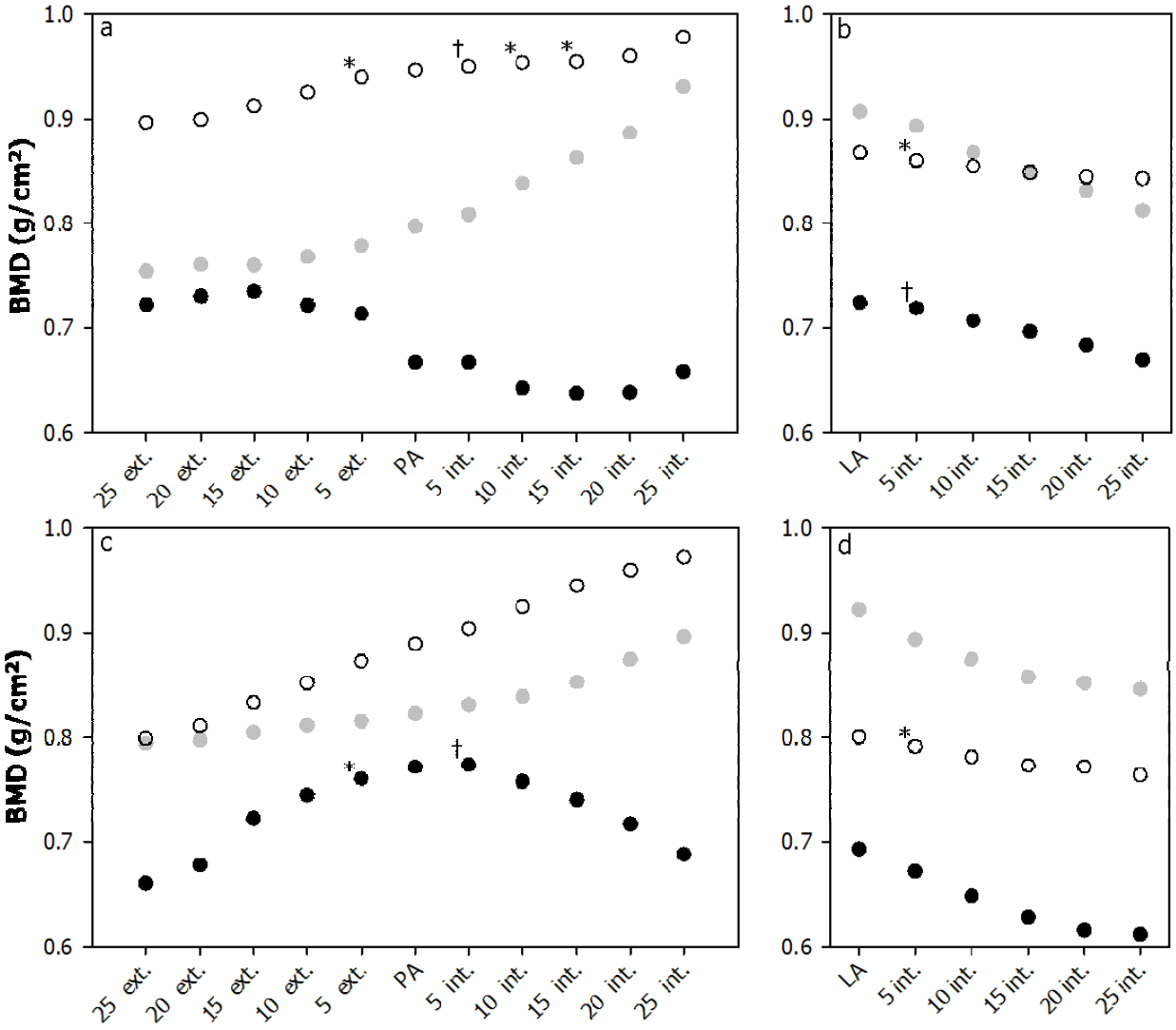


Increase in mean BMD (g/cm^2) before (o) and after cementation (●). PA and LA DXA scans fixed bearing tibial implant and mobile bearing tibial component in ROI 1, 2, and 3. *: $p<0.01$; x: $p>0.05$

The CV for BMD measurement around the FB implant was 0.70% in un-cemented and 0.59% in cemented fixation. For BMD measurements around the MB CV was 0.57% in un-cemented and 0.52% in cemented fixation.

Five to 25 degrees of internal and external rotation from PA (neutral) position and 5–25 degrees of internal rotation from LA position changed BMD measurement in most scans ($p<0.01$). The absolute change in mean BMD caused by rotation ranged from 0.00 to 0.11g/cm^2, and the relative change ranged 0.00 to 14.48% (Figure 11) for both implant groups.

Figure 11 – Impact of rotation on the measured BMD in DXA scans



In vitro BMD measurements (g/cm2) with increasing rotation from neutral position PA (a+c) and lateral position LA (b+d). 5 consecutive scans were performed in each position; mean BMD plotted for 3 Regions of Interest, ● ROI1, ● ROI2 and ○ ROI3. Rotation from PA and LA changed mean BMD significantly in most ROIs both on PA scans and LA scans (no marks) ($p<0.01$);
*: $p<0.05$; †: $p>0.05$.

In vivo – clinical results

A total number of 168 scans were assessed. Visual implant detection (Table 3) was satisfactory for all spine-mode scans in both PA and LA, whereas implant detection in knee-mode scans were correct in 10.7% of PA scans and 94% of LA scans. Tibial bone edge detection in PA scans was correct in 45.2% laterally and 70.2% medially with knee-mode software compared to 0% laterally and 70.2% medially with spine-mode software. In LA scans visual tibial detection was 48.9% anteriorly and 67.9% posteriorly with knee-mode software and compared to spine-mode software with 65.5% correct detection anteriorly and 2.4% posteriorly.

Table 3 – Visual evaluation

PA scans	Knee-mode	Spine-mode	p-value*	LA scans	Knee-mode	Spine-mode	p-value*
Implant detection	7/84	84/84	p<0.01	Implant detection	79/84	84/84	p=0.06
Tibia lateral	38/84	0/84	p<0.01	Tibia anterior	41/84	55/84	p=0.04
Tibia medial	59/84	59/84	p=1.00	Tibia posterior	57/84	2/84	p<0.01

Visual evaluation of correct automatic software detection of implant and bone edges.
PA and LA scans from 42 clinical double examinations DXA knee scans (n=84).
* Chi-Squared test/Fisher's exact test.

Coefficients of variation for the clinical double examinations ranged from 2.78% to 6.19% for knee-mode BMD measurements and from 1.45% to 6.06% for spine-mode BMD measurements (Table 4).

Repeatability standard deviation (S_r) from the 42 patients' double examinations ranged from 0.035 to 0.054 for knee-mode software and from 0.016 to 0.063 for spine-mode software (Table 5). The 95% agreement limits were small (Table 5 and Figures 12 and 13).

Table 4 – DXA precision in vivo

	Knee-mode (n=42)		Spine-mode (n=42)	
	PA scans	LA scans	PA scans	LA scans
ROI1	4.38 %	6.19 %	2.58 %	4.68 %
ROI2	4.64 %	4.57 %	2.43 %	6.06 %
ROI3	2.78 %	4.09 %	1.45 %	3.25 %

Coefficients of variation (in %) for clinical double DXA examinations

Table 5 – DXA precision in vivo

Knee-mode software

	Mean BMD[a] (range)		Bias[b] (95 % CI)		S_r[c]	LOA[d]
PA scans (n=42)						
ROI 1	0.954	(0.497-1.308)	-0.014	(-0.033-0.005)	0.045	0.126
ROI 2	1.107	(0.647-1.649)	-0.017	(-0.040-0.006)	0.054	0.151
ROI 3	1.251	(0.664-1.692)	-0.014	(-0.031-0.003)	0.040	0.112
LA scans (n=42)						
ROI 1	0.834	(0.330-1.421)	0.006	(-0.013-0.025)	0.045	0.123
ROI 2	1.103	(0.605-1.479)	-0.014	(-0.032-0.004)	0.042	0.117
ROI 3	1.107	(0.594-1.568)	-0.011	(-0.026-0.004)	0.035	0.097

Spine-mode software

	Mean BMD[a] (range)		Bias[b] (95 % CI)		S_r[c]	LOA[d]
PA scans (n=42)						
ROI 1	0.882	(0.526-1.471)	0.005	(-0.004-0.015)	0.022	0.061
ROI 2	0.871	(0.404-1.257)	0.004	(-0.005-0.014)	0.022	0.060
ROI 3	1.139	(0.719-1.628)	-0.009	(-0.016--0.002)	0.016	0.046
LA scans (n=42)						
ROI 1	0.944	(0.488-1.585)	0.003	(-0.018-0.024)	0.048	0.133
ROI 2	0.910	(0.186-1.451)	-0.015	(-0.042-0.013)	0.063	0.175
ROI 3	1.018	(0.536-1.572)	0.000	(-0.013-0.014)	0.031	0.087

Repeatability of clinical BMD measurements (double examination)

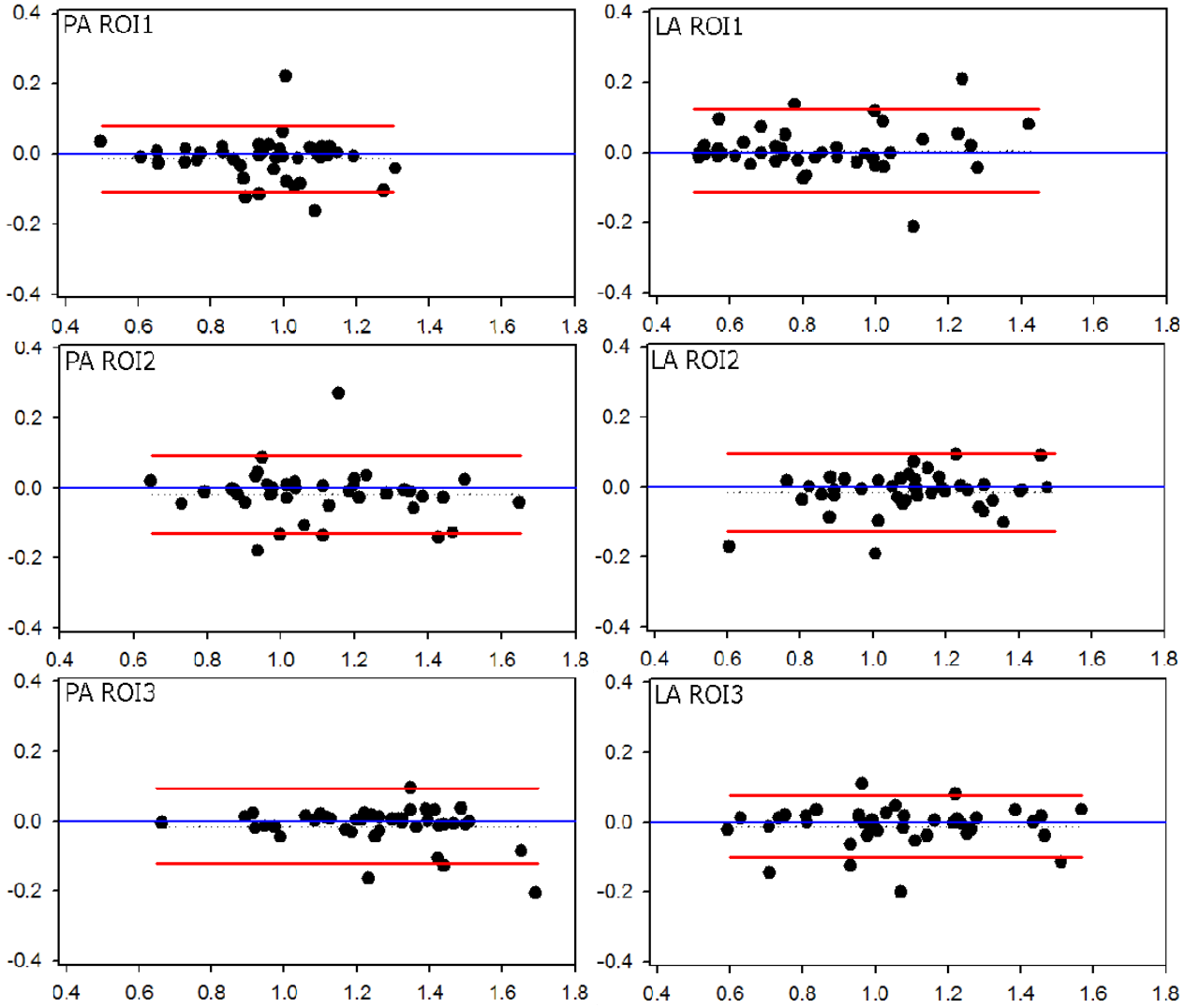
[a] Mean of double BMD scans (g/cm^2), range in brackets.

[b] Mean difference between the first and second scan (systematic variation of repeatability within the ROI).

[c] Repeatability standard deviation for a single BMD scan (ASTM 2008).

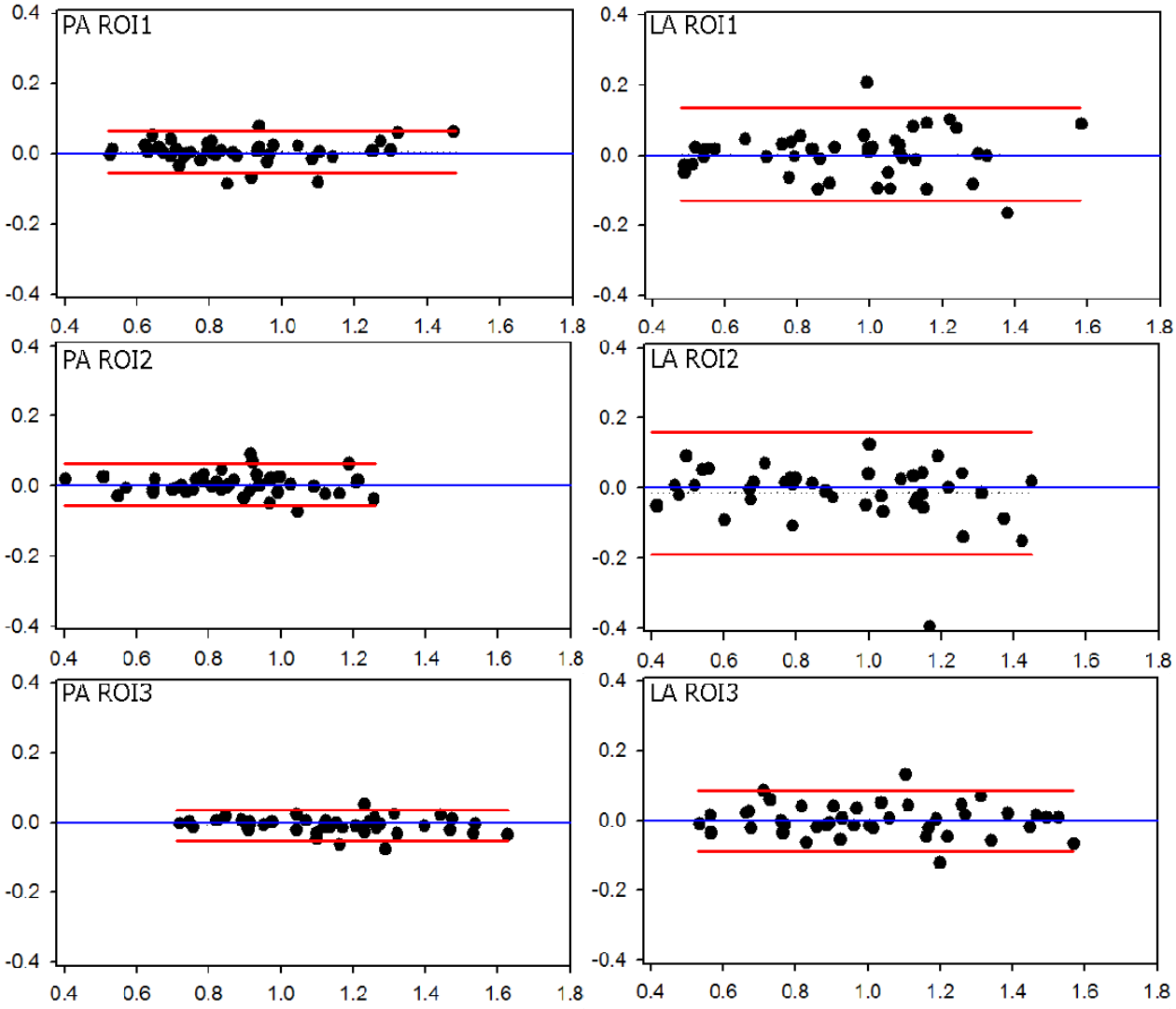
[d] 95 % limit of agreement between 2 test results ($1.96 \times \sqrt{2} \times S_r$).

Figure 12 – DXA repeatability (fixed bearing)



Bland-Altman plot for clinical double examination repeatability with the fixed bearing articulation. X-axis: Average of double DXA measurements (g/cm^2); y-axis: difference between double measurements (g/cm^2); red lines: 95% limits of agreement; dotted line: bias from 0; solid blue line: y=0; dots individual double values.

Figure 13 – DXA repeatability (mobile bearing)



Bland-Altman plot for clinical double examination repeatability with the mobile bearing articulation. X-axis: Average of double DXA measurements (g/cm^2); y-axis: difference between double DXA measurements (g/cm^2); red lines: 95% limits of agreement; dotted line: bias from 0; solid blue line: y=0; dots individual double values

Study II

Gait analysis results

The temporospatial, the kinematic, and the kinetic results from the 12 months' follow-up are shown in Table 6 with the control group values for comparison. Detailed temporospatial, kinematic, and kinetic results from the baseline, 6- and 12-month follow-up are available in Appendix Tables 1–3 with control group values for comparison.

Table 6 – Gait analysis results

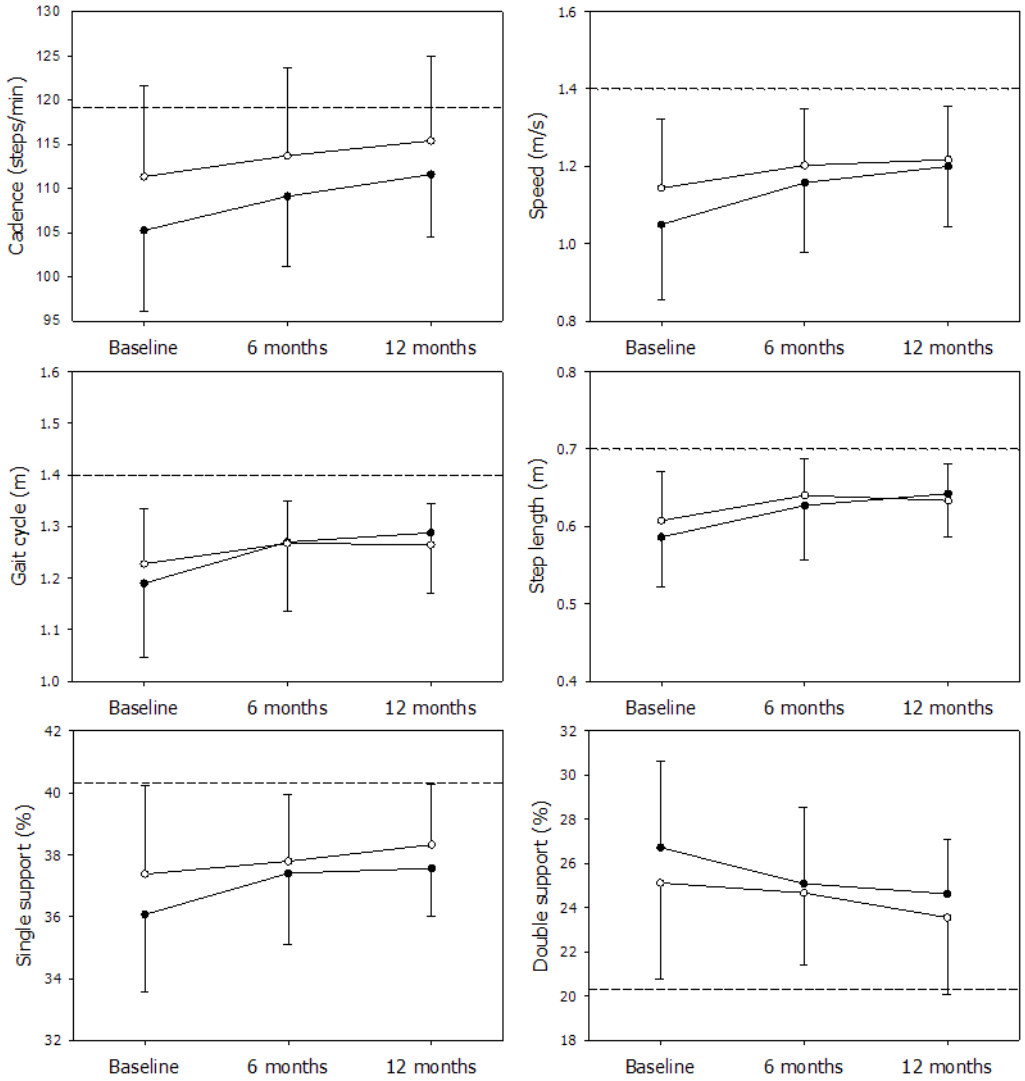
	Fixed bearing (n=26)		Mobile bearing (n=25)		Controls (n=30)		p1	p2	p3
Temporospatial parameters		SD		SD		SD			
Cadence (steps/min)	111.6	(7.1)	115.4	(9.5)	119.1	(9.7)	n.s.	n.s.	0.09
Speed (m/s)	1.2	(0.2)	1.2	(0.1)	1.4	(0.2)	n.s.	n.s.	n.s.
Gait cycle (m)	1.3	(0.1)	1.3	(0.1)	1.4	(0.2)	n.s.	n.s.	n.s.
Step length (m)	0.6	(0.1)	0.6	(0.0)	0.7	(0.1)	n.s.	n.s.	n.s.
Single support (%)	37.6	(1.5)	38.3	(1.9)	40.3	(1.2)	n.s.	n.s.	n.s.
Double support (%)	24.6	(2.4)	23.6	(3.5)	20.3	(2.3)	n.s.	n.s.	n.s.
Kinematic parameters (degrees)		SD		SD		SD			
Flexion (stance)	13.6	(4.1)	13.8	(6.3)	18.4	(4.1)	n.s.	n.s.	n.s.
Flexion (swing)	51.2	(4.6)	53.4	(4.7)	52.8	(5.0)	n.s.	0.09	0.59
Extension	-1.0	(3.6)	2.1	(4.5)	-1.6	(4.2)	0.01	0.44	n.s.
Varus	8.2	(5.1)	7.2	(5.8)	6.5	(4.2)	n.s.	0.09	0.6
Valgus	0.5	(2.9)	0.7	(4.4)	0.9	(2.8)	n.s.	0.48	0.83
External rotation	-14.8	(10.4)	-16.8	(9.1)	-13.0	(7.9)	n.s.	0.71	0.73
Internal rotation	-23.9	(11.2)	-25.3	(8.4)	-24.7	(7.1)	n.s.	0.41	0.07
Kinetic parameters (Nmm/kg)		SD		SD		SD			
Max flexion[1]	0.318	(0.190)	0.403	(0.232)	0.671	(0.200)	n.s	n.s	n.s
Max extension[2]	-0.367	(0.128)	-0.347	(0.114)	-0.450	(0.168)	n.s	n.s	n.s
Max extension[3]	-0.261	(0.184)	-0.152	(0.196)	-0.249	(0.164)	n.s	0.75	n.s
Max valgus[4]	0.426	(0.137)	0.419	(0.109)	0.539	(0.149)	n.s	n.s	n.s
Min valgus[3]	0.238	(0.118)	0.219	(0.114)	0.236	(0.111)	n.s	0.91	0.51
Max rotation[4]	0.160	(0.034)	0.140	(0.039)	0.179	(0.062)	n.s	n.s	n.s
Min rotation[4]	-0.012	(0.010)	-0.007	(0.009)	-0.017	(0.019)	n.s	n.s	n.s

Temporospatial, kinematic and kinetic results for the two implant groups at 12-month follow-up with the control group values with SD.
[1]weight acceptance, [2]touch down, [3]late stance, and [4]stance.
p1: Comparison between the FB and the MB group.
p2: The FB group compared to the controls (H_0: no difference).
p3: The MB group compared to the controls (H_0: no difference).

Temporospatial results

Temporospatial results are shown in Figure 14 and in Table 6. All temporospatial parameters improved towards the normal material during follow-up for both groups, but only in the MB group was cadence statistically equal to the control group at 12 months' follow-up (H_0: no difference; p=0.09) (Table 6 and Figure 14). There were no statistically significant differences between the FB and the MB groups in any of the temporospatial parameters.

Figure 14 – Temporospatial results

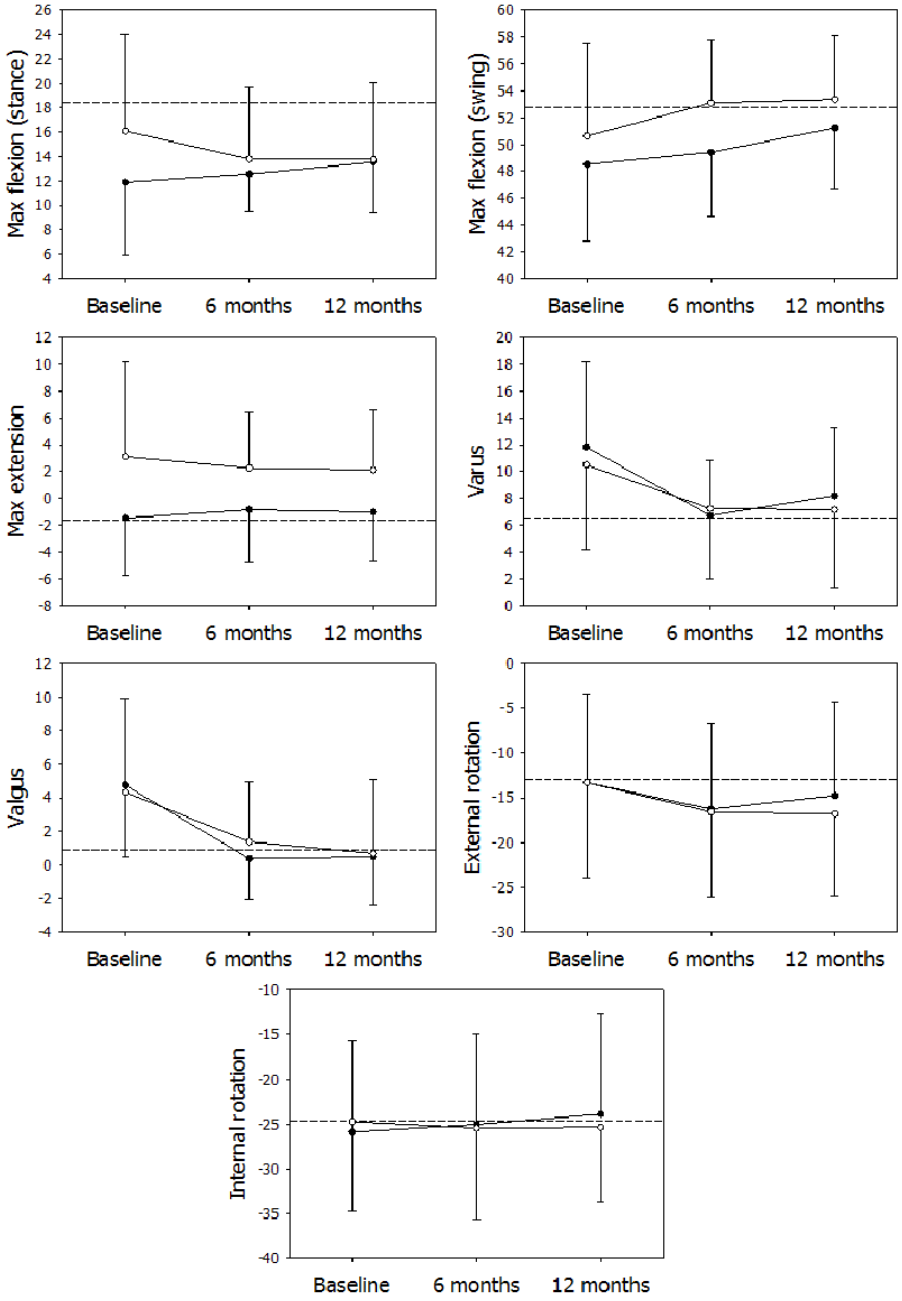


Temporospatial results for the FB (●) and the MB (o) groups at baseline, after 6 and 12 months' follow-up. The dashed line illustrates the control group mean. *: statistically significant normalized value compared to the control group (H_0: no difference).

Kinematic results

Kinematic results are shown in Figure 15 and in Table 6. For both articulation groups there were kinematic values equal to the control group after 12 months' follow-up in knee flexion (swing) and both knee varus/valgus (stance) and internal/external rotation (stance). The knee flexion in stance did not improve to the level of the control group in either of the two articulation designs. The FB group achieved full knee extension compared to the MB group at 12 months' follow-up (p=0.01)

Figure 15 – Kinematic results

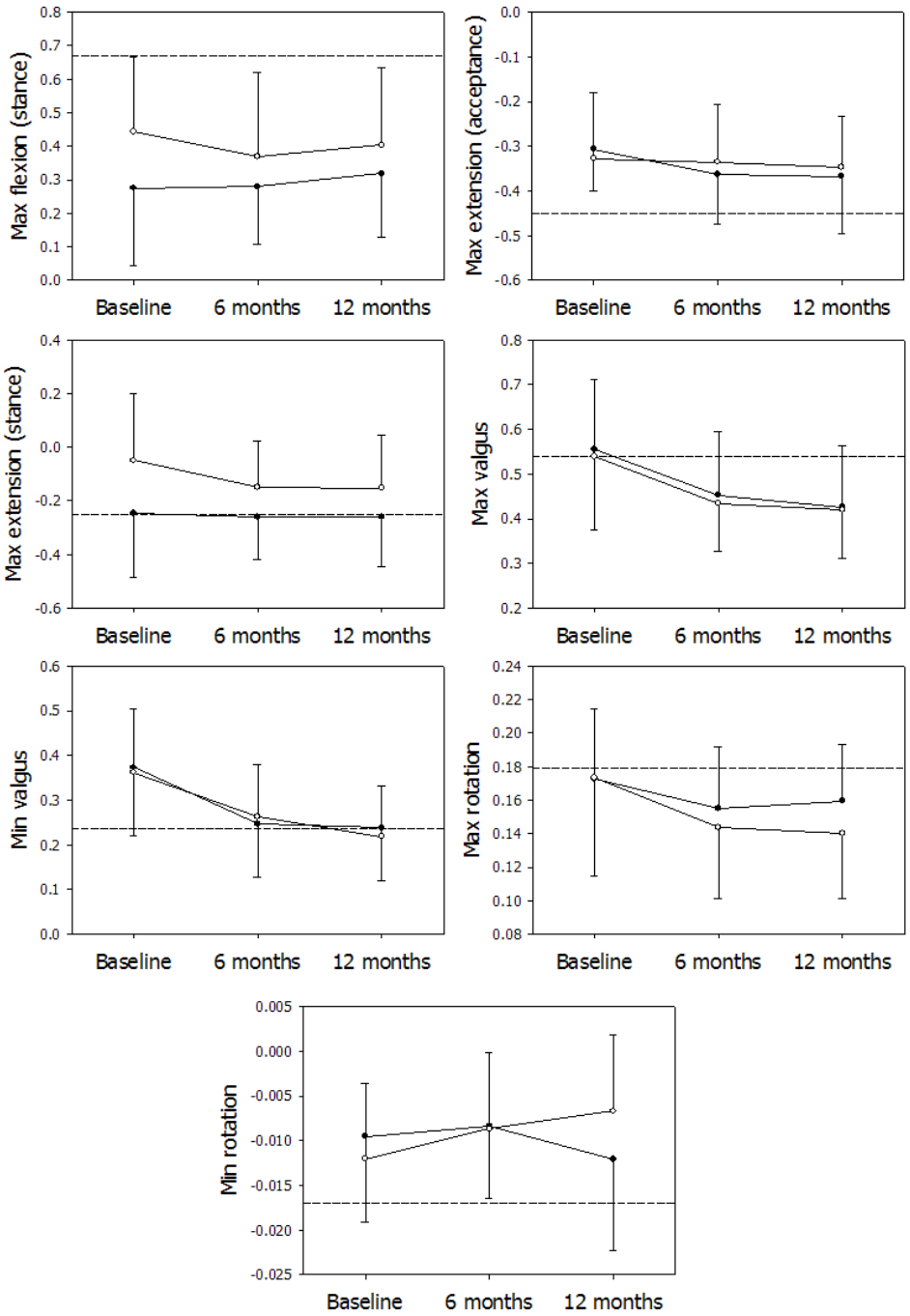


Shows kinematic results (in degrees) for the FB (●) and the MB (o) groups at baseline, after 6 and 12 months' follow-up. The dashed line illustrates the control group mean. *: statistically significant normalized value compared to the control group (H_0: no difference).

Kinetic results

Kinetic results are shown in Figure 16 and in Table 6. Neither the FB nor the MB groups reached control group values in most kinetic parameters after 12 months' follow-up. Only the minimal valgus moment was equal to the control group for both articulation groups at the 12-month follow-up. Furthermore, the FB group showed a maximal extension moment in stance equal to the control group after 12 months' follow-up.

Figure 16 – Kinetic results



Kinetic results (in Nmm/kg) for the FB (●) and the MB (o) groups at baseline, after 6 and 12 months' follow-up. The dashed line illustrates the control group mean. *: statistically significant normalized value compared to the control group (H_0: no difference).

Healthy controls

The demographic values for the healthy controls are shown in Table 1.

The temporospatial, the kinematic, and the kinetic data for the control group are shown alongside the data of the intervention groups in Table 2 and Figures 14–16.

EMG

The mean EMG output (area under curve) from the 6 and 12 months' follow-up relative to the baseline EMG measurements showed decreased values for the operated knees with statistical significance for the vastus lateralis (p=0.010), the biceps femoris (p=0.001), and the gastrocnemius muscles (p=0.007) (Table 3). There were no statistical differences in the EMG values in the contra-lateral (non-operated) knees after 6 and 12 months' follow-up. There were no statistical differences between the FB and the MB groups.

The EMG results from baseline, 6- and 12-month follow-up are available in Appendix Table 4.

Table 7 – Electromyography

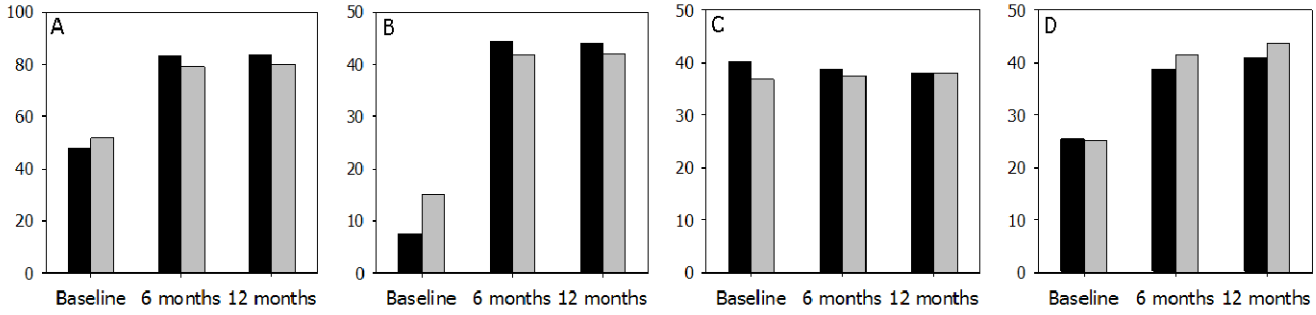
	Fixed bearing (n=26)				Mobile bearing (n=25)				p-values	
	Operated knee		Control		Operated knee		Control		p1	p2
Lateral Vastus	86.1	(4.6)	86.9	(7.5)	83.8	(7.5)	99.5	(7.7)	n.s.	0.010
Femoral Biceps	88.6	(7.8)	93.9	(7.1)	85.5	(5.9)	96.0	(7.8)	n.s.	0.001
Anterior Tibial	93.2	(6.4)	88.4	(6.1)	87.8	(6.0)	100.6	(7.3)	n.s.	n.s.
Gastrocnemius	91.0	(8.8)	88.7	(6.7)	84.6	(7.8)	91.0	(5.1)	n.s.	0.007

Mean EMG (area under curve) values relative to baseline (in %) with SD at 12 months' follow-up.
p1: Comparison between the FB and the MB group (ANOVA).
p2: Comparison between the operated and the control leg (ANOVA).

Knee Scores

Both articulation groups improved significantly on OKS and AKSS from baseline to 6-month follow-up. Results were similar for both knee scores after 6 or 12 months' follow-up for the 2 articulation groups (Figure 17). At the 12-month follow-up, there were similar passive knee joint motion values in both articulation groups (FB/MB); maximal knee flexion (118/113 degrees), maximal extension (3/3 degrees) and ROM (115/110 degrees).

Figure 17 – Knee scores



Mean AKSS (A), mean AKSS pain score (B), mean AKSS clinical score (C), and mean OKS (D) for the FB articulation (black) and the MB articulation (gray).

Study III

Precision of RSA measurements

The repeatability in the phantom study was calculated with the first stereoradiograph as baseline, and the mean migration was calculated to the following stereoradiographs 2 to 9. The systematic error of the RSA examinations (bias), stated as the difference in migration between the two calculations, should optimally be zero. The migration measurement precision was represented by the SD (Table 8).

Table 8 – Precision of RSA (phantom study)

		Fixed bearing					Mobile bearing				
	(mm)	x	y	z	TT	MTPM	x	y	z	TT	MTPM
Model-based	Mean	0.030	-0.020	-0.072	0.201	0.748	-0.001	0.008	0.001	0.224	1.180
	SD	0.116	0.061	0.180	0.103	0.347	0.072	0.100	0.266	0.170	0.571
	PI (1.96 x SD)	0.227	0.119	0.353	0.202	0.681	0.141	0.196	0.522	0.333	1.119
	Min	0.016	0.000	0.050	0.062	0.297	0.005	0.005	0.008	0.018	0.298
	Max	0.214	0.084	0.337	0.356	1.299	0.123	0.165	0.506	0.535	1.827
Marker-based	Mean	-0.005	-0.010	-0.046	0.091	0.192	0.001	0.009	-0.009	0.067	0.163
	SD	0.042	0.053	0.081	0.064	0.128	0.021	0.043	0.059	0.030	0.058
	PI (1.96 x SD)	0.082	0.103	0.158	0.125	0.250	0.041	0.084	0.116	0.058	0.114
	Min	0.002	0.007	0.002	0.015	0.035	0.001	0.006	0.002	0.024	0.103
	Max	0.099	0.122	0.181	0.210	0.430	0.040	0.081	0.100	0.115	0.272

Measurement error of RSA for 9 double-examination stereoradiographs. Signed translations (in mm) for the 2 tibial components are given. The mean value represents the systematic error (bias) of the system. The standard deviation (SD) represents the precision of the system. The prediction interval (PI) represents the expected clinical precision.

The repeatability of the migration measurements was computed based on double RSA examinations at 12-month follow-up in 49 of the 50 participating patients. The postoperative stereoradiographs served as the reference in the migration analysis of the double examinations. The systematic error of the RSA examinations (bias), stated as the difference in migration between the two calculations, should optimally be zero. The migration measurement precision was represented by the SD (Table 9).

Table 9 – RSA precision (clinical study)

Translation	Fixed bearing (n=26)					Mobile bearing (n=23)				
(mm)	x	y	z	TT	MTPM	x	y	z	TT	MTPM
Mean	-0.001	0.002	-0.017	0.288	0.644	0.005	0.018	0.029	0.179	0.499
SD	0.117	0.075	0.330	0.205	0.610	0.072	0.094	0.190	0.135	0.309
PI (1.96 x SD)	0.230	0.147	0.647	0.402	1.196	0.142	0.184	0.373	0.264	0.607
Min	0.002	0.008	0.017	0.081	0.118	0.004	0.004	0.004	0.020	0.098
Max	0.267	0.152	0.905	0.908	1.602	0.167	0.197	0.594	0.621	1.554

Measurement error of moedel-based RSA for 49 double-examination stereoradiographs. Signed translations (in mm) for the 2 tibial components are given. The mean value represents the systematic error (bias) of the system. The standard deviation (SD) represents the precision of the system. The prediction interval (PI) represents the expected clinical precision.

Precision of DXA scans

The repeatability of BMD measurements was calculated based on double DXA examinations of 46 of the 50 participating patients obtained at 12-month follow-up. The coefficient of variation (CV=SD x mean / 100%) was calculated for all 3 ROIs and should optimally be zero (Table 10).

Table 10 – DXA precision

	Fixed bearing (n=25)		Mobile bearing (n=22)	
	AP (CV %)	LA (CV %)	AP (CV %)	LA (CV %)
All ROIs	1.12	11.52	8.76	11.84
ROI 1	2.29	11.04	8.47	16.47
ROI 2	2.85	16.99	11.85	12.82
ROI 3	1.70	9.22	7.03	10.82

Coefficient of Variation (CV) in % for 47 double-examination
DXA scans in AP and LA position.

RSA

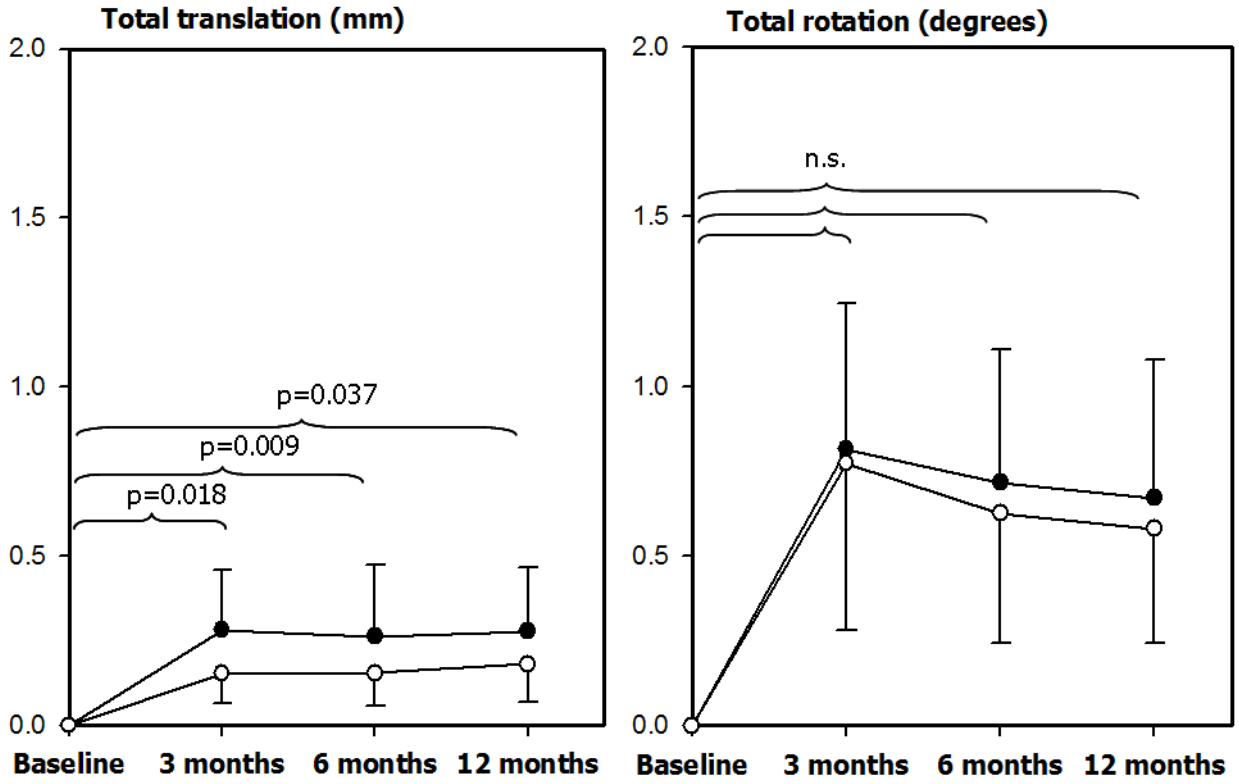
The implants primarily migrated between baseline and 3 months' follow-up (Figure 18). Total translational migration (TT) (in mm) was significantly higher in the FB group at all 3 follow-up times (Figure 18, left); whereas total rotational migration (TR) (in degrees) was similar at all 3 follow-ups for both implant groups (Figure 18, right). Translations and rotations at 12-month follow-up are presented in detail (Table 11) and shown graphically (Figures 18 and 19). The data from the translations and the rotations at 3- and 6-month follow-up are shown in the Appendix, Tables 5 and 6. In summary, there was no trend towards a 1-direction migration pattern in either translation or rotation migrations (signed migration values); we found an even distribution between positive and negative migration values in both articulation groups (Figures 21 and 22).

Correlation between migration and bone loss

Spearman's rho showed a correlation between the total translation and the bone loss for the MB group at 12 months' follow-up in the lateral DXA scans only (rho -0.44, p=0.0372). All other correlation calculations showed no correlation between migration and bone loss.

The 2 patients in both the FB and the MB articulation groups that migrated past the 90th percentile at the 3 follow-ups were different patients at the different follow-ups (Figure 19). These patients had no outlying pattern regarding BMD change (Spearman's rho), and their demographic values showed no skewed pattern with relation to BMI, age, or gender.

Figure 18



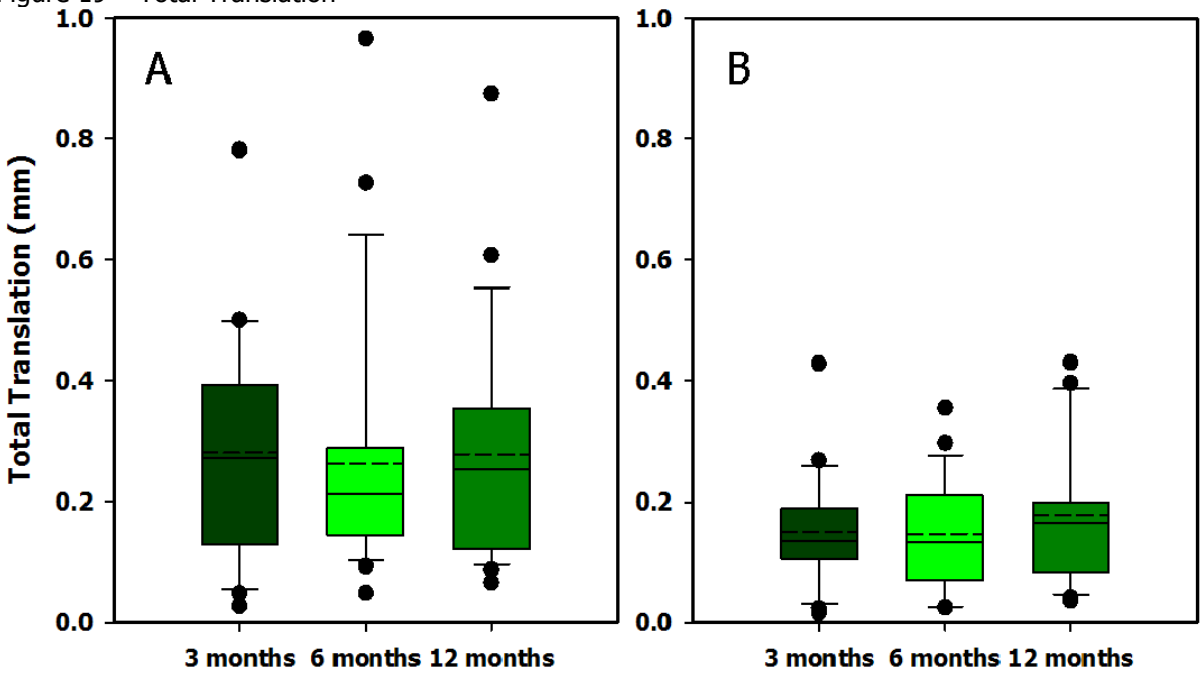
Show Total translation (left graph) and total rotation (right graph) of the FB (●) and the MB (o) articulation at 3, 6 and 12 months' follow-up. TT and TR=$\sqrt{(x^2+y^2+z^2)}$ (3-D Pythagorean Theorem).

Table 11 – Migration at 12 months' follow-up

	Fixed bearing (n=26)					Mobile bearing (n=24)					p-values	
Translations (mm)	x	y	z	TT	MTPM	x	y	z	TT	MTPM	p1	p2
Mean	0.09	0.06	0.23	0.28	0.61	0.06	0.07	0.13	0.18	0.48	0.037	0.081
SD	0.08	0.04	0.20	0.19	0.35	0.07	0.05	0.12	0.11	0.27		
Min	0.00	0.01	0.02	0.07	0.21	0.00	0.01	0.00	0.04	0.18		
Max (-)	-0.18	-0.12	-0.51			-0.21	-0.16	-0.37				
Max (+)	0.32	0.15	0.86	0.87	1.60	0.25	0.15	0.38	0.43	1.51		
Rotations (degrees)	x	y	z	TR		x	y	z	TR		p3	
Mean	0.42	0.38	0.13	0.67		0.32	0.37	0.07	0.56		n.s.	
SD	0.37	0.36	0.10	0.41		0.21	0.36	0.07	0.34			
Min	0.01	0.01	0.01	0.15		0.02	0.03	0.01	0.12			
Max (-)	-0.97	-0.68	-0.33			-0.62	-0.73	-0.33				
Max (+)	1.31	1.83	0.29	1.89		0.72	1.68	0.11	1.73			

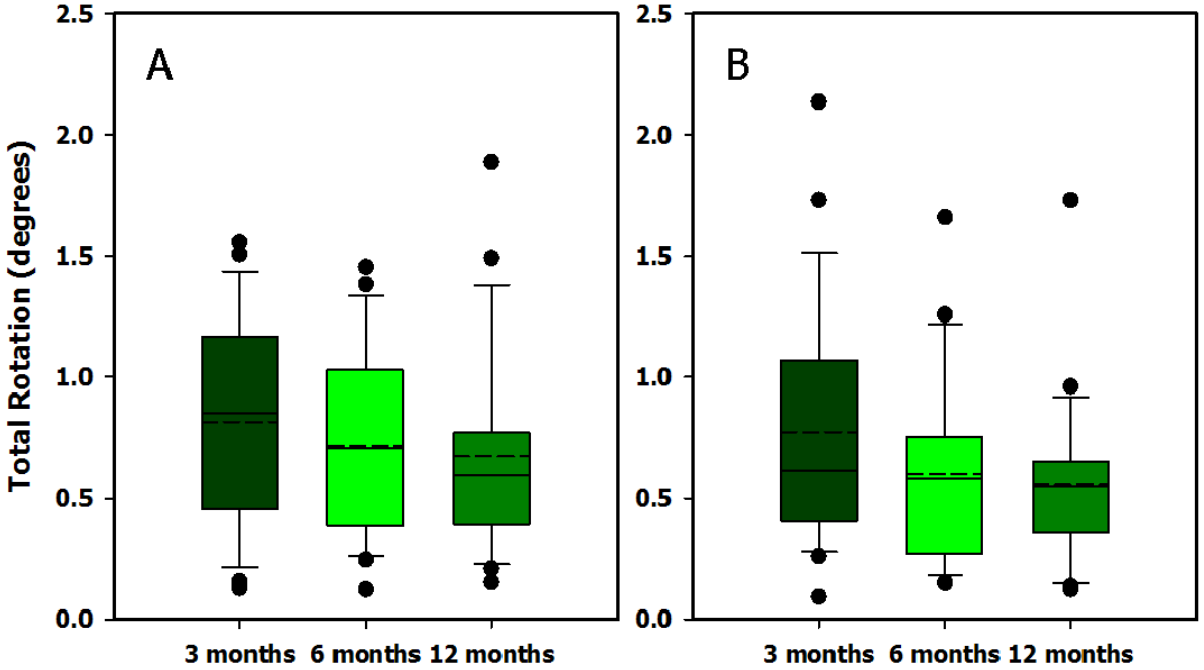
RSA results at 12 months' follow-up calculated from absolute migration values. Max (-) is the maximal migration with negative sign. p1: TT comparison FB vs. MB. p2: MTPM comparison FB vs. MB. p3: TR comparison FB vs. MB. (Wilcoxon ranksum test).

Figure 19 – Total Translation



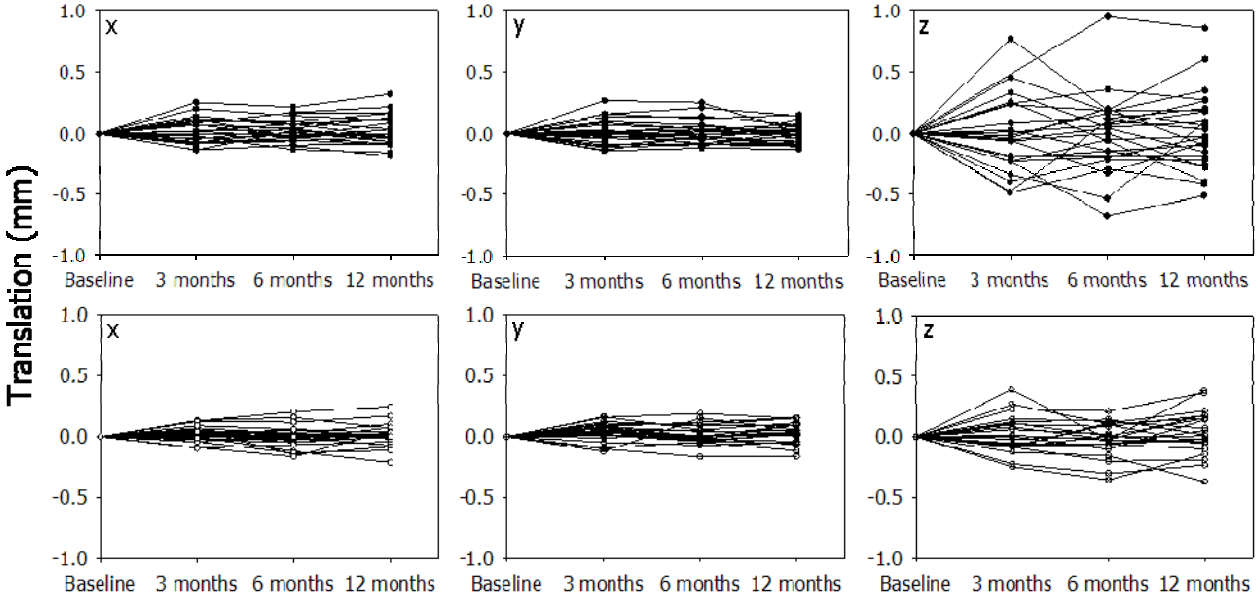
Box plot showing the total translation (in mm) of the tibial implant in the FB group (A) and in the MB group (B). The box shows the interquartile range and the whiskers the 10th and 90th percentiles. The drawn line in each box marks the median and the dotted line in each box marks the mean. The FB articulation had significantly higher translation than the MB articulation at 3-, 6- and 12 month follow-up.

Figure 20 – Total Rotation



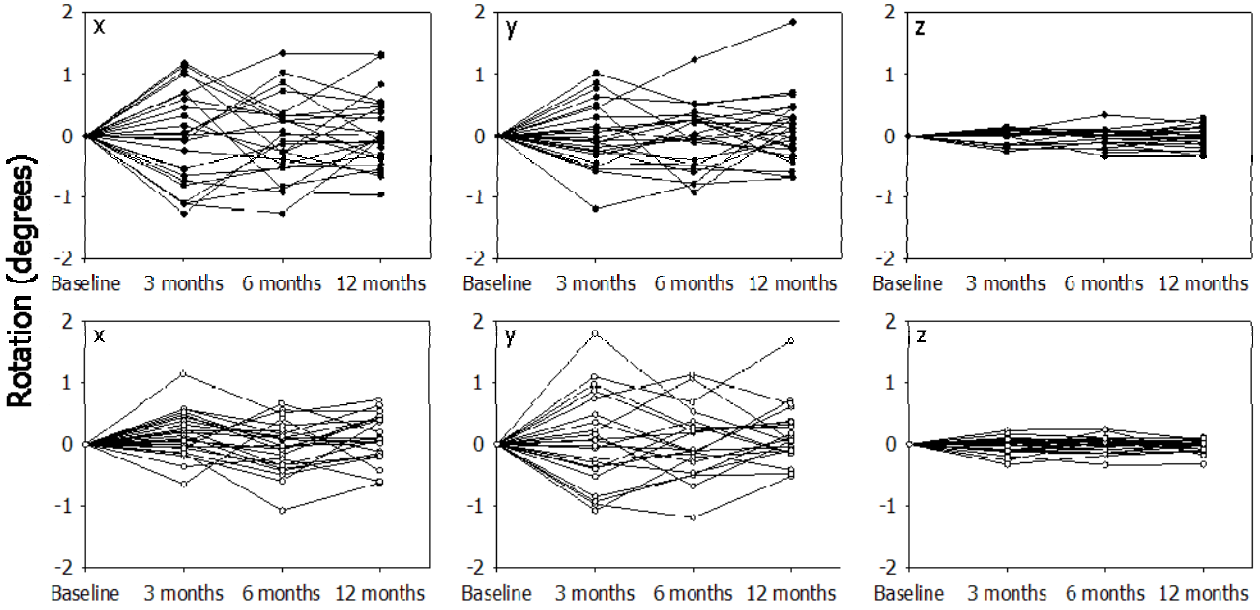
Box plot showing the total rotation (in degrees) of the tibial implant in the FB group (A) and in the MB group (B). The box shows the interquartile range and the whiskers the 10th and 90th percentiles. The drawn line in each box marks the median and the dotted line in each box marks the mean. There was no difference between the two groups in total rotation at any follow-up time.

Figure 21 – RSA translations



Translational migration in the x-, y-, and z-directions for the FB (●) (n=26) and the MB (o) (n=24) articulation.

Figure 22 – RSA rotations

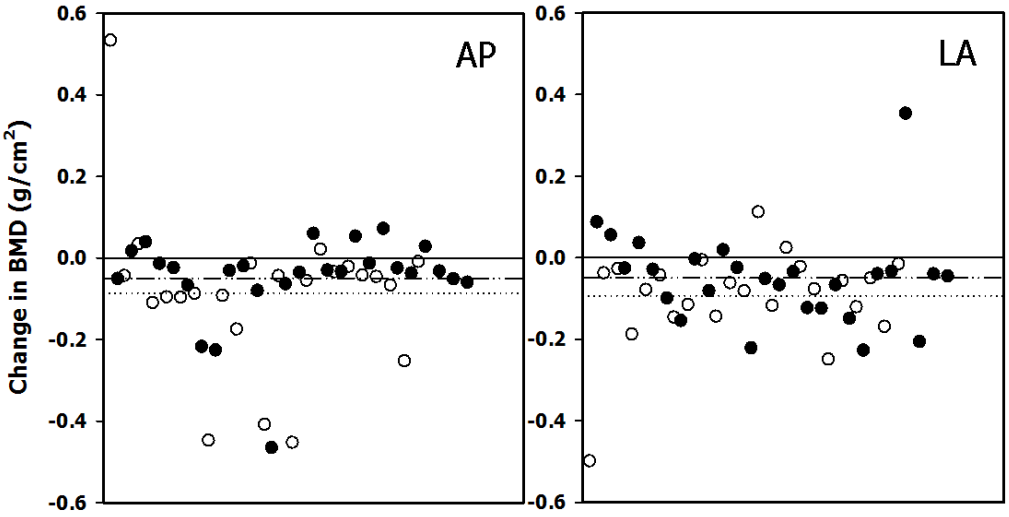


Rotational migration in the x-, y-, and z-planes for the FB (●) (n=26) and the MB (o) (n=24) articulation.

DXA

The total periprosthetic (all 3 ROIs) BMD decreased significantly between baseline and the 12-month follow-up in both the articulation groups. The decrease on the AP scans was 2.81% (p=0.018) in the FB group and 9.03% (p=0.001) in the MB group. The bone loss in the regions just below the mobile bearing implant tended to be higher than the bone loss under the fixed bearing implant, but this tendency was only statistically significant on LA scans in ROI1 (proximal anterior tibia). All the other ROIs showed no difference in BMD change between the fixed bearing group and the mobile bearing group (Table 12). BMD change in AP and LA scans are given for all individual patients in Figure 23.

Figure 23 – BMD change

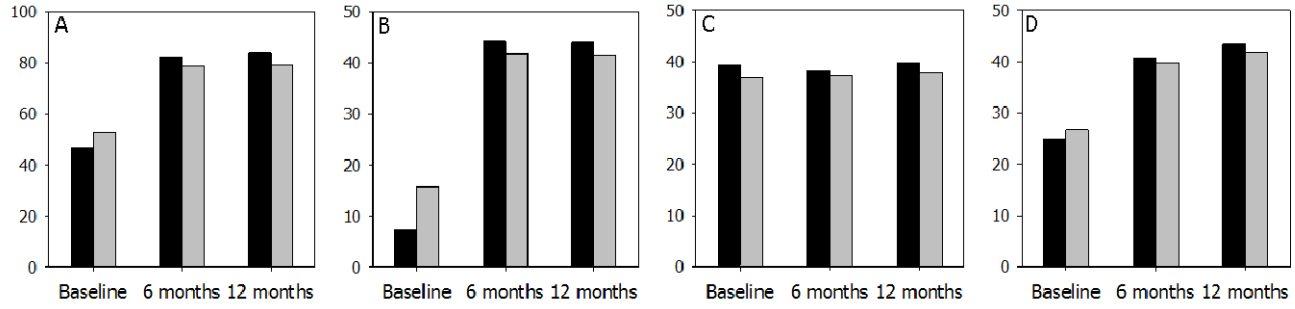


Plot of change in BMD from baseline to 12-month follow-up for all patients in the fixed bearing group (n=26) (•) and in the mobile bearing group (n=24) (o) in AP and LA positions. x=0 is marked with a straight line, the dot-dashed line shows the fixed bearing group mean, and the dotted line shows the mobile bearing group mean.

Knee Scores

Both the implant groups improved significantly on the OKS and the AKSS. There was no difference between the FB group and the MB group in either questionnaire at the 6- or 12-month follow-ups (Figure 24).

Figure 24 – Knee scores



Mean AKSS (A) (max=100), mean AKSS pain score (B) (max=50), mean AKSS clinical score (C) (max=50), and mean OKS (D) (max=48) for the FB articulation (black) and the MB articulation (gray).

Table 12 – DXA scans

		Fixed bearing (n=26)					Mobile bearing (n=24)					p-values		
		Baseline (g/cm^2)	SD	12 months (g/cm^2)	SD	Change (%)	Baseline (g/cm^2)	SD	12 months (g/cm^2)	SD	Change (%)	p1	p2	p3
AP	All ROIs	1.01	(0.17)	0.98	(0.17)	-2.81	0.96	(0.14)	0.87	(0.19)	-9.03	0.018	0.001	n.s.
	ROI 1	1.00	(0.18)	0.94	(0.19)	-6.10	1.00	(0.19)	0.86	(0.21)	-14.72	0.000	0.003	n.s.
	ROI 2	0.91	(0.23)	0.85	(0.18)	-6.36	0.83	(0.13)	0.74	(0.17)	-10.90	n.s.	0.001	n.s.
	ROI 3	1.15	(0.15)	1.12	(0.18)	-2.43	1.06	(0.15)	1.00	(0.21)	-5.64	n.s.	0.005	n.s.
LA	All ROIs	0.91	(0.18)	0.86	(0.21)	-5.43	0.85	(0.17)	0.76	(0.17)	-11.04	0.005	0.000	n.s.
	ROI 1	0.87	(0.27)	0.83	(0.29)	-4.07	0.80	(0.20)	0.69	(0.21)	-13.81	0.028	0.002	0.043
	ROI 2	0.90	(0.22)	0.78	(0.21)	-13.33	0.88	(0.19)	0.72	(0.18)	-17.77	0.000	0.000	n.s.
	ROI 3	0.98	(0.21)	0.99	(0.24)	1.16	0.88	(0.18)	0.82	(0.20)	-6.60	n.s.	0.014	n.s.

DXA scans Mean BMD (in g/cm^2) measurements and SD in AP and LA projections at baseline and after 12 months' follow-up with BMD change (in %).
p1: Mean BMD change from baseline to 12-month follow-up for the fixed bearing group.
p2: Mean BMD change from baseline to 12-month follow-up for the mobile bearing group.
p3: Mean BMD change from baseline to 12-month follow-up: fixed bearing vs. mobile bearing.
(Wilcoxon ranksum test).

Discussion

Key findings

Study I

- Cementation significantly increased the measured BMD without a negative effect on the measurement precision stated as the CV and compared to non-cemented implants. Increased BMD measurement by cementation technique indicates that a part of the cement mantle was included in the area counted as bone.
- In vitro rotation caused significant changes in the measured BMD; however, the absolute changes caused by rotation in BMD measurements were small.
- Knee-specific software was concluded to be a valid tool/software for clinical follow-up, and further, to introduce user-friendly advantages (i.e. no need for tissue equivalent material around the knee during the DXA scan), but as for spine-mode software, the need for frequent manual corrections persisted.

Study II

- The gait cadence normalized in the MB group only.
- Most kinematics normalized for both articulation groups towards the healthy control group (H_0: no difference).
- Full active extension during level walking gait analysis was achieved in the FB group only, but full passive extension was found in both articulation groups from the physical examination (AKSS).
- The maximal extension moment in mid stance normalized significantly for the FB group only.
- The minimal adduction (valgus) moment normalized in both groups.
- Mean EMG values decreased in both groups indicating less co-contraction.

Study III

- We found a significantly higher migration for the FB group compared to the MB group at all follow-ups. Both implant designs were stable throughout 12 months' follow-up.
- There was a correlation between migration and bone loss in the MB group for LA DXA scans only.
- Periprosthetic BMD decreased similarly in both the FB and MB articulation groups after surgery.

Study I

Method considerations

In study I, using human phantom bones, we showed that cementation increased the measured BMD around stemmed tibial components, but without a negative effect on reproducibility stated by CV. For both implant types, the CVs improved slightly after cementation into the phantom. During the DXA scan, the scanner arm moves over the scanner bed and thereby causes minor vibrations. These vibrations could potentially cause press-fit implant micro-scale motion inside the phantom bone (organic material was cooked out of the bones before they were used for the experiment) leading to a slight inaccuracy in the definition/measurement of the metal (implant) artifact. Such potential micro-motions were effectively impaired by cementation and could explain the observed slight improvement of CV after cementation. The knee specific software point-typed implants and bone edges correctly in vitro. Based on these findings we concluded that the knee-specific software was valid for clinical research follow-up and henceforth used it clinically in comparison with our old method (spine-mode software). In the second part of study I (patient double examination), comparison of knee-specific software and spine-mode software showed an inconsistent automatic point typing of implant, tibial bone edges, and tissue in both softwares. Spine mode software outperformed the knee specific software in automatic implant detection, whereas detection of tibial bone edges demanded frequent manual adjustments in both softwares.

Overall, the clinical reproducibility for clinical periprosthetic BMD measurements was comparable for both softwares and comparable to results published by other authors [24;36;92]. In study I we decided to exclude the fibula from all clinical DXA scans (AP and LA), since we did not consider the fibular BMD important for the fixation of the tibial component and, additionally, the fibula was absent in our in vitro measurements from the phantoms. Nevertheless, there could be arguments to leave the fibula uncorrected because it requires manual point-corrections to exclude the fibula, and the proximal part of the fibula will inevitably overlap the tibia in most scans; hence total fibular extraction is impossible. We included the fibula in our analysis protocol for study III.

Comparison to relevant findings of other studies

Li et al. [35] showed a decreased precision in repetitive BMD measurements with non-knee specific software mainly due to an inconsistent soft tissue baseline (they used rice bags as soft tissue substitutes) and reported CVs at 7.3% in AP scans. This was similar to the set-up with the spine-mode software in our study, but we had lower AP CVs. The difference in CV between the 2 studies might be explained by a more automatic ROI placement at follow-up in our study, because the enCORE software makes it possible to fix the ROI template to the tibial bone edges and copy this placement to succeeding follow-up scans. Stilling et al. [36] recently published clinical results for cemented, stemmed TKA (no cement around the stem) using traditional spine-mode software with lower CVs from double examinations than Li et a. [35]. Stilling et al. reported CVs between 1.8% and 3.7% in AP position and between 3.4% and 6.2% in LA position. The leg-

rotation was fixed in their set-up and their conclusion was to avoid differences in knee flexion at follow-up, because even slight flexion (5 degrees) changed the measured BMD. We found clinical repeatability similar to the report by Stilling et al. on double measurements (AP and LA) with both the knee-specific software and the same spine-mode software, and likewise we showed that positioning of the patients at follow-up is a critical matter, because as little as 5 degrees of rotation can change the measured BMD significantly. The range for the relative BMD changes (5 repetitive scans in 2 phantom bones) by 5 degrees of rotation were between 0.00% and 14.48%, but the absolute BMD change was clinically very small and potentially irrelevant (Figure 10). The CVs for AP scans were 2.78 to 4.64% with the knee-specific software, and this is the detection limit for a change in the present study.

Mortimer et al. [38] reported limb rotation to be within easily controllable limits and the associated BMD changes to imply no excessive error. Other DXA studies have reported varying BMD changes in the proximal tibia at follow-up [24;30;34;40;93]. Karbowski et al. found a BMD decrease of 10% measured around tibia nine months post-operatively, but gave no reproducibility calculations. They used large ROIs including all periprosthetic bone around the femur and tibia [93]. Spittlehouse et al. found CVs for DXA measurements of proximal periprosthetic tibial ROIs to be in the range of 6.1% to 12.4% (LA scans) [30]. Soininvaara et al. reported a CV of 2.9% for tibial ROIs (AP and LA mean) [24] and a significantly decreased BMD at 24-month follow-up for the tibial medial diaphyseal and the metaphyseal ROI, whereas they found no difference in the tibial lateral diaphyseal ROI [34]. In another publication, Soininvaara et al. found no change in periprosthetic BMD in neither the lateral nor the medial tibial ROIs at up to 24 months of follow-up, whereas a significant decrease was reported in the tibial diaphyseal ROI [40]. Soininvaara et al. applied tibial ROIs similar to the set-up we used. Some of the difference in CV between studies is explainable by different scanner types and ROI sizes: the smaller the ROI, the more difficult it is to place it right. We found clinical reproducibility CVs of 1.45% to 4.64% for AP scans and 3.25% to 6.19% for LA scans. In vitro BMD changes caused by rotation were between 0.00 to 14.48% (0.00-0.11g/cm^2). The 95% limits of agreement or least detectable significant difference from the in vivo BMD measurements were small (AP 0.112-0.151 g/cm^2 and LA 0.097-0.123 g/cm^2). The BMD changes caused by rotation exceeded the least detectable significant difference in some rotation positions (Figure 10).

In conclusion, we found 1) cementation to significantly increase the measured BMD, but considering the CVs, cementation had no negative effect on in vitro reproducibility. The rotation-dependent BMD changes might be of statistical significance, but the extent of clinical importance deducted from the in vitro scans could be discussed, not least due to the absence of fibular interference in vitro. Our DXA results from study III with lower LA precision underlined the inherent method weakness of not being able to exclude the fibula totally from the analysis, because patient anatomy was quite different in LA position (some had overlapping fibula and tibial and some did not). We suggest the use of a clinical protocol that prevents rotation of the proximal tibia because rotation is a sensitive aspect for BMD measurement precision. Furthermore, we have

shown 2) the clinical reproducibility in double examination scans performed with new knee-specific software to match the reproducibility in scans by the traditional spine-mode software. Apart from the discussion of precision in double measurements or at follow-up, we have 3) presented our results from automatic point typing by the 2 softwares used. Neither spine-mode software nor knee-specific software has the ability to point type the different tissues and implants 100% satisfactorily; hence much time is invested in manual corrections. One should not totally neglect the potential inaccuracies due to manual corrections; however, gross software point-typing mistakes should not be left uncorrected. The used knee-specific software is currently available for clinical research only (not FDA approved for clinical use) and has the substantial user-friendly advantage of alleviating tissue substitutes. Many researchers and technicians might find this advantageous in the daily clinical setting. Future improvements in tissue detection ability in clinical scans would speak clearly in favor of knee-specific software for BMD measurements around tibial components.

Studies II and III

Design limitations

A prospective, randomized design produce the highest level of evidence, because the random allocation aims to provide unbiased comparison (limited case-mix) with high internal study validity. The external validity and the generalisability depend on whether the patients included in this study were comparable to other knee OA patients. From baseline demographics it was obvious that our patients were overweight. The incidence of knee replacement in middle-aged women with a BMI >30 kg/m^2 is 6.4-10.5 times that of women with a BMI <25 kg/m^2 [94-96], so from a BMI point of view, our patients were similar to most other knee OA patients. For comparison to a more active, younger, and leaner patient group our study has its limitations regarding both BMI and age. Our inclusion period was from 2007 to 2010; hence there is a risk of inclusion bias, because many patients were not assessed for eligibility in the study. Selection bias occurs when the association between exposure and outcome differs for the participants and for the non-participants [97]. We used consecutive inclusion, but to what extent participants, patients declining to participate, patients not asked, and excluded patients differed with regard to important prognostic variables and how this might influence the external validity of studies II and III remain uncertain. Substantial proportions of subjects lost at any stage of an RCT may have important implications for the external validity, because the participants might no longer be representative for those eligible for the intervention [98;99].

In contrast to the random allocation, the blinding cannot always be implemented fully in an RCT. The blinding protects the validity of outcomes after allocation [97]. Studies II and III were single-blinded; the patients were not informed to which articulation group they were randomized. Blinding of the surgeons is impossible, naturally. Investigator blinding was followed to the extent that the gait analysis and the knee scoring after surgery were performed by gait lab physiotherapists, who did not know the randomization result. Stereoradiographs and DXA scans were performed by research staff and not the ones responsible for data analysis and interpretation. Even so, during an RCT questions may arise regarding specific images or

gait parameters and in such situations the investigator look into data before termination of inclusion, and this could threat blinding.

Study II

Method considerations

Gait analysis has more possible limitations as a follow-up tool. The skin markers were thoroughly placed according to predefined protocols [63;85], but nevertheless some inaccuracies might arise from the marker placement, because many knee OA patients were overweight. Additional fatty tissue on the anterior superior iliac spine causes displacement of the hip joint center in the software model. If not corrected for, an obese patient shows extreme valgus knee angles; hence the markers in trials with overweight patients must be corrected according to a predefined manual. Avoiding the fatty tissue corrections would require the inclusion of exclusively normal-weight knee OA patients; this would be a long lasting and troublesome quest and have a negative effect on the external validity of the study.

For the measurement of sagital (flexion/extension) and frontal (varus/valgus) values, the skin marker model is more precise than it is for the measurement of transversal values (rotations). This is explained by the relatively large sagital and frontal excursions compared to the relatively limited rotations. The substantially higher SDs from both kinematic and kinetic rotation measurements underline this point.

The temporospatial parameters were based on the patients' self-selected speed and could be criticized for being less objective. Murray showed the duration of gait cycle phases to decrease with increased cadence [100]. However, the self-selected cadence facilitates a smooth, natural, and efficient forward progression of the body's center of gravity in terms of energy required for walking [61]. The cadence is used as a follow-up parameter in other orthopedic research areas, i.e. with "Timed Up and Go" as an indicator of hip fracture healing or in comparison between surgical approaches [101-103]. Only the MB group achieved a cadence equal to our normal material after 12 months' follow-up.

For most kinematic and kinetic measurements, there were no significant changes over time. The sample size was based on the data from a pilot series with cadence as the primary effect parameter. Potentially there might be a type-2 error for other (secondary) gait-parameters, as large standard deviations increase the needed patient sample in each group to show statistical significance of new interventions. Although we did not find statistically significant differences between the articulation groups we did see a positive trend for both groups as they showed gait parameters closer to normal gait 12 months after surgery compared to before surgery. This gait pattern change away from the "stiff knee" is underscored by increased maximal flexion in weight acceptance and swing and decreased peak knee flexion moment in weight acceptance [74]. With the high inter-individual differences (high SDs) comes the question as to whether gait analysis might be more suitable to detect changes in the single patient over time rather than suitable to compare groups, at

least if these groups are small-numbered. Andersson et al. concluded some 30 years ago that the sophisticated set-up in a gait laboratory was of limited value to the surgeon in his clinical assessment even though they found correlation between the improved gait pattern and the patient-reported pain [104].

With knee flexion in weight acceptance and knee extension in stance, the MB group showed no improvement or even a decreased ROM post-operatively. Also in maximal flexion moment, maximal adduction moment, maximal and minimal rotation moment the MB group were not better at 12-month than they were before surgery. Whether this points to an inferiority of the MB implant compared to the FB implant or whether the difference in normalization between FB and MB is explained by inherent gait patterns derived from the years of OA pain and disability prior to surgery is uncertain [83;105]. It has been questioned whether the rotating PE insert rotates after surgery or whether the rotating PE finds a "fixed" position shortly after surgery. Garling et al. reported limited rotation of different MB TKA than the one used in this study [106]. With a combination of fluoroscopic recordings and RSA they found the femoral component to rotate more than the mobile PE relative to the tibial component. The limited mobile PE rotation was explained by limited conformity between the femoral component and the mobile PE insert, the anterior located pivot location of the investigated MB design, PE on metal impingement, and fibrous tissue formation between the MB insert and the tibial plateau [106]. The pivot location of the P.F.C. Sigma MB PE used in this study is positioned less anterior compared to the implant used by Garling et al., but this study contains no measurements that enable us to conclude a higher rotation for the MB PE; the rotation could take place between the femoral and the tibial components rather than between the MB PE and the tibial component. After all, we found no difference in either internal or external rotation between the FB and the MB articulations. A possible solution to avoid MB PE to find a "fixed" position could be the use of MB PE designs allowing both free rotation (as the P.F.C. Sigma) with an anterior-posterior sliding feature as described by Tibesku et al [72]. However, the increased articulation surface over and under a multi-versatile mobile PE might be at risk of encountering a higher wear rate than an MB PE only allowing for single-direction rotations.

The EMG output at 6- and 12-month follow-up relative to the baseline EMG measurements (in %) showed decreased values for the operated knees with statistical significance for the vastus lateralis, the biceps femoris and the gastrocnemius muscles, which we interpreted as less co-contraction around the knee joint and thereby less effort demanded for absolving a gait cycle. There were no statistical differences in the EMG values in the non-operated knees after 6 or 12 months' follow-up, further indicating that the operated knees improved, while the non-operated knees were at "steady-state". There were no statistically significant differences between the FB and the MB groups regarding the EMG measurements. The surface EMG could be criticized for inaccuracies, because the placement of electrodes is crucial for transmission of a good signal. The electrode placement followed a predefined protocol, but differences in fatty tissue thickness might interfere with the measurements.

A possible strategy for future research with gait analysis could be the inclusion of a stair climbing exercise with fluoroscopy: a combination of measurements providing accurate rotation-translation measurements at the replaced knee and complete locomotion patterns at both lower limb joints. This has been shown to be a precise method to quantify precise joint kinematics, however expensive and technically demanding [107]. With higher joint stress than in level walking, stair climbing provides additional information on the kinetic relations in a TKA [77]. The level walking gait analysis generally offers a good presentation of the patients' rehabilitation pattern when compared to healthy normal subjects. Introducing more invasive or for the patients troublesome or pain causing exercises might also lead to a higher dropout rate and selection bias, but is interesting especially for younger patient groups.

Comparison to relevant findings of other studies

The improvement towards a more normal gait pattern alongside no difference between FB and MB corresponds to the results of Tibesku et al., who found no difference in gait analysis and EMG values between an FB implant and an MB implant allowing both rotation and anterior/posterior sliding [72]. To our knowledge, no other studies have compared FB to MB TKA in a prospective, randomized trial using gait analysis with reference to a healthy control group. In a Cochrane review based on 2 studies comparing the FB to the MB articulating principle by knee scores and radiographs [108] and knee scores and ROM assessment [109], Jacobs concluded that there were no substantial advantage with the MB [110]. Other studies have compared a FB to a MB design with knee scores, x-rays, and ROM, but all concluded that the performance of the two articulation principles was similar [111-117].

Overall, we found temporospatial parameters from level walking to normalize towards the gait pattern of healthy controls in both the FB and the MB implant groups; higher single support percentage of the gait cycle and accordingly lower double support percentage of the gait cycle points towards a gait with less limping. The patients' limping was improved, which obviously can be explained from lasting pain relief and misalignment correction after TKA. With less pain and a well-balanced arthroplasty, the basis for a more asymptomatic gait pattern is present. However, the TKA patients did not, however, reach normal values in all gait analysis parameters.

Overall, the kinematic results improved to the level of a normal gait pattern with increased knee flexion in the swing phase and correction of misalignment in the frontal plane (less adduction/abduction). The rotation values changed only little from baseline to 6- and 12-month follow-ups and the values were similar to those in the normal material. The knee extension from the gait analysis was better in the FB group (absence of extension deficit). This finding was not reflected in the clinical part of the AKSS, in which similar scores were found in the passive maximal knee flexion, the extension, and the knee R.O.M in the 2 implant groups.

Hatfield et al. described the major patterns of variability in gait waveforms before and after TKA using principal component analysis [76]. Their study included 2 FB tibial designs and a single MB. Hatfield et al. showed an important change of patterns in knee kinematics and kinetics after a TKA operation that is a very useful reference to describe the end results for both the articulation designs used in our study. They showed the knee flexion angle to increase in both the stance and in the swing phases. Further, they showed the knee extension moments at touch down and in late stance to increase towards, but not to reach, control group values. The maximal knee flexion moment in stance was also shown to increase post-operatively [76]. Similarly Astephen et al. described the change in the biomechanics of the knee, hip, and ankle in relation to knee OA severity and showed a reduced knee flexion moment in weight acceptance and higher knee adduction moment in midstance with increased OA severity [66]. In a review, Foroughi et al. suggesteda correlation of the knee adduction moment with OA severity and with knee varus mal-alignment [118]. Compared to their results our findings suggest a less symptomatic gait function after TKA [66;76;118]. In the present study, the FB articulation showed an increased maximal knee flexion moment in weight acceptance, and both the FB and the MB groups had increased maximal extension moments at both touch-down and in late stance, pointing towards a more asymptomatic gait pattern postoperatively. For the MB group, the maximal flexion moment in weight acceptance decreased postoperatively, indicating absence of improvement compared to FB, but this difference between the 2 groups was statistically insignificant and with the considerable standard deviations, a much larger sample size would be required to show a statistically significant difference. Furthermore, the minimal mid-stance valgus (knee adduction) moment decreased significantly in both the FB and MB groups towards a less symptomatic pattern [66;76;118]. These kinetic changes could result in less stress and pressure in the medial joint compartment [67;119]. The rotation moments decreased insignificantly in the MB group, which could be explained by less force acting on the MB PE in rotation. The MB allowed for rotational motion only in the transverse plane (and not additional anterior/posterior sliding as in other designs [72]), and this could reduce cross-shear stress and ultimately wear by decoupling multi-directional motions into mono-directional motion patterns [120]. In support thereof, retrieval studies showed no signs of excessive backside wear with the uni-directional MB that we investigated [14], and further low wear could be attributed to the large contact area between the mobile PE liner and the femoral component, with lower forces applied per surface unit [121].

The EMG measurements showed decreased values after 6 and 12 months' follow-up in both implant groups for the vastus lateralis muscle, the biceps femoris muscle, and the gastrocnemius muscle in the operated leg alongside no changes in the non-operated leg. To our knowledge no RCT has shown EMG data related to pre-operative status. We have interpreted the EMG decrease to reflect a less co-contraction gait pattern, which follows the change away from the "stiff-knee" as mentioned in connection with the kinematic and kinetic improvements. Other publications showed no difference between an FB and an MB implant after 7 to 70 months of follow-up without regard to pre-operative EMG values [70;72]. EMG is probably improved or changed as a result of "removing pain" and therefore not an effect-size of which articulation type was used.

Regarding the patient-reported clinical performance, we found no difference between the 2 articulation designs. With regard to both the OKS and the AKSS, the 2 groups improved from baseline to 6-month follow-up, and between the 6- and 12-month follow-ups we found only marginally further improvements. Our clinical results are comparable to results from other clinical reports on the P.F.C. Sigma TKA system [18;108;114;122;123]. No report has shown a significant difference between the various articulation principles.

Study II gave us no clear recommendation as to whether the MB or the FB is preferable. A practical advantage of the FB articulation in daily surgery is the peri-operative flexibility with regard to the PCL. If full extension is not achieved with the PCL retained the FB PE insert can be used both with and without the PCL, whereas the MB insert must be stabilized posteriorly with a post/cam feature to minimize the spin-out risk. Another way to achieve full extension without PCL sacrifice is to resect more femoral bone: a solution with the disadvantageous placement of a more proximally knee joint line.

In conclusion, we have shown that both the FB and MB patients experience significantly improved knee scores and improvements in gait after TKA compared to their own pre-operative gait status. In short, the gait improvements were less limping with longer single support, increased knee flexion in swing, and correction of misalignment (less varus/valgus excursions). Only the MB group achieved a cadence equal to the control group. The kinetic measurements showed changes towards a more asymptomatic gait pattern [65;66;76], with increased weight-accepting knee flexion moment, decreased late stance knee flexion moment, and decreased mid stance knee adduction moment. Study II is the first prospective, randomized gait analysis TKA study using a healthy control group as reference. Despite the proper study-design and sample size, but similar to many other papers [18;72;108;109;111-114;114-117;122;123], we cannot appoint either the FB or the MB articulation in TKA as "the winner".

Study III

Method considerations

We used model-based RSA with CAD models and tested the accuracy of motion with a phantom and found a TT detection limit (SD) of 0.12 mm (MB) and 0.2 mm (FB), which result in an expected clinical precision (PI) of 0.24 mm (MB) to 0.40 mm (FB). For the frequently used parameter MTPM the expected clinical precision (PI) was 0.61 mm (MB) to 1.20 mm (FB). The directional detection threshold (SD) in our phantoms were 0.06 mm (MB) and 0.12 mm for x-translation, 0.05 mm (MB) and 0.07 mm (FB) for y-translation and 0.13 mm (MB) to 0.33 mm (FB) for z-translation. Kaptein et al showed RE models to be superior to CAD models in model-based RSA with an SD for RE models of 0.06 mm for translations in the x- and y-directions and 0.14 mm for z-translations [49], which is similar to the precisioni of our MB CAD models. From this comparison it is clear, that our MB CAD models must have been more accurate than the FB CAD models. All

prostheses go through a process of polishing after production of the primary CAD-like implant. Thus, there is a threshold of contour/model match from CAD model to the actual prosthesis. Using RE models is expensive because the expense per component size is the cost of the implant and additionally 350 € for laser scanning. However, RE models might have been able to improve the precision for both articulation models. An advantage of model-based RSA is that migration calculations is based on contour fitting of the model rather than on identification of bead-towers attached to the implant, and thus there is tantalum beads at risk of occlusion behind implant flanges, stem, or baseplate and further no sensitivity in the RSA analysis to loosing 1 marker.

The y-translations will be of interest in future wear estimates, and with the above mentioned precision, we would be able to use the CAD files for this parameter; provided the femur CAD models show the same high RE-similar precision.

From our RSA phantom measurements, it is obvious that MTPM is not a very accurate parameter to use with CAD model-based RSA – prediction intervals up to 1.20 mm (FB) are too high to be suitable for use in clinical follow-up.

Comparison to relevant findings of other studies

The present study's key finding was a significantly higher migration of tibial implants with the FB PE compared to the tibial implants with the MB PE at all follow-ups up to 12 months. In comparison to other publications, however, the migration for both the FB and MB group was relatively small in the present study. Ryd et al. used RSA as a predictor of mechanical knee implant loosening of uncemented tibial implants and found a migration of 2.7 mm (MTPM) among revised implants and 1.0 mm (MTPM) in stable implants at 1-year follow-up [54]. Hansson et al. reported no difference in implant migration (using a marker-based RSA) during a 2-year follow-up by comparing an un-cemented MB to an un-cemented FB TKA [124]. They found an MTPM between 1.4 mm and 1.7 mm at 12-month follow-up, whereas the cemented P.F.C. Sigma implants in the present study migrated markedly less at 12-month follow-up for both the FB and the MB group. For a model-based RSA study, the MTPM is a virtual value based on the point in the model most migratory (out of 5000 points in total). This is because the computer-aided design model of the implant is described by 5000 points (triangles). For marker-based RSA all points in the implant migration are known (normally to 5 tantalum beads attached to the implant), hence the MTPM gives 3D vectored directional information [54]. For didactic and comparison enhancing purposes, we included the MTPM values in the present study. Stilling et al. published 2-year migration results for 2 different uncemented fixed bearing tibial plateaus and reported the 2-year TT to be between 1.14 mm and 1.82 mm with the model-based RSA [125]. In a marker-based RSA study Henricson et al. compared a cemented fixed bearing to a mobile TKA, but found no difference in migration at either the 12- or 24-month follow-ups [126]. At the 12-month follow-up MTPM measured between 0.39 mm and 0.51 mm and at 24 months, MTPM measured between 0.56 mm and

0.57 mm. These migration measures are similar to our results, and the similarity probably arises from a similar fixation in both studies, that is, by bone cement, in both studies. More publications support the finding that cemented implants migrate less than un-cemented ones [54;127-129]. In the present study, 6 patients in each group migrated more than the 90th percentile (TT) at the 3 follow-ups (Figure 19). Of these patients, only 3 showed MTPM > 1 mm. None of these 6 patients had low OKS and AKSS scores and their change in BMD showed no outlying pattern. The patients with high migration improved their knee scores even more than the total patient group; hence the relatively limited migration shown by this study does not point to symptomatically loose implants. Throughout the follow-up period, we found the TT in the FB group to be significantly higher than the TT in the MB group. The reason for this difference in migration could be attributed to the difference in the bearing principle. The MB has been credited for the ability to translate the multi-directional motions of a knee joint into mono-directional motion patterns. This ability should, in principle, reduce cross-shear stress and ultimately reduce wear [120], but it might also be responsible for the reduction in migration shown in this study.

The present study found the periprosthetic BMD to decrease from baseline to 12-month follow-up, which was in accordance with other publications [93;130-132]. Some studies report that BMD to returns to baseline level within 24 months postoperatively [40;42], but other authors report continuous bone loss after TKA in longer follow-up studies [23;132]. We have to wait and see, what the 2 year follow-up concludes.

The use of DXA as follow-up method has been criticized for its inaccuracies [133], and in opposition to the reproducible set-up of RSA, DXA follow-up scans could be influenced by either changes in knee flexion or rotation that cause false estimates of BMD changes. The impact of knee flexion has been investigated previously [36] as the impact of rotation was investigated in study I and is reflected in our precision measurements in this study, which also had a higher CV% for the LA than did the AP DXA scans. However, the CV precision in this study is comparable to other reports [24;35;36]. Another potential source of inaccuracy in BMD analysis of the proximal tibia is the outline and presence of the fibula in the scans. The present study included the fibula and the cortical bone, because total fibular removal would be impossible due to fibular over-projection onto the tibia. Most TKA studies with BMD measurements have used different placements and sizes of ROIs, which could lead to difficulties in comparing the results between studies [41;125]. A consensus on ROI placement in TKA studies similar to the use of Gruen zones with hip arthroplasties would enhance the comparability among knee studies.

Although theoretically obvious, the association between the decrease in BMD and the difference in migration of TKA as well as THA has been reported with different conclusions [42;43;130;134]. Li et al. found no difference in migration using either cemented or non-cemented tibial implants after 2 years' follow-up. In their study most implant migration was observed during the first 3 months [42] as it was the case in the present study. Minoda et al. found no difference in BMD change between the FB and MB tibial implants at

the 2-year follow-up [130]. Petersen et al. found less migration in tibial components in patients with a high preoperative BMD [134]. No post-operative BMD changes were stated in their study; hence their conclusion was that good bone quality improves implant fixation. The different degrees and patterns of BMD change in the post-operative period could mainly be an effect of differences in the distribution of periprosthetic stress between various implant designs [39;44;135] and possible differences in bone necrosis after bone saw-cutting and pulse-lavage, and the toxic and thermal trauma following cementation [42;136].

In 5 patients in the current study, the PCL could not be retained, as it prevented the patients' ability to obtain full extension. Thus, these 5 patients were excluded from the study. PCL removal (posterior release) is 5 among many strategies to obtain full per operative knee joint extension. An alternative to PCL removal is to remove more femoral bone, but this procedure will position the knee joint line higher with risk of future problems with the muscle apparatus around the knee joint. The discussion whether to remove or retain the PCL was reviewed by Jacobs, who found no clear evidence in favor of either of the two methods [137].

In conclusion we found greater migration for the P.F.C. Sigma fixed bearing tibial plateau than for the mobile bearing tibial plateau at all early follow-ups, with equally decreasing periprosthetic BMD at the 1-year follow-up. Overall, the measured implant migration was low and similar to that reported for other well-performing cemented TKAs. Both implant groups showed high patient satisfaction, which is also in accordance with the literature [116;122]. Therefore the decision to use fixed bearing and mobile bearing is still open for discussion and further research, and from our results, both implants can be used according to the surgeon's choice.

Conclusions

Study I

We validated the new knee-specific DXA software for use in research follow-up, and we found the knee-specific software comparable to traditional spine-mode software for automatic tissue detection. The knee-specific software alleviates tissue substitutes around the knee, which is a clear advantage to the observer.
The knee-specific software was found suitable for analysis of both un-cemented and cemented tibial component fixation. We showed knee rotation to cause significant changes in the measured BMD and advocate the use of stabilizing casts to ensure a repeatable positioning of the patients at each follow-up.

Study II

The gait analysis showed the cadence for the MB group only reached a value equal to that of the control group. Both the FB and the MB group improved their gait towards a more asymptomatic gait pattern, but neither the FB nor the MB group achieved a totally asymptomatic gait pattern. Results pointing at a more asymptomatic gait pattern in both groups were the kinematic values, the minimal valgus moment, and the decreased co-contraction measured by EMG. For the FB group, additional improvements were seen in knee extension and maximal extension moment in mid stance.

Study III

The FB group migrated significantly more than the MB group after 3, 6, and 12 months' follow-up with equal decrease in periprosthetic BMD. Overall, the measured implant migration was low and similar to that reported for other well-performing cemented TKAs. Both implant groups showed increase in knee scores in accordance with the literature.

Kinematic results equal to those of the control group and better kinetic results towards a more asymptomatic gait pattern with the MB articulation count in favor of the FB articulation. A cadence that was equal to that of the control group at 12 months' follow-up and a significantly lower migration at all follow-ups count in favor of the MB articulation. Although well exposed, the choice between the 2 articulation designs is not made crystal clear based on the results of this work; both the FB and the MB have their individual advantages and disadvantages. Future research regarding implant migration, bone quality, polyethylene wear and knee-function under higher stresses may bring valuable information to surgeons and patients that will aid them in making a decision.

Future perspectives

All patients in study III will undergo 24 months' RSA and DXA follow-up, which will bring further information to the difference in migration between the FB and the MB implants. With 24 months' follow-up, we will be able to quantify the extent of continuously migrating implants according to Ryd et al.'s recommendations [54;55]. The tibial components of TKA have been studied more intensively in RSA studies, because they have been shown to migrate and loosen more frequently than do the femoral components [138]. However, we decided to insert tantalum beads around the femoral components too, accordingly we will be able to evaluate both the tibial and the femoral component migration patterns at the 24 month follow-up.

We have planned a 5-year follow-up with weight-bearing stereoradiographs with the aim of quantifying wear in the two articulation groups. Y-axis migration between the femoral and the tibial implants from baseline to the 5-year follow-up time will serve as a wear assessment. With improved wear rates as one of the pro-mobile bearing arguments, evidence-based results from an RCT on this issue will be valuable. The wear estimates with the P.F.C. Sigma MB TKA system thus far was promising from an in vitro study [139], but owing to the introduction of the MB articulation in 2000 no long-term results with in vivo wear estimates are available yet.

Future gait analysis on mobile bearings could be combined with fluoroscopic RSA to better determine whether the mobile bearing PE insert actually does contribute to the rotational ROM as questioned by Garling et al [106]. Another perspective in improving gait function is the achieved maximal knee joint flexion after TKA. The development of the hyperflex version of the P.F.C. Sigma MB indicates that further improvements are possible to reach with regard to maximal knee flexion in TKA [21]. How this relatively new design will perform in migration and wear studies is for future studies to determine.

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Appendix

Appendix Table 1 – Temporospatial results

Baseline		Cadence (steps/min)	Speed (m/s)	Gait cycle (m)	Step length (m)	Single support (%)	Double support (%)
Fixed bearing	Mean	105.2	1.0	1.2	0.6	36.1	26.7
(n=26)	SD	9.2	0.2	0.1	0.1	2.5	3.9
	Min	87.4	0.7	1.0	0.5	29.8	18.8
	Max	118.8	1.5	1.5	0.7	39.3	34.6
Mobile bearing	Mean	111.3	1.1	1.2	0.6	37.4	25.1
(n=24)	SD	10.3	0.2	0.1	0.1	2.9	4.4
	Min	93.3	0.8	1.0	0.5	32.4	14.6
	Max	132.5	1.4	1.4	0.7	44.3	33.5

6 months		Cadence (steps/min)	Speed (m/s)	Gait cycle (m)	Step length (m)	Single support (%)	Double support (%)
Fixed bearing	Mean	109.1	1.2	1.3	0.6	37.4	25.1
(n=26)	SD	7.9	0.2	0.1	0.1	2.3	3.4
	Min	93.8	0.8	1.0	0.5	30.9	17.9
	Max	124.5	1.5	1.6	0.7	42.7	33.5
Mobile bearing	Mean	113.7	1.2	1.3	0.6	37.8	24.7
(n=24)	SD	9.9	0.1	0.1	0.0	2.2	3.3
	Min	90.6	0.9	1.1	0.6	32.9	15.0
	Max	128.7	1.5	1.5	0.7	44.0	31.2

12 months		Cadence (steps/min)	Speed (m/s)	Gait cycle (m)	Step length (m)	Single support (%)	Double support (%)
Fixed bearing	Mean	111.6	1.2	1.3	0.6	37.6	24.6
(n=26)	SD	7.1	0.2	0.1	0.1	1.5	2.4
	Min	96.1	0.9	1.0	0.5	34.8	21.1
	Max	126.2	1.5	1.5	0.7	40.0	28.3
Mobile bearing	Mean	115.4[1]	1.2	1.3	0.6	38.3	23.6
(n=24)	SD	9.5	0.1	0.1	0.0	1.9	3.5
	Min	95.8	0.9	1.1	0.5	33.5	16.6
	Max	131.2	1.5	1.4	0.7	41.6	32.5
Normal material	Mean	119.1	1.4	1.4	0.7	40.3	20.3
(n=30)	SD	9.7	0.2	0.2	0.1	1.2	2.3
	Min	97.3	0.9	1.1	0.5	37.8	15.8
	Max	138.7	1.7	1.7	0.8	42.9	24.4

Shows temporospatial parameters for the fixed bearing and mobile bearing articulation groups at baseline, after 6 and 12 months' follow-up with comparison to the normal material.

[1]: The MB group cadence equals normal material cadence after 12 months' follow-up. There was no difference between the MB group and the normal material value (H_0: no difference, $p = 0.09$)

Appendix Table 2 – Kinematic results

Baseline	Degrees	Flexion (stance)	Flexion (swing)	Extension	Varus	Valgus	External rotation	Internal rotation
Fixed bearing	Mean	11.9	48.5	-1.5	11.8	4.8	-13.3	-25.9
(n=26)	SD	6.0	5.7	4.3	6.3	4.3	9.9	10.1
	Min	-1.4	35.7	-11.6	3.7	-5.2	-27.0	-43.0
	Max	27.7	59.5	6.7	27.6	13.8	9.7	-5.3
Mobile bearing	Mean	16.1	50.6	3.1	10.5	4.3	-13.3	-24.7
(n=24)	SD	7.9	7.0	7.1	6.4	5.6	10.7	10.1
	Min	2.6	33.5	-7.6	-3.6	-9.9	-32.4	-45.3
	Max	33.5	62.8	18.2	24.0	12.9	5.7	-5.7

6 months	Degrees	Flexion (stance)	Flexion (swing)	Extension	Varus	Valgus	External rotation	Internal rotation
Fixed bearing	Mean	12.6	49.4	-0.9	6.7	0.4	-16.3	-25.0
(n=26)	SD	3.1	4.8	3.9	4.1	2.4	9.6	10.1
	Min	6.3	38.1	-7.9	2.1	-3.0	-40.0	-48.4
	Max	18.7	57.5	5.1	18.1	5.4	4.4	-2.1
Mobile bearing	Mean	13.8	53.1	2.3	7.2	1.4	-16.6	-25.4
(n=24)	SD	5.9	4.7	4.2	5.3	3.6	9.6	10.3
	Min	1.6	40.5	-7.2	-0.6	-6.7	-33.7	-42.1
	Max	22.2	62.8	10.7	21.5	8.1	2.8	-7.4

12 months	Degrees	Flexion (stance)	Flexion (swing)	Extension	Varus	Valgus	External rotation	Internal rotation
Fixed bearing	Mean	13.6	51.2[1]	-1.0[1]	8.2[1]	0.5[1]	-14.8[1]	-23.9[1]
(n=26)	SD	4.2	4.6	3.6	5.1	2.9	10.4	11.2
	Min	4.1	41.8	-8.4	-0.4	-5.6	-34.4	-46.8
	Max	21.6	59.1	4.1	22.2	6.7	4.7	-4.2
Mobile bearing	Mean	13.8	53.4[1]	2.1[2]	7.2[1]	0.7[1]	-16.8[1]	-25.3[1]
(n=24)	SD	6.3	4.7	4.5	5.8	4.4	9.1	8.4
	Min	2.1	43.9	-6.4	-1.2	-6.8	-36.2	-43.7
	Max	28.3	61.9	13.1	21.6	8.6	-0.7	-10.9
Normal material	Mean	18.4	52.8	-1.6	6.5	0.9	-13.0	-24.7
(n=30)	SD	4.1	5.0	4.2	4.2	2.8	7.9	7.0
	Min	6.9	41.7	-9.2	-1.1	-4.0	-28.3	-41.5
	Max	23.3	60.4	8.0	15.7	7.7	1.1	-13.0

Shows kinematic measurements at baseline, after 6 and 12 months' follow-up for the fixed bearing and the mobile bearing groups with control group values for comparison.

[1]: No difference between patients and the controls (H_0: no difference).

[2]: Not full extension in MB group compared to FB group ($p = 0.01$).

Appendix Table 3 – Kinetic results

Baseline	Nmm/kg	[a]Max flexion	[b]Max extension	[c]Max extension	[d]Max valgus	[c]Min valgus	[d]Max rotation	[d]Min rotation
Fixed bearing	Mean	0.274	-0.306	-0.248	0.555	0.373	0.173	-0.010
(n=26)	SD	0.232	0.093	0.239	0.155	0.153	0.042	0.010
	Min	-0.097	-0.510	-0.687	0.363	0.077	0.116	-0.045
	Max	0.930	-0.145	0.201	0.920	0.682	0.257	0.006
Mobile bearing	Mean	0.443	-0.327	-0.050	0.539	0.362	0.173	-0.012
(n=24)	SD	0.223	0.146	0.249	0.165	0.142	0.059	0.008
	Min	-0.049	-0.864	-0.524	0.179	0.082	0.063	-0.031
	Max	0.811	-0.159	0.482	0.803	0.677	0.279	0.002

6 months	Nmm/kg	[a]Max flexion	[b]Max extension	[c]Max extension	[d]Max valgus	[c]Min valgus	[d]Max rotation	[d]Min rotation
Fixed bearing	Mean	0.279	-0.363	-0.261	0.453	0.247	0.155	-0.008
(n=26)	SD	0.172	0.112	0.157	0.142	0.121	0.037	0.008
	Min	-0.137	-0.586	-0.624	0.254	-0.067	0.106	-0.032
	Max	0.608	-0.138	-0.011	0.788	0.445	0.263	0.003
Mobile bearing	Mean	0.369	-0.335	-0.149	0.434	0.263	0.144	-0.009
(n=24)	SD	0.250	0.129	0.170	0.106	0.117	0.043	0.009
	Min	-0.040	-0.674	-0.489	0.208	0.048	0.056	-0.028
	Max	0.752	-0.127	0.119	0.621	0.456	0.222	0.003

12 months	Nmm/kg	[a]Max flexion	[b]Max extension	[c]Max extension	[d]Max valgus	[c]Min valgus	[d]Max rotation	[d]Min rotation
Fixed bearing	Mean	0.318	-0.367	-0.261[1]	0.426	0.238[1]	0.160	-0.012
(n=26)	SD	0.190	0.128	0.184	0.137	0.118	0.034	0.010
	Min	0.059	-0.664	-0.756	0.221	0.009	0.109	-0.043
	Max	0.706	-0.140	0.055	0.718	0.526	0.243	0.006
Mobile bearing	Mean	0.403	-0.347	-0.152	0.419	0.219[1]	0.140	-0.007
(n=24)	SD	0.232	0.114	0.196	0.109	0.114	0.039	0.009
	Min	-0.044	-0.556	-0.456	0.230	-0.053	0.076	-0.027
	Max	0.844	-0.170	0.206	0.616	0.410	0.208	0.007
Normal material	Mean	0.671	-0.450	-0.249	0.539	0.236	0.179	-0.017
(n=30)	SD	0.200	0.168	0.164	0.149	0.111	0.062	0.019
	Min	0.152	-0.855	-0.619	0.248	-0.078	0.088	-0.109
	Makx	1.162	-0.196	-0.065	0.799	0.459	0.404	-0.003

Shows kinetic measurements at baseline, after 6 and 12 months follow-up for the fixed bearing and mobile bearing groups.
[a]: weight acceptance; [b]: touch down; [c]: mid stance; and [d]: stance.
[1]: No difference between patients and normal group. (= normalized gait pattern).

Appendix Table 4 – EMG results

Baseline	AD	V-I	V-C	T-A	T-C	B-I	B-C	G-I	G-C
Fixed bearing	Mean	0.356	0.293	0.369	0.321	0.427	0.399	0.340	0.328
(n=26)	SD	0.065	0.074	0.080	0.061	0.084	0.083	0.086	0.082
	Min	0.203	0.183	0.201	0.233	0.323	0.237	0.223	0.182
	Max	0.478	0.438	0.512	0.447	0.681	0.547	0.524	0.504
Mobile bearing	Mean	0.379	0.290	0.366	0.312	0.436	0.384	0.388	0.324
(n=24)	SD	0.131	0.070	0.082	0.095	0.134	0.059	0.141	0.098
	Min	0.221	0.137	0.187	0.168	0.318	0.280	0.220	0.179
	Max	0.890	0.441	0.504	0.526	1.021	0.483	0.950	0.671

6 months	AD	V-I	V-C	T-A	T-C	B-I	B-C	G-I	G-C
Fixed bearing	Mean	0.333	0.273	0.352	0.311	0.406	0.393	0.310	0.284
(n=26)	SD	0.082	0.064	0.087	0.089	0.074	0.084	0.056	0.070
	Min	0.186	0.174	0.229	0.167	0.276	0.209	0.118	0.170
	Max	0.626	0.380	0.534	0.555	0.522	0.520	0.393	0.449
Mobile bearing	Mean	0.336	0.292	0.341	0.339	0.378	0.363	0.332	0.276
(n=24)	SD	0.079	0.069	0.065	0.083	0.058	0.087	0.078	0.062
	Min	0.202	0.146	0.179	0.177	0.254	0.095	0.162	0.162
	Max	0.488	0.426	0.444	0.488	0.468	0.496	0.523	0.403

12 months	AD	V-I	V-C	T-A	T-C	B-I	B-C	G-I	G-C
Fixed bearing	Mean	0.306	0.255	0.344	0.284	0.378	0.375	0.309	0.291
(n=26)	SD	0.046	0.075	0.064	0.061	0.078	0.071	0.088	0.067
	Min	0.230	0.115	0.258	0.200	0.199	0.216	0.220	0.191
	Max	0.385	0.382	0.464	0.400	0.512	0.494	0.632	0.440
Mobile bearing	Mean	0.317	0.288	0.321	0.314	0.372	0.368	0.328	0.295
(n=24)	SD	0.075	0.077	0.060	0.073	0.059	0.064	0.078	0.051
	Min	0.182	0.145	0.189	0.213	0.275	0.225	0.209	0.201
	Max	0.474	0.436	0.417	0.465	0.490	0.488	0.526	0.389

Muscle abbreviations: V (vastus lateralis), T (tibialis anterior), B (biceps femoris), G (gastrocnemius).
Side abbreviations: I Ipsilateral (operated knee); C Contralateral (non-operated knee).

Appendix Table 5 – Migration at 3-month follow-up

		Fixed bearing (n=24)					Mobile bearing (n=24)					p-values	
Translations	(mm)	x	y	z	TT	MTPM	x	y	z	TT	MTPM	p1	p2
	Mean	0.09	0.08	0.23	0.28	0.67	0.05	0.07	0.11	0.15	0.59	0.018	n.s.
	SD	0.06	0.07	0.19	0.18	0.36	0.04	0.05	0.09	0.09	0.37		
	Min	0.00	0.00	0.01	0.03	0.14	0.00	0.01	0.00	0.02	0.13		
	Max (-)	-0.13	-0.14	-0.49			-0.10	-0.12	-0.25				
	Max (+)	0.26	0.27	0.77	0.78	1.49	0.13	0.16	0.39	0.43	1.77		
Rotations	(degrees)	x	y	z	TR		x	y	z	TR		p3	
	Mean	0.63	0.41	0.10	0.81		0.29	0.64	0.10	0.77		n.s.	
	SD	0.43	0.32	0.07	0.43		0.27	0.50	0.08	0.49			
	Min	0.03	0.04	0.00	0.13		0.01	0.03	0.00	0.09			
	Max (-)	-1.27	-1.20	-0.25			-0.65	-1.72	-0.33				
	Max (+)	1.18	1.02	0.15	1.55		1.14	1.81	0.22	2.14			

RSA results at 3 months' follow-up calculated from absolute migration values. Max (-) is the maximal migration with negative sign.
p1: TT comparison FB vs. MB. p2: MTPM comparison FB vs. MB. p3: TR comparison FB vs. MB. (Wilcoxon ranksum test).

Appendix Table 6 – Migration at 6-month follow-up

		Fixed bearing (n=25)					Mobile bearing (n=24)					p-values	
Translations	(mm)	x	y	z	TT	MTPM	x	y	z	TT	MTPM	p1	p2
	Mean	0.07	0.07	0.22	0.26	0.61	0.06	0.06	0.10	0.15	0.47	0.009	n.s.
	SD	0.06	0.06	0.22	0.21	0.35	0.06	0.06	0.08	0.09	0.26		
	Min	0.01	0.00	0.00	0.05	0.19	0.00	0.00	0.00	0.03	0.09		
	Max (-)	-0.13	-0.12	-0.68			-0.16	-0.17	-0.35				
	Max (+)	0.22	0.25	0.95	0.97	1.57	0.20	0.19	0.21	0.36	1.12		
Rotations	(degrees)	x	y	z	TR		x	y	z	TR		p3	
	Mean	0.51	0.40	0.10	0.72		0.31	0.44	0.09	0.60		n.s.	
	SD	0.37	0.30	0.10	0.39		0.25	0.37	0.08	0.38			
	Min	0.03	0.00	0.00	0.12		0.02	0.02	0.00	0.15			
	Max (-)	-1.27	-0.93	-0.34			-1.07	-1.24	-0.34				
	Max (+)	1.33	1.23	0.34	1.45		0.66	1.13	0.24	1.66			

RSA results at 6 months' follow-up calculated from absolute migration values. Max (-) is the maximal migration with negative sign.
p1: TT comparison FB vs. MB. p2: MTPM comparison FB vs. MB. p3: TR comparison FB vs. MB. (Wilcoxon ranksum test).

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Original Article

Reproducibility of BMD Measurements in the Prosthetic Knee Comparing Knee-Specific Software to Traditional DXA Software: A Clinical Validation

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Abstract

The aim of this study was to validate new knee-specific dual X-ray absorptiometry (DXA) software for cemented total knee arthroplasty (TKA) before initiation of a randomized controlled trial. Firstly, in a phantom study, we evaluated if cementation influenced the measured BMD (g/cm^2), the scan reproducibility with the new knee-specific software, and the consequences of leg rotation around a vertical axis. Secondly, in a clinical study, we assessed the clinical reproducibility in repetitive scans performed with the new knee-specific software and with traditional spine-mode DXA software, and further compared the 2 softwares' ability to point type implant and bone edges correctly. Cementation increased the measured bone mineral density (BMD) ($p < 0.01$). For reproducibility, the coefficient of variation (CV) was 0.52−0.70% in vitro. Leg rotation around a vertical axis significantly changed the measured BMD in most scans. Automatic point typing of implant and bone edge was of varying quality with frequent need of manual correction for both softwares. CVs of clinical reproducibility ranged from 2.78% to 6.19% for knee-specific software and from 1.45% to 6.06% for spine-mode software. We found the new knee-specific software valid for BMD measurement of the bone in proximity of cemented TKA and with clinical reproducibility and corrections of point typing similar to traditional spine-mode software.

Key Words: BMD; DXA; knee; precision; total knee arthroplasty.

Introduction

Clinical survival of implants is associated with the quality of the periprosthetic bone, and periprosthetic bone *(1−5)* mineral density (BMD) can be quantified by dual X-ray absorptiometry (DXA). Plain radiographs are unreliable for assessment of bone loss *(6−9)*. Less than 25% of bone loss is difficult to detect visually *(7)*, whereas DXA can quantify the bone density precisely *(10)*. BMD measurement in the proximity of orthopedic implants is gaining interest as a follow-up parameter *(3,11,12)* because BMD measurements may correlate with implant fixation.

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The precision of repetitive scans rely on the scanner's hardware and software, and the homogenous position of patients at the follow-up *(8,13−15)*.

Previous methodological studies have described the effect of rotation of the femoral bone to the repeatability of BMD at follow-up *(8,15,16)*, but to our knowledge no previous studies have evaluated the importance of rotation of the proximal tibia to changes in the measured BMD around total knee arthroplasty (TKA) by knee-specific DXA software.

DXA scanners are widely used for BMD measurements in the hip, spine, and forearm to diagnose osteoporosis. Some manufacturers have also improved the software of the scanners with customized packages intended for orthopedic use especially for periprosthetic BMD measurements in proximity of total hip implants. Software specifically designed for measurements of BMD around the knee is less common and not yet validated for clinical use.

Li et al. *(13)* showed non−knee-specific "orthopedic" software with a Lunar DPX-L scanner to result in poor precision (coefficient of variation [CV] ranged 5−9.1%) for tibial BMD measurements around TKA with patients positioned in a supine position.

Our group recently evaluated the use of spine-mode software (Lunar Prodigy Advance 2005 scanner, enCORE software, GE Healthcare, Madison, WI) and the sensitivity of measurements to knee flexion, and found a good clinical precision (CV $<$ 3.7%) *(14)*. Some DXA softwares can automatically detect and subtract metal (automated metal removal), but most softwares leave a margin of bone close to the implant that is not included in the analysis. This is a potential problem because one of the interesting bone regions in TKA is the bone close to the tibial implant. Furthermore, implant cementation is a potential challenge for BMD measurements close to the implant because BMD overestimation might result from inclusion of high-density cement in the analyzed region of interest (ROI) *(17)*.

The aim of this study was to validate the new (non-Food and Drug Administration [FDA] approved) knee-specific software for cemented TKA before initiation of a randomized controlled clinical trial (RCT). The focus points were (1) to examine the effect of cementation on the measured BMD, and evaluate the reproducibility and consequences of leg rotation around a vertical axis in a phantom study, and further, in a clinical setup; (2) to compare the clinical reproducibility in double examination scans performed with the new knee-specific DXA software and with traditional spine-mode DXA software; and (3) to assess the ability of the 2 softwares to point type implant and bone edges correctly.

Materials and Methods

In Vitro/Phantom Study

We used 2 human cadaver tibial bones and prepared them surgically for 2 different tibial components with different stem designs: P.F.C. Sigma Fixed Bearing and Rotating Platform (DePuy International, Leeds, UK) (Fig. 1A and B).

The preparation was done with the original instruments, thereby creating 2 phantoms. The phantoms were fixed tightly in a clamp allowing axial rotation intervals of 1° (Fig. 1A and B).

We measured BMD (g/cm^2) in the 2 phantoms according to a specified protocol; first with the implants press fit (uncemented), and secondly with the implants cemented into the bones. The scan window was 21.3 cm long and 12 cm wide. Tissue equivalent material in the form of nylon boards (4 cm thickness) were placed under the phantom (Fig. 1A and B), resulting in an average tissue thickness of 9.5 cm. We used the default scan mode "thin."

According to a predefined protocol, we performed 5 scans for every 5° of axial rotation from a neutral position (true posteroanterior view [PA]; the X-ray source is beneath the scan table) to 25° of internal and external rotation (Fig. 1A and B). Mean BMD (g/cm^2) was compared between PA and each rotational position. To imitate clinical lateral scans of the tibia, we performed 5 scans for every 5° rotation increment from a true lateral (LA) position until 25° of internal rotation. Mean BMD was compared between LA and each rotational positions. We did not perform scans with the phantom in external rotation from LA position because such a position was considered clinically irrelevant. (Not possible to externally rotate the foot against the bed.)

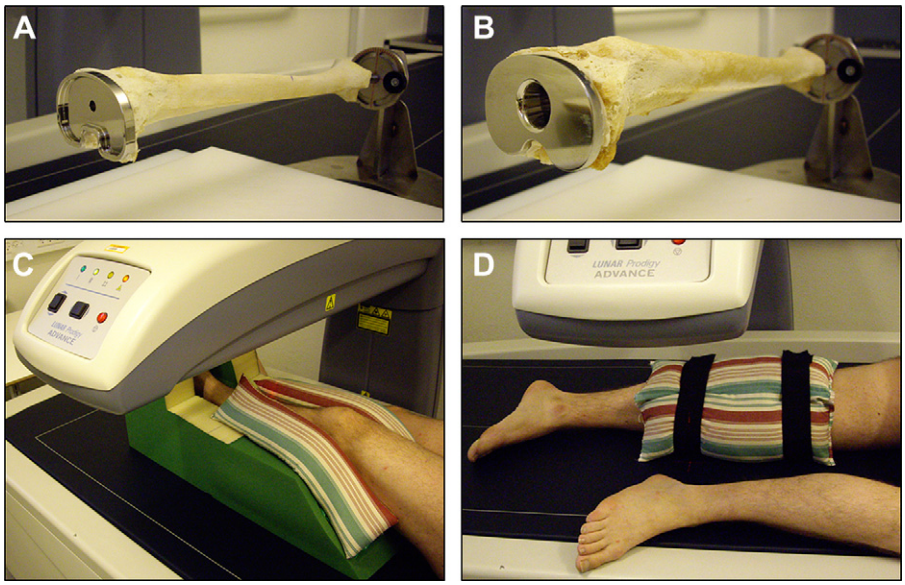

Fig. 1. (**A**−**C**) P.F.C. fixed-bearing tibial plateau (**A**) and rotating platform (**B**) inserted into a human phantom tibia bone. Fixed in a clamp by use of a retrograde nail. Rotation stable foam cast for posteroanterior view scans of periprosthetic bone around total knee arthroplasty (**C**). Patient positioning for lateral scan of periprosthetic bone of right knee (**D**) (patient is positioned on the operated side). Rice bags applied as used with spine-mode software in both (**C**) and (**D**).

We designed a template with 3 ROIs under the tibial plateau and used automatic point typing with detection and subtraction of metal and cement from the bone (Fig. 2). To quantify a change in BMD because of cementation, we calculated the difference in mean BMD before and after cementation for the above-described phantom positions. CVs were calculated from the 5 measurements of each rotational position to determine the scanner's repeatability.

In Vivo/Clinical Assessment

Forty-three patients enrolled in an ongoing RCT on TKA approved by The Central Denmark Region Committees on Biomedical Research Ethics (Registration: 20050031, issue date: June 24th 2005) were further enrolled in this method validation study, and additional permission was granted. All investigations were conducted in accordance with ethical principles of research and informed consent was obtained from all the participants. The 43 patients were invited for an additional clinical examination outside the RCT follow-up program with 2 double DXA scans; 42 patients agreed to participate. The preoperative diagnosis and inclusion criterion was osteoarthritis in all cases and all the patients had a fixed-bearing or rotating-platform tibial component P.F.C. Sigma knee prosthesis because of participation in the RCT. Mean age was 68 yr (range: 55−77 yr), male/female ratio was 19/23, and implant ratio was 22 fixed bearing to 20 rotating platform.

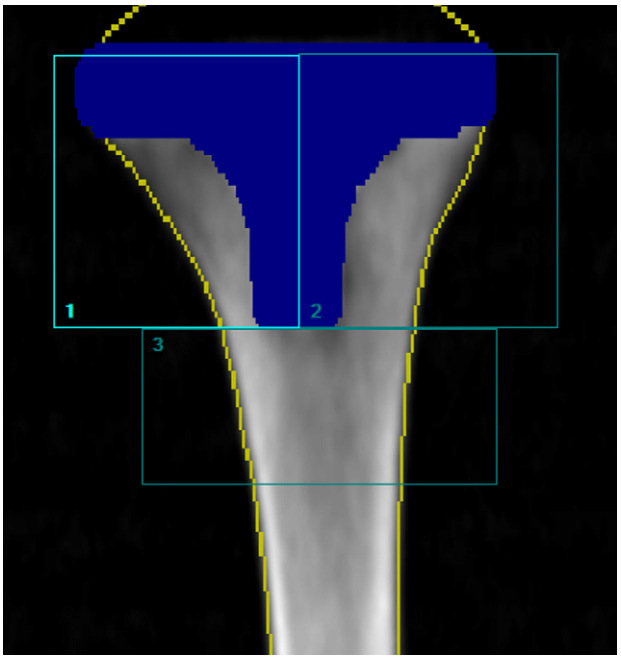

Fig. 2. Posteroanterior view scan of phantom tibia bone with P.F.C. fixed-bearing tibial plateau (uncemented technique). ROI1 placed medial to the implant stem, ROI2 lateral, and ROI3 below. ROI, region of interest.

Scans

All scans were performed using a GE Lunar Prodigy Advance 2005 DXA scanner. We used enCORE 11.40.004 software, scan mode "knee" and "spine."

All DXA scans were performed at a single outpatient visit by 3 trained technicians.

With knee software, we used the default scan mode "thin" meaning that the expected average tissue thickness automatically was less than 13 cm. The scan window was 20.8 cm long and 18 cm wide per default. Knee-mode scans were initiated approximately 12 cm below the proximal patellar pole (measured by cm ruler) and terminated automatically after the preset scan length. This was done according to the manufacturer's advice to ensure a sufficient amount of soft tissue and bone for correct dynamic tissue labeling (point typing).

The knee software is designed to recognize right and left knees by the position of fibula; hence, we consciously used the opposite side specification on the LA scans because fibula anatomically alters its position with respect to tibia in LA position.

With spine software, we also used the option "thin" (average tissue thickness <13 cm). The scan window was 23.5 cm long and 18 cm wide, which is the expected window size for a spine scan in osteoporosis assessment. Spine-mode scans were initiated approximately 19 cm below the proximal patellar pole. Spine-mode scans were terminated 1−2 scan sweeps proximal to the tibial implant. Scan time for both programs was 56 s on average with a radiation dose of 9 μGy. Scan resolution was 0.60×1.05 mm.

In PA scans, patients were placed with their operated knee in a soft foam cast developed to avoid changes in rotation and flexion (Fig. 1C).

For LA scans, the patients were placed with their operated side to the scan bed and the contralateral leg flexed in front (Fig. 1D). In all spine-mode scans, the foam cast was filled with rice and the leg covered with rice bags to imitate the expected tissue volume around a spine and to avoid air in the scan field. In every scan, we checked that the average tissue thickness did not exceed 13 cm ("thin"). Patients were repositioned between double examination scans.

Analysis

Both in vitro and in vivo scans were analyzed using a dynamic tissue detection algorithm in the software, where scan components were typed as bone, tissue, air, artifact (implant + most of the cement), or neutral.

Thereby the tibial implant was subtracted automatically in the BMD calculation. The in vitro scans were all point typed satisfactory; hence, no manual corrections had to be made. For in vivo scans, manual corrections had to be made in some instances to ensure correct point typing of implant and bone edges (Fig. 3).

When manual correction was indicated, we scored the extent separately to compare the 2 softwares. No attempts were made to change the typing around the cement mantle to avoid manual inaccuracies. The fibula was excluded manually where it was not overprojected by the tibia (Fig. 3).

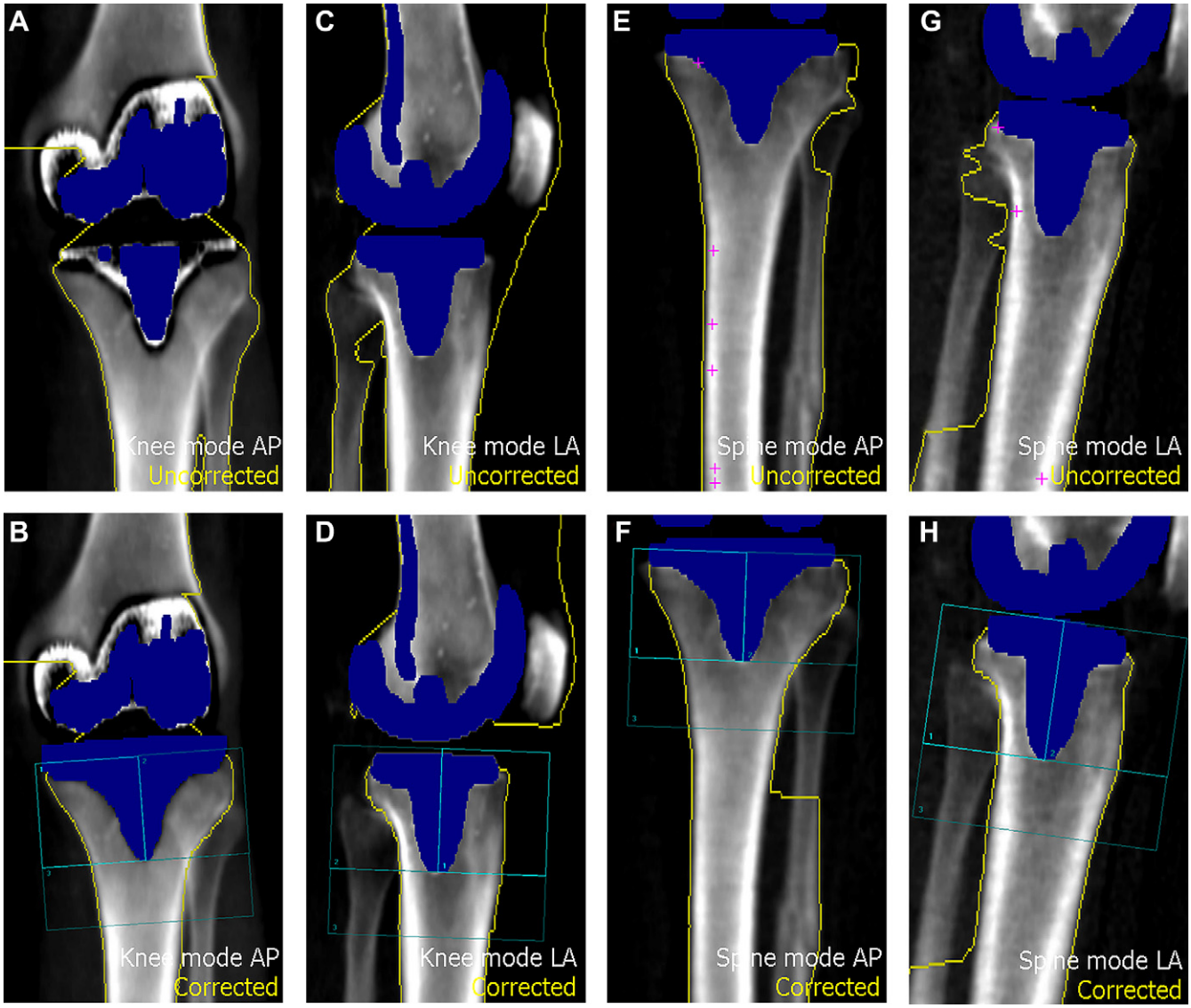

Fig. 3. (**A**–**H**) Uncorrected and manually corrected point typing with knee-mode (**A**–**D**) and spine-mode (**E**–**H**) software. For posteroanterior view scans, ROI1 is placed medially to the implant stem, ROI2 laterally to the stem, and ROI3 below the stem. For lateral scans, ROI1 is placed anteriorly to the implant stem, ROI2 posteriorly to the stem, and ROI3 below the stem. The fibula is left out of all the analyses. For spine-mode scan analyses, ROI1 and ROI2 are swapped to ensure correct comparison. ROI, region of interest.

We used a template of 3 ROIs (Figs. 2 and 3B, D, F, and H). After positioning the ROI template on the baseline scan, the template was fixed to the tibial bone edges and afterward copied to the subsequent scans in the same position, thereby ensuring comparable ROI placement. Where individual anatomy required adjustment of ROI width, this was made without changing ROI height to make all individual BMD measurements comparable.

Because the spine-mode software contained no default distinction between left and right, ROI1 and 2 were switched in the analysis of PA spine-mode scans of right side knees, thereby ensuring ROI1 always to be placed medially and ROI2 always to be placed laterally containing fibula. For LA scans, we switched ROI1 and 2 in spine-mode scans of left side knees, thereby ensuring ROI1 always to contain the anterior tibia and ROI2 always to contain the posterior tibia. The knee-specific software had a side-recognition feature and swopped the ROI template accordingly.

Statistics

In Vitro/Phantoms

Mean BMD (g/cm^2) and standard deviation (SD) in all 3 ROIs were calculated for the 5 consecutive PA and LA scans of the phantoms firstly under uncemented (press fit) and thereafter cemented implant fixation. Mean BMD differences

(normal distribution in QQ plots) were tested by a paired *t*-test (Fig. 4).

The CV (CV% = SD/mean × 100%) was calculated separately for PA and LA scans with implants pressed fit (uncemented) and cemented in the phantoms.

The impact of rotation on mean BMD (normal distribution in QQ plots) was evaluated by an unpaired *t*-test (Fig. 5).

In Vivo/Clinical Scans

Visual scoring of implant detection and bone edge detection was noted for scans made with knee mode vs spine mode, and comparison was made by the Fisher's exact test.

CV was calculated to describe the clinical repeatability of mean BMD from all the 3 ROIs (knee scans and spine scans) because CV is widely used for comparison in the literature. Furthermore, we used the standards of ASTM 2008 for assessment of precision *(18)*, where S_r is the SD of a single measurement. The 95% repeatability limit (random variation) is calculated as $S_r \times \sqrt{2} \times 1.96$. Bias equals the systematic variation between double measurements and is estimated as mean difference between double measurements. Bias followed a normal distribution (QQ plots) and was tested by a paired *t*-test. Bias ± the 95% repeatability limit equals the 95% limits of agreement (LOAs) as described by Bland and Altman *(19)*. We used STATA IC10 software (StataCorp, TX, USA) for all the statistical analyses.

Results

In Vitro

The measured BMD was influenced by cementation in both the implant groups. In the phantom with the fixed-bearing implant, BMD increased 0.06 g/cm^2 on average, and in the

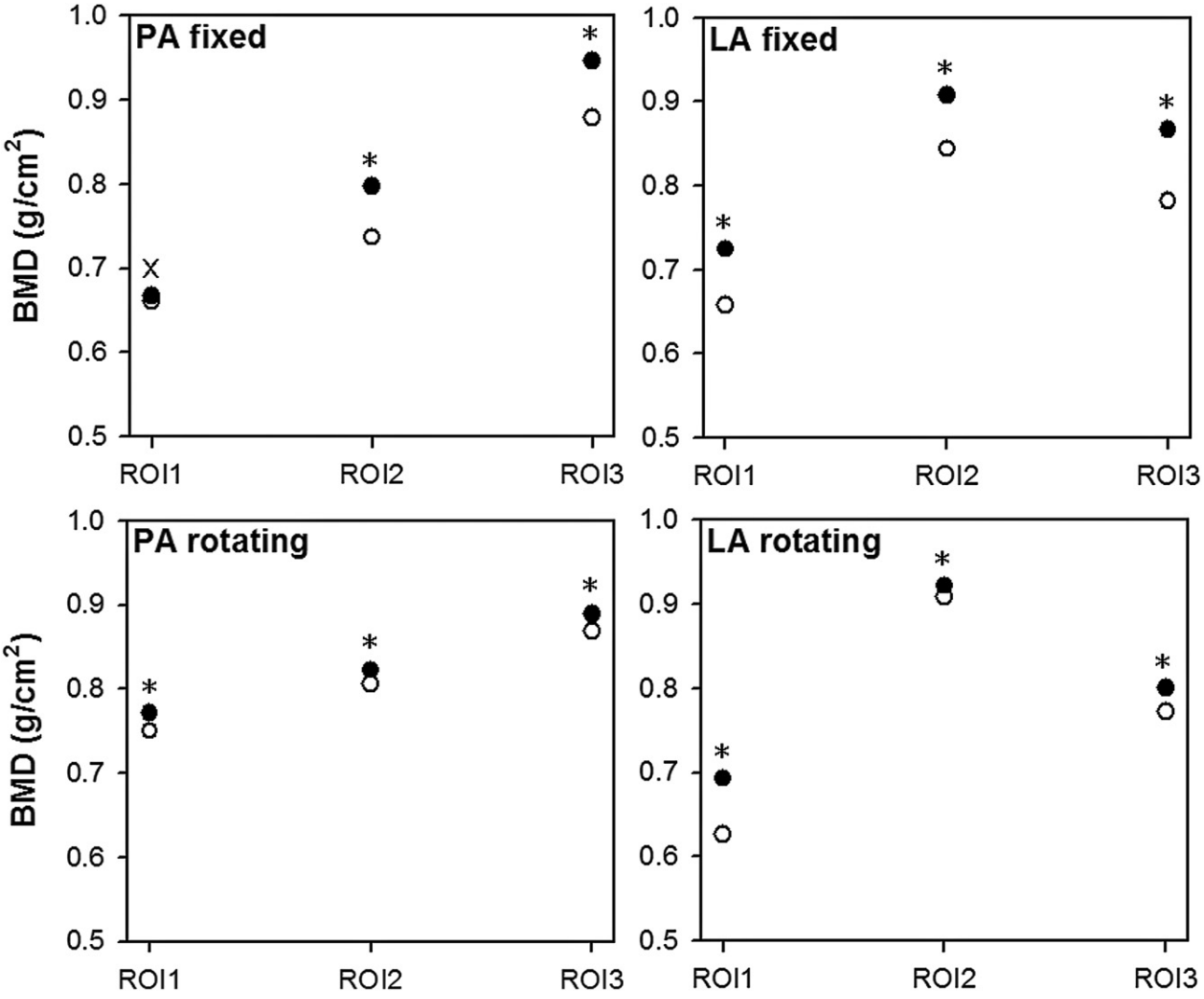

Fig. 4. Increase in mean bone mineral density (BMD, g/cm^2) before (○) and after cementation (●). Posteroanterior view (PA) and lateral (LA) dual X-ray absorptiometry scans fixed-bearing tibial implant and rotating-platform tibial implant in ROI1, ROI2, and ROI3. *$p < 0.01$; $^x p > 0.05$. ROI, region of interest.

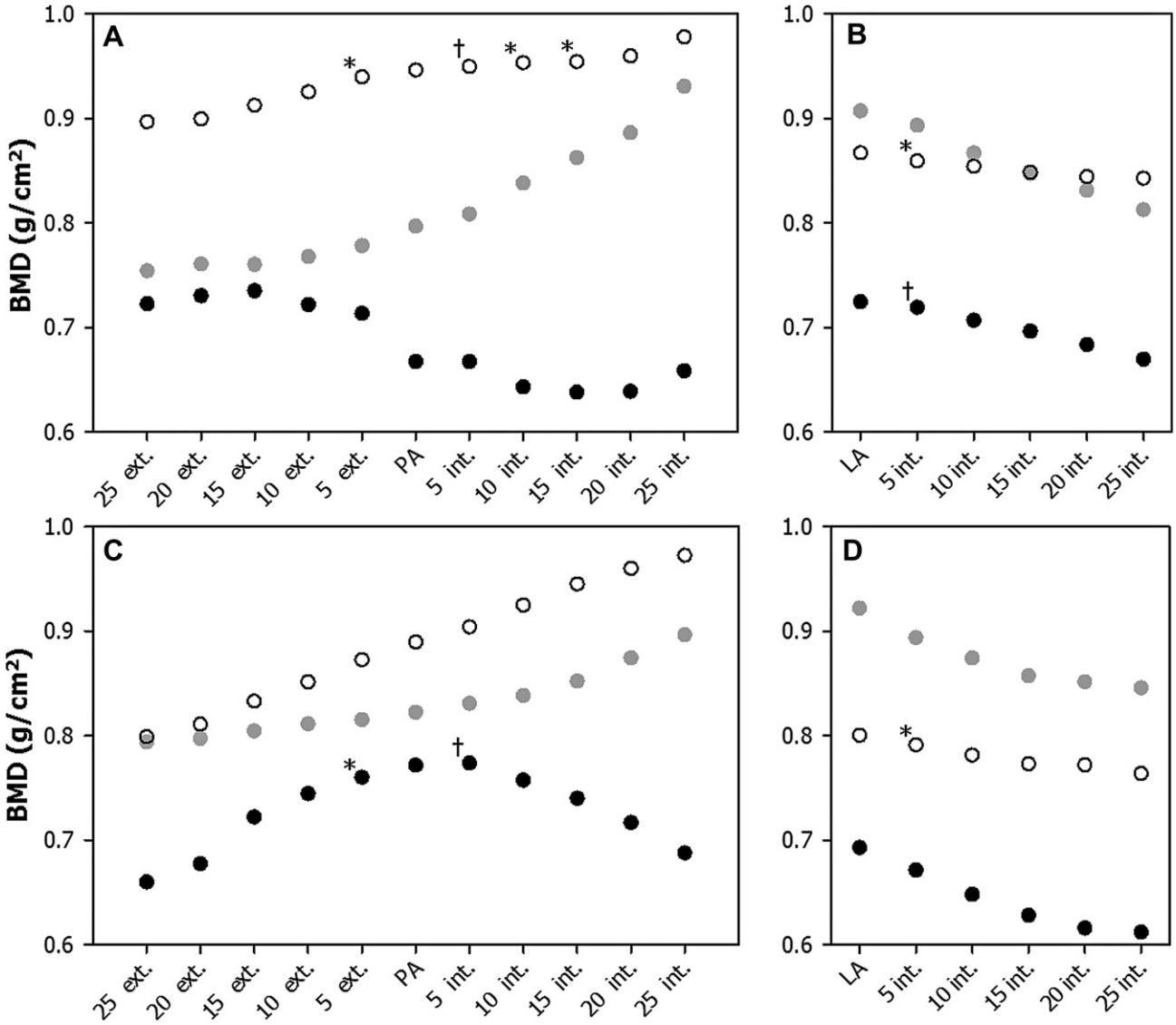

Fig. 5. In vitro bone mineral density (BMD, g/cm^2) measurements with increasing rotation from neutral position posteroanterior view (PA) (**A**, **C**) and lateral (LA) position (**B**, **D**). Five consecutive scans were performed in each position; mean BMD plotted for 3 regions of interest, ● ROI1, ● ROI2, and ○ ROI3. Rotation from PA and LA changes mean BMD significantly in most ROIs both on PA scans and LA scans (no marks) ($p < 0.01$); *$p < 0.05$; $^{\dagger}p > 0.05$. ROI, region of interest.

phantom with the rotating-platform component the average increase in BMD was 0.03 g/cm^2 (Fig. 4). The increase in mean BMD after cementation was statistically significant ($p < 0.01$), except in ROI1 for the fixed-bearing implant in PA position (medially to the implant stem). BMD increase after cementation was similar in both the implant groups ($p = 0.11$).

The CV for BMD measurement around the fixed-bearing implant was 0.70% in an uncemented and 0.59% in cemented fixation. For BMD measurements around the rotating-platform implant, CV was 0.57% in an uncemented and 0.52% in cemented fixation.

Internal and external rotation (5−25°) from PA (neutral) position and 5−25° of internal rotation from LA position changed BMD measurement in most scans ($p < 0.01$). The absolute change in mean BMD caused by rotation ranged from 0.00 to 0.11 g/cm^2, and the relative change ranged from 0.00% to 14.48% (Fig. 5).

In Vivo

Visual implant detection (Table 1) was satisfactory for all the spine-mode scans in both the PA and LA, whereas knee-mode scans were correct in 10.7% of PA scans and 94% of LA scans. Tibial bone edge detection in PA scans was correct in 45.2% laterally and 70.2% medially with knee-mode software compared with 0% laterally and 70.2% medially with spine-mode software. In LA scans, visual tibial detection

Table 1
Visual Evaluation of Correct Automatic Software Detection of Implant and Bone Edges

PA scans	Knee mode	Spine mode	*p* Value[a]	LA scans	Knee mode	Spine mode	*p* Value[a]
Implant detection	7/84	84/84	<0.01	Implant detection	79/84	84/84	0.06
Tibia lateral	38/84	0/84	<0.01	Tibia anterior	41/84	55/84	0.04
Tibia medial	59/84	59/84	1.00	Tibia posterior	57/84	2/84	<0.01

Note: PA and LA scans from 42 clinical double examination DXA knee scans (n = 84).
Abbr: PA, posteroanterior view; LA, lateral; DXA, dual X-ray absorptiometry.
[a]Fisher's exact test.

was 48.9% anteriorly and 67.9% posteriorly with knee-mode software compared with 65.5% correct detection anteriorly and 2.4% posteriorly with spine-mode software.

CVs for the clinical double examinations ranged from 2.78% to 6.19% for knee-mode BMD measurements and from 1.45% to 6.06% for spine-mode BMD measurements (Table 2).

Repeatability SD (S_r) from the 42 patients' double examinations ranged from 0.035 to 0.054 for knee-mode software and from 0.016 to 0.063 for spine-mode software (Appendix). The 95% agreement limits were small (Appendix and Fig. 6A and B).

Discussion

The first part of this study showed cementation to increase measured BMD around stemmed tibial components, but without negative effect on reproducibility stated by CV. For both implant types, the CVs improved slightly after cementation. During the DXA scan, the scanner arm (Fig. 1C and D) moves over the scanner bed and thereby causes minor vibrations. These vibrations could potentially cause press-fit implant motion inside the phantom bone; at least movement of implant to phantom bone is effectively impaired by cementation, which we may see as an improved CV after cementation.

The knee-specific software point typed implants and bone edges correctly in vitro. On the basis of these findings, we concluded the knee-specific software to be valid for clinical research follow-up and henceforth used it clinically in comparison with our old method (spine-mode software).

In the second part of this study (patient's double examination), comparison of knee-specific software and spine-mode software showed an inconsistent automatic point typing of implant, tibial bone edges, and tissue in both softwares. Spine-mode software outperformed the knee-specific software in automatic implant detection, whereas tibial bone edges were detected with frequent need for manual adjustments in both softwares.

Overall, the clinical reproducibility for clinical periprosthetic BMD measurements was comparable for both softwares, and comparable to results published by other authors *(14,20,21)*.

We decided to exclude the fibula from all DXA scans because we had no interest in measuring tibial BMD influenced by fibular bone where possible. Nevertheless, there could be arguments to leave the fibula uncorrected; it requires manual correction to exclude the fibula, and the proximal part of the fibula is overlapping the tibia in most scans; hence, total fibular extraction is impossible.

Li et al. *(13)* showed a decreased precision in repetitive BMD measurements with non−knee-specific software mainly because of inconsistent soft tissue baseline (they used rice bags as soft tissue substitutes) and reported CVs at 7.3%. This was similar to the setup with the spine-mode software in our study, but we had lower CVs. The difference in CV between the 2 studies might be explained by a more automatic ROI placement at follow-up in our study because the enCORE software makes it possible to fix the ROI template to the tibial bone edges and copy this placement to succeeding follow-up scans.

Stilling et al. *(14)* recently published clinical results using traditional spine-mode software with lower CVs; 1.8−3.7% in PA position and 3.4−6.2% in LA position. The leg rotation was fixed in their setup, and their conclusion was to avoid differences in knee flexion at follow-up because even slight flexion (5°) changed the measured BMD.

We found clinical repeatability in double measurements by knee-specific software and the same spine-mode software as used by Stilling et al. to be similar, however, the positioning of the patients at follow-up is a critical matter because as little as 5° of rotation can change the measured BMD significantly. However, the BMD changes (Fig. 5) were small (0.00−14.48%). A relative change of 0.00% would clearly be clinically irrelevant,

Table 2
Coefficients of Variation (in %) for Clinical Double DXA Examinations

	Knee mode		Spine mode	
	PA scans (%)	LA scans (%)	PA scans (%)	LA scans (%)
ROI1	4.38	6.19	2.58	4.68
ROI2	4.64	4.57	2.43	6.06
ROI3	2.78	4.09	1.45	3.25

Abbr: PA, posteroanterior view; LA, lateral; DXA, dual X-ray absorptiometry; ROI, region of interest.

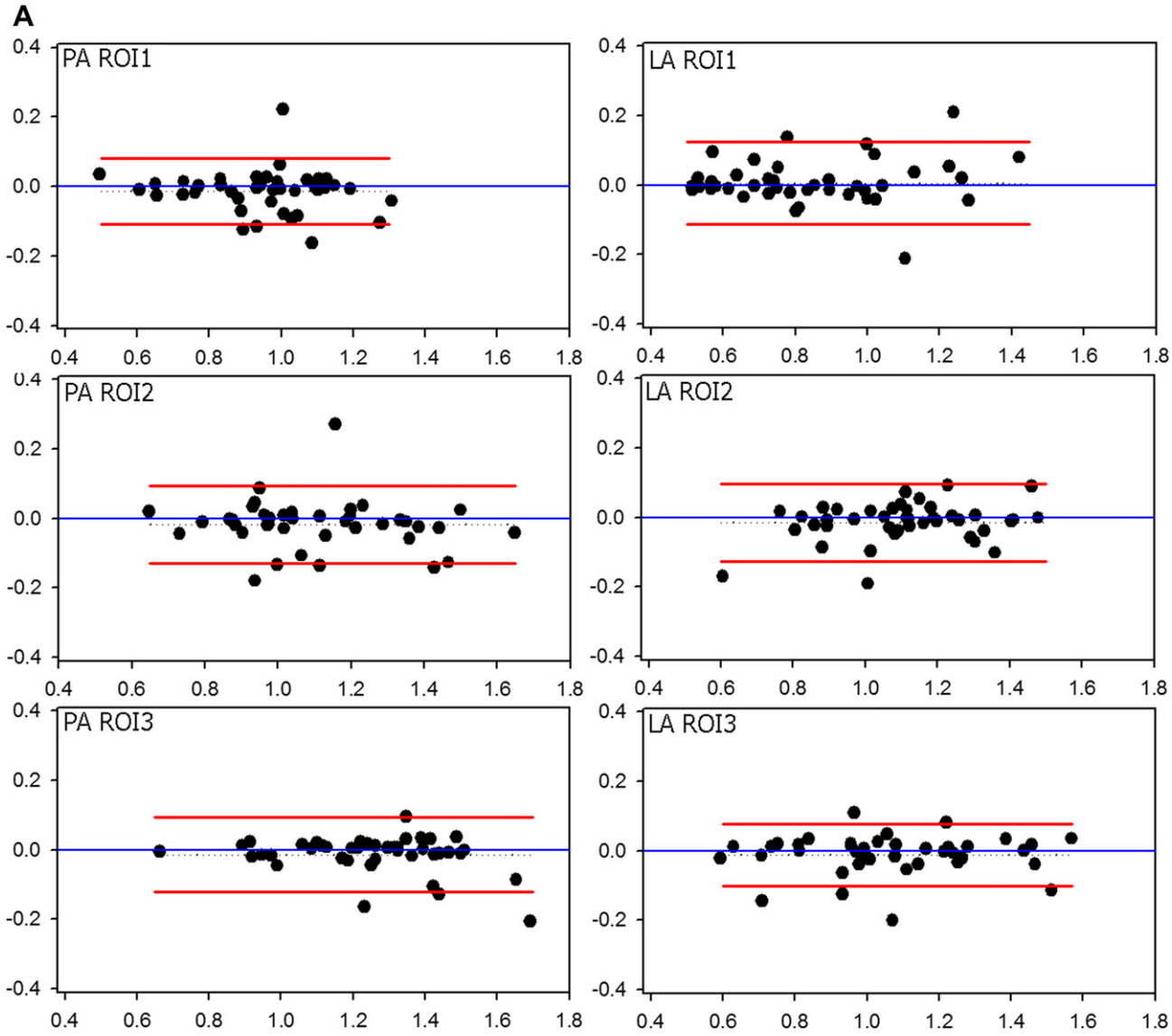

Fig. 6. A. Knee mode: Bland-Altman plot for clinical double examination repeatability. X-axis: Average of double dual X-ray absorptiometry (DXA) measurements (g/cm^2); Y-axis: difference between double measurements (g/cm^2); red lines: 95% limits of agreement (LOAs); dotted line: bias from 0; solid blue line: $y = 0$; dots: individual double values. **B.** Spine mode: Bland-Altman plot for clinical double examination repeatability. X-axis: Average of double DXA measurements (g/cm^2); Y-axis: difference between double DXA measurements (g/cm^2); red lines: 95% LOAs; dotted line: bias from 0; solid blue line: $y = 0$; dots: individual double values.

but the maximal relative BMD change of 14.48% caused by leg rotation was more than twice the CV measured and should not be ignored. Nevertheless, we would not recommend transferring the in vitro findings directly for prediction of rotational impact on the clinical follow-up because we used a naked tibia and had no fibular overlapping in vitro.

Mortimer et al. *(16)* reported limb rotation to be within easily controllable limits and the associated BMD changes to imply no excessive error. Other DXA studies have concluded varying BMD changes in the proximal tibia at follow-up *(3,8,21–23)*. Karbowski et al. *(22)* found a BMD decrease of 10% measured around tibia 9 mo postoperatively, but stated no reproducibility calculations. They used large ROIs including all periprosthetic bone around femur and tibia. Spittlehouse et al. *(8)* found CVs for DXA measurements of proximal periprosthetic tibial ROIs in a range of 6.1–12.4%. Soininvaara et al. *(21)* presented a CV of 2.9% for tibial ROIs and significantly decreased BMD at 24-mo follow-up for the tibial medial diaphyseal and the metaphyseal ROI, whereas they found no difference in the tibial lateral diaphyseal ROI *(3)*. In a recent publication, Soininvaara et al. *(23)* found no change in tibial diaphyseal BMD in neither the

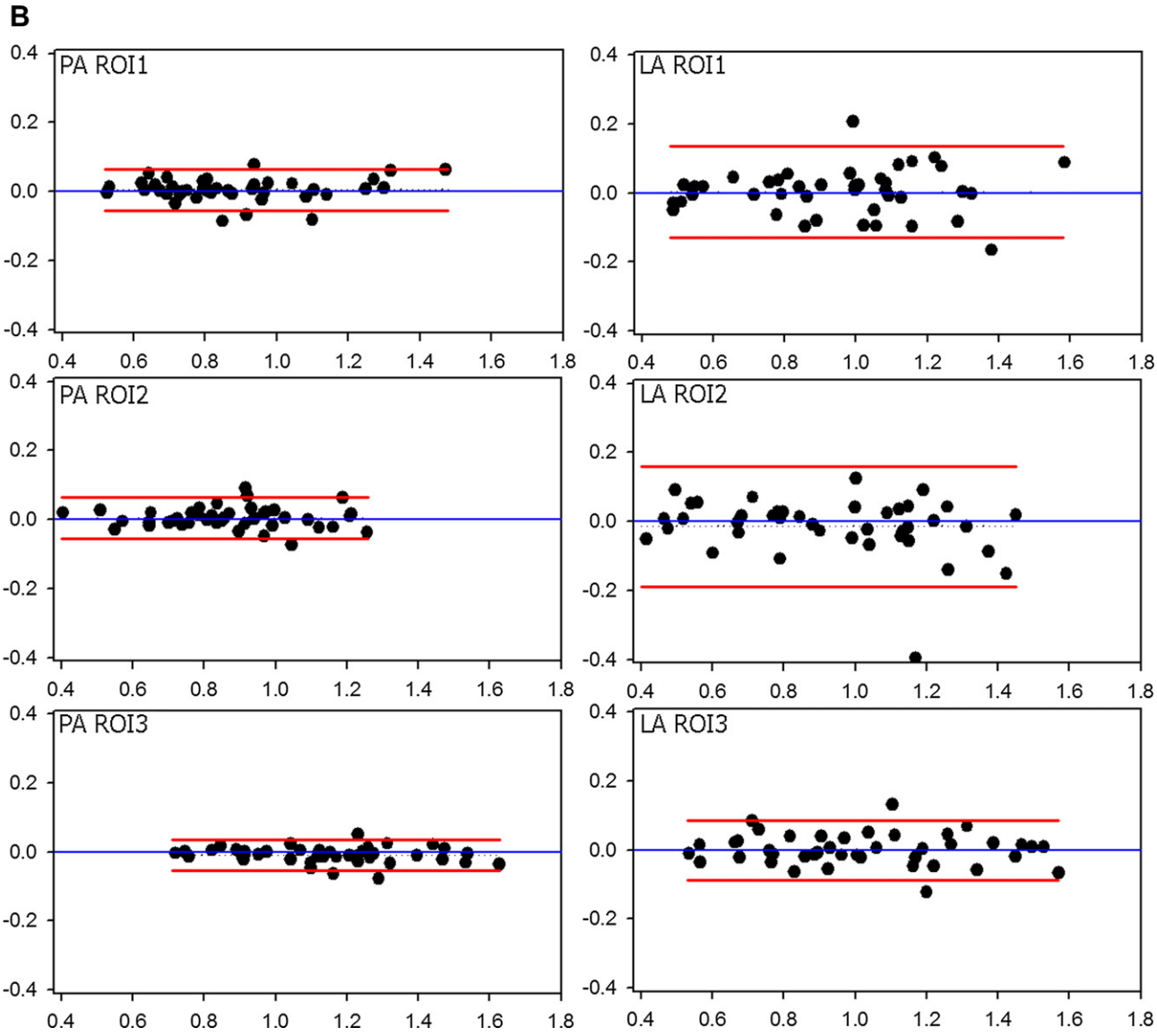

Fig. 6. (*Continued*)

lateral nor the medial tibial ROIs at up to 24-mo of follow-up. Soininvaara et al. applied tibial ROIs similar to the setup we used. Some of the difference in CV between studies is explainable by different scanner types and ROI sizes; the smaller the ROI, the more difficult it is to place it right.

We found reproducibility CVs of 1.45−4.64% for PA scans and 3.25−6.19% for LA scans (Table 2). In vitro BMD changes caused by rotation were between 0.00% and 14.48% (0.00−0.11 g/cm^2). The 95% LOAs or least detectable significant difference from the in vivo BMD measurements (Appendix) were small, but in comparison with the above-stated in vitro BMD changes caused by rotation not in all instances smaller.

In conclusion, we found (1) cementation to significantly increase the measured BMD (Fig. 4), but cementation had no negative effect on in vitro reproducibility stated by CV. The rotation-caused BMD changes might be of statistical significance, but the extent of clinical importance deducted from the in vitro scans is limited, not least due to the absence of fibular interference in vitro. We suggest the use of a clinical protocol to avoid rotation of the proximal tibia and to improve BMD measurement precision. Furthermore, we have shown (2) the clinical reproducibility in double examination scans performed with new knee-specific software to match the reproducibility in scans by the traditional spine-mode software. Apart from the discussion of precision in double measurements or at follow-up, we have (3) presented our results from automatic point typing by the 2 used softwares (Fig. 3 and Table 1). Neither spine-mode software nor knee-specific software has the ability to point type the different tissues and implants 100% satisfactorily; hence, much time is invested in manual corrections. One should not totally neglect the

potential inaccuracies applied by manual corrections; however, gross software point typing mistakes should not be left uncorrected. The used knee-specific software is available for clinical research only (non-FDA approved for clinical use) and has the substantial user-friendly advantage of ''ready to scan'' because no tissue substitutes are necessary. Many researchers and technicians might find this advantageous in the daily clinical setting. Future improvements in tissue detection ability in clinical scans would speak clearly in favor of knee-specific software for DXA follow-up in knee implants.

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Appendix

Repeatability of Clinical BMD Measurements (Double Examination)

	Mean BMD[a] (range)	Bias[b] (95% CI)	S_r[c]	LOA[d]
Knee-mode software				
PA scans				
ROI1	0.954 (0.497−1.308)	−0.014 (−0.033 to 0.005)	0.045	0.126
ROI2	1.107 (0.647−1.649)	−0.017 (−0.040 to 0.006)	0.054	0.151
ROI3	1.251 (0.664−1.692)	−0.014 (−0.031 to 0.003)	0.040	0.112
LA scans				
ROI1	0.834 (0.330−1.421)	0.006 (−0.013 to 0.025)	0.045	0.123
ROI2	1.103 (0.605−1.479)	−0.014 (−0.032 to 0.004)	0.042	0.117
ROI3	1.107 (0.594−1.568)	−0.011 (−0.026 to 0.004)	0.035	0.097
Spine-mode software				
PA scans				
ROI1	0.882 (0.526−1.471)	0.005 (−0.004 to 0.015)	0.022	0.061
ROI2	0.871 (0.404−1.257)	0.004 (−0.005 to 0.014)	0.022	0.060
ROI3	1.139 (0.719−1.628)	−0.009 (−0.016 to 0.002)	0.016	0.046
LA scans				
ROI1	0.944 (0.488−1.585)	0.003 (−0.018 to 0.024)	0.048	0.133
ROI2	0.910 (0.186−1.451)	−0.015 (−0.042 to 0.013)	0.063	0.175
ROI3	1.018 (0.536−1.572)	0.000 (−0.013 to 0.014)	0.031	0.087

Abbr: LOAs, limits of agreement; PA, posteroanterior view; ROI, region of interest; LA, lateral; BMD, bone mineral density; CI, confidence interval.

[a]Mean of double BMD scans (g/cm^2), range in brackets.

[b]Mean difference between the first and second scan (systematic variation of repeatability within the ROI).

[c]Repeatability standard deviation for a single BMD scan (ASTM 2008).

[d]95% LOA between 2 test results ($1.96 \times \sqrt{2} \times S_r$).

Gait Function Before and After Total Knee Arthroplasty
A Randomized Study of Fixed Bearing versus Mobile Bearing Articulation

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Gait Function Before and After Total Knee Arthroplasty
A Randomized Study of Fixed Bearing versus Mobile Bearing Articulation

Abstract

In a prospective, randomized clinical trial we compared 51 osteoarthritis patients operated either with a fixed bearing (FB) or a mobile bearing (MB) total knee arthroplasty by gait-analysis, electromyography and knee-scores before surgery, and at 6 and 12-months follow-up.

Furthermore, a BMI, gender and age-matched control-group was used.

Only the MB group reached a cadence equal to the control group. However, the FB group had other favourable kinetic results. Electromyography results indicated less co-contraction after 12 months in both groups and knee scores improved significantly with both articulation designs.

Both articulation designs demonstrated improved knee scores and favourable changes towards a more normal gait pattern, but no obvious “winner” could be identified.

Brief title: Gait analysis and clinical performance of fixed and mobile bearing TKA

Level of evidence: Prospective randomized study, Level I

Keywords: Knee, Arthroplasty, Mobile bearing, Fixed bearing, Gait analysis, Knee score

Introduction

Total knee arthroplasty (TKA) is the standard treatment at the terminal stadium of gonarthritis. Generally, good results are achieved based on assessment of lasting pain relief, misalignment correction and improved function [1-7]. The functional result of TKA has been documented in several gait analysis studies and improvements have been shown in temporospatial as well as kinematic, kinetic, and electromyography (EMG) measurements [2;8-13]. In spite of these improvements patients with TKA still show gait abnormalities during both level walking and stair climbing. Differences in outcome were partially related to the type of implant used [8;13-15].

In TKA research the aim has been to enhance the success with the achievement of a gait function similar to that of healthy controls. More publications showed changes in kinematic and kinetic measurements away from a healthy gait function with increasing osteoarthritis (OA) severity. The comparison of TKA patients to healthy subjects pointed at similar kinematic and kinetic changes [11;16;17]. Apart from providing the patients lasting pain relief, the success of different TKA designs could be explained by the ability to minimize the differences in gait function between TKA patients and healthy controls.

It has been thoroughly investigated whether to use classic hinge type TKA with fixed bearing (FB) tibial polyethylene (PE) or mobile bearing (MB) implant types that at least in principle should enable physiological knee joint motion [5;6;9;18;19]. MB implants do not constitute a fixed entity, but cover implant designs

where the PE insert may rotate around a PE rod as well as implant plateaus with other possible PE translations to the tibial base plate. The MB implant showed increased motion adaptation with greater surface contact and less surface stress and thereby potentially less PE wear [20;21]. Wear reduction and preventing aseptic loosening were shown to be the key factors in long term TKA survival [22].
Price et al. have shown marginally better subjective knee scores for the MB articulation, but found no functional differences assessed by range of motion (R.O.M.) [6]. Tibesku et al. found better performance assessed by knee scores with a sliding/rotating articulation compared to a FB articulation, but no difference in functional performance from gait analysis and in EMG values [7].
Most clinical studies show no major difference between FB and MB articulation types [1;4;23;24] and a Cochrane review from 2004 [25] based on the above referred works from Kim et al. [5] and Price et al. [6] concluded no major advantages for either TKA type concerning function and patient satisfaction.

A number of randomized clinical trials (RCT) have been performed comparing FB and MB articulations in TKA [1;3-7;23;25;26], but to our knowledge no prospective randomized studies have performed a comparison of the two with reference to the preoperative gait function and the gait function in normal persons of the same age group.
The purpose of this study was to compare the two TKA articulation designs most frequently used in our institution (P.F.C. Sigma FB and MB design) in a RCT investigating new aspects of gait function and restored function following TKA.

The focus points were 1) to compare the patients' pre-surgical level walking and surface electromyography (EMG) to their 6 and 12 months' post-surgical follow-up; 2) to compare the patients' level walking and EMG to a healthy and BMI, gender and age-matched group; and 3) to evaluate if rehabilitation of gait in the two TKA groups were different compared with the healthy control group. Finally we aimed at complementing the objective gait analysis with 4) subjective patient satisfaction and function scores; The American Knee Society Score (AKSS) and the Oxford Knee Score (OKS).

Materials and Methods

This study was conducted in accordance with the ethical principles of the Helsinki II declaration and an informed consent was obtained from all the participants. The study was approved by the Central Denmark Region Committees on Biomedical Research Ethics (Registration: (20050031), issue date: June 24th 2005). The study was registered with the Danish Data Protection Agency and with www.clinicaltrials.gov (NCT01150929). The study is reported in accordance with the CONSORT guidelines for trials [27].

Inclusion, exclusion and randomization procedure

From March 2007 to June 2010, 63 patients were included for a pre-operative gait analysis by one senior consultant. The inclusion demographics are shown in Table 1.

The inclusion criteria were age 50 to 75 years and uni- or bilateral knee osteoarthritis (OA). The exclusion criteria were any neurological disorder affecting the patient gait pattern; any concomitant orthopaedic disease of the ipsi-lateral hip joint, but not disease of the contra-lateral knee or hip joint; senile demented patients; absence of a written consent; patients with a peri-operatively weakened posterior cruciate ligament (PCL); and patients who postoperatively developed a deep infection or an abnormal scaring limiting R.O.M. in the knee joint.
There were some exclusions and drop outs (Figure 1), but a final number of 51 patients attended the 12-months follow-up in this investigation.
Randomization followed a procedure with 98 envelopes built on groups of 4, 6 or 8 numbers to ensure a regular inclusion of both the articulation types during the inclusion period. The uneven group numbers ensured that no randomization had a predictable result.

All patients were operated with the P.F.C. Sigma TKA. This TKA system is available with a choice of either a FB or a MB PE on the tibial plateau as well as either PCL retaining or posterior stabilized PE design. The polyethylene was of the UHMWPE type and sterilized by gamma irradiation. We used the PCL retaining PE for all patients. The femoral components were of an equal design in both the FB and the MB group. All metal components were made from a cobalt-chrome alloy.

The operations were performed by three senior consultant surgeons. The procedure included a midline skin incision followed by a medial parapatellar incision through the quadriceps tendon. The anterior cruciate ligament was excised and the PCL was sought retained. The proximal tibia was resected to attempt a bearing surface perpendicular to the tibial shaft in the coronal plane and in the sagital plane with 3° posterior slope. The distal femoral condyles were resected attempting an alignment of 6° valgus in the coronal plane. The patellar thickness was measured and a resection and preparation was made for the patellar PE component. The tibial, the femoral, and the patellar components were fixed by bone cement (Simplex Bone Cement, Stryker, MI, USA) with pressurizing technique precipitated by pressure-lavage.
All patients followed the same standardized post-operative rehabilitation programme allowing full weight bearing after surgery. At discharge patients were instructed in a home training programme followed by an instruction brush-up with a physiotherapist 14 days postoperatively. All patients were seen at an out-patient visit with a physiotherapist and the surgeon 4 months after their operation.

Follow-up with 3D gait analyses was performed in the Gait Laboratory at Hammel Neurocenter at 6 and 12 months post-operatively.
A Vicon 612 8-camera system (Vicon, Oxford, UK) at 100Hz using a Helen Hayes marker set-up was used [28;29]. An AMTI force plate (Advanced Medical Technology Inc., Watertown, MA, USA) placed in the middle of a 10-meter walk way recorded ground reaction forces at a sample rate of 2000Hz. The EMG skin electrodes were placed in accordance to a predefined protocol. Four electrodes were placed on each leg to

record EMG signals from the vastus lateralis, the biceps femoris, the tibialis anterior, and the gastrocnemius muscles (Motion Lab MA-300.10, MotionLab Systems Inc., Los Angeles, USA).

The force plate data and the camera data were captured and synchronized in a Vicon Workstation. The static and dynamic calibration was performed prior to each measurement session. The reconstruction of a 3D body model and the calculations of angles between each segment in the lower limb as well as the moment of force in each joint were computed with Vicon clinical manager software. Three of 5 trials of each leg were selected as data source for further analysis using Vicon PlugInGait model; the selection criterion was speed similarity between the trials as recommended by Vardaxis et al [30].

We defined the beginning of each gait cycle as the heel strike (touchdown) and the end of the same cycle to be at the next heel strike of the same leg. The gait cycle was normalized to 100% time basis.

The EMG signals were filtered through a 20-500 Hz bandpass filter, thereafter unidirected, and finally 10 Hz lowpass filtered. Both filters used were 2nd order Butterworth filters. The EMG output was in analog digital (AD) units; we used baseline signals as index 100 and the signals from the 6 and 12 months' follow-up were related to the baseline measurement as a percentage value.

Normal material

Our normal material (healthy objects without gait disorders or arthroplasties implanted) was collected from employees and community volunteers around the Regional Hospital Hammel Neurocentre. From an available subject number of 51 (aged 55-75) we used 30 subjects based on their BMI, age and gender being comparable to the included patients (Table 1). Gait analysis of the healthy controls did not include EMG measurements.

Knee scores

The American Knee Society Score (AKSS) was filled out by the senior consultant at the first out-patient visit where patients were not yet randomized. At 6 and 12 months' follow-up AKSS was filled out by one of the three gait laboratory physiotherapists. The AKSS contains a patient reported pain score of 3 questions and a 7-part hospital staff assessment of function, stability and range of motion. The pain score as well as the clinical score can result in 50 points each; maximum total point number is 100 [31].

The Oxford Knee Score was filled out by the patients themselves and handed in to the gait laboratory staff shortly before surgery, after 6 and 12 months' follow-up. The OKS consists of 12 questions regarding patient activities of daily living including experienced pain, function and performance. A maximum of 48 points can be obtained [32].

Sample size

With a minimal relevant difference of 10 steps/minute (gait cadence) (power 90%, alpha 0.05, SD 10 steps/minute) the study was powered for 22 patients in each group. Twenty-five patients per group with an

analyzable baseline gait analysis were aimed at in total to compensate for eventual dropouts during follow-up.

Statistics

The data from the Vicon Workstation was exported to and analyzed with STATA SE11 software (StataCorp, Texas, USA). Statistical significance was assumed at $p<0.05$.

The temporospatial and the kinematic parameters were normally distributed (Shapiro-Wilk test) with unequal variances (F-test). The change in values after 6 and 12 months' follow-up was tested by a paired t-test for unequal variances.

The kinetic and the EMG values showed normal distribution (EMG when log-transformed) with equal variances for the FB and the MB group; hence ANOVA was used to test for change in values over time and between the FB and the MB groups.

The knee score data was not normally distributed and was accordingly tested by Wilcoxon's ranksum test.

At 12 months' follow-up the difference int temporospatial, kinematic and kinetic values was calculated between the normal material and the FB as well as the MB group. These differences were normally distributed (Shapiro Wilk test) with similar variances (F-test). With a one-sample t-test the hypothesis of no difference between patients and normal subjects was tested. Thus a p-value >0.05 indicated normalization (no difference) of gait parameters compared with the control group.

Results

Temporospatial measurements

Temporospatial results are shown in Figure 2 and in Table 2. All temporospatial parameters improved towards the normal material during follow-up for both groups, but only the MB group cadence was statistically equal to the control group at 12 months' follow-up (H0: no difference; $p=0.09$) (Table 2 and Figure 2).

There were no statistically significant differences between the FB and the MB groups in any of the temporospatial parameters.

Kinematics

Kinematic results are shown in Figure 3 and in Table 2. For both articulation groups there were kinematic values equal to the control group after 12 months' follow-up in knee flexion (swing) and both knee varus/valgus (stance) and internal/external rotation (stance). The knee flexion in stance did not improve to the control group level in either of the two articulation designs. The FB group achieved full knee extension compared to the MB group at 12 months' follow-up ($p=0.01$)

Kinetics

Kinetic results are shown in Figure 4 and in Table 2. Neither the FB nor the MB groups reached control group values in most kinetic parameters after 12 months' follow-up. Only the minimal valgus moment was equal to the control group for both articulation groups at the 12-month follow-up time. Furthermore the FB group showed a maximal extension moment in stance equal to the control group after 12 months' follow-up.

Normal material

The demographic values for the healthy controls are shown in Table 1.

The temporospatial, the kinematic and the kinetic data for the control group is shown with the patients' data in Table 2 and Figures 2-4.

EMG

The mean EMG output (area under curve) from the 6 and 12 months' follow-up relative to the baseline EMG measurements showed decreased values for the operated knees with statistical significance for the vastus lateralis ($p=0.010$), the biceps femoris ($p=0.001$), and the gastrocnemius muscles ($p=0.007$) (Table 3). There were no statistical significant differences in the EMG values in the contra-lateral (non-operated) knees after 6 and 12 months' follow-up. There were no statistical significant differences between the FB and the MB groups.

Knee Scores

Both articulation groups improved significantly on OKS and AKSS from baseline to 6 months' follow-up. Results were similar for both knee scores after 6 or 12 months' follow-up for the two articulation groups (Figure 5).

At the 12-month follow-up time there were similar passive knee joint motion values in both articulation groups (FB/MB), maximal knee flexion (118/113 degrees), maximal extension (3/3 degrees) and R.O.M. (115/110 degrees).

Discussion

The purpose of the present study was to compare the FB to the MB articulation principle by assessment of gait function before and after TKA, and to evaluate whether the TKA patients achieved a gait function similar to that of a matched control group. To our knowledge, no other study has compared FB to MB articulation in TKA in a prospective, randomized trial using gait analysis, EMG and a healthy control group.

The key finding of this study was that only the cadence of the MB group was equal to the cadence of the control group after 12 months' follow-up. There was a clinically relevant, yet statistically non-significant difference of 4 steps/min in favour of the MB articulation after 12 months, however, the conclusion in favour of the MB articulation cannot be judged by a single parameter. We observed improvements towards a more normal gait pattern for the FB group and alongside no difference between the FB and the MB articulation

concept of TKA in many of the other gait analysis measurements. Tibesku et al. investigated the gait analysis of patients treated with an MB tibial implant allowing both rotation and anterior/posterior sliding, but they could not conclude advantages over a fixed bearing TKA [7]. In a Cochrane review based on two studies comparing FB to MB articulation using knee scores, radiographs and R.O.M. assessment, Jacobs concluded no substantial advantage of the MB over the FB articulation [25]. Several other studies have also compared FB to MB articulation using knee scores, radiographs and R.O.M. and have also ended at a similar outcome [1;3;4;23;26;33-37].

Overall, we found temporospatial parameters from level walking to normalize towards a gait pattern of healthy controls in both the FB and the MB articulation groups; higher single support percentage of the gait cycle and, accordingly, lower double support percentage of the gait cycle indicating a gait with less limping. This can obviously be explained from lasting pain relief and misalignment correction after TKA. With less pain and a well balanced arthroplasty, the basis for a more asymptomatic gait pattern is present. However, the TKA patients did not reach the healthy controls' values in all gait analysis parameters. The temporospatial parameters are based on the self-selected speed and could be criticized for being less objective. Murray showed the duration of gait cycle phases to decrease with increased cadence [38]. However, the self-selected cadence facilitates a smooth, natural, and efficient forward progression of the body's centre of gravity in terms of the energy required for walking [39]. Further, the cadence is used as an important follow-up parameter in other orthopaedic research areas, i.e. with Timed Up and Go as an indicator of hip fracture healing [40].

Overall the kinematic results improved towards a normal gait pattern with an increased knee flexion in the swing phase and a correction of misalignment in the frontal plane (less adduction/abduction). The rotation values changed only marginally from baseline to 6 and 12 months' follow-up and the values were similar to the normal material. The knee extension from the gait analysis was better in the FB group (absence of extension deficit). However, this finding was not reflected in the clinical part of the AKSS, where similar scores were found in the passive maximal knee flexion, the extension and the knee R.O.M between the two articulation groups.

Hatfield et al. described the major patterns of variability in gait waveforms before and after TKA using principal component analysis [11]. Their study included two FB tibial designs and a single MB. Hatfield et al. showed an important change of patterns in the knee kinematics and kinetics after a TKA operation that was very similar to the results for both the articulation designs used in our study. They showed the knee flexion angle to increase in both the stance and in the swing phases. Further they showed the knee extension moments at touch down and in late stance to increase towards, but not to reach control group values. Also the maximal knee flexion moment in stance was shown to increase post-operatively.

Astephen et al. described the change in biomechanics of the knee, hip and ankle in association to knee OA severity and showed a reduced knee flexion moment in weight acceptance and higher knee adduction moment in midstance with increased OA severity [16]. In a review Foroughi et al. pointed at the knee adduction moment to be correlated to OA severity and to knee varus mal-alignment [17]. With comparison to the results from Hatfield, Astephen and Foroughi et al. we could interpret our findings to point at a less symptomatic gait function after TKA in comparison to severe OA patients [11;16;17]. In this study the FB articulation showed an increased maximal knee flexion moment in weight acceptance and both the FB and the MB groups had increased maximal extension moments at both touch-down and in late stance pointing towards a more asymptomatic gait pattern postoperatively. For the MB group the maximal flexion moment in weight acceptance decreased postoperatively indicating absence of improvement compared to FB, but this difference between the two groups was statistically and clinically insignificant and with the considerable standard deviations a much higher sample size would be required to show an eventual difference statistically. Furthermore the minimal mid-stance valgus (knee adduction) moment decreased significantly in both the FB and MB groups towards a less symptomatic pattern [11;16;17]. These kinetic changes could result in less stress and pressure in the medial joint compartment [41;42]. The rotation moments decreased insignificantly in the MB group, which could be explained by less force acting on the MB in rotation. The MB allows only for rotational motion in the transverse plane (and not additional anterior/posterior sliding as in other designs [7]), and this could reduce cross-shear stress and ultimately wear by decoupling multi-directional motions into mono-directional motion patterns [43]. In support hereof, retrieval studies showed no signs of excessive backside wear with the uni-directional MB that we investigated [44] and further low wear could be attributed to the large contact area between the mobile PE liner and the femoral component with lower forces applied per surface unit [45].

EMG measurements showed decreased values after 6and 12 months' follow-up in both articulation groups for the vastus lateralis muscle, the biceps femoris muscle, and the gastrocnemius muscle in the operated leg and alongside no changes in the non-operated leg.

To our knowledge no RCT have previously shown EMG data related to pre-operative status. We have interpreted the EMG decrease to reflect a reduced co-contraction gait pattern, which follows the change away from the "stiff-knee" as mentioned with the kinematic and kinetic improvements.

Other publications showed no difference between an FB and an MB articulation past 7 to 70 months' follow-up without regard to pre-operative EMG values [7;46]. EMG is probably improved or changed as a result of "removing pain" and therefore not an effect of which articulation type was used.

Both with OKS and AKSS the two groups improved from baseline to 6 and 12 months' follow-up. Our clinical results are comparable to results from other clinical reports on the P.F.C. Sigma TKA system [3-5;23;47]. No report showed a significant difference between the articulation principles.

Some strengths and limitations should be mentioned. The strengths of this study include the prospective, randomized design and the use of gait analysis in the patient assessment with comparison to a normal group of similar BMI, gender and age.

Some weaknesses exist for the gait analysis as a follow-up tool. The skin markers were thoroughly placed [28;29], but nevertheless some inaccuracies might arise from the marker placement, since many patients were overweight. Additional fatty tissue on the anterior superior iliac spine causes displacement of the hip joint centre in the software model. If not corrected for, an obese patient shows extreme valgus knee angles; hence the markers in trials with overweight patients were corrected according to a predefined manual. Avoiding the fatty tissue corrections would require the inclusion of exclusively normal weight knee OA patients which would be a troublesome quest and furthermore the external validity of the study would be low, since most knee OA patients are overweight. For the measurement of sagital (flexion/extension) and frontal (varus/valgus) values the skin marker model is more suited than for transversal measurements (rotations). This is explained by the relatively large sagital and frontal excursions compared to the relatively limited rotations. The substantially higher variability as we observed with both kinematic and kinetic rotation measurements stresses this point [48]. For many kinematic and kinetic measurements we could not show statistically significant changes over time. The classical explanation is a “type 2 error” in spite of a wide-margin pre-study sample size; however, it might also be that in functional reality no difference exists between the two different articulation TKA designs. In support of the latter, the trend in our data was a normalization of gait parameters at 12 months after surgery for both of the assessed articulations as compared to before surgery. Increasing the joint stresses higher than in level walking i.e. to stair climbing provides additional information to the kinetic relations in a TKA [8] and stair climbing exercise assessed with fluoroscopy has been shown to provide highly accurate rotation-translation measurements at the replaced knee and complete locomotion patterns at both lower limb joints [10]. Since the MB articulation is intended for the young and active patient, further investigations should aim at knee function and gait differences between FB and MB articulations during higher loads and stresses.

With the results of this gait analysis study we have no clear recommendation to prefer the MB over the FB. A practical advantage of the FB articulation in daily surgery is the peri-operative flexibility with regard to the PCL. If full extension is not achieved with the PCL retained the FB PE insert can be used both with and without the PCL, whereas the MB insert must be posterior stabilized with a post/cam feature to minimize the spin-out risk. Another way to achieve full extension without PCL sacrifice is to resect more femoral bone; a solution with the risk of a functionally disadvantageous more proximally placed knee joint line.

Retaining the posterior cruciate ligament (PCL) is considered important to both the stability and the proprioception of the knee joint [15;49]. Even so a Cochrane review [50] considered the choice of either retention or sacrifice of the PCL to be without solid evidence. We used only the cruciate retaining version of both the FB and MB articulation to avoid inclusion bias and thus the PCL was not an independent focus point in the current study.

In conclusion we have shown significantly improved knee scores and improvements in gait for both the FB and MB articulations of the P.F.C. Sigma TKA compared to the pre-operative gait status of the operated patients. In short, the gait improvements were less limping with longer single support, increased knee flexion in swing, and misalignment correction (less varus/valgus excursions). Only the MB group achieved a cadence equal to the control group. The kinetic measurements showed changes towards a more asymptomatic gait pattern [11;16] with increased weight acceptance knee flexion moment, decreased late stance knee flexion moment, and decreased mid stance knee adduction moment.

This study is the first prospective, randomized gait analysis TKA study with reference to a healthy control group. Both articulation designs demonstrated improved knee scores and favourable changes towards a more asymptomatic gait pattern, but in accordance to previous studies no obvious “winner” could be identified. This is similar to many other papers [1;3-7;23;33-37;47]. Future RCTs should focus should focus on implant migration, bone quality, polyethylene wear, and knee-function under higher stresses.

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Table 1

	Fixed bearing (n=26)		Mobile bearing (n=25)		Controls (n=30)	
	Mean	Range	Mean	Range	Mean	Range
Weight (kg)	88	(67-119)	80	(60-104)	81	(61-109)
Height (cm)	171	(155-183)	171	(160-185)	170	(153-184)
BMI (kg/m2)	30	(23-39)	27	(23-34)	28	(24-34)
Age (years)	66	(56-73)	66	(54-74)	64	(55-75)
Gender (male/female)		(14/14)		(10/14)		(17/13)
OP side (right/left)		(14/14)		(14/10)		
Implant size	3.5	(2.5-5)	3.3	(2.5-5)		
Knee flexion (degrees)	120	(77-144)	117	(77-144)		
Extension defect (degrees)	3	(0-11)	5	(0-11)		
R.O.M. (degrees)	117	(66-144)	113	(66-144)		

Baseline demographics for the FB, the MB and the control groups.

Table 2

	Fixed bearing (n=26)		Mobile bearing (n=25)		Controls (n=30)		p1	p 2	p 3
Temporospatial parameters		SD		SD		SD			
Cadence (steps/min)	111.6	(7.1)	115.4	(9.5)	119.1	(9.7)	n.s.	n.s.	0.09
Speed (m/s)	1.2	(0.2)	1.2	(0.1)	1.4	(0.2)	n.s.	n.s.	n.s.
Gait cycle (m)	1.3	(0.1)	1.3	(0.1)	1.4	(0.2)	n.s.	n.s.	n.s.
Step length (m)	0.6	(0.1)	0.6	(0.0)	0.7	(0.1)	n.s.	n.s.	n.s.
Single support (%)	37.6	(1.5)	38.3	(1.9)	40.3	(1.2)	n.s.	n.s.	n.s.
Double support (%)	24.6	(2.4)	23.6	(3.5)	20.3	(2.3)	n.s.	n.s.	n.s.
Kinematic parameters (degrees)		SD		SD		SD			
Flexion (stance)	13.6	(4.1)	13.8	(6.3)	18.4	(4.1)	n.s.	n.s.	n.s.
Flexion (swing)	51.2	(4.6)	53.4	(4.7)	52.8	(5.0)	n.s.	0.09	0.59
Extension	-1.0	(3.6)	2.1	(4.5)	-1.6	(4.2)	0.01	0.44	n.s.
Varus	8.2	(5.1)	7.2	(5.8)	6.5	(4.2)	n.s.	0.09	0.6
Valgus	0.5	(2.9)	0.7	(4.4)	0.9	(2.8)	n.s.	0.48	0.83
External rotation	-14.8	(10.4)	-16.8	(9.1)	-13.0	(7.9)	n.s.	0.71	0.73
Internal rotation	-23.9	(11.2)	-25.3	(8.4)	-24.7	(7.1)	n.s.	0.41	0.07
Kinetic parameters (Nmm/kg)		SD		SD		SD			
Max flexion (weight acceptance)	0.318	(0.190)	0.403	(0.232)	0.671	(0.200)	n.s	n.s	n.s
Max extension (touch down)	-0.367	(0.128)	-0.347	(0.114)	-0.450	(0.168)	n.s	n.s	n.s
Max extension (late stance)	-0.261	(0.184)	-0.152	(0.196)	-0.249	(0.164)	n.s	0.75	n.s
Max valgus (stance)	0.426	(0.137)	0.419	(0.109)	0.539	(0.149)	n.s	n.s	n.s
Min valgus (late stance)	0.238	(0.118)	0.219	(0.114)	0.236	(0.111)	n.s	0.91	0.51
Max rotation (stance)	0.160	(0.034)	0.140	(0.039)	0.179	(0.062)	n.s	n.s	n.s
Min rotation (stance)	-0.012	(0.010)	-0.007	(0.009)	-0.017	(0.019)	n.s	n.s	n.s

Temporospatial, kinematic and kinetic results at 12 months' follow-up with the control group.
p1: FB vs. MB. p2: FB vs. controls. p3 MB vs. controls (H_0: no difference).

Table 3

	Fixed bearing (n=26)		Mobile bearing (n=25)		p-values	
	Operated knee	Control	Operated knee	Control	p1	p2
Lateral Vastus	86.1 (4.6)	86.9 (7.5)	83.8 (7.5)	99.5 (7.7)	n.s.	0.01
Femoral Biceps	88.6 (7.8)	93.9 (7.1)	85.5 (5.9)	96.0 (7.8)	n.s.	<0.01
Anterior Tibial	93.2 (6.4)	88.4 (6.1)	87.8 (6.0)	100.6 (7.3)	n.s.	n.s.
Gastrocnemius	91.0 (8.8)	88.7 (6.7)	84.6 (7.8)	91.0 (5.1)	n.s.	0.01

Mean EMG (area under curve) values relative to baseline (in %) with standard deviation at 12 months' follow-up. p1: FB vs. MB. p2: Operated vs. and the non-operated control leg.

Figure 1 – CONSORT flowchart of RCT

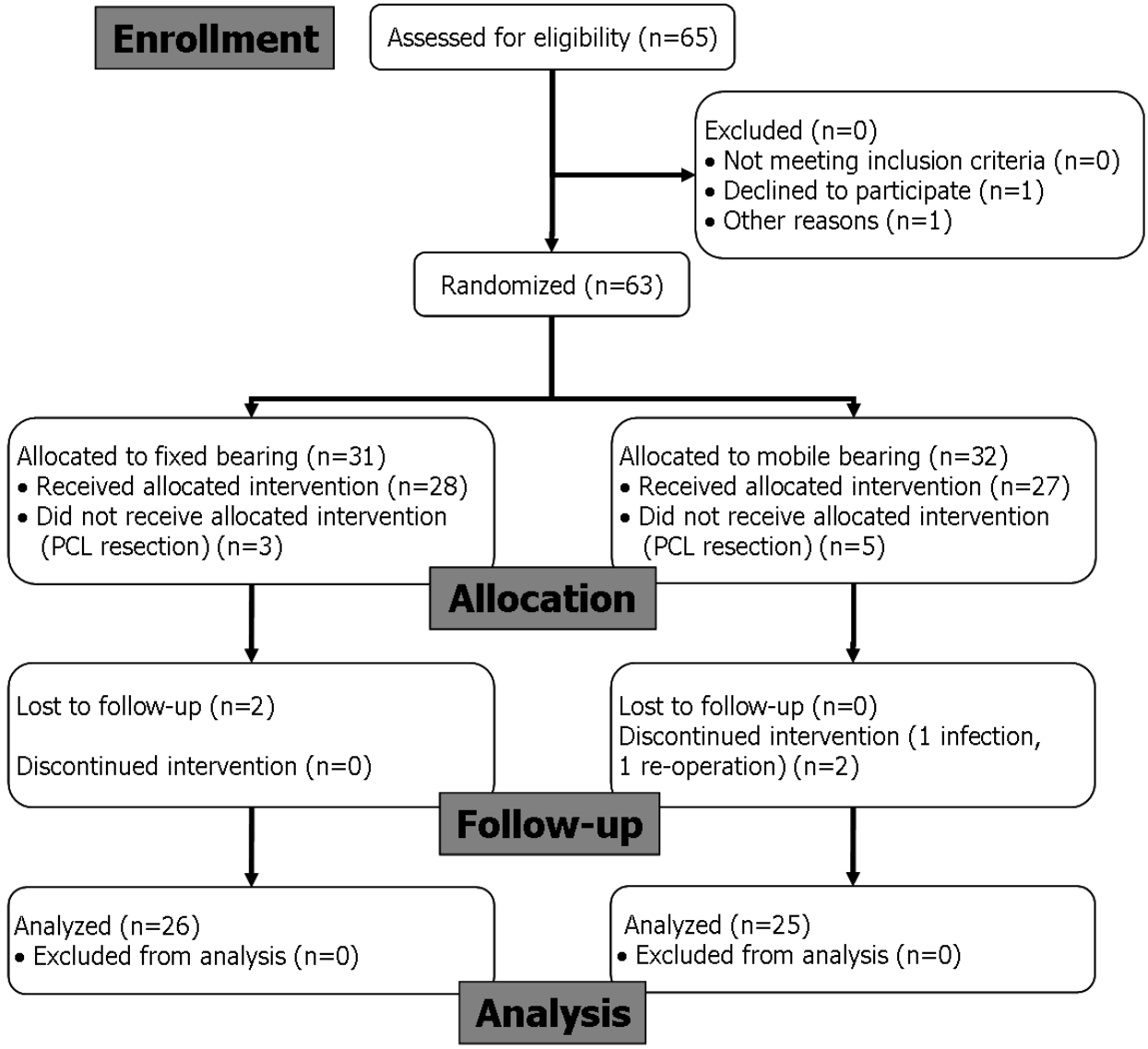
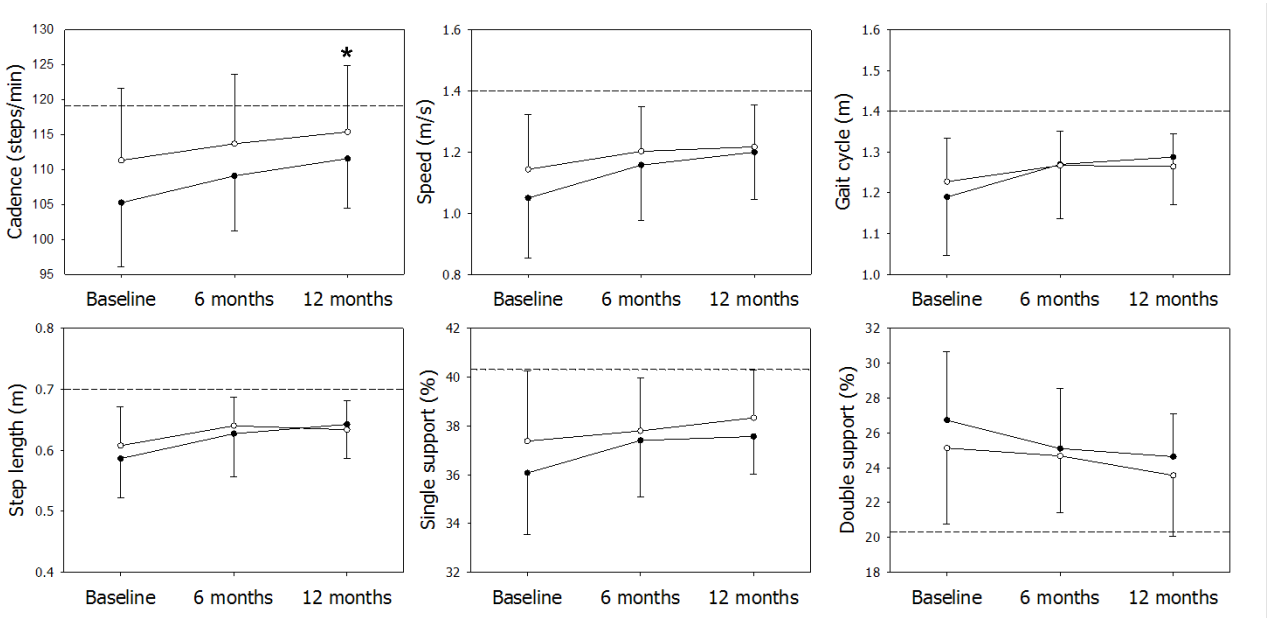
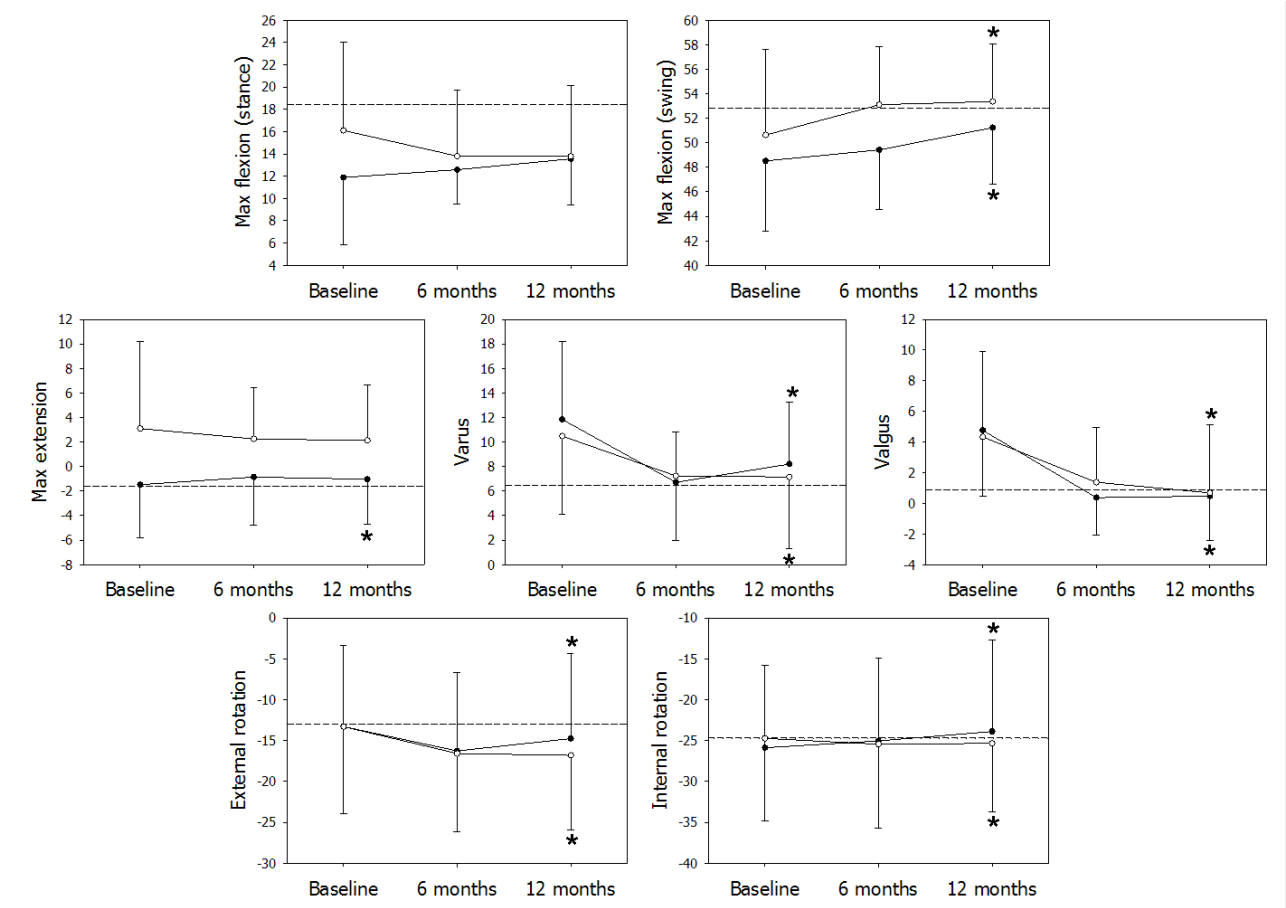


Figure 2



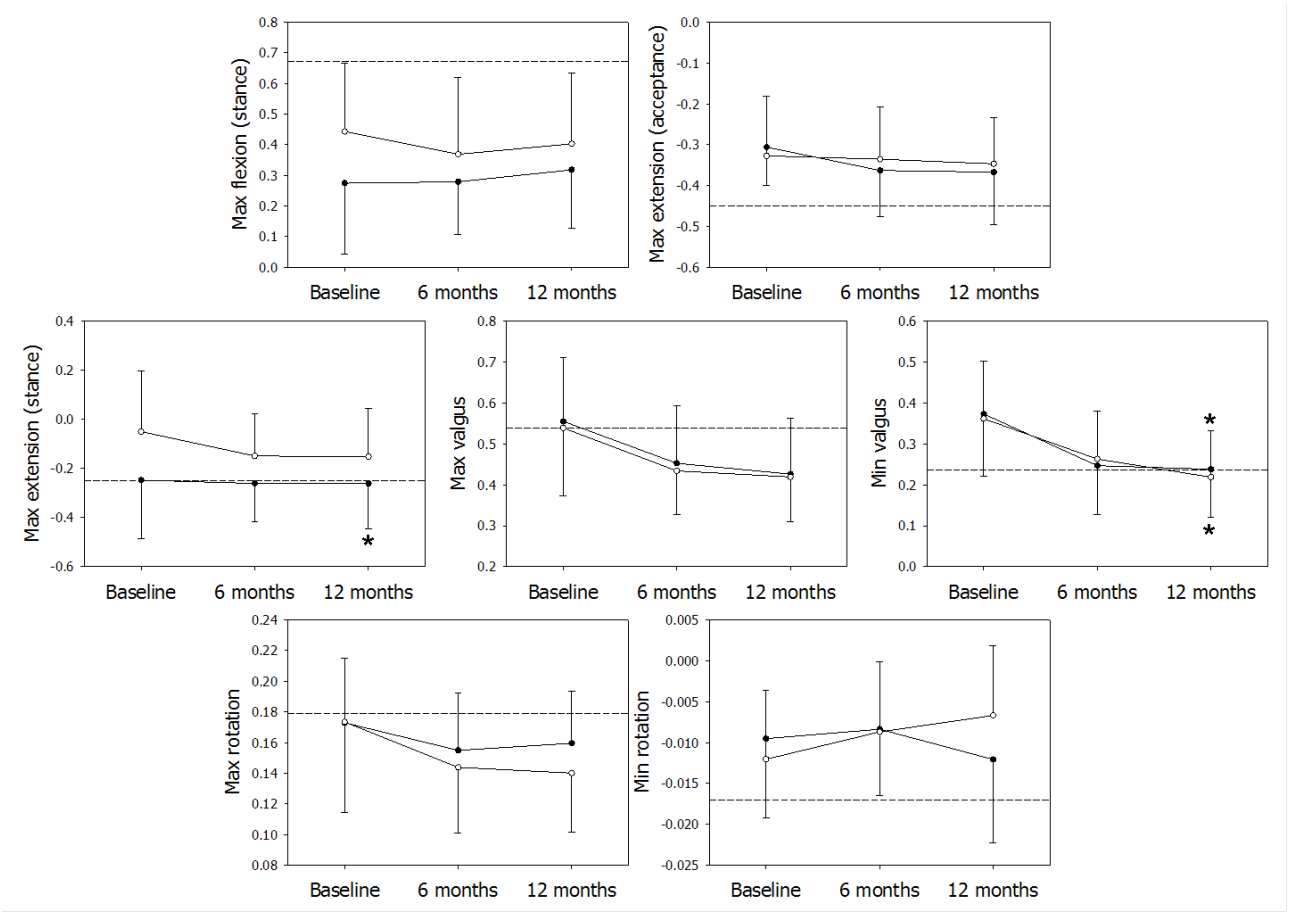
Temporospatial results for FB (●) and MB (o) articulation. Error bars (SD). Dashed line (control group mean). *: value equal to the control group (H_0: no difference).

Figure 3



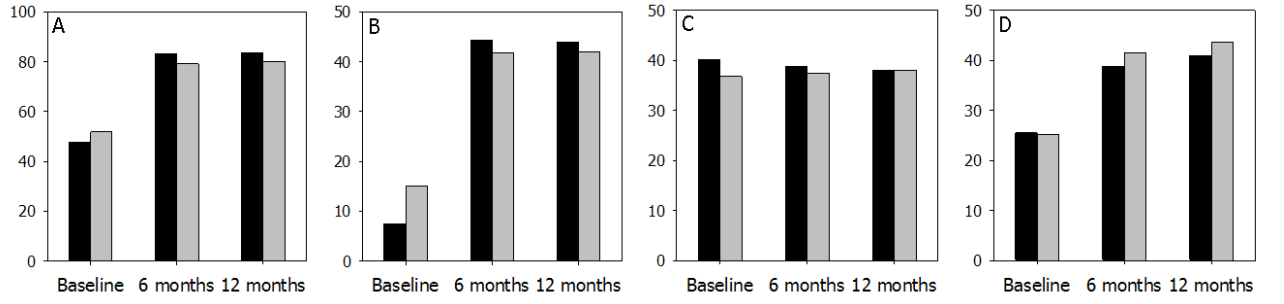
Kinematic results (in degrees) for FB (●) and MB (o) articulation. Error bars (SD). Dashed line (control group mean). *: value equal to the control group (H_0: no difference).

Figure 4



Kinetic results (in Nmm/kg) for FB (●) and MB (o) articulation. Error bars (SD). Dashed line (control group mean). *: value equal to the control group (H_0: no difference).

Figure 5



A) AKSS (max=100), B) AKSS pain score (max=50), C) AKSS clinical score (max=50) and D) Oxford Knee Score (OKS) (max=48) for the FB (black) and the MB (grey) articulation.

Mobile versus Fixed Bearing Total Knee Replacement

A Randomized Radiostereometric and Bone Mineral Density Study

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Mobile vs. Fixed Bearing Total Knee Replacement
A Randomized Radiostereometric and Bone Mineral Density Study

Abstract

This randomized study presents 1-year implant migration, periprosthetic bone mineral density (BMD) and patient reported outcomes (American Knee Society Score and Oxford Knee Score) for the P.F.C. Sigma total knee arthroplasty.

Fifty osteoarthritis patients were allocated to either fixed-bearing (FB) or mobile-bearing tibial articulation (MB).

At 12 months the mean total translation (implant migration) was significantly higher for the FB implant (0.28mm; standard deviation 0.19mm) than for the MB implant (0.18mm; standard deviation 0.19mm) (p=0.037).

There was no difference in BMD decrease at 12 months' follow-up (FB: 2.81%; MB: 9.03%; p=0.062). Both groups' knee-scores improved equally well.

The FB tibial implant migrated more than the MB. Presumably, the mobile polyethylene partly absorbs the force transmitted to the metal tibial tray, thereby significantly preventing micro-motion.

Brief title: RSA and DXA in P.F.C. Sigma mobile vs. fixed bearing

Level of evidence: Prospective randomized study, Level I

Keywords: Knee, Arthroplasty, Mobile bearing, Fixed bearing, RSA, DXA, TKA

Introduction

The mobile bearing (MB) principle was introduced to total knee arthroplasty (TKA) in 1977 due to its theoretical advantages such as reduced contact stress resulting in reduced polyethylene wear and a lower risk of tibial component loosening [1;2]. In spite of many clinical evaluations the expected advantages for MB TKA have not been definitively substantiated. In fact, many publications have noted that mobile and fixed bearing (FB) implant designs performed equally well in terms of longevity, loosening, wear and clinical performance in many publications [3-10]. To our knowledge, only one prospective, randomized study showed results partially in favour of the mobile bearing design [11].

In a Radiostereometric Analysis (RSA) review Ryd et al. showed early stability to be important for a successful prognosis of implant survival and further noted that the tibial component was at higher risk of aseptic loosening than the femoral component [12].

Owing to the correlation between excessive early implant migration and an increased risk of mechanical failure [13-15] migration studies became commonly acknowledged as crucial for promoting new designs for general use [12].

Dual-energy X-ray Absorptiometry (DXA) is a validated and suitable method to monitor bone remodelling in the proximity of implants during the post-operative period [16-19].
Reduced proximal tibial bone mineral density (BMD) is well documented and could complicate revision surgery [15].
Li et al. noticed that decreased periprosthetic BMD and increased tibial component migration do not correlate [20;21]. They found BMD to reach baseline level after 24 months and found early implant migration to be related more to interface issues such as the general trabecular bone condition than BMD changes below the implant. Likewise in total hip arthroplasty, a connection between implant migration and change in BMD has not been documented [22;23].

Although decades of clinical research results have been unable to outline the mobile principle as a winner, it has always been a popular choice among surgeons because of its surgically forgiving design and its improved mobile conditions which are considered optimal for the "active life-style" patient. On the other hand the possible disadvantages of the mobile bearing design such as excessive backside wear, PE instability or even spin-out have been reported as rare complications [24;25]. In studies with up to 20 years' follow-up, the PE instability of the mobile bearing was between 0% to 2.2% [25;26]. Retrieval studies showed no signs of excessive backside wear [25]. This could be attributed to a large contact area with lower forces applied per surface unit [27]. For mobile bearings that allow only rotational motion (and not additional anterior/posterior sliding as do more recent designs) a decoupling of multi-directional motions into mono-directional motion patterns would reduce cross-shear stress and thereby wear [28].
The aim of this randomized trial was to provide an evidence based comparison of the mobile and fixed bearing designs of the posterior cruciate ligament (PCL) retaining press fit condylar TKA in order to facilitate the surgeons' choice between fixed and mobile bearing tibial design.

Materials and methods

This study was designed as a single-blinded randomized controlled trial and was approved by The Central Denmark Region Committees on Biomedical Research Ethics (registration number: (20050031): issue date: (June 24th 2005). All investigations were conducted in accordance with the ethical principles of research (Helsinki II declaration) and informed consent was obtained from all the participants. The study was registered with the Danish Data Protection Agency and with www.clinicaltrials.gov (NTC01150929). The study is reported in accordance with the CONSORT guidelines for trials and the recent RSA guidelines [29;30].

Sample size

With a minimal relevant difference of 0.6mm total translation (power 90%, alpha 0.05, standard deviation (SD) 0.6mm) the study was powered for 22 patients in each group [31;32]. Fifty patients with analyzable baseline stereoradiographs were aimed at in total to compensate for eventual dropouts during follow-up.

Inclusion and exclusion

From March 2007 to June 2010, 63 patients gave written consent to study-participation at an outpatient visit at the Department of Orthopaedic Surgery at Silkeborg Regional Hospital. The baseline demograpics are given in Table 1 and the CONSORT flow scheme (Figure 1) provides further information on dropouts and missing data. None of the participants had been taking medication to improve their BMD prior to surgery (i.e. bisphosphonates).

Inclusion criteria were age 50 to 75 years, uni- or bilateral osteoarthritis (OA), and less than 15 degrees of knee joint extension defect. Exclusion criteria were any neurological disorders affecting gait pattern, concomitant orthopaedic disease of the ipsi-lateral hip joint, senile demented patients; absence of written consent; patients with a peri-operatively weakened or lacking PCL; and patients who postoperatively developed deep infection or abnormal scaring in the knee joint that caused a decreased range of motion.

Randomization followed a procedure with 98 envelopes built on groups of four, six, or eight numbers to ensure a regular inclusion of both implant types during the inclusion period. The uneven group numbers ensured that no randomization number had a predictable result. The envelopes were drawn just before surgery.

Implants

The tibial implants were all P.F.C. Sigma PCL retaining TKA (DePuy International, Leeds, UK) with fixed or mobile bearing tibial designs. The alloy consisted of Co-Cr with a polished surface under the PE. The FB surface facing the bone cement was smooth and the MB surface facing the bone cement was with a slightly more structured finish, though the MB surface was not coated with additional layers. There was no difference in design regarding the femoral components. All surgical procedures included bone pressure lavage followed by patellar resurfacing and cementation (Simplex Bone Cement, Stryker, MI, USA) of the femoral, tibial and patellar components through a pressurizing technique.

Operations were performed by three senior surgeons. The procedure included a midline incision with a para-patellar approach into the knee joint in all patients. The anterior cruciate ligament was excised and the PCL was retained.

The proximal tibia was resected to attempt an implant bearing surface that was perpendicular to the tibial shaft in the coronal plan, but had a 3° posterior slope in the sagital plane. The distal femoral condyles were resected to attemp an alignment of 6° valgus in the coronal plane. The standard guide system from DePuy was used. For radiostereometric analysis a minimum of six one-mm tantalum beads were randomly inserted in the bone surrounding the femoral and tibial implants, respectively.

All patients followed the same standardized post-operative rehabilitation programme allowing full weight bearing immediately after surgery. At discharge patients were instructed in a home training programme

followed by an instruction brush-up with a physiotherapist 14 days postoperatively. All patients were seen at an out-patient visit with a physiotherapist and the surgeon 4 months after their operation.

Implant migration by RSA

Stereo radiographs were obtained 3 days (range 2 to 7 days) after surgery and served as the baseline stereo radiographs for the follow-up visits at 3, 6, and 12 months.

The patients were placed in a supine position with the operated knee parallel to the calibration box so that the anatomical axis of the leg was parallel with the y-axis of the calibration box.

We used a standard RSA setup with two synchronized ceiling-fixed roentgen tubes (Arco-Ceil/Medira, Santax Medico, Aarhus, Denmark) with an unfocussed uniplanar carbon calibration box (Medis Specials, Leiden, The Netherlands). All stereo radiographs were digitized (1,760 x 2,140 pixels). The upper limit for mean error rigid body fitting (stable markers used for migration analysis) was 0.5mm. The mean condition number (dispersion of the bone markers in the tibia) was 17.29 (SD: 4.62; range 9.70-30.10).

Analyses of all stereo radiographs were performed by one observer with Model-Based RSA (MB-RSA) version 3.31 (Medis Specials, Leiden, The Netherlands). The observer used 3D implant computer aided design (CAD) models that were provided by the implant manufacturer and were subsequently implemented in the MB-RSA software. Implant migration was calculated using the 3 follow-up radiographs with the postoperative radiograph as the reference [33]. The point of measurement was the centre of gravity of the CAD-model in relation to the tibial bone markers as the fixed rigid body reference.

Implant translations (implant motion along the axes) were expressed as x-translation (medial and lateral), y-translation (proximal and distal), z-translation (anterior and posterior) and maximal total point motion [29;34]. Rotations (implant movement around the axes) were expressed as x-rotation (anterior and posterior tilt), y-rotation (internal and external rotation) and z-rotation (varus and valgus tilt). Total translation (TT) and total rotation (TR) were calculated using the 3D Pythagorean Theorem ($TT=\sqrt{(a2+b2+c2)}$ [35]. Maximal Total Point Movement (MTPM) [29;34] was given by the MB-RSA software as the unspecified point moving the farthest among the 5000 points from which the implant CAD-models were constructed.

Bone mineral density measured by DXA

BMD was determined 3 days (range 2 to 7) postoperatively and at 12 months' follow-up.

All scans were performed using a GE Lunar Prodigy Advance 2005 DXA scanner. The observers used enCORE 11.40.004 "knee" software (investigational software).

This knee software is investigational and has not yet been approved by the FDA.

This software was earlier shown to be an effective tool in research of periprosthetic bone loss [36]. The patients had their operated knee scanned posterior-anteriorly (PA) while placed in a special designed foam cast to aid identical positioning at each follow-up [19;36]. Further lateral scans (LA) were performed with the patient placed on his or her side with the operated knee toward the scan bed. All DXA scans were

performed at an outpatient visit by one of three trained technicians. The default scan mode was “thin”, which means that the expected average tissue thickness was less than 13 cm. The scan window was 20.8 cm long and 18 cm wide per default. Scans were initiated approximately 12 cm below the proximal patellar pole (measured by a cm ruler) and terminated automatically. This ensured a sufficient amount of soft tissue and bone for correct dynamic tissue labelling (point typing). The knee software was designed to recognize right and left knees by the position of the fibula; hence, we consciously used the opposite side specification on the lateral scans since the fibula anatomically alters its position with respect to tibia in the lateral position.

We designed a template with three regions of interest (ROI) (Figure 2) under the tibial plateau and used an automated dynamic tissue detection algorithm for point typing, detection, and subtraction of metal and cement from the tibial bone. In this way, we automatically subtracted the tibial implant in the BMD calculation. After positioning the ROI template on the baseline scan, the template was fixed to the tibial bone edges and afterwards copied to the successive scans in the same position, thereby ensuring comparable ROI placement on the follow-up scans. No attempts were made to exclude the fibula, since the fibula partly overlap the tibia in all scans and are not entirely and equally removable.

Precision of RSA and DXA

The repeatability of the migration measurements was computed based on double RSA examinations at 12 months’ follow-up in 49 of the 50 participating patients. The postoperative stereo radiographs served as the reference in the migration analysis of the double examinations, and the difference was calculated. The difference in migration between the double examination migration results should optimally be zero, and if not, it represents the bias (systematic error) of the method and along the 3 migration axes the bias was x (0.09mm), y (0.06mm) and z (0.25mm) and for the MB group x (0.06mm), y (0.07mm) and z (0.13mm), respectively. The migration measurement precision (random error = 1.96 x SD) along the 3 migration axes for the FB group was x (0.23mm), y (0.15mm) and z (0.64mm) and for the MB group x (0.11mm), y (0.10mm) and z (0.25mm), respectively. The measurement precision of the TT and the MTPM measurements in the 2 articulation groups was 0.40mm and 1.20mm for the FB group and 0.24mm and 0.61mm for the MB group.

The repeatability of the BMD measurements was calculated based on double DXA examinations of 46 of the 50 participating patients obtained at 12 months’ follow-up. The coefficient of variation (CV=SD x mean / 100%) was calculated for all 3 ROIs and should optimally be zero. The CV with the FB articulation in the AP and LA scans was 1.12% and 11.52% and with the MB articulation 8.76% and 11.84%, respectively.

Knee scores

The Oxford Knee Score (OKS) was filled out by the patients themselves before surgery and at 6 and 12 months’ follow-up. OKS consists of 12 questions regarding the patient’s experienced pain, function and

performance. A maximum of 48 points can be obtained [37]. American Knee Society Score (AKSS) was filled out by the patients (for the pain score) and a physiotherapist (for the clinical score) preoperatively and after 6 and 12 months follow-up. AKSS contains a patient reported pain score consisting of 3 questions and a 7-part hospital staff assessment of function, stability, and range of motion. The pain score as well as the clinical score can result in 50 points each, so the maximum total point number is 100 [38].

Statistics

We compared the FB and MB groups regarding migration, change in BMD and knee scores by using the non-parametric Wilcoxon's ranksum test owing to the absence of normal data distribution. The primary endpoints were the total translation and total rotations values.

The correlation between implant migration and change in BMD was investigated with Spearman's rho test. Statistical significance was assumed at $p<0.05$. All statistical analyses were computed with STATA SE11.1 (StataCorp., TX, USA).

Results

RSA

The implants primarily migrated between baseline and 3 months' follow-up (Figure 3). Total translational migration (TT) (in mm) was significantly higher in the FB group at all 3 follow-up times, whereas the total rotational migration (TR) (in degrees) was similar between groups at all 3 follow-up times and all components seemed well fixed throughout the follow-up period (Figure 3). Translations and rotations at 12 months' follow-up are presented in detail (Table 2) and shown graphically for the translations (Figure 4). In all both translation and rotation directions there was no trend towards a one-direction migration pattern; we found an even distribution between positive and negative migration values in both implant groups.

At each follow-up, two patients in both the FB and the MB group migrated past the 90th percentile (Figure 4). These patients had no outlying pattern regarding BMD change.

DXA

Total periprosthetic (all 3 ROIs) BMD decreased significantly between baseline and 12 months' follow-up in both implant groups. The decrease on the AP scans was 2.81% ($p=0.018$) in the FB group and 9.03% ($p=0.001$) in the MB group. The bone loss in the regions just below the mobile bearing implant tended to be higher than the bone loss under the fixed bearing implant, but this tendency was only statistically significant on LA scans in ROI1 (proximal anterior tibia). All the other ROIs showed no difference in BMD change between the fixed bearing group and the mobile bearing group (Table 3).

Correlation between migration and bone loss

Spearman's rho showed a correlation between the total translation and the bone loss for the MB group at 12 months' follow-up in the lateral DXA scans only (rho -0.44, p=0.0372). All other correlation calculations were insignificant.

Clinical performance

Both the implant groups improved significantly on the OKS and the AKSS from baseline to 6 months' follow-up. There was no difference between the FB group and the MB group in either questionnaire at the 6 or 12 month follow-up times (Figure 5).

Discussion

The present study's key finding was a significantly higher migration of tibial implants with the fixed bearing PE compared to the tibial implants with the mobile bearing PE. In comparison to other publications, however, the migration for both the fixed bearing and mobile bearing articulation was relatively small in the present study.

Ryd et al. [34] used RSA as a predictor of mechanical knee implant loosening of uncemented tibial implants and found migration of 2.7mm (MTPM) among revised implants and 1.0mm (MTPM) in stable implants at the one-year follow-up.

Hansson et al. [4] reported no difference in implant migration (using a marker-based RSA) during a 2-year follow-up by comparing an un-cemented mobile bearing to a fixed bearing tibial component. They found an MTPM between 1.4mm and 1.7mm at 12 months' follow-up, whereas the cemented P.F.C. Sigma implants in the present study had migrated markedly less at 12-months' follow-up for both the fixed bearing and the mobile bearing group. Using a model-based RSA evaluation method, the MTPM is a virtual value based on the one most migratory point out of 5000 points in total. This is because the computer aided design model of the implant is described by 5000 points (triangles). For marker-based RSA all points in the implant migration are known (normally three to five tantalum beads attached to the implant), hence the MTPM gives 3D vectored direction information, but without a direction representing the magnitude of the migration [34]. Even so, for didactic and comparison enhancing purposes, we included the MTPM values in the present study.

In a marker-based RSA study Henricson et al. [5] compared a cemented fixed bearing to a mobile TKA, but found no difference in migration at either 12 or 24 months' follow-up. At 12 months' follow-up they measured MTPM between 0.39mm and 0.51mm and at 24 months, they measured MTPM between 0.56mm and 0.57mm. These migration measures are similar to our results, as was fixation principle (cemented) and stemmed component design in both studies. More publications support the finding that cemented implants migrate less than un-cemented ones [34;39]. The present study witnessed 6 patients in each group migrating more than the 90th percentile (TT). Of these 12 patients only 3 showed MTPM >1mm. None of these 12 patients had low OKS and AKSS scores, and their change in BMD showed no outlying pattern. The

patients with high migration improved their knee scores even more than the total patient group; hence the relatively limited migration shown by this study does not point to symptomatically loose implants. Throughout the follow-up period we found the TT in the FB group to be significantly higher than the TT in the MB group. The reason for this difference in migration could be attributed to the difference in the bearing principle. The MB has been credited for the ability to translate the multi-directional motions of a knee joint into mono-directional motion patterns. This ability should, in principle, reduce cross-shear stress and ultimately reduce wear [28], but it might also be responsible for the reduction in migration shown in this study.

The present study also found the BMD to decrease from baseline to 12 months' follow-up, which was in accordance with other publications [40-43]. Some studies reported BMD to return to baseline level within 24 months postoperatively [18;21], but other authors reported continuous bone loss after TKA in longer follow-up studies [16;43]. The use of DXA as follow-up method has been criticized for its inaccuracies [44], and in opposition to the reproducible set-up of RSA DXA follow-up scans could be influenced by either changes in knee flexion or rotation that cause false estimates of BMD changes [19;36]. The precision measurements for DXA in this study showed a higher CV% for the LA than did the AP DXA scans; however, the CV-precision in this study is comparable to other reports [17;19;36;45]. Another potential source of inaccuracy in BMD analysis of the proximal tibia is the outline and presence of the fibula in the scans. The present study included the fibula and the cortical bone, since total fibular extraction would be impossible due to fibular over-projection onto the tibia. Most TKA studies with BMD measurements have used different placements and sizes of ROIs, which makes comparison of results between studies difficult [19;20]. A consensus on ROI placement in TKA studies similar to the use of Gruen zones with hip arthroplasties would enhance the comparability among knee studies. Finally, the two tibial tray designs have lateral flanges connecting the tibial plateau and the stem. When the leg is rotated, these flanges cover various parts of the bone in the ROI and for the MB tibial tray this coverage could be more interfering, since the MB lateral flanges are a little wider than the FB flanges.

Although theoretically obvious, the association between the decrease in BMD and the increase in migration of TKA as well as THA has been reported with different conclusions [21;22;46]. In the present study we found a correlation between the migration (total translation) and the bone loss after 12 months' follow-up only in the MB group and solitary for the LA DXA scans. The correlation found might be explained by the lower precision in the LA scans compared to the AP scans as discusses earlier. Therefore one should avoid overestimating this finding. Li et al. found no difference in migration using either cemented or non-cemented tibial implants after 2 years' follow-up. In their study most implant migration was observed during the first three months [21] as was the case in the present study. Minoda et al. found no difference in BMD change between the FB and MB tibial implants at the two-year follow-up [41]. Petersen et al. found less migration in

tibial components with high preoperative BMD [46]. No post-operative BMD changes were stated in their study, hence their conclusion was that good bone quality improves implant fixation.
The different size and patterns of BMD change in the post-operative period could mainly be an effect of periprosthetic stress distributed differently by various implant designs [15;23;47] and possible differences in bone necrosis after bone saw-cutting, pulse-lavage, and furthermore the toxic and thermal trauma following cementation [21;48].

In five patients of the current study, the PCL could not be retained, as it prevented the patients' ability to obtain full extension. Thus, these five patients were excluded from the study. PCL removal (posterior release) is one among many strategies to obtain full per operative knee joint extension. An alternative to PCL removal is to remove more femoral bone, but this procedure will position the knee joint line higher with risk of future problems with the muscle apparatus around the knee joint. The discussion whether to remove or retain the PCL was reviewed by Jacobs, who found no clear evidence in favour of either of the two methods [6].

In conclusion we found higher migration for the P.F.C. Sigma fixed bearing tibial plateau than for the mobile bearing tibial plateau with equal loss of periprosthetic BMD at the one-year follow-up time. Overall, the measured implant migration was low overall and similar to that reported for other well-performing cemented TKAs. Both implant groups showed high patient satisfaction which is also in accordance with the literature [49;50]. Therefore, the decision between fixed bearing and mobile bearing is still open for discussion and further research and from our results both implants can be used according to the surgeons' choice.
The authors plan to follow the same 50 patients with a longer follow-up period with an extended investigational programme.

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Figure 1 – CONSORT flow diagram of RCT

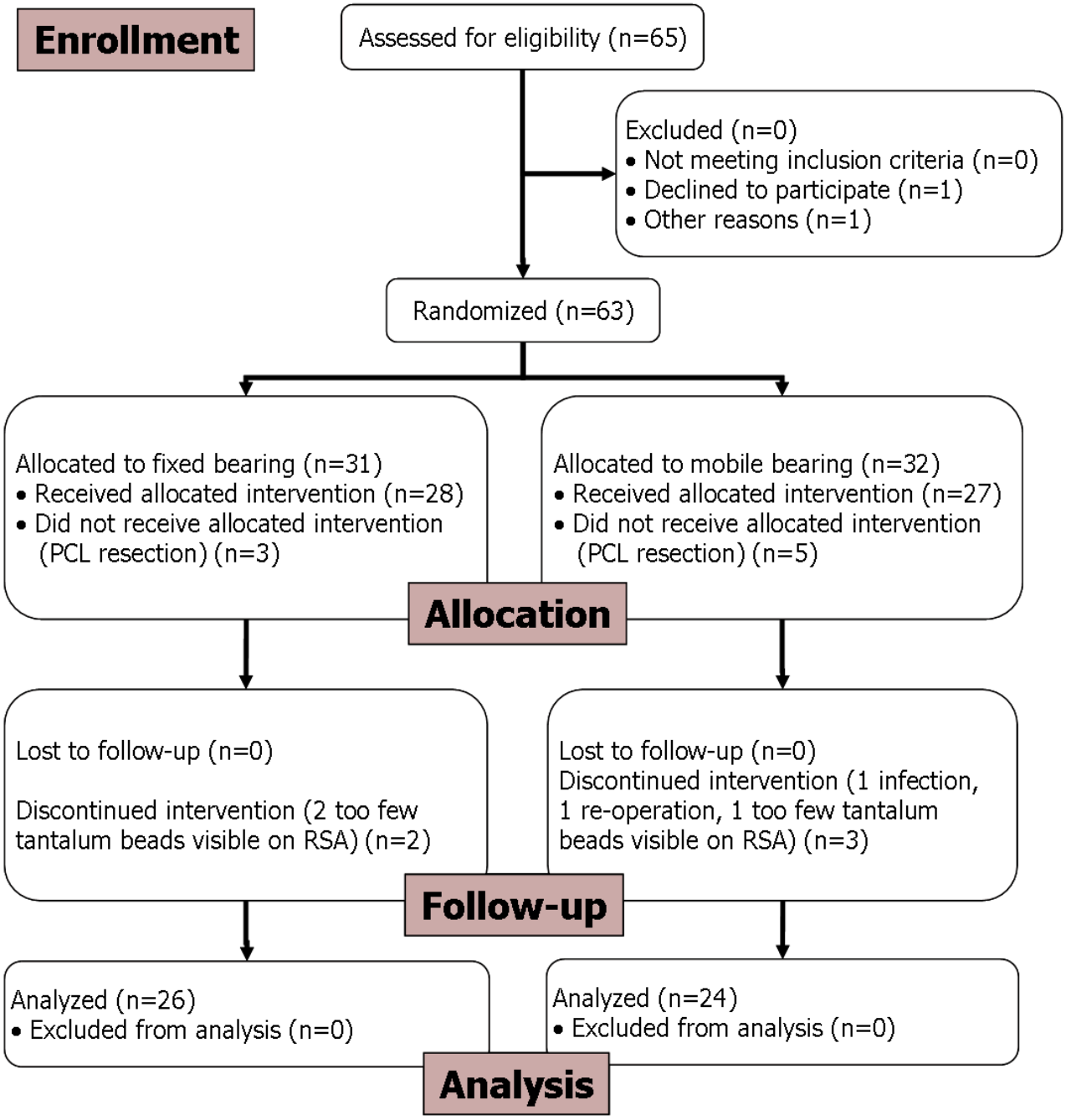
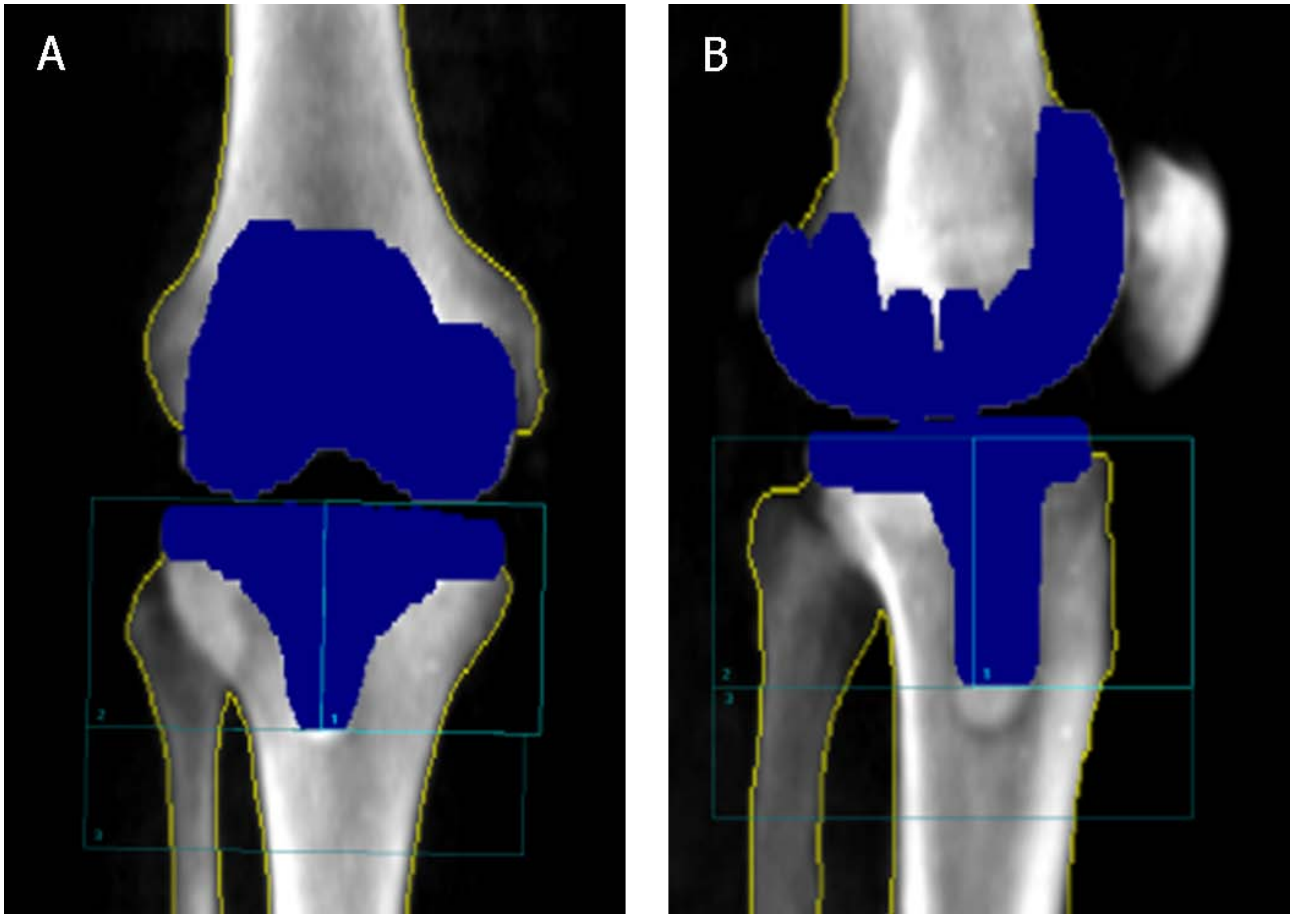
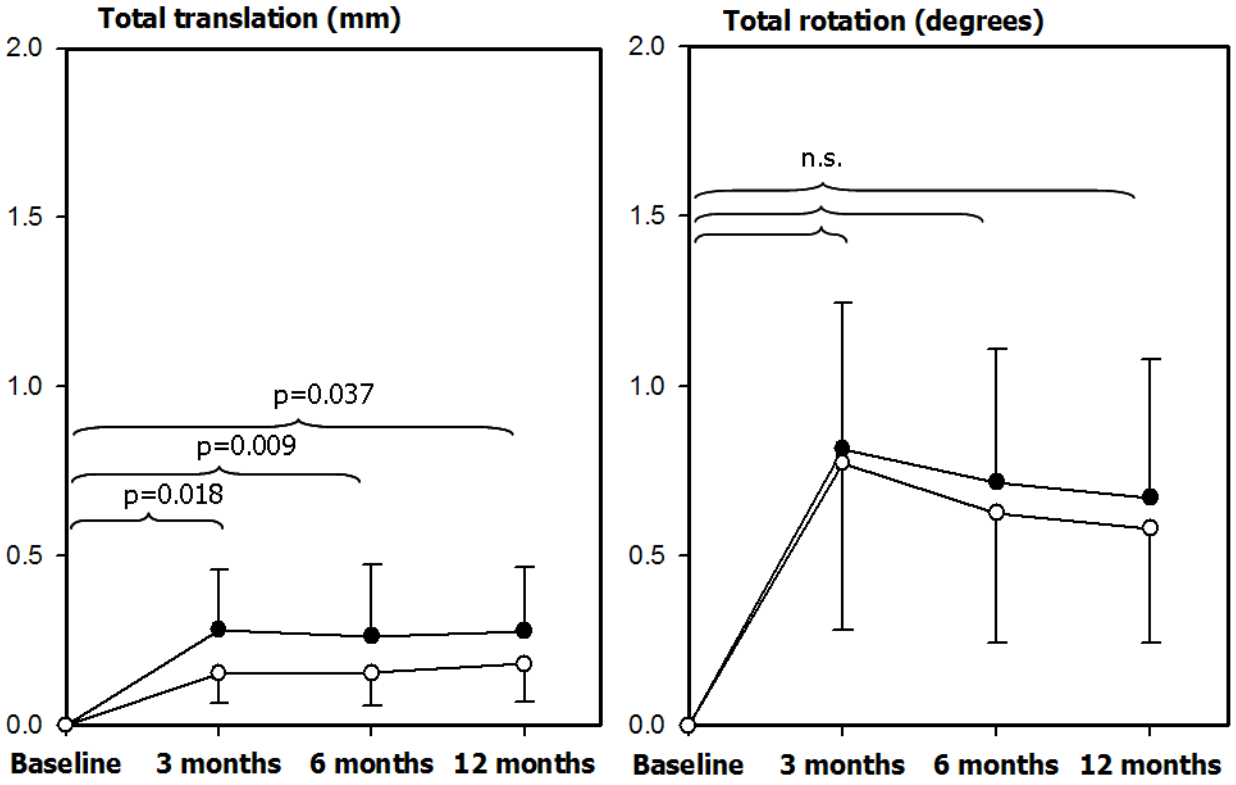


Figure 2



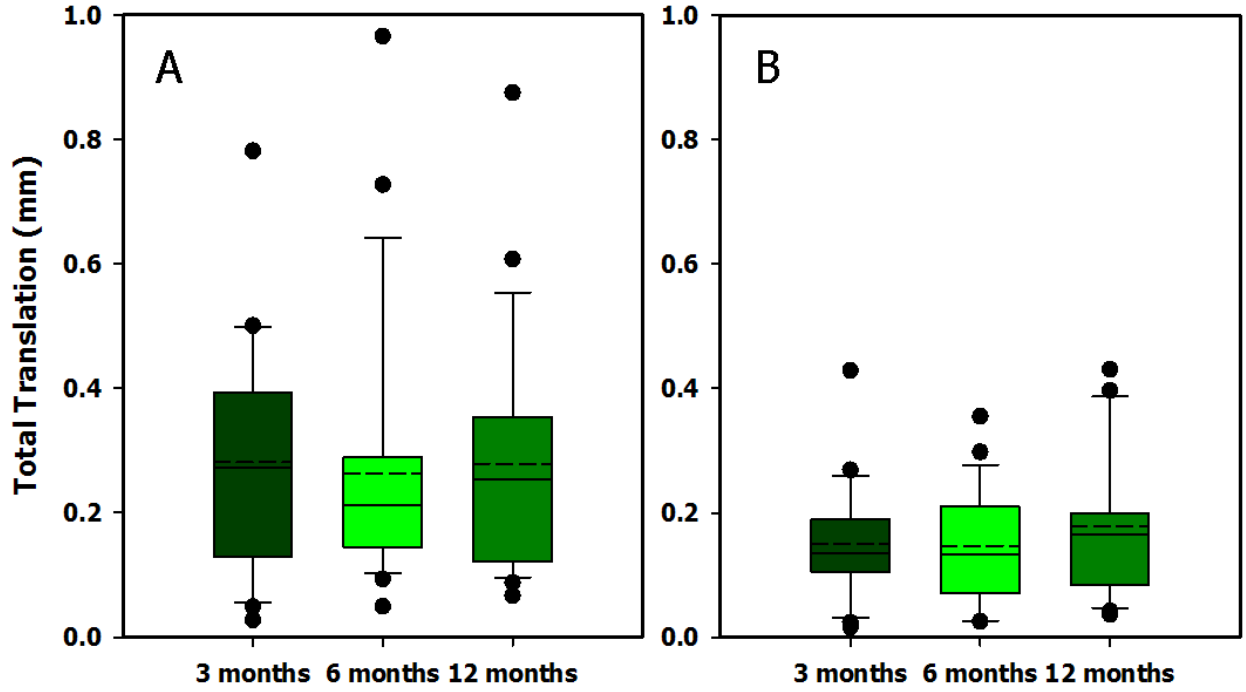
DXA scans images in AP (A) and LA (B) positions AP: ROI1 medially; ROI2 laterally; and ROI3 below implant. LA: ROI1 anteriorly; RIO2 posteriorly; and ROI3 below implant.

Figure 3



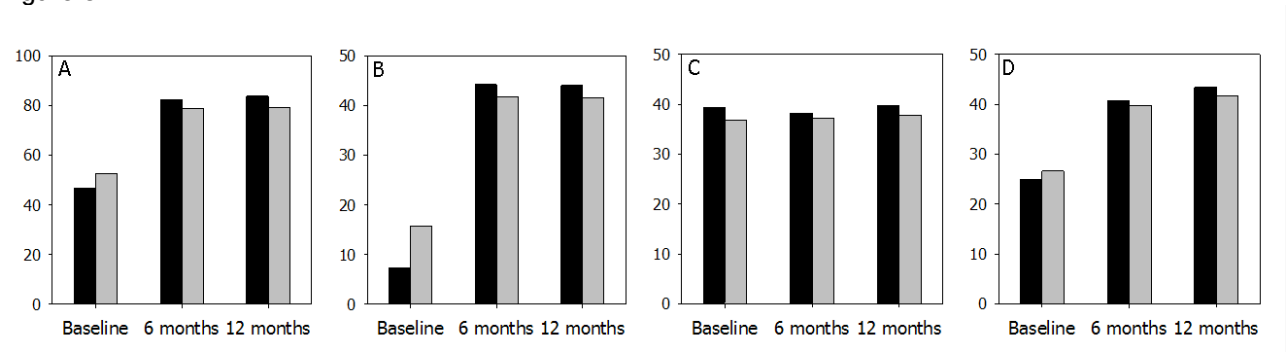
Total translation (left graph) and total rotation (right graph) for the FB (•) and MB (o) articulations. The whiskers represent the standard deviation.

Figure 4



Total translation for the FB (A) and the MB (B) articulations. The whiskers indicate the 10th and 90th percentiles, the drawn line the median and the dotted line the mean.

Figure 5



AKSS (A) (max=100), AKSS pain score (B) (max=50), AKSS clinical score (C) (max=50), and OKS (D) (max=48) for the FB (black) and the MB articulation (gray).

Table 1

	Fixed bearing (n=26)		Mobile bearing (n=24)	
Weight (kg)	87	(67-119)	80	(60-104)
Height (cm)	171	(155-183)	170	(160-185)
BMI (kg/m^2)	30	(23-39)	27	(23-34)
Age (years)	66	(56-73)	66	(54-75)
Gender (male/female)		(14/12)		(9/15)
OP side (right/left)		(12/14)		(14/10)
Implant size	4	(2.5-5)	3	(2.5-5)
Knee flexion (degrees)	119	(77-144)	117	(77-144)
Extension defect (degrees)	3	(0-11)	5	(0-11)
R.O.M. (degrees)	116	(88-144)	112	(88-144)

Baseline demographics and knee joint flexion/extension. Values are mean (range).

Table 2

Translations (mm)		Fixed bearing (n=26) x	y	z	TT	MTPM	Mobile bearing (n=24) x	y	z	TT	MTPM	p-values p1	p2
	Mean	0.09	0.06	0.23	0.28	0.61	0.06	0.07	0.13	0.18	0.48	0.037	n.s.
	SD	0.08	0.04	0.20	0.19	0.35	0.07	0.05	0.12	0.11	0.27		
	Min	0.00	0.01	0.02	0.07	0.21	0.00	0.01	0.00	0.04	0.18		
	Max (-)	-0.18	-0.12	-0.51			-0.21	-0.16	-0.37				
	Max (+)	0.32	0.15	0.86	0.87	1.60	0.25	0.15	0.38	0.43	1.51		
Rotations (degrees)		x	y	z	TR		x	y	z	TR		p3	
	Mean	0.42	0.38	0.13	0.67		0.32	0.37	0.07	0.56		n.s.	
	SD	0.37	0.36	0.10	0.41		0.21	0.36	0.07	0.34			
	Min	0.01	0.01	0.01	0.15		0.02	0.03	0.01	0.12			
	Max (-)	-0.97	-0.68	-0.33			-0.62	-0.73	-0.33				
	Max (+)	1.31	1.83	0.29	1.89		0.72	1.68	0.11	1.73			

12 months' migration results.alues. Max (-) is the maximal migration with negative sign.
p1: TT comparison FB vs. MB. p2: MTPM comparison FB vs. MB. p3: TR comparison FB vs. MB.

Table 3

		Fixed bearing (n=26) Baseline (SD)	12 months (SD)	Change (%)	Mobile bearing (n=24) Baseline (SD)	12months (SD)	Change (%)	p-values p1	p2	p3
AP	All ROIs	1.01 (0.17)	0.98 (0.17)	-2.81	0.96 (0.14)	0.87 (0.19)	-9.03	0.02	0.00	n.s.
	ROI 1	1.00 (0.18)	0.94 (0.19)	-6.1	1.00 (0.19)	0.86 (0.21)	-14.72	0.00	0.00	n.s.
	ROI 2	0.91 (0.23)	0.85 (0.18)	-6.36	0.83 (0.13)	0.74 (0.17)	-10.9	n.s.	0.00	n.s.
	ROI 3	1.15 (0.15)	1.12 (0.18)	-2.43	1.06 (0.15)	1.00 (0.21)	-5.64	n.s.	0.01	n.s.
LA	All ROIs	0.91 (0.18)	0.86 (0.21)	-5.43	0.85 (0.17)	0.76 (0.17)	-11.04	0.01	0.00	n.s.
	ROI 1	0.87 (0.27)	0.83 (0.29)	-4.07	0.80 (0.20)	0.69 (0.21)	-13.81	0.03	0.00	0.04
	ROI 2	0.90 (0.22)	0.78 (0.21)	-13.33	0.88 (0.19)	0.72 (0.18)	-17.77	0.00	0.00	n.s.
	ROI 3	0.98 (0.21)	0.99 (0.24)	1.16	0.88 (0.18)	0.82 (0.82)	-6.6	n.s.	0.01	n.s.

Mean BMD (in g/cm^2) with standard deviations.
p1 and p2: Comparison of baseline to 12 months' follow-up for FB and MB, respectively. p3: FB vs. MB at 12 months.