Life with arthroplasty:
the *k*need for an integrative approach

Arthur J. Kievit

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Chapter 1

General introduction

Prologue

The structure of this thesis traces the journey usually taken by patients presenting with knee OA, from surgical treatments, outcomes, possible complications such as loosening and revision surgery to follow-up care and the ability to return to work.

Background

OsteoArthritis (OA) of the hip and knee is one of the leading causes of global disability according to the 2020 'Global burden of disease' study by the World Health Organisation (WHO) and The Lancet.[1 2] Globally, of 369 conditions reported, OA of the hip and knee was ranked as the 11th highest contributor to global disability. The global age-standardised prevalence of knee OA is reported to be 3.8% (with a 95% uncertainty interval (UI) 3.6% to 4.1%). The Years Lived with Disease (YLDs) for knee OA increased from 10.5 million in 1990 (0.42% of total DALYs) to 17.1 million in 2010. [3 4] Based on health insurance data in the Netherlands, half of the 1.5 million visits to the family doctor related to OA are because of knee OA.[5] Dutch primary care databases show that estimates of incidence and prevalence based on codified data from electronic health records alone are underestimates due to missing data. [6] Narrative data (written text) as reported by the family doctor in the medical file should be incorporated in addition to codified (data in numbers) data to identify knee OA patients more accurately.

The knee is a modified hinge joint and has six degrees of freedom in motion. It permits three types of rotation i.e. flexion and extension, varus and valgus and internal and external rotation, as well as three types of translation i.e. anteroposterior translation, mediolateral translation and compression distraction. Flexion-extension and internal-externa rotation can be considered as the primary functional motions.[7] It is structurally made up out of bone, cartilage, ligaments, capsule, synovium and synovial fluid, tendons, nerves and blood vessels.. It consists of three articulating surfaces; the lateral and medial compartment, with menisci in both, and the patellofemoral compartment. OA can develop in isolation in any of these compartments (i.e. in post-traumatic OA based on an intra-articular fracture) or as a more generalized disease affecting all parts of the knee. OA is classed in four stages from doubtful (I) to severe (IV) (*figure 1)*. It can lead to complaints of joint pain, stiffness, swelling, night pain and loss of function.

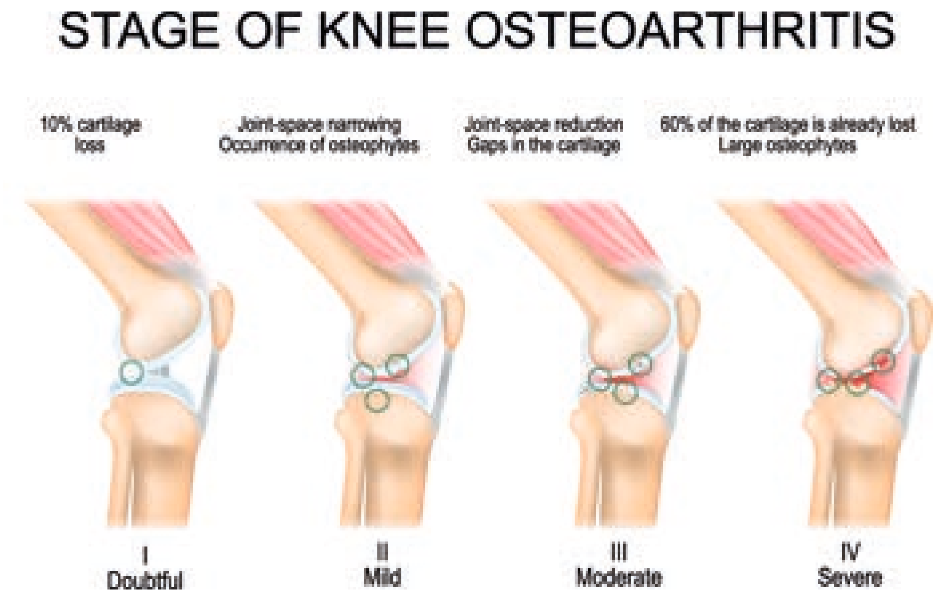

Figure 1. The four stages I, II, III, IV of OA, circles point out area where the joint changes. (Source: iStock.com with permission)

Treatment of knee OA

Complaints of OA are mainly pain, joint stiffness, tenderness, loss of flexibility, grating sensations bone spurs and swelling. OA cannot be cured. Management of knee OA must be tailored to the individual patient. Non-operative options to treat the symptoms are usually indicated for stage I and II OA and include: patient education, self-management, exercise therapy (with or without physiotherapy), correctional braces and lifestyle changes such as weight loss.[8] This is supported by the 2023 revised recommendations by the European Alliance of Associations for Rheumatology (EULAR) that include eight evidence-based recommendations including (1) an individualised, multicomponent management plan; (2) information, education and self-management; (3) exercise with adequate tailoring of dosage and progression; (4) mode of exercise delivery; (5) maintenance of healthy weight and weight loss; (6) footwear, walking aids and assistive devices; (7) work-related advice and (8) behaviour change techniques to improve lifestyle.[9] The pharmacological methods most often recommended in guidelines include paracetamol and Non-Steroidal Anti-Inflammatory Drugs (NSAIDs) and intra-articular injections with, for instance, cortisones or hyaluronic acid. The guidelines advise tailoring care to each individual patient. If non-operative methods have had no or insufficient effect after 3-6 months, patients are advised to consult an orthopaedic surgeon to discuss which surgical options are feasible.[8 10] Mainstream surgical management is usually indicated for stage III and IV knee OA and consists mainly of corrective osteotomy (*figure* 2), Uni-compartmental Knee Arthroplasty (UKA) (*figure* 3) or Total Knee Arthroplasty (TKA) (*figure* 2 *& 4*).

Figure 2. On the left in this image the result of a corrective osteotomy on a right knee and on the right in this image a Total Knee Arthroplasty (TKA) in the left knee is shown. (Source: iStock.com with permission)

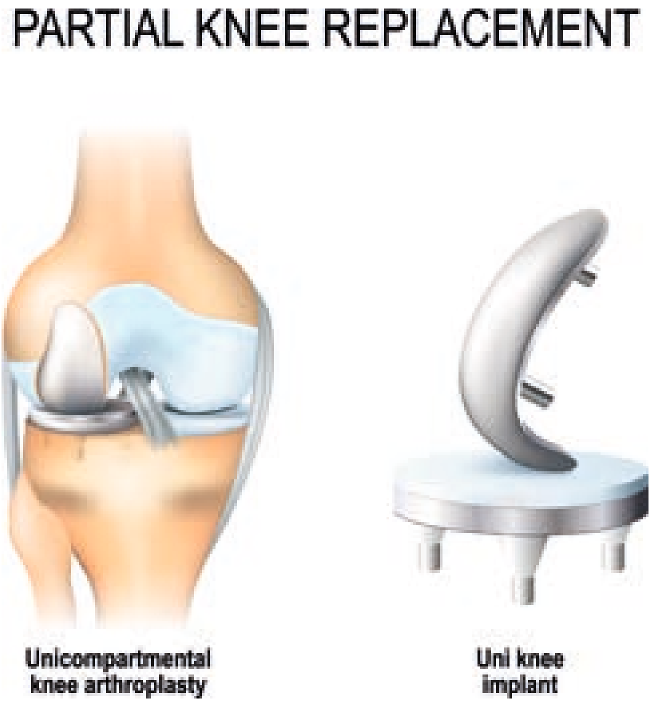

Figure 3. Partial, uni-compartmental knee arthroplasty (UKA). (Source: iStock.com with permission)

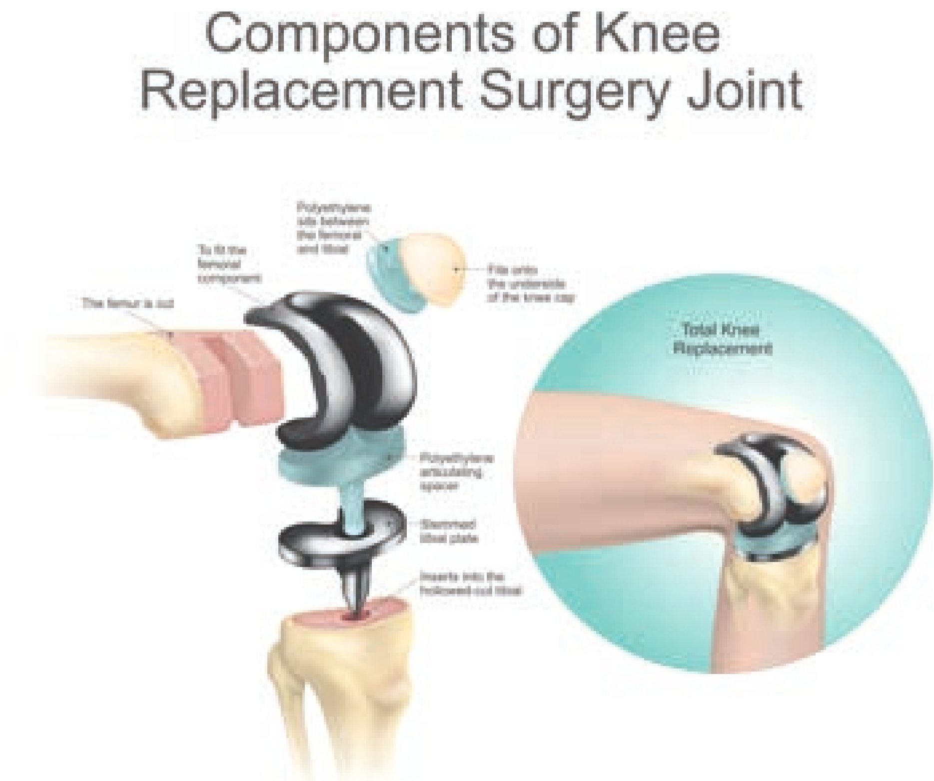

Figure 4. The components of Total Knee Arthroplasty (TKA), the medial and lateral knee compartment, anterior cruciate ligament and in some cases the posterior cruciate ligament and patellofemoral joint are replaced. (Source: iStock.com with permission)

In younger active patients showing earlier stages of OA, corrective osteotomy can be a good option. [11] This is a procedure to reduce the load on the affected area of the native knee joint by re-aligning the mechanical axis of the leg via an osteotomy with fixation. More recently as an alternative to corrective osteotomy, and prior to joint-replacement surgery, surgical joint distraction has been introduced. Knee joint distraction is a more recently developed surgical joint-preserving treatment that also appears to be associated with, at least short term, joint tissue repair but is still being evaluated for longer term effects.[12] If corrective osteotomy or distraction is not indicated or chosen, the alternative is to perform joint-replacement surgery. This is a clinically relevant and cost-effective treatment. It is indicated if non-operative methods have had little impact in patients with stage IV OA. [13-15]

(T)KA surgery

There are a number of options for joint replacement surgery. If only the medial or lateral compartment (i.e. UKA procedure) is resurfaced, the Anterior Cruciate Ligament (ACL) and posterior Cruciate Ligament (PCL) are spared. The patellofemoral compartment can be resurfaced in isolation, also preserving the ACL and PCL. In TKA either the ACL alone of both the ACL and PCL are removed and their function incorporated in the implant.

In total-joint replacement surgery specific steps are followed to implant the prosthesis.

In general, the knee joint is exposed and possible TKA implant sizes are determined. All bone cuts are made in concordance with the selected implant sizes. Standard procedure to achieve the correct bone cuts is by using the alignment instruments provided by each specific implant supplier. The orientations of the bone cuts and implants can often be adjusted to ensure that the limb is properly aligned.

Restoration of knee alignment is considered one of the mainstays of successful TKA surgery as it is important to try to achieve a neutral mechanical axis passing from the centre of femoral head through the centre of the knee joint line to the centre of the ankle.[16] TKA alignment is a relative concept and indeed there are two separate views of alignment: component alignment and limb alignment which may interact and can result in the same limb alignment but with a different knee kinematics and motion. [17] Mechanical Alignment (MA) is the most widely used method with high reproducibility and easiness. [18] MA requires an initial femoral cut that is perpendicular to the mechanical long axis of the femur; the tibial cut must be performed perpendicular to the mechanical long axis of the tibia. The knee is then, usually, aligned at 4°–5° valgus of the femoral side but this may be adapted according to the patient's height and taking into consideration previous limb morphology. In general, someone who is used to a varus knee, will not be happy with post-op valgus knees and vice versa. Purpose of this alignment is to ensure an even load distribution on the new joint line, the articulating space between the femoral component and the tibial polyethylene component. Furthermore, the femoral component is positioned at 3° of external rotation in order to balance flexion and extension gaps.

Mechanical alignment of the TKA achieves the best distribution of implant load as the tibial implant is loaded in line with the bone with the least mediolateral shear forces, which are known to be a risk for implant loosening. However, a native joint has an average joint line obliquity of 3° in the coronal plane. Because these three degrees of obliquity have to be removed in mechanically aligned knees this could contribute to the knee feeling less normal. There are other options to align the TKA that allow the prosthesis to be implanted with a more natural native obliquity. [19] Nowadays, different principles and surgical alignment approaches have been described that can be classified in three main categories (figure 5), as described by Matassi. [20]

1) *Systematic alignment*, which includes mechanical alignment (MA) as mentioned above and anatomic alignment (AA) which allows for joint line obliquity but both

with the goals to restore neutral alignment with hip–knee–ankle axis (HKA) of 180° for all patients independently from preoperative alignment;

2) *Patient-specific alignment* such as Kinematic Alignment (KA) that aims to maintain the native limb alignment as well as joint line inclination;
3) *Hybrid alignment* such as restricted kinematic alignment (rKA), inverse kinematic alignment (iKA), adjusted mechanical alignment (aMA) and functional alignment (FA) with the aim to allowing some native obliquity but to restore the coronal alignment within an HKA angle safe zone of 177° to 183° and reduced the risk of implant failure.

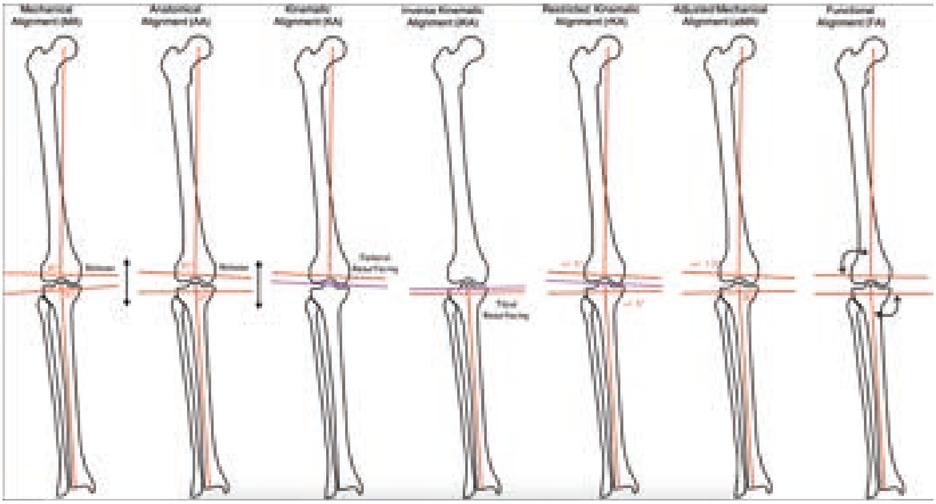

Figure 5. Various alignment techniques. Journal of Orthopaedics and Traumatology Open Access. (Reproduced with permission [20])

Implant failure (and loosening) is a greater risk if too much obliquity in the coronal plane is allowed. In anatomic alignment for instance the TKA will be loaded more medially with a medial tibial plateau fixation failure as a risk. [18] The aim of patient specific alignment methods such as KA is to restore normal knee function by aligning the distal and posterior femoral joint line of the femoral component according the functional femoral transverse axes and joint line of the tibial component to those of the normal or pre-arthritic status. [16] Issues have arisen that this may also lead to earlier implant failure and loosening due to shear forces across the bone-implant fixation interface. [21] [22] Studies are still ongoing to find out what the best implant position and orientation is that leads to a combination of high patient satisfaction as well as longevity in implant survival. Whatever the future holds, it is important that the preoperatively planned implant position and orientation can be adequately performed during surgery.

In order to reduce the risk of intraoperative malpositioning, more accurate and precise intraoperative bone cut techniques are required to ensure precise arthroplasty placement. To achieve this, special instruments based on Computed Tomography (CT) or Magnetic Resonance Imaging (MRI) imaging per patient have been developed to tailor the surgical technique to specific patient anatomy and selected alignment goal.[23] Most of the large implant suppliers have a commercial Patient Specific Instrumentation (PSI) system available for use in their knee arthroplasty procedures. The Signature™ Personalized Patient Care system (*Biomet Signature Knee System*: in collaborative partnership with *Materialise* NV) is one of these.[24] More recently robotic assisted surgery has become even more popular as an alternative.[25]

Complications

Orthopaedic surgeons can prevent many problems by taking the steps necessary to position the arthroplasty implant in the technically precise way described above. If complications (footnote[1] [26 27]) occur, in some cases revision surgery is required. Malalignment or the wrongly sized arthroplasty are major causes of arthroplasty failure in TKA with dissatisfied patients suffering from persistent discomfort and pain, instability and even loosening of the implant components.[28] For instance, too much *varus* malalignment is associated with higher rates of arthroplasty loosening and revision.[22 29 30] Other well-known complications are instability, infection, patellofemoral pain, arthrofibrosis, dislocation of the patella, fracture, thrombosis, insert wear or component loosening. The latter is one of the most reported reasons for revision and bad outcomes. The top three reasons for revision surgery in the Netherlands from 2014-2022 were: instability (26%), patellar pain (21%) and loosening of the tibial component (20%) (Table 1).[31]

The risk for revision is higher in the younger more active patient population. Compared to patients who receive a TKA above 70, the lifetime risk for revision surgery was 35% higher for men who had their first TKA in their early 50s (95% CI 30.9–39.1) although this was lower (15%) for women in the same age group (figure 6). [32] It seems that especially (male) patients of the working age are at higher risk for revision TKA surgery over time.

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1 Sokol and Wilson's defined a surgical complication as 'any undesirable, unintended, and direct result of an operation affecting the patient, which would not have occurred had the operation gone as well as could reasonably be hoped [...] a surgical complication is not a fixed reality [...] it is dependent on the level of surgical skill and the facilities available'. [25,26]

Year	2020	2021	2022	Total 2014-2022
Knee revision arthroplasty (n)	2,496	2,601	2,985	25,278
Reasons for revision; Proportion[1] (%)	%	%	%	%
Instability	26.2	26.3	24.6	**26.1**
Patellar pain	18.7	17.8	23.9	**20.8**
Loosening of tibia component	19.5	19.0	18.7	**20.4**
Infection	23.7	22.0	22.4	20.1
Malalignment	10.6	11.0	8.9	11.8
Progression of OA	7.6	8.9	11.9	8.9
Loosening of femur component	8.0	8.8	8.4	8.8
Insert wear	7.0	7.7	10.3	7.7
Revision after knee removal	5.1	4.3	4.9	5.3
Arthrofibrosis	3.9	4.3	3.9	4.6
Patellar dislocation	2.8	2.2	2.6	2.4
Periprosthetic fracture	2.6	2.7	2.5	2.1
Loosening of patella component	1.8	1.7	1.6	1.7
Bearing dislocation[2]			3.7	
Other	7.5	8.7	8.7	8.1

[1] One patient may have more than one reason for revision. As such, the total proportion is over 100%.
[2] Please note: Bearing dislocation was not registered before 2022.

TABLE 1. Trend (proportion [%] per year) in reasons for revision in patients who underwent a knee revision arthroplasty in the Netherlands in 2014-2022 [31]

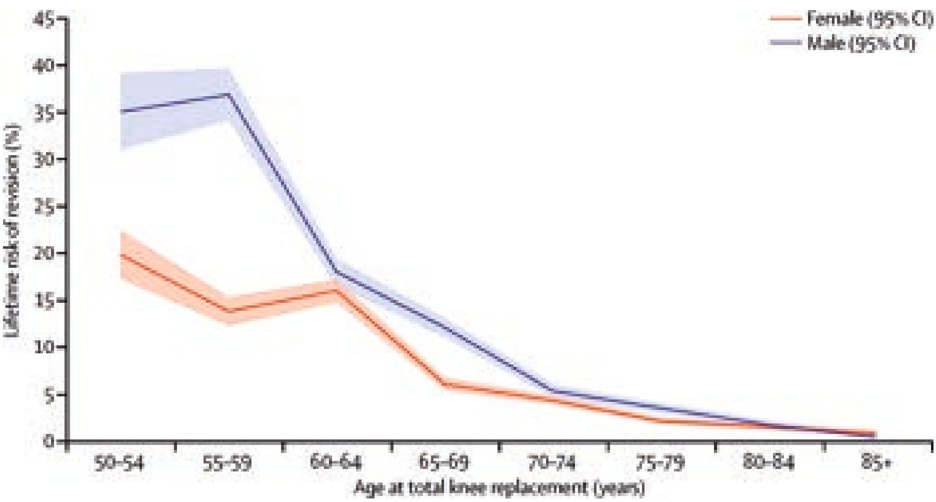

Figure 6. The effect of patient age at intervention on risk of implant revision after total replacement of the hip or knee: a population-based cohort study. Lancet Open Access (Reproduced with permission [32])

In this thesis aseptic loosening as the indication for revision is addressed in more detail. Patients who are suspected of loosening of their TKA generally complain of pain in the tibia or femur on weight bearing. Currently, the most common diagnostic signs of aseptic TKA loosening with various imaging modalities are: radiographic sign of radiolucency, TKA migration compared to the surrounding bone over time, and high bone turnover on bone scintigraphy and PET-CT.[33] Despite being used a lot, according to an update in 2023 from the American College of Radiology (ACR), these imaging modalities are either insufficiently sensitive or insufficiently specific to be able to diagnose arthroplasty loosening accurately. [34] These tests merely support the suspicion that there may be arthroplasty loosening and are burdensome to patients and costly to society without being sufficiently effective. When infection is excluded and aseptic loosening is suspected, the ACR only advise MRI or CT without intravenous contrast or, in some cases, the 3-phase bone scan knee. All other methods are considered "Usually Not Appropriate".[34] A review and meta-analysis that evaluated available diagnostic modalities to aid the diagnosis of knee arthroplasty loosening suggests that, based on a low certainty of evidence, MRI and SPECT/CT are currently the most accurate modalities available to aid the diagnosis of aseptic loosening of TKA.[35] It must be noted that the evidence currently available has a high risk of bias. The total number of patients studied for each modality is very small. The lack of specificity of these tests could lead to a large number of patients undergoing risky revision surgery for the wrong diagnosis. Further studies are warranted. [36] A combination of clinical signs with imaging gives the highest probability of loosening being correctly identified. In a recent international Delphi consensus study weight-bearing pain and implant migration, progressive radiolucency's, radiolucency more than 2 mm and subsidence on radiographs and CT are generally accepted criteria for knee arthroplasty loosening.[37]

All above-described imaging modalities do not show actual implant movement relative to the bone. Patients often have a loose prosthesis for a while before the correct diagnosis can be made due to a lack of sensitivity, reducing functional satisfaction for this group. To improve care for this group, an imaging modality is required that can make a timely diagnosis of loosening with high sensitivity and specificity. The current gold standard to evaluate actual implant loosening is visible fluid motion on manipulation during intraoperatively testing.[38] Therefore, a new image modality should ideally actually quantify implant movement relative to the adjacent bone or cement interface instead of merely visualising the secondary effects of loosening such as radiolucent lines or high bone turnover.

Outcome of surgery

In an ideal world, the surgical procedure for knee OA would remove all pain and would restore mobility function to the level before the onset of symptoms. However, KA surgery is not (yet) able to deliver such results. The discrepancy between ideal and actual outcomes can be measured using the Forgotten Joint Score (FJS)[39], which is a Patient Reported Outcome Measure (PROM) designed to measure whether a patient "forgets" (no longer notices) the treated joint during activities of daily life on a scale from 0 (= bad) to 100 (=perfect). It was estimated that the FJS threshold to consider surgery as a success is 74 and 70 at 12 and 24 months postoperatively respectively.[40] After TKA the average reported FJS score at 12 months postoperatively ranges from 68-76, which means that the criterion for successful surgery is not met in about half of the patients.[41 42] Moreover, FJS scores tend to deteriorate over time down to an average of 64.4 ± 29.0 at 60 months.[42]

After TKA surgery, patients may be disappointed that their 'new' knee does not function as well as their 'old' knee did when it was healthy, even though pain is considerably reduced in most patients. Flexion movement is usually reduced to around 125 degrees with extension usually reduced to 0 degrees (normal hyperextension diminishes to 0 degrees). This reduced level of range-of-motion means that patients can usually still walk, climb stairs, cycle or drive a car but most will not be able to crouch down, clamber or do a sitting kneel (e.g. for prayer or yoga position).[43] In other words, TKA does not give patients a 'new' version of their once healthy knee but the TKA is an artificial replacement with specific benefits and limitations.

The nature and severity of the knee OA complaints as well as the various possible outcomes regarding pain and mobility, with and without (non) operative treatment, should be discussed between doctor and patient using Shared Decision Making (SDM).

"In SDM four steps can be distinguished: (1) the professional informs the patient that a decision is to be made and that the patient's opinion is important; (2) the professional explains the options and their pros and cons; (3) the professional and the patient discuss the patient's preferences and the professional supports the patient in deliberation; (4) the professional and patient discuss the patient's wish to make the decision, they make or defer the decision, and discuss follow-up." [44]

These steps assist the process of SDM, leading to more realistic expectations and better preparation for either non-operative management or surgery. In such doctor-patient communications, each realistically available option is given equal attention to avoid choosing surgery as 'the solution' too early on. The Dutch Orthopaedic Federation (*Nederlandse Orthopaedische Vereniging – NOV*) strongly advocates stepped care (*Richtlijn "Conservatieve behandeling van artrose in de heup of knie*" en richtlijn "Totale knieprothese"). [10 45]

The absolute number of primary TKAs currently performed is increasing and expected to double or even triple over the next ten years.[15 46-49] In 2022, 26.708 TKAs and 6.972 UKA's were performed in the Netherlands (*Landelijk Register Orthopaedische implantaten - LROI*), but it is estimated that this number will rise to 60,000 a year in 2030.[31 50]

When looking beyond the Netherlands, the Organisation for Economic Co-operation and Development (OECD) countries reported in "health at a glance 2021: OECD indicators" that 137 Total Knee Arthroplasties (TKAs) were performed per 100.000 of the population.[47] That amounts to more than 1.9 million TKAs per year. On average, knee replacement rates increased by 35% between 2009 and 2019.[47] This number is expected to increase, especially among patients in the working age. [51]

The symptoms of pain and the level of impaired mobility following TKA have a considerable impact on the ability and length of time it takes to resume day to day activities and return to work. Care for TKA patients is a comprehensive (holistic) process and success depends on ensuring that the appropriate treatment is delivered at the right time and in the right way.

Patient satisfaction remains low

About two in ten patients are not satisfied after total knee arthroplasty (TKA) and dissatisfied patients incur about 41-57% more costs than satisfied patients during the first year after TKA from a societal perspective. [52-54] A recent study suggests that to improve the functional satisfaction of TKA requires restoration of kinematics in early flexion and management of patient's pain and expectations. [55] Other surgical treatments have been explored where possible with the aim of achieving more normal kinematics. The most well-known of these is the UKA, a procedure performed in patients with less generalized knee OA where only the medial or lateral compartment is affected. As mentioned above, UKA is a less invasive procedure that only replaces the damaged uni-compartmental joint surface (medial or lateral) and thus largely preserves the natural biomechanics of the joint because the cruciate ligaments are not removed and natural rollback, a specific dorsal translation of the femur relative to the tibia in deep flexion in a native knee, is preserved. UKA patients have better post-operative clinical outcomes and function (i.e. range of motion) and are more likely to be able to return to sports than TKA patients although revision rates are higher.[56-58] Peersman reported TKA patients with average FJS scores of 55 (49-60) whereas UKA patients scored an average of 91 (85-97) at 1-year follow-up.[59] Although UKA results seem promising in comparable patient groups, it is not entirely clear to what extent selection bias (e.g. OA less severe; patients more active; younger age) has contributed to these favourable outcomes.

Given the poor FJS results for TKA over time it would seem that impaired knee-function and changes in biomechanics remain an issue for far too many patients and probably explains why patient satisfaction after TKA surgery is not optimal. [53] When comparing

TKA to Total Hip Arthroplasty (THA), THA outperforms TKA both on improvement of function as well as quality of life. [60] The success of THA might also play a role in dissatisfaction of TKA patients if they expect the same results as for THA. Patient satisfaction is multifactorial in nature. The personal characteristics of the patient, surgical factors, the type of knee arthroplasty chosen, perioperative control of pain, nursing and medical care, rehabilitation, social and family support all play important roles in patients' ratings of how satisfied they are with the operative procedure.[61] Additionally, realistic pre-operative expectations are associated with greater patient satisfaction after surgery.[62] According to Deakin et al, there is a clear association between fulfilment of preoperative expectations and patient satisfaction following TKA.[63] Residual pain also has an impact on the level of satisfaction. A review based on the England and Wales National Joint Registry reported that one year after TKA, pain was most often the reason patients were not satisfied with the outcome (18%).[64] Of all TKA patients in one study, 44% reported experiencing persistent postsurgical pain of any severity, while 15% of TKA patients reporting severe-extreme persistent pain 3 to 4 years post-surgery.[65]

The sources of pain can be defined as intra-articular, peri-articular, and extra-articular (Box 1).

Box 1
Differential diagnosis of the painful total knee arthroplasty

Intra-articular

- Infection
- Aseptic loosening
- Instability
  - Axial
  - Flexion
  - Midflexion
- Malalignment
- Polyethylene wear
- Osteolysis
- Component overhang
- Implant failure
- Arthrofibrosis
- Implant fracture
- Recurrent hemarthrosis
- Loose cement
- Extensor mechanism dysfunction
  - Unsurfaced patella
  - Undersized/oversized patella
  - Patellar baja
  - Lateral facet impingement
  - Patellar clunk
  - Osteonecrosis

Peri-articular

- Periprosthetic fractures
  - Traumatic fracture
  - Tibial stress fracture
  - Patellar stress fracture
- Popliteal tendon impingement
- Biceps tendonitis
- Pes bursitis
- Quadriceps tendonitis/rupture
- Patellar tendonitis/rupture
- Neuroma

Extra-articular

- Hip pathology
- Lumbar spine pathology
- Vascular claudication
- Complex regional pain syndrome

Box 1, The differential diagnosis of the painful total knee arthroplasty [66]

The management of a painful TKA knee requires a multidisciplinary team approach that involves orthopaedic surgeons, physical therapists, pain management physicians, and primary care doctors.[33 66 67] Orthopaedic surgeons can do much to improve the patient's experience. Primarily, of course, by performing the best technically sound surgical procedure but also by giving patients the right information, managing their expectations and supervising a peri-operative care plan, including pain management.

Return to work

Historically, outcome measures following KA have focussed primarily on limb function and pain reduction. Societal participation in the form of return to work has been severely underreported.[43] If KA surgery has been successful, reducing the patients' pain and increasing their mobility, it becomes important for both patients' health and society that they return to normal daily life activities. The largest increase in primary KA demands is namely not among the classic knee arthroplasty population of patients aged 70 years and older, but among patients of working age.[68] As an example, in the past 30 years, a threefold increase was seen in patients receiving TKA aged 45– 65 years as reported in the Swedish knee arthroplasty register. Germany foresees the highest increase in patients aged 50– 65 years until 2050, and in also among patients aged 40–49 years until 2040. [69 70] In several countries, the current proportion of knee arthroplasty patients under 65 years is already substantial at 30–40%. It is expected in the USA, followed by the UK, the majority of these patients will be younger than 65 years in the near future.[71 72]

Previously, little was known about return to work in either employed or self-employed patients receiving TKA. It is important to find out which factors will help or hinder patients in returning to work following surgery in a swift and also effective manner. Patients have varying expectations about returning to work after KA surgery. When realistic goals are set and expectations are adjusted this might improve perceived outcome. [73]

Information on the ability to return to work following KA can help SDM and whether KA is the appropriate treatment for the patient's problem. Furthermore, it is not yet known whether UKA patients return to work sooner or perform better than patients with TKA. UKA surgery is less invasive and patients seem to function better, are active and in some cases are even able to return to sport sooner despite reported higher revision rates.[56 58]

There is an increasing interest in development of health-care towards more outcome-oriented care in a broad sense. Outcome-oriented care can be defined as the outcome that really matters for the health and well-being of a specific patient. In outcome-oriented care the choice of treatment relies on what best fits the specific individual's situation instead of population based group outcomes. This approach can lead to better SDM and more timely work-directed care.

The Dutch Ministry of Health, Welfare and Sport (VWS) wrote a letter to Parliament in 2018 with the accompanying reports "Development of outcome-oriented care 2018-2022" and "More patient management through more outcome information in 2022".

This included an explanation of the development of health-care towards more outcome-oriented care in a broad sense, in which the choice of treatment looks at what best fits the specific situation of the patient. More recently this goal was once again strengthened for the years to come by the Dutch Ministry of Health, Welfare and Sport published a new integral health agreement in which one of the main future goals is patient tailored care and support, together with the patient, on the right spot with emphasis on health. [74]

Aims

In this thesis, the aim is to apply the paradigm of outcome-oriented care to the problem of KA and contribute to improving individualized care.

Firstly, this thesis evaluates the impact of technical improvements in surgical procedures that ensure arthroplasties are placed as accurately as possible to produce better outcomes. Additionally a new technique was developed to diagnose the complication of loosening, one of the primary reasons for revision surgery in a growingly more active TKA population, more accurately. Following surgery, a large group of patients was evaluated for general outcome of the Vanguard Knee System. To move towards more patient tailored information, when and how successfully TKA patients returned to work in comparison to UKA patients is investigated and the significant prognostic factors were explored. For this purpose, a new questionnaire had to be developed and validated.

The treatment of knee OA involves by TKA surgery involves many aspects all of which must be brought together as a whole to deliver the best care for patients. The next goal will be to identify which factors in the treatment of knee OA through TKA and UKA, can predict a successful outcome and what measures should be taken to address concerns that are relevant primarily to patients.

Outline of the rest of this thesis

- **Chapter 2** describes the development of a 3D CT based imaging technique to measure the transfer accuracy of a virtually planned osteotomy.
- In **Chapter 3** predicted osteotomy planes are evaluated on accuracy when using patient-specific instrumentation (PSI) for total knee arthroplasty.
- **Chapter 4** describes a new and now patented method for diagnosing loosening, a complication of Total Knee Arthroplasty (TKA), using CT and inducible displacement.
- In **Chapter 5** the predominant patient group, used implant and location is described. It reports on the results of the hospitals in which our studies are performed as well as the survival for the used TKP is given and risk factors for revision.
- **In Chapter 6** a new patient reported outcome measure is developed, the Work, Osteoarthritis and joint-Replacement Questionnaire (WORQ). The reliability, validity and responsiveness are tested and reported.
- **Chapter 7** reports on the results of a cross-sectional multicentre survey on return to work following TKA.

- **Chapter 8** evaluates differences in return to work between TKA and the less invasive Unicompartmental Knee Arthroplasty (UKA).
- In **Chapter 9** it is assessed which patients do not return to work after TKA.
- **Chapter 10** provides the General discussion

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Chapter 2

Evaluation of a CT-based technique to measure the transfer accuracy of a virtually planned osteotomy

Dobbe JG, Kievit AJ, Schafroth MU, Blankevoort L, Streekstra GJ.
Med Eng Phys. 2014 Aug;36(8):1081-7. doi: 10.1016/j.medengphy.2014.05.012. Epub 2014 Jun 6. PMID: 24908356.

Abstract

Accurate transfer of a preoperatively planned osteotomy plane to the bone is of significance for corrective surgery, tumor resection, implant positioning and evaluation of new osteotomy techniques. Methods for comparing a preoperatively planned osteotomy plane with a surgical cut exist but the accuracy of these techniques are either limited or unknown. This paper proposes and evaluates a CT-based technique that enables comparing virtual with actual osteotomy planes. The methodological accuracy and reproducibility of the technique is evaluated using CT-derived volume data of a cadaver limb, which serves to plan TKA osteotomies in 3-D space and to simulate perfect osteotomies not hampered by surgical errors. The methodological variability of the technique is further investigated with repeated CT scans after actual osteotomy surgery of the same cadaver specimen. Plane displacement (d_{err}) and angulation errors in the sagittal and coronal plane (β_{err}, g_{err}) are measured with high accuracy and reproducibility (d_{err} = −0.11 ± 0.06 mm; b_{err} = 0.08 ± 0.04◦, g_{err} = −0.03 ± 0.03◦). The proposed method for evaluating an osteotomy plane position and orientation has a high intrinsic accuracy and reproducibility. The method can be of great value for measuring the transfer accuracy of new techniques for positioning and orienting a surgical cut in 3-D space.

Introduction

Computer-assisted techniques are increasingly being used to preoperatively plan an osteotomy. To accurately transfer the osteotomy plane to the bone intraoperatively, navigation equipment [1] or patient-specific instrumentation (PSI) is often used for a range of surgical indications such as spinal surgery [2], mandibular reconstructions [3], osteotomies of the upper extremity [4], osteotomies for total hip arthroplasty (THA) [5], total knee arthroplasty (TKA) [6, 7] and for tumor resection [8, 9, 10].

Osteotomies navigated with computer-assisted 3-D surgery (CAS) techniques and osteotomies guided by PSI have shown to provide more accurate positioning than conventional surgery although clinical improvements are not always substantial [11, 12, 13]. In many PSI [14, 15, 16, 17, 18, 19] and CAS studies [20, 21] however, the osteotomy plane is planned while the implant position is evaluated, which may not directly relate to the planned osteotomy plane if the surgeon decides to make peroperative adjustments or uses a cement layer between bone and implant. Additionally, many studies do not report the accuracy of the evaluation technique itself [8, 10, 14, 17, 19, 22], which may bias the evaluation of osteotomy-based techniques. Recent studies have found that the accuracy of navigation systems depend on the distance between the stereoscopic camera system and the surgical tools [23] and on registration of the intraoperative bone to the virtual bone, introducing displacement errors of up to 2 mm [24]. CT-based methods have been reported [8, 25, 26] to compare a virtual with an actual plane in CAS studies, however, the accuracy of these methods remain unknown.

Regulations for the application of medical implant devices tend to become stricter and pre-clinical trials are recommended, e.g., before using new total joint arthroplasty on a larger scale [5]. In the case of PSI and CAS, this trend requires an accurate technique for comparing a preoperatively planned osteotomy plane with the actual plane obtained during surgery. Such a technique also enables comparing a surgical cutting plane obtained with conventional instrumentation with those obtained with more advanced systems such as PSI or CAS.

This paper proposes and evaluates the intrinsic accuracy and reproducibility of a CT-based method for comparing the position and orientation of a preoperatively planned osteotomy plane with the corresponding plane obtained during surgery. The main research question is: what is the methodological error in comparing a virtually planned plane with an actual surgical cut using the proposed technique?

Materials and Methods

In this paper we chose PSI-based TKA surgery as application for evaluating the methodological accuracy. The method for plane comparison, however, can be equally utilized for other osteotomy types as well. In the chosen TKA procedure one tibial and one femoral osteotomy are virtually planned.

Comparing virtual with actual planes

During preoperative virtual planning an osteotomy plane is defined by a normal vector $\mathbf{n}_p$ perpendicular to the cutting plane P_p (Fig. 1a), and a position vector (not shown). Intraoperatively, the planned plane is transferred to the bone by using CAS or cutting guides. Evaluating the transfer accuracy of the cutting plane comprises comparing a preoperatively defined virtual plane with an actual intraoperative plane. Standardized methods are proposed to describe plane characteristics, such as parallelism, flatness and surface roughness for evaluating osteotomy techniques [27, 28]. Some of these parameters are determined after fitting a plane through measured data describing the actual cutting surface. In the current study we merely focus on comparing plane orientation and position, which equally relies on plane fitting.

The preoperatively planned virtual cutting plane and the actual cutting plane are defined in different CT scans, and need to be linked by registration. The preoperative image is used as the reference image since it is also used for planning and therefore enables easy plane comparison. Before registration, an osteotomized bone is first segmented using a threshold-connected region-growing algorithm. Residual holes inside the bone and at the bone surface are subsequently filled by a binary closing algorithm [4, 29]. This intermediate segmentation result is used to initialize a Laplacian level-set segmentation growth algorithm [30], which adjusts the edges towards the edges of the bone image. A surface mesh is finally extracted at the zero level using the marching cubes algorithm [31]. The surface mesh is used for 3-D visualization and for planning the osteotomy plane. Intensity-based point-to-image registration [4] is used for registration of the segmented bone to the reference image. To this end, points are selected by sampling the gray-level CT image 0.3-mm towards the inside (bright voxels) and outside (dark voxels) of the segmented bone. This results in a double-contour surface mesh, which includes the gray-levels at each vertex. Registration of these many gray-level points with the gray-valued reference image renders the registration accurate [4, 29]. To successfully register comparable geometries, the bone regions that are removed by the osteotomies are excluded by clipping (Fig. 1b, dotted regions remain). Registration results in transformation matrices ($\mathbf{M}_T$ and $\mathbf{M}_F$) that bring the tibia and femur bone models from the evaluation image to the preoperative reference image (Fig. 1).

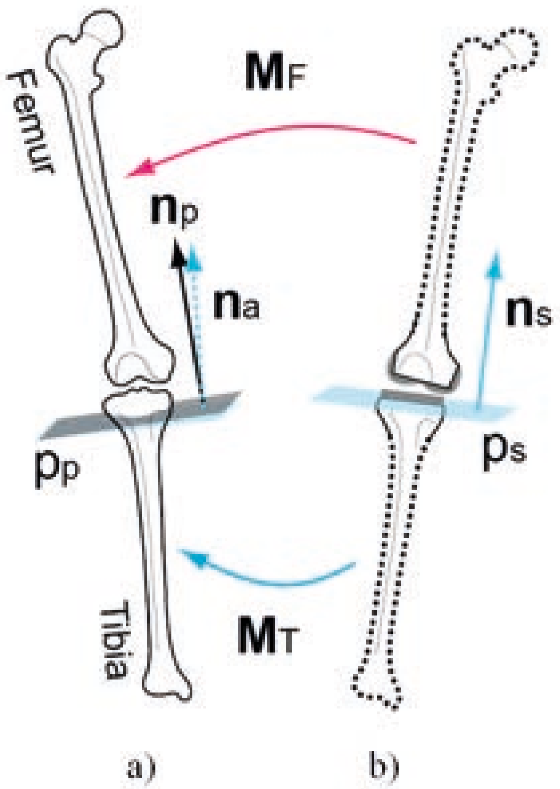

Fig. 1 Method for comparing a preoperatively planned cutting plane P_p with a surgical osteotomy plane P_s. The preoperative image, a), serves as reference and is used for planning the osteotomy plane. The evaluation image, b), with the actual cutting surface is used to segment the bones. The dotted regions represent the bone contours, which are selected for registration with the respective bones in the reference image, and result in transformation matrix **MF** that aligns the femur in the evaluation scan with the reference image, and **MT** that aligns the tibia with the reference image. Comparing the orientation of the planned cutting plane $\mathbf{n}_p$ with the achieved osteotomy plane $\mathbf{n}_a$ (= **MT** $\mathbf{n}_s$) yields the residual orientation error parameters.

After transforming the bone models, one or more local cutting plane regions are selected in each bone model by positioning 3-D spheres of adjustable size and using the enclosed surface patches for finding the parameters of the best fitting plane. A plane fit is performed using the moment of inertia tensor and eigenvector analysis [32, 33]. The plane normal $\mathbf{n}_a$ (always pointing in the cranial direction in this study) represents the orientation of the achieved cutting plane (Fig. 2a).

For evaluation purposes, the osteotomy plane orientation is defined by projecting the vectors $\mathbf{n}_a$ and $\mathbf{n}_p$ into the sagittal and coronal planes (Fig. 2b), providing the sagittal angle (*b*) and the coronal angle (*g*) for the virtually planned plane and the actual surgical plane, equivalent to [28]. The angular differences provide the angulation errors in the sagittal plane (b_{err}) and in the coronal plane (g_{err}). To this end anatomical coordinate systems are defined for the femur and the tibia [34, 35, 36], as follows: The z-axis points proximally and is parallel to the mechanical axis (the line connecting the center of the femoral head and the point midway the epicondyles); the line between the epicondyles is projected into the plane perpendicular to the z-axis and provides the x-axis; the y-axis is perpendicular to the x- and z-axes, pointing in the posterior direction. The z-axis of the tibia is equal to that of the femur; the y-axis is directed posteriorly along the line between the tuberosity and the sulcus; the x-axis is perpendicular to the y- and z-axes. Right-handed coordinate systems are used.

The distance error (d_{err}) is derived from the centroids of the points describing the cross sections of the planned and the achieved plane (Fig. 2a). It is defined as the Eular distance between the centroids of the achieved and planned cross sections, i.e., the length of the distance vector **d**. The distance error is taken positive if the dot product of **d** and $\mathbf{n}_a$ is positive.

Custom software [4] was written for segmentation of bone models and registration of these models to the reference image. The software was extended to calculate the plane that best fits a selected region of vertices representing a cutting plane.

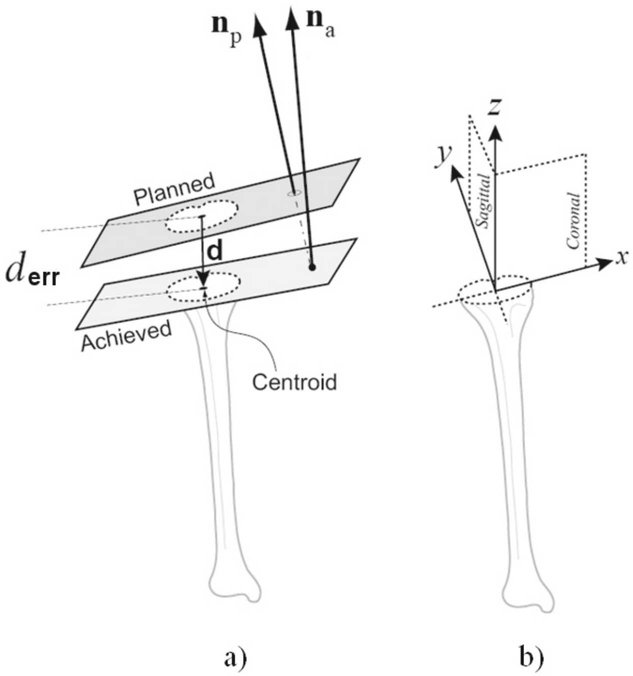

Fig. 2 a) The planned and achieved planes, defined by their normal vectors ($\mathbf{n}_p$ and $\mathbf{n}_a$, both pointing in the cranial direction), are used to find two bone cross sections (dotted polygons). The distance error is defined as the distance between the centroids of the points describing these cross sectional outlines. This distance is taken positive if the dot product of **d** and $\mathbf{n}_a$ is positive. b) An anatomical coordiante system is used to project the vectors $\mathbf{n}_a$ and $\mathbf{n}_p$ into the sagittal and coronal planes of an anatomical coordinate system. The angular differences between these projections provide the angulation error in the sagittal plane (b_{err}) and in the coronal plane (g_{err}).

Experiments

A fresh frozen cadaver limb was thawed for at least 72 hours and was used to evaluate the methodological error of plane comparison. CT scans were made using a Brilliance 64-channel CT scanner (Philips Healthcare, Best, The Netherlands). A clinical scanning protocol was used to acquire CT scans for both planning and evaluation of the actual cutting planes (tube voltage 120 kV; automatic exposure control, planning: ~160 mAs, evaluation: ~400 mAs; collimation 64´0.625 mm; slice thickness 1 mm and pitch 0.609). The scans were reconstructed into a 3-D volume with voxel spacing of 0.45´0.45´1.00 mm.

In the proposed methodology, the error parameters (i.e., d_{err}, b_{err} and g_{err}) depend on the noise content of the CT images, on image discretization, on variations due to segmentation and registration [4]. Besides these methodological errors, the surgical procedure may also contribute to errors in the osteotomy plane, e.g., due to errors in guide positioning, surface roughness or irregularities due to deflection of the cutting blade.

In this paper we focus on methodological errors of the CT-based evaluation method and first investigate the errors in comparing a virtually planned plane with perfect osteotomies in simulated CT scans. We further investigate parameter variability caused by the method in repeated scans of an actual TKA case with tibia and femur osteotomies.

Methodological error in comparing a virtually planned osteotomy plane with perfect osteotomies in simulated evaluation 3-D scans

In the first experiments perfect osteotomies are simulated using a CT scan of the cadaver limb (Fig. 3a). These osteotomy planes are not hampered by surgical variation and the experiments therefore provide the methodological error for comparing a virtual with an actual osteotomy plane. These methodological errors are related to image acquisition and image analysis.

To simulate the femur and tibia osteotomies, 22 image slices (total thickness 22 mm) of the CT image, centered at the knee joint, were set to the background intensity (-976 HU) (Fig 3b). CT scanning and reconstruction is generally associated with noise and blurring in the 3-D image. Gaussian noise, comparable to the background noise (*SD* = 7 HU) is therefore added to these osteotomy slices (Fig. 3c). Blurring causes sharp edges to be imaged as smooth edges. By CT scanning a cubic phantom, with sharp edges, the Gaussian smoothing factor (*s*) was determined using line-spread analysis of the edges [37], yielding s_{xyz} = (0.5, 0.5, 0.6) mm. Finally a 3-D region, slightly larger than the selected osteotomy slices is smoothed with a Gaussian filter to simulate the point spread of the images acquired with the CT protocol. This simulated image serves as preoperative image in which the planned osteotomy planes are clearly known.

The image described above was slightly repositioned (10´) in six degrees of freedom, and Gaussian noise was added to each entire image (*SD* = 20 HU) to simulate rescanning the limb at slightly different positions (Fig. 3d). These images represent evaluation CT scans with perfect osteotomies that are in agreement with the planned osteotomy plane. After analyzing these 10 images with the proposed method, the mean value of d_{err}, b_{err} and g_{err} represent the methodological error (accuracy/bias) of the method. The standard deviations serve to express the reproducibility (precision) of the method.

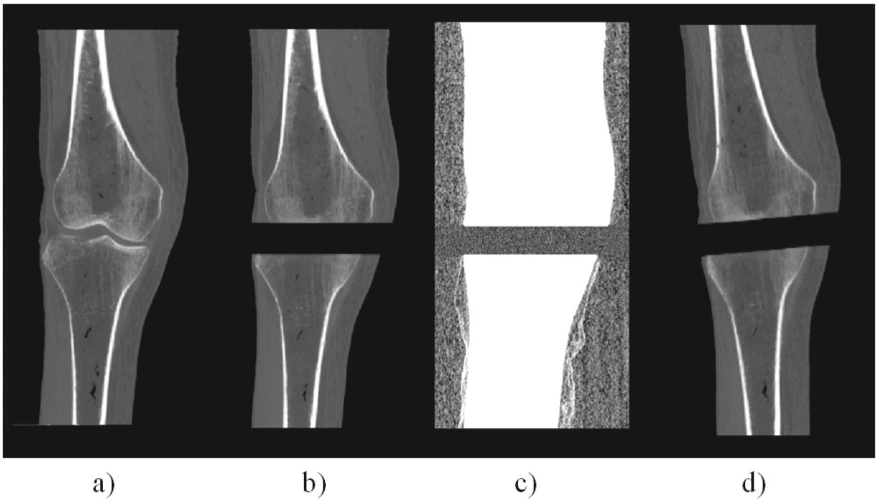

Fig. 3 a) A full lower-limb CT scan (a single slice is partly shown) was used for simulation experiments. b) A perfect osteotomy plane of the femur and tibia is simulated by setting 22 image slices to the background intensity. c) Level and window adjusted to show simulated noise in the osteotomy gap. d) Image repositioning to simulate rescanning the limb at a slightly different position.

Since the methodological error parameters depend on the size of the evaluation patches, we first investigate this effect by segmenting the femur (10×) in each simulated CT scan, and determining error parameters after registration to the preoperative image. To this end a femoral surface patch is selected inside a sphere with a radius ranging from 2 to 12 mm in 2 mm increments.

In actual TKA surgery the size of evaluation patches is sometimes limited by the surface area of the osteotomy plane. In this respect, the surface areas of actual femoral osteotomy planes are relatively small compared to the single tibia osteotomy plane. The available surface area may further be limited due to existing pinholes. In these practical cases averaging the results of multiple regions provides a better estimate of plane evaluation parameters. To determine the methodological error of comparing plane parameters using multiple spherical regions, we mimic positioning and sizing of spherical regions as in an actual TKA case (Fig. 5, bottom row) but effectively apply these spherical regions to the simulated tibia and femur osteotomies. The error parameters are determined per spherical region and by combining these regions.

Variability in comparing virtually planned osteotomy planes with actual surgical cuts in TKA surgery

In this experiment tibia and femur osteotomies were performed with the Signature Knee System® (BioMet Inc, Warsaw, IN, USA, in collaboration with Materialise NV, Leuven, Belgium) using the same cadaver specimen as described in the previous section. Preoperative planning of the osteotomy planes, defining the anatomical coordinate systems, and the design of the guides for pin drilling is based on the preoperative CT scan and is performed by Materialise. Figure 5 (bottom row) shows the segmented bone after utilization of the Signature Knee System with a 1.37 mm cutting blade. After the osteotomies, 10 evaluation CT scans were made in which the leg was slightly repositioned to take into account image alterations caused by discretization and noise. The tibia and femur were segmented in these scans and registered to the scan containing the preoperative plan. The mean d_{err}, b_{err} and g_{err} in this experiment where determined using the same spherical selection regions as in the simulation experiment described above, and represent the plane transfer accuracy, which includes methodological and surgical errors. The standard deviations serve to express the methodological reproducibility for this specific case.

The remaining femoral cuts (Fig. 5, bottom row) that result from utilizing the Signature Knee System are not evaluated since they are obtained by using a cutting block. As such they are not part of the standard planning protocol.

Results

Methodological error in comparing a virtually planned osteotomy plane with perfect osteotomies in simulated 3-D scans

Figure 4a shows how the methodological error parameters (d_{err}, b_{err} and g_{err}) change with the size of the spherical selection region. Both the residual error and the reproducibility improve with patch size. The average vertex count for patches selected with spherical selection regions with radii of 2, 4, 6, 8, 10 and 12 mm, was 109, 334, 678, 1127, 1687 and 2359. A 12 mm radius for the spherical selection region resulted in (d_{err}, b_{err} and g_{err}) = (0.10±0.23mm; 0.06±0.15°; -0.04±0.14°). Figure 4b shows an example of fitting a plane through the vertices encapsulated by a spherical selection region with a radius of 10 mm. It clearly shows the digitization remnants, which markedly affect the error parameters for small evaluation patches. The methodological error for multiple patches, in which positioning and size of the spherical selection regions mimic those for an actual TKA case, is shown in Fig. 5. The error is given for the separate evaluation patches (tibia: 3 patches, radius 13 mm, 2733±40 vertices per sphere; femur: 4 patches, radius 5 mm, 493±6 vertices per sphere) and by averaging the patch results for a single osteotomy plane per evaluation image (Fig. 5, indicated by “all patches”). The latter parameter effectively increases the point count for plane fitting and reduces the variation. For the tibia this results in error parameters (d_{err}, b_{err} and g_{err}) = (-0.11±0.06 mm; 0.08±0.04°;

-0.03±0.03°). For the femur the error parameters were (d_{err}, b_{err} and g_{err}) = (0.15±0.19 mm; -0.06±0.13°; 0.05±0.29°).

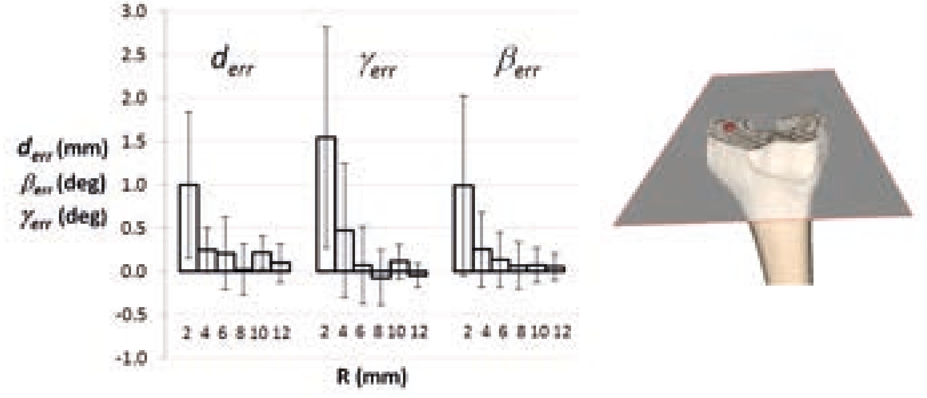

Fig. 4. a) Methodological accuracy (mean) and reproducibility (SD) of comparing plane parameters in simulated CT scans of an osteotomized femur, showing the translation error (d_{err}), the angulation error in the coronal plane (g_{err}) and the angulation error in the sagittal plane (β_{err}) and their dependency on patch size (R = radius of spherical selection region). b) Plane fitted through osteotomy plane showing remnants of digitization.

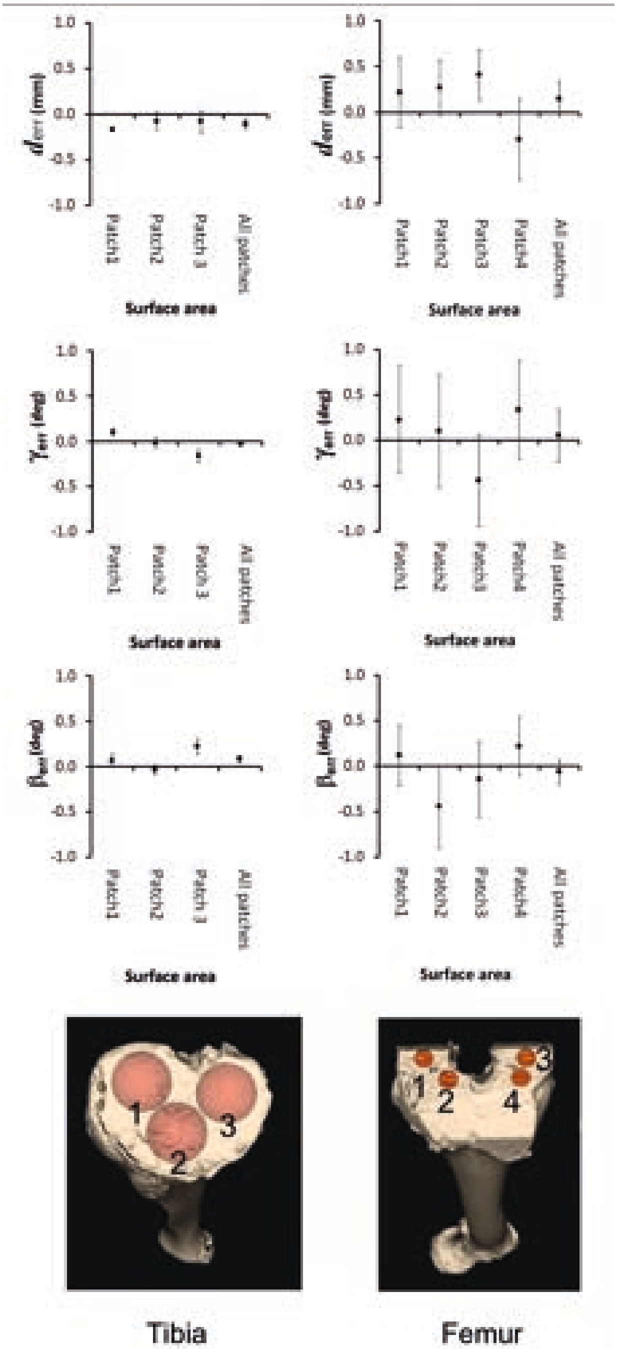

Fig. 5 Methodological accuracy and reproducibility of comparing the proximal osteotomy plane of the tibia (left column) and distal osteotomy plane of the femur (right column) as obtained from a series of simulated CT scans using a single cadaver specimen. The first, second and third row show the translation error (d_{err}), the angulation error in the coronal plane (g_{err}) and the angulation

error in the sagittal plane (v_{err}). The error parameters were determined for spherical selection regions that were positioned and sized to mimic evaluating actual osteotomy planes in TKA surgery (tibia:3´ diameter 26 mm, femur:4´, diameter 10 mm, see bottom row), although evaluated for the simulated images (see Fig. 4b for a femur model as actually used for this evaluation). Whiskers represent standard deviations.

Variability in comparing virtually planned osteotomy planes with actual surgical cuts in TKA surgery

The plane evaluation parameters were determined after actual TKA surgery on a cadaver limb using the separate evaluation patches (tibia: 3 patches, radius 13 mm, 2902±13 vertices per sphere; femur: 4 patches, radius 5 mm, 521±6 vertices per sphere, see Fig. 5, bottom row) and by averaging these patch results, which reduces the variation as explained in the previous section. Analysis of the 10 postoperative CT scans after TKA surgery showed (d_{err}, b_{err} and g_{err}) = (3.21±0.27mm; -9.32±0.07°; 1.93±0.03°) for the tibia and (4.22±0.44mm; -3.93±0.11°; -3.81±0.11°) for the femur. The mean values represent the residual displacement and angulation errors, which are mainly the result of the surgical procedure since they are much larger than the methodological error found in the previous section. The variability in the error parameters represents the overall variability for this specific surgical case.

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Discussion

Inadequate transfer of a preoperatively planned osteotomy plane to an actual bone during surgery affects the success of corrective surgery, implant positioning, and tumor resection. Accurate techniques for comparing virtual and actual osteotomies are of great importance for evaluating osteotomy techniques, such as CAS and PSI. This paper proposed and evaluated the methodological accuracy of a CT-based technique for comparing virtual with actual osteotomy planes in 3-D space.

The simulation experiments showed small methodological errors. It also showed that reproducibility improves with the number of vertices within the selected surfaces for plane evaluation. For this reason the reproducibility is inferior for the femur experiments. This seems quite logical since including a larger region reduces the effect of noise and the effect of image discretization. The methodological variability as observed for the actual TKA osteotomies was in the same order of magnitude as those in the simulation experiments.

Other methods have been reported to evaluate planar cutting of bones based on probing systems [9, 27, 28, 31]. In these methods planning and evaluation are performed in a single frame of reference, and therefore do not require registration between the separate scans. For experimental evaluations these methods are of specific interest since they are very accurate. When comparing virtual with actual osteotomies in different frames of reference, as is common in surgical cases, registration of these frames introduces methodological errors, which have shown to be small in our method. Other registration-based methods rely on optical navigation systems. Recent studies have found that these systems introduce displacement errors of up to 2 mm [23, 24]. In this respect, the proposed method outperforms these camera-based navigation systems. Similar accuracy may be observed by comparable CT-based registration methods [8, 26].

Some studies aim on standardizing plane characteristics, such as orientation, position, plane roughness or flatness and parallelism, in a generalized [28] or application specific fashion [27]. This enables comparing results between different studies. In our study we focused on plane angulation and distance parameters. Plane angulation parameters (β_{err}, γ_{err}) were in agreement with the parameters proposed by Cartiaux et al [28]. However, their plane location parameter t is measured along one axis of a chosen coordinate system. Comparing one plane location (t_1) with the other (t_2) in this way would yield an error measure (t_2-t_1) that depends on the position of the axis along which t is measured. In our study we defined the plane-to-plane distance error as the Euler distance between the centroids of the planned and achieved bone cross sections. This parameter does not depend on the definition of a coordinate system. However, when the cross sections are very divergent, e.g., when either of the cross sections gets very close to the distal or proximal end of a bone, this method may be suboptimal.

This study and the proposed method have a few limitations. A single cadaver specimen was used, which has its same specific morphology and bone density, for all experiments. Although bone density was average, different bone morphologies may slightly affect the results of registration. Since the number of points used for registration is very large this effect is probably negligible. The method may also be limited if the evaluation is based on very small surfaces especially if the resolution or the signal-to-noise ratio of the evaluation scan is very low. The method relies on a second evaluation CT scan for determining plane deviations. For clinical utilization this may be a problem since, to date, operating rooms are hardly equipped with CT scanners. Plane evaluation is also greatly impeded if metal artifacts exist in the evaluation CT scan, e.g., due to the presence of an implant.

The proposed CT-based method for comparing virtual with actual osteotomy planes in different frames of reference has shown to be very accurate and reproducible, especially if a large surface area is selected. The method is potentially of great value for evaluating techniques that help the surgeon in positioning and orienting a surgical cut in 3-D space and for evaluating new saw blade technologies in pre-clinical studies.

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Chapter 3

Predicted osteotomy planes are accurate when using patient-specific instrumentation for total knee arthroplasty in cadavers: a descriptive analysis.

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Abstract

Purpose Malalignment of implants is a major source of failure during total knee arthroplasty. To achieve more accurate 3D planning and execution of the osteotomy cuts during surgery, the Signature (Biomet, Warsaw) patient-specific instrumentation (PSI) was used to produce pin guides for the positioning of the osteotomy blocks by means of computer-aided manufacture based on CT scan images. The research question of this study is: what is the transfer accuracy of osteotomy planes predicted by the Signature PSI system for preoperative 3D planning and intraoperative block-guided pin placement to perform total knee arthroplasty procedures? Methods The transfer accuracy achieved by using the Signature PSI system was evaluated by comparing the osteotomy planes predicted preoperatively with the osteotomy planes seen intraoperatively in human cadaveric legs. Outcomes were measured in terms of translational and rotational errors (varus, valgus, flexion, extension and axial rotation) for both tibia and femur osteotomies.

Results Average translational errors between the osteotomy planes predicted using the Signature system and the actual osteotomy planes achieved was 0.8 mm (± 0.5 mm) for the tibia and 0.7 mm (± 4.0 mm) for the femur. Average rotational errors in relation to predicted and achieved osteotomy planes were 0.1° (± 1.2°) of varus and 0.4° (± 1.7°) of anterior slope (extension) for the tibia, and 2.8° (± 2.0°) of varus and 0.9° (± 2.7°) of flexion and 1.4° (± 2.2°) of external rotation for the femur.

Conclusion The similarity between osteotomy planes predicted using the Signature system and osteotomy planes actually achieved was excellent for the tibia although some discrepancies were seen for the femur. The use of 3D system techniques in TKA surgery can provide accurate intraoperative guidance, especially for patients with deformed bone, tailored to individual patients and ensure better placement of the implant.

Introduction

Malalignment or an incorrectly sized implant is the major cause of failure in total knee arthroplasty (TKA) [12]. In conventional TKA preoperative planning, patients are assessed on the basis of standing anteroposterior and lateral radiographs, sunrise view of the patella or standing whole leg radiographs to determine the mechanical and anatomical axis. The aim of preoperative planning and assessment of the tibia and femur is to determine the quality of bone stock, to estimate correct relative axial rotational and translational alignment and the position of the joint line and also to select a correctly sized implant. The additional benefits of accurate planning are shorter operation times and reduced risk of complications.

Until recently, preoperative planning based on 2D radiographs was the recommended method to prepare for total knee arthroplasty (TKA). However, recent studies have shown that 2D preoperative methods are not always reliable for TKA [1–3, 14, 16]. More accurate 3D computer-assisted techniques are now being employed; for example, the navigation techniques in computer-assisted surgery (CAS) help increase alignment accuracy [5, 9].

Likewise, 3D patient-specific instrumentation (PSI) systems are increasingly used in preoperative planning for TKA to predict the alignment of osteotomy planes. Currently, nine commercial PSI systems are available for use in knee arthroplasty procedures [19] of which the Signature™ Personalized Patient Care system (Biomet Signature Knee System: in collaborative partnership with Materialise NV) is most commonly used [25]. The Signature technique processes data from preoperative CTs or MRIs of patients' entire lower limbs to produce patient-specific guides that match each individual's anatomical geometry. These patient-specific guides ensure optimal placement of the stainless-steel mechanism guiding the oscillating saw that cuts the planes in tibia and femur. The aim of patient-specific guides is to improve the accuracy between predicted and achieved osteotomy planes and thus reduce operation time and the risk of complications. Moreover, this technique does not cause intramedullary damage, in theory, reducing the risk of fat embolisms [13] although this claim has not yet been proven. A further advantage of such a system is for use in patients where standard anatomical landmarks are unreliable because of bone deformation caused by (iatrogenic) trauma or developmental problems.

The added value of PSI has been questioned in recent studies [4, 6, 18, 23], even though more than 80,000 PSI-assisted operations were performed in 2012 worldwide [25]. Many of these recent PSI studies only looked at the final position of the implant as a measure of success. However, implant position does not necessarily indicate that the optimal osteotomy plane was actually achieved as the cement used can obscure the planes. It is clear that to justify the use of PSI, the prediction and orientation of achieved osteotomy planes should be better, or at least as accurate, as conventional 2D systems reported in the literature.

Therefore, this study aims to show the added value of a 3D based system for predicting the position and orientation of osteotomy planes preoperatively in individual patients so as to provide accurate intraoperative guidance and ensure better placement of the implant and a greater chance of recovery.

Materials and methods

3D prediction, planning and surgery

The preoperative prediction study was performed using CT images of nine fresh-frozen whole human legs (foot to femur head) as data for the 3D Signature Personalized Patient Care software (Biomet, Warsaw, USA). The specimens had a median age of 82 years (min–max 71–92; six males and three females; six right and three left limbs). The CT was chosen for scanning, as images are considered more accurate than those from MRI [26]. CT scans were made using a Brilliance 64-channel CT scanner (Philips Healthcare, Best, the Netherlands). A clinical scanning protocol was used to make the CT scans for both the planning and evaluation of the actual cutting planes. The osteotomies of interest were the distal femur cut, the posterior femur cut and the proximal tibia cut as they are made using pin placement via the guides. The femur osteotomy planes were predicted using the Signature software with zero degrees of extra varus/ valgus (coronal projection) adjustment along the anatomical axis, three degrees of flexion (sagittal projection) in the femur and zero degrees of rotation in the axial projection. The tibia osteotomy was predicted at a standard zero degree of varus/valgus and zero degrees of posterior slope. Subsequently, the researchers sent the CT data sets via Biomet to Materialise (Leuven, Belgium), who manufactured the specific femur and tibia guides and sent these to the surgeon. A single surgeon, with extensive experience in TKA surgery, carried out the surgical procedures. A standard medial parapatellar approach was used to expose the femur and tibia. Firstly, the tailor-made femur guide was positioned correctly in relation to the supplied 3D bone model. Once the surgeon was satisfied with the guide placement, the guide was fixed in place with four pins (Fig. 1).

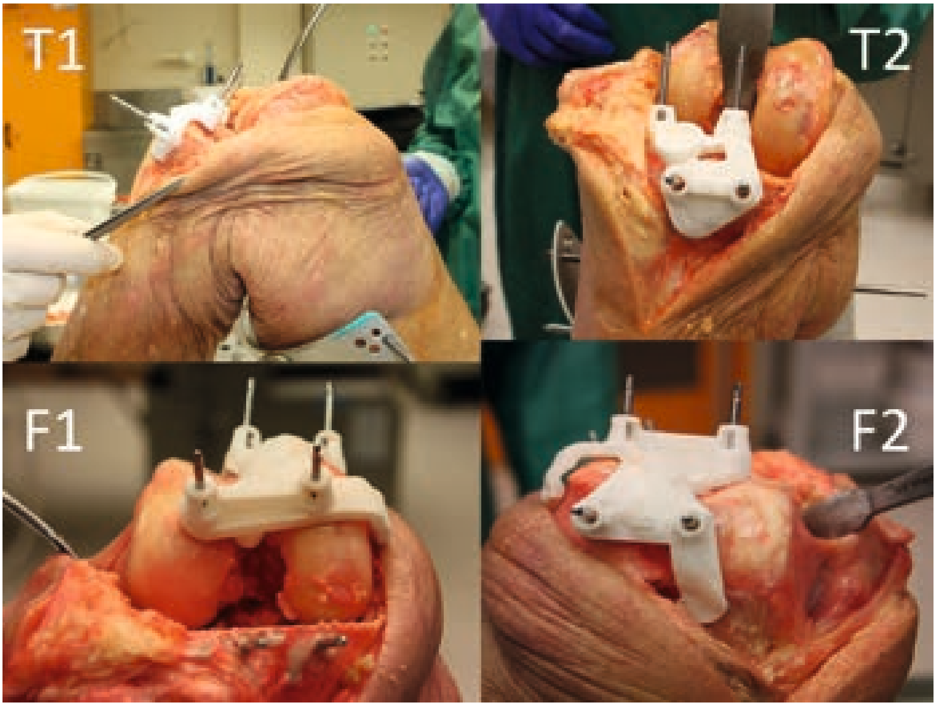

Fig. 1 Pin-positioning guides snugly fit to the proximal tibia in lateral view (T1) and anteroposterior view (T2). The femoral guide is shown from distal to proximal, above being the anterior femur (F1), and from anterior to posterior, above being the distal femur (F2)

Subsequently, the cutting guide for the surgical saw was slid over the pins and the osteotomies were performed. Three planes were used for evaluation, i.e. the distal femur cut, the posterior femur cut and the proximal tibia cut (Fig. 2).

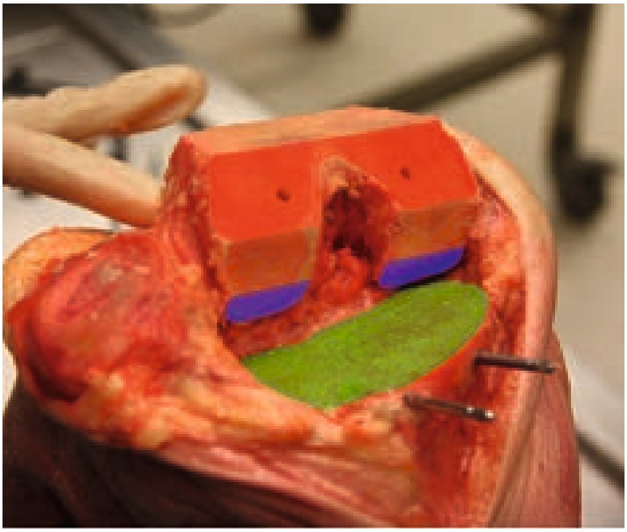

Fig. 2 End result after all osteotomies. The distal femur (red), posterior condyle plane (blue) and proximal tibia plane (green) used for evaluation are shown

To ensure that the methods and surgery were comparable and executed as intended, all osteotomies were planned and performed in the same hospital using the Signature software.

Comparing planned osteotomy planes with actual planes

To evaluate the postoperative osteotomies, another CT scan was made after the osteotomies had been performed. A validated and accurate method was used for assessment of the orientation and positioning of osteotomy cuts [10, 11]. This method uses the preoperative planning CT scan as a reference. The accuracy and reproducibility (test–retest was performed) of the method were below 0.2 mm for translations and 0.3° for rotations in the previous technical note. Therefore, differences between the planned and achieved osteotomy, which exceed methodological error, are believed to be caused by transfer errors. Following surgery, a further evaluation CT scan was made. The postoperative CT scan was used to create 3D polygons, digital models of the tibia and femur. After transforming the femur and tibia polygons into reference images, regions were selected to represent each polygon's cutting plane. A position and a normal vector defined each plane. Several regions on the plane were sampled by automated selection of multiple points within a 3D sphere, positioned within the software (Fig. 3a). The corresponding plane that best fitted the average of these regions was determined and compared in terms of distance and rotational errors to the preoperatively predicted plane (Fig. 3b).

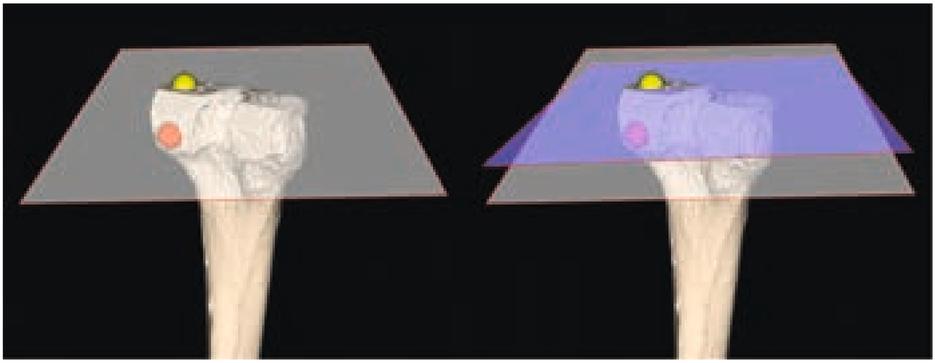

Fig. 3 (a. Left) 3D spherical regions (only one region is shown per osteotomy) (red: posterior femur; yellow: distal femur) chosen for selecting points in the bone model for evaluating the cutting plane orientation. The plane fitted to the osteotomy is shown for the distal femur. (b. Right) The fitted plane (grey) deviates from the planned plane (blue)

Differences in the planned and achieved plane are expressed by the absolute angulation error and the distance error (Fig. 4a). The absolute angulation error is defined as the angle between the normal vectors of the planned and the achieved plane in 3D space. For a better clinical understanding of the difference, these vectors were also projected into the sagittal, coronal and axial planes to evaluate the angular errors in flexion and extension as well as varus and valgus and rotation (Fig. 4b). To this end, anatomical coordinate systems were defined for the femur and the tibia. An extensive explanation of this method and how the coordinate system was defined can be found in Dobbe et al. [11].

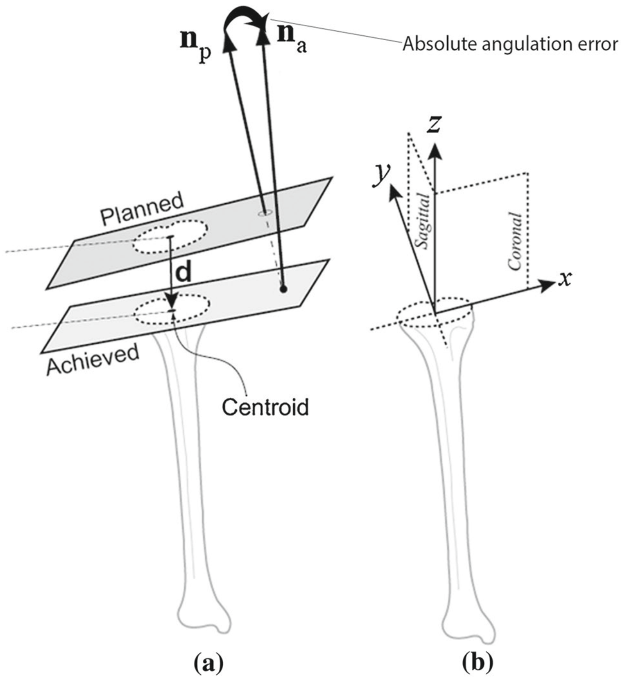

Fig. 4 a Both the tibial planned as well as achieved planes with their corresponding normal vectors ($n_{planned} = n_p$ and $n_{achieved} = n_a$) and the absolute angulation error between them. ***b*** For a better clinical understanding of the difference, these vectors were also projected into the sagittal, coronal and axial planes to evaluate the angular errors in flexion and extension (sagittal) as well as varus and valgus (coronal) and rotation (axial)

Results

For planes on the tibias, the average displacement error, d_{err} (± SD), of the system was 0.8 mm (± 0.5 mm). There was an absolute rotational error of 2.0° (± 0.9°) when compared to the predicted planes (Fig. 5).

Broken down into coronal and sagittal projections, the rotational errors were 0.1° (± 1.2°) of varus and 0.4° (± 1.7°) of anterior slope (extension) (Table 1).

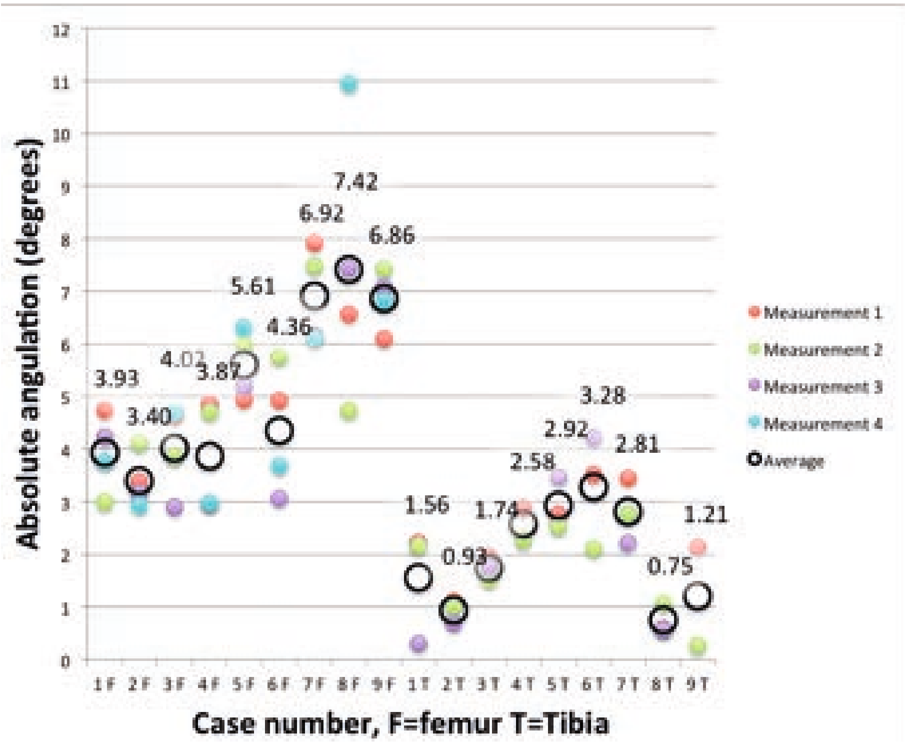

Fig. 5 Absolute angulation difference, combined difference between planned and achieved planes for femur (1F-9F) and tibia (1T-9T). Black circles represent the average differences and colours are the different measurements per knee per osteotomy

Tibia			
	Distance along Z axis (mm) (*)	Varus (+) / valgus (-) (°)	Flexion (+) / Extension (-) (°)
Case 1	-0,8	-0,9	1,0
Case 2	-1,3	0,2	0,7
Case 3	-0,6	0,5	-1,5
Case 4	-1,5	-1,2	2,1
Case 5	-1,5	2,6	-2,3
Case 6	0,1	0,9	-3,1
Case 7	-0,9	-0,8	-0,3
Case 8	-0,5	0,6	0,4
Case 9	-0,4	-0,8	-0,5
Average	**-0,8**	**0,1**	**-0,4**
SD of cases	0,5	1,2	1,7

The bottom row represents the standard deviation of the error parameters.
(*) Negative values indicate that more bone was removed than intended

Table 1 Separate values of all three local tibial measurements with distance in mm and angulation errors in °

For the femur, the average displacement error was 0.7 mm (± 4.0 mm). There was an absolute rotational error of 5.2° (± 1.6°) when compared to the planned planes (Fig. 5). Broken down into an average angulation difference of 2.8° (± 2.0°) in varus and 0.9° (± 2.7°) of flexion (Table 2).

	Femur			
	Distance along Z axis (mm) (*)	Varus (+) / valgus (-) in °	Flexion (-) / Extension (+) in °	External (+) / intenal (-) rotation in °
Case 1	0,6	0,3	3,9	1,5
Case 2	-1,6	-0,6	-3,0	5,0
Case 3	-1,9	2,8	-2,8	1,2
Case 4	0,9	3,6	1,1	-1,4
Case 5	0,3	5,7	0,1	1,2
Case 6	10,9	3,4	-2,8	4,1
Case 7	-1,5	4,8	-5,0	1,4
Case 8	0,6	2,1	-3,4	0,7
Case 9	-1,8	3,4	1,9	-1,4
Average	**0,7**	**2,8**	**-0,9**	**1,4**
SD of cases	4,0	2,0	2,7	2,2

The bottom row represents the standard deviation of the error parameters.
(*) Negative values indicate that more bone was removed than intended

Table 2 Separate values of all four local femoral measurements with distance in mm and angulation errors in (°)

The average rotation about the Z axis of the femur was 1.4° (± 2.2°) of external rotation (Table 2). In general, transfer errors were smaller for planes on the tibia than the femur (Tables 1, 2, Fig. 5).

Discussion

The most important finding of this study is that the discrepancies for the tibia are so small that they can be considered to be clinically irrelevant. The discrepancies for planes on the femur were larger than those on the tibia. For the femurs, we saw systematic discrepancies in the plane orientation towards varus, flexion and external rotation. A combined (absolute error) of 5.2° is still impressive from a surgical perspective. The varus error, in particular, could change the mechanical axis and, therefore, the placement of the prosthesis. Too little slope might result in a slightly narrow flexion gap. This could be clinically relevant, as this would change the mechanical axis of the leg during walking. The flexion would be less of a problem because the curved shape of the prosthesis. A slight exorotation is preferable as it eases patellar tracking. However, rotational errors are also known to cause clinical complaints so this relevant for some patients. In one specimen (#6), there was a large error (> 1 cm), with too little bone osteotomized from the distal femur. It is not clear why this difference occurred but could be caused by incorrect placement of the cutting guide or osteotomy block, although the angular errors were not equally large in this specimen. In a live patient, this problem would be apparent and dealt with during surgery as placing the implant would be difficult because the extension gap would be too narrow. It would cause noticeable displacement of the joint line and a larger flexion gap if corrected by decreasing the implant size. Two specimens (#5 & #7) showed a varus error of around 5° which could produce a clinically relevant change of the mechanical axis of the leg and increased stress on the medial compartment. If the tibial osteotomy also caused too much varus (as in specimen #5, i.e., 2.6° of varus) the problem would be exacerbated.

Sawing with the oscillating saw from medial towards the lateral condyle could, in theory, explain the varus orientation. Under the assumption that cutting blade deflection increases with the distance from the cutting guide, errors are likely to be largest near the lateral condyle. Furthermore, after the saw blade passes through the medial condyle, it then bridges the intercondylar notch after which it will enter the lateral condyle at a slight angle because of anatomy. This may result in increased deflection of the saw compared to a situation where it enters at a 90-° angle, as for the tibia. However, after studying the data of our study in detail, it was clear that the most medial sections of the osteotomies show an average varus of 2.5° and the most lateral sections 2.5°. Therefore, it is unlikely that saw blade deflection is causal to the errors found in this study as the difference between medial and lateral is negligible. It is more likely that asymmetrical positioning of the femur guides would have caused the varus, flexion and external rotation. If the cutting-guide contact points with the femur are slightly higher distally than proximally, for instance because of remaining or overlapping cartilage interposition in the notch, this could result in more varus, flexion and external rotation than desirable. Another explanation could be that producing the guide is easier for the more proximal rounded part of the femur than, for instance, in the notch, which is anatomically more difficult to map.

Most of the previous reports on the accuracy of PSI systems use final implant position as the measure to judge positioning accuracy [6, 8, 15, 17, 18, 23]. Nam et al. [21] compared 41 knees implanted using CAS with 41 knees implanted using the Signature MRI-based PSI method. They noted that in the Signature PSI group, 88% of tibial components had an alignment within 2° perpendicular to the neutral mechanical axis. For the femoral components, 90% had an alignment within 2° perpendicular to the femur mechanical axis. Their results are better than the results reported in our study, but the numbers are difficult to compare, as they did not evaluate the osteotomies. In their study, the prosthesis orientation was measured by hand on plane radiographs, and no measurement error was given for the evaluation method. In a study by Ng et al. [22], 569 implants using Signature were reviewed retrospectively. Again the position of the implant was evaluated using long-leg radiographs. It was reported that the mechanical axis passed through the central third of the knee more often with Signature PSI (88%) than with manual instrumentation (78%). Furthermore, they reported that PSI had 10% outliers (> 2°) for the tibial component and 22% for the femoral component. The finding that the femoral orientation is less accurate is consistent with our study. A third study used postoperative CT to evaluate the Signature system in 23 TKA patients [24], but they only reported femoral implant rotation about the long axis. This study also used final implant position as a measure of success and also omits reporting the measurement error of the evaluation method and the variability in their observations. They did see median postoperative rotation of 0° for the femur as planned. Some previous studies have tried to assess the transfer accuracy of other PSI systems more accurately by using computer navigation to assess the position and orientation of the cutting guide [7, 20]. Conteduca et al. reported that for 12 procedures the mean deviation of the tibial guide from the ideal alignment on the coronal plane was 1.2° (± 1.5°) and in the sagittal plane 3.8° (± 2.4°) [7]. On the coronal plane, the mean deviation of the femoral guide from the ideal alignment was 1.2° (± 0.6°) and in the sagittal plane was 3.7° (± 2°). Lustig et al. reported that for 60 procedures, the mean deviation of the tibial guide from the ideal alignment on the coronal plane was 0.6° (± 1.9°) and in the sagittal plane −0.1° (± 2.6°) [20]. On the coronal plane, the mean deviation of the femoral guide from the ideal alignment was 0.2° (± 1.8°) and in the sagittal plane was 2.1° (± 2.8°). No researchers investigated the system studied in this paper. The results described in these studies seem to corroborate the data reported in our study. However, computer navigation has been known to result in displacement errors of up to 2 mm caused by the effect of the distance between the stereoscopic camera system and surgical tools [27]. Furthermore, the computer navigation approach does not take into account that the achieved osteotomy might not have a direct relationship with the guide because of the saw blade deflection mentioned previously or changes made on basis of clinical judgment after placing the guides. Changes might also occur with the removal of the pin-positioning guides and placement of the saw guide. Therefore, the position of the guide might not actually be related to achieving the actual planned plane. Thus, the above-mentioned studies are not equipped to evaluate the transfer accuracy of the osteotomy plane itself. It could be hypothesized that cutting block guides produced with a slit to guide the saw directly are more accurate than pin-positioned guides because the first technique avoids an extra intraoperative step. One study reported on the mean discrepancies of distal femoral and proximal tibial cuts using the Visionaire systems, a cutting block-guided system, by measuring the thickness of the removed bone segment and comparing it to the planned values [28]. The mean discrepancy was reported to be 3.1 ± 1.0 and 3.1 ± 1.1 mm for distal femoral medial end lateral cuts, respectively, and 2.7 ± 0.9 mm for both proximal tibial medial and lateral cuts. In our study, an average discrepancy of 0.7 ± 4.0 mm for femoral cuts and 0.8 ± 0.5 mm for tibial cuts was found. Therefore, it seems that using a cutting block guide does not result in fewer discrepancies. However, it is arguable that the two measuring techniques are too diverse to make this comparison.

The accuracy and reproducibility of the method used in our study were below 0.2 mm for translations and 0.3° for rotations in the previous technical note [11]. Therefore, differences between planned and achieved osteotomies exceeding the methodological error are expected to be caused by transfer errors.

In the here reported study, CT scan data was used to plan and evaluate the osteotomy planes because CT scans yield high bone-soft tissue contrast which makes it easier to assess the transfer accuracy of the osteotomy planes. Therefore, our results cannot be applied to the MRI version of the Signature system. Further studies should systematically compare both CT and MRI systems to confirm which yields more accurate results. The downside of a guide produced on the basis of CT data is that it needs supporting points that lie outside the cartilage layer. MRI-produced guides sit adjacent to the cartilage layer and have a larger surface area to ensure adequate placement. However, MRI-produced guides have been shown to be less accurate than CT-produced guides in other systems [26].

There are some limitations to this study. The system currently studied is a pin-positioning guide. After placements of the pins, the guide needs to be replaced by a standard cutting block. This potentially introduces the risk of pin movement and thus decreased accuracy. Guides with a slotted saw blade sleeve could potentially be more accurate. Furthermore, this is a cadaveric study so the clinical effects and outcome cannot be measured and the results may not be transferrable to real-life total knee replacement surgery. Not all the cadavers had arthritic knees, so the positioning of the guides might be less accurate on osteophytic bones in a live patient. To position the guide for correct cutting, any soft tissue trapped between bone and guide could alter the orientation of the guide. In cadaver limbs, any obstructing soft tissues can simply be cut away and the guide positioned on the bone accurately. However, for patients, it is important to cause as little soft tissue damage as possible during surgery as this can impair the recovery process. Nevertheless, great care was taken to perform the operations as if on a live patient. It would have been preferable to analyze a larger number of specimens but the cost aspect limited us to a restricted number of specimens. However, the size of the study group is, in part, compensated by the highly accurate evaluation technique. Cost also prevented us from actually placing expensive implants so prosthesis positioning could not be evaluated. This has been studied by several other authors and was not the main focus of the here reported study. Finally, we only evaluate the most commonly used system (Signature) so the validity of this study for other systems is not necessarily transferrable.

Conclusion

The production of guides produced by means of a 3D system based on CT data was assessed on cadaver specimen knees. The predicted osteotomy planes were more accurate for the tibia than for the femur. The use of 3D system techniques in TKA surgery provides accurate intraoperative guidance tailored to individual patients ensuring better placement of the implant, even for patients with bone deformities. Future studies could investigate further benefits such as reduced operation time, potentially fewer complications and longer implant survival with this method of controlled and improved component alignment.

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Conflict of interest

The authors declare that they have no conflict of interest.

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Ethical approval

Institutional review board approval was deemed not necessary as the study involved anonymous human cadaveric material as acquired with permission in accordance with the Dutch donor system.

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Chapter 4

Promising results of an non-invasive measurement of knee implant loosening using a loading device, CT-scans and 3D image analysis

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Abstract

Background: After total knee arthroplasty up to 13% requires revision surgery to address loosening. No current diagnostic modalities have a sensitivity or specificity higher than 70-80% to detect loosening, leading to 20-30% of patients undergoing unnecessary, risky, and expensive revision surgery. A reliable imaging modality is required to diagnose loosening. This study presents a new and non-invasive method and evaluates its reproducibility and reliability in a cadaveric study.

Methods: Ten cadaveric specimens were implanted with a loosely fitted tibial components and CT scanned under load towards valgus and varus using a loading device. Advanced three-dimensional imaging software was used to quantify displacement. Subsequently, the implants were fixed to the bone and scanned to determine the differences between the fixed and the loose state. Reproducibility errors were quantified using a frozen specimen in which displacement was absent.

Findings: Reproducibility errors, expressed as mean target registration error, screw-axis rotation and maximum total point motion were 0.073 mm (SD 0.033), 0.129 degrees (SD 0.039) and 0.116 mm (SD 0.031), respectively. In the loose condition, all displacements and rotation changes were larger than the reported reproducibility errors. Comparing the mean target registration error, screw axis rotation and maximum total point motion in the loose condition to the fixed condition resulted in mean differences of 0.463 mm (SD 0.279; $p = 0.001$), 1.769 degrees (SD 0.868; $p < 0.001$) and 1.339 mm (SD 0.712; $p < 0.001$), respectively.

Interpretation: The results of this cadaveric study show that this non-invasive method is reproducible and reliable for detection of displacement differences between fixed and loose tibial components.

Introduction

Total Knee Arthroplasty (TKA) is highly effective in treating pain caused by rheumatoid arthritis or osteoarthritis of the knee [1]. Nevertheless, according to a study which combined the national implant registries of 6 different countries, within 10 years, up to 13% of patients will have undergone revision surgery [2]. In most of the cases the indication is loosening of the tibial component [2]. The main additional tests to aid the diagnosis of aseptic TKA loosening are conventional x-rays, Computed Tomography Scan (CT), white blood cell (WBC) scanning, 3-phase bone scintigraphy and the Positron Emission Tomography combined with CT (PET-CT) [3]. However, according to the American College of Radiology these imaging modalities (with a reported sensitivity and specificity of 70-80%) are insufficiently sensitive and specific and measure secondary and non-specific effects, such as increased bone turnover and osteoclastic activity [4]. These are effects that are seen with loosening but can also be caused by other physiological processes. Therefore, nuclear scanning may put an unsubstantiated burden on patients to merely indicate a suspicion of implant loosening [4].

Yet, if patients present with pain around the knee on ambulation and current imaging modalities raise a suspicion of loosening, the TKA is usually revised. However, 20-30% of the patients who undergo revision surgery for TKA loosening, do not actually need this surgery as the prosthesis appears to be fixed during revision surgery [4]. Furthermore, the same percentage of wrongly conservatively treated patients, would benefit from revision surgery with a correct diagnosis. Detecting actual displacement and rotation of the implant with respect to the bone may be a more reliable and direct approach to detect TKA loosening.

Roentgen stereo photogrammetric analysis (RSA) and model-based RSA are currently the only imaging techniques showing sufficient precision to quantify prosthetic micro-motion. Model-based RSA is a biplane x-ray technique that utilizes known Computer Aided Design (CAD) models of a prosthesis and quantifies its movement with respect to tantalum beads in the bone. These beads need to be implanted, which renders the method invasive. Inducible displacement tests have mostly been performed in small groups of patients with a fixed-knee prosthesis due to the experimental nature, invasiveness, and cost of the RSA technique [5-9].

Therefore, this study presents and evaluates a new non-invasive method to detect induced displacement of the tibial component for potential future clinical use. In this method the displacement of the tibial TKA component is induced by the application of a varus- and valgus load by use of a loading device. With each load a CT-scan is made of the knee. Advanced imaging analysis techniques are applied to process the 3D CT-scan images and to calculate displacement of the tibial component relative to the bone.

The hypothesis is that this non-invasive method can detect implant displacement and rotations with reproducibility and reliability similar to invasive methods. Therefore, the research questions are: 1. What is the reproducibility of the proposed method? 2. Is this method sufficiently reliable to detect displacement differences between fixed and loose TKAs in a laboratory setting using cadaver specimens?

Methods

A two-stage cadaveric study was developed with the aim to evaluate reproducibility and reliability of this new non-invasive method for detection of TKA loosening in a laboratory cadaveric setting. This method consists of a hardware component (loading device) and software component (advanced 3D image analysis of acquired CT-images made under valgus and varus loading, using the loading device.).

Hardware component

For the purpose of this study, a prototype loading device was developed to apply consecutive varus and valgus loading to the knee. This device applies a bending moment up to 20 Nm, similar to loading during walking, in 20 degrees of knee flexion to relieve posterior capsule tension.[10] It consists of four contact points, two on the tibia and two on the femur resulting in a four-point bending mechanism. These contact points are connected with a stabilizing frame and equipped with a force application device and force measurement sensor (Figure 1a and 2). The setup ensures that a four-point bending is performed, and no force is applied directly to the prosthesis itself. A contact force between tibia and femur in a compartment, medial or lateral, combined with the tensile forces in the opposite capsule and collateral ligament balances the externally applied bending moment. The application of a bending moment in the frontal plane of the tibia is important for the reproducibility of the induced force and allows for variation of the positioning of the knee along the length of the leg. The prototype is mainly made of aluminum to guarantee a low level of image scattering. The prototype is shown in Figure 1a and 2.

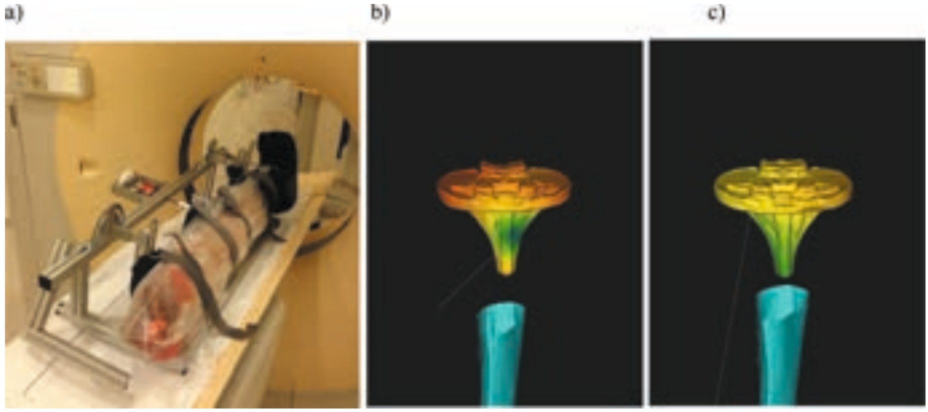

Figure 1a/b/c: a) Cadaveric leg placed in loading device and CT-scan, b) A 3D image example of the loose condition on a scale from 0.0 mm displacement (green) to 0.5 mm displacement (red), c) A 3D image example of the fixed condition with above described color gradations.

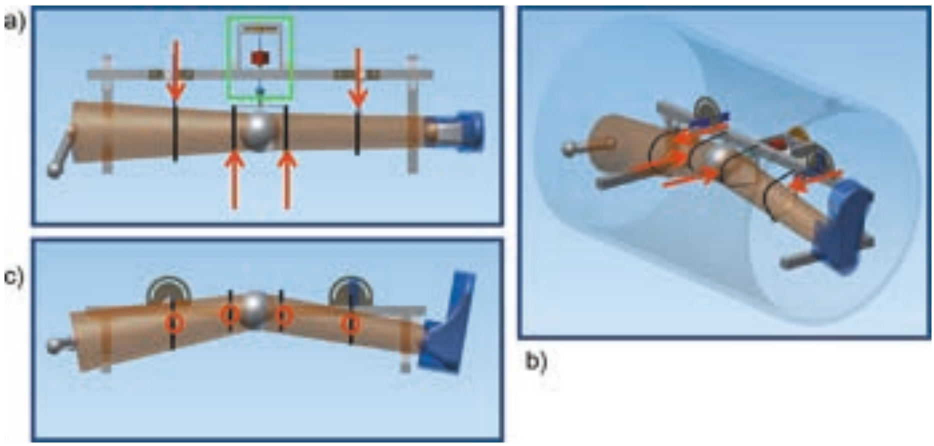

Figure 2a/b/c: schematic drawing of a leg in the loading device, with red arrow pointing out the four points where a bending moment of 20 Nm is applied and a load transducer (green box), measuring the applied moment.

Software component

The non-commercial custom-made 3-D image analysis software specifically developed for this study uses a three-step approach to visualize and quantify prosthesis displacement using CT-images: segmentation, registration and calculation and visualization. C++ programming language (Visual Studio 2013, Microsoft, Redmond, WA). The Qt toolkit [31] was used for GUI programming (Qt 4.8.6, The Qt Company, Espoo, Finland), the Visualization ToolKit [30] was used for 3D visualization (VTK 7.1.0, Kitware Inc., New York, NY), and the Insight ToolKit [26] for level-set segmentation (ITK 4.10.1, Kitware, Inc., Clifton Park, NY). The methods for segmentation and registration were performed in accordance with a protocol described by Dobbe et al [11].

Segmentation

The tibial implant and the tibia were segmented from the valgus CT-scan. Each object was first segmented using threshold-connected region growing. For the implant, a high threshold (2900 HU) was selected to manage metal artifacts as much as possible. For bone segmentation, the chosen threshold was approximately 300 HU. A binary closing algorithm subsequently filled residual holes inside the segmented object and at the surface. This intermediate segmentation result was used to initialize a Laplacian level-set segmentation growth algorithm, which adjusted the edges towards the highest intensity gradient of the implant and bone image. Finally, a polygon was extracted at the zero-level using the marching cubes algorithm. The tibial implant causes metal artifacts in the reconstruction of the CT image. This hampers segmentation of the proximal segment of the tibia. For this reason, the proximal segment was removed by polygon clipping (Figure 3a, dotted blue tibia segment remains). The resulting polygons were used for 3-D visualization of the implant and the tibia, and for subsequent registration of both virtual objects with the same objects in the varus CT-scan. A visual inspection of the virtual objects was performed to ensure that a complete model of the tibial tray and tibial bone was created.

Registration

Intensity-based point-to-image registration was used for registration of the implant and the tibia to the valgus CT-scan. To this end, points were selected by sampling the gray-level CT image 0.3-mm towards the inside (bright voxels) and outside (dark voxels) of the segmented bone. This resulted in a double-contour polygon, which included the gray-levels at each vertex. Registration resulted in a transformation matrix, MT, describing rotation and translation, which brings the tibia polygon to the varus image (Figure 3a) and a second transformation matrix, MI, which aligns the tibia polygon with the varus image. These matrices were combined to find the loosening matrix, ML= MT-1 MI, which brings the virtual implant from the valgus to the varus position, within the frame of reference of the valgus CT-scan (Figure 3b).

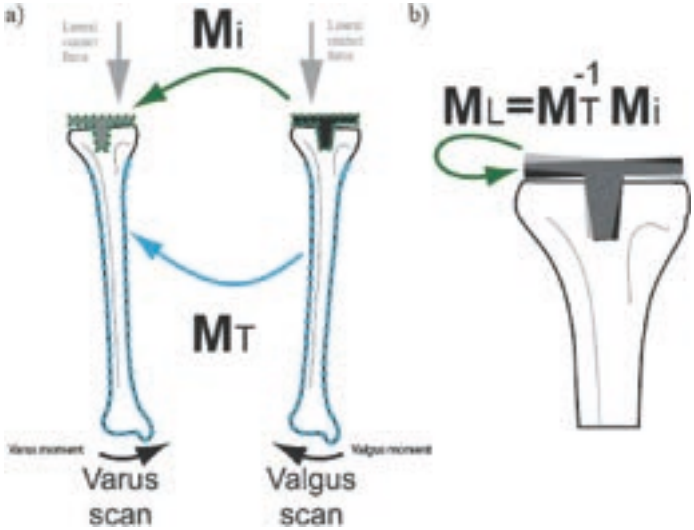

Figure 3a/b: Registration of the tibial bone resulted in a transformation matrix (blue dots; MT) and tibial component (green dots; MI), describing rotation and translation, which brings the tibia polygon to the varus image. These matrices were combined to find the displacement matrix, ML= MT-1 MI, which brings the virtual implant from the valgus to the varus position, within the frame of reference of the valgus scan.

Calculation and visualization

In case of a displaced tibial component, the implant position and orientation with respect to the tibia is different for the valgus and varus images. Implant displacement is quantified using the rotational change along the screw axis in degrees (rotation), the average point displacement of points in the implant mesh between the valgus and varus position (mean target registration error [mTRE]) and the maximum valgus-to-varus displacement of any point across the surface of the implant's polygon-mesh model (maximum total point motion [MTPM]). Calculated displacements are visualized in a heat map, with more reddish colors indicating a large displacement as opposed to more greenish colors indicating a small displacement (0.0 up to 0.5mm).

Experiments

First stage: Reproducibility

To evaluate reproducibility, a whole frozen cadaver leg was used and a TKA was performed on a whole frozen leg in accordance with the standard operative technique. Since the cadaveric leg was scanned in frozen condition, the absence of any motion between implant component and the bone can be assumed. Furthermore, fixation of the implant to the bone was ensured by visual verification after implantation. Therefore, any apparent implant displacement can be attributed to image noise, segmentation and/or registration errors. The leg was CT-scanned in ten slightly different (~ 5 degrees) orientations without application of any load.

Second stage: Reliability
To determine the reliability of the measurements of induced displacement of the tibial component in fixed tibial TKA components as opposed to loose tibial TKA components a second stage experiment was performed. Ten thawed, previously fresh-frozen cadaveric whole leg specimens were used and implanted with a TKA.

First, a loose implant was simulated in all ten legs by inserting an implant and moving it around slightly to simulate an area of bone resorption as found around loose implants. Looseness of the implant was ensured by visual verification. Looseness was defined as confirmed when manual induced movement of the tibial tray was visible after implantation. After which, all legs were scanned twice, first under varus loading and second under valgus loading. The loose condition was assessed first, as it would have been difficult to loosen the cement.

Second, all ten tibial loosely implanted components were fixed to the tibial bone using bone cement. The tibial component was removed, and both the bone and prosthesis were cleaned. Thereafter, bone cement was applied, and the implant was repositioned using pressurizing. Definitive fixation was defined as the inability to manually induce visual displacement of the tibial tray. All specimens were then again scanned in the same consecution.

Statistics and materials
Results of the loose condition were compared to the fixed condition and statistically tested using a paired sample T-test, as the assumption was made that the data are normally distributed. The results of unloaded first experiment were compared to the results of the fixed condition of the second stage experiment. This comparison was also tested using a paired sample t-test under the same assumption.

Authors' decision to use ten cadaveric legs resulted from convenience sampling. Post-hoc sample size evaluations were performed using ClinCalc Post-hoc Power Calculator (Alpha: 0.05) [12]. The specimens had a median age of 82 years (min – max; 68 – 92; six males and four females). A p-value < 0.05 was considered statistically significant. Statistical analyzes were performed using SPSS (IBM Corp. Released 2021. SPSS Statistics for Windows, Version 28, Armonk, NY: IBM Corp).

For all experimental evaluations, the vanguard TKA (Zimmer Biomet, Warsaw, Indiana, United States) was used.[13] Palacos bone cement (Heraeus, Hanau, Germany) was used for cementation of the implants.[14] All CT scans were made using a Brilliance 64-channel CT scanner (Philips Healthcare, Best, The Netherlands) (isotropic voxel spacing of 0.3 mm).

Ethical statements and source of funding

This study has been conducted following the recommendations of Committee of Ministers as stated in The Recommendation Rec (2006)4 [15,16]. This study was funded by an internal pre-seed grant from the Amsterdam University Medical Centers.

Results

Reproducibility

For reproducibility, the mean error in mTRE was 0.07 mm (SD 0.03 mm). The mean error for rotation was 0.13 degrees (SD 0.04 degrees). The mean error in MTPM was 0,12 mm (SD 0.03 mm) (Table 1, Supplementary Table 1).

Scan #	mTRE (mm)	Rotation (deg)	MTPM (mm)
1	0	0	0
2	0.08	0.09	0.11
3	0.05	0.09	0.10
4	0.05	0.09	0.08
5	0.08	0.20	0.15
6	0.11	0.15	0.13
7	0.04	0.13	0.08
8	0.05	0.15	0.10
9	0.07	0.16	0.13
10	0.14	0.12	0.17
Mean	**0.07**	**0.13**	**0.12**
SD	0.03	0.04	0.31

Table 1: Quantified and calculated values of the reproducibility experiment with all variables; rotation about the screw-axis (rotation), mean Target Registration Error (mTRE) and Maximum Total Point Motion (MTPM).

Reliability

Post-hoc sample size evaluations for mTRE, rotation and MTPM resulted in an estimated post-hoc power of 99.6%, 100% and 96.1% respectively.

In the fixed condition, the mean mTRE was 0.60 mm (SD 0.21 mm) compared to 1.06 mm (SD 0.33 mm) for the loose condition. The mean rotation was 0.67 degrees (SD 0.33 degrees) compared to 2.44 degrees (SD 0.97 degrees) when loose. The mean MTPM when fixed was 0.84 mm (SD 0,31 mm) compared to 2.18 mm (SD 0.86 mm) for the loose condition. (Table 2, Supplementary Table 2a/b). All displacements and rotational changes were larger than the measurement error reported for the reproducibility experiments. An example of the visualizations of the loose and fixed condition are shown in Figure 1b and 1c.

	Loose condition			Fixed condition		
Leg #	mTRE (mm)	Rotation (deg)	MTPM (mm)	mTRE (mm)	Rotation (deg)	MTPM (mm)
1	0.75	1.62	1.28	0.58	0.64	0.74
2	1.21	2.10	2.43	0.60	0.67	0.87
3	0.83	1.27	1.19	0.39	0.23	0.46
4	0.85	2.59	1.96	0.82	0.95	1.14
5	0.83	2.05	1.94	0.38	0.40	0.55
6	1.67	2.08	3.23	1.06	1.22	1.51
7	1.16	3.44	2.63	0.42	0.44	0.67
8	1.52	4.65	3.82	0.58	1.12	0.96
9	0.97	2.55	1.85	0.65	0.67	0.83
10	0.84	2.07	1.48	0.55	0.38	0.69
Mean	1.06	2.44	2.18	0.60	0.67	0.31
SD	0.33	0.97	0.86	0.21	0.66	0.78

Table 2: Calculated values of both the loose and fixed condition with the following variables: mean Target Registration Error (mTRE), rotation about the screw-axis (rotation) and Maximum Total Point Motion (MTPM).

The assumption that the data was normally distributed was considered satisfied as the skew and kurtosis levels were estimated as less than the maximum allowable values for a t-test (i.e. -3.0 > skewness < 3.0 and -10 > kurtosis < 10.0).[17] (Table 3a).

	Skewness	**Std. Error**	**Kurtosis**	**Std. Error**
Reproducibility				
mTRE	1.11	0.72	0.69	1.40
Rotation	0.57	0.72	-0.07	1.40
MTPM	0.39	0.72	0.93	1.40
Reliability				
Loose				
mTRE	1.09	0.69	0.02	1.33
Rotation	1.42	0.69	2.31	1.33
MTPM	0.80	0.69	-0.07	1.33
Fixed				
mTRE	1.16	0.69	1.37	1.33
Rotation	0.50	0.69	-0.90	1.33
MTPM	1.14	0.69	1.54	1.33

Table 3a: Distribution of data presented with skewness and kurtosis. mean Target Registration Error (mTRE), rotation about the screw-axis (rotation) and Maximum Total Point Motion (MTPM).

Comparing the mTREs, rotations and MTPMs in the loose condition to the fixed condition resulted in mean differences of 0.46 mm (SD 0.28 mm; p=0.001), 1.77 degrees

(SD 0.87 degrees; p<0.001) and 1.34 mm (SD 0.71 mm; p<0.001), respectively. Results of paired sample t-tests are shown in Table 3b and Figure 4.

	Paired Differences				
	Mean	**SD**	**95% CI (Lower)**	**95% CI (Upper)**	***p*-value (2-tailed)**
Loose mTRE - Fixed mTRE (mm)	0.46	0.28	-0.26	0.66	0.001
Loose Rotation - Fixed Rotation (deg)	1.77	0.87	1.150	2.39	< 0.001
Loose MTPM - Fixed MTPM (mm)	1.34	0.71	0.83	1.85	< 0.001

Table 3b: Results of paired samples test for means of loose mTRE – Fixed mTRE, Loose rotation – Fixed rotation, Loose MTPM – fixed MTPM, with means, standard deviations (SD), 95% confidence intervals (CI) and p-values. mean Target Registration Error (mTRE), rotation about the screw-axis (rotation) and Maximum Total Point Motion (MTPM).

Comparison of the mTREs, rotations and MTPMs of the results of the non-loaded first stage to the loaded second stage fixed condition resulted in mean differences of 0.54 mm (SD 0.12 mm; p<0.001), 0.56 degrees (SD 0.33 degrees; p<0.001) and 0.74 mm (SD 0.31 mm; p<0.001).

Figure 4a/b/c: Visualization of the individual changes in the rotation about the screw-axis, mTRE and MTPM for each cadaveric leg.

Discussion

The most important finding of this study is that this non-invasive method can significantly detect displacement differences between a loose implant compared to a fixed implant in a reproducible and reliable manner.

Mandalia et al. stated that pain after operation occurs in 1 in 8 patients despite an absence of clinical or radiological abnormalities [18]. Currently, findings from various imaging techniques are used to aid the diagnose of TKA loosening. These are mainly radiolucent lines on X-ray imaging and CT. Because of the low costs and fast processing, radiographs are usually the first diagnostic method, but there are some disadvantages to them. The intra- and inter-observer reliability is low, and the visibility of the radiolucent lines can be poor [19,20]. The reported sensitivity and specificity were 83% and 72% for detecting aseptic loosening of the tibial component [21]. Therefore, Mandalia et al. concluded that the clinical significance of radiolucent lines on x-ray imaging or CT is uncertain [18]. Despite reported low sensitivity and specificity, nuclear scans are one of the first diagnostic tools used by default after X-ray and CT. Nevertheless, nuclear scans measure osteoclastic activity and are therefore only useful after a minimum of one year after the last surgical procedure or else normal post-operative bone remodeling activity can be misinterpreted as signs of loosening [22].

Marker- and model-based RSA are considered the golden standard when it comes to quantifying implant migration, where the gradual migration of a prosthetic component in the bone over time can be measured. In this cadaveric study, the reported measurement error for the proposed method is similar to both RSA methods [23,24]. Theoretically, both RSA methods could be used to assess patients with complaints consistent with the diagnosis implant loosening overtime. However, a patient then will need to undergo surgery to implant the beads. This renders marker-based RSA useless as a non-invasive measurement in patients that were not previously evaluated using RSA. Furthermore, model-based RSA cannot be used for implants for which CAD models are not available or not supplied by the manufacturer. In the here proposed method, none of these disadvantages occur. No additional surgery is required, and the implant type and model need not to be known. This method can be performed in a non-invasive manner on any patient with complaints following TKA surgery, making this method potentially a replacement for current diagnostic methods like bone scanning and PET-CT scanning.

As reported in the results section, the fixed implants still show a displacement and angulation change, albeit being smaller than the loose condition. This may be caused the arbitrary visual confirmation of implant fixation after implantation, although performed similar to the intraoperative assessment of implantation fixation in revision surgery patients. Furthermore, these displacement changes may be caused by the suboptimal cementing technique used in this experimental setting, as the used cementing technique may have resulted in some interposition of fatty residues between the cement and the tibial tray. With a good cementing technique, however, the differences would only have been greater between the loose and fixed condition. It is, therefore, more likely that these changes are due to elastic deformity of the tibial bone. This is supported by the statistically significant differences for the comparison the results of the non-loaded reproducibility experiment and results of the loaded fixed condition and additionally strengthened by the reported overlap in displacement measures between the loose condition with the fixed condition for different cadaveric legs. Due to these differences, together with the potential effects of the used cementing technique and the cadaveric design of this study, the absolute results of this study cannot be used as a reference for what is to be defined as a loose or a fixed implant. A clinical feasibility study, including both symptomatic- and asymptomatic patients, is needed to evaluate potential clinically significant thresholds.

Conclusions

In conclusion, implant displacement can be measured in a reproducible and reliable manner similar as reported for invasive methods using this new method by a combination of induced displacement by a bending moment applied to the knee joint, CT-scans and a software algorithm with segmentation and registration.

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Chapter 5

Early experience with the Vanguard complete total knee system: 2-7 years of follow-up and risk factors for revision.

Kievit AJ, Schafroth MU, Blankevoort L, Sierevelt IN, van Dijk CN, van Geenen RC

J Arthroplasty. 2014 Feb;29(2):348-54. doi: 10.1016/j.arth.2013.05.018. Epub 2013 Jun 15.
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Abstract

A cross-sectional study in two hospitals was performed on 807 patients with a primary Vanguard (Biomet) total knee Arthroplasty (TKA). The research questions addressed were (1) what are the two- and six year survival rates of the Vanguard, (2) what are the clinical outcome scores, (3) what are the findings at revision and (4) what are predictors for revision? The mean age at time of surgery was 67.0 (SD 10.0). The mean follow-up was 3.6 years (95% CI 3.56–3.73). At two years the survival was 97.2% for all-reasons (767 patients remaining) and 99%, for prosthesis-related-reasons (777 remaining). At six years this was 96.5% (40 remaining) and 98.6% (41 remaining). The mean clinical results (84% response on KOOS, Oxford and NRS) were good. A previous osteotomy was a risk factor for revision (hazard ratio 5.1, $P = 0.001$). This early experience with the Vanguard shows a good survival with no adverse outcomes related to the implant and therefore further use of the implant is justified.

Introduction

Total knee arthroplasty (TKA) is a highly effective treatment for debilitating pain resulting from osteoarthritis of the knee [1]. The Vanguard Complete Knee System (Biomet, Inc, Warsaw, Ind) is a relatively new knee arthroplasty system that was introduced in 2003. Its design is a result of experience with the earlier AGC and Maxim prostheses. However, to date the midterm survival and patient reported outcome measures (PROMs) for this prosthesis are unknown.

The revision rate of an implant is an important outcome measure in evaluating survival of a new TKA design. To make survival data comparable between different prostheses designs, revision is used as a failure end-point. The rate of 'Revisions per 100 observed component years' can then be calculated. According to a recent study which combined the national databases of 6 different countries there are 1.26 revisions per 100 observed component years [2]. This number is the average revision rate for different knee designs in multiple countries. Clinical studies are valuable in addition to registry data as they can provide more details on the study population, the procedure and other aspects of the outcome.

If the early survival rate would be known, and turns out to be good in comparison with other prostheses, then this would justify further use of the Vanguard TKA.

The primary research question was therefore what are the two- and six-year survival rates of the Vanguard TKA. Secondary research questions are what are the clinical outcome scores, what are findings at the time of revision surgery and what are potential preoperative and perioperative predictors for revision.

Materials and Methods

A retrospective cross-sectional study was performed. All primary Vanguard total knee arthroplasties of two hospitals involved in the same residential program were included. In the Academic Medical Center, a university medical center, the prosthesis was introduced in April 2007 and in the Amphia Hospital in June 2005. For all patients the indication for surgery was based on patient history and physical examination combined with anteroposterior and lateral radiography. Both posterior stabilized (PS) and cruciate retaining (CR) prostheses were implanted. Only patients operated at least 2 years prior to February 2012 were included in this study.

For all patients follow-up, age at operation, indication for surgery, revision and revision date, complications, the presence of rheumatoid arthritis, diabetes, smoking status, body mass index (BMI), operation time, type of anesthesia, pre-operative hemoglobin as well as 1- and 3-day post-operative hemoglobin and admittance period were registered.

If patients were still alive at follow-up they were invited to fill out two questionnaires and a pain score as described below.

Operative Technique and Rehabilitation

The operative technique was in accordance with the surgical technique guide provided by Biomet. Surgery was performed or supervised by an experienced orthopedic surgeon. Pre-operative antibiotics were given thirty minutes before incision. Patients started with mobilization on the day after surgery dependent on pain. Normal expectancy was unaided walking after 6 weeks of rehabilitation. The mean Hospital stay was 5 days. In the questionnaires patients are asked if they had received a revision operation in any other hospital.

Clinical Outcome on KOOS, Oxford and NRS

The Knee injury Osteoarthritis Outcome Score (KOOS [3]) questionnaire, an Oxford[4] questionnaire and an 11-point Numeric Rating Scale (NRS) for pain ranging from 0 to 10 were used at follow-up. The KOOS is a 42 item site specific questionnaire, resulting in five 0–100 scores (higher is better) for Pain, Symptoms, activities of daily life (ADL), Sport & Recreation and quality of life (QOL). The Oxford is a 12 item site specific score, ranging from 0 to 48 (higher is better). For a proper comparison with the Swedish Knee Arthroplasty Register (SKAR) [5], the results are presented as means with 95% confidence intervals.

Findings During Revision

All operative reports of the revised patients were reviewed and intra-operative findings were noted.

Risk Factors for Revision

Predictors for revision that were analyzed were based on the SKAR [5]. Age at operation, BMI, ASA classification, implantation in the first year of the introduction of the prosthesis in either clinic (learning curve issues), gender, rheumatoid arthritis and post-osteotomy osteoarthritis were evaluated.

Statistical Analysis

For statistical analysis SPSS 20.0 (IBM SPSS Statistics) was used to calculate survival rate of the knee arthroplasty according to the method of Kaplan–Meier (observed cumulative survival). The end point was defined as the addition or change of one or more components of the prosthesis. Separate analyzes were performed for the endpoints “revision for prosthesis related reasons” (RPR) as well as “revision for all reasons” (RAR). RPR was defined as revision for mechanical aseptic loosening, wear of one or more parts of the implant, breakage or instability due to implant failure that required surgical arthroplasty of one or more components. RAR is defined as all the above reasons with the addition of septic loosening, revision for malpositioning of the prosthesis or patellofemoral knee pain requiring a patella prosthesis placement. Deaths without revision were treated as censored data (with censoring the date of death). The survival curves were plotted using R statistics (The Comprehensive R Archive Network).

The risk factors for revision were entered as covariate factors in a Cox proportional hazards model using backward LR method to determine whether the risk of requiring revision surgery was related to these factors.

The null hypothesis was that these covariate factors were not related to revision. Hazard ratios (HR) and corresponding 95% confidence intervals (CI) were reported. For categorical variables in the model (ASA, first year, gender, rheumatoid arthritis and post-osteotomy osteoarthritis) one category was defined as a reference having the relative risk of 1.0, to which the other categories were then compared. For numerical variables (age at operation and BMI), the risk ratio is related to the change in risk if the variable increases by one unit. To determine the Odds Ratio (OR) of revision surgery for specific risk factors a multivariate logistic regression analysis was performed.

Standard descriptive statistics were used to describe the demographic data and baseline characteristics. Normally distributed data, as tested with the Shapiro/Wilk test and additional visual inspection, were reported by mean and 95% confidence interval (CI). Not-normally distributed data by median and range. For normally distributed variables the unpaired t-tests were performed, Mann-Whitney tests were used for continuous non-normally distributed variables and chi-square tests for dichotomous variables to verify homogeneity between groups. For the casemix table, means and 95% CI were presented so data would be comparable to SKAR. A p-value smaller than 0.05 was considered statistically significant.

Results

Between June 2005 and 15 February 2010, 807 patients, 289 male and 518 female, with a mean age of 67.0 (SD 10.0; range 37.8–93.1) received a primary Vanguard total knee arthroplasty in the Academic Medical Center Amsterdam and the Amphia Hospital in Breda (Table 1). The mean follow-up was 3.6 years (95% CI 3.56–3.73) ranging from two to seven years.0

		All n=807	Male n=289 (35.8%)	Female n=518 (64.2%)
Age (Years) mean (SD)		**67.0 (10.0)**	65.0 (10.1)	68.0 (9.8)
BMI (kg/m2) mean (SD)		**29.4 (4.8)**	28.6 (4.4)	29.9 (4.9)
Follow-up mean (SD)		**3.6 (1.3)**	3.6 (1.3)	3.6 (1.2)
Hospitilization period in days median (range)		**6 (1-38)**	6 (2-38)	6 (1-37)
Pre-op hemoglobine, mean (SD)		**8.6 (0.8)**	9.1 (0.8)	8.4 (0.7)
Post-op hemoglobine day 1, mean (SD)		**7.2 (0.8)**	7.5 (0.9)	7.0 (0.7)
Post-op hemoglobine day 3, mean (SD)		**6.5 (0.9)**	6.7 (0.9)	6.4 (0.8)
		N (%)	N (%)	N (%)
Side	Left	**273 (33.9)**	115 (39.8)	158 (30.6)
	Right	**310 (38.5)**	108 (37.4)	202 (39.1)
	Both	**223 (27.7)**	66 (22.8)	157 (30.4)
ASA classification	1	**144 (18.5)**	62 (22.5)	82 (16.3)
	2	**457 (58.7)**	150 (54.5)	307 (60.9)
	3	**175 (22.5)**	60 (21.8)	115 (22.8)
	4	**3 (0.4)**	3 (1.1)	0 (0)
Smoking at operation	No	**681 (84.4)**	229 (79.2)	452 (87.3)
	Yes	**126 (15.6)**	60 (20.8)	66 (12.7)
Diabetes at operation	No	**698 (86.5)**	252 (87.2)	446 (86.1)
	Yes	**109 (13.5)**	37 (12.8)	72 (13.9)
Reumatoid arthritis at operation	No	**769 (95.3)**	275 (95.2)	494 (95.4)
	Yes	**38 (4.7)**	14 (4.8)	24 (4.6)
Osteotomy before operation	No	**771 (95.5)**	267 (92.4)	504 (97.3)
	Yes	**36 (4.5)**	22 (7.6)	14 (2.7)
Type prothesis – Cruciate retaining (CR) vs posterior stabilized (PS)	CR	**383 (48.7)**	141 (50.4)	242 (47.7)
	PS	**404 (51.3)**	139 (49.6)	265 (52.3)
Anaesthesia used	General	**397 (50.8)**	141 (51.1)	256 (50.7)
	Spinal	**384 (49.2)**	135 (48.9)	249 (49.3)

Table 1. Demographics at index operation

Survival Analysis

The RPR survival rate was 99% (95% CI: 98.2–99.8) at 2 years with 777 patients remaining, 98.6% (95% CI: 97.8–99.4) at 6 years with 41patients remaining. The RAR survival was 97.2% (95% CI: 96.0–98.4) at 2 years with 767 patients remaining, 96.5% (95% CI: 95.1–97.9) at 6 years with 40 patients remaining (Fig. 1). Expressed in revisions per 100 prosthesis years, RPR was 0.38/ 100 years and RAR was 0.94/100 years.

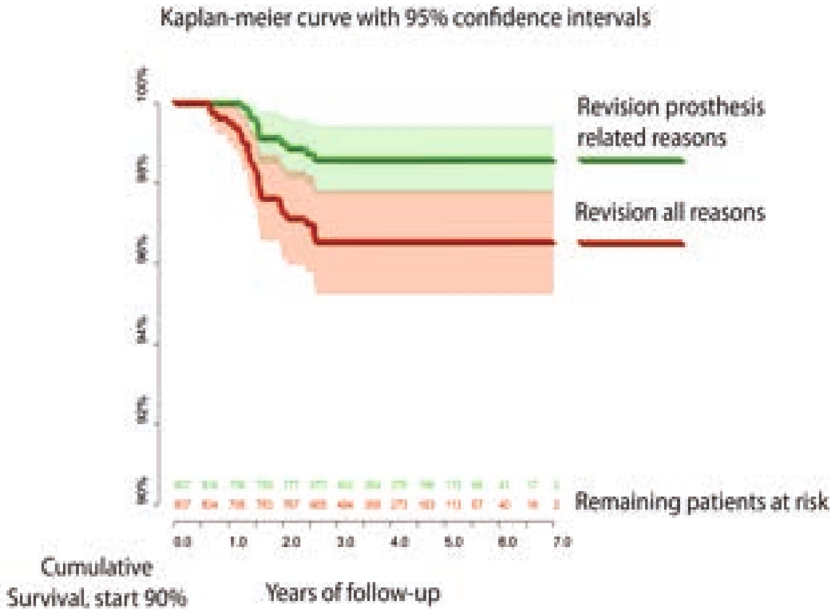

Fig. 1. Kaplan–Meier survival function with 95% confidence intervals for prosthesis related reasons and for all reasons.

Clinical Outcome on KOOS, Oxford and NRS

Of the 807 patients identified as having received a primary Vanguard total knee arthroplasty 43 (5%) had died at follow-up. This left 764 patients to be invited to participate in the questionnaire follow-up, of which 640 responded (84%). Of these responders, 78 did not want to participate (Fig. 2). None of these patients had undergone revision surgery. The means of the clinical results as measured with the KOOS were Pain 76.8 (95% CI: 74.9–78.8), Symptoms 73.2 (95% CI: 71.5–74.8), ADL 73.5 (95% CI: 71.5–75.5), Sport & Recreation 38.3 (95% CI: 35.5–41.1) and QOL 60.0 (95% CI: 57.7–62.3). The mean Oxford score was 36.3 (95% CI: 35.5–37.2) and NRS 2.5 (95% CI: 2.3–2.7) (Table 2).

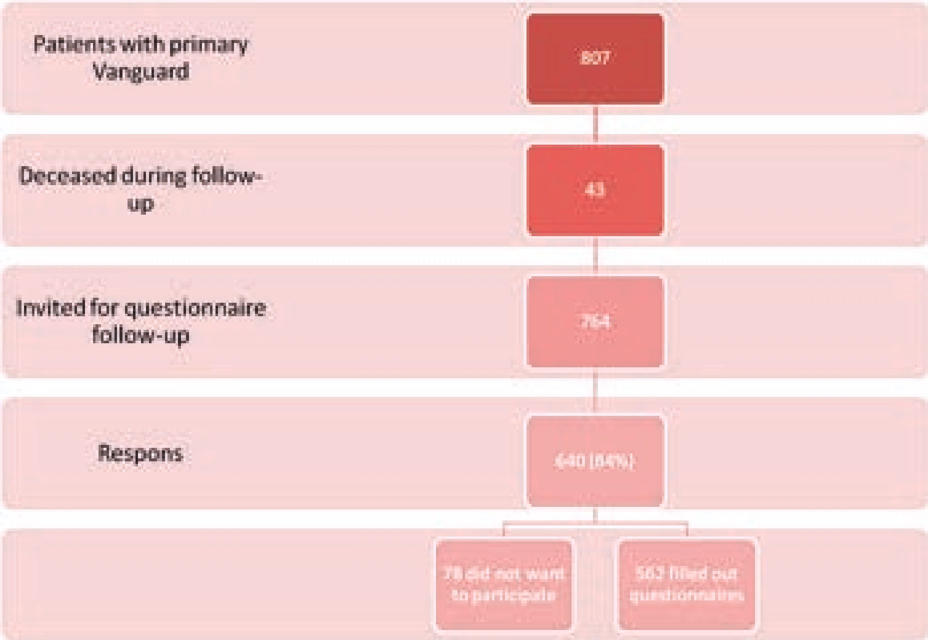

Fig. 2. Flow-chart for patient inclusion.

		Pain	Symptom	ADL	Sport & Recreation	QOL	Total Oxford score	NRS for pain
	Count	Mean (95%CI)	Mean (95%CI)	Mean (95%CI)	Mean (95%CI)	Mean (95%CI)	Mean (95%CI)	Mean (95%CI)
Total	**807**	**76.8 (74.9-78.8)**	**73.2 (71.5-74.8)**	**73.5 (71.5-75.5)**	**38.3 (35.5-41.1)**	**60.0 (57.7-62.3)**	**36.3 (35.5-37.2)**	**2.5 (2.3-2.7)**
Gender								
Male	289	80.8 (77.9-83.7)	75.1 (72.3-77.9)	78.0 (74.9-81.0)	44.7 (40.1-49.2)	62.7 (59.0-66.5)	38.3 (37.0-39.6)	2.1 (1.8-2.5)
Female	518	74.5 (72.0-77.1)	72.0 (70.0-74.0)	70.9 (68.3-73.5)	34.5 (31.0-38.0)	58.5 (55.6-61.3)	35.2 (34.1-36.2)	2.7 (2.4-3.0)
Age group at operation								
<55	98	76.4 (70.3-82.6)	67.7 (62.8-72.5)	73.9 (67.8-79.9)	42.1 (34.0-50.1)	56.8 (50.7-62.9)	35.6 (33.1-38.1)	2.6 (2.0-3.3)
55-65	256	78.2 (75.0-81.4)	72.5 (69.6-75.3)	76.0 (72.8-79.2)	39.3 (34.9-43.8)	60.7 (56.9-64.5)	37.1 (35.7-38.6)	2.4 (2.1-2.8)
65-75	253	76.9 (73.5-8.4)	74.5 (71.7-77.2)	74.6 (71.2-78.1)	39.1 (34.3-44.0)	60.7 (56.7-64.8)	36.8 (35.4-38.1)	2.4 (2.0-2.9)
75-85	190	73.4 (69.1-77.7)	74.6 (71.1-78.1)	65.5 (60.8-70.2)	29.1 (22.1-36.1)	58.2 (52.7-63.7)	34.5 (32.5-36.4)	2.8 (2.2-3.3)
>85	10	93.9 (81.9-105.9)	94.7 (88.9-100.5)	90.9 (73.0-108.8)	80.0 (44.0-116.0)	90.0 (70.4-109.6)	37.4 (27.4-47.5)	0.8 (-0.6-2.2)
BMI group at operation								
Healthy	131	82.5 (78.4-86.6)	77.1 (73.2-80.9)	81.2 (77.5-85.0)	42.9 (42.9-36.8)	65.8 (60.7-70.9)	39.1 (37.4-40.8)	2.1 (1.6-2.6)
Overweight	327	77.1 (74.1-80.1)	73.4 (70.9-75.8)	73.5 (70.4-76.6)	37.0 (32.8-41.2)	59.9 (56.4-63.4)	36.8 (35.6-38.1)	2.4 (2.0-2.7)
Obese	290	74.7 (71.3-78.1)	70.7 (67.9-73.6)	70.8 (67.3-74.3)	37.5 (32.6-42.4)	58.1 (54.2-62.0)	34.8 (33.3-36.3)	2.7 (2.3-3.1)
Morbidly obese	19	66.7 (51.2-82.1)	77.3 (69.0-85.6)	61.4 (44.4-78.3)	48.5 (23.0-74.0)	48.9 (33.7-64.0)	32.5 (25.4-39.5)	3.9 (1.4-6.4)
ASA								
1&2	601	77.8 (75.6-80.0)	73.5 (71.7-75.4)	75.6 (73.4-77.9)	39.9 (36.8-43.1)	61.1 (58.5-63.7)	37.1 (36.2-38.0)	2.4 (2.1-2.6)
3&4	178	74.5 (70.2-78.9)	72.7 (69.2-76.3)	66.8 (62.1-71.6)	33.6 (26.8-40.4)	56.3 (51.1-61.5)	33.6 (31.7-35.6)	3.0 (2.4-3.5)
Year of surgery								
2005	27	71.4 (60.7-82.1)	72.9 (63.9-81.9)	72.9 (61.9-83.8)	32.1 (19.6-44.6)	59.4 (47.1-71.7)	33.4 (27.7-39.0)	3.6 (2.0-5.1)
2006	62	78.4 (71.7-85.1)	72.6 (66.7-78.4)	75.0 (67.8-82.1)	36.0 (26.8-45.3)	60.2 (52.2-68.2)	37.4 (34.3-40.5)	2.3 (1.5-3.2)
2007	186	74.3 (69.7-78.9)	72.8 (69.4-76.3)	71.4 (66.7-76.1)	40.1 (33.7-46.6)	59.3 (53.8-64.7)	35.7 (33.7-37.8)	2.5 (2.0-3.0)
2008	155	73.5 (68.7-78.4)	72.0 (68.2-75.7)	71.4 (66.7-76.2)	35.9 (29.7-42.2)	59.4 (54.1-64.7)	35.0 (33.1-36.9)	2.5 (2.0-3.0)
2009	329	79.5 (76.6-82.3)	74.4 (71.9-77.0)	75.0 (72.0-78.0)	38.9 (34.5-43.2)	61.2 (57.8-64.7)	37.0 (35.8-38.3)	2.4 (2.0-2.7)
2010-February	48	79.1 (72.8-85.3)	70.5 (64.2-76.8)	75.7 (69.5-81.9)	41.5 (30.8-52.1)	56.9 (48.9-64.9)	37.9 (35.3-40.5)	2.7 (1.8-3.5)

Table 2. Casemix data of study group

Findings During Revision

RPR was performed in 11 patients. Six of these 11 patients had aseptic loosening of the tibial component of whom 1 patient also required the addition of a patellar component. In five of these patients the prosthesis–cement interface failed and in one patient the bone– cement interface failed. Four of these 11 patients had aseptic loosening of both the femoral and the tibial component of whom one patient also required a patellar component. One of these 11 patients had femoral loosening and required a patellar component. All the loosened components had been cemented at initial operation. All the loosened components were revised while the fixed components were left in situ.

RAR was performed in an additional 16 patients. Fourteen patellar prostheses were added for treating the patellofemoral pain. Two femoral revisions were performed for malpositioning. One 2-stage revision was performed for septic loosening. One femoral component exchange, from CR to PS, was performed for persistent post-traumatic instability due to posterior cruciate ligament insufficiency.

Risk Factors for Revision

The multivariate logistic regression analysis showed that an osteotomy prior to the TKA increased the risk of RAR (odds ratio (OR) 6.9, P b 0.001) in a model with age, BMI, ASA classification, first year of implantation, gender and rheumatoid arthritis. A prior osteotomy increases the risk for an early revision (hazard ratio (HR) 5.1, P value = 0.001) (Figs. 3 and 4).

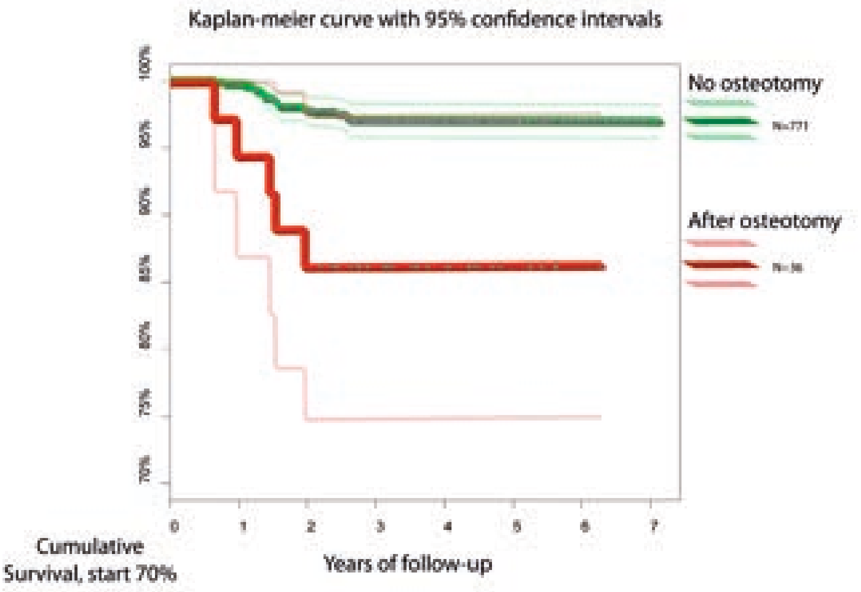

Figure 3, Kaplan-Meier survival function with 95% confidence intervals for patients who had undergone osteotomy and patients who had not

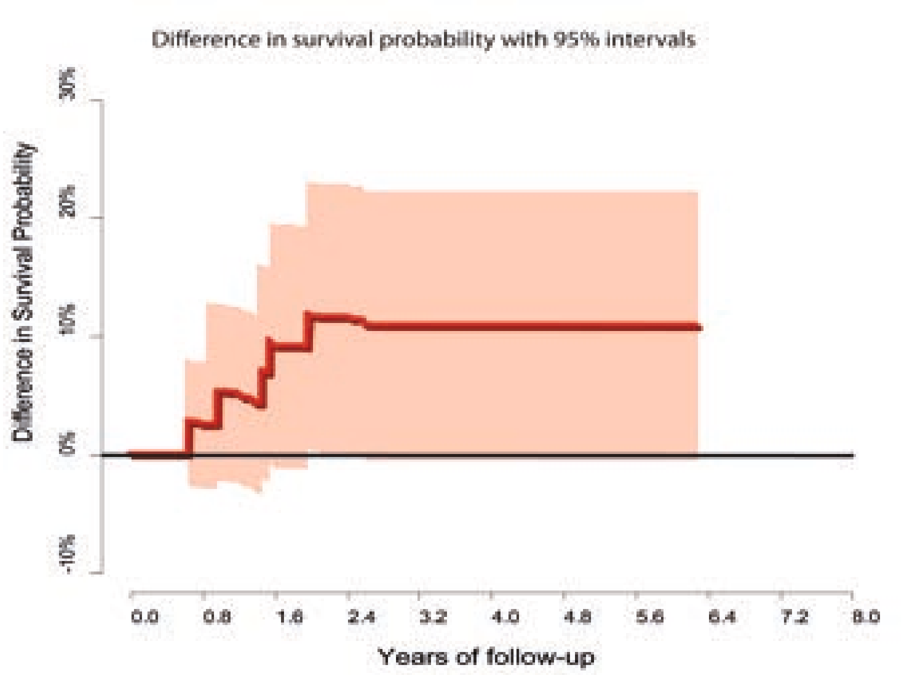

Figure 4, Difference in survival probability with 95 % confidence intervals between patients who had undergone osteotomy and patients who had not

All revisions had a previous open wedge HTO but there was insufficient detail in the operative reports to report the specific technique used. After finding this risk factor for revision an analysis was performed to test for differences in clinical outcome scores for these two patient groups but no statistically significant differences were found (Table 3).

	No osteotomy		**Osteotomy**		
	Median (Range)	Count	Median (Range)	Count	p-value (a)
Pain	86 (0-100)	528	80 (6-94)	25	.518
Symptom	75 (11-100)	532	79 (29-71)	25	.891
ADL	80 (0-100)	528	78 (0-100)	25	.657
Sport & Recreation	33 (0-100)	493	25 (0-100)	25	.597
QOL	63 (0-100)	524	50 (0-100)	25	.301
Total Oxford score	40 (0-48)	535	39 (7-48)	24	.548
NRS for pain	1 (0-10)	496	3 (0-9)	23	.081

a. Mann-Whitney test

Table 3. Outcome scores for no osteotomy and osteotomy patients

5

Discussion

The RAR survival was 97.2% at 2 years with 767 patients remaining, 96.5% at 6 years with 40 patients remaining. A recent study on the long term survival results of the AGC reported a comparable 98% survival at two years and 95% at six years for all reasons [6]. The RPR survival was 99% at 2 years with 777 patients remaining, 98.6% at 6 years with 41 patients remaining. Expressed in revisions per 100 prosthesis years, RPR was 0.38/100 years and RAR was 0.94/100 years.

These results can be considered better than average with 6% revision after 5 years and 1.26/100 years being the expected value as calculated from 6 national implant registers [2].

The patient reported outcome measures (PROMs) are comparably good when compared to previous reports using the same PROMs (Fig. 5) [5,7,8]. A difference is considered clinically relevant when it is more than 10 points on the KOOS as well as on the 0–100 VAS [5,7]. To compare the mean VAS of previous studies with the mean NRS of the current study, the NRS score was multiplied by ten. For this comparison it should be considered that NRS scores are generally answered slightly different from VAS scores. There seem to be no clinically relevant differences between the studies. The Vanguard in the current study seems to perform equally well on PROMs as compared to the AGC-studies and the SKAR.

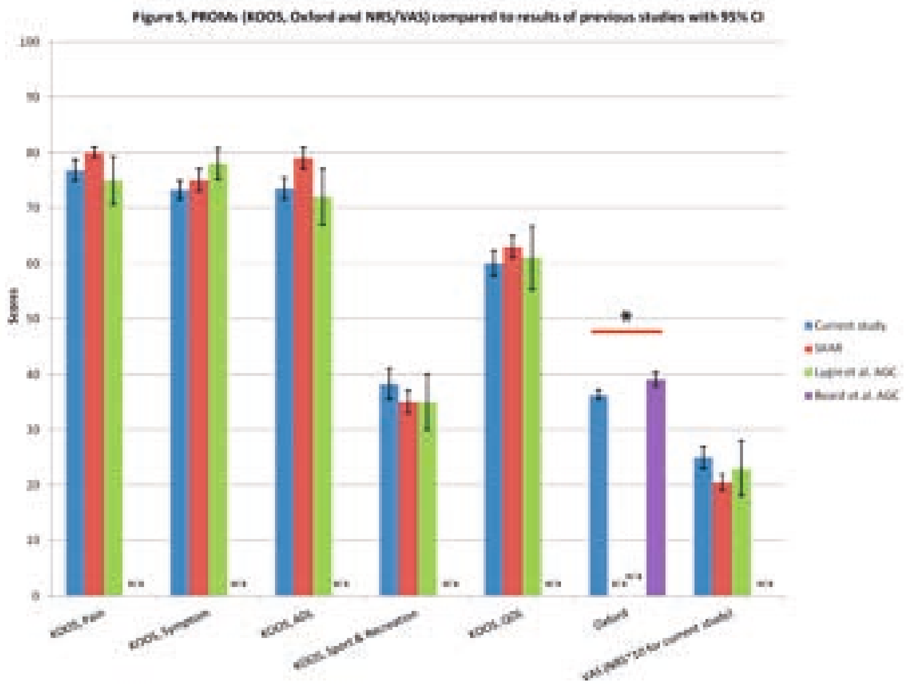

Figure 5, Patient reported outcome measures, KOOS (0-100, higher better), Oxford (0-48, higher better) and NRS/VAS (0-100, lower better), compared to results of previous studies with 95% CI (SKAR = Swedish Knee Arthroplasty Registry; n/a = not available; * = maximum Oxford-score)

The main revision issue in the short-term follow-up period was the addition of a patellar prosthesis at follow-up with 17 (2%) patellar prostheses being added. In a recent meta-analysis it was reported that 48 (6%) of 792 knees in the non-resurfacing group had further procedures because of anterior knee pain [9]. In this meta-analysis it was reported that follow-up of the randomized controlled trials was short, with the latest follow-up often being five years of the index procedure. As in this study the percentage was lower (2%), it was assumed that these revisions were to be expected based on natural progression of patellofemoral arthritis rather than being due to, for example, trochlear groove design.

One of the findings of this study is that a prior osteotomy significantly increases the chance of needing a RAR during follow-up. The rate of revision after osteotomy was 4.01 revisions/100 prosthesis years at 3.46 years. There were five revisions in 36 patients, three patellar additions for patellofemoral pain and two component changes. All these patients had undergone an open wedge high tibial osteotomy. Several studies have reported on previous osteotomy in relation to the revision rate of TKA among which two large studies [10,11]. For the purpose of comparison, the revision rates per 100 prosthesis years were calculated. This resulted in respectively 1.33 [11] and 2.70 [10] revisions/100 prosthesis years for these studies at 4.7 and 5.0 years of follow-up. Hence, the TKA revisions rates after a prior osteotomy are higher than the average 1.26 revisions/100 years reported for a normal TKA. The reason for this might be the changed geometry of the knee joint. High tibial osteotomy can result in patella baja or patella alta depending on the choice of a close wedge or an open wedge osteotomy.

A case could be made that in these patients a patellar component should always be implanted due to changes in the geometry and the risk of patellar maltracking. Furthermore due to a potential asymmetric tibial cut during TKA placement a more than average ligamentous misbalance in need of more releases and balancing can arise [12]. It has been reported that TKA after high tibial osteotomy can lead to increased loosening and lysis during follow-up [12]. Some studies have reported similar outcome scores for patients following HTO [13– 15] while others have reported inferior results [12,16–18]. In this study no differences in outcome scores were found between these two groups but this was after some patients had been reoperated and the cause of the pain had been treated. It must be taken into account that HTO can postpone the need for TKA by many years so it should not be concluded that HTO should no longer be performed. It is however important to realize that these patients need to be informed about a higher revision rate if they need a TKA, even after years of successful outcome following HTO. Significant differences in HTO technique can play a role in outcome for the index operation and revision to TKA. In this study detailed information on different techniques could not be identified, although it was known that all HTO procedures had been open wedge procedures. Future research should focus on the outcome of TKA following different HTO techniques.

The study design was retrospective in nature with prospectively recorded surgical and clinical details. With the number of events being low, one could argue that the study was underpowered to adequately prove statistically significant risk factors for revision. Nonetheless, a prior osteotomy was a statistically significant factor. It must be mentioned however that the lack of more detailed information on the different HTO techniques used is a limitation. Furthermore, there is a chance that patients have undergone a revision operation in another hospital. In this study the patients were asked for re-operations performed in another hospital. Two patients answered that this was indeed the case. It was unclear however if this had been a revision operation or a reoperation for any other reasons as patients gave no clear details. The method of calculating 'Revisions per 100 observed component years' has a downside in that it does not take into account that prosthesis survival curves are not linear. As a result, at midterm follow-up the revision rate will be relatively high compared to for instance at 10 year follow-up, as most revisions within this period occur in the first few years.

The current study was performed in two centers, one university hospital and one general hospital, in different parts of the Netherlands. This resulted in a heterogeneous patient population making the results more externally valid, at least for the Netherlands. In one hospital on average 120 and in the other 500 TKAs are performed annually. The response rate was high which resulted in an adequate representation of the patient population. The database was extensive in detail for pre-operative demographics. All patients who received a primary Vanguard were included and a good sample size was achieved for the survival analysis.

The patient group will be followed until long-term follow-up analysis can be performed to check if this new design continues to perform equally well or better than previous designs.

Conclusion

This early experience with the Vanguard shows a good survival with no adverse outcomes related to the implant and therefore further use of the implant is justified. The main reason for revision is patellofemoral pain. Patients who have undergone a prior osteotomy have a fivefold higher chance of revision compared to patients without.

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Chapter 6

A reliable, valid and responsive questionnaire to score the impact of knee complaints on work following total knee arthroplasty: the WORQ.

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Abstract

The Work, Osteoarthritis or joint-Replacement Questionnaire (WORQ) was developed to assess physical difficulty experienced in work before or following total knee arthroplasty (TKA). Thirteen questions were designed. The WORQ was tested for *internal consistency* by factor analysis, *internal reliability* (Crohnbach's α), and *construct validity*. A test–retest *reproducibility* was performed for analyzing standard error of measurement (SEM agreement), reliability (ICC) and smallest detectable change (SDC) in individuals and groups. Lastly *responsiveness* (standardized response means [SRM]), fl*oor and ceiling effects* and *interpretability* (minimal important change [MIC]) were analyzed. It is shown that the WORQ is a reliable, valid and responsive questionnaire that can be used to evaluate the impact of knee complaints following TKA on patients' ability to work.

Introduction

Although total knee arthroplasty (TKA) is highly effective in treating knee pain and functional limitations, little is known about how it impacts patients' potential to resume work [1]. Likewise, it is unclear what the optimum time for surgery is which will increase the chance of a successful return to work [2,3].

The absolute number of primary TKA procedures performed worldwide is increasing and expected to keep rising [1,4]. The number of patients aged 45–65 years receiving a TKA has tripled since 1996. Nearly 1.5 million of the people who currently have a TKA in the United States are between 50 and 69 years old [5,6]. A substantial group of these patients do paid or voluntary work before the operation and hope to continue. This illustrates the importance of obtaining a deeper insight into which factors hinder or promote the ability to work for such patients.

Patient-reported outcome measures (PROMs) are becoming important because the patient plays a central role in evaluating the outcome of surgical treatment. As yet, there are currently no PROMs to assess the impact of TKA on return to work. PROMs that are commonly applied to TKA patients are the KOOS [7], Oxford [8] and the new Knee Society Scoring System [9] questionnaires. However, these mainly assess home-life activities (ADL), and do not look at those activities that are necessary to work.

There is a need for a specific questionnaire that measures and scores the impact of TKA on work. This will also improve decision making about whether, and at what stage, it is advisable for patients to undergo surgery [1]. Furthermore, risk factors that might prevent return to work after TKA have not been identified because there is, as yet, no method available to assess work conditions and obstacles in the work place. Identifying such work-related factors will help physicians and other professionals to make a more adequate assessment of which obstacles would impede to certain types of work. Subsequently, work tasks could be adapted by the employer and employee and thus reduce loss of labor related to disability. A specific questionnaire that scores, measures, and monitors work activities will allow us to identify those risk factors that hamper adequate return to work. In this way, disability evaluations, decision making and treatments could be improved.

Our aim was to develop a work activity-related questionnaire for patients suffering from knee complaints or following TKA surgery and report its [1] *content validity*. Further questions of this study are as follows: what is the [2] *internal consistency* measured by factor analysis and what are the internal reliability (Crohnbach's α) [3], what is the *reproducibility* (test–retest) in *agreement*—standard error of measurement (SEM agreement), smallest detectable change (SDC) for individuals and for groups—and *reliability* (ICC)? Furthermore [4] *construct validity* is reported, as well as [5] *responsiveness* (standardized response means [SRM] and the relation between SDC and MIC)[6] fl*oor and ceiling effects* (%) and [7] *interpretability* (minimal important change [MIC].

Materials and Methods

Several researchers offer criteria for the evaluation of questionnaires. The best known are by the Scientific Advisory Committee (SAC) of the Medical Outcomes trust [10]. They identified eight attributes to assess the properties of a questionnaire. However there are no specific guidelines about how many hypotheses need to be confirmed before a questionnaire can be considered to have sufficient clinimetric quality. Seven of the criteria proposed by Terwee et al [11], were extrapolated to predict the quality of our proposed outcome questionnaire. One of the criteria, criterion validity, needs to be tested against a gold standard but hypotheses about the concepts we investigate are not yet sufficient to speak of a gold standard.

Content Validity

The questionnaire named Work, Osteoarthritis or joint-Replacement Questionnaire (WORQ) was devised to assess the "impact on work" in patients who had knee-related complaints following treatment and worked (or wanted to). The purpose of the WORQ was to evaluate, discriminate and predict a patient's ability to work after TKA surgery. It contains questions to assess a patient's capacities in paid or voluntary work and evaluates the level of physical difficulty experienced in carrying out tasks that could be influenced by knee function. The questionnaire was developed by a team of five orthopaedic and two occupational health experts who identified a set of work-related activities that are likely to be affected by knee problems. This was done in three consensus meetings. The first draft of the WORQ questionnaire was presented for feedback at a meeting of the Netherlands School of Public & Occupational Health (NSPOH) where 21 occupational physicians and 7 insurance physicians were present. The opinions of these experts were used to check whether the items in the WOR Questionnaire matched activities that TKA patients would be likely to perform.

Thirteen physical activities were considered: kneeling, crouching, lifting/carrying, pushing/pulling, climbing stairs, standing, sitting, clambering, driving a vehicle, walking on level ground, walking on rough terrain, operating foot pedals and working with hands below knee height. In addition, a subgroup of 40 TKA patients were interviewed and asked to express if they felt that this set of activities covered the difficulties they experienced at work in relation to their knee complaint. Patients were asked to grade how difficult it was to perform activities on a five-point scale: none, mild, moderate, severe or extreme (i.e. unable to perform), which corresponded to the scores 4, 3, 2, 1 and 0 respectively. The sum of the item scores was converted to a 0–100 score where 0 is the worst score and 100 the best. Furthermore, all patients were asked to report per activity how frequently they had performed this task at work before surgery. Moreover, as a check to see if the activities deemed to be important for work had previously been carried out, patients were also asked to report how often they had performed each activity. If less than 25% of patients reported that an activity had been performed "sometimes," it was be deemed an invalid question and dropped.

The WOR Questionnaire was tested on a group of patients who were known to have undergone TKA. For factor analysis it is recommended to have at least 10 times as many patients as variables, therefore at least 130 patients were needed [12]. All patients had had surgery on at the Academic Medical Center (AMC) in Amsterdam or at the Amphia teaching hospital in Breda, the Netherlands. Patients were only asked to fill out the questionnaire if they had held a job within 2 years prior to surgery. Patients were asked to assess retrospectively the difficulty they experienced with the knee-burdening activities at work in the 3 months before TKA and 2 years after TKA. By choosing these particular intervals, the WOR Questionnaire was tested at the worst possible moment in time (immediately prior to surgery) and at a time when complete recovery from the operation was expected (2 years after surgery).

The WOR Questionnaire met the requirements for content validity as the domain of interest is covered comprehensively by the items in the questionnaire [11].

Measurement Properties

Standard descriptive statistics were used to describe the demo graphic data and baseline characteristics of the patients.

Internal Consistency

To assess the internal consistency and dimensionality of WORQ, an exploratory factor analysis was performed *preTKA*, within 3 months before TKA to establish which factors account for most of the variance in the questionnaire. Because 5-point Likert scales, are susceptible to departures from normality, we used principal axis factoring which does not require the assumption of multivariate normality [13]. However, previous studies suggest that exploratory factor analysis is robust for small and moderate departures from normality. Therefore, maximum likelihood solutions for the WOR Questionnaire will probably yield similar results [14]. Principle axis factoring analysis with oblique rotation (*oblimin*) was used to determine dimensionality, considering eigenvalues higher than 1 (Kaiser's criterion) [12]. Factor loadings over 0.4 were retained [15]. The Kaiser–Meyer–Olkin (KMO) measure was used to verify sampling adequacy of the analysis, with an acceptable limit for KMO values for individual items greater than .5 [12]. Internal consistency was evaluated as a measure of reliability. The internal consistency is the degree to which items of (sub) scales are inter correlated and was assessed by calculation of Cronbach's α coefficient [11]. Additionally, the effect of deleting items on the internal reliability of each domain score was assessed systematically. A Cronbach's α coefficient of 0.7 or higher was considered satisfactory [16].

Reproducibility

The test–retest reliability of the WORQ scale was determined in a subgroup of 57 patients who are still working to this day. To make sure results will be applicable to diverse patients (before and after surgery), patients awaiting TKA (N = 14) as well as patients who are currently in work after a TKA or unicompartmental knee arthroplasty (N43=) were included in the study. Patients were asked to report difficulties experienced with the specific tasks in their work during the last week. The scores were obtained from two subsequent questionnaires, T1 (the first questionnaire) and T2 (the second questionnaire) with at least 1 week and maximum of 2 weeks in between. This period is long enough to prevent recall but short enough to ensure that clinical change is unlikely to have occurred. Patients were asked to fill out the second WOR Questionnaire on the same day of the week to minimize change due to other factors than merely measurement error. Finally patients were also asked to report if they had the same, less or more complaints as compared to the first time they filled out the questionnaire. Patients who reported a change in complaints or had an interval of more than 14 days between WORQ T1 and T2 were excluded from the analysis.

Agreement

The standard error of measurement (SEM) was calculated by taking the square root of the error variance of the ANOVA analysis with inclusion of systematic differences (SEM agreement). The SEM can then be converted into a number that represents the smallest detectable change (SDC) by means of the formula $1.96 * \sqrt{2} * SEM$. This number reflects the smallest within-person change in a score that can be considered to be a real change above any measurement error within one individual (SDC individual). This can in turn be converted into the SDC for a group of people (SDC group) by dividing the SDC individual by $\sqrt{n}$. For evaluative purposes, agreement is rated as positive if the absolute measurement error (SDC individual for change within individuals and SDC group for change between groups) is smaller than the minimal important change (MIC, see interpretability) that is considered to be clinically relevant [11].

Reliability

The intra-class correlation coefficient (ICC) is the most suitable and most commonly used parameter to assess the reliability of continuous measures. ICC agreement was calculated for the total scores on the questionnaire, ranging from a minimum score of 0 to a maximum score of 100, in a two-way random-effects model. An ICC higher than 0.70 is recommended as a minimum standard for reliability [11].

Construct Validity

Construct validity refers to the extent to which scores on a particular instrument relate to other measures in a manner that is consistent with theoretically derived hypotheses concerning the concepts that are being measured. Construct validity was assessed using Pearson's rank correlation coefficient (*R*). As it is hypothesized that the WORQ measures a different, but related, construct than that measured by currently available questionnaires, the correlations were not expected to be very strong. The correlation value was considered to be very strong if it was between 0.9 and 1.0, strong if it was between 0.7 and 0.9, moderate if it was within 0.5–0.7, and weak if it was below 0.2–0.5 [17,18]. The Knee injury Osteoarthritis Outcome Score (KOOS) [7] questionnaire and an Oxford [8] questionnaire were used at follow-up. The KOOS is a 42-item site-specific questionnaire, resulting in five 0–100 scores (higher is better) for Pain, Symptoms, Activities of Daily Living (ADL), Sport & Recreation and Quality of Life (QOL). The Oxford is a 12-item site-specific score, ranging from 0 to 48 (higher is better). It was hypothesized that the construct of the WORQ correlates with the KOOS and the WORQ scores. However, the strength is expected to be low to moderate (0.2–0.7) as the WORQ should measure similar but not the same constructs.

Responsiveness

Responsiveness has been defined as the ability of a questionnaire to detect clinically important changes over time, even if these changes are small. In other words it is the ability of a PROM to respond appropriately when a patient's clinical state changes. As a first criterion, the SDC should be smaller than the MIC for a questionnaire to be responsive [11]. For the WORQ to be useful it should be able to distinguish between physical difficulties experienced pre-TKA and post-TKA. Furthermore, standardized response means (SRM), which are used to measure responsiveness when data for which two time points in the same patients are being compared, were also calculated [19]. The SRM of other questionnaires is known which makes comparison possible. According to Cohen, a SRM of b 0.2 is considered a trivial effect, 0.2–0.5 as a small effect, 0.5–0.8 as a moderate effect and N 0.8 as a large effect [20]. SRM was calculated by dividing the mean difference between WORQ scores preTKA and WORQ scores TKA-recovered, by the standard deviation of the mean difference. This meant that this calculation was only applicable to patients who returned to work because scores both for WORQ preTKA and WORQ TKA-recovered were necessary.

Floor and Ceiling Effects

If floor or ceiling effects are present, it is likely that extreme items are missing in the lower or upper end of the scale, indicating limited content validity. The presence of ceiling and floor effects was evaluated on the basis of the percentage of patients with the maximum or minimum WORQ score and was considered present if this was the case in 15% or more of the patients [11].

Interpretability

Means and standard deviations of scores of patients before and after treatment of known efficacy, TKA in this case, are given for the purpose of interpretability. Minimal important change (MIC), defined as "the smallest difference in score in the domain of interest which patients perceive as beneficial," was analyzed in an anchor-based approach. To calculate the MIC, it was decided to use patient satisfaction about their work ability using the TKA knee as an anchor question. Patients who “totally agreed” or “agreed” with the questionnaire item measuring satisfaction with the treatment were considered to have had a clinically relevant change. Pearson’s correlation coefficients will be analyzed based on changes in WORQ scores to changes in the anchor measure in order to confirm the usefulness of the anchor question. A correlation coefficient of 0.30 or more is required to be regarded as a good anchor [21].

All analyzes were done using SPSS 20.0 statistics software (IBM, Armonk, New York, USA). A P-value b 0.05 was considered statistically significant.

Results

Participants

Seven hundred sixty-four patients received the invitation to participate, of which 558 (73%) responded (Fig. 1). Seventy-eight patients declined and 480 filled out a questionnaire of which 173 (36%) had active work in the 2 years prior to surgery. The average age of the group with a job prior to surgery was 60 (SD 8.6) years. The gender distribution of patients with work prior to surgery was 49% male and 51% female (Table 1).

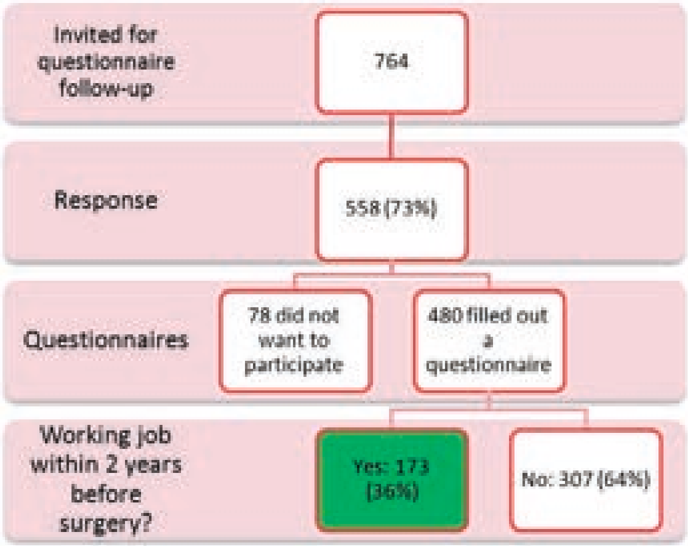

Fig. 1. Flowchart of patient inclusion.

Work n=173 (36%)		
Age (Years), mean (SD)		60.1 (8.6)
BMI (kg/m2), mean (SD)		29.5 (4.7)
Years after TKA, mean (SD)		3.8 (1.3)
N (%)		
Gender	Male	85 (49.1)
	Female	88 (50.9)
ASA*	1 or 2	148 (87.1)
	3 or 4	22 (12.9)

*ASA classification was missing in the patient data for three patients.

Table 1. Baseline Characteristics of the Patient Group.

Content Validity

Of the subgroup of 40 patients that was interviewed about the activities addressed, more than 80% reported that the set of activities was adequate to evaluate the difficulty experienced in work due to their knee complaints. Some patients suggested an extra activity specific to their work, like for instance walking on slippery floors, but at this time no activities were added as suggestions were not reproduced by different patients. All activities were performed at least “sometimes” by 25% of patients at WORQ preTKA, therefore, all questions were left and used in the sum scores (Table 2).

6

Activity	**Performed at least “sometimes” at 3 months prior to TKA by % of patients**	**Performed at least “sometimes” at 2 months prior to TKA by % of patients**
Walking on level ground	87	86
Operating a vehicle	73	69
Operating foot pedals	56	52
Sitting	88	90
Walking on rough terrain	59	50
Taking the stairs	75	74
Standing	85	83
Lifting or carrying	65	60
Pushing or pulling	59	54
Working with hands below knee height	53	40
Crouching	52	40
Kneeling	55	39
Clambering	30	22

Table 2. Percentage of Patients That Reported to Have Performed Certain Activities at Least “Sometimes” in Their Work.

Measurement Properties

Internal Consistency

A factor analysis was conducted on the 13 items with oblique rotation (oblimin) to allow the factors to correlate. Patients with incomplete data were removed list-wise prior to the factor analysis, leaving N = 149. The Kaiser–Meyer–Olkin (KMO) measure verified the sampling adequacy for the analysis, KMO = .88 ("Meritorious" according to Hutcheson and Sofroniou [22]), and all KMO values for individual items were greater than the acceptable limit of .5 with the lowest being .75 [12]. An initial analysis was performed to generate eigenvalues for each factor in the data. Both the Kaiser's criterion (Table 3) and the scree plot (Fig. 2) suggested retaining two factors, which together explained 64.9% of the variance (Table 3).

Total Variance Explained							
Factor	**Initial Eigenvalues**			**Extraction Sums of Squared Loadings**			**Rotation Sums of Squared Loadings[a]**
	Total	**% of Variance**	**Cumulative %**	**Total**	**% of Variance**	**Cumulative %**	**Total**
1	6.65	51.14	51.14	6.26	48.14	48.14	5.25
2	1.79	13.74	64.88	1.46	11.21	59.35	4.35
3	0.89	6.84	71.72				
4	0.78	6.00	77.72				
5	0.64	4.91	82.63				
6	0.48	3.71	86.34				
7	0.40	3.04	89.38				
8	0.33	2.52	91.90				
9	0.31	2.40	94.30				
10	0.24	1.87	96.17				
11	0.22	1.71	97.88				
12	0.20	1.50	99.38				
13	0.08	0.62	100.00				

Extraction Method: Principal Axis Factoring. a. When factors are correlated, sums of squared loadings cannot be added to obtain a total variance.

Table 3. Total Variance Explained and Eigenvalues.

The scree plot showed inflexion that justified retaining two factors (Fig. 2). Two factors were retained based on Kaiser's criterion and the scree plot. Table 3 shows the factor loadings after rotation with factor loadings below .4 suppressed. As said, factor loadings over .4 were retained [15]. Items clustering on the same factor, suggest that factor 1 represents activities involving "Knee coordination," and factor 2 represents activities involving "Strenuous knee flexion." As can be seen in the pattern matrix, two items had factor loadings above .4 on both factors but the highest loading determined for which factor they were considered most representative (Table 4). "Knee coordination" and "Strenuous knee flexion" both had high reliabilities, with Cronbach's α of respectively .90 and .85. Cronbach's α for the total score was .90.

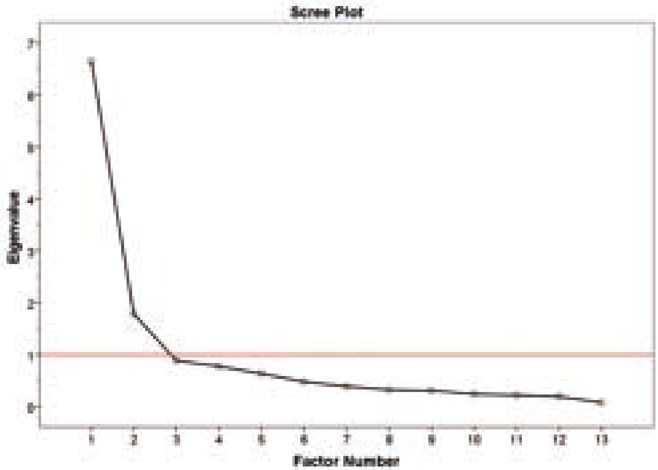

Fig. 2. Scree plot of eigenvalues with Kaiser's criterion of 1, the different factor numbers are shown on the x-axis.

	Factor	
	1 **"Knee coordination"**	**2** **"Strenuous knee flexion"**
Walking on level ground	0.80	
Operating a vehicle	0.76	
Operating foot pedals	0.74	
Sitting	0.65	
Walking on rough terrain	0.63	
Taking the stairs	0.56	
Standing	0.52	
Lifting or carrying	0.48	-0.47
Pushing or pulling	0.48	
Working with hands below knee height	0.41	
Crouching		-0.96
Kneeling		-0.93
Clambering	0.44	-0.47

Extraction method: Principal axis factoring. Rotation method: Oblimin with kaiser normalization. Rotation converged in 17 iterations.

Table 4. Pattern Matrix After Oblimin Rotation.

Reproducibility
Fifty-seven patients were enrolled in the test–retest study. Of these 54 filled out the questionnaire twice, 5 patients were excluded because they reported a change in their complaints and 4 patients were excluded because they exceeded the 14-day maximum allowed period. This left 45 patients for analysis of agreement and reliability.

Agreement
SEM agreement was 3.43, the SDC individual was therefore 9.52 and the SDC group was 1.42 as analyzed for the 45 patients. The SDC individual and SDC group were both smaller than the MIC (13, see "Interpretability").

Reliability
The ICC was .97 for the total scores and higher than the threshold of .70.

Construct Validity
Factor scores were used to assess the construct validity. Factor 1 "Knee coordination" was statistically significantly correlated with KOOS pain (R = 0.46), symptom (R = 0.37), ADL (R = 0.47), Sport & Recreation (R = 0.35), QOL (R = 0.39) and the Oxford score (R = 0.49). Factor 2 "Strenuous knee flexion" was statistically significantly correlated with KOOS pain (R = 0.37), symptom (R = 0.22), ADL (R = 0.35), Sport & Recreation (R = 0.69), QOL (R = 0.47) and the Oxford score (R = 0.50).

Responsiveness
The SDC individual and group (10 and 2) are smaller than the MIC (13), therefore the WORQ will be responsive. One hundred eight questionnaires were available for analysis of responsiveness with the SRM. The SRM was 0.70, moderate according to Cohen [20].

Floor and Ceiling Effects
Floor effects were observed in b 1% of cases at WORQ preTKA (valid n = 164) and b 1% at WORQ TKA-recovered (valid n = 114). Ceiling effects were observed in 3.6% of cases at WORQ preTKA and 8.8% at WORQ TKA-recovered. Ceiling or floor effects were considered not to be present as the percentages did not exceed 15% [11].

Interpretability
The correlation coefficient between the WORQ TKA-recovered and the anchor question for patient satisfaction was 0.54 (P b .001) for 114 patients meeting the criteria of sample size and a coefficient N 0.3 [21]. Patients who "totally agreed" or "agreed" to the statement on satisfaction, improved from a mean score of 53.9 to 78.9 (25 points improvement) and from 57.3 to 70.6 respectively (13). For patients who neither "agreed" nor "disagreed" there was some improvement, this was from 48.8 to 57.0 (8). For patients who "disagreed" or "strongly disagreed," the mean scores respectively went from 58.4 to 49.7 (decrease of 9) and 47.6 to 42.4 (decrease of 5) (Table 5). It is concluded that an improvement of at least 13 points on the 0–100 scale can be considered to be clinically relevant.

Satisfaction of working capability with respect to the knee						
	Totally agree	Agree	Neither agree, nor disagree	Disagree	Totally disagree	MIC
Mean score just before operation (SD)	53.9 (23.5)	57.3 (22.4)	48.8 (22.4)	58.4 (25.0)	47.6 (18.3)	
Mean score two years after operation (SD)	78.9 (18.9)	70.6 (15.0)	57.0 (18.1)	49.7 (24.2)	42.4 (19.1)	
Change in score	↑25	↑13	↑8	↓9	↓5	13

Table 5. Minimal Clinically Important Difference Scores.

Discussion

The content and construct of the WOR Questionnaire are valid and consist of two main factors with high internal consistency, good reproducibility with good agreement (small SEM and SDC) and reliability (high ICC), moderate responsiveness, no floor and ceiling effects, and good interpretability. WORQ can be used to score, assess and follow-up patients' ability to work in relation to knee complaints and can also be used to compare outcomes between groups following two different treatment options.

6

The results of this study, through exploratory factor analysis, led us to hypothesize that knee demanding activities at work represent two factors: Factor 1 represents activities involving "Knee coordination" while Factor 2 represents activities involving "Strenuous knee flexion." The finding that the activities involving deep knee flexion cluster on one factor (factor 2) is logical as deep knee flexion is the main restriction encountered in current TKA, where most designs have a maximum average flexion of 125 degrees. The items that cluster on factor 1 involve less flexion and correspond more with coordination of the leg, for instance operating vehicles or pedals, pushing and pulling or walking. The finding that the two factors have clinically meaningful interpretations further supports the sensitivity of the questionnaire. Future work can further validate the separate predictive value of these two dimensions, for instance by means of a confirmatory factor analysis with prospectively collected data in different patient groups and countries.

The WORQ has high reliabilities for both factors. Based on the literature a Cronbach's α coefficient of higher than 0.7 is acceptable for satisfactory internal consistency [16]. The Cronbach's α coefficient of the WORQ is higher than this threshold with a coefficient of 0.92 overall, 0.90 for factor 1 and 0.85 for factor 2. Other widely used PROMs for monitoring follow-up of TKA patients have similar known Cronbach's α of 0.74–0.94 for the five KOOS subscales [7], 0.87 for the Oxford [8] and 0.68–0.95 for the subjective parts of the new Knee Society Scoring System [9]. The WORQ appears to be supported in its construct validity as correlations to the KOOS and Oxford exists, but as they are low to moderate as hypothesized, they do not exactly measure the same construct but are merely related as they assess knee function in different ways. Small SEM, SDC individual and SDC group were found in test–

retest results T1 and T2 within the group that reported no change and were within the 14-day limit. Due to this small measurement error individual patients can be followed up at intervals to assess an increase in score. Groups can be compared to study different treatment effects on knee complaints and work ability. The responsiveness was moderate with a total score of 0.70. The values of responsiveness are similar to other known PROMs used in workers with musculoskeletal disorders with SRM values for SF-36 of 0.65, the Nottingham Health Profile 0.66, Sickness Impact Profile 0.66, the Duke Health Profile 0.48 and Ontario Health Survey 0.57 [23]. No floor or ceiling effects were seen at the time points when patients experienced most knee complaints or after TKA (WORQ preTKA and WORQ TKA-recovered) supporting the clinical usefulness of the WORQ in this population. On the total score the MIC was deemed to be 13 points on the 0–100 scale. As the SDC individual and SDC group are smaller than the MIC, the WORQ is able to distinguish score improvements that are clinically relevant for both individual patients as well as groups of patients.

PROMs have been used for decades in improving outcome of treatment. Using PROMs the patient is central in assessing their own outcome ensuring a minimal bias. PROMs like the KOOS [7] and Oxford [8] score have been widely used to test the effectiveness of surgical interventions in decreasing complaints but do not ask specific activities performed mostly at work. Little is known about the impact of TKA on patients' reintegration into the workplace [2,3]. Nine studies have reported to some extent at what point in time patients return to work [24–32]. The information was mostly limited to the percentage of patients who returned to work and at what point in time. No specific data were given about the activities performed. Another study found that high motivation, being female and being self-employed accelerated early return to work while having less pain pre-operatively, having a physically demanding job and receiving sickness compensation were decelerators. [25] These types of studies however lack information on difficulty experienced in work-related activities and would probably benefit from the WORQ in extending the information and strengthening the conclusions. Outcome solely based on the timing of return to work is insufficient for assessing the extent of adequate return to work. As more patients undergo TKA while of working age, it will be increasingly important to know how well or poorly patients can perform work-related activities before (with knee complaints) and after TKA.

The WORQ can be used to follow up patients at different moments in time. Future studies can use the WORQ to assess the effect of rehabilitation, surgical or non-surgical treatments and multi-disciplinary clinical and occupational interventions on their effectiveness in increasing patients working ability. Furthermore, studies trying to identify patients pre-operatively for having a higher risk of not or inadequately returning to work can be performed as the WORQ is responsive and has a small measurement error. For this purpose however a prospective cohort design would be most suitable. It will be valuable to identify which preoperative WORQ scores predict sufficient or insufficient outcome in the long run for specific patient groups. This will aid doctors in identifying specific patients that might need extra attention to ensure a better overall outcome.

Dutch and English versions (Appendixes A and B; available online at www.arthroplastyjournal.org) of the WORQ are attached to this article for use by other clinicians and researchers and they will be made available online.

Limitations

The factor structure might differ in qualitatively distinct patient populations. For instance, in an older subpopulation following TKA, difficulty with kneeling and crouching might be differentially affected due to the influence of additional co-morbidity such as hip osteoarthritis, leading to different response patterns. For this reason, it is advisable to repeat the factor analysis in populations that differ from the population presented here.

A point of critique of the study is the retrospective nature of the patients' reports about their perceived difficulties at work, which means that there is a risk of recall bias in the results. However, we assume that patients should be able to assess work-specific tasks at the two different and distinct time points. Furthermore, it is unlikely that this has effect on the factor structure, Cronbach's α, responsiveness, floor or ceiling effects and interpretability. To perform a valid test–retest, a subgroup of patients that work to this day were asked for the reproducibility study as recall bias could influence test–retest results. For an adequate presentation, patients included TKA and UKA patients, some of which were awaiting surgery and some had had surgery in the past. However, the WORQ has not yet been tested on other patient populations. Criterion validity has not yet been assessed as the retrospective design of the study would probably not yield reliable and valid results in this respect. In addition, a careful decision has to be made in selecting the appropriate reference or gold standard with which to test criterion validity.

Future research will need to focus on testing the questionnaire in different patient groups and in different countries for the purpose of interpretability. Moreover, criterion validity in a prospective series of patients will need to be addressed. The hypotheses from the exploratory factor analysis in this study can be used to perform a confirmatory factor analysis in future reports. In a next study the WORQ will be used to report on the impact of TKA on work in coincidence with more detailed information.

Conclusion

WORQ is a new questionnaire with good clinimetric quality. It was tested and found to be sufficient with respect to content validity, internal consistency, reproducibility, construct validity, responsive ness, floor and ceiling effects and interpretability in a population of TKA patients. It can be used for both individuals and groups to assess knee problems experienced in carrying out work-related activities. The WORQ is freely available and can be used to compare different interventions in patient groups and to follow up patients' change in scores over time.

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6

Appendix A. Work, Osteoarthritis and joint-Replacement Questionnaire (WORQ) [Dutch]

Als uw antwoord er niet tussen staat geef dan het antwoord dat het dichtst bij uw mening in de buurt komt.

Datum:_____________________________________
Naam:______________________________________
Geslacht:___________________________________
Geboortedatum:______________________________

Wilt u voor elk van de onderstaande activiteiten aangeven hoeveel moeite u de afgelopen week heeft ervaren tijdens deze activiteiten vanwege uw knie?

	Geen 4	Gering 3	Matig 2	Veel 1	Erg veel/ kan ik niet 0
Hurken?	□	□	□	□	□
Knielen?	□	□	□	□	□
Klimmen en/of klauteren?	□	□	□	□	□
Lopen op gelijke ondergrond?	□	□	□	□	□
Besturen van een voertuig?	□	□	□	□	□
Pedalen bedienen met de voeten?	□	□	□	□	□
Zitten?	□	□	□	□	□
Lopen op ongelijke ondergrond?	□	□	□	□	□
Traplopen?	□	□	□	□	□
Staan?	□	□	□	□	□
Tillen en/of dragen?	□	□	□	□	□
Duwen en/of trekken?	□	□	□	□	□
Werken met handen onder de kniehoogte?	□	□	□	□	□

Appendix B. Work, Osteoarthritis and joint-Replacement Questionnaire (WORQ) [English]

Please give an answer that is closest to your opinion for every activity

Date of today:____________________________________
Name:____________________________________
Gender:____________________________________
Date of birth:______________________________

How much difficulty did you experienced with the following activities during the last week because of your knee?

	None 4	Mild 3	Moderate 2	Severe 1	Extreme/unable to perform 0
Crouching?	☐	☐	☐	☐	☐
Kneeling?	☐	☐	☐	☐	☐
Clambering?	☐	☐	☐	☐	☐
Walking on level ground?	☐	☐	☐	☐	☐
Operating a vehicle?	☐	☐	☐	☐	☐
Operating foot pedals?	☐	☐	☐	☐	☐
Sitting?	☐	☐	☐	☐	☐
Walking on rough terrain?	☐	☐	☐	☐	☐
Taking the stairs?	☐	☐	☐	☐	☐
Standing?	☐	☐	☐	☐	☐
Lifting or carrying?	☐	☐	☐	☐	☐
Pushing or pulling?	☐	☐	☐	☐	☐
Working with hands below knee height?	☐	☐	☐	☐	☐

Chapter 7

Total knee arthroplasty and the unforeseen impact on return to work: a cross-sectional multicenter survey.

Kievit AJ, van Geenen RC, Kuijer PPFM, Pahlplatz TM, Blankevoort L, Schafroth MU
J Arthroplasty. 2014 Jun;29(6):1163-8. doi: 10.1016/j.arth.2014.01.004. Epub 2014 Jan 10. PubMed PMID: 24524779.

Abstract

The number of patients receiving a TKA during working life is increasing but little is known about the impact of TKA on patients' reintegration into the workplace. In this cross-sectional survey it was found that 173 of 480 responders worked within 2 years prior to surgery. Sixty-three percent of the working patients stopped within two weeks prior to surgery and 102 patients returned within 6 months. One third never returned to work. Activities that most improved were operating foot pedals, operating vehicles, standing and walking on level terrain. Activities that least improved were kneeling, crouching and clambering. Fifty patients scored 5 or less on the Work Ability Index. Thirty patients were dissatisfied. TKA significantly, but unequally, reduces difficulties in carrying out knee-burdening work activities.

Introduction

Total Knee Arthroplasty (TKA) is highly effective in treating pain caused by rheumatoid arthritis or osteoarthritis of the knee [1]. However, little is known about the impact of TKA on patients' reintegration into the workplace [2,3]. Recently it was found that the combined loss of productivity plus medical costs for conservatively treated symptomatic knee osteoarthritis for those in paid employment in the Netherlands amounts to €871 per patient per month, with loss of productivity accounting for 83% and medical costs for 17% [4]. The impact of this problem on societies is substantial. In the USA, 650,000 TKAs were performed in 2008 and 77,500 in the UK in 2009 [1]. The absolute number of primary TKA being performed is increasing and expected to rise exponentially [1,5]. Currently about 20,000 TKAs are performed in the Netherlands each year but it is estimated that this number will rise to 60,000 a year in 2030 [6]. Historically, TKA has mostly been performed in older retired patients. Recent studies, however, have shown that since 1996 the number of patients aged 45– 65 years who have undergone TKA has tripled [7]. In the United States nearly 1.5 million people of those with a primary TKA are fifty to sixty-nine years old [8]. People nowadays have higher expectations with respect to physical mobility as they age. Moreover, certain lifestyles are leading to an increase in younger patients needing TKA. In addition, the increase of obesity in middle-aged people in the western world, an important risk factor for developing osteoarthritis, will further add to this [9]. Because TKA is now performed on younger people while, at the same time, the age for retirement is expected to rise in the Netherlands and other western countries, patients are more likely to be of working age at the time of surgery.

Most studies on TKA examine surgical measures such as clinical outcome and survival while taking surgical revision as the endpoint. Patient reported outcome measures (PROMs) are becoming more important because these position the patient at the center of an evaluation of surgical treatment. TKA has proven to be highly effective in reducing pain and increasing quality of life. Studies showed that, only 8% of 25,275 patients were dissatisfied regarding their TKA at 2–17 years postoperatively [10]. It was, therefore, expected to be effective in ensuring a timely and sustainable return to work in patients and so reducing loss of productivity for society. For patients, active work participation is an important factor in enhancing quality of life. Patients feel useful to society. It gives structure to day-to-day life [11]. Until now, only a few studies have reported how long it takes for patients to return to work after TKA and then mostly by secondary outcome measures [12–20].

Improved decision making about whether and when it is indicated that a patient should undergo a TKA procedure is needed [1]. If there is more detailed knowledge about the impact of TKA on work, patients and doctors can make more informed decisions about whether TKA is the appropriate treatment to increase the ability to participate at work. More knowledge will also provide a basis to test the potential positive impact of interventions on the return to work.

The questions addressed in this study are, therefore: (1) when do patients stop work because of knee complaints and when do they return to work (RTW) after Total Knee Arthroplasty (TKA)?; (2) are specific knee-burdening work activities improved by surgery?; (3) what do patients report with respect to physical ability and satisfaction after TKA?

Materials and Methods

A multicenter cross-sectional study was performed on data from two centers, the Academic Medical Center (AMC) in Amsterdam and the Amphia hospital in Breda. The Medical Ethics Review Committee of the AMC deemed that the Medical Research Involving Human Subjects Act (WMO) does not apply to the study and official approval was not required.

Patient population

All patients from 2005 on who received a primary Vanguard TKA (Biomet Inc., Warsaw, Indiana, USA) and had a follow-up of at least two years were approached. Surgical details were noted as well as the follow-up period, age at operation, the presence of rheumatoid arthritis or osteoarthritis, ASA classification, diabetes, smoking status, body mass index (BMI) and admittance period.

All patients who were still alive at follow-up were sent an invitation with a reply form to participate either via a web-based questionnaire or a paper-based questionnaire. They could also respond by replying they did not want to participate. Non-responders were contacted by phone at least twice after the first invitation. If no contact was established, the remaining non-responders were sent a paper questionnaire once more.

A link to a digital questionnaire was sent to the e-mail address supplied by the patient. Patients were given a personal code to ensure anonymity of their Internet questionnaires. The use of this code meant that no medical information could be traced back to the patient without the code file that was stored on a secure in-house server at the AMC hospital.

Paper-based questionnaires were sent to the patients' home address. After completing the questionnaires, patients were asked to return them in the stamped addressed envelope provided.

Impact on Work

An 'impact on work' questionnaire named Work, Osteoarthritis or joint-Replacement Questionnaire (WORQ) was developed containing questions about patients' experiences in both paid and voluntary work. In the previous article [21], on the development of the WORQ score the reliability, validity and other measurement properties of the questionnaire are studied and reported.

Only patients who had had been in work within the 2 years prior to surgery were asked to fill out the full questionnaire. The survey contained three sections. The first section contained questions on the type of job, the time when patients stopped working pre-operatively, the time when patients returned to work post-operatively, changes in physically demanding tasks following surgery (less, the same or more), changes in working hours (less, the same or more), the type of job 2 years after surgery and, if patients stopped working, what the reason was for stopping (for instance retirement, knee complaints, other health complaints).

If job titles were reported in enough detail, they were categorized independently by two occupational health experts into light work, medium work or heavy work regarding knee-demanding activities. Both experts are experienced in performing systematic real time task analyzes on the worksite to assess the physical work demands of occupations. The expert classification into light, medium and heavy work was performed using the evidence based exposure criteria for work-relatedness of knee disorders of the Netherlands Center for Occupational Diseases [22]. If disagreement existed this was resolved by discussion.

The second section of the questionnaire contained questions to assess difficulty with knee-burdening activities at work at three points in time: (T0) before the knee problems arose, (T1) within three months before TKA and (T2) at two years after TKA. The WORQ score resulting from a sum of these difficulties ranges from 0 (worst score) to 100 (the best score, no difficulties at all) and showed the impact of TKA on knee-burdening activities in patients who did return to work. This score is validated in a previous report on the WORQ.

The third section of the questionnaire contained the single item: ‘current physical work ability’ from the Work Ability Index (WAI [23,24]) on a scale from 0 ‘completely unable to work’ to 10 ‘work ability normal’. Patients were also presented with the statement – I am satisfied with my ability to work with respect to my TKA – and were asked to choose the following answers: strongly disagree, disagree, neither agree nor disagree, agree, strongly agree. The answer was scored respectively 0 to 4 on a Likert scale.

Statistical analysis

Standard descriptive statistics were used to describe demographic data and baseline characteristics. For normally distributed variables, unpaired t-tests were used. Mann–Whitney tests were used for continuous non-normally distributed variables and chi-square tests for dichotomous variables to test for differences between working and non-working TKA patients at baseline. The effectiveness of TKA in reducing patients' difficulty performing specific knee-burdening activities was evaluated. The results are given in percentage of score improvement between three months before the TKA (T1) and two years after TKA (T2) and sorted from most improvement to least. The difference in scores between T1 and T2 was tested non-parametrically with paired testing. All analyzes were done using SPSS 20.0 statistics software (IBM, Armonk, New York, USA). A P value b 0.05 was considered statistically significant.

Results

A preliminary review of all TKA patients from both hospitals resulted in 807 suitable to approach. The 764 patients who were still alive received an invitation to participate to which 558 (73%) responded (Fig. 1). Seventy-eight patients declined and 480 filled out a questionnaire. The questionnaires revealed that 173 were in work within two years prior to surgery. From the 137 interpretable job types, 48% performed light work, 32% performed medium work and 20% performed heavy work regarding knee-burdening activities in their previous work life. The average age of patients included in the study group was 60 (SD 9) with a gender distribution that was fifty-fifty (Table 1).

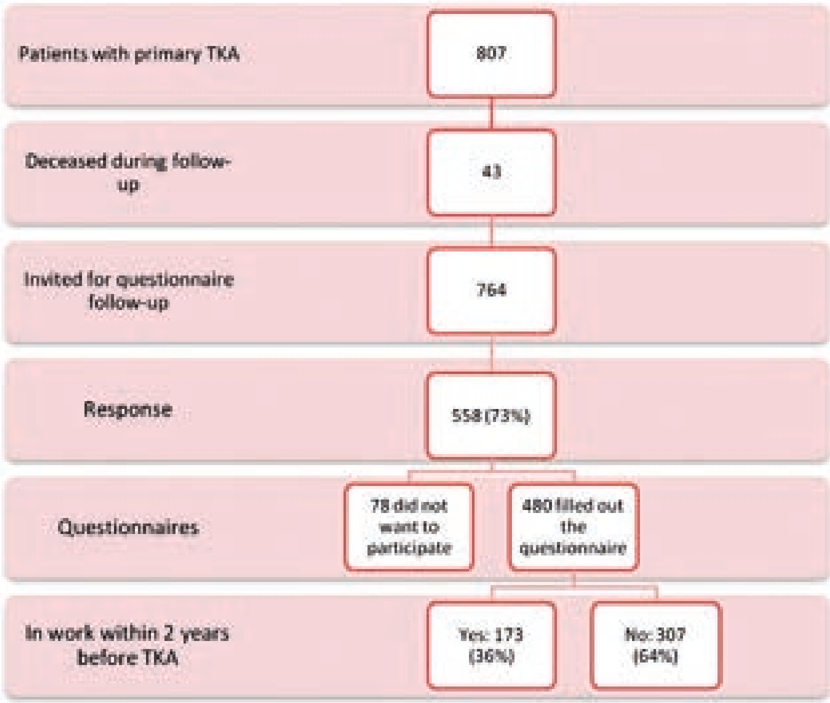

Fig. 1. Flow chart of inclusion of patient group.

		All n=480	Work n=173 (36%)	No work n=307 (64%)	P-value
Age (Years) mean (SD)		66.0 (9.7)	**60.1 (8.6)**	69.3 (8.6)	0.000 a
BMI (kg/m2) mean (SD)		29.4 (4.6)	**29.5(4.7)**	29.3 (4.5)	0.730 a
Follow-up mean (SD)		3.8 (1.2)	**3.8 (1.3)**	3.7 (1.2)	0.297 a
Hospitalization period in days median (range)		6 (2-38)	**5 (3-30)**	6 (2-38)	0.094 b
		N (%)	**N (%)**	N (%)	
Gender	Male	179 (37.3)	**85 (49.1)**	94 (30.6)	
	Female	301 (63.7)	**88 (50.9)**	213 (69.4)	0.000 c
ASA	1 or 2	374 (80.3)	**148 (87.1)**	226 (76.4)	
	3 or 4	92 (19.7)	**22 (12.9)**	70 (23.6)	0.005 c
Smoking at operation	No	411 (85.6)	**142 (82.1)**	269 (87.6)	
	Yes	69 (14.4)	**31 (17.9)**	38 (12.4)	0.105 c
Diabetes at operation	No	423 (88.1)	**160 (92.5)**	263 (85.7)	
	Yes	57 (11.9)	**13 (7.5)**	44 (14.3)	0.028 c
Rheumatoid arthritis at operation	No	457 (95.2)	**170 (98.3)**	287 (93.5)	
	Yes	23 (4.8)	**3 (1.7)**	30 (6.5)	0.024 c
a. T-test, b. Mann-Whitney, c. Chi-square					

Table 1 Baseline Characteristics of All Patients Who Worked as Well as Patients Who Did Not Work Within 2 Years Prior to Surgery.

Stopping and returning to work

Of the 173 patients who worked in the 2 years before TKA, 29 patients stopped at least 6 months prior to the operation and this rose to 40 at three months prior to the operation. After surgery 117 (68%) patients returned to work of which 59 had returned to work within three months after TKA and by six months this rose to 102. After surgery 49 patients never returned to work (Figs. 2 and 3). There was no significant correlation between the physical demands of jobs and the timing of stopping or returning to work.

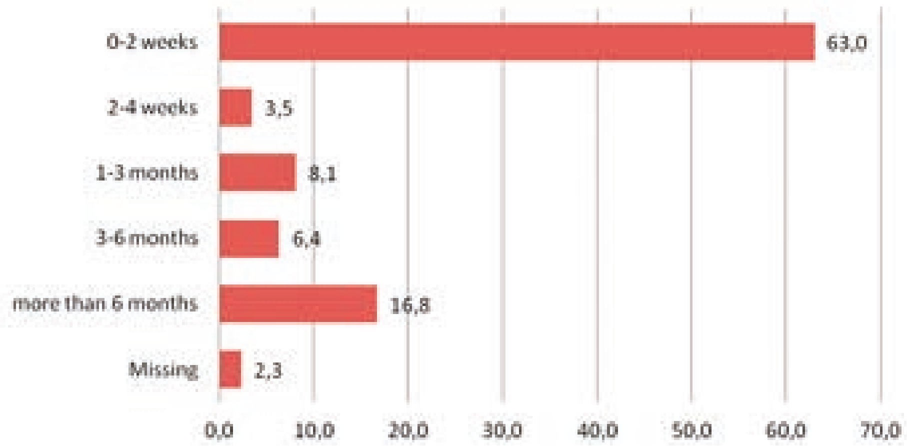

Fig. 2. Time when patients stopped work before total knee arthroplasty in % (N=173).

Fig. 3. Time when patients resumed work after total knee arthroplasty in % (N=173).

Changes in physical burden at work

Of the 117 patients that returned to work, 19 had a less physically demanding job, 78 had an equally physically demanding job and nine had a more physically demanding job after TKA as compared to before TKA (11 patients had unclear or missing answers). In addition, nine of the patients worked fewer hours, 94 worked the same amount of hours and five worked more hours after TKA (nine patients had unclear or missing answers).

At the time of filling in the questionnaire, at a mean of 3.8 (SD 1.3) years after surgery, 70 patients were still working, 89 patients no longer worked of which 11 patients blamed their TKA, 49 patients had retired, 17 blamed other physical complaints and 12 reported other reasons. Fourteen patients left this question unanswered. Most patients that still worked had the same job but eight patients worked in a different type of job.

The mean difficulty score per activity (Fig. 4) shows the impact of the arthritic knee or the knee after TKA on the difficulty experienced performing knee-burdening activities. Overall, at 2 years after surgery, patients experienced significantly less difficulty performing such activities compared to the 3 months prior to surgery (*P* =b .005). Activities that improved most after TKA were operating foot pedals (53% score improvement), operating a vehicle (48%) and walking on level terrain (48%). Activities that least improved by TKA were kneeling (19% score improvement), crouching (22%) and clambering (30%).

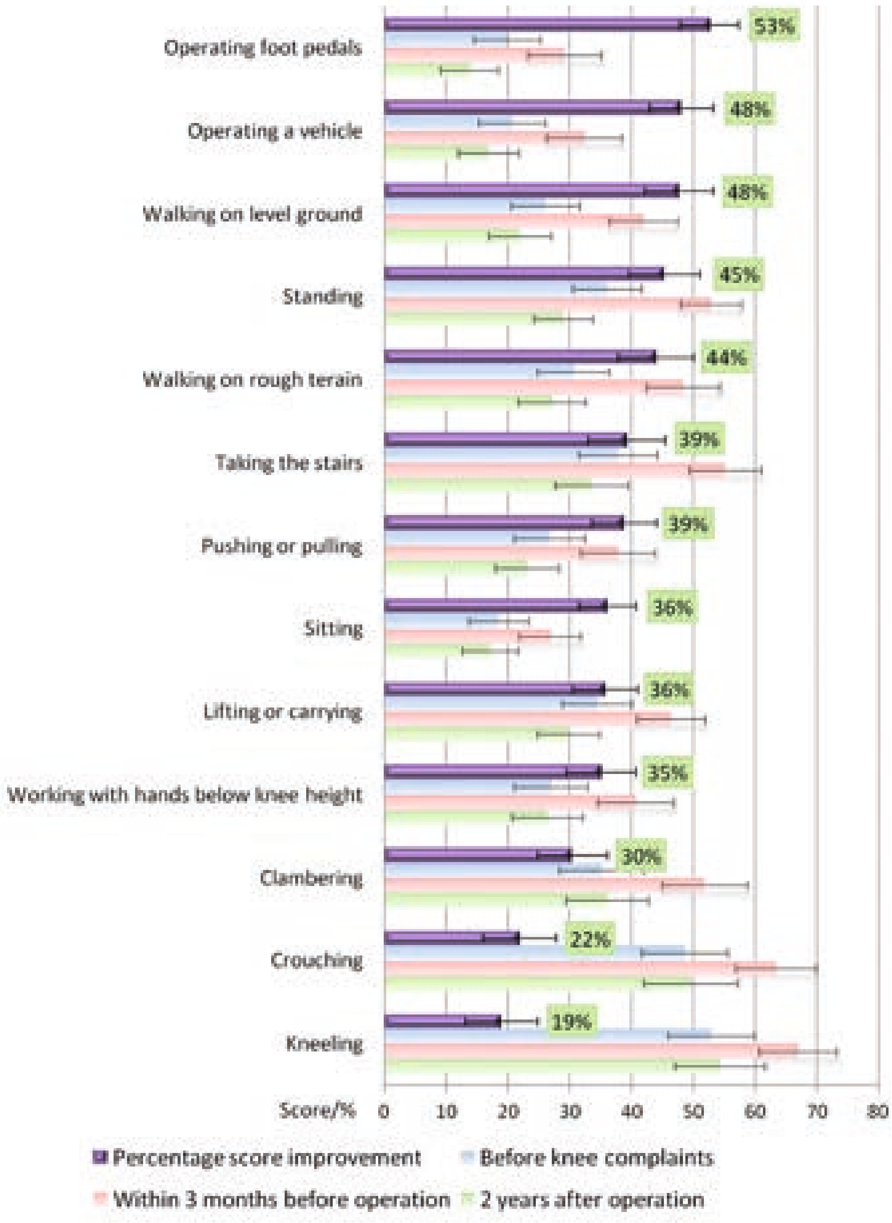

Fig. 4. Mean difficulty scores for specific knee-burdening activities at 3 intervals: T0 (before the knee problems arose); T1 (within three months before TKA); and T2 (at two years after TKA). Scale 0–100 with 95% CI, for T0, T1 and T2 — dimmed bars: purple bar % score core improvement between T0 and T2.

Further details of sum scores for specific subgroups of patients are shown in the casemix table (Table 2).

	Mean scores (95% confidence interval) for:	Before operation	N=	Missing scores	2 years post-op	N=	Missing scores
Gender	Male	54 (49-58)	82	0	69 (64-75)	63	4
	Female	55 (50-60)	85	2	69 (63-75)	58	3
Age	<55	48 (38-57)	26	0	68 (56-80)	21	0
	55-65	51 (46-56)	75	2	70 (66-74)	59	3
	65-75	62 (56-68)	54	0	73 (66-81)*	34	3
	>75	52 (41-62)	12	0	45 (24-65)*	7	1
Work Ability Index score	Above 6	55 (51-59)	103	1	74 (70-78)	87	2
	Below 6	49 (43-56)	50	0	49 (40-57)*	23	0
Satisfied with knee specific working capability	Yes	56 (52-60)	136	0	73 (69-76)	103	4
	No	46 (38-54)	30	1	46 (35-57)*	17	2
Primary indication	Osteoarthritis	56 (52-59)	144	2	69 (65-73)	105	6
	Reumatoid arthritis	53 (26-79	3	0	45 (2-89)*	2	0
	Post-traumatic osteoarthritis	37 (13-60)	5	0	73 (48-98)	3	0
	Secundary osteoarthritis	35 (25-44)	4	0	65 (30-99)	3	0
	Osteoarthritis post osteotomy	54 (40-40)	11	0	76 (62-91)	8	1
Diabetes	No	55 (51-58)	155	2	71 (67-75)	112	7
	Yes	52 (42-63)	12	0	49 (37-62)*	9	0
Obese (BMI>30)	No	52 (47-56)	96	1	70 (65-75)	71	5
	Yes	58 (52-64)	68	1	69 (63-75)*	47	2
ASA	1 or 2	54 (50-57)	144	2	70 (66-74)	106	7
	3 or 4	60 (51-70)	20	0	63 (52-75)*	13	0
Smoker at operation	No	55 (51-59)	136	2	68 (64-72)	99	6
	Yes	51 (43-60)	31	0	74 (67-82)	22	1
Type of work 3months before operation	Light work	57 (51-62)	66	1	70 (64-76)	53	2
	Medium work	57 (51-63)	44	0	72 (64-79)	25	0
	Heavy work	48 (39-57)	27	0	73 (65-80)	22	2

*** is a change that is not clinically relevant. A score that improved more than 13 points is seen as a clinically relevant change on the WORQ questionnaire.**

Table 2. Casemix Table Showing WORQ Scores for Different Subgroups of Patients at Three Months Prior to Surgery and 2 Years After Surgery.

Patients' opinion about their physical ability to work

After surgery, 50 patients scored a 5 or lower on the WAI to describe their physical work ability. The mean score was 6.2 (95% CI 5.8 to 6.7). To the statement "I am satisfied with my ability to work with respect to my TKA", 30 patients answered that they either disagreed or strongly disagreed which meant they were (strongly) dissatisfied.

Discussion

The most important outcome of this study is that of the patients who were in work before TKA surgery, only 68% returned to work after TKA and of the patients not returning to work 11 reported that this was because of their TKA. In addition, 50 of 173 TKA patients gave a score of 5 or lower for their ability to work and 30 (17%) were (strongly) dissatisfied with their ability to work because of their TKA. The satisfaction for working patients is twice as low as expected based on previously reported 8% dissatisfied patients following TKA [10].

A literature search was performed to find what other studies reported about 'return to work' after TKA. The search terms 'Return to work AND "Arthroplasty"[Mesh]' were used and this yielded 68 studies. Nine studies were eventually found that specifically reported on 'return to work' after TKA [12–20]. The information was mostly limited to the percentage of patients who returned to work and at what point in time. On average, 70% of patients returned to work at some point during follow-up (Table 3).

Our present study showed a similar percentage. Both hospitals in our study are large regional expertise centers that generally have a mixed patient population with normal patients as well as some patients requiring additional expertise due to less common comorbidities like gross deformities, hemophilia, sickle-cells disease or a post-kidney transplantation condition. If the other studies included less specialized hospitals this could entail a more healthy patient population with a better prognosis for return to work.

Author	Journal	Pubmed ID	Year	Age at operation of patients with TKA	Total number of patients with TKA	Patients working pre-op	Number of patients returning to work post-op (%)	Median of RTW in weeks	RTW assessed at
Clyde et al.	J Arthroplasty	23583541	2013	55	98	98	64 (65)	15.5 (N=98, mean)	17-125 months
Husted et al.	J Bone Joint Surg Br.	21357957	2011	68.3	421	82	46 (56)	-*	24 months
Styron et al.	J Bone Joint Surg Am.	21209263	2011	57.0	162	162	122 (75)	8,9 (N=162)	3 months
Foote et al.	Knee	19632120	2009	54.1	41	27	23 (85)	12 (N=27)	14-61 months
Lombardi et al.	Clin Orthop Relat Res.	19225852	2009	62.0*	103*	-*	-*	8 (N=103)	2-52 months
Walton et al.	J Knee Surg.	16642887	2006	71.5	120	21	17 (81%)	-*	
Jorn et al.	Acta Orthop Scand.	10569263	1999	56.0	162	88	52 (59)	(54% within 26 weeks)	2 years post surgery
Nielsen et al.	Ugeskr Laeger.	10434787	1999	-*	926	51	40 (78)	-*	1 year post surgery
Weingarten et al	Am J Med.	9688019	1998	69.7	287	50.56	41 (81)	-*	3-5 months
Summary / mean				**Weighted mean 64.5**	**Total 2217**	**Total 580**	**Total 405 (70)**	**Weighted mean 10.5**	
Present study			2013	60,1	480	173	121 (70)	50,4% within 12 weeks	24-86 months

* = not used for the column sum/mean in the summary/mean row.

Table 3. ‘Return to Work’ Following Total Knee Arthroplasty (Primary, Revision or Uni-Knee Arthroplasties) According to Other Studies.

None of the studies we looked at described the impact of TKA on specific knee-burdening activities, so our results could not be compared to other studies. The impact of TKA on the difficulty patients experienced performing knee-burdensome activities, was clear and we found that surgery resulted in patients' scoring a level comparable to the period before their knee complaints started. TKA can, therefore, be considered to contribute to increasing the ability to work. However, even though patients reported reduced difficulty in performing all activities, the improvement was not equally great for every activity. Patients with work that requires a lot of kneeling, crouching and clambering benefit less from TKA. Our results imply that patients whose work requires bending or kneeling on the ground, for instance plumbers, floor layers and gardeners, should be warned that TKA may relieve the pain but only marginally improve difficulty in performing these tasks. This might be because a TKA has a limited range of movement (ROM) compared to a normal knee. High flex knee TKA designs might be considered in these patients although they have not yet proven to add much more flexion until now [25]. In our previous report on the questionnaire a clinically significant improvement was an improvement of at least 13 points on the WORQ questionnaire. It is interesting to note that it seems that patients that returned to work with age above 65, diabetes, obesity, ASA 3 or 4 or rheumatoid arthritis seems not to have a clinically relevant improvement with respect to their total WORQ score (Table 2). This might suggest that other limiting factors play a more important role for these patients although the numbers reported here are small.

The patients who benefit most from TKA are those whose work involves operating a vehicle, like taxi or lorry drivers, or who have a job which requires periods of standing or walking on level ground, for instance working in a bar, as a postman or as a warehouse worker. For these activities, the ROM is less important whereas pain reduction is likely to play a more important role.

Of the study group 50 patients scored a 5 or lower on the WAI to describe their physical work ability, which can be considered an unsatisfactory result. There were no studies that looked at the WAI in patients with knee osteoarthritis or after TKA so it is hard to put this aspect in perspective. To the statement – I am satisfied with my ability to work with respect to my TKA – 30 (17%) patients stated they were (strongly) dissatisfied. It has been reported that 8% of patients are dissatisfied with the outcome at 2–17 years [10]. It seems that with respect to the ability to work, patients are far less satisfied with the result of TKA.

Limitations

The rating of the knee burdening activities section of the questionnaire we developed was new and although validated in our previous report not yet broadly used. As this is a novel field of research there are no other validated questionnaires that could be used. A second issue is the retrospective nature of reports by patients about their 'return to work'. Hence, there is a potential for recall bias in the results. This is why categories were made with respect to the time interval for return to work instead of an exact amount in weeks or months. It is assumed that patients are able to assess work specific tasks at three different and distinct time points. In future research, the questionnaire will be given to patients pre-operatively and at regular follow-up moments to generate more precise results.

Strengths

Our patient group is thought to be large and varied enough to give a representative picture of the impact of TKA in the Netherlands on ‘return to work’. Patients came from two different areas in the Netherlands, which improves the external validity of the results. To ensure that the results are adequate and interpretable, the questionnaire was carefully developed and validated by a team that consisted of orthopedic and occupational health experts as well as the patient population itself. The WAI was introduced in 1997 [23,24] and has been proven reliable [26] and the single item has a moderate predictive validity for return to physically demanding work [27]. The purpose of the WORQ was to obtain an adequate range to discover which of work related activities remain difficult to perform and which benefit most from TKA. We believe it has proven adequate to answer our research questions.

Clinical and public health implications

It is increasingly important for society that people are able to work longer. Pension funds suffer because of lower contributions from a decreasing work force while the burden to pay out increases as a greater proportion of the population retire and pensioners live longer. It is known that the aspects of high motivation, being female and being self-employed accelerate early return to work while having less pain pre-operatively, having a physically demanding job and receiving sick pay are decelerators [13]. Further research should, however, not only focus on when patients ‘return to work’ but also on how well they are able to perform work. It will be useful to find out more about predictors for adequate ‘return to work’ and which limitations patients perceive in their work with respect to their knee function. Multidisciplinary interventions, such as guidance by an occupational health physician or advice to tailor work activities temporarily, can then be evaluated to ensure speedier and more sustainable return to work for a group of patients that is likely to increase substantially in the upcoming decades. By improving TKA outcome with respect to the ability to work, patients can expect more fulfilment and a better quality of life. This will potentially benefit not only patients of working age but also employers and, ultimately, society as a whole by reducing costs related to sick leave, early retirement and diminished productivity. Thereby, the cost-effectiveness of TKA surgery is likely to increase substantially from society’s perspective.

Conclusion

TKA reduces pain and improves function but has a less positive impact on return to work than we expected: in fact one third of patients do not return to work. TKA significantly, but unequally, reduces difficulties in carrying out knee-burdensome work activities and a considerable percentage of patients reported impaired ability to work and that they were dissatisfied with their level of ability to perform work. A holistic approach to TKA that includes adequate work-related support and a flexible attitude to tailoring work interventions to what is feasible for a specific TKA patients will be vital to ensure a timely and sustainable 'return to work' in a patient group that is likely to increase substantially in the coming decades.

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Conflict of Interest

No benefits in any form have been received or will be received from a commercial party related directly or indirectly to the subject of this article.

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Chapter 8

Patients Return To Work Sooner after Unicompartmental Knee Arthroplasty than after Total Knee Arthroplasty

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Abstract

Purpose It is not yet known if unicompartmental knee arthroplasty (UKA) patients are more likely to return to work sooner or have improved ability to work (i.e., workability) than total knee arthroplasty (TKA) patients. The following questions were addressed: patients were assessed to determine: (1) whether they returned to work sooner following UKA compared to TKA; (2) whether UKA patients had better WORQ function scores compared to TKA patients; and (3) if UKA patients have higher workability scores and greater satisfaction regarding workability than TKA patients.

Methods A multicenter retrospective cohort study was performed that included patients at least 2 years after having undergone either UKA or TKA surgery and on the condition that patients had been in work in the 2 years prior to surgery. Time period between stopping work and returning to work was assessed; the WORQ scores (0 = worst–100 = best) and the Work Ability Index (WAI = 0–10) and reported satisfaction with work ability.

Results UKA patients (n = 157, median 60 years, 51% male) were compared to TKA patients (n = 167, median 60 years, 49% male) (n.s.). Of the 157 UKA patients, 115 (73%) returned to work within 2 years compared to 121 (72%) of TKA patients (n.s.). More UKA patients return to work within 3 months (73% versus 48%) ($p < 0.01$). WORQ scores improved similarly in both groups. The WAI was also comparable between the groups. Dissatisfaction with workability was comparable (UKA 15% versus TKA 18% (n.s.).

Conclusion TKA and UKA patients have similar WORQ, WAI, and satisfaction scores. However, in this study population, UKA patients to return to work after surgery significantly sooner than TKA patients, which improves their quality of life and allows them to participate actively in society. This information can help health care providers and patients weigh-up the pros and cons and choose the best treatment and timing for patients in the working population.

Introduction

Knee arthroplasty is highly effective in treating pain caused by osteoarthritis of the knee [3]. However, recently, it was found that total knee arthroplasty (TKA) has a less positive impact on return to work than expected; in fact, one-third of patients do not return to work [14]. TKA does allow carrying out some knee-burdensome work activities, but a considerable percentage of TKA patients reported impaired ability to work and that they were dissatisfied with their level of ability to work. This is important as active work participation is an important factor in enhancing patients' quality of life and it gives structure to day-to-day life [47].

In the 1970s, the medial unicompartmental knee arthroplasty (UKA) was introduced. The UKA is a less invasive procedure and an attractive alternative to TKA, because the natural biomechanics of the knee are largely preserved, whereas in (TKA), the anterior cruciate ligament is sacrificed and the biomechanics change substantially [20]. This might contribute to better postoperative clinical outcomes following UKA compared to TKA [29]. Recently, it was also reported that UKA yields better range of motion than TKA in patients less than 65 years of age [15]. Furthermore, less intraoperative complications such as blood transfusion, stroke, thromboembolism, and myocardial infarction have been reported for UKA [23]. UKA shows promising results in increasing speed of recovery and outpatient surgery programs with good satisfaction and high activity levels [46]. Therefore, UKA is expected to improve patients' return to work and so reduce loss of productivity for society.

The absolute number of primary TKA currently being performed is increasing and expected to rise exponentially [3, 21, 32], largely due to the obesity epidemic. Because knee arthroplasty (KA) is being performed on younger people, while, at the same time, the age for retirement is predicted to rise in The Netherlands and other western countries, KA patients are more likely to be of working age at the time of surgery. Furthermore, the number of UKA's being implanted is increasing at a higher rate than that of TKA [33].

If there is more detailed knowledge about the impact of UKA on work, patients and doctors can make more informed decisions about whether UKA or TKA is the most appropriate choice to increase the ability to participate at work. It is hypothesized that UKA patients return to work sooner have better WORQ scores and higher workability and satisfaction levels than TKA patients. Therefore, the questions addressed in this study are: (1) do patients return to work sooner following UKA compared to TKA; (2) do UKA patients have better WORQ function scores compared to TKA; and (3) do UKA patients have higher workability scores and satisfaction regarding workability than TKA patients?

Materials and methods

The materials and methods were the same as a previous study on TKA patients performed by the same research collaboration [13, 14]. The Medical Ethics Review Committee of the Amsterdam University Medical Center deemed that the Medical Research Involving Human Subjects Act (WMO) does not apply to the study and official approval was not required. (Part of return to work initiative, approval ID W13_019# 13.7.0037).

In short, a multicenter cross-sectional study was performed in which the survival of the Vanguard TKA (Zimmer Biomet Inc., Warsaw, Indiana, USA) was assessed, since start of use both for survival as well as return to work. This TKA study was performed in two large teaching hospitals in The Netherlands, the Amsterdam UMC—location Academic Medical Center (AMC) in Amsterdam and the Amphia Hospital in Breda. In this present cross-sectional study, in addition, data on UKA patients from the Amphia Hospital were collected. The AMC does not perform the UKA procedure. The Medical Ethics Review Committee again deemed that the Medical Research Involving Human Subjects Act (WMO) did not apply to this study and official approval was not required. All patients did provide informed consent. The newly gathered data from the UKA patients and were compared to the data from the above-mentioned study on TKA performed in the same centers in The Netherlands using the same methods [13, 14]. The goal of this study is to inform health professionals about work ability and return to work following UKA. As little is known about the topic, all TKA patients from the same centers, in the same period with the same data, are shown for the purpose of reference.

Patient population

As little is known on return to work in UKA patients, the goal was to include as many patients as possible in the study period to have a comparable group size as the TKA study (n = 167). All patients who received a primary Oxford UKA (Zimmer Biomet Inc., Warsaw, Indiana, USA), since the start of use in January 2003 until January 2012 that also had a follow-up of at least 2 years was approached. The indication for UKA was anteromedial osteoarthritis with intact cruciate and collateral ligaments. Similar as in the TKA study, they had to have work (paid or voluntary) within 2 years prior to surgery. For all patients, the following characteristics were collected: age at operation, sex, body mass index (BMI), diabetes, smoking status, admittance period, and ASA classification.

All patients who were still alive at follow-up were sent an invitation with a reply form to participate either via a webbased questionnaire or a paper-based questionnaire. Patients who were deceased were excluded. They could also respond by replying that they did not want to participate. Nonresponders were contacted by phone at least twice after the first invitation. If no contact was established, the remaining non-responders were sent a paper questionnaire once more. A link to a digital questionnaire was sent to the e-mail address supplied by the patient. Patients were given a personal code to ensure anonymity of their Internet questionnaires. The use of this code meant that no medical information could be traced back to the patient without the code file that was stored on a secure in-house server. Paper-based questionnaires were sent to the patients' home address. After completing the questionnaires, patients were asked to return them in the stamped addressed envelope provided.

Impact on work

First, all patients were assessed for baseline characteristics. As mentioned previously, only patients who reported that they had been in work during the 2 years prior to surgery were asked to fill out the full questionnaire. The survey contained three sections. The first section contained questions on the type of job, the time when patients stopped working pre-operatively, the time when patients returned to work post-operatively, changes in the kind of physically demanding tasks following surgery (less, the same, or more), changes in working hours (less, the same or more), the type of job performed 2 years after surgery, and if patients stopped working, what the reason was for stopping (for instance retirement, knee complaints or other health complaints).

If job descriptions were reported in enough detail, patients were categorized independently by two occupational health experts with respect to knee-burdensome activities into: light work, medium work, or heavy work. Both experts were experienced in performing systematic real-time task analyzes in the workplace to assess the physical demands of work in different occupations. The classification by experts into light, medium, and heavy work was performed using the evidence-based exposure criteria for work relatedness of knee disorders of The Netherlands Center for Occupational Diseases [19]. If disagreement existed, this was resolved by discussion between experts. Examples of jobs classified as light work are a hairdresser or receptionist; examples of medium work are lorry drivers or household workers, and examples of heavy work are bricklayers or farmers.

The second part of the survey consisted of the previously validated Work, Osteoarthritis, or joint-Replacement Questionnaire (WORQ) [12]. The WORQ was tested for internal consistency by factor analysis resulting in two main factors, "Knee coordination", and "Strenuous knee flexion" that both had high reliabilities, with Cronbach's α of, respectively, 0.90 and 0.85. Cronbach's α for the total score was 0.90. A test–retest reproducibility was performed for analyzing standard error of measurement (SEM agreement which was 3.43), reliability (ICC was 0.97), and smallest detectable change (SDC) in individuals (being 9.52) and groups (being 1.42). Finally, responsiveness was analyzed and reported by standardized response means (SRM was 0.70), and floor (less than 1%) and ceiling (8.8%) effects were deemed absent, as it was less than 15% and interpretability as minimal important change (MIC was 13) [12]. The survey contained questions to assess difficulty in performing knee-burdensome work activities at three points in time. This were: (T0) before the knee problems arose (T1) within 3 months before UKA or TKA and (T2) at 2 years after UKA or TKA. The WORQ score resulting from the sum of these difficulties ranges from 0 (worst score) to 100 (the best score, no difficulty at all) and showed the impact of UKA or TKA on knee-burdening activities in those patients who did return to work.

The third section of the questionnaire contained the single item: 'current physical work ability' from the Work Ability Index (WAI [41, 42]) on a scale from 0 'completely unable to work' to 10 'work ability normal'. Patients were also presented with the statement—*I am satisfied with my ability to work with respect to my TKA or UKA*—and were asked to choose one of the following answers: strongly disagree, disagree, neither agree nor disagree, agree, and strongly agree. Their answer was scored, respectively, 0–4 on a Likert scale.

Statistical analysis
Standard descriptive statistics were used to describe demographic data and baseline characteristics. For normally distributed variables, unpaired *t* tests were used to compare the UKA and TKA groups. Mann–Whitney tests were used for continuous non-normally distributed variables and Chi-square tests for dichotomous variables to test for differences between TKA and UKA patients at baseline. The effectiveness of UKA in reducing patients' difficulty in performing specific kneeburdensome activities was evaluated. The results are given in percentage of score improvement between 3 months before the UKA (T1) and 2 years after UKA (T2) and sorted from most improvement to least. The difference in scores between T1 and T2 was tested non-parametrically with paired testing. All analyzes were done using SPSS 25.0 statistics software (IBM, Armonk, New York, USA). A *P* value <0.05 was considered statistically significant.

Results

Of all, TKA patients from both hospitals resulted in 807 suitable to approach. The 764 patients who were still alive received an invitation to participate, 558 (73%) responded, 78 patients declined, and 480 filled out a questionnaire. This resulted in a group of 167 TKA patients with work within 2 years prior to surgery—median 60 years, range 40–84, 49%:51%, respectively, male:female. Of the 501 eligible UKA patients, 52 patients had since died, and 449 were approached of which 315 (70%) responded. Fifty-two patients declined and 263 filled out a questionnaire. This resulted in a group of 157 eligible patients with work within 2 years prior to surgery—median 60 years, range 40–83, 51%:49% male:female. Baseline characteristics and comparison between groups are given in Table 1.

		TKA n=167	UKA n=157	P-value
Age (Years) mean (SD)		**60.1 (8)**	60 (7)	n.s
BMI (kg/m2) mean (SD)		**29.5(4.7)**	30.7 (5.1)	n.s
Follow-up mean (SD)		**3.8 (1.3)**	3.4 (1)	n.s
		N (%)		
Gender	Male	**82 (49.1)**	78 (51%)	n.s
	Female	**85 (50.9)**	75 (49%)	n.s
ASA	1 or 2	**148 (87.1)**	126 (92%)	n.s
	3 or 4	**22 (12.9)**	11 (8%)	n.s
Smoking at operation	No	**142 (82.1)**	100 (83%)	n.s
	Yes	**31 (17.9)**	21 (17%)	n.s
Diabetes at operation	No	**160 (92.5)**	99 (82%)	n.s
	Yes	**13 (7.5)**	22 (18%)	n.s
Rheumatoid arthritis at operation	No	**170 (98.3)**	120 (99%)	n.s
	Yes	**3 (1.7)**	1 (1%)	n.s.
T-test, b. Mann-Whitney, c. Chi-square				

Table 1. Baseline characteristics of all TKA and UKA patients who worked within 2 years prior to surgery.

From the 137 interpretable job types in the TKA group, 66 (48%) performed light work, 44 (32%) performed medium work, and 27 (20%) performed heavy work regarding knee-burdening work-related activities [14].

The job types performed by UKA patients before surgery that could be classified were as follows: *n* = 110 divided into 58 (53%) light work, 30 (27%) medium work, and 22 (20%) heavy work in the sense of knee-burdensome activities.

Stopping and returning to work

Of all 157 UKA patients, a total of 117 (75%) returned to work. Notably, of these 117 patients, 32 (27%) returned within 4 weeks and a further 85 (73%) within just 3 months (Figure 1). Of all 167 TKA patients 122 (72%) returned to work but only 8 (7%) returned within 4 weeks and only a further 59 (49%) within 3 months (Figure 2). The % of patients who eventually returned to work after two years was almost the same for both groups. However, the UKA patients returned to work significantly sooner than TKA patients ($p < 0.01$).

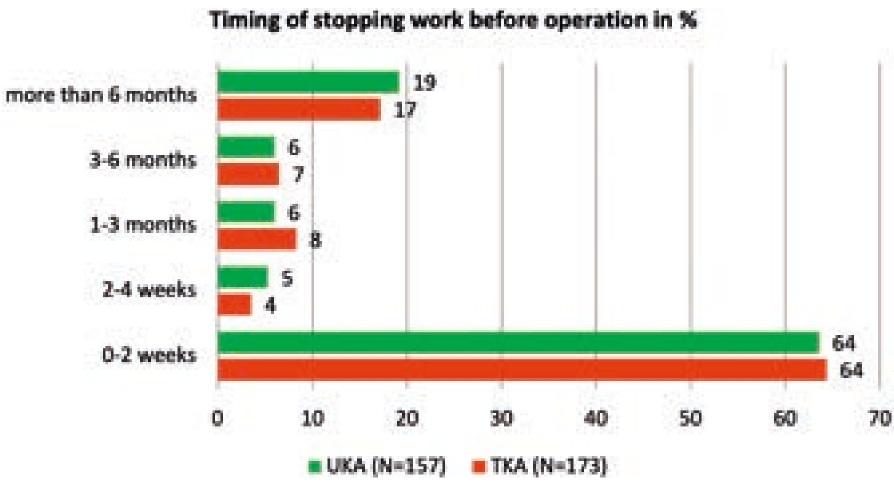

Figure 1. Time when patients stopped work before uni and total knee arthroplasty in %

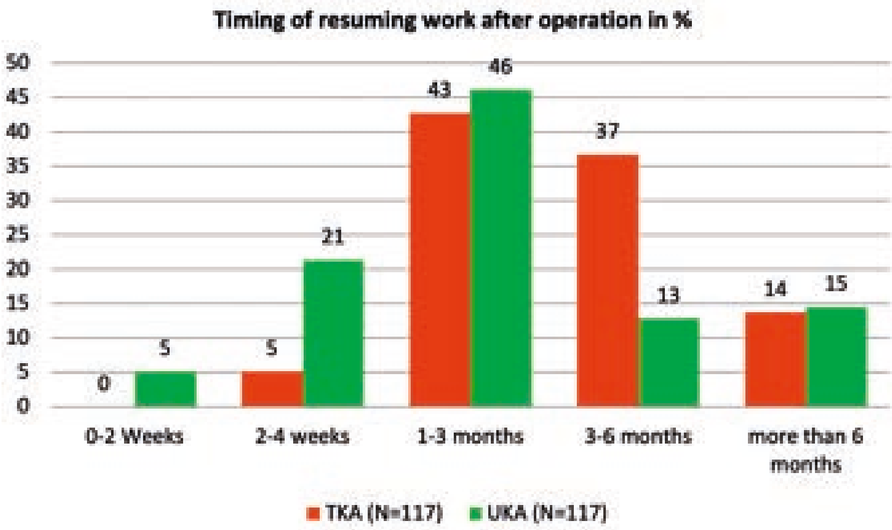

Figure 2. Time when patients resumed work after uni and total knee arthroplasty in %

Changes in physical burden at work

Of the 117 UKA patients who returned to work, 18 (15%) had a less, 58 (50%) an equally and 17 (15%) a more physically demanding job after UKA. In addition, 15 (13%) of the patients worked fewer, 73 (62%) worked the same, and 3 (3%) worked more hours after UKA.

Of the 40 patients who did not return to work, six (15%) patients blamed their UKA (compared to 11% of TKA patients [14]), 21 (53%) patients had retired, 5 (13%) blamed other physical complaints, and 4 (10%) reported other reasons. Most patients returned to the same job (TKA 82% and UKA 75%).

Overall, in both groups, at 2 years after surgery, patients experienced significantly less difficulty performing activities compared to the 3 months prior to surgery ($P \leqslant 0.01$). Median WORQ scores improved similarly between the two groups from 56 to 77 (+ 21) for UKA versus 54–71 (+ 17) for TKA patients, and post-operative scores did not differ significantly (n.s.). Improvement in scores for specific activities is given in Figs. 3 and 4, and differences were non-significant.

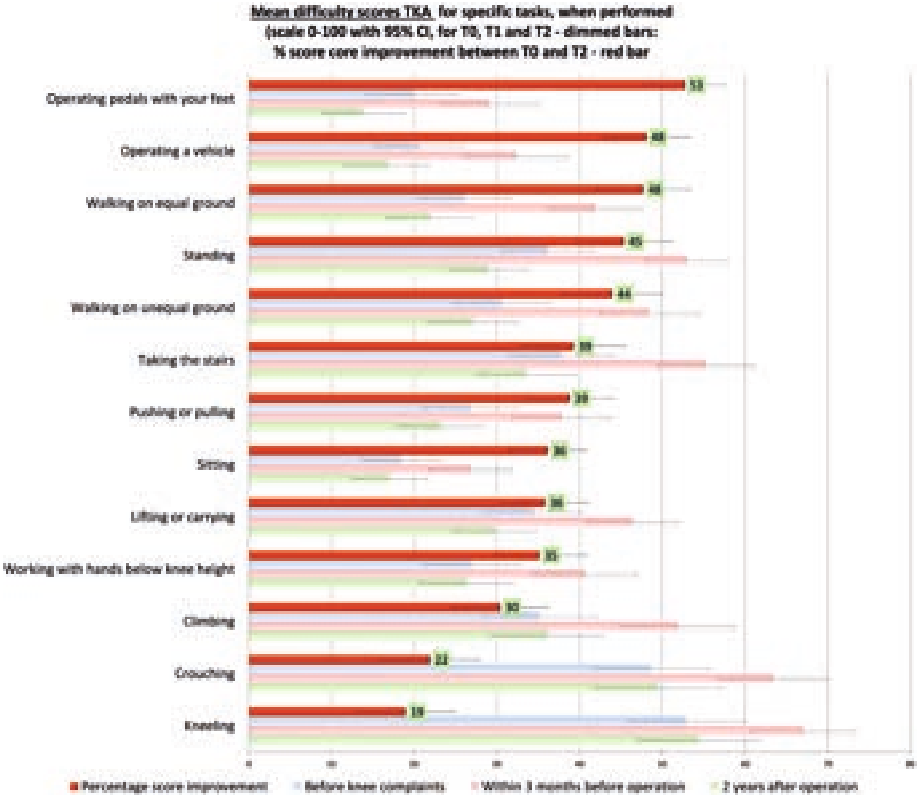

Figure 3. Mean difficulty scores for specific knee-burdening activities at 3 intervals: T0 (before the knee problems arose); T1 (within three months before TKA) and; T2 (at two years after TKA). Scale 0-100 with 95% CI, for T0, T1 and T2 dimmed bars: red bar % score improvement between T0 and T2

8

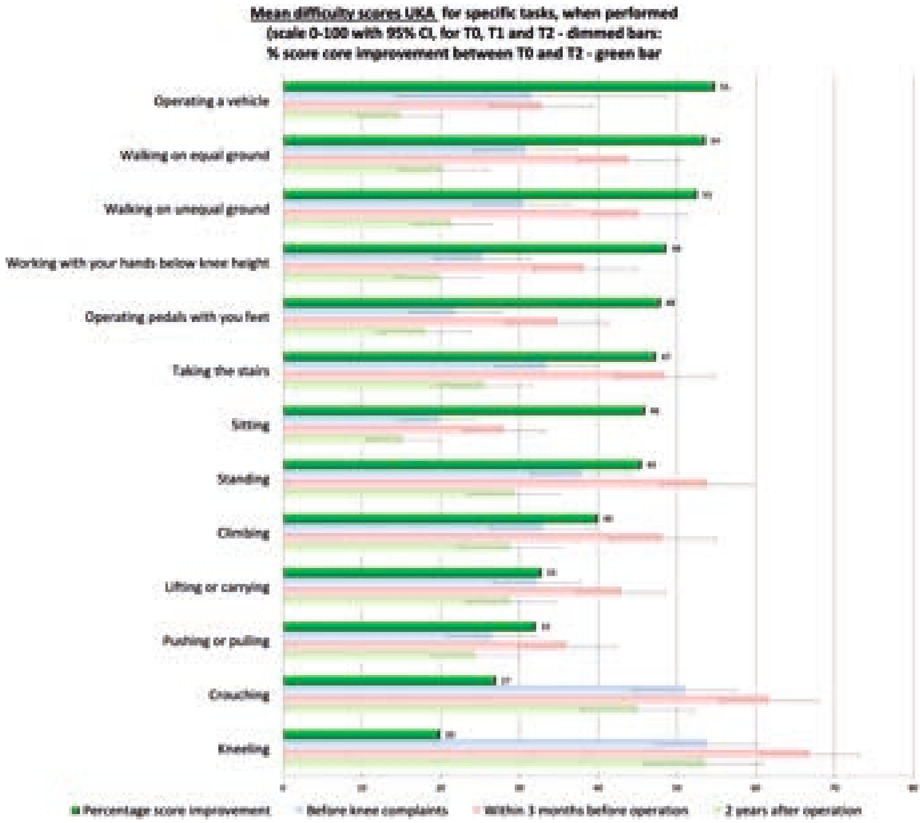

Figure 4. Mean difficulty scores for specific knee-burdening activities at 3 intervals: T0 (before the knee problems arose); T1 (within three months before UKA) and; T2 (at two years after UKA). Scale 0-100 with 95% CI, for T0, T1 and T2 dimmed bars: green bar % score improvement between T0 and T2

Patients' opinion about their physical ability to work

The median WAI was 8 for UKA patients (IQR 5–8) and 7 for TKA (IQR 5–8) (n.s.). Of UKA patients, 12% were dissatisfied with their ability to work compared to 17% of TKA patients (n.s.).

Discussion

The most important outcome of this study is that, following surgery, UKA patients are able to return to work significantly sooner than TKA patients, even though both groups have similar WORQ, WAI, and satisfaction scores. This is important, as active work participation is an important factor in enhancing patients' quality of life, mental well-being, and gives structure to day-to-day life [47]. A literature search was performed to find what other studies reported about 'return to work' after UKA. The search terms "return to work" AND ("Unicondylar Knee Replacement" OR "Unicompartmental Knee Arthroplasty" OR "Knee Arthroplasty, Unicondylar" OR "Knee Replacement, Unicompartmental" OR "Unicompartmental Knee Replacement") were used and the search produced 35 studies. Our study is the first large study to report on return to work in a large group of UKA patients in comparison to TKA patients. Furthermore none of the studies we looked at described the impact of UKA on specific knee-burdening activities, so our results could not be compared to other studies. One recent study reported a mean return to work of 6.4 weeks (SD=3.4) in patients following robotic assisted UKA [10], this seems similar to our results (27% at 1 month, 73% at three months). A further analysis that can be done is to compare results with previously reported outcomes of TKA and return to work. In Table 2, a summary is given of all studies reporting on patients returning to work after either UKA or TKA as well as the time of return to work, if reported. It seems that patients who return to work following surgery return sooner after UKA than after TKA.

Author	Journal	Pubmed ID	Year	Total patients with TKA	Total patients with UKA	Age at operation of study group	Patients working pre-op	Patients returning to work post-op	% returned	Interval return to work in median weeks	Definition
Present study			2018		315	60	157	117	75	27% at 1 month, 73% at 3 months	Assessed at mean 3.1 years post-surgery
Jinnah et al. [10]	Surg Technol Int	29611158	2018		30		30			6.4 (mean)	Assessed at 2, 4, 6 and 12 weeks
Scott et al. [36]	Bone Joint J	28768780	2017	289		59.0	261	105	40	13.5 (mean)	Assessed at 2-4 years post-surgery
Stigmar et al. [38]	Acta Orthop.	27996342	2017	4421		55.0	996	857	86	15	Assessed until 24 months post-surgery (Calculated from median sick leave of F:M 117:96 days)
Leichtenberg et al. [22]	Ann R Coll Surg Engl	27138849	2016	120		56.0	56	50	89	-	Assessed at 12 months post-surgery
Bardgett et al. [1]	BMJ Open.	26832426	2016	10		54.0	10	10	100	9.4 (mean)	Assessed at 8-35 months post-surgery
Tilbury et al. [40]	Rheumatol Int.	26119221	2015	322		57.4	64	56	83	12.9 (mean)	Assessed at 12 months post-surgery
Kleim et al. [16]	Knee Surg Sports Traumatol Arthrosc	25193567	2015	127		54.0	50	41	82	13	Assessed at mean 21 months
Belmont et al. [2]	J Arthroplasty.	25677939	2015	159		45.7	159	130	82		Assesssed at 24 months post-surgery
Kievit et al. [14]	J Arthroplasty	24524779	2013	480		66	173	121	70	50.4% within 12 weeks	Assessed at 24-86 months
Glebus et al. [7]	J Arthroplasty	23830502	2013	20	2	45.0	22	?	86		Assessed at 4.5 years post-surgery

Author	Journal	Pubmed ID	Year	Total patients with TKA	Total patients with UKA	Age at operation of study group	Patients working pre-op	Patients returning to work post-op	% returned	Interval return to work in median weeks	Definition
Sankar et al. [35]	Osteoarthritis Cartilage.	23774473	2013	494		57.5	170	144	85	24% at 1 month. 57% at 3 months	Assessed untill 1 year post-surgery
Lombardi et al. [26]	Clin Orthop Relat Res.	23761175	2013	661		54.0	494	482	98	8.9	Assessed at 12-36 months post-surgery
Clyde et al. [4]	J Arthroplasty	23583541	2013	98		55.0	98	64	65	15.5 (mean)	Assesssed at 17-125 months
Husted et al. [9]	J Bone Joint Surg Br.	21357957	2011	421		68.3	82	46	56	-	Assessed at 24 months
Styron et al. [39]	J Bone Joint Surg Am.	21209263	2011	162		57.0	162	122	75	8.9	Assessed at 3 months
Lyall et al. [28]	Ann R Coll Surg Engl.	19344550	2009	56		57.9	41	40	98	10 (mean)	Assessed at 47-112 months post-surgery
Foote et al. [6]	Knee	19632120	2009	41		54.1	27	22	82	12	Assessed at 14-61 months
Foote et al. [6]	Knee	19632120	2009		31	52.6	22	18	82	11	Assessed at 14-61 months
Lombardi et al. [25]	Clin Orthop Relat Res.	19225852	2009	113	113	62	-	-	-	8	Assessed at 2-52 months post-surgery
Walton et al. [43]	J Knee Surg.	16642887	2006	120		71.5	21	17	81	-	
Jorn et al. [11]	Acta Orthop Scand.	10569263	1999	102	60	56.0	88	52	59	(54% within 26 weeks)	Assessed at 2 years post-surgery
Nielsen et al. [30]	Ugeskr Laeger.	10434787	1999	926		-	51	40	78	-	Assessed at 1 year post-surgery
Weingarten et al. [44]	Am J Med.	9688019	1998	287		69.7	56	41	81	-	Assessed at 3-5 months
Sumarized				9429	551	58	3285	2575	78		

Table 2. 'Return to work' following Total Knee Arthroplasty (primary, revision or uni-knee arthroplasties) according to other studies

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The impact of surgery on the difficulty patients experienced performing knee-burdensome activities, was clear and we found that, also for UKA, surgery resulted in patients' scoring a level comparable to the period before their knee complaints started. UKA can be considered to contribute to improving the ability to work. Known advantages of the UKA over the TKA are a lower risk of complications [23], better range of motion [15, 27], and better PROMs [24]. On the other hand, there is an ongoing debate about the use of UKA because of data registry that shows a lower survival rate of the implant after UKA compared to TKA [15, 17, 31]. It seems that for a definitive one-step treatment, TKA would be superior. The lower threshold for revision and the insufficient number of suitable surgeons might be an explanation for this for the difference in revision rates [24]. Apart from the physical and quality-of-life advantages of UKA over TKA, cost-effectiveness is also important in the light of an increasing financial burden on society, as the number of arthroplasties increases. Despite the poorer survival rate of a UKA device compared to a TKA, cost-effectiveness studies seem to favor UKA [37, 45]. These studies are limited to costs of the procedure and its complications and/or revisions; unfortunately, sick leave was not included. Where there is no preference to either TKA or UKA, and there is surgical expertise available to assess the indication and perform UKA, it seems that there is evidence for better outcome in the working population at least with respect to midterm results and speedier return to work, despite the higher chance of revision surgery 10 year follow-up.

Recently, it was found that the combined loss of productivity plus medical costs for conservatively treated symptomatic knee osteoarthritis for those in paid employment in The Netherlands amounts to €871 per patient per month, with loss of productivity accounting for 83% and medical costs for 17% [8]. Returning to work sooner can potentially benefit not only patients of working age but also employers and, ultimately, society as a whole by reducing costs related to sick leave and quality of life. Thereby, the cost effectiveness of UKA surgery could increase further from society's perspective when compared to TKA, at least during working life and if there is a similar indication. Furthermore, patient expectation can be steered with respect to the results of this study.

TKA patients benefit least if their work requires mainly kneeling, crouching, and clambering. UKA patients benefit least if their work requires kneeling, crouching, and pushing or pulling. Kneeling and crouching improvement was similar for both TKA and UKA. The results for both procedures imply that patients whose work requires crouching or kneeling on the ground, for instance, plumbers, floor layers, and gardeners should be warned that knee replacement might relieve the pain, but will only marginally reduce difficulties y in performing these tasks. For TKA patients, it might be, because a TKA has a limited range of movement (ROM) compared to a normal knee. UKA patients tend to have better flexion, but do not score better on performing difficult tasks than TKA patients. In our previous report on the questionnaire, a clinically significant improvement was an improvement of at least 13 points on the WORQ questionnaire.

Therefore, as an overall group, both TKA and UKA patients report a clinically relevant improvement of their WORQ scores. The patients who benefit most from knee replacement are those whose work involves operating a vehicle, or who have a job that involves periods of standing or walking on level ground. For these activities, the ROM is less important, whereas pain reduction is likely to play a more important role.

No difference was found with respect to WAI to describe physical work ability. One would expect UKA patients to have a better WAI, as recovery is sooner, and possibly, ROM is better. The fact that no difference was found coincides with the more reliable WORQ scores, which also did not differ significantly. There might be a trend towards overall slightly better scores, be it said not significant, for different aspects for the UKA group. As trends to superiority are found across different variables, the study might just be underpowered to find these differences. To the statement—am satisfied with my ability to work with respect to my TKA or UKA—30 (17%) TKA patients stated that they were (strongly) dissatisfied compared to 19 (12%) UKA patients. These percentages seem higher than reported in the previous literature, where 8% of overall patients are dissatisfied with the outcome at 2–17 years [34]. It might be that with respect to the ability to work, patients are less satisfied with the result of TKA or UKA.

A limitation is the retrospective nature of reports by patients about their 'return to work'. Hence, there is a potential for recall bias in the overall results. This is why categories were made with respect to the time interval for return to work instead of an exact amount in weeks or months. It is assumed that patients are able to assess work specific tasks at three different and distinct time points. As the same methods were used for both the TKA and UKA group, this is unlikely to influence comparability. In future research, the questionnaire should be given to patients pre-operatively and at regular follow-up moments to generate more precise results. The WORQ is validated for TKA patients, not yet specifically for UKA patients. However, as the construct is very much the same, it is assumed that the WORQ is equally valid for UKA patients, although the minimal clinical important change might differ between these two groups given their expectations pre-operatively. A validation study for the WORQ in UKA patients is currently being performed. Furthermore, there are similarities, but also differences in indication for TKA and UKA.

In the previous study, the average age of TKA patients was slightly younger than that of the general population of patients undergoing TKA [14]. This is probably due to the fact that the two involved centers are tertiary referral centers for advanced osteoarthritis in younger patients as well as severe post-traumatic deformities. Therefore, it would be good to repeat such a study in a more general primary population too.

In general, UKA patients have a more limited, anteromedial osteoarthritis and tend to be younger. Furthermore, the ACL must be intact. Surgery itself is less invasive and the wound and exposure are more limited leading to less blood loss. Rehabilitation time is generally shorter due to these differences. Therefore, it cannot be concluded based on this study that if all TKA patients would have undergone UKA surgery, they would have returned to work sooner. To answer such a question a randomized design would be needed, where patients with anteromedial osteoarthritis with an intact ACL would be allocated either to UKA or TKA surgery. The fact that UKA patients in this study return to work sooner is, therefore, multifactorial and not simply addressable to the type of prosthesis choice alone.

The patient group in The Netherlands was considered large and varied enough to give a representative picture of the impact of TKA and UKA on 'return to work'. The exact same methods were used to collect and analyze patient data for both the TKA and UKA group to make sure collection bias was minimal. The period in which the procedures were performed were the same to reduce possible time-bias. To ensure that the results are adequate and interpretable, the validated WORQ questionnaire was used. The purpose of the WORQ was to obtain an adequate range to discover which of work-related activities remain difficult to perform and which benefit most from TKA. The WAI was introduced in 1997 [41, 42] and has been proven reliable [5] and the single item has a moderate predictive validity for return to physically demanding work [18].

It continues to be increasingly important for society that people are able to work longer. As stated before pension, funds suffer because of lower contributions from a decreasing work force, while the burden to pay out increases as a greater proportion of the population retire and pensioners live longer. As patients who undergo UKA return to work significantly sooner than TKA, in case of a working patient with a similar indication for both procedures, UKA should be chosen. This will save costs, both in loss of productivity as well as medical costs. It will be useful to find out more about differences in predictors for adequate 'return to work' and if there are differences between TKA and UKA in limitations that patients perceive in their work with respect to their knee function.

Conclusion

TKA and UKA patients have similar WORQ, WAI, and satisfaction scores. However, UKA patients return to work after surgery significantly sooner than TKA patients in this study population, which improves their quality of life and allows them to participate actively in society.

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Compliance with ethical standards

Conflict of interest

The authors declare that there is no conflict of interest apart from the unrestricted funding as mentioned above.

Ethical approval

The Medical Ethics Review Committee of the AMC deemed that the Medical Research Involving Human Subjects Act (WMO) does not apply to the study and official approval was not required.

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Chapter 9

Which patients do not return to work after total knee arthroplasty?

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Abstract

Total knee arthroplasty (TKA) is increasingly being performed among working patients suffering from knee osteoarthritis. Two out of ten patients do not return to work (RTW) after TKA. Little evidence is available about these patients to guide clinicians. Therefore, this study investigates patients' characteristics associated with no RTW. A multicenter retrospective cohort study was performed among working patients having undergone a primary TKA during 2005–2010. The following preoperative characteristics were assessed: age at surgery, sex, comorbidity, body mass index (BMI), preoperative sick-leave duration, patient-reported work-relatedness of knee symptoms, and physical job demands. In addition, the Knee injury and Osteoarthritis Outcome Scores (KOOS) after TKA were assessed. Backward stepwise logistic regression analyzes were performed to predict no RTW. Seven hundred and sixty-four patients were approached, and 558 patients (73 %) responded. One hundred and sixty-seven met the inclusion criteria and 46 did not RTW. A preoperative sick-leave duration >2 weeks (OR 12.5, 90 % CI 5.0–31.5) was most strongly associated with no RTW. Other associations found were: female sex (OR 3.2, 90 % CI 1.3–8.2), BMI 30 (OR 2.8, 90 % CI 1.1–7.1), patient-reported work-relatedness of knee symptoms (OR 5.3, 90 % CI 2.0–14.1), and a physically knee demanding job (OR 3.3, 90 % CI 1.2–8.9). Age and KOOS were not associated with no RTW. Especially obese female workers, with a preoperative sick-leave duration >2 weeks, who perform knee-demanding work and indicate that their knee symptoms are work-related have a high chance for no RTW after TKA. These results stress the importance of a more timely referral for work-directed care of patients at risk for no RTW after TKA.

Introduction

Total knee arthroplasty (TKA) is highly effective in treating pain and loss of function caused by knee osteoarthritis (OA) [1]. Historically, TKA has mostly been performed in older retired patients. However, recent studies show that more patients are of working age. In the USA, more than 50 % of the primary TKA patients are younger than 65 years old by 2016 [2]. In the Netherlands in 2013, the incidence of TKA surgery among 45to 64-year-old patients more than tripled between 1995 and 2005 [3]. The prediction for the Netherlands is that the number of patients receiving TKA will increase by about 300 % to 57,900 annually in 2030 [3]. For the UK, these figures increase to at least 118,666 in 2035, with 11 % being younger than 60 years old [4]. At the same time, the age for retirement is expected to rise in the Netherlands and other western countries. Therefore, an increasing number of knee OA patients will need to be able to RTW after TKA surgery. However, based on data from 11 studies, 307 out of 1417 patients working before TKA surgery (22 %) did not RTW [5, 6]. Given the increasing numbers of TKAs performed among working knee OA patients worldwide, this ratio reflects a large group of workers.

RTW is a multidimensional concept with disease and non-disease-specific prognostic factors [7]. Remarkably little disease-specific evidence is available for clinicians to guide RTW. Only two studies, including a total of 332 TKA patients, have assessed TKA-specific factors associated with RTW based on multivariate analyzes [8, 9]. Two factors hindered RTW in both studies: sex and physical job demands. Both studies agreed on high physical job demands. For sex, one study found that being a male hindered RTW [9], while the other study found the same for being a female [8]. To ensure an appropriate and timely diagnosis for additional work-directed care, knowledge on characteristics of TKA patients at risk for no RTW is urgently needed [10–13]. Therefore, this study investigates patient characteristics associated with no RTW after TKA.

Methods

Study design and setting

A multicenter retrospective cohort study was performed in 2012 [14]. Patients eligible for inclusion had undergone a primary Vanguard TKA between 2005 and 2010 and were working preoperatively within 2 years, and had a follow-upof at least 2 years. The study received approval from the Medical Ethics Committee of the Academic Medical Center in Amsterdam (AMC), the Netherlands. A total of 764 eligible patients who had undergone TKA received an invitation from two Dutch hospitals to participate. Patient informed consent was obtained.

Data collection

Patient characteristics and RTW were obtained from the patient file and a questionnaire sent in 2012.

Patient characteristics associated with no RTW

The included patient characteristics for RTW were based on studies on work participation among patients with TKA and hip arthroplasty [5, 6, 8, 9, 15, 16]. From the patients' files we retrieved: sex (female or male), age at surgery (years), body mass index (BMI, kg/m2), classified in two categories <30 "normal" and ⩾30 "obese," and comorbidity according to the first three categories of the American Society of Anesthesiologists physical status classification before surgery: healthy, mild systemic disease, and severe systemic disease. In the questionnaire, we assessed the Knee injury and Osteoarthritis Outcome Score (KOOS) after TKA for pain, other symptoms, activities of daily living (ADL), functioning in sports and recreation (Sport/ Rec), and knee-related quality of life (QoL). All subscales received a sum score between 0 and 100, with 0 representing extreme knee problems and 100 representing no knee problems. The values were dichotomized based on care-seeking behavior: pain ⩽86.1; symptoms ⩽85.7; ADL ⩽86.8; Sport/Rec ⩽85.0; and QoL ⩽87.5 [17]. In addition, the following characteristics were retrospectively assessed in the questionnaire: preoperative sick leave before TKA surgery (0–2, 2–4, 1–3 months, 3–6 months, or more than 6 months, dichotomized into 0–2 and >2 weeks), and whether the patient thought their work had caused or aggravated their knee symptoms, finally resulting in TKA (patient-reported work-relatedness of knee symptoms dichotomized into yes for "totally agree", "agree" and "neither disagree nor agree", and no for "disagree" and "totally disagree"). The kind of job patients performed before TKA surgery was classified based on job title by two occupational health experts into light-, medium-, and heavy knee demanding work based on work-related risk factors for knee OA [5, 18].

No return to work

Patients responding affirmatively to the question "I didn't get back to work" after TKA surgery in the follow-up questionnaire were classified as not having returned to work (no RTW). The reference category consisted of patients that did return to work.

Data analyzes

Backward stepwise regression analysis was performed to build a model for no RTW using IBM SPSS Statistics 22. Due to the relatively small number of patients included (n = 332) in the only two other prognostic multivariate studies on RTW specific for TKA, all factors were a priori included in the regression analysis after controlling for multicollinearity (variance inflation factors >10 and tolerance <0.1). To overcome bias due to differences in fol-low-up time between TKA surgery and filling in the questionnaire, this period was also included in the regression analysis. In the case of factors with more than two categories, dummies were used. odds ratios (OR) were calculated, including 90 % confidence intervals (CI) to prevent possibly relevant clinical variables from being opted out.

Results

Patient characteristics before surgery

Five hundred and fifty-eight patients of the contacted 764 patients responded (response rate 73 %), of which 78 patients did not wish to participate. The remaining 480 participants all filled in the questionnaire. The mean follow-up time of the questionnaire survey was 3.8 years (SD 1.3) after TKA surgery. Of these 480 patients, 167 worked before TKA surgery and were included in the analysis (Table 1). The male/female ratio was 49 %:51 %. The mean age at TKA surgery was 60 years (SD 8), and the mean age at follow-up was 64 years (SD 8). Fifty-eight percent had a BMI < 30 kg/m^2 and 42 % a BMI 30. Sixty-five percent of the patients had a preoperative sick leave of 2 weeks or less. Forty-eight percent performed light-, 32 % medium-, and 20 % heavy knee-demanding work before TKA surgery. Thirty-one percent of the TKA patients were of the opinion that their work had caused or aggravated their knee symptoms. Out of the five postoperative KOOS's, pain had the most favorable outcome: a mean of 79.6 for the group as a whole (Table 1). After TKA surgery, 46 patients (38 %) never returned to work (Table 1).

		All n=167		**RTW n=121**		**No RTW n=46**	
Preoperative							
Sex (n, %)	male	82	(49.1)	63	(52.1)	19	(41.3)
	female	85	(50.9)	58	(47.9)	27	(58.7)
Age at surgery (mean, SD)	year	59.7	(8.4)	58.8	(8.3)	62.1	(8.3)
	<60 (n, %)	85	(50.9)	69	(57)	16	(35)
	>=60 (n, %)	82	(49.1)	52	(43)	30	(65)
Body height (mean, SD)	m	1.74	(0.09)	1.75	(0.09)	1.72	(0.11)
Body weight (mean, SD)	kg	88.7	(15.6)	89.2	(15.6)	87.5	(15.6)
Body mass index (n, %)	<30 kg/m^2	96	(58.5)	70	(59.8)	25	(54.3)
	⩾30 kg/m^2	68	(41.5)	47	(40.2)	21	(45.7)
ASA classification (n, %)	Type 1	51	(31.1)	38	(31.9)	13	(28.9)
	Type 2	93	(56.7)	68	(57.1)	25	(55.6)
	Type 3	20	(12.2)	13	(10.9)	7	(15.6)
Preoperative sick leave (n, %)	0-2 weeks	108	(65.5)	95	(79.2)	13	(28.9)
	2-4 weeks	6	(3.6)	4	(3.3)	2	(4.4)
	1-3 months	14	(8.5)	10	(8.3)	4	(8.9)
	3-6 months	11	(6.7)	5	(4.2)	6	(13.3)
	>6 months	26	(15.8)	6	(5.0)	20	(44.4)
Knee-demanding work (n, %)	Light	66	(48.2)	53	(53.0)	13	(35.1)
	Medium	44	(32.1)	25	(25.0)	19	(51.4)
	Heavy	27	(19.7)	22	(22.0)	5	(13.5)

		All n=167		RTW n=121		No RTW n=46	
Work-relatedness knee complaints (n, %)	No	115	(68.9)	92	(76.0)	23	(50.0)
	Yes	52	(31.1)	29	(24.0)	23	(50.0)
Postoperative							
KOOS Pain (mean, SD)	0-100	79.6	(22.3)	81.9	(20.5)	73.6	(25.8)
	≤86.1 (n, %)	69	(41.6)	49	(40.5)	20	(43.5)
KOOS Symptoms (mean, SD)	0-100	72.6	(19.8)	73.8	(19.5)	69.4	(20.6)
	≤85.7 (n, %)	110	(66.3)	77	(63.6)	33	(71.7)
KOOS ADL (mean, SD)	0-100	77.5	(22.7)	80.6	(19.8)	69.4	(27.7)
	≤86.8 (n, %)	166	(53.6)	63	(52.1)	26	(56.5)
KOOS Sport/Rec (mean, SD)	0-100	39.3	(31.5)	42.9	(31.1)	30.1	(31.1)
	≤85.0 (n, %)	144	(89.4)	101	(83.5)	43	(93.5)
KOOS QoL (mean, SD)	0-100	59.6	(26.6)	63.3	(24.4)	49.9	(29.9)
	≤87.5 (n, %)	138	(84.1)	98	(81.0)	40	(87.0)

Table 1 Pre- and postoperative characteristics [mean, standard deviation (SD) or number (n) and percentage (%)] of TKA patients of the group as a whole (All) and specified for the patients that returned (RTW) and did not return to work (no RTW)

Eight (17 %) reported that this was due to their TKA, seven (15 %) reported other physical complaints, and twenty-six reported that they had “retired” (57 %). One hundred and twenty-one (72 %) patients returned to work, of which eight (7 %) within 1 month, 50 (41 %) between 1 and 3 months, 43 (36 %) within 3–6 months, and 20 (17 %) after 6 months. Of these TKA patients, 19 reported that they had a less physically demanding job after RTW, 79 had an equally physically demanding job, and 12 had a more physically demanding job after RTW. Regarding working hours, 11 patients physical job demands hinder RTW [8, 9]. Interestingly, this association was established only for medium knee demanding work and not for heavy knee-demanding work. This appears in line with Lombardi et al., who found that reported fewer working hours, 96 reported the same number of working hours, and five reported more working hours.

Factors associated with no RTW

Multicollinearity was not present for the included factors. Five distinct patient characteristics remained in the final model for no RTW (Table 2).

Predictors for no RTW	Reference	OR	90%CI	
Preoperative sick-leave duration>2 weeks	0-2 weeks	12.5	5.0	31.5
Work-relatedness of knee symptoms (Yes)	No	5.3	2.0	14.1
Medium knee-demanding job	Light	3.3	1.2	8.9
Female	Male	3.2	1.3	8.2
Body mass index ⩾30.0	<30	2.8	1.1	7.1

Table 2. The five predictors remaining in the final model after backward stepwise logistic regression for not returning to work (no RTW) including Odds Ratios (OR) and 90% Confidence Intervals (CI).

The strongest association with no RTW was found for preoperative sick-leave duration of more than two weeks (OR 12.5, 90 % CI 5.0–31.5). Patient-reported work-relatedness of the knee symptoms finally resulting in TKA had the second highest OR of 5.3 (90 % CI 2.0–14.1). The other three were: a medium physically knee-demanding job (OR 3.3, 90 % CI 1.2–8.9), female sex (OR 3.2, 90 % CI 1.3–8.2), and BMI 30 (OR 2.8, 90 % CI 1.1–7.1). This model explained 50 % of the variance (Nagelkerke R^2 = 0.50).

Discussion

TKA is being performed on an increasingly younger population of knee OA patients for whom participating in work is of critical importance. This study showed that KOOS pain, symptoms, ADL, and Sport/Rec were not associated with no RTW after TKA. Therefore, clinicians should be aware that proxies for participating in work go beyond outcomes like pain or function [6]. Additionally, the standardized care pathways after TKA focusing on minimizing pain and maximizing function like improving strength and mobility are probably not suited to overcoming hindering factors for RTW. A focus on rehabilitation on the performance of relevant work-related knee-demanding activities might be more promising, given the reported limitations in these activities before and after TKA [5].

Five predictors for no RTW among TKA patients were found in the present study. The strongest was having had a preoperative sick leave >2 weeks. This highlights the the highest percentage of patients that were still working at 1 year after TKA were those in very heavily demanding jobs: 98 %, 135 out of 138 patients [6]. An explanation might be the healthy worker selection effect. This means that, despite their TKA, this selected group of workers is more fit than the selection of workers involved in medium knee-demanding work. The reason is that unfit workers would have left their heavy knee-demanding work in an earlier phase in their career due to health complaints than their counterparts in medium knee-demanding work. This study also confirmed that sex is not associated with no RTW for males [9], but the opposite is true for females [8]. We can only speculate on the actual underlying reasons for this association; perhaps the fact that most men are the primary wage earners or that women in general have poorer outcomes after TKA due, for instance, to depression, low back pain, and symptomatic joint count [20]. A BMI ⩾30 and having a TKA might further reduce sports participation and thereby increase the risk for no RTW [21, 22]. The fifth predictor for no RTW was the self-reported work-relatedness of symptoms leading to the TKA. This patient characteristic has not been reported in other joint replacement studies on RTW. Interestingly, this characteristic was not associated with the classification of the job into light-, medium-, and heavy knee-demanding work, and perhaps it is associated with the motivation of TKA patients for RTW [9]. Taken together, these five predictors explained 50 % of no RTW: a relatively high impact. To improve the ease of use of these predictors in a clinical setting, the corresponding patient characteristics were dichotomized or trichotomized. These predictors can guide clinicians to select patients at risk for no RTW. For instance, a plausible first step seems to be active referral of target patients characterized by the above-mentioned predictors to an occupational physician. Preferably, this should be done preoperatively TKA to secure timely work-directed care.

Two limitations of the present study should be discussed. The first limitation is the potential presence of recall bias. To reduce this bias, we categorized the answers, most often in two categories and not more than three. In addition, to overcome differences due to follow-up time between TKA surgery and filling in the questionnaire between patients, this period was included in the regression analysis and appeared not to be associated with no RTW. A second limitation is the relatively small number of patients that did not RTW, resulting in less precision of the risk estimates: 46 patients (28 % of 167) in the present study with a follow-up of at least 2 years. However, in the previous multivariate studies on RTW after TKA, the absolute number of patients not returning to work was even less: 45 (28 % of 162) TKA patients not returning to work at the 3-month postoperative end point [9] and 26 (15 % of 170) TKA patients not returning to work at the 12-month postoperative end point [8]. Given the estimated increasing number of working TKA patients in the coming years, multivariate prognostic studies on RTW with sufficient power are needed to critically understand the disease-specific mechanisms for no RTW, including relevant comorbidity [23]. Meanwhile, patients at risk for no RTW—especially obese female workers with a preoperative sick-leave duration >2 weeks who perform knee demanding work and indicate that their knee symptoms are work-related, should actively be referred for workdirected care.

Compliance with ethical standards

The study received approval from the Medical Ethics Committee of the Academic Medical Center in Amsterdam (AMC), The Netherlands.

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Conflict of interest

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Chapter 10

General discussion

This discussion covers briefly the key findings. These are compared with existing literature, in particular where they differ. The potential consequences for care and for patient's health are discussed. The strengths and limitations of the studies are covered. In the closing remarks the remaining or new questions are discussed, followed by the conclusions and future prospects.

Improving accuracy of TKA surgery

Optimal planning and placement of total knee arthroplasty (TKA) components improves postoperative joint function and thus patients' quality of life, and reduces reoperations. In contrast, malalignment is the major cause of failure in TKA.[1-3] Correct alignment can only be achieved by performing accurate bone cuts, or osteotomies.

In order to assess whether actual surgical osteotomy planes accurately match their respective preoperatively planned virtual planes, a measurement system is needed that can quantify 3D characteristics of such planes. Accurate tools to compare virtual with actual bone cuts are, therefore, of major importance in evaluating bone cutting techniques, such as with patient-specific instrumentation (PSI) systems as well as novel robotics.[4 5]

A CT-based technique (Chapter 2) can compare virtual with actual osteotomy planes with high accuracy, and thus is a reliable method to assess whether the osteotomy that was executed matches with the one that was planned.

Other plane-assessment methods have been reported, but tend to provide accurate information with a more limited scope, such as on a single plane of reference on a 2D image, instead of providing the full 3D information that is required in joint replacement measurements.

The accurate 3D measurement using the CT-based technique, described in Chapter 2, allows not only for accurate quality control of joint replacements, but also paves the way for continuous prospective quality improvement of joint replacement surgery using the cycle Plan, Do, Study, Act (PDSA). This is illustrated by the evaluation of the accuracy of the *Signature™* PSI system (Zimmer Biomet), a tool that assists in planning and performing the bone cuts, and thus aims at improving surgical performance (Chapter 3). It was demonstrated that the PSI system provides adequate plane transfer accuracy, better so for bone cuts of the tibia than for bone cuts of the femur, showing more rotational error in the latter. Comparable results have been reported in other studies.[6-8]

Given these results, it remains to be determined whether the PSI technique is worth the extra costs. In a recent study, using the Signature PSI system resulted in a statistically significant reduction (>50%) of the number of instrument trays used.[9] However, the technique did not show any statistically significant differences in clinically more relevant intermediate outcomes such as cut-to-sew-time, implant position, and leg axis, nor in patient-relevant short-term outcomes such as post-operative pain or joint function. Thus, the increased cost of this technology so far seems not to be justified by better patient-outcome. [9] Likewise, with respect to PROMs and postoperative complications, PSI has not yet been shown to improve short-term results; long-term follow-up data have not yet been collected. [10] A recent study, using the same Signature PSI technique as reported in Chapter 2 and 3 to perform TKA, reported on excellent patient satisfaction and functional scores at mid-term (minimum 5 year) follow-up . [11] It is unclear which part PSI actually played in these good results as this was not a needed well-designed randomized controlled trial (RCT). It is not clear whether the same good outcome may or may not have been achieved using conventional instrumentation in that exact same population.

The importance of accurate bone cuts for future research lies in the fact that patients with good anatomical alignment through improved surgical performance after knee arthroplasty have been shown to have better functional outcomes, rehabilitate more quickly, and have lower in-hospital length of stay.[12] The optimal placement and alignment is difficult to standardise as patients' anatomy can vary. Therefore, pre-operative measurements must be carefully performed per individual. In the development of TKA surgery, Freeman and Insall introduced the concept of right-angled femoral and tibial bone cuts (MA) and the idea of parallel and equal flexion and extension gaps. [13 14] Neutral lower limb alignment is currently the standard goal in TKA surgery and is represented by a hip-knee-ankle angle target of 180° ± 3°. This method leads to all TKA's being placed in the same way without regard for a patient's individual physical anatomy. This one-size-fits-all approach seems at odds with the fact that our gait is as unique to us as our fingerprint and is so specific that it may very well be the next step in biometrics.[15] Native (natural) knees show a high variability of the coronal knee alignment in non-osteoarthritic as well as in arthritic knees.[16 17] Due to this variation, unequal medial–lateral or flexion–extension bone resections are made in many patient's leading to an imbalance and possible difficulty walking or more post-operative pain on the medial or lateral side for instance. This is then corrected by a selection of releases to rebalance the knee.[13] This might be one of the underlying reasons why so many patients report that a TKA does not feel like their own native knee. Mechanically aligned TKAs may demonstrate good long-term implant survival, but in spite of this, functional outcomes and patient satisfaction can be lower than wished and expected. There are still high rates of dissatisfaction and residual symptoms despite the many improvements in implant design and precision surgical preparation (navigation system, patient-specific instrumentation, robotics).[10 18-21]

Once bone cuts can be performed more accurately and precisely, other methods of alignment can be explored in more detail, such a Kinematical Alignment (KA) instead of Mechanical Alignment (MA) of total knee replacement. The KA technique enables faster recovery and generally generates higher functional TKA outcomes in comparison to the

MA technique.[22-25] For kinematic alignment – and in fact for all methods of planned alignment - it is of utmost importance that the actual surgery, i.e. the bone cuts, are performed accurately, precise and according to plan. For this reason, PSI or other such accurate and precise techniques might in the future play an increasingly important role.[22] Unicompartmental knee arthroplasty (UKA) is a form of kinematic alignment KA. So far, not much is yet known about the long-term follow-up in patients with other than mechanically aligned knees. Furthermore, aligning knees kinematically in patients with excessive deformities could lead to a higher risk of arthroplasty loosening related to increased mediolateral shear forces mainly on the tibial component, because the implants position and orientation is determined by the native anatomy. Nakamura et al. reported that compared to a mechanically aligned TKA, the maximum stress on the tibial insert and on the tibial resection surface increases by 47% and 25%, respectively, if the kinematically aligned TKA resulted in a limb with 6° varus.[26] This result was also reported in a study by Ishikawa et al. which states that kinematically aligned TKAs produce near-normal knee kinematics, but that concerns for long-term outcome might arise because of high interface stresses (stress on the fixation between bone and prosthesis).[27] Despite these concerns, more natural motion should in principle be expected to give better (short and intermediate term) results and supports the aim of improving outcome by performing more individualised and patient specific care.

Loosening as a complication following TKA

Currently the main tests to aid in the diagnosis of TKA failure are radiographic evidence of radiolucency or migration, evidence pointing towards infection such as laboratory tests and white blood cell (WBC) scanning, or high bone turnover on bone scintigraphy and PET-CT.[28] Specifically for the diagnosis of prosthesis loosening, a form of failure, the results of the available tests are based on indirect signs, and according to the American College of Radiology are costly, insufficiently sensitive and specific, slow, and only able to suggest an increased likelihood of suspected implant loosening, without real proof.[29] More recently a review and meta-analysis by Buijs et al. described that of the evaluated available diagnostic modalities to aid the diagnosis of knee arthroplasty loosening, MRI and SPECT/CT are currently the most accurate modalities available to aid the diagnosis of aseptic loosening of knee arthroplasty components, but with a low level of evidence.[30] The alternative for the methods described above, is to assess and quantify the implant-to-bone/interface-movement in a non-invasive manner (Chapter 4). It demonstrated promising early results. The technique is similar in accuracy and reproducibility to the measurement error of Radio Stereometric Analysis (RSA). The measurement error is less than the maximum component movement that was found by Wilson in asymptomatic patients who underwent induced displacement using RSA (ranging from an average of 0.26 mm for cemented TKA's to 0.17 mm for uncemented TKAs).[31] The range of Maximum Total Point Motion (MTPM) through inducible displacement typically exhibited by a stable TKA component ranges from 0.2 to 0.6 mm in previous RSA studies.[32-36]

So far, RSA could theoretically be used to assess patients with complaints that suggest implant loosening. However, RSA requires that a patient underwent surgery to implant the beads in the bone, which in itself is then a form of revision surgery. In addition, RSA requires information on 3D surface-geometry models of the implant the be supplied by the manufacturer for each implant size. The proposed CT technique does not require implanted beads nor a-prior known implant geometry. The preliminary results of measuring implant movement with this technique suggest that this new technique holds great promise for the accurate non-invasive diagnosis of TKA loosening. It can be applied to all patients with various designs and sizes, because the 3D geometric models are generated directly from the performed CT-scans.

The first clinical trial with TKA patients, of whom 34 had symptomatic knees and 38 had asymptomatic knees, has recently been completed to determine this system's clinical value. It shows that it has excellent to good intra- and interrater reliabilities. Diagnostic accuracy analysis resulted in a sensitivity of 0.91 (95% confidence interval [CI]: 0.72-0.97) and a specificity of 0.72 (95% CI: 0.43-0.90).[37] The combination of a speedy diagnosis with high accuracy and lower cost makes this a new development that will potentially decrease not only (false-positive) unnecessary surgery, but also decrease the time to diagnosis and therefore decrease (false-negative) non-operative policy in patients whose complaints could be alleviated through revision surgery. If loosening occurs in a working-age patient, the current lack of effective diagnostic modalities means that it will usually take between 6-12 months before a decision is made to perform surgery. This delay results in avoidable pain and disability, and in loss of productivity and high societal cost. [38]

Both these changes - preventing (false-positive) unnecessary surgery as well as preventing that those in need of surgery (false-negatively) are unoperated, is expected in the future to result in more appropriate care, lower patient suffering, and lower cost.

As promising results have so far have been obtained in a limited number of patients, they need to be replicated in larger studies. A multi-centre study is currently being initiated. This relatively new diagnostic technique will be further perfected and standardised, for instance by more accurately determining the optimal cut-off point for discriminating between patients that have pain because of a loose TKA that requires surgery, and those that are symptomatic because of other reasons.

Outcome of the Vanguard Knee System

Chapter 5 described the short- and mid-term clinical outcome of the Vanguard TKA-system (Zimmer Biomet), a knee-prosthesis that at the time of publication was relatively new. The introduction on the market was in 2003. The study focused on two types of clinically relevant outcomes; revision rates, and patient reported outcomes (PROMS).

At the time of publication, the outcome was an equal or lower revision rate for the Vanguard as compared to the older AGC arthroplasty-system (the precursor of the Vanguard), and a lower revision than the average as calculated from 6 national implant registers (0.94 revisions/100 years versus 1.26/100 years respectively). [39 40] The PROMS, as measured by the KOOS and Oxford questionnaires, and by an 11-point Numeric Rating Scale (NRS) for pain, showed no clinically relevant differences with three previous reports on TKA using the same PROMs.[41-43] Thus, on both types of outcomes, the study results suggest that the Vanguard performs equal or better than older TKA-systems.

A limitation of these early results may be that the follow-up is relatively short (varying between 2 and 7 years), and that serious complications and revisions may in particular occur at longer follow-up (10 years or more). A cross sectional sample of this patient group is currently being evaluated as a long-term survival analysis. Kaipel et al. described a revision rate of 3.6% in a small group of 83 patients with an average follow-up of 10.3 years.[44] Crawford et al. studied a group of 1312 patients (1664 knees) who underwent primary total knee arthroplasty with the Vanguard Complete Knee System and reported a revision rate of 5.3% at an average of 11.9 years of follow-up.[45]

The population, methods and outcomes as reported in Chapter 5 are consistent with literature findings, and thus suggest adequate external study-validity. In spite of this, further studies are required if one wants to better assess the even longer-term outcomes of this prosthesis in larger numbers of patients. The study also demonstrated that a relatively large portion of patients do not perform well on the PROMS, and also that a large part of patients are within working age. The PROMS used in this study are de facto the current standard for reporting outcomes. They are very non-specific and focus on activities of daily living, but are not specifically aimed at patients within the working age and still working or aiming to return to work (RTW) after TKA surgery.

WORQ as the alternative PROM for post-operative follow-up of TKA

Patient-reported outcome measures (PROMs) commonly applied to TKA patients are the KOOS, Oxford and the new Knee Society Scoring System questionnaires. The downside of these PROMS is these mainly assess activities of daily living (ADL) and do not look at those activities that are necessary to return to the work place. The WORQ, is a questionnaire that complies with 7 of the criteria proposed by the COSMIN-group and Terwee et al. The study described in chapter 6 demonstrate that WORQ is a reliable, valid and responsive questionnaire.[46] The positive results were supported by Gagnier *et al* , who performed a review of PROMs for TKA, to critically appraise, compare, and summarize their psychometric properties using accepted methods. They found that many TKA PROMs have limited evidence for their psychometric properties, but concluded that the WORQ had the highest overall ratings for the PROM-evaluation of patients undergoing TKA.[47]

This suggests that the WORQ is an appropriate instrument to support the return-to-work effectiveness of TKA in patients who were still actively working at the time of surgery and aiming to RTW. Since the 2014 publications, at least 54 published studies have cited the WORQ, including a translation into Korean and subsequent validation [48] As example of its use, a recent study has focused on the question if a prediction can be made at 3 months postoperatively how patients will RTW later on. It proved that at three months post-TKA, the WORQ can be used to distinguish early-, intermediate-, and late-recovery groups, which are associated with the ability to perform work-related activities at six and 12 months post-TKA and RTW at three and six months.[49] This is valuable information as it helps to identify patients with possible worse RTW outcomes at an early stage and tailor possible interventions aimed at improving their RTW.

Based on WORQ outcomes, of the patients who worked before TKA, around a third did not RTW following knee arthroplasty surgery (Chapter 7). The outcomes are in part dependent on the type of work. In particular patients with work that requires a lot of kneeling, crouching and clambering benefit less from TKA, maybe due to the limitation of flexion following TKA.[50] On average, patients have a mean flexion of less than 120 degrees. The high-flex knee designs, having higher flexion ranges, are associated with more aseptic loosening of the tibial component. This information is relevant for patients and care providers, as managing pre-operative expectations is important for postoperative satisfaction.[51 52] This is especially the case for patients approaching their retirement age who struggle with their productivity and consider retirement. They will need to weigh (the costs of) an average of three months of sick leave as well as the burden and cost of TKA surgery against the potential improvement of productivity in the subsequent final years of their career. Thus, nearer to retirement age, arthroplasty surgery will improve general quality of life but not necessarily work-productivity for most plumbers, gardeners, builders and similar physically demanding occupations. Then again if a patient's work mainly consists of driving a vehicle (or of other ways of operating foot pedals), such as is the case in bus or lorry drivers, it might be better to perform arthroplasty surgery earlier on as these activities do seem to improve. Productivity for this specific group might actually improve. [53]

Besides the fact that it is important for society to keep people at work, it is also important to mention the benefits of keeping the retired population mobile enough to care for themselves, stay fit and provide other health benefits. This will indirectly lighten the societal care burden of an aging population. The keys here are to fit the intervention to the requirements for ADL and work and to consider the chance of an outcome that is less than the mean outcome as reported. The previously described issue of maximum functional flexion is a good example.

The above information allows for more individualised and appropriate care for all patients, but in particular for those who still work, and for whom the expected consequences of knee-arthroplasty for the postoperative ability to RTW are relevant. Further studies in larger numbers of patients will be needed to improve and refine the predictive value of various risk factors for returning - or not - to work after TKA.

Patients that receive UKA, RTW significantly sooner than patients who undergo TKA (Chapter 8). This improves their quality of life and allows them to re-participate in society earlier and more actively. [53 54] However, implant survival of a UKA is shorter than that of TKA, despite better clinical and functional performances.[55] More recently this was supported by a systematic review by Ng et al. which reported that limited evidence from the included studies with moderate quality suggests that UKA allows patients to RTW faster, with a high rate of RTW and improved functional outcomes. [56] This makes the choice for one or the other a trade-off between short-term and long-term outcomes, and might increase the overall cost in UKA patients. This information supports well-informed shared decision making, allowing patients who wish to RTW as soon as possible the choice for UKA, while supporting the choice for TKA in those patients who aim for a more definitive solution that will last longer. Further research is indicated to investigate how these different short- and long-term outcomes influence decision making and post-TKA satisfaction in different groups of patients.

Preoperative sick-leave of more than 2 weeks is the best predictor of no RTW (Chapter 9). Other associations found were with female sex, BMI >=30, patient-reported work-related knee symptoms (WORQ score) and a physically knee-demanding job. Age and KOOS scores were not associated with no RTW.

In previous research, three key factors were identified that influenced RTW from the patients' perspective. [57] The first factor reported was that patients did not receive specific advice to facilitate their RTW following surgery. The second reported factor was that patients perceived that the current provision of information for joint replacement patients is focused on the needs of elderly patients. The third was that these patients reported a lack of post-TKA support and adaptation in the workplace to be a negative influence on their experience of RTW. The results as reported in Chapter 9 were recently confirmed by a review on prognostic factors for RTW where the most important prognostic factors associated with a slower or no RTW were a more physically demanding job and preoperative absence from work. [58] A Cochrane review to examine four prognostic factors for return to work that can be used to manage patient expectations, enhance shared decision-making, and improve timely, multidisciplinary, work-directed care following knee arthroplasty is currently in progress. [59]

With better insight into what a specific patient needs to be able RTW, better advise on the choice and timing of treatment can be provided which will help in the shared decision-making process and also may improve RTW. Rehabilitation efforts should be tailored to prioritise the performance of work activities to see if patients can return sooner.

One could expect that knee arthroplasty surgery will reduce loss of productivity costs in the right patient but by how much? If arthroplasty surgery could reduce the loss of productivity to zero due to knee osteoarthritis at the moment of RTW at three months, and the total cost of KA surgery is on average around €10.000[60] in the Dutch situation, surgery would accrue positive cost-benefit outcome if that patient with knee arthroplasty is at work without productivity loss for 12 months or more, assuming €871 monthly productivity loss of knee osteoarthritis without surgery. [38]

However, these rough estimates do not take into account the fact that 3 out of 10 patients do not RTW, or that some patients will have complications such as loosening which require additional surgery.

The total economic cost to society for treatment of severe knee osteoarthritis in a relatively young working person is markedly lower with total knee arthroplasty than it is with non-operative treatment, as reported by a study in the USA. [61] There is a need to account for the implications of treatment choices, not only at the individual patient level, but also for society at large. When deciding among available treatment options, patients, physicians, payers, and policymakers must consider individual treatment cost and effectiveness but also should account for future potential earnings generated when a treatment may restore a patient's ability to contribute to society.[61] Therefore knee arthroplasty could become more and more important to keep patient's active as members of the work force.

The research described in this thesis aims to contribute to the improvement of the planning, execution and follow-up of patients who undergo primary or revision-TKA surgery. By providing better diagnostic insight, and improving information on which benefits may or may not be expected from (revision-) surgery, it contributes to better shared decision making and expectation management, and thus to more appropriate care. At a societal level, this will most likely mean more tailored care and better patient outcomes at lower costs. This is relevant not only for the individual patient, and for hospitals struggling to provide all the appropriate care with limited budgets and personnel, but in particular at a time when society as a whole faces increasing demands from an aging population while at the same time needing to control rising healthcare cost.

Conclusions and Future Prospects

The findings and advancements detailed in this thesis suggest several promising avenues for the future of TKA and related surgical techniques. Below are key areas where future research and clinical practice may evolve, based on the current evidence and remaining challenges:

Precision in surgical techniques:
The use of CT-based techniques to compare virtual and actual osteotomy planes has shown high accuracy and significant potential in evaluating and subsequently improving the precision of bone cuts. In future all new technologies that claim to improve accuracy should be evaluated with this useful tool.

Exploring kinematic alignment further with accurate osteotomies:
As more accurate bone resections lead to better alignment and reduced complications, the integration of advanced imaging techniques, patient-specific instrumentation (PSI), and robotic systems will likely become more widespread in the coming years. However, the cost-effectiveness of PSI as well as robotics needs further investigation to ensure that these technological advancements provide value in terms of patient outcomes and healthcare resource utilization. With mechanical alignment (MA) being the current standard in TKA, research is increasingly focusing on kinematic alignment (KA), which offers a more personalized approach based on each patient's unique anatomy. Future research will explore the long-term outcomes of KA, particularly in patients with severe deformities, as concerns about implant stability and increased stress on components remain. As surgical precision improves, KA may become a more viable and widely adopted technique, potentially offering better functional outcomes and faster recovery times for patients.

Non-invasive diagnostic tools for implant loosening:
The development of non-invasive CT-based techniques to detect implant loosening has shown promise. This method could revolutionize postoperative care by enabling faster and more accurate diagnosis without the need for invasive procedures like radiostereometric analysis (RSA). Ongoing and future multi-center studies are essential to validate and refine this technique, ensuring its accuracy and cost-effectiveness. These advancements could lead to more timely interventions, reducing patient suffering and healthcare costs associated with prolonged diagnostic delays. Besides this the technique is accurate enough to evaluate new implant designs on safety in a relatively small patient group.

Long-Term Outcomes of the Vanguard knee system:
While early to mid-term outcomes of the Vanguard system have been encouraging, there is a need for longer-term follow-up to assess the durability and complication rates of this implant. Future studies should extend beyond the current 7–10 year follow-up

periods to better understand the longevity and performance of this implant in diverse patient populations.

Improving Patient-Reported Outcome Measures (PROMs) with the WORQ:
Traditional PROMs like KOOS and Oxford questionnaires focus on general daily activities, but they often miss key factors relevant to younger, working-age patients. The development and validation of the WORQ questionnaire has highlighted the importance of assessing return-to-work outcomes, particularly for patients who still have active careers. Further research should focus on integrating work-related outcomes into standard PROMs to better predict postoperative recovery and help guide patient-centered care, especially for those nearing retirement age or those in physically demanding professions.

Balancing Short-Term and Long-Term Outcomes of UKA vs. TKA:
Unicompartmental knee arthroplasty (UKA) has been shown to offer faster recovery and RTW compared to TKA, but its long-term implant survival remains a concern. Future research should aim to better understand the trade-offs between short-term functional benefits and long-term durability of UKA. This will enable more informed shared decision-making between surgeons and patients, helping to match the right procedure with each patient's needs and expectations.

Economic and Societal Impact of TKA:
As knee arthroplasty procedures become more refined, there will be a growing need to assess their economic impact on both individual patients and society. Future research should focus on the cost-benefit analysis of TKA and UKA, particularly in terms of productivity loss, return-to-work rates, and healthcare resource utilization. Additionally, with an aging population, the ability to keep patients mobile and independent through successful knee surgeries will have broader societal benefits, potentially reducing the overall burden on healthcare systems.

In conclusion, the future of TKA and related surgeries will likely be shaped by the integration of personalized care, technological advancements in surgical precision, improved diagnostic tools, and a greater emphasis on work-related outcomes. These developments, along with ongoing research into the long-term efficacy of various surgical approaches and implant designs, will contribute to better patient care, enhanced quality of life, and reduced healthcare costs in the long-term.

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Summary

In the following, we will shortly summarize the ten chapters of this thesis. After the introduction, the chapters 2-4 focus on (improving) the technical aspects of knee arthroplasty, while the subsequent chapters 5-9 focus on the results of these procedures for patients and society. The thesis then ends with chapter 10, the general discussion:

Chapter 1 provides the General Introduction.

Chapter 2 describes the development of a 3D CT based imaging technique to measure the transfer accuracy of a virtually planned osteotomy.

In **Chapter 3** predicted osteotomy planes are evaluated on accuracy when using patient-specific instrumentation (PSI) for total knee arthroplasty.

In **Chapter 4** we describe a new and now patented method for diagnosing loosening, a complication of Total Knee Arthroplasty (TKP), using CT and inducible displacement.

In **Chapter 5** our predominant patient group and location is described. It reports on the results of the hospitals in which our studies are performed as well as the survival for the used TKP is given and risk factors for revision.

In **Chapter 6** a new questionnaire is developed, the Work, Osteoarthritis and joint-Replacement Questionnaire (WORQ). The reliability, validity and responsiveness are tested and reported.

Chapter 7 reports on the results of a cross-sectional multicentre survey on return to work following TKP.

Chapter 8 looks into differences in return to work between TKP and the less invasive Unicompartmental Knee Arthroplasty (UKP).

In **Chapter 9** it is assessed which patients do not return to work after TKP.

Chapter 10 provides the General discussion

Chapter 1

Osteo Arthritis (OA) of the hip and knee is one of the leading causes of global disability. Globally, of 369 conditions reported, OA of the hip and knee was ranked as the 11th highest contributor to global disability. Osteoarthritis can develop isolated in the medial or lateral compartment of the knee (i.e. in post-traumatic osteoarthritis based on an intra-articular fracture) or as a more generalized disease affecting all parts of the knee. Non-operative options are usually indicated for stage I and II osteoarthritis and include patient education, self-management, exercise therapy (with or without physiotherapy), correctional braces and lifestyle changes such as weight loss. Surgical management is usually indicated for stage III and IV knee OA and consists mainly of corrective osteotomy, UKP or TKP. Restoration of knee alignment is considered one of the mainstays of successful TKP. In order to reduce the risk of intraoperative malalignment and malpositioning, more accurate and precise intraoperative bone cut techniques are necessary to ensure precise arthroplasty placement. PSI is such a technique; however a tool is needed to evaluate the accuracy of such techniques. If an implant is malpositioned it is at risk of early aseptic loosening. Current tests are either insufficiently sensitive or insufficiently specific to be able to diagnose arthroplasty loosening accurately. To improve care for this group, an imaging modality is needed that can make a timely diagnosis of loosening with high sensitivity and specificity. This image modality should ideally quantify implant movement in relation to the adjacent bone or cement interface, instead of merely visualising the side effects of loosening such as radiolucent lines or high bone turnover.

If new implants are released onto the market, it is important to evaluate if they are non-inferior or even better than what is currently available. Historically outcome measures following knee arthroplasty have focussed primarily on survival data, limb function and pain reduction, while the broader relevance of societal participation, and in particular return to work, has been severely underreported. A new questionnaire is needed to evaluate how well patients can return to work following total knee arthroplasty. With such a measure it will be possible to evaluate how fast and how well patients return to work. It may also make it possible to compare differences between for instance UKP and TKP with respect to return to work. Furthermore it is important to know which patients will most probably not return to work after knee arthroplasty.

Chapter 2

Accurate transfer of a preoperatively planned osteotomy plane to the bone during surgery is of significance for corrective surgery, tumour resection, implant positioning and evaluation of new osteotomy techniques. Methods for comparing a preoperatively planned osteotomy plane with the real life surgical cut exist but the accuracy of these techniques are either limited or unknown. This paper proposes and evaluates a CT-based technique that enables comparing virtual with actual osteotomy planes. The methodological accuracy and reproducibility of the technique is evaluated using

CT-derived volume data of a cadaver limb, which serves to plan TKP osteotomies in 3-D space and to simulate perfect osteotomies not hampered by surgical errors. The methodological variability of the technique is further investigated with repeated CT scans after actual osteotomy surgery of the same cadaver specimen. Plane displacement (d_{err}) and angulation errors in the sagittal and coronal plane (b_{err}, g_{err}) are measured with high accuracy and reproducibility (d_{err} = −0.11 ± 0.06 mm; b_{err} = 0.08 ± 0.04°, g_{err} = −0.03 ± 0.03°). The proposed method for evaluating an osteotomy plane position and orientation has a high intrinsic accuracy and reproducibility. The method can be of great value for measuring the transfer accuracy of new techniques for positioning and orienting a surgical cut in 3-D space.

Chapter 3

Malalignment of implants is a major source of failure during total knee arthroplasty. To achieve more accurate 3D planning and execution of the osteotomy cuts during surgery, the Signature (Biomet, Warsaw) patient-specific instrumentation was used to produce pin guides for the positioning of the osteotomy blocks by means of computer-aided manufacture based on CT scan images. The research question of this study is: what is the transfer accuracy of osteotomy planes predicted by the Signature PSI system for preoperative 3D planning on the one hand, and intraoperative block-guided pin placement during total knee arthroplasty on the other?

The transfer accuracy achieved by using the Signature PSI system was evaluated by comparing the osteotomy planes predicted preoperatively with actual intraoperative osteotomy planes in human cadaveric legs. Outcomes were measured in terms of translational and rotational errors (varus, valgus, flexion, extension and axial rotation) for both tibia and femur osteotomies.

Average translational errors between the osteotomy planes predicted and their actual counterparts was 0.8 mm (± 0.5 mm) for the tibia and 0.7 mm (± 4.0 mm) for the femur. Average rotational errors in relation to predicted and achieved osteotomy planes were 0.1° (± 1.2°) of varus and 0.4° (± 1.7°) of anterior slope (extension) for the tibia, and 2.8° (± 2.0°) of varus and 0.9° (± 2.7°) of flexion and 1.4° (± 2.2°) of external rotation for the femur.

The similarity between osteotomy planes predicted using the Signature system and osteotomy planes actually achieved was excellent for the tibia, while slightly lower accuracy was found for the femur. The use of 3D system techniques in TKP can provide accurate intraoperative guidance, tailored to individual patients, in particular for patients with bone deformity, and ensure better placement of the implant.

Chapter 4

After total knee arthroplasty in up to 13% of patients revision surgery is required to address loosening. No current diagnostic modalities have a sensitivity or specificity higher than 70–80% to detect loosening, leading to 20–30% of patients undergoing unnecessary, risky and expensive revision surgery, or inappropriate surgical delay. A reliable imaging modality is required to diagnose loosening. This study presents a new and non-invasive method and evaluates its reproducibility and reliability in a cadaveric study.

Ten cadaveric specimens were implanted with loosely fitted tibial knee components and CT scanned under load towards valgus and varus using a loading device. Advanced three-dimensional imaging software was used to quantify displacement. Subsequently, the implants were fixed to the bone and scanned to determine the differences between the fixed and the loose state. Reproducibility errors were quantified using a frozen specimen in which displacement was absent. Reproducibility errors, expressed as mean target registration error, screw-axis rotation and maximum total point motion were 0.073 mm (SD 0.033), 0.129 degrees (SD 0.039) and 0.116 mm (SD 0.031), respectively. In the loose condition, all displacements and rotation changes were larger than the reported reproducibility errors. Comparing the mean target registration error, screw axis rotation and maximum total point motion in the loose condition to the fixed condition resulted in mean differences of 0.463 mm (SD 0.279; $p = 0.001$), 1.769 degrees (SD 0.868; $p < 0.001$) and 1.339 mm (SD 0.712; $p < 0.001$), respectively.

The results of this cadaveric study show that this non-invasive method now called AtMoves is reproducible and reliable for detection of displacement differences between fixed and loose tibial components.

Chapter 5

The revision rate of an implant is an important outcome measure in evaluating arthroplasty-survival of a new TKP design. If the early arthroplasty-survival rate would be known, and turns out to be good in comparison with other prostheses, this would justify further use and evaluation of a new implant, such as the Vanguard TKP.

A cross-sectional study in two hospitals was performed on 807 patients with the primary Vanguard (Biomet) total knee Arthroplasty (TKP). The research questions addressed were (1) what are the two and six-year arthroplasty-survival rates of the Vanguard, (2) what are the clinical outcome scores, (3) what are the findings at revision and (4) what are predictors for revision?

The mean age at time of surgery was 67.0 (SD 10.0). The mean follow-up was 3.6 years (95% CI 3.56–3.73). At two years the survival was 97.2% for all-reasons (767 patients remaining), and 99% for prosthesis-related-reasons (777 remaining). At six years this was 96.5% (40 remaining) and 98.6% (41 remaining) respectively. The overall clinical results (84% response on KOOS, Oxford and NRS) were good. A previous osteotomy was a risk factor for revision (hazard ratio 5.1, P = 0.001).

This early experience with the Vanguard shows a good survival with almost no adverse outcomes related to the implant and therefore further use of the implant is justified.

Chapter 6

Although TKP is highly effective in treating knee pain and functional limitations, little is known about how it impacts patients' potential to resume work. Likewise, it is unclear to what extent the chance of a successful return to work is influenced by the timing of surgery is which will.

The Work, Osteoarthritis or joint-Replacement Questionnaire (WORQ) was developed to assess physical difficulty experienced in work before or following total knee arthroplasty (TKP). Thirteen questions were designed. The WORQ was tested for *internal consistency* by factor analysis, *internal reliability* (Crohnbach's α), and *construct validity*. A test–retest *reproducibility* was performed for analyzing standard error of measurement (SEM agreement), reliability (ICC) and smallest detectable change (SDC) in individuals and groups. Lastly *responsiveness* (standardized response means [SRM]), fl*oor and ceiling effects* and *interpretability* (minimal important change [MIC]) were analyzed.

It is shown that the WORQ is a reliable, valid and responsive questionnaire that can be used to evaluate the impact of knee complaints following TKP on patients' ability to work.

WORQ is a new questionnaire with good clinimetric quality. It was tested and found to be sufficient with respect to content validity, internal consistency, reproducibility, construct validity, responsiveness, floor and ceiling effects, and interpretability in a population of TKP patients. It can be used for both individuals and groups to assess knee problems experienced in carrying out work-related activities.

Chapter 7

The number of patients receiving a TKP during working life is increasing but little is known about the impact of TKP on patients' reintegration into the workplace.

We sent out questionnaires, concerning their work activity before and after surgery, to patients who had previously undergone knee arthroplasty. In this cross-sectional survey it was found that 173 of 480 responders worked within 2 years prior to surgery.

Sixty-three percent of the working patients stopped within two weeks prior to surgery and 102 patients returned within 6 months. One third of those who worked prior to surgery never returned to work. Activities that most improved were operating foot pedals, operating vehicles, standing, and walking on level terrain. Activities that least improved were kneeling, crouching and clambering. Fifty patients scored 5 or less on the Work Ability Index. Thirty patients were dissatisfied.

TKP significantly, but to a different extent reduces difficulties in carrying out knee-burdening work activities between patients with different work-related knee demands.

Chapter 8

It is not yet known if UKPpatients are more likely to return to work sooner or have improved ability to work (i.e., workability) than total knee arthroplasty (TKP) patients. The objectives of our study were to determine: (1) whether patients returned to work sooner following UKP than following TKP; (2) whether UKP patients had better WORQ function scores than TKP patients; and (3) whether UKP patients have higher postoperative workability scores and greater satisfaction regarding workability than TKP patients.

A multicenter retrospective cohort study was performed that on patients at least 2 years after either UKP or TKP surgery, including only those patients that had been working in the 2 years prior to surgery. Time period between stopping work and returning to work was assessed; the WORQ scores (0 = worst–100 = best) and the Work Ability Index (WAI = 0–10) and reported satisfaction with work ability.

UKP patients (n = 157, median 60 years, 51% male) were compared to TKP patients (n = 167, median 60 years, 49% male) (n.s.). Of the 157 UKP patients, 115 (73%) returned to work within 2 years compared to 121 (72%) of TKP patients (n.s.). More UKP patients return to work within 3 months (73% versus 48%) ($p < 0.01$). WORQ scores improved similarly in both groups. The WAI was also comparable between the groups. Dissatisfaction with workability was comparable (UKP 15% versus TKP 18% (n.s.).

TKP and UKP patients have similar WORQ, WAI, and satisfaction scores. However, in this study population, UKP patients to return to work after surgery significantly sooner than TKP patients, which improves their quality of life and allows them to participate actively in society earlier. This information can help health care providers and patients weigh-up the pros and cons and choose the best treatment and timing for patients in the working population.

Chapter 9

TKP is increasingly being performed among working patients suffering from knee osteoarthritis. Two out of ten patients do not return to work (RTW) after TKP. Little evidence is available about these patients to guide clinicians. Therefore, this study investigates patients' characteristics associated with no RTW.

A multicenter retrospective cohort study was performed among working patients having undergone a primary TKP during 2005–2010. The following preoperative characteristics were assessed: age at surgery, sex, comorbidity, body mass index (BMI), preoperative sick-leave duration, patient-reported work-relatedness of knee symptoms, and physical job demands. In addition, the Knee injury and Osteoarthritis Outcome Scores (KOOS) after TKP were assessed. Backward stepwise logistic regression analyzes were performed to predict no RTW.

One hundred and sixty-seven met the inclusion criteria and 46 did not RTW. A preoperative sick-leave duration >2 weeks (OR 12.5, 90 % CI 5.0–31.5) was most strongly associated with no RTW. Other associations found were: female sex (OR 3.2, 90 % CI 1.3–8.2), BMI 30 (OR 2.8, 90 % CI 1.1–7.1), patient-reported work-relatedness of knee symptoms (OR 5.3, 90 % CI 2.0–14.1), and a physically knee demanding job (OR 3.3, 90 % CI 1.2–8.9). Age and KOOS were not associated with no RTW.

Especially obese female workers, with a preoperative sick-leave duration >2 weeks, who perform knee-demanding work and indicate that their knee symptoms are work-related have a high chance for no RTW after TKP. These results stress the importance of a more timely referral for work-directed care of patients at risk for no RTW after TKP.

Chapter 10

Once bone cuts can be performed accurately and precisely, other methods of alignment besides mechanical alignment, such as kinematic alignment, can be explored in more detail. Techniques for a more accurate placement of TKP's include using patient specific instrumentation. These techniques can be tested with the evaluation tool reported in chapter 2 to assess if the claimed accuracy can be proven. The Signature system has been proven to be accurate. Such tools could be useful to further improve TKP placement and so reduce the risk of complications such as TKP loosening. The lack of sensitivity and specificity of current diagnostic modalities to prove aseptic loosening leads to an unacceptably high number of unnecessary revisions, and on the other hand may leave others wrongly non-operated. The AtMoves technique has proven to be an effective new way of visualizing and quantifying arthroplasty loosening. The combination of a speedy diagnosis with high accuracy and lower cost than the current total care pathway makes this a promising new development. The population used in this thesis as reported in chapter 5 is comparable to a standard TKP population. Our population, methods and outcomes are consistent with literature findings, and thus suggest adequate external study-validity for the results of the return to work studies. It was shown that WORQ is a reliable, valid and responsive questionnaire and by applying the WORQ to the working population of patients undergoing knee arthroplasty in chapter 7 it was found that around a third of patients does not return to work following knee arthroplasty surgery. Patients seem to return to work sooner after UKP than after TKP. Implant survival of a UKP is shorter than that of TKP. The results of this study facilitate share decision making, by supporting well-informed choice in case of anteromedial osteoarthritis where both UKP and TKP are realistic choice options. If it is important for a patient to return to work as soon as possible, the UKP could be the preferred option. If a patient finds it most important to receive an arthroplasty which will last longer and thus obviate redo-surgery, a TKP can be chosen despite its longer return to work interval.

Despite good results in most patients there are still a number of patients who do not or cannot return to work, but who may or may not have other reasons to consider surgery. With better insight and more appropriate expectation management, shared decision making can be supported, and thus both the yes-no choice and timing of treatment can be improved. This is likely to result in more appropriate care and higher patient satisfaction, and may also improve RTW for those who aspire to do so. In those patients, rehabilitation efforts could be tailored to prioritise the performance of work activities, and those hopefully allow these patients to return even sooner.

The insight this thesis provides inevitably leads to new questions, and this points new directions for future research. Among these are for instance the evaluation of the now upcoming robotics which in some cases is now replacing PSI. But also from a patient perspective it is interesting to see if more patient specific alignment such as kinematic alignment techniques can increase the natural feel of a TKP and help improve the ability to work with a TKP because of this. Further research should focus on specific interventions to improve return to work, but also to look in patient specific cases when would be the best time to undergo TKP surgery weighing in all the pros and cons.

Nederlandse samenvatting

In het volgende zullen we kort de tien hoofdstukken van dit proefschrift samenvatten. Na de algemene inleiding richten de hoofdstukken 2-4 zich op (het verbeteren van) de technische aspecten van de totale knieprothese (TKP) operatie, terwijl de daaropvolgende hoofdstukken 5-9 zich richten op de resultaten van deze procedures voor patiënten en de samenleving. Dit proefschrift eindigt met hoofdstuk 10, de algemene discussie:

• **Hoofdstuk 1** geeft de algemene inleiding.

• **Hoofdstuk 2** beschrijft de ontwikkeling van een op CT gebaseerde techniek om de overdrachtsnauwkeurigheid van een virtueel geplande osteotomie naar de definitieve osteotomie te meten.

• **Hoofdstuk 3** evalueert de nauwkeurigheid van de voorspelde osteotomievlakken bereikt na het gebruik van de *Signature* patiënt specifieke instrumentatie (PSI) voor een totale knie prothese (TKP).

• In **Hoofdstuk 4** beschrijven we een nieuwe en nu gepatenteerde methode voor het diagnosticeren van loslating, een bekende complicatie van TKP, met behulp van CT scan en geïnduceerde verplaatsing.

• **Hoofdstuk 5** beschrijft onze voornamelijk patiëntengroep en locatie. Het rapporteert over de resultaten van de ziekenhuizen waarin onze studies worden uitgevoerd, evenals de levensduur van gebruikte TKPs en de risicofactoren voor revisie.

• In **Hoofdstuk 6** wordt een nieuwe vragenlijst ontwikkeld, de Werk, Artrose en Gewrichtsvervangingsvragenlijst (WORQ). De betrouwbaarheid, validiteit en responsiviteit worden getest en gerapporteerd.

• **Hoofdstuk 7** rapporteert over de resultaten van een dwarsdoorsnede multicenter-onderzoek naar terugkeer naar werk *(Return to Work*) na TKP.

• **Hoofdstuk 8** onderzoekt verschillen in 'terugkeer naar werk' na behandeling met TKP in vergelijking met de minder invasieve Unicompartmentale Knie Prothese (UKP).

• **Hoofdstuk 9** onderzoekt welke patiënten niet terugkeren naar werk na TKP en waarom.

• **Hoofdstuk 10** biedt de Algemene Discussie.

Hoofdstuk 1
Artrose (OA) van de heup en knie is een van de belangrijkste oorzaken van wereldwijde invaliditeit. Wereldwijd, van 369 gemelde aandoeningen, stond OA van de heup en knie op de 11e plaats als bijdrager aan wereldwijde invaliditeit. Artrose kan zich geïsoleerd ontwikkelen in het mediale of laterale compartiment van de knie (bijv. bij posttraumatische artrose op basis van een intra-articulaire fractuur) of als een meer gegeneraliseerde ziekte die alle delen van de knie aantast. Niet-operatieve opties worden meestal aangeboden voor stadium I en II artrose en omvatten patiëntenvoorlichting, zelfmanagement, oefentherapie (al dan niet met fysiotherapie), corrigerende braces en levensstijlveranderingen zoals gewichtsverlies. Chirurgisch opties zij meestal geïndiceerd voor stadium III en IV knieartrose en bestaan voornamelijk uit een variserende of valgiserende osteotomie, of bij gewrichtsvervanging een UKP of TKP. Het herstel van de knie-uitlijning wordt beschouwd als een van de pijlers van een succesvolle TKP. Om het risico op intra-operatieve malalignement en verkeerde positionering te verminderen, zijn nauwkeurigere en preciezere intra-operatieve methoden voor het verrichten van bot osteotomieën (zaagsnedes door het bot) nodig om een nauwkeurige plaatsing van de prothese te garanderen. PSI is zo'n techniek; echter, een tool is nodig om de nauwkeurigheid van dergelijke technieken te evalueren. Als een implantaat verkeerd is gepositioneerd, is er een verhoogd risico op vroegtijdige aseptische loslating. Huidige tests zijn ofwel onvoldoende gevoelig of onvoldoende specifiek om loslating nauwkeurig te kunnen diagnosticeren. Om de zorg voor deze groep patiënten te verbeteren, is een beeldvormende modaliteit nodig die een tijdige en snelle diagnose van loslating met hoge gevoeligheid en specificiteit kan stellen. Deze beeldvormingsmodaliteit moet idealiter de beweging van het implantaat kwantificeren ten opzichte van het aangrenzende bot- of cementoppervlak, in plaats van alleen de neveneffecten van loslating, zoals radiolucente lijnen of een hoge botomzetting, te visualiseren.

Als er nieuwe implantaten op de markt worden gebracht, is het belangrijk om te evalueren of ze niet inferieur zijn of zelfs beter zijn dan wat momenteel beschikbaar is. Historisch gezien hebben uitkomstmaten na een knieprothese zich voornamelijk gericht op overlevingsgegevens van het implantaat, mate van kniebeweging en pijnvermindering, terwijl de bredere relevantie van maatschappelijke participatie, en met name terugkeer naar werk, ernstig onderbelicht is gebleven. Er is een nieuwe vragenlijst nodig om te beoordelen hoe goed patiënten kunnen terugkeren naar werk na een TKP. Met zo'n vragenlijst is het mogelijk om te evalueren hoe snel en hoe goed patiënten terugkeren naar werk. Het kan ook mogelijk maken om verschillen te vergelijken tussen bijvoorbeeld UKP en TKP wat betreft terugkeer naar werk. Bovendien is het belangrijk om te weten welke patiënten waarschijnlijk niet zullen terugkeren naar werk na knieprothese om zo eventuele interventies te ontwikkelen om dit te verbeteren..

Hoofdstuk 2
Nauwkeurige overdracht van een preoperatief gepland osteotomievlak naar het bot tijdens de operatie is van belang voor correctie osteotomie chirurgie, tumorresecties, implantaat positionering en nieuwe knieprothese osteotomietechnieken zoals PSI of de meer recente robot chirurgie. Methoden om een preoperatief gepland osteotomievlak te vergelijken met de werkelijke chirurgische ontstane vlak bestaan, maar de nauwkeurigheid van deze technieken is beperkt of onbekend. Dit artikel stelt een op CT gebaseerde techniek voor die het mogelijk maakt om virtuele osteotomievlakken te vergelijken met de daadwerkelijke osteotomievlakken. De methodologische nauwkeurigheid en reproduceerbaarheid van de techniek worden geëvalueerd met behulp van CT-afgeleide volumedata van kadaverbenen, dat dient om TKP-osteotomieën in 3D-ruimte te plannen en perfecte osteotomieën te simuleren die niet gehinderd worden door chirurgische fouten. De methodologische variabiliteit van de techniek wordt verder onderzocht met herhaalde CT-scans na werkelijke osteotomiechirurgie van hetzelfde kadaverpreparaat. Verplaatsingsfouten (d_{err}) en hoekfouten in het sagittale en coronale vlak (b_{err}, g_{err}) worden gemeten met hoge nauwkeurigheid en reproduceerbaarheid (d_{err} = −0.11 ± 0.06 mm; b_{err} = 0.08 ± 0.04°, g_{err} = −0.03 ± 0.03°). De voorgestelde methode om de positie en oriëntatie van een osteotomievlak te evalueren, heeft een hoge intrinsieke nauwkeurigheid en reproduceerbaarheid. De methode kan van grote waarde zijn voor het meten van de overdrachtsnauwkeurigheid van nieuwe technieken voor positionering en oriëntatie van een chirurgische snede in 3D-ruimte.

Hoofdstuk 3
Malalignement van implantaten is een belangrijke oorzaak van falen na een TKP. Om nauwkeurigere 3D-planning en uitvoering van de osteotomiesneden tijdens de operatie te bereiken, werd de Signature (*Biomet*, Warschau) patiënt specifieke instrumentatie gebruikt om pin-geleiders te produceren voor de positionering van de osteotomieblokken door middel van computergestuurde fabricage op basis van CT-scanbeelden. De onderzoeksvraag van deze studie is: wat is de overdrachtsnauwkeurigheid van de osteotomievlakken gepland en uitgevoerd door het Signature PSI-systeem als de preoperatieve 3D-planning met de intra-operatieve osteotomie vlakken tijdens een TKP worden vergeleken?

De overdrachtsnauwkeurigheid die wordt bereikt door het gebruik van het *Signature* PSI-systeem werd geëvalueerd door de voorspelde osteotomievlakken preoperatief te vergelijken met de daadwerkelijke intra-operatieve osteotomievlakken in menselijke kadaverbenen. Resultaten werden gemeten in termen van translatie en rotatiefouten (varus, valgus, flexie, extensie en axiale rotatie) voor zowel tibia- als femur-osteotomieën.

Gemiddelde translatie fouten tussen de geplande osteotomievlakken en de daadwerkelijke resulterende osteotomievlakken waren 0,8 mm (± 0,5 mm) voor de tibia en 0,7 mm (± 4,0 mm) voor de femur. Gemiddelde rotatiefouten ten opzichte van voorspelde en bereikte osteotomievlakken waren 0,1° (± 1,2°) varus en 0,4° (± 1,7°) voorste helling (extensie) voor de tibia, en 2,8° (± 2,0°) varus en 0,9° (± 2,7°) flexie en 1,4° (± 2,2°) externe rotatie voor de femur.

De overeenkomst tussen osteotomievlakken gepland met behulp van het Signature-systeem en daadwerkelijk bereikte osteotomievlakken was uitstekend voor de tibia, terwijl een iets lagere nauwkeurigheid werd gevonden voor de femur. Het gebruik van de Signature 3D-osteotomie techniek bij TKP kan nauwkeurige osteotomievlakken realiseren, op maat gemaakt voor individuele patiënten, met name voor patiënten met botmisvorming, en zorgen voor een betere plaatsing van het implantaat.

Hoofdstuk 4

Na een TKP is bij ongeveer 13% van de patiënten revisiechirurgie nodig om aseptische loslating aan te pakken. Geen van de huidige diagnostische modaliteiten heeft een gevoeligheid of specificiteit hoger dan 70-80% om loslating te detecteren, wat leidt tot 20-30% van de patiënten die onnodige, risicovolle en dure revisiechirurgie ondergaan, of ongepaste chirurgische vertraging bij patiënten die juist wel die operatie nodig hebben en nu niet-operatief worden behandeld. Een betrouwbare beeldvormingsmodaliteit is nodig om aseptische loslating te diagnosticeren. Deze studie presenteert een nieuwe, niet-invasieve methode en evalueert de reproduceerbaarheid en betrouwbaarheid ervan in een kadaverstudie.

Tien kadavers werden geïmplanteerd met losjes passende tibiale kniecomponenten en CT-scans werden gemaakt onder valgus en varus belasting met behulp van een ontwikkeld belasting apparaat. Geavanceerde driedimensionale beeldvormingssoftware werd gebruikt om de verplaatsing te kwantificeren. Vervolgens werden de implantaten aan het bot bevestigd en gescand om de verschillen tussen de vaste en losse toestand te bepalen. Reproduceerbaarheidsfouten werden gekwantificeerd met behulp van een bevroren specimen waarin geen verplaatsing kon zijn bij 10 herhaalde scans in verschillende posities. Reproduceerbaarheidsfouten, uitgedrukt als gemiddelde doelregistratiefout, schroefasrotatie en maximale totale puntbeweging, waren respectievelijk 0,073 mm (SD 0,033), 0,129 graden (SD 0,039) en 0,116 mm (SD 0,031). In de losse toestand waren alle verplaatsingen en rotatieveranderingen groter dan de gerapporteerde reproduceerbaarheidsfouten. Het vergelijken van de gemiddelde doelregistratiefout, schroefasrotatie en maximale totale puntbeweging in de losse toestand met de vaste toestand resulteerde in gemiddelde verschillen van respectievelijk 0,463 mm (SD 0,279; $p = 0,001$), 1,769 graden (SD 0,868; $p < 0,001$) en 1,339 mm (SD 0,712; $p < 0,001$).

De resultaten van dit kadaveronderzoek laten zien dat deze niet-invasieve methode, nu AtMoves genoemd, reproduceerbaar en betrouwbaar is voor het detecteren van geïnduceerde bewegingsverschillen tussen vaste en losse tibiale componenten.

Hoofdstuk 5

De overlevingspercentages van een implantaat per verschillende tijdseenheid is een belangrijke uitkomstmaat bij het beoordelen van de overleving van een nieuwe TKP-ontwerp. Als de vroege overleving van de prothese bekend zou zijn en deze blijkt goed te zijn in vergelijking met andere prothesen, zou dit het verdere gebruik van een nieuw implantaat rechtvaardigen, zoals die van de Vanguard TKP.

In twee ziekenhuizen werd een cross-sectioneel onderzoek uitgevoerd bij 807 patiënten die een primaire *Vanguard* (Biomet) TKP hadden ontvangen. De onderzoeksvragen waren (1) wat zijn de overlevingspercentages van de *Vanguard* TKP na twee en zes jaar, (2) wat zijn de klinische resultaatscores middels patient reported outcome measures, (3) wat zijn de bevindingen bij revisie en (4) wat zijn voorspellers voor revisie?

De gemiddelde leeftijd op het moment van de operatie was 67,0 (SD 10,0). De gemiddelde follow-up was 3,6 jaar (95% CI 3,56-3,73). Na twee jaar was de overleving 97,2% voor bij revisie voor alle redenen als uitkomst maat (767 patiënten overgebleven) en 99% bij revisie voor prothese-gerelateerde redenen (777 overgebleven). Na zes jaar was dit respectievelijk 96,5% (40 overgebleven) en 98,6% (41 overgebleven). De algehele klinische resultaten (84% respons op KOOS, Oxford en NRS) waren goed. Een eerdere corrigerende tibia koposteotomie was een risicofactor voor revisie (hazard ratio 5.1, P = 0.001).

Deze vroege ervaring met de *Vanguard* laat zien dat het implantaat een goede levensduur heeft met bijna geen nadelige uitkomsten gerelateerd aan het implantaat en rechtvaardigt daarom verder gebruik van het implantaat.

Hoofdstuk 6

Hoewel TKP zeer effectief is bij het behandelen van kniepijn en functionele beperkingen, is er weinig bekend over hoe veel invloed het heeft op de mogelijkheid van patiënten om weer aan het werk te gaan.. Ook is het onduidelijk in hoeverre de kans op een succesvolle terugkeer naar werk wordt beïnvloed door het tijdstip van de operatie.

De Work, Osteoarthritis or joint-Replacement Questionnaire (WORQ) is ontwikkeld om de fysieke moeilijkheden te beoordelen die worden ervaren op het werk vóór en na een TKP. Er werden dertien vragen ontworpen. De WORQ is getest op interne consistentie door middel van factoranalyze, interne betrouwbaarheid (Cronbach's α) en constructvaliditeit. Er werd een test-hertest voor betrouwbaarheid uitgevoerd om de standaardfout van de meting (SEM-overeenkomst), betrouwbaarheid (ICC) en kleinste detecteerbare verandering (SDC) te analyseren bij individuen en groepen. Ten slotte werden responsiviteit (gestandaardiseerde responsmiddelen [SRM]), vloer- en plafondeffecten en interpreteerbaarheid (minimaal belangrijke verandering [MIC]) geanalyseerd.

Het is aangetoond dat de WORQ een betrouwbare, valide en responsieve vragenlijst is die kan worden gebruikt om de impact van knieklachten na een TKP op het vermogen van patiënten om te werken te beoordelen.

WORQ is een nieuwe vragenlijst met goede klinimetrische kwaliteit. Het is getest en blijkt goed te zijn wat betreft validiteit, interne consistentie, reproduceerbaarheid, constructvaliditeit, responsiviteit, vloer- en plafondeffecten, en interpreteerbaarheid in een populatie van TKP-patiënten. Het kan worden gebruikt voor zowel individuen als groepen om knieproblemen te beoordelen die worden ervaren bij het uitvoeren van werk gerelateerde activiteiten.

Hoofdstuk 7

Het aantal patiënten dat een TKP ontvangt tijdens hun werkende leven neemt toe, maar er is weinig bekend over de impact van een TKP op de re-integratie van patiënten op de werkvloer. We hebben vragenlijsten verstuurd aan patiënten die een TKP hebben ondergaan met vragen over hun werkactiviteiten voor en na de operatie. Uit dit cross-sectioneel onderzoek bleek dat 173 van de 480 respondenten binnen 2 jaar voor de operatie betaald of onbetaald werk verrichtte. Zestig procent van de werkende patiënten stopte binnen twee weken voor de operatie en 102 patiënten keerden binnen 6 maanden terug. Een derde van degenen die voor de operatie werkten, keerde nooit terug naar het werk. Activiteiten die het meest verbeterden waren het bedienen van voetpedalen, voertuigen besturen, staan en lopen op vlak terrein. Activiteiten die het minst verbeterden, waren knielen, hurken en klauteren. Vijftig patiënten scoorden 5 of minder op de Work Ability Index. Dertig patiënten waren ontevreden. Een TKP vermindert aanzienlijk de moeilijkheden bij het uitvoeren van knie belastende werkactiviteiten, maar wel in verschillende mate tussen patiënten met verschillende knie gerelateerde werkvereisten.

Hoofdstuk 8

Het is nog niet bekend of patiënten na UKP eerder terugkeren naar werk of een verbeterde werkcapaciteit hebben dan patiënten na een TKP. Ons onderzoek had tot doel om te bepalen: (1) of patiënten na UKP eerder terugkeren naar werk dan na TKP; (2) of UKP-patiënten betere WORQ-functiescores hebben dan TKP-patiënten; en (3) of UKP-patiënten hogere postoperatieve werkbaarheidsscores en grotere tevredenheid hebben over werkbaarheid dan TKP-patiënten. Een multicenter retrospectieve cohortstudie werd uitgevoerd op patiënten die minstens 2 jaar na UKP- of TKP-operatie waren. Alleen patiënten die in de 2 jaar voorafgaand aan de operatie hadden gewerkt, betaald of onbetaald werk, werden geïncludeerd. De periode tussen het stoppen met werken en het hervatten van werk werd beoordeeld; de WORQ-scores (0 = slecht, 100 = best) en de Work Ability Index (WAI = 0–10) en gerapporteerde tevredenheid over werkcapaciteit werden geanalyseerd. UKP-patiënten (n = 157, mediane leeftijd 60 jaar, 51% man) werden vergeleken met TKP-patiënten (n = 167, mediane leeftijd 60 jaar, 49% man) (n.s.). Van de 157 UKP-patiënten keerden er 115 (73%) binnen 2 jaar terug naar werk, vergeleken met 121 (72%) van de TKP-patiënten (n.s.). Meer UKP-patiënten keerden terug naar werk binnen 3 maanden (73% versus 48%) ($p < 0,01$). WORQ-scores verbeterden op vergelijkbare wijze in beide groepen. De WAI was ook vergelijkbaar tussen de groepen. Ontevredenheid over werkbaarheid was vergelijkbaar (UKP 15% versus TKP 18%) (n.s.). TKP- en UKP-patiënten hebben vergelijkbare WORQ-, WAI- en tevredenheidsscores. Echter, in deze onderzoekspopulatie keren UKP-patiënten significant eerder terug naar werk na de operatie dan TKP-patiënten, wat hun kwaliteit van leven verbetert en hen in staat stelt eerder actief deel te nemen aan de samenleving. Deze informatie kan zorgverleners en patiënten helpen de voor- en nadelen af te wegen en de beste behandeling en timing te kiezen voor werkende patiënten.

Hoofdstuk 9
TKP wordt steeds vaker uitgevoerd bij werkende patiënten met knieartrose. Twee op de tien patiënten keren niet Terug Naar Werk (TNW) na een TKP. Er is weinig bewijs beschikbaar over deze patiënten om clinici te begeleiden. Deze studie onderzoekt daarom kenmerken van patiënten die niet TNW keren na een TKP. Een multicenter retrospectieve cohortstudie werd uitgevoerd bij werkende patiënten die tussen 2005 en 2010 een primaire TKP hadden ondergaan. De volgende preoperatieve kenmerken werden beoordeeld: leeftijd bij de operatie, geslacht, co-morbiditeit, body mass index (BMI), preoperatieve ziekteduur, door de patiënt gemelde werk gerelateerdheid van knieklachten en fysieke werkeisen. Bovendien werden de Knee injury and Osteoarthritis Outcome Scores (KOOS) na TKP beoordeeld. Achterwaartse stapsgewijze logistische regressieanalyses werden uitgevoerd om geen TNW te voorspellen. Een honderdzevenenzestig voldeden aan de inclusiecriteria en 46 keerden niet TNW. Een preoperatieve ziekteduur >2 weken (OR 12,5, 90% CI 5,0–31,5) was het sterkst geassocieerd met geen TNW. Andere gevonden associaties waren vrouwelijk geslacht (OR 3,2, 90% CI 1,3–8,2), BMI 30 (OR 2,8, 90% CI 1,1–7,1), door de patiënt gemelde werk gerelateerdheid van knieklachten (OR 5,3, 90% CI 2,0–14,1) en een fysiek belastende baan voor de knie (OR 3,3, 90% CI 1,2–8,9). Leeftijd en KOOS waren niet geassocieerd met geen TNW. Vooral zwaarlijvige vrouwelijke werknemers, met een preoperatieve ziekteduur >2 weken, die knie-belastend werk verrichten en aangeven dat hun knieklachten werk gerelateerd zijn, hebben een hoge kans om na een TKP niet TNW te keren. Deze resultaten benadrukken het belang van een tijdige verwijzing voor op werk gerichte zorg bij patiënten die risico lopen om na een TKP niet TNW te keren.

Hoofdstuk 10
Zodra bot osteotomievlakken nauwkeurig en precies kunnen worden uitgevoerd, kunnen andere methoden van uitlijning dan de klassieke mechanische uitlijning, zoals kinematische uitlijning, nader worden onderzocht. Technieken voor een nauwkeuriger plaatsing van de TKP zijn onder meer het gebruik van patiënt specifieke instrumentatie. Deze technieken kunnen worden getest met de evaluatietool die is gerapporteerd in hoofdstuk 2 om te beoordelen of de beweerde nauwkeurigheid kan worden aangetoond.

Het Signature-systeem is bewezen nauwkeurig. Dergelijke tools kunnen nuttig zijn om de plaatsing van TKP's verder te verbeteren en zo het risico op complicaties zoals aseptische loslating van de TKP te verminderen. Als loslating dan toch optreedt, leidt het gebrek aan gevoeligheid en specificiteit van huidige diagnostische modaliteiten om aseptische loslating aan te tonen tot een onaanvaardbaar hoog aantal onnodige revisies. Tevens leidt dit aan de andere kant anderen kant van de medaille tot ten onrechte niet-geopereerde patiënten. De AtMoves-techniek heeft zich bewezen als een effectieve nieuwe manier om loslating van prothesen te visualiseren en te kwantificeren. De combinatie van een snelle diagnose met hoge nauwkeurigheid en lagere kosten dan het huidige totale zorgtraject maakt dit een veelbelovende nieuwe ontwikkeling. De populatie die in dit proefschrift wordt beschreven in hoofdstuk 5 is vergelijkbaar met een standaardpopulatie van TKP's. Onze populatie, methoden en resultaten zijn consistent met bevindingen in de literatuur en suggereren dus een adequate externe studievaliditeit voor de resultaten van de studies over terugkeer naar werk. Er werd aangetoond dat WORQ een betrouwbare, geldige en responsieve vragenlijst is en door de WORQ toe te passen op de werkende populatie van patiënten die een TKP ondergaan bleek dat ongeveer een derde van de patiënten na de TKP niet terugkeert naar werk. Patiënten lijken eerder terug te keren naar werk na UKP dan na TKP. De overleving van een UKP-implantaat is korter dan die van een TKP. De resultaten van deze studie vergemakkelijken het nemen van beslissingen door een goed geïnformeerde keuze te ondersteunen in geval van anteromediale artrose waarbij zowel UKP als TKP realistische keuzemogelijkheden zijn. Als het voor een patiënt belangrijk is om zo snel mogelijk terug te keren naar werk, kan de UKP de voorkeurskeuze zijn. Als een patiënt het belangrijkst vindt om een prothese te ontvangen die langer meegaat en dus herhaaloperatie overbodig maakt, kan een TKP worden gekozen ondanks het langere TNW-interval. Ondanks goede resultaten bij de meeste patiënten zijn er nog steeds een aantal patiënten die niet of niet kunnen terugkeren naar werk, maar die mogelijk andere redenen hebben om een operatie te overwegen. Met beter inzicht en meer geschikt verwachtingsmanagement kan gedeelde besluitvorming worden ondersteund, en zo zowel de ja-nee-keuze als de timing van de behandeling worden verbeterd. Dit leidt waarschijnlijk tot meer geschikte zorg en een hogere patiënttevredenheid, en kan ook de TNW verbeteren voor degenen die dit ambiëren. Bij deze patiënten kunnen revalidatie-inspanningen worden afgestemd om de uitvoering van werkactiviteiten te prioriteren, en hopelijk kunnen deze patiënten zo nog sneller terugkeren.

Het inzicht dat dit proefschrift biedt, leidt onvermijdelijk tot nieuwe vragen en wijst op nieuwe richtingen voor toekomstig onderzoek. Hieronder vallen bijvoorbeeld de evaluatie van de nu opkomende robotica die in sommige gevallen nu PSI vervangt. Maar ook vanuit het perspectief van de patiënt is het interessant om te zien of meer patiënt specifieke uitlijningstechnieken, zoals kinematische uitlijningstechnieken, het natuurlijke gevoel van een TKP kunnen vergroten en kunnen helpen de werkbaarheid met een TKP te verbeteren. Verder onderzoek moet zich richten op specifieke interventies om de terugkeer naar werk te verbeteren, maar ook om in patiënt specifieke gevallen te kijken wanneer het beste moment is om een TKP-operatie te ondergaan, waarbij alle voor- en nadelen worden afgewogen.

Dankwoord

Gino, bedankt voor al de jaren van hulp, leiderschap maar bovenal vriendschap, het is een genot om met je te werken en het leven te delen ook buiten het werk. Lead the way you would like to be led. Ik kijk uit naar de hopelijk vele komende jaren samen.

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PhD Portfolio

Name PhD student: Arthur Johan Kievit
PhD period: January 2011 – August 2024
Names of PhD supervisor(s) & co-supervisor(s):
prof. dr. G.M.M.J. Kerkhoffs (promotor)
Dr. ir. Leendert Blankevoort (promotor)
Dr. Matthias Ulrich Schafroth (co-promotor)
Dr. P.P.F.M. Kuijer (co-promotor)

1. PhD training

	Year	ECTS
General courses		
Course Entrepreneurship in Health and Life Sciences; winner best pitch award	2012	1.5
Good Clinical Practice	2011	1
Course in Practical Biostatistics	2012	1.4
Scientific writing in English	2011	1.5
Oral Presentation in English	2011	1
The AMC World of Science	2011	0.7
Basic Course Legislation and Organization	2011	1.5
Course Epidemiology Collegium Chirurgicum Neerlandicum	2010	1
Specific courses		
Advanced Trauma and Life Support Instructor Course Amsterdam	2023	2
Advanced Trauma and Life Support Refresher Course Amsterdam	2022	1
Hospital Major Incident Medical Management and Support course (HMIMMS) ALSG	2021	1
Stryker Triathlon and MAKO training	2019	0.5
“Stralingshygiëne voor medisch specialisten 2019” - IV (Nieuwegein)	2019	1
Oxford Instructional Knee Course Oxford	2017	1
Advanced Trauma and Life Support Refresher Course – New York	2017	1
AO Advanced Principles of Fracture Management for Surgeons - Leeds	2017	1
Basic Principles in Fracture Treatment – AO in Davos	2014	1
Advances Trauma and Life Support - Baltimore	2013	1
Presentations		
Periprosthetic acetabular fractures, traumadagen	2023	0.5
Business pitch Diagnosing loosening of joint prosthesis at Healthy Ideas, Healthy Returns	2019	0.5
The Vanguard Complete Knee System: 10 Years Of FollowUp, EFFORT Barcelona	2018	0.5
“Vroege resultaten van Vanguard totale knieprothese” NOV najaarscongres	2013	0.5
“Terugkeer naar werk na een totale knieprothese” NOV najaarscongres	2013	0.5
ISIAT congress in Barcelona Dupra trial	2013	0.5

Course Entrepreneurship in Health and Life Sciences; winner best pitch award/ Pitch knee arthroplasty loosening	2012	0.5
"Anterior cruciate ligament reconstruction surgery and osteoarthritis; primary reconstructions versus revision reconstructions using allograft material" ESSKA congress poster presentation	2012	0.5
(Inter)national conferences		
AAOS Annual Meeting 2024, San Fransisco, USA	2024	2.0
ESSKA, Milan, Italy	2024	1.5
NOV congresses, yearly	2011-2024	5
Member of Scientific committee 18th Biennial ESSKA Congress Glasgow	2016-2018	2
Zimmer Biomet Meeting Totally Hip - Gothenburg	2017	2
ESSKA meeting Barcelona	2016	1
ESSKA Amsterdam	2014	1
Other		
Organizer Ride for Research http://www.traumaplatform.org/challenge2016/	2016	1
Organizer ESSKA Cycle for Science Amsterdam-Barcelona, for Prof. C.N. van Dijk	2016	2
Skate for science	2015	1
Organizer of obligatory national knee arthroplasty residents course	2012-2014 and 2020-2024	4
Book coördinator ESSKA/AFAS Talar OCD With special emphasis on Diagnosis, Planning and Rehabilitation (van Dijk, Kennedy, ISBN 978-3-642-45097-6)	2012-2014	3
ESSKA-AFAS Amsterdam Foot and Ankle Course support, Prof. Dr. C.N. van Dijk	2012-2014	2
Member of "AMC actueel" taskforce. Lead Dr. Linthorst and director of AMC Prof. Levi en Prof. Heineman	2012- 2014	0.5
Secretary for Aprove (AMC PhD association with 1200 members) www.aprove.nl	2011 - 2014	6
Chairman of Aprove PhD symposium organisation committee "Science & Scams: Stop fraud and flourish!" 200 guests, Westergasfabriek, subsidy received by ZonMw	2012	3
Weekly Journal Clubs (Amsterdam UMC)	2010 - 2014	3.0
Science meetings Orthopedic surgery and sports medicine, Amsterdam UMC	2010 - 2024	4.0
Amsterdam Movement Sciences Annual Meeting	2021	0.6

2. Teaching		
	Year	**ECTS**
Lecturing		
Presenter and educator for return to work following Total Knee Arthroplasty Netherlands School of Public and Occupational Health (NSPOH)	2013-2019	3
Lecturing orthopaedic residents on hip and knee disease	2020-2024	1
Tutoring, Mentoring Mentor medical students group	2023-2024	2
Supervising		
Bachelor and master thesis projects: Jens te Velde, Chiel Klein, Bastiaan van Zanten, Steven van der Aart, Samantha Eikenhout, Judith Groot, Gerjanne Reins, Ilse Pos and Jarno de Haas	2010-2024	9
PhD candidates: George Buijs, Alon Hopman, Yvonne van Zaanen, Annemieke Ter Wee, Caroline Mag, Thijs Pahplatz, Jan Ophuis, Brent van der Doelen	2010-2024	8
2x Advanced Trauma and Life Support Instructor Tilburg	2023	2

3. Parameters of Esteem	
	Year
Share holder for AMC startup company AtMoves, previously Orthokey Inventor on patents US US-2019-0000631-A1 EU patent 16815687	2021-present
Grants (**Primary applicant and co-applicant**) Total €2.797.694	
€571.791 Doelmatigheidsonderzoek ZonMW Open Ronde 2025 Arthroscopy vs. minimal invasive needle arthroscopy for patients with bacterial knee arthritis - RCT	**2024**
€82.502,70 Unrestricted research grant by Zimmer Biomet	**2023**
€249.674 Kansen voor West	**2023**
€250.000 Take-off 2 grant ZonMw-NWI	**2022**
€227.935 Nano-arthroscopie, scopiëren zonder gebruik van steeds meer begrensde OK capaciteit	**2021**
€656.892 NL Health Holland – TKI –PPP grant “Comforthod – an innovative tool to diagnose loosening of a total knee arthroplasty”	**2021**
€150.000 NWO demonstrator grant subsidy: DisJoint: a non-invasive method for detecting implant loosening in knee arthroplasty	**2020**
€ 46.900 STW Take-Off grant	**2017**
€ 28.000 Stichting Steun Orthopedie AMC	**2017**
€250.000 ZonMW/NGI pre-seed grant: Developing new diagnostic techniques for knee arthroplasty loosening	**2014**
€ 24.000 AMC BDDA pre-seed project knee arthroplasty loosening	**2014**
€ 10.000 Fastforward meeting Deloitte en Pontes: winner best pitch & business plan from the AMC, VUMC and UMCU	2014
€ 250.000 unrestricted research grant Zimmer Biomet	2014
Awards and Prizes	
Winner best pitch award, Course Entrepreneurship in Health and Life Sciences	**2012**

List of publications

2024

- Y. van Zaanen, M.J.M. Hoozemans, **A.J. Kievit**, P.P.F.M. Kuijer, R.C.I. van Geenen, T.M.J. Pahlplatz, L. Blankevoort, M.U. Schafroth, D. Haverkamp, T.M.J.S. Vervest, D.H.P.W. Das, V.A. Scholtes, Predictive Validity of the Work, Osteoarthritis, or Joint Replacement Questionnaire (WORQ) for Return to Work after Total Knee Arthroplasty: A 12-Month Multicenter Prospective Cohort Study, The Journal of Arthroplasty, 2024, ISSN 0883-5403, https://doi.org/10.1016/j.arth.2024.08.057.
- George S. Buijs, **Arthur J. Kievit**, Matthias U. Schafroth, Leendert Blankevoort, An evaluation of the diagnostic performance of the triphasic bone scintigraphy in patients suspected of aseptic total knee arthroplasty loosening, Journal of Orthopaedics, Volume 59, 2025, Pages 106-110, ISSN 0972-978X, https://doi.org/10.1016/j.jor.2024.08.007.
- Ibtissam Acem, Ewout W Steyerberg, Marta Spreafico, Dirk J Grünhagen, Dario Callegaro, Robert J Spinner, Courtney Pendleton, J Henk Coert, Rosalba Miceli, Giulia Abruzzese, Uta E Flucke, Willem-Bart M Slooff, Thijs van Dalen, Lukas B Been, Han J Bonenkamp, Monique H M E Anten, Martinus P G Broen, Marc H A Bemelmans, Jos A M Bramer, Gerard R Schaap, **Arthur J Kievit**, Jos van der Hage, Winan J van Houdt, Michiel A J van de Sande, Alessandro Gronchi, Cornelis Verhoef, Enrico Martin, Survival after resection of malignant peripheral nerve sheath tumors: Introducing and validating a novel type-specific prognostic model, Neuro-Oncology Advances, Volume 6, Issue 1, January-December 2024, vdae083, https://doi.org/10.1093/noajnl/vdae083
- **Kievit AJ**, Buijs GS, Dobbe JGG, Ter Wee MA, Kerkhoffs GMMJ, Streekstra GJ, Schafroth MU, Blankevoort L. Corrigendum to "Promising results of a non-invasive measurement of knee implant loosening using a loading device, CT-scans and 3D image analysis" [Clinical Biomechanics volume 104, 105930, April 2023, 105930]. Clin Biomech (Bristol, Avon). 2024 Jun;116:106283. doi: 10.1016/j.clinbiomech.2024.106283. Epub 2024 Jun 4. Erratum for: Clin Biomech (Bristol, Avon). 2023 Apr;104:105930. doi: 10.1016/j.clinbiomech.2023.105930. PMID: 38834383.
- Buijs, G.S., **Kievit, A.J.,** Ter Wee, M.A., Magg, C., Dobbe, J.G.G., Streekstra, G.J. et al. (2024) Non-invasive quantitative assessment of induced component displacement can safely and accurately diagnose tibial component loosening in patients: a prospective diagnostic study. Knee Surgery, Sports Traumatology, Arthroscopy, 1–12. https://doi.org/10.1002/ksa.12299
- Buijs, G.S., Kooijenga, A.C., Rikken, Q.G.H., Schafroth, M.U., **Kievit, A.J.** & Blankevoort, L. (2024) MRI and SPECT/CT demonstrate, with low certainty of evidence, the highest diagnostic accuracy for aseptic knee arthroplasty loosening: a systematic comparative diagnostic test review and meta-analysis. Knee Surgery, Sports Traumatology, Arthroscopy, 32, 2061–2074. https://doi.org/10.1002/ksa.12206
- Caroline Magg, Maaike A. ter Wee, George S. Buijs, **Arthur J. Kievit,** Dennis A. Krap, Johannes G. G. Dobbe, Geert J. Streekstra, Leendert Blankevoort, Clara I. Sánchez,

"Towards automation in non-invasive measurement of knee implant displacement," Proc. SPIE 12927, Medical Imaging 2024: Computer-Aided Diagnosis, 129270R (3 April 2024); https://doi.org/10.1117/12.3008090
- Clinical meaningful variability in recovery trajectories of work-related knee-straining activities and return to work in total knee arthroplasty patients of working age. A multicenter 12 months prospective cohort study Zaanen, Yvonne v. ; Hoozemans, Marco J. ; **Kievit, Arthur J**. ; van Geenen, Rutger C. ; Pahlplatz, Thijs M. ; Blankevoort, Leendert ; Schafroth, Matthias U. ; Haverkamp, Daniel ; Vervest, Ton M. ; Das, Dirk ; Scholtes, Vanessa A. ; Kuijer, P.Paul F. Osteoarthritis and cartilage, 2024-04, Vol.32, p.S540
- Walinga, A.B., Janssen, S.J., **Kievit, A.J.,** The International Panel of Clinical Experts, de Borgie, C.A.J.M. & Kerkhoffs, G.M.M.J. (2024) Consensus on the definition and criteria for failure of surgical treatment in bacterial arthritis of a native joint: an international Delphi study. Knee Surgery, Sports Traumatology, Arthroscopy, 32, 235–242. https://doi.org/10.1002/ksa.12027

2023

- Te Velde JP, Buijs GS, Schafroth MU, Saouti R, Kerkhoffs GMMJ, **Kievit AJ**. Total Hip Arthroplasty in Teenagers: A Systematic Literature Review. J Pediatr Orthop. 2023 Nov 29. doi: 10.1097/BPO.0000000000002578. Epub ahead of print. PMID: 38018793.
- van Zaanen Y, Siertsema T, **Kievit AJ**, van Geenen RCI, Pahlplatz TMJ, Hoozemans MJM, Blankevoort L, Schafroth MU, Haverkamp D, Vervest TMJS, Das DHPW, Scholtes VA, Kuijer PPFM. Only Low Patients' Expectations Are Prognostic for Dissatisfaction With Performing Work-Related Knee-Straining Activities After Total Knee Arthroplasty: A Prospective Multicenter Cohort Study. Arch Phys Med Rehabil. 2023 Dec;104(12):2051-2058. doi: 10.1016/j.apmr.2023.05.004. Epub 2023 Jun 2. PMID: 37270023.
- **Kievit AJ**, Buijs GS, Dobbe JGG, Ter Wee A, Kerkhoffs GMMJ, Streekstra GJ, Schafroth MU, Blankevoort L. Promising results of an non-invasive measurement of knee implant loosening using a loading device, CT-scans and 3D image analysis. Clin Biomech (Bristol, Avon). 2023 Apr;104:105930. doi: 10.1016/j.clinbiomech.2023.105930. Epub 2023 Mar 3. PMID: 36906985.
- van Zaanen Y, **Kievit AJ**, van Geenen RCI, Pahlplatz TMJ, Hoozemans MJM, Blankevoort L, Schafroth MU, Haverkamp D, Vervest TMJS, Das DHPW, Scholtes VA, van der Beek AJ, Kuijer PPFM. Does Consulting an Occupational Medicine Specialist Decrease Time to Return to Work Among Total Knee Arthroplasty Patients? A 12-Month Prospective Multicenter Cohort Study. J Occup Rehabil. 2023 Jun;33(2):267-276. doi: 10.1007/s10926-022-10068-1. Epub 2022 Sep 9. PMID: 36083360; PMCID: PMC10172284.
- van Zaanen Y, Siertsema T, **Kievit AJ**, van Geenen RCI, Pahlplatz TMJ, Hoozemans MJM, Blankevoort L, Schafroth MU, Haverkamp D, Vervest TMJS, Das DHPW, Scholtes VA, Kuijer PPFM. Only Low Patients' Expectations Are Prognostic for

Dissatisfaction With Performing Work-Related Knee-Straining Activities After Total Knee Arthroplasty: A Prospective Multicenter Cohort Study. Arch Phys Med Rehabil. 2023 Dec;104(12):2051-2058. doi: 10.1016/j.apmr.2023.05.004. Epub 2023 Jun 2. PMID: 37270023.

- Walinga AB, Stornebrink T, Emanuel KS, **Kievit AJ**, Janssen SJ, Kerkhoffs GMMJ. Failure rates in surgical treatment in adults with bacterial arthritis of a native joint: a systematic review of 8,586 native joints. Arch Orthop Trauma Surg. 2023 Nov;143(11):6547-6559. doi: 10.1007/s00402-023-04958-z. Epub 2023 Jul 3. PMID: 37395855; PMCID: PMC10541340.
- van Dijk ML, Te Loo LM, Vrijsen J, van den Akker-Scheek I, Westerveld S, Annema M, van Beek A, van den Berg J, Boerboom AL, Bouma A, de Bruijne M, Crasborn J, van Dongen JM, Driessen A, Eijkelenkamp K, Goelema N, Holla J, de Jong J, de Joode A, **Kievit AJ**, Klooster JV, Kruizenga H, van der Leeden M, Linders L, Marks-Vieveen J, Mulder DJ, Muller F, van Nassau F, Nauta J, Oostvogels S, Oude Sogtoen J, van der Ploeg HP, Rijnbeek P, Schouten L, Schuling R, Serné EH, Smuling S, Soeters MR, Verhagen EALM, Zwerver J, Dekker R, van Mechelen W, Jelsma JGM. LOFIT (Lifestyle front Office For Integrating lifestyle medicine in the Treatment of patients): a novel care model towards community-based options for lifestyle change-study protocol. Trials. 2023 Feb 17;24(1):114. doi: 10.1186/s13063-022-06960-z. PMID: 36803271; PMCID: PMC9936650.
- ter Wee, M.A., Dobbe, J.G.G., Buijs, G.S., **A. J. Kievit**, M. U. Schafroth, M. Maas, L. Blankevoort & G. J. Streekstra. Load-induced deformation of the tibia and its effect on implant loosening detection. Sci Rep 13, 21769 (2023). https://doi.org/10.1038/s41598-023-49177-z

2022

- van Zaanen, Y., **A.J. Kievit**, van Geenen, R.C.I. et al. Does Consulting an Occupational Medicine Specialist Decrease Time to Return to Work Among Total Knee Arthroplasty Patients? A 12-Month Prospective Multicenter Cohort Study. J Occup Rehabil (2022). https://doi.org/10.1007/s10926-022-10068-1
- Alex B. Walinga, Tobias Stornebrink, Stein J. Janssen, Miki Dalmau-Pastor, **Arthur J. Kievit**, Gino M.MJ. Kerkhoffs. Needle Arthroscopy for Bacterial Arthritis of a Native Joint: Surgical Technique for the Shoulder, Elbow, Wrist, Knee, and Ankle Under Local Anesthesia. Arthroscopy Techniques, Volume 11, Issue 9, 2022, Pages e1641-e1648, ISSN 2212-6287, https://doi.org/10.1016/j.eats.2022.05.011.
- Alex B. Walinga, Peter A.A. Struijs, Sheryl de Waard, Gino M.M.J. Kerkhoffs, **Arthur J. Kievit.** Needle arthroscopy in the treatment of bacterial arthritis of the hip in a neonate and two infants, Journal of Pediatric Surgery Case Reports, Volume 87, 2022, 102470, ISSN 2213-5766, https://doi.org/10.1016/j.epsc.2022.102470.
- **A.J. Kievit**, M.U. Schafroth, P.P.F.M. Kuijer. (2022) Return to Work Following Knee Arthroplasty. In: Noyes F.R., Barber-Westin S. (eds) Critical Rehabilitation for Partial

and Total Knee Arthroplasty. Springer, Cham. https://doi.org/10.1007/978-3-030-87003-4_11

- L Blankevoort, **AJ Kievit,** MU Schafroth. Device and method for determination of the moment-induced movement of a joint implant. US Patent 11,504,243

2021

- T. Stornebrink, S.J. Janssen, **A.J. Kievit**, N.P Mercer, J.G. Kennedy, S.A.S. Stufkens, G.M.M.J. Kerkhoffs. Bacterial arthritis of native joints can be successfully managed with needle arthroscopy. J Exp Orthop. 2021 Aug 24;8(1):67. doi: 10.1186/s40634-021-00384-5
- E. Martin, C. Pendleton, C. Verhoef, R.J. Spinner, J.H. Coert, U.E. Flucke, W-B.M. Slooff, T. van Dalen, M.A.J. van de Sande, D.J. Grünhagen, W.J. van Houdt, L.B. Been, H.J. Bonenkamp, M.H.M.E. Anten, M.P.G. Broen, M.H.A. Bemelmans, J.A.M. Bramer, G.R. Schaap, **A.J. Kievit**. Morbidity and Function Loss after Resection of Malignant Peripheral Nerve Sheath Tumors.Neurosurgery. 2021 September 15.

2020

- **A.J. Kievit**. P.P.F.M. Kuijer, L.J. de Haan, K.L.M. Koenraadt, G.M.M.J. Kerkhoffs, M.U. Schafroth, R.C.I. van Geenen. Patients Return To Work Sooner after Unicompartmental Knee Arthroplasty than after Total Knee Arthroplasty. Augustus 2019. Knee Surg Sports Traumatol Arthrosc. 2020 Sep;28(9):2905-2916. doi: 10.1007/s00167-019-05667-0. Epub 2019 Aug 30

2019

- **A.J. Kievit**, J. G. G. Dobbe, W.H. Mallee, L. Blankevoort, G. J. Streekstra, M. U. Schafroth. The accuracy of a simple mechanical device that uses the anterior pelvic plane for cup positioning in Total Hip Arthroplasty: a Comprehensive 3D Analysis. September 2019 *Hip International*
- Y. van Zaanen, R.C.I. van Geenen, T.M.J. Pahlplatz, **A.J. Kievit**, M.J.M. Hoozemans, E.W.P. Bakker, L. Blankevoort, M.U. Schafroth, D. Haverkamp, T.M.J.S. Vervest, D.H.P.W. Das, W. van der Weegen, V.A. Scholtes, M.H.W. Frings-Dresen, P.P.F.M. Kuijer. Three out of ten working patients expect no clinical improvement of their ability to perform work-related knee-demanding activities after Total Knee Arthroplasty. A multicenter study. Journal of Occupational Rehabilitation
- Paul Kuijer, Alexander Hoorntje, Yvonne van Zaanen, **Arthur Kievit**, Koen Koenraadt, Matthias Schafroth, Suzanne Witjes, Bas Sorgdrager, Rutger Geenen, Gino Kerkhoffs. Twintig jaar op je knieën: Knieartrose: brede samenwerking helpt. Medisch Contact. 2019. 74(49), pp 11-13.

2018

- P.P.F.M. Kuijer, Y. van Zaanen, **A.J. Kievit**. Weer werken met een knieprothese – quiz. April 2018. FysioPraxis 27(3):11/29

- P.P.F.M. Kuijer, Y. van Zaanen, R. Kok, J.L. Hoving, **A.J. Kievit**. Chauffeur en belader van bedrijfsafval met ernstige knieartrose: welke werkactiviteiten verbeteren na een totale knieprothese-operatie? Quintesse. January 2018. P 40/43
- **A.J. Kievit**, J.G.G. Dobbe, G.J. Streekstra, L. Blankevoort, M.U. Schafroth. Predicted osteotomy planes are accurate when using patient-specific instrumentation for total knee arthroplasty in cadavers: a descriptive analysis. Knee Surg Sports Traumatol Arthrosc. 2018 Jun;26(6):1751-1758. Epub 2017 Sep 25

2017

- J.A.M. Groot, F. J. Jonkers, **A.J. Kievit**, P.P.F.M. Kuijer, M.J.M. Hoozemans. Beneficial and limiting factors for return to work following anterior cruciate ligament reconstruction: a retrospective cohort study. Archives of Orthopaedic and Trauma Surgery. February 2017, Volume 137, Issue 2, pp 155–166
- J. Verbeek, C. Mischke, R. Robinson, S. Ijaz, P.P.F.M. Kuijer, **A.J. Kievit**, A. Ojajärvi, K. Neuvonen. Occupational exposure to knee loading and the risk of osteoarthritis of the knee: a systematic review and a dose response meta-analysis. Safety and Health at Work (submitted 2016, accepted for publication 2017)

2016

- P.P.F.M. Kuijer, TM.J. Pahlplatz, M.U. Schafroth, L. Blankevoort, R.C.I. van Geenen, M.H.W. Frings-Dresen, **A.J. Kievit.** Weer aan het werk na een totale knieprothese. TBV – Tijdschrift voor Bedrijfs- en Verzekeringsgeneeskunde. December 2016, Volume 24, Issue 10, pp 496–498
- P.P.F.M. Kuijer, **A.J. Kievit,** T.M.J. Pahlplatz, T. Hooiveld, M.J.M. Hoozemans, L. Blankevoort, M.U. Schafroth, R.C.I. van Geenen, M.H.W. Frings-Dresen. Which patients do not return to work after total knee arthroplasty? Rheumatology International. September 2016, Volume 36, Issue 9, pp 1249–1254
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2014

- Talar Osteochondral Defects. Diagnosis, Planning, Treatment, and Rehabilitation. Editors: van Dijk, C. Niek, Kennedy, John G. (Eds.) Book coordinator: **A.J. Kievit**. (ISBN 978-3-642-45097-6)
- Dobbe JG, **Kievit AJ**, Schafroth MU, Blankevoort L, Streekstra GJ. Evaluation of a CT-based technique to measure the transfer accuracy of a virtually planned osteotomy. Med Eng Phys. 2014 Aug;36(8):1081-7. doi: 10.1016/j.medengphy.2014.05.012. Epub 2014 Jun 6. PubMed PMID: 24908356.

- **Kievit AJ,** Kuijer PP, Kievit RA, Sierevelt IN, Blankevoort L, Frings-Dresen MH. A reliable, valid and responsive questionnaire to score the impact of knee complaints on work following total knee arthroplasty: the WORQ. J Arthroplasty. 2014 Jun;29(6):1169-1175.e2. doi: 10.1016/j.arth.2014.01.016. Epub 2014 Jan 21. PubMed PMID: 24581898.
- **Kievit AJ,** van Geenen RC, Kuijer PP, Pahlplatz TM, Blankevoort L, Schafroth MU. Total knee arthroplasty and the unforeseen impact on return to work: a cross-sectional multicenter survey. J Arthroplasty. 2014 Jun;29(6):1163-8. doi: 10.1016/j.arth.2014.01.004. Epub 2014 Jan 10. PubMed PMID: 24524779.

2013

- **Kievit AJ**, Breugem SJ, Sierevelt IN, Heesterbeek PJ, van de Groes SA, Kremers KC, Koëter S, Haverkamp D. Dutch translation of the Kujala Anterior Knee Pain Scale and validation in patients after knee arthroplasty. Knee Surg Sports Traumatol Arthrosc. 2013 Nov;21(11):2647-53. doi: 10.1007/s00167-013-2635-4. Epub 2013 Sep 12. PubMed PMID: 24026342.
- **Kievit AJ**, Schafroth MU, Blankevoort L, Sierevelt IN, van Dijk CN, van Geenen RC. Early experience with the Vanguard complete total knee system: 2-7 years of follow-up and risk factors for revision. J Arthroplasty. 2014 Feb;29(2):348-54. doi: 10.1016/j.arth.2013.05.018. Epub 2013 Jun 15. PubMed PMID: 23773964.
- **Kievit AJ**, van Duijvenbode DC, Stavenuiter MH. The successful treatment of genu recurvatum as a complication following eight-Plate epiphysiodesis in a 10-year-old girl: a case report with a 3.5-year follow-up. J Pediatr Orthop B. 2013 Jul;22(4):318-21. doi: 10.1097/BPB.0b013e3283623b2c. PubMed PMID: 23652968.
- **Kievit AJ**, Jonkers FJ, Barentsz JH, Blankevoort L. A cross-sectional study comparing the rates of osteoarthritis, laxity, and quality of life in primary and revision anterior cruciate ligament reconstructions. Arthroscopy. 2013 May;29(5):898-905. doi: 10.1016/j.arthro.2013.01.020. Epub 2013 Mar 19. PubMed PMID: 23523126.

2010

- **Kievit AJ**, Tinnemans JG, Idu MM, Groothoff JW, Surachno S, Aronson DC. Outcome of total parathyroidectomy and autotransplantation as treatment of secondary and tertiary hyperparathyroidism in children and adults. World J Surg. 2010 May;34(5):993-1000. doi: 10.1007/s00268-010-0446-z. PubMed PMID: 20145928; PubMed Central PMCID: PMC2848726.
- **Kievit A.J.**, L.C.M. Keijser. Patiëntenfolder “Hemi-knie Prothese” voor Medisch Centrum Alkmaar.

About the Author

Sinds aanvang van de opleiding tot orthopedisch chirurg heeft de uitgebreide prothesiologie mijn interesse. Al voordat ik aan de opleiding begon heb ik meerdere multidisciplinaire onderzoekslijnen en projecten op gezet in deze richting. Met name op het gebied van diagnostiek van loslating van protheses, evaluatie van chirurgische vernieuwingen, onderzoek naar heupaandoeningen bij adolescenten en in sommige gevallen prothesiologie bij deze groep als ook onderzoek naar werkhervatting rondom prothesiologie heeft geleid tot meerdere internationale publicaties. Vanuit het onderzoek naar prothese loslating hebben we via goede samenwerking tussen de afdeling orthopedie en sportgeneeskunde en de afdeling biomedical engineering & physics een aantal patenten geregistreerd. Tevens is van hieruit een spin-off bedrijf gestart in samenwerking met het AUMC waar ik in deelneem, genaamd Atmoves (www.atmoves.nl). Gedurende de opleiding heb ik mij met name gekoppeld aan ervaren specialisten in onder andere het Amsterdam UMC, Tergooi ziekenhuizen, Noordwest Ziekenhuisgroep en het Slotervaart ziekenhuis. Mijn loopbaan als medisch specialist begon met het volgen van een fellowship oncologie met bijbehorende oncologische prothesiologie. Inmiddels ligt de focus met name bij de complexe (revisie) prothesiologie en draai ik mee in de traumatologie. Naast de volwassen orthopedie richt ik mij ook op de heupaandoeningen bij adolescenten. Voorbeelden hiervan zijn dat wij een verwijscentrum zijn voor het kind met een extreme Slipped Capital Femoral Epiphysis (SCFE) die we behandelen middels de modified Dunn procedure. Daarnaast is er extra aandacht voor prothesiologie bij kinderen met zeldzamen aandoeningen, zoals post-traumatische of postinfectieuze destructie van de heup, heupluxaties bij cerebrale parese, stapelings- en stofwisselingsziekten en dergelijke. Ik zal mij mijn hele carrière blijven inzetten voor deze specifieke patiënten groepen.

In mijn vrije tijd geniet ik vooral van fietsen, sporten, klussen in en rond het huis en mijn belangrijkste taak thuis als man van Tessa en vader van Alexa, Mia, Bob en Ted.

Curriculum Vitae A.J. Kievit, MD

PERSONAL INFORMATION:

Name:	Kievit
First name:	Arthur Johan
E-mail:	a.j.kievit@amsterdamumc.nl
Date of birth:	28-12-1983
Place of birth:	Delft
Sex:	Male
Nationality:	Dutch
Family:	Married, four children
BIG:	39912680701, date first registration orthopedic surgeon 1-1-2020

CHARACTERISTICS:

Analytical	Stereoscopic visual acuity	Ambitious	Social
Team player	Open minded	Curious	Energetic

WORK EXPERIENCE:

1/1/2021 – present	0.9 Fte Orthopaedic Surgeon and NOV-NVOT Certified Orthopaedic Trauma surgeon –Amsterdam University Medical Center. Expertise in complex hip and knee (revision) arthroplasty, adolescent hip surgery, (metastatic) traumatology
1/1/2020 – 31/12/2020	Fellowship orthopaedic oncology Amsterdam University Medical Center
2014 - present	Project leader of research group AtMoves: to develop new diagnostic techniques to detect knee arthroplasty loosening.
1/1/2014 -31/12/2019	Resident orthopedic surgery. Training locations: ROGO AUMC - Amsterdam, Tergooi – Hilversum, MC Slotervaart – Amsterdam, NWZ - Alkmaar
2011 - present	PhD research: Topic knee arthroplasty, Department of Orthopaedic surgery, Academic Medical Centre, Amsterdam. Supervisors Prof. G.M.M.J. Kerkhoffs MD PhD; L. Blankevoort Ir. PhD; M.U. Schafroth MD PhD; P.P.F.M. Kuijer PhD
2010-2011	Primary researcher at Centre for Orthopaedic Research Alkmaar http://coralnwz.nl
2010-2011	ANIOS orthopaedic surgery at Alkmaar Medical Center
2007	Lung function technician, Department of Pulmonology, AMC, Amsterdam.
2005-2007	Care worker at Amsterdam *Homecare*. Providing professional care for elderly, sick & disabled.

Publications:	see ‘Kievit AJ[AU]’ in PubMed, and/or see addendum
Reviewing	Reviewer for Archives of Orthopaedic and Trauma Surgery, The Knee and Bone & Joint Journal
Other work experience:	
2001-2007	Work experience: restaurants, events, janitor (Netherlands Institute for Advanced Study in the Humanities (NIAS-KNAW), Promotion work for *Het Leidsch Dagblad*, Leiden

ADDITIONAL TRAINING:

Courses:	
Yearly	Dutch Orthopaedic Federation meetings
2024	Traumadagen
2024	AAOS Annual Meeting 2024, San Fransisco, USA
2024	ESSKA, Milan, Italy
2023	Advanced Trauma and Life Support Instructor Course Amsterdam
2022	Advanced Trauma and Life Support Refresher Course Amsterdam
2021	Hispotal Major Incident Medical Management and Support course (HMIMMS) ALSG
2020	NOV-NVOT Certified Orthopaedic Trauma surgeon
2019	Stryker Triathlon and MAKO training
2019	“Stralingshygiëne voor medisch specialisten 2019” - IV (Nieuwegein)
2019	European Musculo Skeletal Oncology Society Meeting Florence
2018	Foot and ankle Arthroscopy Sports Traumatology (FAST) course Amsterdam
2018	ESSKA Meeting Member Research Committee - Glasgow
2017	Advanced Trauma and Life Support Refresher Course – New York
2017	Oxford Instructional Knee Course Oxford
2017	Zimmer Biomet Meeting Totally Hip - Gothenborg
2017	AO Advanced Principles of Fracture Management for Surgeons - Leeds
2016	Inventor (patented) new diagnostic test for diagnosing aseptic loosening in total knee arthroplasty
2016	ESSKA meeting Barcelona
2014	Basic Principles in Fracture Treatment – AO in Davos
2014	ESSKA Amsterdam
2013	Advances Trauma and Life Support - Baltimore
2012	Course Entrepreneurship in Health and Life Sciences; winner best pitch award
2012	Course in Practical Biostatistics
2011	Basic Course Legislation and Organization
2010	Course Epidemiology Collegium Chirurgicum Neerlandicum
2010	PADI Advanced Open Water Diver

2008:	Car mechanics
2002:	Italian language training, Istituto Italiano, Centro di Lingua e Cultura Rome

Tutoring, Mentoring

2023-2024	Mentor coassistenten group

Supervising

2014-2024	Bachelor and master thesis projects: Jens te Velde, Chiel Klein, Bastiaan van Zanten, Steven van der Aart, Samantha Eikenhout, Judith Groot, Gerjanne Reins, Ilse Pos and Jarno de Haas
2014-2024	PhD candidates: George Buijs, Alon Hopman, Yvonne van Zaanen, Annemieke Ter Wee, Caroline Mag, Thijs Pahplatz, Jan Ophuis, Brent van der Doelen

Education:

2003-2010	MD, with distinction (Cum Laude) 23 April 2010, Academic Medical Centre Amsterdam
1996-2002	Grammar school Stedelijk Gymnasium Leiden

Language Skills:

Dutch – native	English – native	French - reasonable
German - reasonable	Italian – reasonable	Spanish - learning

ADDIONAL INFORMATION:

Grants and awards:

Total	*€2.797.695*
2024	€571.791 Doelmatigheidsonderzoek ZonMW Open Ronde 2025 Arthroscopy vs. minimal invasive needle arthroscopy for patients with bacterial knee arthritis - RCT
2024	€82.502,70 Unrestricted research grant by Zimmerbiomet
2023	€249.674 Kansen voor West
2022	€250.000 Take-off 2 grant ZonMw-NWI
2021	€227.935 Nano-arthroscopie, scopiëren zonder gebruik van steeds meer begrensde OK capaciteit
2021	€656.892 NL Health Holland – TKI –PPP grant “Comforthod – an innovative tool to diagnose loosening of a total knee arthroplasty”
2020	€150.000 Co-applicant NWO demonstrator grant subsidy: DisJoint: a non-invasive method for detecting implant loosening in knee arthroplasty
2017	€ 46.900 STW Take-Off grant

2017	€ 28.000 Stichting Steun Orthopedie AMC
2014	€250.000 Primary applicant and project leader ZonMW/NGI pre-seed grant: Developing new diagnostic techniques for knee arthroplasty loosening
2014	€ 24.000 AMC BDDA pre-seed project knee arthroplasty loosening
2014	€ 10.000 Fastforward meeting Deloitte en Pontes: winner best pitch & business plan from the AMC, VUMC and UMCU
2014	€ 250.000Coapplicant unrestricted research grant Zimmer Biomet, Warsaw, approximately
2012	Winner best pitch award, Course Entrepreneurship in Health and Life Sciences

Inventor on Patents:

WO/2017/105232	22-06-2017	
NL-1041624	17-07-2017	Licensed
EP-3389473	24-10-2018	Pending
US-20190000631-A1	03-01-2019	Licensed
US-11504243-B2	22-11-2022	Licensed

Memberships and committees:

2023-2024	Advanced trauma and life Support instructor
2022-present	Treasurer of NVOT (Nederlandse Vereniging voor Orthopedische Traumatologie)
2021	AUMC: Minimal invasive surgery committee, roster maker orthopaedic department
2012- present	Dutch orthopaedic federation member Membership of subgroups of the Dutch Orthopaedic Federation (werkgroep Knie, werkgroep NVOT, werkgroep Bot en Weke-delen Tumoren)
2020	Federatie Medisch Specialisten
2013-2019	Presenter and educator for return to work following Total Knee Arthroplasty Netherlands School of Public and Occupational Health (NSPOH)
2017-today	Landelijke vereniging voor Artsen in Dienstverband
2016-2018	Member of Scientific committee 18th Biennial ESSKA Congress Glasgow
2017- present	Member "De Jonge Specialist"
2012- present	ESSKA member – EKA ubgroup member
2016	Organizer ESSKA Cycle for Science Amsterdam-Barcelona, for Prof. C.N. van Dijk

2016	Organizer Ride for Research http://www.traumaplatform.org/challenge2016/
2012-2014	Book coördinator ESSKA/AFAS Talar OCD With special emphasis on Diagnosis, Planning and Rehabilitation (van Dijk, Kennedy, ISBN 978-3-642-45097-6)
2012-2014	Organizer of obligatory national knee arthroplasty residents course, with M.U. Schafroth AMC
2012-2014	ESSKA-AFAS Amsterdam Foot and Ankle Course support, Prof. Dr. C.N. van Dijk
2012- 2014	Member of "AMC actueel" taskforce. Lead Dr. Linthorst and director of AMC Prof. Levi en Prof. Heineman
2011 - 2014	Secretary for Aprove (AMC PhD association with 1200 members) www.aprove.nl
2012	Chairman of Aprove PhD symposium "Science & Scams: Stop fraud and flourish!" 200 guests, Westergasfabriek, subsidy received by ZonMw
2003 - 2010	Member Medical Faculty of Amsterdam Students (MFAS). Member student society
2006	Treasurer (budget 20.000 €) and Chair of SSRA (Student Fraternity)
1996 - 2002	Grammar school student council; main speaker for national school debating competition; pupil mentor; member of school committee Uno Sumus Animo

Sports and interests:

Family, entrepreneurship, cycling, fitness, skiing, car mechanics, swimming, diving, travelling, home improvement work

LINKED IN:

https:// www.linkedin.com/in/arthur-j-kievit-3a98934b

REFERENCES:

- For AUMC: Prof. G.M.M.J. Kerkhoffs, MD PhD, orthopedic surgeon, AMC Amsterdam, g.m.kerkhoffs@amc.uva.nl
- For AUMC: M.U. Schafroth, MD, PhD, orthopaedic surgeon, AMC Amsterdam, m.u.schafroth@amc.nl
- For AUMC: Ir. L. Blankevoort, MD PhD, head of orthopaedic research, AMC Amsterdam, l.blankevoort@amc.nl
- For Tergooi: Dr. R.A.W. Verhagen, orthopedic surgeon, Tergooi Hospital, Hilversum, rverhagen@tergooi.nl
- For NWZ Alkmaar: B.J. Burger, MD PhD, orthopedic surgeon, Noordwest Ziekenhuisgroep Alkmaar, b.j.burger@mca.nl

Amsterdam
Movement
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VU VRIJE UNIVERSITEIT AMSTERDAM

Amsterdam UMC
University Medical Centers

Amsterdam Movement Sciences conducts scientific research to optimize physical performance in health and disease based on a fundamental understanding of human movement in order to contribute to the fulfillment of a meaningful life.