Clinical and Mechanical Assessment of Total Knee Arthroplasty

A multifactorial approach

Huub Meijerink
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Introduction
Introduction

Total knee arthroplasty (TKA) is a successful treatment for advanced and symptomatic osteoarthritis and rheumatoid arthritis of the knee joint. The first knee implantations were performed in 1891 by a German surgeon, Theophilus Gluck, who implanted a hinged knee prosthesis made of ivory [46]. Gluck’s technique was updated several times using metal and plastic components, but due to the fact that these systems were still formed into a hinge-type device, they were too constraining and loosening was a frequent complication [33, 64]. The modern era of total knee replacements evolved in the early 1970s. First, Gunston reported on his Polycentric knee after he had recognised that the knee does not rotate around a single axis like a hinge, but that the femoral condyles roll and glide on the tibia with multiple centres of rotation [27]. A few years later, Insall et al. introduced the total condylar knee replacement [34]. This refers to a more anatomical implant design and replacement of diseased cartilage with femoral and tibial resurfacing, and optional patellofemoral resurfacing. Over the years the results of contemporary total condylar knee replacements have considerably improved and an increasing number of patients are operated on worldwide each year. Nowadays, roughly 15,000 TKAs are performed annually in The Netherlands [44], while this number is around 400,000 in the United States [38, 39]. The number of TKAs is expected to increase exponentially over the next few decades because of an aging patient population with higher demands [39, 44].

Considerable pain relief and functional improvement can mostly be expected following TKA, and excellent longevity of the implants has been reached: survival rates of 90-96% after 12-19 years have recently been reported [1, 9, 10, 53]. Most early failures resulted from infection, instability, malalignment, stiffness and patella problems. Many of these problems can be avoided by proper surgical technique, implant selection, appropriate post-operative pain management and an adequate rehabilitation program. Nevertheless, complete pain relief, full range of motion and normal knee kinematics are not always achieved. Some patients still complain of pain and most of the time it cannot be predicted in which patients this will occur. Becker et al. [7] distinguished between biological, mechanical, intra-articular and extra-articular factors, but despite substantial advances in surgical technique and implant design, the prevalence of medically unexplained pain after TKA has been reported at around 15% [14, 30, 65]. Moreover, multiple studies indicate that only 81% to 89% of patients were satisfied with their TKA [4, 11, 20, 32, 42, 50, 57]. Meeting the patients expectations appears to be very important in achieving patient satisfaction [11, 20, 32, 40, 42]. Furthermore, since the biomechanical situation of the knee is not fully replicated by contemporary knee replacements, functional limitations especially during activities such as squatting, kneeling and twisting- result in dissatisfaction in
high-demanding patients [37, 43, 63]. Thus, a variety of implant-, surgeon- and patient-related factors affect the outcome, and the relative importance of each part may vary amongst different patients.

Therefore, the assessment of TKAs requires a multifactorial approach. In this thesis we will further analyse some clinical and mechanical aspects that are related to the outcome of a TKA. Of the many possible variables that we could study we selected 4 aspects:

A: Different ways in which surgeons assess the quality of TKAs.
B: Changes in patellofemoral positioning after placement of a TKA.
C: How clinical outcome is affected by prosthetic design.
D: The influence of femoral stem extensions on the stability of bicondylar reconstructions in revision TKA.

The issues in these four research areas are described in more detail below:

A: Different ways in which surgeons assess the quality of TKAs.

Traditional clinical rating systems like the Knee Society Score (KSS) [35] are still an important tool in evaluating the outcome of a TKA, although it has been reported that those knee scores are unreliable [54]. Moreover, the KSS score might not be discriminative enough [8, 17] and because many recent Randomized Controlled Trials (RCTs) which compare the clinical performance of different prosthetic systems failed to demonstrate a superior design [21, 28, 45], the subtle differences in current practice probably require more sensitive instruments. The surgeon may have a feeling of satisfaction with the result of the TKA. This satisfaction can easily be scored on a Visual Analogue Scale (VAS) [22, 51]. Probably a simple satisfaction VAS by the surgeon is a useful extension in evaluating the clinical outcome of a TKA, but the degree of satisfaction may vary among surgeons depending on what an individual surgeon considers an excellent, good, fair or poor result.

Furthermore, it would be interesting if the outcome of a TKA could be predicted at an early stage. Different studies show that satisfaction after TKA is primarily determined by the expectations of the patient [11, 20, 40, 42]. However, many surgeons feel that their expectations of a TKA are very valuable as well and should be related to the clinical outcome, but it has not been assessed if this is indeed the case. Hence, in a prospective study the surgeon’s preoperative assessment of the difficulty of the procedure and the surgeon’s immediate postoperative satisfaction were analysed in relation to different outcome measurements at one year after TKA.

B: Changes in patellofemoral positioning after placement of a TKA.

After implantation of a TKA, patellofemoral complaints is one of the complications with the highest incidence (1-24%) and is an important reason for revision surgery [13, 15, 29, 31]. Most patellofemoral complications are associated with abnormal patellar tracking [29, 36]. Although manufacturers of total knee implants often claim that their design adequately restores physiological patella tracking, the geometries and anatomical variations of the patellofemoral joint are complex and patellar kinematics are sensitive to multiple factors (e.g. design, size and alignment of the implants, surgical approach, capsular tension, location of the tuberosity). It is therefore not certain that a TKA will reproduce physiological patella tracking even if the components are perfectly aligned. Hence, in a cadaver experiment we compared the patella kinematics before and after the implantation of a TKA.

Anatomical alignment of the prosthetic components is not always achieved and several studies have shown that small modifications in alignment of the femoral component cause significant changes in patella tracking [2, 3, 26, 41, 48]. Abnormal tracking can lead to subluxation, higher contact forces, smaller contact areas and excessive soft tissue tensions [6, 47, 58]. These issues may result in postoperative complications such as patellar instability, pain, wear and loosening [48, 49]. Anatomical studies have examined the relative position of the femoral trochlea groove to anatomical landmarks such as the transepicondylar axis and the posterior femoral condyles and reported considerable variations [23, 24, 25]. This indicates the difficulty in replicating femoral trochlea groove position and reinforces that surgical assessment and prosthetic design are important issues in patellofemoral complications. Therefore, we analysed intra-operatively the medio-lateral placement of the trochlea of a TKA and assessed whether there is a systematic error of the position of the prosthetic groove relative to the anatomical trochlea.

C: How clinical outcome is affected by prosthetic design.

In order to address the above mentioned problems in the outcome of TKA (pain, malfunction, loosening, instability, dissatisfaction), research groups and companies continuously attempt to further optimise prosthetic designs. The challenge is to find a fully anatomical design, with a lifetime survival and an unrestricted use. Based on previous research at our institution that the natural patella groove has not an isolated lateral orientation [5], we wondered what the influence of a different groove design would be on the outcome of a TKA and started to use the CKS prosthesis (Stratec Medical, Oberdorf, Switzerland). In contrast to our standard prosthesis (PFC, DePuy/Johnson & Johnson, Warsaw, IN, USA) with a lateral orientation of the patellar groove, the trochlea of the CKS prosthesis is deeper and has a neutral direction. Other aspects of the two systems (CKS versus PFC) were very similar, but a retrospective study executed at our institution tended to show some differences...
in functional outcome [16]. However, the study was inconclusive in showing significant differences between the two systems which prompted us to compare these designs thoroughly. We decided to assess whether small differences in design can be quantified by kinematic analyses and if an RCT between these designs would show differences in clinical outcome.

D: The influence of femoral stem extensions on the stability of bicondylar reconstructions in revision TKA.

Surgeons often underestimate the amount of femoral bone loss in revision TKA patients, and may be surprised intra-operatively by large defects that require reconstruction [19, 52, 61]. Massive bone graft, cement and metal augmentations have been used to reconstruct the defects. In view of the very good long-term results in revision total hip arthroplasty (THA) [18, 55, 56], impacted morselized bone grafts (MBG) have also been proposed in revision TKAs. In cases of uncontained bone loss in THA, metal meshes are often used to create containment for the impacted MBG. However, these meshes are less applicable in TKA, since the mandatory soft tissue coverage is often absent or insufficient. It appears that within the reconstruction of contained unicondylar femoral bone defects, a stem extension is necessary to obtain adequate mechanical stability [62]. Unfortunately, the disadvantage of femoral components extended with rigid stems is that long-term bone resorption is promoted due to stress shielding [12, 59, 60]. Therefore, we developed a sliding stem device and analysed the stability of the reconstruction of uncontained bicondylar defects in revision TKA with this novel sliding design.

After considering these subjects, the following research questions were postulated as the aims of this thesis:

A1: Are different surgeons equally satisfied after TKA? (Chapter 2)
A2: Do surgeons’ expectations predict the outcome of a TKA? (Chapter 3)
B1: Does the implantation of a TKA restore a physiological patella tracking? (Chapter 4)
B2: Is there an anatomical mediolateral placement of the trochlea in TKA? (Chapter 5)
C1: Can small differences be quantified with kinematic analyses? (Chapter 6)
C2: Do relatively small differences in design result in differences in clinical outcome? (Chapter 7)
D1: Can a stable reconstruction of bicondylar defects be created in revision TKA and what is the influence of different stem extensions? (Chapter 8)

References
Are surgeons equally satisfied after total knee arthroplasty?


CHAPTER 2 ARE SURGEONS EQUALLY SATISFIED AFTER TOTAL KNEE ARTHROPLASTY?

Abstract

Introduction: We performed a clinical follow-up study to investigate whether three orthopaedic surgeons are equally satisfied after total knee arthroplasty (TKA).

Patients and methods: Thirty-six patients (39 TKAs, mean follow-up 12 months) were reviewed, using the Knee Society Clinical Rating System (KSCRS). For the assessment of satisfaction a visual analogue scale (VAS) was used.

Results: We did not find a significant difference in satisfaction between the surgeons. However, there was a significant difference in the knee score and function score of the KSCRS as evaluated by the orthopaedic surgeons (p = 0.006 and p = 0.04, respectively). The correlations between the knee score and the surgeons’ satisfaction was high, which indicates that pain, range of motion and deformity are important success criteria for surgeons.

Conclusions: In this study, surgeons scored differently in the KSCRS, but were equally satisfied after TKA.

Introduction

Total knee arthroplasty (TKA) is a successful therapy for relieving pain and improving function in the advanced symptomatic degeneration of the knee joint [8, 9]. Success can be expressed in different ways. Traditionally, objective clinical outcome rating systems, such as the Knee Society Clinical Rating System (KSCRS) [5, 8], have been used to evaluate the outcome of the TKA. These objective methods are based on the assessment of pain and functional disability, and are scored by the orthopaedic surgeon. Pain, range of motion and deformity are considered important aspects for patients and surgeons. This will lead to a subjective feeling of satisfaction about the outcome of TKA for surgeons and patients. Satisfaction can be expressed on a visual analogue scale (VAS), similar to pain VAS [3, 6]. The degree of satisfaction among surgeons may vary according to what an individual surgeon considers an excellent, good, fair, or poor result. For instance, some surgeons find range of motion very important and strive for 125 degrees, while others are satisfied when 90 degrees is achieved. The aim of this study was to investigate whether a significant difference in satisfaction after TKA was present between three orthopaedic surgeons (one in training).

Materials and Methods

Between January 1999 and June 2000, 96 cemented primary TKAs were implanted in 89 patients. Of this group, 40 patients were randomly selected and invited to the Outpatient Department for clinical evaluation. Four patients refused to participate. A total of 36 patients (39 knees), 9 men and 27 women, participated in this retrospective clinical follow-up study. The mean age of the patients at the time of operation was 60 years (28 to 82 years). There were 25 patients with osteoarthritis (OA) and 11 patients with rheumatoid arthritis. In 18 knees the Press Fit Condylar (PFC) TKA was used (Johnson and Johnson Professional, Raynham, MA, USA) and in 21 knees the Continuum Knee System (CKS) (Stratec Medical, Oberdorf, Switzerland) was used. The mean follow-up was 12 months (6 - 22 months). In the Outpatient Department the patients were sequentially examined by two consultant orthopaedic surgeons (surgeon A and B, MWM and AvK), and 1 registrar in orthopaedics in the final year of training (surgeon C, CvL) without information from the patients’ medical records. Surgeon A and B have had over 15 years’ experience in primary and revision TKA. The patients were strictly instructed by a nurse-practitioner not to mention information about the examination by the other surgeons and only to answer the questions. The surgeons took the history, performed the physical examination and determined the KSCRS (knee and functional scores). The surgeons
reviewed the postoperative and latest follow-up radiographs of the TKA. Thereafter, the surgeons scored their satisfaction on a VAS. After the examination the patients filled out the Western Ontario and McMasters universities Osteoarthritis Index (WOMAC) [1], and scored their pain and satisfaction on a VAS in a different room without the presence of the surgeons.

**Knee Society Clinical Rating System**
The KSCRS score is divided into a knee score and a function score. The knee score evaluates pain, stability, and range of motion, with deductions for flexion contracture, extension lag and malalignment. The function score assesses walking distance and walking stairs, with deductions for walking aids [4]. Both scores range from 0 (worst) to 100 (best) points.

**Pain VAS**
The VAS was used to evaluate the pain at rest and during activity located around the knee region. The scale consists of a 100-mm-long horizontal line ranging from 0 mm (indicating no pain) to 100 mm (indicating intolerable pain). Patients were asked to mark the line vertically at a point that matched their pain [3, 6]. With a ruler, the number of millimetres was measured and converted to the same number of points.

**Satisfaction VAS**
The VAS was also used to evaluate the patient’s satisfaction and surgeon’s satisfaction at follow-up. This system was similar to the one used to measure pain [3, 6]. In the same way, the number of millimetres on a line from 0 mm (indicating total dissatisfaction) to 100 mm (indicating complete satisfaction) was converted to the corresponding number of points.

**WOMAC**
The WOMAC index is a self-administered health validated questionnaire specifically designed for patients with OA of the hip or knee [1]. This questionnaire contains three subscales: WOMAC pain (5 items), WOMAC stiffness (2 items) and WOMAC physical function (17 items). The questions are ranked on a 5 point (none, slight, moderate, severe, extreme) Likert scale. The WOMAC subscale scores were transformed from 1 (best) to 5 (worst) points in each item to a system of 0 (worst) to 100 (best) points, to compare these scores with the VAS scores.

**Statistics**
The data were expressed as mean and standard deviation. The difference in satisfaction between the orthopaedic surgeons was tested using Friedman’s test. The Friedman’s test was also used to determine if the differences in the KSCRS score between the surgeons was significant. Pearson’s correlation test was used to compare the KSCRS and the satisfaction VAS for each observer individually. A p-value < 0.05 was considered significant.

**Results**
The mean follow-up knee score from the three surgeons for the 39 knees was 85.4 (SD 12.1), whereas the mean follow up function score was 68.8 (SD 22.4) (Table 1). A significant difference was found in the KSCRS scored by the orthopaedic surgeons for the knee score (p = 0.006) and function score (p = 0.04). Surgeon A scored significantly lower on the knee score and significantly higher on the function score of the KSCRS in comparison with the scores of surgeon B and C.

<table>
<thead>
<tr>
<th>Table 1</th>
<th>Mean KSCRS (knee and function score) with standard deviation for each surgeon and for the surgeons combined.</th>
</tr>
</thead>
<tbody>
<tr>
<td>KSCRS</td>
<td>Surgeon A</td>
</tr>
<tr>
<td>Knee score</td>
<td>83.2 (SD 15.1)</td>
</tr>
<tr>
<td>Function score</td>
<td>71.5 (SD 25.7)</td>
</tr>
</tbody>
</table>

The mean patient satisfaction VAS was 87.7 (SD 23.2). The mean surgeon satisfaction VAS was 84.3 (SD 16.7) (Table 2). There was no significant difference in satisfaction VAS between the orthopaedic surgeons (p = 0.125), nor was there a significant difference between patient and surgeon satisfaction (p = 0.09). The mean follow-up pain VAS at rest was 8.7 points (SD 12.9), and the mean follow-up pain VAS during activity was 18.2 points (SD 20.7).

<table>
<thead>
<tr>
<th>Table 2</th>
<th>Mean satisfaction (SD) for each surgeon and for the surgeons combined.</th>
</tr>
</thead>
<tbody>
<tr>
<td>Satisfaction</td>
<td>Patient</td>
</tr>
<tr>
<td>VAS</td>
<td>87.7 (SD 23.2)</td>
</tr>
</tbody>
</table>
The mean WOMAC scores divided in three categories were 85.8 (SD 15.9) for pain, 77.6 (SD 20.7) for stiffness, and 78.9 (SD 18.5) for physical function. The combined mean WOMAC score was 80.2 (SD 17.0).

There was an excellent correlation between the knee score of the KSCRS and the VAS satisfaction for each observer (0.84-0.85) (Table 3). However, the correlation between the function score of the KSCRS and the VAS satisfaction varied from 0.23-0.54.

<table>
<thead>
<tr>
<th>Table 3</th>
<th>Pearson’s correlation coefficients of the VAS satisfaction and KSCRS for each observer separately.</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Satisfaction VAS</td>
</tr>
<tr>
<td></td>
<td>Surgeon A</td>
</tr>
<tr>
<td>Knee score</td>
<td>0.84</td>
</tr>
<tr>
<td>Function score</td>
<td>0.54</td>
</tr>
<tr>
<td>Total Knee score</td>
<td>0.75</td>
</tr>
</tbody>
</table>

Discussion

In our clinical follow-up study of 39 TKAs, we found that three orthopaedic surgeons scored differently in the KSCRS, but were equally satisfied about the outcome of a TKA. The relative small sample size and heterogeneity were limitations of this study. However, the blinded standardized protocol used, provides interesting data concerning patient and surgeon satisfaction after TKA. To evaluate the results of a TKA, most studies used objective clinical rating systems, such as the KSCRS, including pain, function and disability [5, 8]. The orthopaedic surgeon assessed pain, function and disability in these objective tests. This will lead to a subjective feeling of satisfaction about the outcome of TKA for surgeons and patients. After 121 total hip arthroplasties, Brokelman et al. found no difference between the the patient and surgeon satisfaction [2]. In this study, we also found no difference between the patient and surgeons satisfaction after TKA. Before this report, no study had been published which evaluated the satisfaction after arthroplasty between different orthopaedic surgeons. In this study we found no difference in satisfaction between the three observers. However, we did observe a significant difference in the KSCRS for both the knee and function score. This could be explained by the different interpretation of pain (knee score) and stairclimbing (function score) between the surgeons, because within those items there was the greatest interobserver variability. Ryd et al. also found a difference between observers using knee scores for evaluation of TKA [7]. In this study 10 experienced orthopaedic surgeons used three commonly used knee scoring systems, including KSCRS, to assess 15 TKAs. This could mean that the KSCRS is a good tool to evaluate the outcome of TKA for one observer, but is not useful to compare the outcome of TKA between different observers. The high correlations between the knee score (expressing pain, range of motion and deformity), indicate that pain, range of motion and deformity are important aspects for surgeons. However, they are not the only aspects, because surgeon satisfaction also takes into account the patient’s functionality and patient satisfaction. Our study showed that a simple satisfaction VAS is a useful extension in evaluating the clinical outcome of a TKA. In this study, orthopaedic surgeons scored differently in the KSCRS, but were equally satisfied about the outcome of TKA.
References

Surgeon’s expectations do not predict the outcome of a total knee arthroplasty

H.J. Meijerink, R.B.G. Brokelman, C.J.M. van Loon, A. van Kampen, M.C. de Waal Malefijt

Abstract

Introduction: It is fascinating for both the patient and the surgeon to predict the outcome of a TKA at an early stage. Satisfaction after TKA is primarily determined by the preoperative expectations of the patient. The purpose of this study was to investigate if the peri-operative expectations of the surgeon predicted the outcome of a TKA.

Patients and methods: A prospective study of 53 primary TKAs was performed. Preoperatively, the surgeon described the assessment of the difficulty of the TKA on a VAS. Immediately postoperative, the surgeon gave his satisfaction VAS about the procedure. After 1 year the surgeon’s satisfaction VAS, the patient’s satisfaction VAS and the KSCRS were determined.

Results: The Spearman’s correlation coefficients between the preoperative difficulty assessment, the immediate postoperative satisfaction and the outcome measurements after 1 year were all very poor (-0.01 to 0.23).

Conclusions: The outcome of a TKA depends on multiple factors. Both the surgeon’s preoperative assessment of the difficulty and the surgeon’s immediate postoperative satisfaction do not independently predict the outcome of a TKA.

Introduction

Total knee arthroplasty (TKA) is a successful therapy for pain relief and function improvement in advanced symptomatic degeneration of the knee joint [8,11,13,15,16]. Objective clinical outcome rating systems, such as the Knee Society Clinical Rating System (KSCRS), have traditionally been used to evaluate the outcome of the TKA [8,11,13,15,16]. However, the patient as well as the surgeon generally has a more subjective feeling of satisfaction about the result of the TKA and especially the patient does not think in terms of KSCRS. Satisfaction can be expressed on a visual analogue scale (VAS), similar to the pain VAS [4,14]. Brokelman et al. [1] described that a satisfaction VAS after 1 year is a useful extension in evaluating the clinical outcome of a TKA. In that study, surgeons scored differently in the KSCRS, but were equally satisfied after a TKA and there was no difference between the surgeon and patient satisfaction after 1 year.

Regardless, it is interesting if the outcome of a TKA is predictable at an earlier stage. Both Noble et al. [12] and Mahomed et al. [10] reported that satisfaction after TKA is primarily determined by the preoperative expectations of the patient. Nevertheless, it has not been described previously, how the peri-operative expectations of the surgeon are related to the results of a TKA. Immediately postoperative, most surgeons already have a certain feeling of (dis)satisfaction about the procedure of the TKA and there are preoperatively several degrees of knee destructions with different expectations of the surgeon. Therefore, the purpose of this study was to investigate if the surgeon’s preoperative assessment of the difficulty of the procedure and the surgeon’s immediate postoperative satisfaction will predict the outcome of a TKA in terms of the KSCRS as well as the patient and surgeon satisfaction.

Materials and Methods

Between November 2002 and December 2004, we performed a prospective study of 53 primary TKAs implanted in 51 patients. There were 15 men and 36 women with a mean age at the time of operation of 67 years (range 45–89 years). There were 45 patients with osteoarthritis and 6 patients with rheumatoid arthritis. Preoperatively, 24 knees had a flexion contracture of 5° or more; 19 knees between 5 and 9°, 4 knees between 10 and 14° and in one knee the flexion contracture was more than 15°. There were 18 knees with a varus or valgus alignment of 5° or more; 12 knees between 5 and 10° and 6 knees of more than 10°. The mean preoperative KSCRS knee score and function score were, respectively, 54.3 and 43.2. In 26 knees the press-fit condylar (PFC, DePuy, Warsaw, IN, USA) TKA was implanted,
and in 27 knees the Continuum Knee System (CKS, Stratec Medical, Oberdorf, Switzerland) was used. There were two surgeons participating in this study (MWM and AvK), with, respectively, 18 and 23 years of experience as orthopaedic surgeon and both are yearly performing about 50 TKAs. Surgeon 1 included 39 TKAs and surgeon 2 included 14 TKAs. The mean duration of the operative procedure was 104 min and the mean blood loss during the operation was 206 ml.

Preoperatively, the assessment of the difficulty of the procedure of the TKA was described by the surgeon on a VAS. The difficulty was based on previous operations and incisions, contractures and deformities and the preoperative radiographs. This means that patients with a history of a fracture or an osteotomy around the knee joint and patients with a flexion contracture or a fixed valgus deformity received a high difficulty VAS. Patients without previous surgery, patients without contractures and malalignment and patients without radiographic abnormalities other than the signs of osteoarthritis were assessed with a low difficulty VAS. Immediately after finishing the TKA, the surgeon gave his satisfaction VAS about the procedure. Before this study started, both surgeons were instructed how to determine the different VAS scores. For all VAS scores we used a 100-mm-long horizontal line. The numbers of millimetres on this line from 0 mm (indicating a very easy procedure or total dissatisfaction) to 100 mm (indicating a very difficult procedure or complete satisfaction) was converted to the same number of points [4,14].

All patients were evaluated after a mean of 1 year (range 9-16 months) at the outpatient department by the same orthopaedic surgeon who performed the operation. There were no patients lost to follow up. The surgeon took the history, performed the physical examination and reviewed the radiographs. Thereafter, the surgeon scored his satisfaction of the result of the TKA on a VAS and the KSCRS was determined by an independent observer. This KSCRS score is divided into a knee score and a function score. Both scores range from 0 (worst) to 100 (best) points. The knee score evaluates pain, stability and range of motion, with deductions for flexion contracture, extension lag and malalignment. The function score assesses walking distance and walking stairs, with deductions for walking aids [5].

One year postoperatively, the patients also scored their satisfaction of the TKA on a VAS after standardised instructions by an independent observer in a different room without the presence of the surgeon. Statistical analysis was performed by means of SPSS statistical software (SPSS, Inc., Chicago, IL). The Spearman’s correlation coefficients between the preoperative difficulty VAS or the immediate postoperative surgeon satisfaction VAS, and the 1-year surgeon satisfaction VAS, the 1-year patient satisfaction VAS, the 1-year KSCRS knee score and the 1-year KSCRS function score were determined.

Results

The mean, range and standard deviation of all VAS scores and both KSCRS scores are described in Table 1 for all patients together and both surgeons separately. The correlation between the immediate postoperative satisfaction VAS and the 1-year postoperative satisfaction VAS of the surgeon was 0.09 (Table 2). The correlations between the preoperative difficulty VAS and the 1-year postoperative satisfaction VAS of the surgeon, the 1 year postoperative satisfaction VAS of the patient, and both KSCRS scores were all very poor as well. Figures 1 and 2 shows the relation

<table>
<thead>
<tr>
<th>Table 1</th>
<th>The mean, range and standard deviation (SD) of all VAS scores and both KSCRS scores for all patients and both surgeons separately.</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>All patients</td>
</tr>
<tr>
<td>Preoperative difficulty VAS</td>
<td>34.3</td>
</tr>
<tr>
<td>Immediate postoperative satisfaction VAS</td>
<td>88.3</td>
</tr>
<tr>
<td>1-year surgeon satisfaction VAS</td>
<td>82.7</td>
</tr>
<tr>
<td>1-year patient satisfaction VAS</td>
<td>78.1</td>
</tr>
<tr>
<td>1-year KSCRS knee score</td>
<td>85.2</td>
</tr>
<tr>
<td>1-year KSCRS function score</td>
<td>63.5</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Table 2</th>
<th>Spearman’s correlation coefficients between the preoperative difficulty VAS or the immediate postoperative surgeon satisfaction VAS, and the 1-year surgeon satisfaction VAS, the 1-year patient satisfaction VAS, the 1-year KSCRS knee score and the 1-year KSCRS function score.</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Preoperative difficulty VAS</td>
</tr>
<tr>
<td>1-year surgeon satisfaction VAS</td>
<td>0.11</td>
</tr>
<tr>
<td>1-year patient satisfaction VAS</td>
<td>0.23</td>
</tr>
<tr>
<td>1-year KSCRS knee score</td>
<td>-0.01</td>
</tr>
<tr>
<td>1-year KSCRS function score</td>
<td>0.05</td>
</tr>
</tbody>
</table>
Patient satisfaction after TKA becomes increasingly important and for both the patient and the surgeon it is attractive to predict the outcome of a TKA at an early stage. According to Fortin et al. [6,7], the preoperative status of the patient is the strongest determinant of functional outcomes at 6 months and 2 years following hip and knee surgery. Nevertheless, both Noble et al. [12] and Mahomed et al. [10] reported that satisfaction with TKA is primarily determined by the expectations of the patient. In this study we analyzed how the peri-operative expectations of the surgeon are related to different outcome measurements of a TKA.

There were very poor correlations between the surgeon’s immediate postoperative satisfaction VAS and all outcome measurements 1 year after a TKA. The correlation between the direct postoperative satisfaction VAS of the surgeon and the satisfaction VAS of the same surgeon one year later was 0.09. The mean immediate postoperative satisfaction was 88.3 and the mean satisfaction of the surgeon after one year was 82.7. These satisfaction scores are comparable with previous satisfaction studies after TKA [1,2,3]. Although most patients had both a high immediate postoperative satisfaction VAS and a high satisfaction VAS after 1 year, there were patients with a high immediate postoperative surgeon satisfaction VAS who had low satisfaction scores after 1 year, and patients with a low immediate postoperative surgeon satisfaction VAS who reached high satisfactions after 1 year. Brokelman et al. [1] described a high correlation between the KSCRS knee score and the satisfaction VAS of three surgeons 1 year after TKA. This indicated that pain, range of motion and deformity are important aspects for surgeons. Nevertheless, with the patient under anaesthesia, pain cannot be assessed and measurement of the range of motion is not always reliable. Therefore, in the immediate postoperative situation the satisfaction VAS of the surgeon is more of a satisfaction of the technical result of the TKA. It appears that a good technical result of a TKA does not always result in a high satisfaction and a good clinical outcome after 1 year. Moreover, even with a lesser technical result, the satisfaction of both the patient and the surgeon and the clinical outcome 1 year after TKA can sometimes be excellent. Thus, the surgeon’s immediate postoperative satisfaction is not a good predictor of the outcome of a TKA.

There were also very poor correlations between the surgeon’s preoperative assessment of the difficulty of the procedure and all outcome measurements 1 year after a TKA. One should probably expect a lesser result of the TKA in case of a
preoperative assessment of a higher difficulty. For example, sometimes a severe flexion contracture (with a high preoperative difficulty VAS) is not resolved completely, which results in a lower KSCRS. Nevertheless, there were patients with preoperatively a very severe knee disorder (high flexion contracture and a fixed valgus deformity; high preoperative difficulty VAS) who reached a higher KSCRS and satisfaction after 1 year than several patients with a low preoperative assessment of the difficulty. Undoubtedly, in some patients the difficulty of the procedure will cause a lesser outcome. Otherwise, patients with the greatest preoperative deformity have low KSCRS scores and thus more to gain, which could result in a higher satisfaction after TKA. It seems that we established no strong relation between the difficulty of the procedure and the outcome of the TKA, because the outcome of a TKA depends on multiple factors. Fortin et al. [6,7] described that the preoperative status of the patient is the strongest determinant of functional outcomes at six months and 2 years following hip and knee surgery. Lingard et al. [9] showed that marked functional limitations, severe pain, a low mental health score and other comorbid conditions are more likely to have a worse outcome after TKA. Furthermore, Noble et al. [12] reported that satisfaction with TKA is primarily determined by the expectations of the patient and Mahomed et al. [10] described that patient expectation of complete pain relief following total joint arthroplasty is a good predictor of the functional outcome. Thus, the outcome of a TKA can not easily be predicted. Many factors seem to affect the outcome more or less, and the relative importance of each part may vary with the individual. We did not determine an interobserver variability between the surgeons’ assessments. Within this study design with relatively small patient numbers, it is not possible to determine a reliable intraobserver variability of the surgeon’s assessments, because the surgeon should mostly remember the case at the next assessment. Regardless, it seemed that both surgeons have comparable VAS assessments. Although the short follow-up period of 1 year is a limitation of this study, since we know that changes one year after TKA are very unlikely, longer follow-up should probably not change the conclusions. Nevertheless, further research has to prove that. In conclusion, the outcome of a TKA depends on multiple factors. The preoperative status and the expectations of the patient are strong determinants of the outcome of a TKA. Therefore, both the surgeon’s preoperative assessment of the difficulty of the procedure and the surgeon’s immediate postoperative satisfaction do not independently predict the outcome of a TKA.

References

Asymmetrical total knee arthroplasty does not improve patella tracking

a study without patella resurfacing

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CHAPTER 4

ASYMMETRICAL TOTAL KNEE ARTHROPLASTY DOES NOT IMPROVE PATELLA TRACKING

Abstract

It is often suggested that patella tracking after TKA with an asymmetrical patella groove is more physiological than with a symmetrical patella groove. Therefore, this study tried addressed two questions: what is the effect of TKA on patella tracking, and is patella tracking after asymmetrical TKA more physiological than patella tracking after symmetrical TKA? The patellar and tibial kinematics of five cadaveric knee specimens were measured in the intact situation, after the incision and suturing of a zipper, and after placement of a symmetrical TKA and asymmetrical TKA, respectively. The patellae were not resurfaced. The flexion-extension kinematics were measured with an internal- and external tibial moment to determine the envelope of motion (laxity bandwidth) of the tibio-femoral and patello-femoral articulation. The kinematics after TKA showed statistical significant changes in comparison to the intact situation: patellar medio-lateral translation, patellar tilt and tibial rotation were significantly affected. No statistical significant differences in knee kinematics were found between the symmetrical and the asymmetrical TKA.

We conclude that conventional TKA significantly changes physiological patello-femoral kinematics and TKA with an asymmetrical patella groove does not improve the non-physiological tracking of the patella.

Introduction

Manufacturers of orthopaedic implants often claim that the design of their total knee implants restores adequate physiological patella tracking. However, the anatomical variations of the patella-femoral joint are considerable and the geometries involved are quite complex. It is therefore not obvious that a Total Knee Arthroplasty (TKA) design reproduces physiological patella tracking even if the components are perfectly aligned.

An important design aspect of TKAs, concerning the restoration of physiological patella tracking, is the groove orientation. The early TKA’s were all designed with a neutral or symmetrical patella groove. However, most of the new TKA designs have a laterally oriented or asymmetrical patella groove as this is thought to be more anatomical [13]. However, an improved functional or clinical performance has not been proven up to now [4, 8, 27]. This raises the question whether an asymmetrical groove design actually results in a more physiological patella tracking.

Patellar kinematics are sensitive to multiple factors. (e.g. design and alignment of the implant, capsular tension, location of the tuberosity). It is therefore difficult to determine the relation between a single parameter and patellar kinematics when other parameters are changed at the same time. This is left under exposed in other studies in which several parameters were changed simultaneously [4,11,28]. In the current study, we developed a procedure to determine the effect of a single parameter on patellar kinematics.

Hence, this study tried to answer two questions. (1) What is the effect of TKA on patella tracking relative to the intact situation, and (2) is the patella tracking after TKA with an asymmetrical patella groove more physiological than the patella tracking after TKA with a symmetrical patella groove, as is often suggested? The authors therefore studied the in-vitro kinematics of the knee in detail, before and after TKA, and in case of a symmetrical and asymmetrical groove design.

Materials and Methods

About 15 fresh frozen, right sided, anatomic knee specimens were x-rayed and templated. From these series, five specimens were selected for use with a medium sized femoral knee component. The specimens were obtained from the Department of Anatomy of the hospital. There was no information available regarding cause of death, age, or gender. The specimens were prepared for use in a knee joint motion and loading apparatus (Fig. 1) [25]. Therefore, the upper and lower leg were transectioned at about 20 cm from the knee joint centre. The transectioned ends of the bones were potted in autopolymer to allow fixation into the apparatus. The
asymmetrical total knee arthroplasty does not improve patella tracking

applied to the tibia to obtain the external rotational pathway (ERP). The IRP and ERP represent boundaries (or extremes) of the motion pathway. Hence, the difference between the IRP and the ERP shows the envelope of motion. After this measurement, a medial incision was used to open the capsule, and a plastic zipper was sewed into it. This zipper replaced the surgical sutures and made it possible to insert different TKAs and measure the knee kinematics under identical capsular circumstances. The measurements were repeated with only the zipper in situ to assess the individual effect of the incision on the knee kinematics.

A conventional CKS prosthesis (Continuum Knee System, Biomet/STRATEC, Warsaw, IN, USA) was implanted by an experienced knee surgeon, who also used this implant as the standard primary TKA clinically. The CKS is a posterior cruciate retaining Total Knee Prosthesis with a symmetrical patellar groove. The implantation procedure was similar as performed clinically, according to the instructions of the manufacturer and using the CKS instrumentation. The instructions of the manufacturer included a 3 degrees external rotation (around the mechanical axis of the femur) of the femoral component to balance the flexion gap. The patella was not resurfaced in this study. A medium size of the implant was used for all 5 specimens. The femoral and tibial components were all manufactured from polymer to prevent metal artefacts with the measuring system. The kinematic measurements were repeated with the conventional CKS prosthesis in situ.

After these measurements, the conventional femoral component was replaced with an asymmetrical prototype CKS femoral component. The difference between the prototype and conventional design was that the symmetrical patella groove was replaced with an asymmetrical groove (a groove with a 7 degrees lateral orientation on the anterior flange). The measurements were repeated once more. Both the symmetrical and asymmetrical femoral components were located at the same (medio-lateral) position.

The main focus in this study was on adaptations in patellar kinematics. To differentiate between the effects of different parameters on the kinematics, the authors compared 4 different situations: 1) intact, 2) after the incision and the suturing of the zipper, 3) after the implantation of the conventional CKS prosthesis and 4) after the implantation of the prototype CKS prosthesis. As the patellar kinematics are also largely dependent on the tibial kinematics both patellar- and tibial kinematics were measured.
A two-way ANOVA with a Tukey test for multiple pairwise comparisons was applied to the data of the 5 specimens at fixed flexion angles (0, 5, 10…,100 degrees) to determine whether differences between the four situations were statistically significant (p < 0.05). Separate statistical tests were performed for the IRP’s and ERP’s.

Results

The effect of the incision and the suturing of the zipper
The zipper did not impose statistical significant differences in comparison to the intact situation, except for the patellar rotation. Therefore, the zipper only had a minor effect on the knee kinematics. The patella rotation was not further used for comparison for the remaining part of this study.

The effect of total knee arthroplasty on knee kinematics
Relative to the zipper situation, the symmetrical TKA did impose significant changes to the kinematics of the patella (Fig. 3). Symmetrical TKA resulted in a significantly more medial position of the patella in flexion (Table 1: statistical significant difference between 65 and 90 degrees of flexion for the IRPs, and between 80 and 90 degrees of flexion for the ERPs). It also resulted in significantly more lateral tilt of the patella at lower flexion angles (Table 1: statistical significant difference between 10 and 30
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ASYMMETRICAL TOTAL KNEE ARTHROPLASTY DOES NOT IMPROVE PATELLA TRACKING

Finally, the symmetrical TKA resulted in significantly less internal tibial rotation along the IRP (Table 1: statistical significant difference between 45 and 95 degrees of flexion for the IRPs. The symmetrical TKA also resulted in some more varus angulation of the tibia (Fig. 3d). However, this difference was not statistically significant (Table 1).

Table 1 Statistical significant differences (p < 0.05) between the situation with the zipper and the situation with symmetrical TKA, for different flexion angles.
The difference in kinematics between TKAs with a symmetrical and asymmetrical patellar groove

The symmetrical TKA showed a somewhat more lateral patellar position (Fig 4b) and lateral patellar tilt (Fig 4c) between 5 and 50 degrees of flexion. Furthermore, it showed more varus angulation (Fig 4d) of the tibia. However, the differences between the symmetrical- and asymmetrical TKA were never found to be statistically significant.

Figure 4 The envelope of motion for patella and tibia: the effect of a lateral groove design: a) patellar flexion, b) patellar medio-lateral position, c) patellar tilt, d) tibial varus-valgus, e) tibial rotation.
Discussion

The results found in the pre-operative situation were generally in good agreement with the results from earlier measurements [2, 11, 14, 16, 17, 20, 21, 26].

The trochlea is the main determinant for the patellar position at flexion angles higher than 30 degrees. Hence, the medio-lateral translation of the patella should also correlate with the orientation of the trochlea or groove [1]. The orientation of the natural trochlea is mainly medial [8], which correlates with the medial translation of the patella during knee extension from 90 to 20 degrees of flexion (note that the patella is not located in the trochlea in extension). The orientation of the prosthetic patella groove in the implanted situation is lateral [7], which also correlates with the lateral translation of the patella during extension of the knee as found in this study.

The effect of total knee arthroplasty on knee kinematics

Relative to the situation with the zipper, the patellar flexion pathways did not show significant differences after TKA implantation, except for one individual flexion angle for the ERP (90 degrees). This indicates that the sagittal geometry of the TKA resembled the sagittal geometry of the normal knee relatively well.

At 5-10 degrees of flexion, the medio-lateral position of the patella, after TKA, was close to the medio-lateral position of the patella in the normal knee. This indicated that current alignment and design of the femoral component is able to replicate the patellar position in extension, and that there was no tendency of patellar dislocation. However, at 80-90 degrees of flexion, the pathways of the patellar medio-lateral translation, before and after TKA, were significantly different. The patella was located about 3 mm more medially post-operatively, which increases the Q-angle. Hence, the patella was displaced significantly in high flexion angles, a situation where substantial patellar loading is expected [10, 19]. It is therefore expected that this non-physiological patellar position will increase the patellar contact forces. A probable cause for the patellar medialization at 90 degrees of flexion is the alignment of the femoral component. In the intact situation, the medial compartment of the joint is wider, because the medial- and lateral condyle are not parallel [22]. However, the femoral prosthetic component has condyles of equal width. The medio-lateral alignment of the femoral component is based on a compromise between a central placement and good bone coverage (by the anterior flange). It is likely that this may cause the patella groove of the TKA to be located more medially than the anatomic sulcus.

TKA caused the patella to tilt significantly more laterally between 20 and 30 degrees of flexion. This tilt pattern can be explained by the configuration of the distal femur after TKA. The femoral components were placed with 3 degrees of external rotation relative to the femur. These components do not have a raised lateral ridge on the anterior flange. Hence, the medial prosthetic condyle reaches more anteriorly than the lateral prosthetic condyle, which leads to a very pronounced lateral tilt at lower knee flexion angles. The patellar tilt in the intact situation can be explained in a similar way by the anatomical configuration of the distal femur, which was already described by Van Kampen et al [26].

TKA did induce a statistical significant difference in the IRP of the tibial rotation between 45 and 95 degrees of flexion. Possible reasons for this behaviour are small changes in knee laxity and the changed curvature of the proximal tibia (a prosthetic condyle running up a slope of the tibial insert).

Summarizing, the TKA procedure induced significant changes to the knee kinematics, however, the changes are consequences of the design and placement parameters. This suggests that they can consequently be reduced by design improvements, e.g. asymmetrical condylar width to restore the anatomical medio-lateral patellar position and built-in external rotation for the femoral component to restore the anatomical patellar tilt.

The difference in kinematics between TKAs with a symmetrical and asymmetrical patellar groove

The results did not show any statistical significant difference in kinematics between the symmetrical and asymmetrical TKA. Worland et al. [27] and Ashraf et al. [4] also did not find that the asymmetrical TKA improved patella tracking clinically. The asymmetrical groove is apparently not functional, which can be explained by the fact that the difference in prosthetic groove orientation between the symmetrical and asymmetrical TKA only exists on the anterior flange of the femoral component. This is the location of the patella, when the knee is close to extension (0-20 degrees of flexion) and it is the area where the soft tissue structures are the main determinants for the patellar position [14]. This factor apparently overrules the design differences of the anterior flanges. Hence, a more lateral prosthetic groove orientation on the anterior flange of the femoral component does not have the expected influence on the patellar position.

A problem in many patella tracking studies is the high variability within the results and the large number of parameters influencing the results. In this study, the authors have reduced the number of influential parameters by using an intra-specimen comparison, which allowed to use a relatively small group size for the experiments. Instead of suturing the incision after each variation [3, 11, 20], a zipper was sutured into the incision [12]. This zipper could be opened to insert or change components and closed to run the tests. The use of a zipper within this study prevents that the differences in soft tissue tension between the tests will affect the results. It allows an intra-specimen comparison, which is a very pure way to assess effects under variable circumstances (human material). This study showed that the incision and...
the zipper only induced significant changes on the patellar rotation. The other kinematic patterns and trends were not significantly affected, indicating that the zipper had only little influence. It is expected that the effect of the zipper is not very different from the effect of the standard surgical sutures immediately after surgery. The same order of implantations and measurements was used during all experiments. During testing with cadaver material over time, the knee may have become somewhat more lax. However, the envelope of motion of the asymmetrical vs. the symmetrical TKA did not increase (Fig. 4). Hence, the results indicate that the order of implantations do not really affect the laxity.

The muscles in this study were loaded equally in their muscle directions. The loads were small and not physiological with regard to the muscle loads in vivo. However, in this study the muscle forces were applied to generate tensioning of the capsule and (thereby) joint stability.

Usually, patella-femoral kinematics are measured during flexion-extension motion while applying a general, relatively simple, flexion-extension loading configuration. These kinematics may also be relatively sensitive to small variations in the loading configuration. In vivo there are, of course, many different loading configurations with different complexities affecting patellar kinematics. Hence, the patella moves within an area or envelope of motion (laxity bandwidth). In this study, the envelope of motion for the patella and tibia were therefore determined using an internal- and external rotational torque. The value of 3 Nm for this torque is within physiological boundaries and gives a good description of the extremes of the envelope of motion [9]. In this study fresh frozen cadaver specimens were used to enable in vivo circumstances as close as possible. The transsection of the femur and the tibia is only expected to have minor influence on the knee kinematics. The transsection of the bones does not affect the actual joint structures. However, the alignment of the prosthetic components becomes somewhat more difficult when the bones are transected.

The standard procedure within our institution is not to resurface the patella during primary TKA. This is a common procedure during many TKAs in the world (e.g. in England/Wales, Norway, Sweden, Australia and Ontario, the patella is not resurfaced in 63% [18], 95% [15], 89% [23], 57% [5] and 25% [24] of primary TKAs, respectively). Therefore, the patella was also not resurfaced in this study, in contrast to many other patella tracking studies [3, 11, 20]. Not resurfacing of the patella had an additional advantage concerning the intra-specimen comparison. The alignment and the design of a patellar component are additional parameters which would influence patellar tracking. These additional parameters were excluded in the current situation.

The first question, which we tried to answer in this study, was about the effect of TKA on patella tracking. The results of this study showed that statistically significant changes were induced on the kinematics through symmetrical TKA. These changes could be related to design and alignment. In this way, the patellar medio-lateral translation could be related to the groove orientation [6, 7] and to the medio-lateral location of the femoral component. Furthermore, the difference in patellar tilt could be related to the shape of the condyles and the external rotation of the femoral component. The findings can be utilized for improvement for new TKA designs and instrumentation.

The second question, which we addressed, was whether patella tracking after TKA with an asymmetrical groove was more physiological than patella tracking after TKA with a symmetrical groove. The differences between the kinematics of both TKAs were very small and not statistically significant. Therefore, this study does not show a more physiological patella tracking in case of the asymmetrical (lateral) groove orientation.

In conclusion: conventional TKA significantly changes physiological patello-femoral kinematics and TKA with an asymmetrical patella groove does not improve the non-physiological tracking of the patella.
References

The trochlea is medialized by total knee arthroplasty

An intraoperative assessment in 61 patients

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CHAPTER 5

The Trochlea Is Medialized by Total Knee Arthroplasty

Introduction

After implantation of a total knee arthroplasty (TKA), patellofemoral complaints is one of the complications with the highest incidence (1–24%) [4, 9, 10], and is an important reason for revision surgery. Most patellofemoral complications are associated with abnormal patellar tracking [9]. Thus, patella tracking is an important issue in TKA, which is, among other parameters, influenced by the mediolateral and rotational position of the femoral component. Several studies have shown that small modifications in alignment of the femoral component cause significant changes in patella tracking [1, 8, 14, 17].

In a recent cadaver experiment involving TKAs without resurfacing of the patella, we observed that the patella in a TKA is displaced to the medial side in a flexed knee, when compared to the preoperative position [3]. A medialization of the patella results in a higher Q-angle, as the direction of the patella tendon differs more from the vector of the Quadriceps. Because the loads are maximal in a flexed knee [16], one could expect an increase in compressive and shear forces on the patellar joint [13]. Armstrong et al. [2] described that the position of the patella changes with any malposition of the femoral component, which could result in patellar instability, pain, wear, and failure. Furthermore, Rhoads et al. [17,18] concluded that medial femoral displacement produces abnormal patellar tracking patterns with higher stresses on the patella. Although these authors also described problems with medialization of the femoral component and the patella, they defined medialization in relation to the standard or neutral position of the femoral component, but omitted to compare it to the preoperative, anatomical position of the trochlea. We therefore assessed whether there is a systematic error of the position of the prosthetic groove relative to the anatomical trochlea.

Materials and Methods

We developed a special instrument to measure intraoperatively the mediolateral position of the trochlea (Figure 1). After preparing the knee for a primary TKA, just before any bone resection took place, this instrument was placed on the distal femur. 3 hollow cylinders with a diameter of 2.7 mm were positioned in the epicondyles as reference points and the 3 fixing pins of the instrument were slid into those cylinders. Perpendicular to the mediolateral scale was a sliding part of the instrument with a plastic disc as probe. This probe simulated the articular surface of the patella, and had 2 different diameters (33 and 55 mm) to choose the best...
3 surgeons measured the mediolateral error of the prosthetic groove in a primary TKA in 61 patients. All patients were operated for symptomatic osteoarthritis or rheumatoid arthritis. There were no exclusion criteria. All surgeons were experienced knee surgeons with more than 4 years of experience with the implant. None of the patellae were resurfaced. Surgeon A routinely placed an LCS rotating platform prosthesis (DePuy, Warsaw, IN) and determined the mediolateral error in 21 patients. Surgeons B and C placed a PFC prosthesis (DePuy, Warsaw, IN) and both measured the mediolateral error in 20 patients each. All three surgeons used their own criteria for the mediolateral positioning of the femoral component; surgeons A and B both strived for optimal coverage of both condyles, and surgeon C preferred a flush position of the femoral component relative to the lateral epicondyle. The LCS prosthesis, as used by surgeon A, has a resection guide that is placed on the distal femur after the distal resection is performed. The position of this resection guide is fixed, and after the other resections are made the trial component has exactly the same mediolateral position. Thus, the mediolateral position of the femoral component of the LCS prosthesis (surgeon A) has been based on the distal resection plane. In contrast to the LCS system, with the system of the PFC prosthesis, the trial component can be moved more medially or laterally after all resections are performed. Thus, surgeons B and C could overview the whole distal femur, including the anterior and posterior part, during the positioning of the femoral component.

In addition to the question of whether there is a systematic error of the position of the prosthetic groove relative to the anatomical trochlea, we compared the mediolateral positioning of the trochlea of 2 different prosthetic designs and 3 different surgeons, each with their own criteria for mediolateral positioning of the femoral component. Moreover, we analyzed the influence of difference in size of the prosthesis on mediolateral positioning of the prosthetic groove.

**Statistics**

Statistical analysis to assess whether there was a systematic error in the position of the prosthetic groove relative to the anatomical trochlea was performed with the one-sample t-test for all patients together, and for each surgeon and prosthetic design separately. For the assessment of the difference in mediolateral error between the 3 surgeons, we used one-way ANOVA with Bonferroni correction for pairwise testing. For the difference in mediolateral error between the 2 prosthetic designs, a t-test for 2 independent samples was used. The influence of prosthetic size on the mediolateral error was analyzed with linear regression. P-values less than 0.05 were defined as being statistically significant.
Results

There was a medial error (p < 0.001) of the prosthetic groove relative to the preoperative position of the trochlea in all 61 patients together, with a mean medial error of 2.5 mm (SD 3.3, 95% CI: 1.7–3.3 mm) (Table). Surgeon B placed the prosthetic groove significantly more medially than surgeon A (p = 0.01) and surgeon C (p = 0.02). The difference in mediolateral error between the 2 prosthetic designs was not significant (p = 0.08). The correlation between size of the femoral component and mediolateral error was not significant (R = 0.24, p = 0.06) (Figure 2).

<table>
<thead>
<tr>
<th>Group</th>
<th>Mean (mm)</th>
<th>Range (mm)</th>
<th>SD (mm)</th>
<th>95% CI (mm)</th>
<th>P-value</th>
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</thead>
<tbody>
<tr>
<td>All patients</td>
<td>2.5</td>
<td>-4 to 9</td>
<td>3.3</td>
<td>1.7 – 3.3</td>
<td>&lt; 0.001</td>
</tr>
<tr>
<td>Surgeon A</td>
<td>1.5</td>
<td>-3 to 7</td>
<td>2.5</td>
<td>0.3 – 2.6</td>
<td>0.01</td>
</tr>
<tr>
<td>Surgeon B</td>
<td>4.4</td>
<td>0 to 9</td>
<td>2.7</td>
<td>3.1 – 5.6</td>
<td>&lt; 0.001</td>
</tr>
<tr>
<td>Surgeon C</td>
<td>1.7</td>
<td>-4 to 8</td>
<td>3.7</td>
<td>-0.1 – 3.5</td>
<td>0.06</td>
</tr>
<tr>
<td>LCS Prosthesis (surgeon A)</td>
<td>1.5</td>
<td>-3 to 7</td>
<td>2.5</td>
<td>0.3 – 2.6</td>
<td>0.01</td>
</tr>
<tr>
<td>PFC Prosthesis (surgeon B + C)</td>
<td>3.0</td>
<td>-4 to 9</td>
<td>3.5</td>
<td>1.9 – 4.1</td>
<td>&lt; 0.001</td>
</tr>
</tbody>
</table>

The mean, range, standard deviation (SD), 95% confidence interval (CI) and the significance of the error of each group are shown.

Discussion

Our findings indicate that there is a systematic medial error in the position of the prosthetic groove. This is in agreement with our cadaver experiment involving TKAs without resurfacing of the patella, where we observed that the patella in a TKA was displaced to the medial side in a flexed knee, as compared to the preoperative position [3]. A plausible cause for this medial error might be the difference in distal position of the femoral condyles. Morphological studies of the distal femur have shown that in most femurs the medial condyle is positioned more distally [15, 20]. This means that the resection area of the medial condyle is greater than that of the lateral condyle, when the resection is performed in a plane perpendicular to the mechanical axis of the leg. Thus, when a femoral component is placed exactly in the middle of the distal resection, the middle of the prosthesis will be shifted to the wider resection area of the medial condyle and will therefore cause a medial displacement of the trochlea (Figure 3). Moreover, Eckhoff et al. [6, 7] showed that the sulcus of the trochlea is lateral to the mid-plane between the condyles. This could be another aspect of the asymmetrical distal resection area to explain a medial error of the trochlea in TKA in the case of femoral components with equal widths of the medial and lateral condyles. It therefore seems more appropriate to develop femoral components with a wider medial condyle than the lateral condyle, to achieve an anatomical position of the prosthetic groove and good coverage of both condyles as well. To our knowledge, there is only one prosthetic design with a wider medial condyle on the market (3DKnee, Encore Medical, Austin, TX).

In addition, we had expected a greater medial error with greater sizes of the femoral components, because greater sizes should give more discrepancy in the widths of the condylar resection area. Moreover, Eckhoff et al. [7] speculated that the sulcus of the anatomical distal femur is more lateral in a wider femur. We found a tendency (p = 0.06) for a larger size of femoral prosthesis to have a greater medial error.
One important issue is the clinical consequence of a displacement of the prosthetic groove in the medial direction. Rhoads et al. [17, 18] concluded that medial femoral displacement produces abnormal patellar tracking patterns with higher stresses on the patella. Armstrong et al. [2] described that the position of the patella changes with any malposition of the femoral component. In this study, we determined the mediolateral position of the most distal point of the trochlea, which is assumed to prescribe the position of the patella in flexion of the knee joint. Although we had already observed in a cadaver experiment (involving TKAs without resurfacing of the patella) that the patella in a TKA is displaced to the medial side in a flexed knee [3], we did not analyze the position of the patella in the current study. Furthermore, when there is resurfacing of the patella, a conscious medialization of the patellar component could compensate for a medially displaced prosthetic groove, and medialization of the patellar component has been suggested as a means of improving patellar tracking [5, 19]. Although some good initial results of patellar component medialization in TKA have been described [11, 12], it seems better to strive for an anatomical positioning of the TKA than to compensate for a medial error of the femoral component by placing a medially displaced patella prosthesis. The conclusion of our study is that the trochlea is medialized by TKA. Because a conscious medialization of the femoral component in a TKA produces abnormal patellar tracking patterns—which could result in patellar instability, pain, wear, and failure—further investigations will be needed to analyze the clinical consequences of this medialization of the trochlea.

Another remarkable result was that surgeon B placed the prosthetic groove significantly more medial than surgeons A and C. Although surgeon A used another prosthetic design than surgeons B and C, we did not find any significant difference in mediolateral error between these prosthetic designs. This indicates that surgical judgement may govern mediolateral positioning, rather than the prosthetic system. Surgeon C preferred a flush position of the femoral component relative to the lateral epicondyle, and was consequently less influenced by the asymmetrical distal resection area of the condyles. Surgeon C was the only surgeon for whom the medial error was not significant. Surgeons A and B both strived for optimal coverage of both condyles. Surgeon A had to base the positioning of the femoral component only on the distal resection plane, with the resection guide placed on the distal femur. After all bone resections were performed, surgeon B could view the whole distal femur during the mediolateral positioning. The exact anatomy seems less obvious after all bone resections, and it appears that with a complete overview of the whole distal femur, surgeon B was more affected by the asymmetrical distal resection area, which causes a shift of the prosthetic groove to the wider medial condyle.
References


Physical examination and in vivo kinematics in two posterior cruciate ligament retaining total knee arthroplasty designs

MJM Ploegmakers, B Ginsel, HJ Meijerink, JW de Rooy, MC de Waal Malofijt, N Verdonschot, SA Banks

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Abstract

The aim of this study was to investigate anteroposterior instability in the CKS and the PFC total knee arthroplasty (TKA) designs. Physical examinations, including VAS, IKS and WOMAC were performed in combination with a detailed fluoroscopic measurement technique for three-dimensional kinematic assessment of TKA design function. Anteroposterior instability rated with the IKS was not significantly different (p=0.34), but patients with a CKS design showed more limitations according to the WOMAC joint stiffness total score, and for items regarding higher flexion activities in the WOMAC score for knee disability. Kinematic analyses showed that the CKS design tended to have more anterior sliding of the femur on the tibia during mid- and deep flexion activities. The sliding distance was larger at the medial than at the lateral side. This phenomenon has also been described for posterior cruciate ligament deficient knees. Furthermore, the CKS design showed a significantly lower range of tibial rotation (p<0.05) from maximum extension to maximum flexion during deep knee bend activities. Kinematic differences can be ascribed to posterior cruciate ligament deficiency/ laxity or differences in TKA designs.

Introduction

Between 1998 and 2001, two different posterior cruciate ligament (PCL) retaining total knee arthroplasty (TKA) designs were used in the Department of Orthopaedics. The Press Fit Condylar Sigma (Johnson & Johnson) and the Continuum Knee System (Stratec Medical), PFC and CKS, respectively. The designs were introduced sequentially. A subjective assessment during follow-up indicated patients with the CKS design exhibited less anterior-posterior (AP) knee stability. The CKS design has a symmetric femoral component and the sagittal curve of the condyles has a larger radius distally than posteriorly. The tibial insert is curved in sagittal and coronal planes. The femoral part of the PFC design has an asymmetric anterior flange with a more uniform sagittal condylar curve. The tibial insert has a modest curvature in the anteroposterior direction with some posterior slope (Figure 1). The upper surface of the polyethylene tibial component of the CKS design has a wider, more angular and more prominent shape in the intercondylar area compared to the PFC design. In addition, on the posterior side the PE component of the CKS has a sharp corner which potentially interacts with the PCL (Figure 1 C and D). We believe that these geometric differences, especially the curvature of the tibial insert, could affect the intrinsic stability of the design, and therefore might affect the function of the PCL and the overall stability of the knee.

A number of techniques have been reported for the dynamic measurement of knee motion. Techniques using skin-mounted markers or fixtures inherently have difficulties to accurately measure bony segment rotations and translations due to relative skin-bone movements [7, 20, 24, 27, 32]. Another technique to directly measure skeletal motion uses invasive markers or specially marked implants in roentgen stereophotogrammetric analysis [12, 15, 21, 33]. These problems can be overcome using a fluoroscopic technique [28, 34] permitting accurate measurement of three dimensional knee kinematics during dynamic weight-bearing, step up and step down (or knee bend activities, KB), and deep knee bend (DKB) activities. This method is sufficiently accurate to provide a detailed analysis of in vivo prosthetic function with minimal radiation dose for the patient.

This study was undertaken based on the qualitative clinical impression that patients implanted with different TKA designs (CKS and PFC) exhibit different mechanical function. We sought to answer two specific questions. First, is there a difference in clinical performance between these TKA designs? Second, is there a difference in functional knee kinematics during weight-bearing KB and DKB activities between these TKA designs? Both questions were focused specially on knee AP instability.

We hypothesized that the design with less intrinsic stability (CKS) would exhibit lower clinical scores and greater tibiofemoral translations and rotations during functional motion.
Materials and Methods

In our hospital patients used to be implanted with a PFC design. This was at some time changed to the CKS design. During follow up, the surgeons believed the latter showed inferior clinical results and decided to stop using the CKS design. Patients with a TKA because of primary osteoarthritis or rheumatoid arthritis were included in this study. Patients with a posterior stabilized TKA or posterior cruciate resection were excluded. This study was approved by the local medical ethics committee (2002/074) and all participating patients signed a written consent. The target number for patient enrollment was based on earlier studies where groups of approximately 10-15 knees were sufficient to demonstrate statistically significant differences in knee kinematics between two TKA designs [1, 34]. Patients were randomly selected from a large CKS group by an independent researcher. We then selected diagnosis and age matched patients from the PFC group. We started with 20 implants in each group. Seven (1 PFC and 6 CKS designs) could not participate (2 patients were lost to follow up, 2 patients did not signed informed consent, 1 patient had to work abroad, 1 patient had his knee twisted and 1 patient was otherwise unable to participate). The remaining 19 PFC and 14 CKS designs were included in the study for physical and fluoroscopic examination. At the time of investigation, we first examined clinical performance (Table 1). Thereafter, patients performed the fluoroscopic exercises. The median age was 69 years (interquartile range IQR 14) in the PFC group and 69 years (IQR 8 years) in the CKS group. Physical examination (including maximal extension and flexion), the Visual Analogue Scale (VAS) for pain and satisfaction, the International Knee Society (IKS) rating and the Western Ontario and McMaster Universities osteoarthritis index (WOMAC) were analyzed by a blinded investigator. A percentage score was calculated for the latter.

Fluoroscopic investigation, where the foot was placed on a 30 cm step, included three cycles each step-up (KB) and DKB activities. The anterior aspect of the tibia was placed against a stabilizing frame to assist keeping the knee in the fluoroscope field of view. A lateral view of the knee was recorded using fluoroscopy (OEC9800, GE Medical) for each activity. Computer Aided Design model based shape matching was performed to determine the 3D positions of the components [3]. The AP locations of femoral condyles were approximated as the locations where the femoral condyles were closest to the surface of the tibial baseplate, which is a reasonable approximation as internal and external rotations remain relatively small. Condylar locations and ranges of translation were averaged over ten degree flexion intervals for both groups.

Statistical analyses were performed with SPSS Version 11 for the Windows operating system. The two-tailed non-parametric Mann-Whitney U-test was used for analysis.
of physical examination and VAS, IKS and WOMAC questionnaires. Knee kinematics were compared using a two-factor repeated measures ANOVA with post-hoc pairwise multiple comparisons using Tukey’s Honestly Significant Difference. Differences were considered to be statistically significant when p≤0.05.

Results

Unfortunately, in several patients (8 PFC, 4 CKS), model matching could not be performed due to missing data or blurred images, resulting from high velocity movements. These patients were excluded from statistical analysis of kinematic studies.

At the time of physical and fluoroscopic investigation, we examined the VAS, IKS and WOMAC questionnaires (Table 1). The median follow up was 40 months (IQR 4.3 months) and 32 months (IQR 3.3 months) in the PFC and CKS group, respectively. Because of the sequential introduction of the two TKA designs, there was a significant difference in follow up time (p<0.001).

Physical examination

AP instability scored according to the IKS was not significantly different (p=0.34). The WOMAC joint stiffness total score for the PFC and CKS groups were 87.5% (25.0) and 75.0% (46.9) respectively (p=0.050), indicating that the CKS patients exhibited more joint stiffness. Furthermore, the WOMAC questionnaire contains 17 items to determine knee disability. An average total score of 0% indicates severe limitations and 100% no limitations in these 17 items. Although the total WOMAC score for knee disability was not significantly different (p=0.15), individual items such as walking down a stair (p=0.046), getting out of bed (p=0.029) and getting onto and off the toilet (p=0.013), did show statistically significant differences, with patients in the CKS group having more limitations.

No differences were found for VAS pain and VAS satisfaction. Also, the IKS score showed no statistically significant differences for range of motion (ROM), stability, limitations and total knee score.

Kinematics

Table 2 shows the condylar translations and axial rotations for the CKS and PFC design for KB and DKB activities. No significant differences were found for the total range of condylar translations and the condylar translations from maximal extension to maximal flexion.

Table 1 Clinical profiles of the PFC and CKS designs.

<table>
<thead>
<tr>
<th></th>
<th>Total population</th>
<th>Population analyzed in the kinematic studies</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>PFC</td>
<td>CKS</td>
</tr>
<tr>
<td>Number of designs</td>
<td>19</td>
<td>14</td>
</tr>
<tr>
<td>Follow up (months)</td>
<td>40 (4.3)</td>
<td>32 (3.3)*</td>
</tr>
<tr>
<td>Age (years)</td>
<td>69 (14)</td>
<td>69 (8.4)</td>
</tr>
<tr>
<td>Male/Female</td>
<td>6/13</td>
<td>3/11</td>
</tr>
<tr>
<td>Right/Left</td>
<td>9/10</td>
<td>9/5</td>
</tr>
<tr>
<td>Rheumatoid arthritis/Osteoarthritis</td>
<td>3/16</td>
<td>2/12</td>
</tr>
<tr>
<td>VAS pain daily life</td>
<td>10 (10)</td>
<td>12 (16)</td>
</tr>
<tr>
<td>VAS satisfaction</td>
<td>3.0 (14)</td>
<td>6.0 (18)</td>
</tr>
<tr>
<td>IKS pain</td>
<td>45 (5.0)</td>
<td>50 (5.0)</td>
</tr>
<tr>
<td>IKS range of motion</td>
<td>21 (3.0)</td>
<td>21 (3.0)</td>
</tr>
<tr>
<td>IKS AP instability (mm)</td>
<td>10 (0.0)</td>
<td>10 (0.0)</td>
</tr>
<tr>
<td>IKS knee-score total (%)</td>
<td>93 (9.5)</td>
<td>94 (9.0)</td>
</tr>
<tr>
<td>IKS function-score total (%)</td>
<td>80 (33)</td>
<td>68 (20.0)</td>
</tr>
<tr>
<td>IKS total (%)</td>
<td>89 (19)</td>
<td>89 (19)</td>
</tr>
<tr>
<td>WOMAC pain total (%)</td>
<td>95 (13)</td>
<td>93 (8.8)</td>
</tr>
<tr>
<td>WOMAC joint stiffness total (%)</td>
<td>88 (25)</td>
<td>81 (31)</td>
</tr>
<tr>
<td>WOMAC knee disability total (%)</td>
<td>81 (18)</td>
<td>82 (16)</td>
</tr>
<tr>
<td>WOMAC total (%)</td>
<td>84 (15)</td>
<td>84 (11)</td>
</tr>
</tbody>
</table>

Data are represented as median (Inter Quartile Range). VAS, Visual Analogue Scale; IKS, International Knee Society; WOMAC, Western Ontario and McMaster Universities osteoarthritis index. * Significantly different according to the Mann-Whitney test (p≤0.05).

Both designs showed tibial internal rotation during flexion from 0° to 80° in the KB activity (Figure 2a). Tibial external rotation was observed during DKB activities from 70° to 100° flexion for both designs (Figure 2b). During both KB and DKB activities, the CKS design tibia was more internally rotated (p<0.05, ANOVA). The CKS knees showed significantly more tibial internal rotation at 80° flexion during KB activity (p<0.05, Tukey pair-wise post hoc test, Figure 2a). From maximum extension to maximum flexion during DKB activities, the CKS design showed a significantly lower range of tibial rotation than the PFC design (p<0.05).
The kinematics of both designs were analyzed with a fluoroscopic technique during KB and DKB activities. This fluoroscopic technique enables accurate measurement of TKA kinematics [3, 13, 35, 37] and has already been applied in many studies [2, 3].

Condylar translation from 0° to 30° was not significantly different for the two designs. However, from 30° to 100° flexion the medial contact locations were significantly more anterior in the CKS knees (p<0.05). The lateral contact location at 70° to 80° flexion also was significantly different (p<0.05) during the KB activity, with the CKS translating more anteriorly. Anterior condylar translation with flexion was larger at the medial than at the lateral contact locations (Figure 2; c - f).

The average center of rotation was lateral for both the CKS and the PFC designs, indicating that the dominant motion was anterior translation of the medial condyle with flexion, rotating about a relatively less mobile lateral condyle (Figure 3).

**Table 2** Average axial rotation and condylar AP translation during knee bend (KB) and deep knee bend (DKB) activities.

<table>
<thead>
<tr>
<th></th>
<th>Knee bend</th>
<th>Deep knee bend</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>CKS</td>
<td>PFC</td>
</tr>
<tr>
<td><strong>Maximum Range</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Tibial external rotation (degrees)</td>
<td>10±6</td>
<td>9±2</td>
</tr>
<tr>
<td>Medial Condyle AP translation (mm)</td>
<td>8±3</td>
<td>5±2</td>
</tr>
<tr>
<td>Lateral Condyle AP translation (mm)</td>
<td>3±1</td>
<td>2±1</td>
</tr>
<tr>
<td><strong>From Maximum Extension to Maximum Flexion</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Tibial external rotation (degrees)</td>
<td>-9±6</td>
<td>-8±3</td>
</tr>
<tr>
<td>Medial Condyle AP translation (mm)</td>
<td>7±4</td>
<td>5±2</td>
</tr>
<tr>
<td>Lateral Condyle AP translation (mm)</td>
<td>0±2</td>
<td>-1±1</td>
</tr>
</tbody>
</table>

The maximum range between the two most extreme rotation angles and the two most extreme AP translation measurements, and the ranges from maximum extension to maximum flexion were measured. Data are represented as mean ± SD. * Significantly different between CKS and PFC (p<0.05).

**Discussion**

We hypothesized that the CKS design had inferior performance in AP knee translation and rotation compared with the PFC design, based on qualitative clinical observations and comparison of the differences in shape of both designs. To test this hypothesis, we analyzed the clinical performance and fluoroscopic kinematics of 11 PFC and 10 CKS designs. We concluded that the CKS design did exhibit significantly greater clinical stiffness and greater anterior translation of the medial condyle with flexion. The global clinical ratings, including the VAS, IKS, and total WOMAC scores [6, 25, 26], did not show statistically significant differences. However, the WOMAC joint stiffness total score and items regarding higher flexion and higher demand activities (walking down stairs, getting out of bed and getting onto and off the toilet) showed statistically significantly greater limitations in knees with the CKS design.

The kinematics of both designs were analyzed with a fluoroscopic technique during KB and DKB activities. This fluoroscopic technique enables accurate measurement of TKA kinematics [3, 13, 35, 37] and has already been applied in many studies [2,
activities, and the lateral condyle was significantly more anterior from 70° - 80° flexion in the KB activity.

During KB activities both designs exhibited tibial internal rotation (CKS: 9° and PFC: 8°), which has also been reported in other PCL retaining TKA during KB activities [4, 5, 18, 22, 34]. During stair-climbing, normal knees exhibit a tibial internal rotation averaging at 8° in early flexion and the observed ROM are similar for healthy and reconstructed knees [2]. During DKB activities, both designs showed external rotation with increasing flexion from 70° - 100° flexion (CKS: 0° and PFC: 2°). Stiehl et al. found tibial internal rotation of 4.7° ± 3.7 during a DKB activity with a single PCL retaining TKA design [31]. Banks et al. reported an average of 8° tibial internal rotation in a deep KB activity in 63 fixed-bearing PCL-retaining TKA of seven different designs averaging 109° flexion [1]. Similar to our findings, Li et al. found that PCL deficiency significantly increased the posterior tibial translation and external tibial rotation above 60° using simulated muscle loads in an in vitro experimental study [17].

Our hypothesis that the CKS design exhibited inferior functional performance was supported by the finding of greater joint stiffness and disability scores, greater anterior condylar translation with flexion, and the clinical observation of inferior knee stability. In our study, the CKS design showed a more internally rotated tibia compared with the femur than the PFC design, during both KB and DKB activities. Furthermore, medial and lateral condylar translation were significantly different from 30°-100° and 70°-80° flexion, respectively. This is in line with our findings from physical examination, showing differences between both designs at higher flexion angle activities (walking down a stair, getting out of bed and getting onto and of the toilet).

Unfortunately, the specific mechanism for reduced performance of the CKS design cannot be identified, and both surgical and design factors could influence the results. Importantly, the operative technique was identical for all patients, with the exception of the design, so surgical factors likely to affect the outcome were not a factor in the observed differences. The CKS design exhibited larger anterior condylar translations with flexion compared to the PFC design. This may be explained by inadequate PCL functioning in the patient group with a CKS design.

The CKS design utilizes a tibial insert having a more prominent and sharp posterior edge (Figure 1 C and D) as compared with the PFC design. This sharp edge may come in contact with the PCL, leading to damage and subsequent PCL laxity. Hence, this may explain some of the differences seen in the kinematic analyses. The study has a number of limitations. First, because of sequential introduction of the two TKA designs, we did not obtain groups with identical follow up periods. Although we cannot rule out any effects of these different follow-up times (in terms of differences in PE wear and creep, for example), it seems fair to assume that full

![Figure 3](image_url)
rehabilitation has occurred within 12 months. Pope et al. found no differences in mean flexion, overall ROM, fixed flexion deformity or functional results, independent of rehabilitation protocols already at 12 months follow up [23]. Therefore, we believe that both groups should have fully recovered at 39 (median follow-up PFC) and 52 (median follow-up CKS) months. We believe that for the purpose of this study, both groups can be considered to be equal in terms of post-operative follow-up time. Second, the fluoroscopic equipment imposed several constraints on the speed and range of activities that could be observed. Only slow movements could be observed clearly due to motion blur at faster speeds. Furthermore, the fluoroscope had a small diameter (15cm) image intensifier which restricted observation to closely controlled activities. A rigid frame was placed in front of the knee to keep it in the fluoroscope field of view, and it is possible that these slow movements and the brace could have influenced muscle activation or imposed a posterior drawer force on the knee joint. Presumably, these constraints would similarly affect both patient groups. Third, the subject matching procedure for the two patient groups focused only on patient age and diagnosis and did not take into account pre-operative knee scores or knee alignment.

In conclusion, the clinical scores and kinematic analyses revealed differences between the two designs used in this study. Kinematic analyses confirmed the suspicion that the CKS design has larger AP translations, and physical examination showed significantly more joint stiffness. However, it remains unclear whether this can be ascribed to PCL deficiency, or whether it is a combination of implant design factors and post-operative ligament laxity.

References

Similar TKA designs with differences in clinical outcome

A randomized controlled trial of 77 knees with a mean follow-up of 6 years

Meijerink HJ, Verdonschot N, van Loon CJM, Hannink G and de Waal Malefijt MC.

## Abstract

**Background and purpose:** To try to improve the outcome of our TKAs, we started to use the CKS prosthesis. However, in a retrospective analysis this design tended to give worse results. We therefore conducted a randomized, controlled trial comparing this CKS prosthesis and our standard PFC prosthesis. Because many randomized studies between different TKA concepts generally fail to show superiority of a particular design, we hypothesized that these seemingly similar designs would not lead to any difference in clinical outcome.

**Patients and methods:** 82 patients (90 knees) were randomly allocated to one or other prosthesis, and 38 PFC prostheses and 36 CKS prostheses could be followed for mean 5.6 years. No patients were lost to follow-up. At each follow-up, patients were evaluated clinically and radiographically, and the KSS, WOMAC, VAS patient satisfaction scores and VAS for pain were recorded.

**Results:** With total Knee Society score (KSS) as primary endpoint, there was a difference in favor of the PFC group at final follow-up (p = 0.04). Whereas there was one revision in the PFC group, there were 6 revisions in the CKS group (p = 0.1). The survival analysis with any reoperation as endpoint showed better survival in the PFC group (97% (95% CI: 92–100) for the PFC group vs. 79% (95% CI: 66–92) for the CKS group) (p = 0.02).

**Interpretation:** Our hypothesis that there would be no difference in clinical outcome was rejected in this study. The PFC system showed excellent results that were comparable to those in previous reports. The CKS design had differences that had considerable negative consequences clinically. The relatively poor results have discouraged us from using this design.

## Introduction

Although current results of total knee arthroplasty (TKA) are relatively good, there is still room for improvement. There is constant research and development, with a view to obtain longer survival rates [19, 34], a better range of motion (high-flex TKA) [7, 25, 26], or a more anatomical reconstruction of the joint, such as posterior and anterior cruciate ligament retaining designs [32, 35] and gender-specific TKA [8, 21].

We started to use the CKS prosthesis (Stratec Medical, Oberdorf, Switzerland), based on previous research at our institution showing that the natural patella groove does not have an isolated lateral orientation [1]. In contrast to our standard prosthesis (PFC; DePuy/Johnson and Johnson, Warsaw, IN) with a lateral orientation of the patellar groove, the trochlea of the CKS prosthesis is deeper and has a neutral direction. However, in a retrospective analysis, after 1 year the CKS prosthesis tended to have worse Knee Society scores (KSSs) [6]. We decided to compare the outcome thoroughly and started a randomized, controlled trial between the CKS and the PFC prostheses.

Many randomized studies of TKAs with different bearings [15, 33], cruciate-retaining or -substituting devices [20], gender-specific designs [21], and high-flex designs [7, 25, 26] generally fail to show superiority of one of the devices over the other. We therefore hypothesized that the seemingly small differences in design between the CKS and PFC system would not lead to differences in clinical outcome in our study.

## Patients and methods

We designed a randomized, controlled trial with 2 posterior cruciate ligament (PCL) retaining total knee designs. The study protocol was approved by the institutional review board at our hospital and it was carried out in line with the Helsinki Declaration. The study was registered in the ClinicalTrials.gov Protocol Registration System (Identifier: NCT 00228137). All patients who were scheduled to undergo primary total knee arthroplasty because of osteoarthritis or rheumatoid arthritis at the Radboud University Nijmegen Medical Centre were considered for inclusion and were enrolled prospectively. Exclusion criteria were dementia, hemophilia, juvenile rheumatoid arthritis, and ligament insufficiency that needed a posterior-stabilized or otherwise more constrained type of design. Between November 2002 and December 2004, 87 consecutive patients (95 knees) were assessed for eligibility. 5 patients (5 knees) were excluded before randomization: 2 patients refused to participate, 2 patients had hemophilia, and 1 patient had dementia. After written informed consent had been obtained, the knees were randomly allocated to 2 groups. 45 knees received a press-fit condylar prosthesis (PFC; DePuy/)
Johnson and Johnson, Warsaw, IN) and 45 knees received a continuum knee system prosthesis (CKS; Stratec Medical, Oberdorf, Switzerland). Computer-generated randomization with stratification for age, co-morbidity, and flexion contracture was performed by an independent observer to allocate the patients in equal numbers to the 2 groups.

Both cemented designs are PCL-retaining and have a fixed polyethylene (PE) insert on a tibial tray with central keel. The femoral and tibial components are made of the same material (cobalt-chromium-molybdenum and titanium-aluminium-vanadium alloy, respectively). In contrast to the lateral orientation of the patellar groove in the PFC prosthesis, the trochlea of the CKS prosthesis is deeper and has a neutral direction. The femoral component of the PFC has a fixation peg in both condyles, whereas the CKS design uses one central peg. Furthermore, the CKS prosthesis has a different surface texture of the femoral component. Additionally, the PE insert of the CKS design has a more prominent and sharp posterior edge compared to the PFC design (Figure 1).

Identical surgical techniques were used in the groups according to the manuals of the designers. 6 surgeons were involved in the study. All procedures were performed by an experienced knee surgeon or under the direct supervision of one. A pneumatic tourniquet was used for all patients. A medial parapatellar capsular incision was used. No patellas were resurfaced. All implants were cemented after pulsed lavage, drying, and pressurization of the cement (Surgical Simplex, Stryker Howmedica). Continuous passive motion was started on the second postoperative day. Thereafter, active range-of-motion exercises and walking were started under the supervision of a physiotherapist.

Routine follow-up evaluation was scheduled at postoperative intervals of 3 months, 6 months, 1 year, and annually thereafter. Preoperative and postoperative review data were recorded by a physician assistant who was blinded regarding patient allocation. At each follow-up visit, we took anteroposterior, lateral, and skyline patellar radiographs, which were evaluated according to the guidelines of the Knee Society [10]. The primary endpoint of the study was the between-group difference in total KSS [18]. Pre-specified secondary endpoints to provide supportive evidence for the primary objective included results on the KSS subscores, the Western Ontario and McMaster Universities Osteoarthritis Index (WOMAC) score [2], range of motion, survival, and patient satisfaction and pain, both of which were assessed using a visual analog scale (VAS; 0 — total dissatisfaction or no pain and 100 — complete satisfaction or intolerable pain). A reoperation was defined as any operative procedure at the involved knee. A revision was defined as any removal, exchange, or addition of one or more of the prosthetic components.
Statistics
A sample size estimation showed that 37 knees per group would be required to detect a clinically relevant difference of 10 points with a standard deviation of 15 points in the total KSS, with an alpha of 0.05 and a power of 80%. Intergroup differences were determined using Student’s t-test for continuous variables and the Pearson chi-square test or Fisher’s exact test for categorical variables. Survival analyses were performed using the Kaplan-Meier method and compared using log-rank tests. Survival estimates are presented with 95% confidence intervals (CI). For all data sets, differences were considered statistically significant at p-values < 0.05.

Results
After randomization, 5 patients were excluded because a posterior-stabilized design was needed after routinely sacrificing the PCL in cases with a flexion contracture of 25 degrees or more (1 in the CKS group and 4 in the PFC group). Because bilateral involvement might cause bias, 8 other knees were excluded (5 in the CKS group and 3 in the PFC group). No patients were lost to follow-up, but 12 relatively elderly patients died of unrelated causes. These patients were analyzed according to the latest available follow-up. Consequently, we analyzed 39 knees with a CKS prosthesis and 38 knees with a PFC prosthesis (Table 1 and Figure 2), with a mean follow-up of 5.6 (1.2–7.7) years (i.e. 5.4 (1.5–7.7) years for the CKS group and 5.7 (1.2–7.7) years PFC group).

With total KSS as primary endpoint, there was a difference between groups in favor of the PFC group at final follow-up (p = 0.04) (Table 2). Evaluation of the postoperative KSS subscores, WOMAC score, range of motion, VAS for patient satisfaction, and VAS for pain all tended to be superior for the PFC group (Table 2). At final follow-up, there were differences in KSS knee sub-score (p = 0.04) and VAS satisfaction (p = 0.04) in favor of the PFC system.

There was 1 revision in the PFC group; a thicker polyethylene insert was placed for instability. In contrast, there were 6 revisions in the CKS group: in 5 patients, the CKS prosthesis was removed because of poor function and pain and 1 patient was treated with arthrolysis and secondary resurfacing of the patella. During the removal of the prostheses, it appeared that all femoral components of the failed CKS group were easy to remove, leaving an intact cement layer on the bones indicating inadequate fixation between prosthesis and cement. Cultures were positive in 2 of the CKS revisions. 8-year survival analysis with revision for any reason as endpoint showed 97% (95% CI: 92–100) survival for the PFC group and 84% (72–96) survival for the CKS group (p = 0.05) (Figure 3A). The survival values for aseptic revision were 97% (92–100) and 89% (78–99) respectively (p = 0.2) (Figure 3B).

Table 1 Patient demographics and baseline clinical status.

<table>
<thead>
<tr>
<th></th>
<th>PFC group (n=38)</th>
<th>CKS Group (n=39)</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Sex (female/male)</strong> (no.)</td>
<td>26/12</td>
<td>24/15</td>
</tr>
<tr>
<td><strong>Age</strong> <em>(yr)</em></td>
<td>65 ± 10 (45-81)</td>
<td>69 ± 11 (48-88)</td>
</tr>
<tr>
<td><strong>Height</strong> <em>(cm)</em></td>
<td>169 ± 9 (154-187)</td>
<td>170 ± 11 (148-190)</td>
</tr>
<tr>
<td><strong>Weight</strong> <em>(kg)</em></td>
<td>85 ± 18 (61-130)</td>
<td>82 ± 15 (60-120)</td>
</tr>
<tr>
<td><strong>BMI</strong> <em>(kg/m²)</em></td>
<td>30 ± 5 (21-45)</td>
<td>28 ± 4 (21-39)</td>
</tr>
<tr>
<td><strong>Diagnosis (OA/RA)</strong> (no.)</td>
<td>33/5</td>
<td>37/2</td>
</tr>
<tr>
<td><strong>ROM</strong> <em>(deg)</em></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Extension</td>
<td>-4 ± 6 (-20-0)</td>
<td>-5 ± 6 (-20-5)</td>
</tr>
<tr>
<td>Flexion</td>
<td>109 ± 14 (75-135)</td>
<td>111 ± 19 (70-140)</td>
</tr>
<tr>
<td>Total ROM</td>
<td>104 ± 16 (65-125)</td>
<td>106 ± 20 (70-140)</td>
</tr>
<tr>
<td><strong>KSS</strong> <em>(points)</em></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Knee</td>
<td>53 ± 17 (9-95)</td>
<td>51 ± 17 (15-91)</td>
</tr>
<tr>
<td>Function</td>
<td>37 ± 20 (5-70)</td>
<td>42 ± 20 (10-90)</td>
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<tr>
<td>Total</td>
<td>89 ± 32 (4-150)</td>
<td>92 ± 29 (40-177)</td>
</tr>
<tr>
<td><strong>WOMAC score</strong> <em>(points)</em></td>
<td>54 ± 13 (25-75)</td>
<td>52 ± 14 (25-95)</td>
</tr>
<tr>
<td><strong>VAS pain</strong> <em>(points)</em></td>
<td>62 ± 17 (26-90)</td>
<td>55 ± 17 (20-91)</td>
</tr>
</tbody>
</table>

*The values are presented as the mean and the standard deviation with the range in parentheses. 2 other patients in the CKS group were reoperated. 1 patient developed postoperative arthrofibrosis and was manipulated under anesthesia, but the knee remained stiff with 20° fixed flexion deformity and 70° of flexion. 1 patient was treated with open debridement followed by antibiotics for 6 months because of a culture-proven deep infection. 4 years later, there were no signs of infection and the knee functioned well. 2 patients (1 in each group) developed a hematoma, both of which were treated conservatively. There were no thromboembolic complications. The 8-year survival analysis with any reoperation as endpoint showed a difference between the PFC group and the CKS group (97% (92–100) for PFC and 79% (CI: 66–92) for CKS; p = 0.02) (Figure 4A). The survival values for aseptic reoperation were 97% (92–100) and 85% (73–97) respectively (p = 0.08) (Figure 4B).
Analysis of the radiographs at final follow-up showed a radiolucency smaller than 2 mm in one zone under the tibial component in 2 cases in the PFC group and in 3 cases in the CKS group. These radiolucent lines were already present in the direct postoperative radiographs and no radiolucent line was progressive; none of these 5 cases were classified as radiographic loosening. The skyline patellar radiographs did not show (sub)luxation of the patella in the PFC group or in the CKS group.
Figure 3 Kaplan-Meier survival plots.

A. With revision for any reason as endpoint, the PFC group had a survival of 97% (95% CI: 92–100) after 8 years and the CKS group had a survival of 84% (72–96) (p = 0.05).

B. With aseptic revision as endpoint, the PFC group had a survival of 97% (92–100) after 8 years and the CKS group had a survival of 89% (78–99) (p = 0.2).

Figure 4 Kaplan-Meier survival plots.

A. With any reoperation as endpoint, the PFC group has a survival of 97% (95% CI: 92–100) after 8 years and the CKS group had a survival of 79% (66–92) (p = 0.02).

B. With aseptic reoperation as endpoint, the PFC group had a survival of 97% (92–100) after 8 years and the CKS group had a survival of 85% (73–97) (p = 0.08).
Discussion

Our hypothesis that there would be no difference in clinical outcome between the PFC prosthesis and the CKS prosthesis was rejected. With total KSS as primary endpoint, and for survival with any reoperation as endpoint, the CKS group showed a worse result. With our standard prosthesis, the PFC, we found an excellent survival rate of 97% for any revision after 8 years. Other authors have recently reported similar 10-year survival rates for the PFC prosthesis: 97% survival for aseptic loosening [38] and 97% survival for revision with any reason other than infection as endpoint [9]. The functional results of the PFC prosthesis in our study were also comparable to those in previous reports [9, 14, 15].

The excellent clinical scores of the PFC prosthesis do not leave a lot of room for improvement, which is probably why recent RCTs have failed to show a superior design [7, 15, 33]. Subtle differences in outcome after TKA require more sensitive instruments. It has been reported that patient-based questionnaires such as WOMAC and the KSS are subjective and largely influenced by pain [38, 40]. Objective, functional tests may be a valuable additional tool in comparing TKA systems. We have previously shown that monitoring of both knee extension velocity and loading symmetry during sit-to-stand movements is objective and has good discriminative capacity [3]. Similar performance-based measurements to quantify functionality in TKA patients have been reported by others [27, 31, 39].

In addition, we have to realize that the outcome after TKA not only depends on the type of implant; Fortin et al. [11, 12] stated that the preoperative status of the patient is the strongest determinant of functional outcomes after hip and knee surgery, and Noble et al. [28] and Mahomed et al. [22] emphasized the importance of the expectations of the patients. Nevertheless, our study showed an inferior outcome with the CKS design. Although different results have been published about the CKS prosthesis in the limited amount of literature that is available [13, 24], a 79% survival rate for any reoperation after 8 years in our study is unacceptably low which made us decide to stop further using the CKS implant system.

The question remains as to why we found such a difference between the PFC and the CKS prostheses, as the designs appear to be quite similar. Concerning the articular part of the prosthesis, the most prominent difference is the orientation of the patella groove. Although patellofemoral complaints are one of the complications after TKA, with the highest incidence (1–24%) and an important reason for revision surgery [4, 16, 17], it seems to be illogical that only a more anatomical trochlea orientation in the CKS design would be responsible for a worse outcome.

An important issue is the observation of bad fixation strength of the prosthetic components to the bone. It appeared that all femoral components of the failed CKS group were easy to remove. Only 2 revisions could be attributed to positive bacterial cultures; the other 3 revisions were defined as aseptic loosening after 13, 16, and 51 months. This high rate of aseptic loosening is uncommon, especially at this early stage [5, 37, 41]. Moreover, during the removal of the CKS prostheses there was an intact cement layer on the bones, indicating inadequate fixation between the prosthesis and cement. Thus, we believe that an important problem of the CKS design is limited cement-metal interfacial strength of the femoral components.

We therefore wondered what the reason could be for a weak cement-metal interface of the CKS components. We analyzed the differences in the backside of both designs. The femoral component of the PFC has fixation pegs in both condyles, whereas the CKS design uses only 1 central peg. 2 pegs might enhance the fixation relative to 1 central peg, but to our knowledge this has not been described in the literature. We also analyzed the surface roughness of the femoral components and found that the CKS components had a lower surface roughness value than the PFC design (Ra = 1.3 ± 0.1 μm vs. 1.9 ± 0.3 μm; p = 0.01). As shown by Walsch et al. [42] and Manley et al. [23], a lower surface roughness reduces fixation strength of the implant-cement interface and may explain why the revised CKS components could be removed so easily.

Another difference between the designs concerns the PE insert. The CKS design uses a tibial insert with a more prominent and sharp posterior edge compared to the PFC design. This sharp edge may come in contact with the PCL, leading to damage and subsequent PCL laxity. In a previous study comparing the CKS and the PFC prostheses, kinematic analysis supported the suspicion that the CKS design has larger AP translations than the PFC design [30]. Although clinical ratings such as the KSS, total WOMAC, and VAS did not show any statistically significant difference in that study, subscores regarding higher flexion and higher-demanding activities showed greater limitations in knees with a CKS design. Moreover, it has been described that in addition to AP instability, PCL insufficiency may cause (anterior knee) pain and result in malfunction [29, 43]. Thus, the worse functional outcome for the CKS system that we found may also be explained by PCL insufficiency due to in vivo damage of the PCL at the sharp posterior edge of the tibial insert.

Our study had some limitations. First, a relatively high number of patients (12) died before final follow-up. Even so, all the patients were analyzed with the latest available (and minimal 1-year) follow-up. Including these patients, the mean follow-up was 5.6 years. Furthermore, no patients were lost to follow-up. Another possible limitation is the potential bias from there being 6 different surgeons involved in this study. However, since we are a teaching hospital all procedures were performed by—or under direct supervision of—an experienced knee surgeon and none of the reoperated cases had originally been operated by a surgeon with low volume.

One strength of our study was the randomization process with stratification for age, flexion contracture, and co-morbidity. Consequently, patient demographics and
the baseline clinical status of both groups were similar. Thus, we are convinced that the differences in clinical function and survival between the groups were caused by the differences in design between the CKS and the PFC prostheses. Our study was not designed to determine the reason for the worse results of the CKS design. We believe that the reason may have been multi-factorial, and a combination of low fixation strength and possible PCL insufficiency. Initially, we thought that the CKS system was very similar to the PFC system, but the large differences in clinical outcome were evident and discouraged us from further use of the CKS system.

References


35. Reis M D. Effect of ACL sacrifice, retention, or substitution on kinematics after TKA. Orthopedics 2007; 30: 74-6.


38. Stratford P W, Kennedy D M. Performance measures were necessary to obtain a complete picture of osteoarthritic patients. J Clin Epidemiol 2006; 59: 160-7.


A sliding stem in revision total knee arthroplasty provides stability and reduces stress shielding

*an RSA study using impaction bone grafting in synthetic femora*

Meijerink HJ, van Loon CJM, de Waal Malefijt MC, van Kampen A and Verdonschot N.

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A SLIDING STEM IN REVISION TKA PROVIDES STABILITY AND REDUCES STRESS SHIELDING

Abstract

Background and purpose: In the reconstruction of unicondylar femoral bone defects with morselized bone grafts in revision total knee arthroplasty, a stem extension appears to be critical to obtain adequate mechanical stability. Whether stability is still assured by this reconstruction technique in bicondylar defects has not been assessed. The disadvantage of relatively stiff stem extensions is that bone resorption is promoted due to stress shielding. We therefore designed a stem that would permit axial sliding movements of the articulating part relative to the intramedullary stem.

Methods: This stem was used in the reconstruction with impaction bone grafting (IBG) of 5 synthetic distal femora with a bicondylar defect. A cyclically axial load was applied to the prosthetic condyles to assess the stability of the reconstruction. Radiostereometry was used to determine the migrations of the femoral component with a rigidly connected stem, a sliding stem, and no stem extension.

Results: We found a stable reconstruction of the bicondylar femoral defects with IBG in the case of a rigidly connected stem. After disconnecting the stem, the femoral component showed substantially more migrations. With a sliding stem, rotational migrations were similar to those of a rigidly connected stem. However, the sliding stem allowed proximal migration of the condylar component, thereby compressing the IBG.

Interpretation: The presence of a functional stem extension is important for the stability of a bicondylar reconstruction. A sliding stem provides adequate stability, while stress shielding is reduced because compressive contact forces are still transmitted to the distal femoral bone.

Introduction

In revision total knee arthroplasty (TKA) the distal femoral bone stock may be compromised as a result of stress shielding, polyethylene wear, or loosening of the femoral component [7, 15, 21, 22, 31, 35]. Smaller unicondylar defects may be treated with morselized bone grafts and mechanical tests have indicated that a stable situation can be created in unicondylar femoral bone defect cases [36]. However, femoral bone defects encountered in TKA are frequently bicondylar and lack cortical support. In these cases, the use of a femoral stem extension has been suggested to provide adequate postoperative stability and to protect bone grafts from failing by fracture, disintegration, or non-union [9, 12]. In the reconstruction of larger unicondylar femoral bone defects, a stem extension appears to be important in order to obtain adequate mechanical stability under loaded conditions [37]. However, whether the stability is still assured by this reconstruction technique (bone grafts in combination with a stem extension) in cases with severe bicondylar bony defects has not been assessed.

With the limited clinical experience of impacted bone grafting (IBG) in revision knee surgery as reported in the literature, a lack of stability has emerged as a main concern [5, 14, 28, 33]. As a result, long, rigid stem extensions have been used to maximize the stability of the reconstruction. Although these stems may ensure greater initial stability, the disadvantage of femoral components extended with relatively stiff stems is that long-term bone resorption is promoted due to stress shielding [4, 31, 32]. Moreover, strain on the impacted bone graft may contribute to bony incorporation [2]. Thus, there appears to be incompatibility caused by the fact that on the one hand direct postoperative stability is improved, whereas on the other hand long-term bone quality is jeopardized by a stem extension. The challenge is therefore to develop a system that creates the same stability as with a stem extension, yet does not contribute to stress shielding.

Finite-element (FE) models of TKAs predict less bone resorption when the femoral reconstruction is less rigid with a thinner stem (instead of a thick pressfit stem) or a fully unbonded prosthesis-cement interface [32]. Thus, we developed a relatively thin intramedullary stem that permitted axial sliding movements of the articulating part relative to the intramedullary stem. The hypothesis behind the design was that compressive contact forces would be directly transmitted to the distal femoral bone, whereas adequate stability would be provided by the sliding intramedullary stem. A prototype was made of this new knee revision design and it was applied to the reconstruction of uncontained bicondylar femoral bone defects with IBG.

We analyzed the stability of the reconstruction of uncontained bicondylar femoral bone defects in TKA with IBG and a thin stem extension. In addition, we determined the differences in stability between a rigidly connected stem, a sliding stem, and no stem extension. The stability was analyzed by radiostereometric analysis (RSA).
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Materials and methods

Designs and operative technique
Distal synthetic femora were used and bicondylar defects were created that were reconstructed with impaction bone grafting. Subsequently, a stemmed femoral component was implanted and tested for mechanical stability. Using a custom-made connection between the stem and the condylar part of the prosthesis, it was possible to assess the stability of the reconstruction using a fixed stem, a sliding stem, and a disconnected stem in sequential order for one reconstructed specimen. Five synthetic distal femora were produced from resin (SL170; 3D Systems Europe Ltd., Hemel Hempstead, UK) using a stereolithographic process. The geometry of the cortex was designed to reproduce the anatomy of the distal femur and to fit a size-3 femoral component of a PFC TKA (Press-Fit Condylar; Johnson and Johnson, Raynham, MA). The cured resin had an elastic modulus of 3.7–4.2 GPa, approximately one quarter of the stiffness of healthy femoral cortical bone. There was a standardized F2b defect according to the AORI classification [9] of approximately 10 cm³ at each condyle (Figure 1). Preliminary testing and evaluation was carried out to develop specific instrumentation and a standardized technique to ensure reproducible, consistent impaction of the morselized grafts.

Figure 1 The reconstructed distal femur just before implantation of the stemmed femoral component.

A. Synthetic distal femur in upside-down position. B. Reconstructed condyle with IBG. C. Femoral component with a thin cement layer. D. Connector with tantalum pellets glued at the flange for RSA measurements. E. Tantalum pellet inserted at the femoral shaft.

Mechanical testing

The synthetic distal femur was clamped in a holder in an upside-down position. A guide wire was screwed at the bottom, centrally in the intramedullary canal and 170 mm proximal to the most distal point of the femoral cortical shell. Fresh-frozen femoral (bovine) heads were morselized using a bone mill (Noviomagnus; SMT, Nijmegen, the Netherlands). Two different cutters produced bone particles with a diameter of approximately 2.0 mm and 6.0 mm [3]. The small grafts were used for the shaft and the larger grafts were used to reconstruct the metaphysis and the condyles. The morselized grafts were impacted in the diaphysis in a stepwise manner, sliding over the guide wire with different tapered impactors, similarly to the femoral reconstructions in revision THAs [23]. The final impactor had the same diameter as the later-inserted fluted stem: the sliding mechanism had a diameter of 15 mm and the fluted part had an inner diameter of 10 mm (Figure 2). The additional wings of the fluted stem generated further compression of the bone graft. The smallest inner diameter of the femoral shaft was 21 mm. Thus, we theoretically created a circumferential layer of IBG around the impactor of at least 3 mm.

The final impactor was kept in the femur during building of the metaphysis and the condyles. We used a template to contain the condylar defects during impaction. The template had a shape such that after firm impaction of the morselized grafts and subsequent removal of the template, the condyles were completely reconstructed and a revision prosthesis would fit exactly to the reconstructed bone. Bone cement (CMW3; CMW/De Puy, Blackpool, UK) was prepared and the guide wire, the final impactor, and the template were gently removed. A tantalum pellet with a diameter of 0.8 mm was glued to the tip of a 125-mm fluted stem. A thin liquid cement layer was applied to the femoral component, whereas the stem and the intercondylar box were left free of cement and the component was cemented to the distal femur. There was no contact of the femoral component with any distal cortex, because the impacted reconstruction involved the whole distal femur. The stem was connected to the intercondylar box of the femoral component by a custom-made hexagonal fixation screw. A 6-Nm moment, measured with a torque wrench, was applied to the screw to provide a standardized connection of the stem to the intercondylar box. Into this screw, another screw was designed to lock or initiate the sliding mechanism of the box towards the stem (Figure 2). 5 specimens were prepared for mechanical testing.

Mechanical testing

The reconstructed distal femur was clamped in the upside-down position in a testing machine (MTS model 458020; MTS Systems Corporation Minneapolis, MN) with the joint line parallel to the working bench. 6 tantalum pellets, diameter 0.8 mm, were glued with a connector to the femoral component and another 6 pellets were inserted in the shaft of the distal femur model (Figure 1). A unicondylar axial
The loading tests were performed in the following sequence. Test A: 1,800 cycles with a rigidly connected stem. Test B: 1,800 cycles with a sliding stem. Test C: 1,800 cycles with a disconnected stem. Between tests A and B, we removed the inner screw to initiate the sliding stem mechanism (Figure 3). Complete disconnection of the stem from the femoral component as tested in test C was achieved by removing the hexagonal fixation screw, whereas the stem remained in the intramedullary canal. All the experiments were performed by one surgeon (HJM). Stereoradiographs of unloaded and medially and laterally loaded situations were produced at the beginning and at the end of tests A, B, and C.

The loading tests were performed in the following sequence. Test A: 1,800 cycles with a rigidly connected stem. Test B: 1,800 cycles with a sliding stem. Test C: 1,800 cycles with a disconnected stem. Between tests A and B, we removed the inner screw to initiate the sliding stem mechanism (Figure 3). Complete disconnection of the stem from the femoral component as tested in test C was achieved by removing the hexagonal fixation screw, whereas the stem remained in the intramedullary canal. All the experiments were performed by one surgeon (HJM). Stereoradiographs of unloaded and medially and laterally loaded situations were produced at the beginning and at the end of tests A, B, and C.

Figure 2 The sliding stem mechanism.

- A: Inner screw to lock or initiate the sliding mechanism.
- B: Hexagonal screw to connect the stem to the intercondylar box of the femoral component.
- C: Sliding part of the stem.
- D: Cylindrical protector, keeping the bone graft out of the sliding mechanism.
- E: Fluted stem with an inner diameter of 10 mm and an outer diameter of 12 mm.

Figure 3 Schematic representation of tests A, B and C.

The distal femur is marked as A, the impacted bone graft as B, the femoral component as C and the sliding stem connection as D. During test A, the femoral component was extended with a rigidly connected stem. Before Test B, the inner screw was removed to initiate the sliding stem mechanism. To disconnect the stem from the femoral component, the hexagonal screw was removed before test C.
Statistics
The stereoradiographs were digitized manually to determine the positions of the pellets and their 3-D positions were calculated using specialized software [24]. The center of the intercondylar box was chosen as the origin of the coordinate system relative to which rotations and translations of the component in relation to the femur were expressed. Migration was calculated as 3 translations along and 3 rotations about the femoral axes. However, we focused the results on the translation of the prosthesis in axial direction and the prosthetic rotation in varus-valgus and flexion-extension directions. In an earlier knee kinematic study performed at the authors’ institution, the estimated error for the same RSA set-up was less than 50 μm for repeated measurements, with a standard deviation of 0.1 mm [1]. Statistical analysis of the dataset was performed with Friedman repeated measures analysis of variance by ranks, followed by Wilcoxon signed rank tests of differences in migrations between tests A and B and between tests B and C; p-values less than 0.05 were considered significant.

Results
On visual inspection during the alternating medially and laterally axial loading, there was a stable reconstruction of the bicondylar femoral defects with IBG in the case of a rigid stem connection being used (test A). After 30 min of alternating axial loading, the stereoradiographs showed that the median proximal migration of the femoral component with a rigid stem connection was 0.13 (0.05–0.19) mm in the case of medially loading and 0.11 (0–0.16) mm in the case of laterally loading (Figure 4A). On the same stereoradiographs, the median varus rotations were 0.65 (0.61–0.86) degrees and −0.60 (−0.36 to −0.79) degrees, respectively, and the median flexion tilt 0.40 (0.21–0.78) degrees and 0.33 (0.17–0.41) degrees, respectively (Figure 4B and C).

After changing the stem connection from rigid to sliding, the reconstruction did not produce much more rotational migration than with the rigid connection (Figure 4B and C); there were no statistically significant differences in any rotational migration observed between the reconstruction with a rigid stem connection and the reconstruction with a sliding stem connection (Table). However, the sliding stem allowed proximal migration of the condylar component onto the femoral condyles, thereby compressing the impacted bone grafts. The average increase in proximal migration after 30 min of loading with the sliding stem compared with the loaded rigid stem connection was 0.14 mm.

After complete disconnection of the stem, the reconstructions showed a high degree of instability with extrusion of the impacted graft under the component. There were
Discussion

There have only been a few reports of genuine impaction bone grafting in revision TKA [14, 16, 17, 26, 29]. Ullmark and Hovelius [29] published the first description of the technique. They essentially adopted the Slooff-Ling hip concept of a short stem totally surrounded by graft and cemented in situ [13]. Although the early clinical results of IBG in revision TKA have been promising [5, 14, 16, 17, 26, 29], the mechanical stability of the reconstruction of bicondylar defects with IBG has not been described. Our study shows that a stable reconstruction of uncontained bicondylar femoral defects could be created with IBG and a TKA with a thin stem extension. Although IBG is time consuming and technically demanding as regards incorporation of the bone graft into host bone and remodeling over time [30, 33], IBG has excellent durability and versatility. Thus, compared to reconstructions with cement or metal augmentations, the restoration of the bone stock with IBG is preferable, particularly in younger patients if a further revision in future is considered likely.

It appeared that the presence of a functional stem extension was important for the stability of the bicondylar reconstruction. After disconnection of the stem, the femoral component showed more rotational and translational migrations with visible extrusion of the graft under the component. Previous reports have already suggested the necessity of a stem extension in revision TKA with bone grafting [4, 9, 10, 12, 19]. Moreover, an earlier study at the authors’ institution on the reconstruction of unicondylar femoral bone defects had already demonstrated that a stem extension of the femoral component in TKA increases mechanical stability [37]. In that study, bone grafting provided only a minor contribution to stability compared to a stem extension.

Despite these advantages, the disadvantage of a femoral component extended with a rigid stem is that long-term bone resorption is promoted due to stress shielding [4, 6, 31, 32]. Hence, an incompatibility is present, which has prompted an ongoing discussion in the recent literature on the best way of stem fixation [18, 19, 39]. Although the use of cementless stems is currently more popular, the available literature suggests that cemented stem fixation provides a more reliable and durable construct for revision TKA associated with severe bone deficiency [11, 18, 38]. Nevertheless, an FE study of femoral stems in revision TKA showed that cemented stems reduced more than half of the load transferred to bone graft under the femoral component, while press-fit stems reduced it only by one-sixth relative to stemless implants [8]. The authors concluded that the higher levels of load reduction can promote late resorption of the graft and they advocated press-fit stems as a more adequate choice after graft incorporation.

Based on the fact that previous FE models of TKAs predicted less bone resorption when the femoral reconstruction was less rigid or fully unbonded [32], we developed statistically significantly more rotational and translational migrations of the femoral component in the reconstruction without a functional stem extension (p = 0.04) (Table). The stereoradiographs of the loaded situations showed that the median proximal migrations of the femoral component without a functional stem connection after 30 min of alternating axial loading were about 1.5 mm (Figure 4A). At the same time, the median varus rotations were more than 3 degrees, and the median flexion tilts were about 4 degrees (Figure 4B and C).

<table>
<thead>
<tr>
<th>Table 1</th>
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<td>Test A vs B</td>
<td>Test A vs B</td>
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<tr>
<td>medial loaded</td>
<td>lateral loaded</td>
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<tr>
<td>Proximal migration</td>
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<tr>
<td>Varus rotation</td>
<td>0.2</td>
</tr>
<tr>
<td>Flexion tilt</td>
<td>0.9</td>
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</tbody>
</table>
A SLIDING STEM IN REVISION TKA PROVIDES STABILITY AND REDUCES STRESS SHIELDING

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a sliding stem mechanism. In the present study, any rotational migration was similar between the reconstruction with a rigid stem connection and the reconstruction with a sliding stem connection. However, the sliding stem allowed proximal migration of the condylar component onto the femoral condyles, thereby compressing the impacted bone grafts. This supports our hypothesis concerning the sliding stem mechanism that adequate stability is provided by the sliding stem, while compressive contact forces are still transmitted to the distal femoral bone. Clinical studies will have to confirm that our sliding stem mechanism reduces stress shielding and maintains bone quality after revision TKAs.

The question remains as to how much stem sliding is acceptable. In this study, the sliding stem showed no more than 0.20 mm of shortening. The extent of sliding probably depends on the quality of the IBG at the femoral condyles. With continued loading, the condylar component further compresses the bone graft in the case of less firmly impacted reconstructions. The worse the quality of the IBG, the more proximal is the migration of the condylar component. Proximal migration of the joint line produces ligamentous instability in extension and causes impaired functional results of a TKA [20, 25]. Thus, the sliding stem mechanism will only be successful if combined with a proper impaction technique.

As in all experimental studies, the present study had some shortcomings. First, the synthetic distal femora had an elastic modulus of approximately one quarter of the stiffness of healthy femoral cortical bone, which should therefore be regarded as a worst case of osteoporotic bone, as often occurs in revision TKA with IBG. The advantage of using artificial bones was that the geometry of the 5 specimens was exactly the same, which optimized the reproducibility of the results obtained in the tests. Secondly, we did not use a highly standardized impaction technique, for example, by using dropping weights as is used in other studies. We selected a more clinically relevant impaction technique (stepwise impaction by a single surgeon) because the impaction in the condylar area was done from all kinds of angles in order to obtain a firm and stable bone construct. Moreover, the reconstructed specimens served as their own control, which made the outcome less sensitive to variations in impaction grade between the specimens. Thirdly, the alternating loading of 500 N seemed to be low. Although the distal femur is normally loaded up to 2.5 times body weight during walking [27], both femoral condyles share the patient’s body weight and a delay in full weight bearing is commonly advised when bone grafting is performed. Thus, the unicondylar load with 500 N in our study exceeded the clinical situation directly after surgery. Furthermore, with the alternating way of loading of the medially and laterally condyles, our study design was somewhat unconventional. However, from this the (varus-valgus) stability of the reconstruction was tested in a much more rigorous way than if we had used a dynamic force at a constant point of application. Fourthly, a potential danger of sequentially testing of a rigid stem, a sliding stem, and a disconnected stem is that earlier tests will influence the later tests because of accumulated damage. However, the results of the rigid stem connection and the sliding stem connection did not show any progressive migration during the 30 min of loading; the minimal migrations in the case of a rigid and a sliding stem were negligible compared to the migrations we found after disconnection of the stem. Thus, it is unlikely that considerable damage had accumulated in the constructs with a rigid or sliding stem and this indicates that those earlier tests did not influence (or only very mildly influenced) the high degree of migration in the case of a disconnected stem. Moreover, the advantage of sequential testing with one reconstructed specimen is that the reconstruction serves as their own control, with the type of stem fixation as the only variable. Fifthly, the standardized created defects of the femoral condyles had a flat surface, whereas in clinical practice these defects are usually irregular. Finally, the stem was not removed from the intramedullary canal after disconnection, to avoid removal and reapplication of the cemented femoral component. The presence of the stem in the canal after disconnection may have influenced the varus and valgus bending of the distal femur on loading, but probably did not influence the movements between the femoral component and the distal femur.

In summary, the present study shows that a stable reconstruction of uncontained bicondylar femoral defects could be created with IBG and a TKA with a thin stem extension. It appears that the presence of a functional stem extension is important for the stability of the bicondylar reconstruction. In an effort to reduce stress shielding, we developed a sliding stem mechanism. This sliding stem provides adequate stability, while compressive contact forces are still transmitted to the distal femoral bone. Clinical studies must still confirm that our sliding stem mechanism leads to long-term bone maintenance after revision TKAs.
References


General Discussion
With the increasing numbers of TKAs, it is imperative that the outcome after the procedure is assessed using validated, reproducible and selective instruments. Traditionally, surgeon-based outcome measurements such as the KSS have been used, in which the level of pain and return to specific activities are scored, followed by the surgeon measuring range of motion and joint stability in a subjective manner. Although in Chapter 2 three different orthopaedic surgeons were equally satisfied after evaluating the same patients, they scored differently in the KSS knee score and function score. This could be explained by different interpretations of pain and function between the surgeons. Ryd et al. [38] also found differences between observers using three knee scoring systems, including the KSS. They concluded that knee scores are unreliable.

Bullens et al. [9] described that the KSS alone is not sensitive enough and advocated the additional use of patient-based systems in evaluating the outcome of TKAs. The patient’s opinion about the outcome is important, because the patient is the most prominent participant [1]. Research in many areas of medicine and surgery has shown that the patient can provide a reliable and valid judgment of his or her health status and the effects of treatment [12]. In Chapter 2 we did not find a difference between the satisfaction of the patient and the satisfaction of the surgeon after TKA. However, due to the fact that surgeons usually focus on range of motion, alignment and stability, whereas patients focus on the functionality of the knee as a whole, other studies showed a difference between the ratings of surgeons and patients [1, 22, 27]. Moreover, it has been reported that patient-based questionnaires like the WOMAC and the Short Form-36 (SF-36) are largely influenced by pain [41, 44].

Thus, patient satisfaction is an important outcome measurement and has increasingly been used as a measurement of TKA success. Patient satisfaction ratings often reach beyond regaining basic mobility, and therefore measuring satisfaction can add another dimension to outcome assessment. Patient satisfaction scores were determined in all the clinical studies described in this thesis (Chapters 2, 3 and 7). The mean satisfaction scores in these studies ranged from 71 to 88 points, on a scale between 0 (indicating total dissatisfaction) and 100 points (indicating total satisfaction). However, good clinical and functional outcome is not always confirmed by patient satisfaction. Despite substantial advances in patient selection, surgical technique, and implant design, multiple studies indicate that only 81% to 89% of patients were satisfied with their TKA [5, 10, 20, 32, 37]. However, dissatisfaction may also be a manifestation of unrealistic expectations, rather than the result of a poor outcome. On the other hand, measuring patient satisfaction is limited because patients may indicate that they are satisfied, despite experiencing considerable
pain and functional disability, because they want appear grateful to the surgeon. Therefore, true rates of dissatisfaction may be higher than those reported in the literature.

Within this perspective we also have to critically evaluate the widely used revision rates. Although national registers compare implants by their revision rates, the insensitivity and lack of objectivity of revision rates have recently been described [14, 52]. The susceptibility to revision highly depends on the (un) willingness and ability of the surgeon to re-operate. Moreover, Goodfellow et al. [14] demonstrated the insensitivity of the revision rate to clinical failure, because only about 10% of TKAs that give little or no benefit were identified by the revision rate. They concluded that the results of joint replacement registers based on revision rate as the sole measure of outcome need to be reconsidered and advocate -in accordance with Bullens et al. [9]- the use of additional outcome measurements. Moreover, since many recent RCTs which compare the clinical performance of different prosthetic systems failed to demonstrate a superior design [11, 17, 34], the subtle differences in current practice require more selective instruments. For this reason, objective, functional tests may be a valuable additional tool in comparing TKA systems. It has been shown in a study executed at our institution that monitoring the knee extension velocity and loading symmetry during sit-to-stand movements are objective and have a good discriminative capacity [3]. Similar performance-based measurements to quantify functionality of TKA patients have been reported by others [29, 33, 42]. In Chapter 6 the kinematics of two similar TKA designs were compared using a detailed fluoroscopic measurement technique. The kinematic analyses showed a difference in anterior condylar translation of the femur on the tibia between the two designs. Afterwards, the clinical differences between the designs appeared evident. In the RCT comparing the two designs (Chapter 7) even less sensitive outcome measurements such as the KSS and the survival rate were significantly different. We established that relatively small differences in design had substantial consequences. Therefore, the design of a prosthesis is an important aspect that influences the outcome of a TKA.

Several studies have tried to determine patient characteristics that influence the outcome of a TKA as well. In particular, a worse pre-operative status, higher age, additional co-morbidities and the presence of depression have been described as specific risk factors for a poor outcome [5, 13, 24, 39, 53]. Moreover, patient expectations exert a strong influence on functional outcome and meeting the patient expectations appears important in achieving patient satisfaction [5, 10, 20, 26, 32]. Thus, the outcome of a TKA depends on multiple factors and the relative importance of each part may vary amongst different patients. Therefore, the perioperative expectations of the surgeon (Chapter 3) alone are not able to predict the outcome of a TKA. Nevertheless, it would be wise for orthopaedic surgeons and patients to discuss expectations before TKA surgery to ensure that these are realistic. It is evident that a subsection of the TKA population exists who gain little or no benefit from the operation and the limitations of TKA in restoring the functionality to the level of the healthy population should be emphasised. In addition, the knowledge of specific risk factors is important in the improvement of patient selection, by identifying those patients at risk of having a poor outcome before they undergo TKA, particularly if there are risk factors that might be amenable to pre- or post-operative interventions.

Although the origin of the malfunction after TKA is multifactorial, patients frequently localize their complaints around the patella. Therefore, van Loon et al. [49] described the patella as the mirror of a TKA. The incidence of patellofemoral complaints after TKA is reported up to 24% and it is an important reason for revision surgery [7, 18, 19]. The continuing discussion about patella resurfacing in TKA underlines the clinical importance of the patellofemoral articulation. Many patellofemoral complaints are associated with abnormal patellar tracking [18], which is influenced by the mediolateral position of the femoral component [15, 28, 35]. The studies described in Chapters 4 and 5 independently showed a significant medialization of the artificial trochlea and the patella in TKA compared to the pre-operative situation. Rhoads et al. [35, 36] described that a medial femoral displacement produces abnormal patellar tracking patterns with higher stress on the patella. Armstrong et al. [2] concluded that the position of the patella changes with any femoral component malposition, which could result in patellar instability, pain, wear and failure. Further investigations will be needed to analyse the clinical consequences of this accidental but structural medialization. Unfortunately, like the problem in the patella resurfacing discussion, there is a paucity of validated outcome measurements for the assessment of (isolated) patellofemoral pain and function [4].

Despite the limitations of the outcome measurements after TKA and the efforts to improve the outcome, the number of revision TKAs continues to increase [23]. Bone loss is often a problem in revision TKA as a result of the mechanism of failure, design of the prosthesis, technical error at the initial procedure or progress of the original disease [50]. Radiological assessment using standard anteroposterior and lateral views is known to underestimate bone loss [30]. Several options for the management of bone loss in revision TKA have been described: cement, metal augmentations, metaphyseal cones, bone grafting and the use of tumour, hinged or custom-made implants. The choice of technique depends on the age and level of activity of the patient, the extent and distribution of bone loss, the quality of remaining bone, the experience of the surgeon and the availability of bone graft and implants [50]. A biological restoration of the bone stock with IBG seems preferable, especially in younger patients, if a further revision in the future is considered.
likely. Nevertheless, in case of IBG a lack of stability has emerged as a main concern [8, 21, 45, 48]. The study in Chapter 8 showed that a stable reconstruction of uncontained bicondylar defects can be created with IBG and a TKA with a stem extension. However, the outcome of a revision TKA also depends on multiple factors. In particular, the indication of the revision appears to be very important. For instance, revisions performed for patellofemoral subluxation or infection show higher failure rates than revisions for mechanical loosening, and revisions for arthrofibrosis or undiagnosed pain achieve worse functional results [16, 40, 43]. Detailed information about different indications allow a better formulation of risk factors and expectations regarding revision TKA and once more emphasise the importance of an optimal outcome measurement after TKA. Like primary TKA, the design of the implant will influence the outcome of a revision TKA as well. To ensure primary stability, stem extensions have increasingly been used [25, 31, 51]. In an effort to reduce stress shielding associated with stemmed implants [6, 46, 47], we introduced a sliding stem device. Although the mechanical assessments of this novel sliding design are hopeful (Chapter 8), clinical assessments with detailed outcome measurements as discussed in this thesis are still necessary for a valid and reliable evaluation.

References

CHAPTER 9

GENERAL DISCUSSION


Summary, addressing the research questions and conclusions
Summary, addressing the research questions and conclusions

The outcome after TKA has considerably improved over the last decades and the number of TKAs is expected to increase exponentially. However, complete pain relief, full range of motion and normal knee kinematics are not always achieved. Moreover, only about 85% of the patients are satisfied with their TKA. Since several patient-, surgeon- and implant-related factors contribute to the success of a TKA, the assessment of TKAs requires a multifactorial approach. In this thesis some clinical and mechanical aspects that are related to the outcome of a TKA were analysed.

A1: Are different surgeons equally satisfied after TKA?
In Chapter 2 the degree of satisfaction of three orthopaedic surgeons after TKA was investigated in a clinical follow-up study. There was no difference in satisfaction between these three observers, nor was there a difference between the patient and surgeon satisfaction after TKA. The correlation between the surgeon's satisfaction and the KSS knee score was high, which indicates that pain, range of motion and deformity are important aspects for surgeons. Thus, a simple satisfaction VAS can be a useful extension in evaluating the clinical outcome of a TKA.

A2: Do surgeons’ expectations predict the outcome of a TKA?
The usefulness of the surgeon’s expectations of a TKA were assessed in Chapter 3. There were very poor correlations between the surgeon’s immediate postoperative satisfaction VAS and different outcome measurements one year later, including the satisfaction VAS by the same surgeon. There were also very poor correlations between the surgeon’s preoperative assessment of the difficulty of the procedure and all outcome measurements one year after a TKA. Because the outcome of a TKA depends on multiple factors, surgeons’ peri-operative expectations do not independently predict the outcome of a TKA.

B1: Does the implantation of a TKA restore a physiological patella tracking?
The effect of the implantation of a TKA on the patella tracking was analysed in Chapter 4. The kinematics after TKA showed significant changes in comparison to the pre-operative situation: the implantation of a TKA resulted in a more medial position of the patella in flexion and a more lateral tilt of the patella at lower flexion angles. Although it is often suggested that the patella tracking after TKA with an asymmetrical patella groove is more physiologic, we found no significant difference in knee kinematics between TKAs with a symmetrical or an asymmetrical patella groove.
B2: Is there an anatomical mediolateral placement of the trochlea in TKA?
Chapter 5 describes the intra-operative analysis of the mediolateral placement of the trochlea of a TKA. There was a significant medial error of the prosthetic groove relative to the pre-operative, anatomical position of the trochlea, with a mean medial error of 2.5 mm. This is in agreement with the cadaver study described in Chapter 4, where the same medial displacement of the patella was found in a flexed TKA, as compared with the pre-operative position. The amount of the medial error of the trochlea differed between the surgeons, but there was no significant difference between the two prosthetic designs.

C1: Can small differences in design be quantified by kinematic analyses?
In Chapter 6 the clinical performance and in vivo kinematics of two different TKA designs, PFC (DePuy-Johnson & Johnson, Warsaw, IN, USA) and CKS (Stratec Medical, Oberdorf, Switzerland) were compared. The WOMAC joint stiffness total score and items regarding higher flexion and higher demand activities showed greater limitations in knees with the CKS design. The fluoroscopic examinations of the knee kinematics confirmed the suspicion that the CKS design exhibited larger anterior condylar translations of the femur on the tibia. Although this phenomenon has also been described for PCL deficient knees, it remains unclear whether these results can be ascribed to PCL deficiency, or whether it is a combination of implant design and post-operative ligament laxity.

C2: Do relatively small differences in design result in differences in clinical outcome?
Chapter 7 describes a randomized controlled trial involving the same two TKA designs used in Chapter 6. This study also showed a worse clinical performance of the CKS design; evaluation of the postoperative KSS score, WOMAC score, range of motion, VAS patient satisfaction and VAS pain tended all to be superior for the PFC group. At final follow-up, there were significant differences in the total KSS score, the KSS knee score and the VAS patient satisfaction in favour of the PFC system. Moreover, the survival analysis with endpoint any re-operation showed a significant lower survival after 8 years for the CKS group. The reason for the worse results of the CKS design may have been multifactorial and a combination of low fixation strength and possible PCL insufficiency. Initially, the CKS system seems to be very similar to the PFC system, but the large differences in clinical outcome were evident and refrained us from further using the CKS system.

D1: Can a stable reconstruction of bicondylar defects be created in revision TKA and what is the influence of different stem extensions?
Chapter 8 describes the results of the reconstruction of uncontained bicondylar defects in revision TKA. A stable reconstruction could be created with IBG and a TKA with a stem extension. The presence of a functional stem extension was important for the stability of the bicondylar reconstruction. Nevertheless, the disadvantage of a rigid stem is that long-term bone resorption is promoted due to stress shielding. Therefore, we developed a sliding stem mechanism. It appeared that rotational migrations were similar between the reconstruction with a rigid stem connection and the reconstruction with a sliding stem connection. However, the sliding stem allowed proximal migration of the condylar component onto the femoral condyles, thereby compressing the impacted bone grafts. This supports our hypothesis that adequate stability is provided by the sliding stem mechanism, while compressive contact forces are still transmitted to the distal femoral bone.

Conclusions
The clinical and mechanical assessments of TKA that are described in this thesis show that:
- Surgeon expectations do not predict the outcome of a TKA.
- The patella and trochlea are medialized by TKA.
- Apparently similar TKA designs exhibit different clinical outcomes.

Meeting the patient expectations is of the utmost importance in achieving patient satisfaction after TKA. It would be wise for orthopaedic surgeons and patients to discuss expectations before TKA surgery to ensure that these are realistic. Despite substantial advances in surgical technique and implant design, there still exists a subsection of the TKA population who experience little or no benefit from the operation. Because the outcome of a TKA depends on multiple factors, further improvement in the quality of TKAs requires a multifactorial approach.
Samenvatting, beantwoording van de onderzoeksvragen en conclusies
Samenvatting, beantwoording van de onderzoeksvragen en conclusies

Het resultaat van een totale knie prothese (TKP) is aanzienlijk verbeterd in de afgelopen decennia en het aantal TKPs zal naar verwachting exponentieel stijgen. Echter, complete pijnverlichting, een volledige beweeglijkheid en normale knie kinematica worden niet altijd bereikt. Bovendien is slechts ongeveer 85% van de patiënten tevreden met zijn of haar TKP. Aangezien verschillende patiënt-, chirurg- en implantaat-gere lateerde factoren bijdragen aan het succes van een TKP, vereist de beoordeling van TKPs een multifactoriële benadering. In dit proefschrift werden een aantal klinische en mechanische aspecten die gerelateerd zijn aan de uitkomst van een TKP geanalyseerd.

A1: Zijn verschillende chirurgen even tevreden na een TKP?
In hoofdstuk 2 werd de mate van tevredenheid na TKP van drie orthopedisch chirurgen onderzocht in een klinische follow-up studie. Er was geen verschil in tevredenheid tussen deze drie waarnemers, noch was er een verschil tussen de tevredenheid van de patiënt en de chirurg na TKP. De correlatie tussen de tevredenheid van de chirurg en de KSS knie score was hoog, wat aangeeft dat pijn, beweeglijkheid en deformiteit belangrijke aspecten zijn voor chirurgen. Daarom kan een eenvoudige tevredenheid VAS een waardevolle uitbreiding zijn bij de evaluatie van de klinische uitkomst van een TKP.

A2: Voorspellen de verwachtingen van chirurgen de uitkomst van een TKP?
De bruikbaarheid van de verwachtingen van de chirurg ten aanzien van een TKP werden beoordeeld in hoofdstuk 3. Er waren zeer slechte correlaties tussen de direct post-operatieve tevredenheid VAS van de chirurg en verschillende uitkomstmaten een jaar later, inclusief de tevredenheid VAS van dezelfde chirurg. Er waren ook zeer slechte correlaties tussen de pre-operatieve beoordeling door de chirurg van de moeilijkheidsgraad van de procedure en alle uitkomstmaten een jaar na TKP plaatsing. Omdat de uitkomst van een TKP afhankelijk is van multipel factoren, kunnen enkel de peri-operatieve verwachtingen van de chirurg het resultaat van een TKP niet voorspellen.

B1: Hersteld de implantatie van een TKP een fysiologische patella sporing?
Het effect van de implantatie van een TKP op de patella sporing werd geanalyseerd in hoofdstuk 4. De kinematica na TKP plaatsing toont significante veranderingen in vergelijking met de pre-operatieve situatie: de implantatie van een TKP resulteerde
in een meer mediale positie van de knieschijf in flexie en een laterale kanteling van de knieschijf bij lagere flexiehoeken. Hoewel vaak wordt gesuggereerd dat de patella fysiologisch spoort na TKP plaatsing met een asymmetrische patella groeve, vonden wij geen significant verschil in de knie kinematica tussen TKPs met een symmetrische of een asymmetrische patella groeve.

**B2: Is er een anatomische mediolaterale plaatsing van de trochlea bij TKPs?**

**Hoofdstuk 5** beschrijft de intra-operatieve analyse van de mediolaterale plaatsing van de trochlea van een TKP. Er was een significante mediale plaatsing ten opzichte van de pre-operatieve, anatomische positie van de trochlea, met een gemiddelde mediale verplaatsing van 2.5 mm. Dit is in overeenstemming met de beschreven kadaver studie in **Hoofdstuk 4**, waar dezelfde mediale verplaatsing van de patella werd gevonden bij een gebogen TKP, in vergelijking met de pre-operatieve positie. De mate van de mediale verplaatsing van de trochlea verschilde tussen de chirurgen, maar er was geen significant verschil tussen de twee TKP ontwerpen.

**C1: Kunnen kleine verschillen in het ontwerp gekwantificeerd worden door kinematische analyses?**

In **Hoofdstuk 6** werden de klinische prestaties en de in vivo kinematica van twee verschillende TKP ontwerpen, PFC (DePuy / Johnson & Johnson, Warsaw, IN, USA) en CKS (Stratec Medical, Oberdorf, Zwitserland) met elkaar vergeleken. De WOMAC gewrichtsstijfheid totale score en onderdelen betreffende een hogere kniebuiging en meer vereisende activiteiten toonden grotere beperkingen bij de knieën met het CKS ontwerp. Het fluoroscopisch onderzoek van de knie kinematica bevestigde het vermoeven dat het CKS ontwerp grotere voorste condylaire translaties laat zien van het femur op de tibia. Hoewel dit verschijnsel ook is beschreven voor Achterste Kruisband (AKB) insufficiënte knieën, blijft het onduidelijk of deze resultaten kunnen worden toegeschreven aan AKB insufficiëntie, of dat het een combinatie is van implantaat ontwerp en post-operatieve ligament laxiteit.

**C2: Veroorzaken relatief kleine verschillen in ontwerp verschillende klinische uitkomsten?**

**Hoofdstuk 7** beschrijft een gerandomiseerde gecontroleerde studie met dezelfde twee TKP ontwerpen als die worden gebruikt in hoofdstuk 6. Deze studie toonde ook een slechter klinisch resultaat van het CKS ontwerp; evaluatie van de post-operatieve KSS score, WOMAC score, kniefunctie, VAS tevredenheid van de patiënt en de VAS pijn neigden allen superieur te zijn voor de PFC-groep. Bij de laatste follow-up waren er significante verschillen in de totale KSS score, de KSS knie score en de VAS tevredenheid van patiënt ten gunste van het PFC systeem. Bovendien toonde de survival analyse met als eindpunt elke re-operatie bij de CKS groep een significant lagere overleving na 8 jaar. De reden voor de slechtere resultaten van het CKS ontwerp kan multifactorieel zijn geweest en een combinatie zijn van malige fixatie sterkte en mogelijk AKB insufficiëntie. In eerste instantie leek het CKS systeem erg vergelijkbaar met het PFC systeem, maar de grote verschillen in klinische uitkomsten waren duidelijk, waardoor wij hebben afgezien van het verder gebruiken van het CKS-systeem.

**D1: Kan er bij revisie TKPs een stabiele reconstructie van bicondylaire defecten gecreëerd worden en wat is de invloed van verschillende steel verlengers?**

**Hoofdstuk 8** beschrijft de resultaten van de reconstructie van niet met bot omgeven bicondylaire defecten bij revisie TKPs. Een stabiele reconstructie kon worden verkregen met IBG en een TKP met een steel verlenging. De aanwezigheid van een liggend steel mechanisme was belangrijk voor de stabiliteit van de bicondylaire reconstructie. Toch is het nadeel van een rigide steel dat door stress shielding op de lange termijn botresorptie wordt bevorderd. Daarom hebben we een glijdend steel mechanisme ontwikkeld. Het bleek dat rotatoire migraties vergelijkbaar waren tussen de reconstructie met een rigide steel verbinding en de reconstructie met een glijdend steel verbinding. Echter, de glijdende steel liet proximale migratie van de condylaire component op de femurcondylen toe, waardoor de glijdende steel mechanisme gefusedeerd. Dit ondersteunt onze hypothese dat adequate stabiliteit door het glijdende steel mechanisme gewaarborgd blijft, terwijl compressie krachten nog steeds aan het distale femorale bot worden doorgegeven.

**Conclusies**

De klinische en mechanische beoordeling van TKPs die worden beschreven in dit proefschrift tonen aan dat:

- Verwachtingen van chirurgen voorspellen het resultaat van een TKP niet.
- De patella en trochlea worden gemedialiseerd bij TKPs.
- Verwachtingen van chirurgen voorspellen het resultaat van een TKP niet.
- Een glijdend steel mechanisme bij revisie TKPs verschafde adequate stabiliteit en stress shielding.
- De patella en trochlea worden gemedialiseerd bij TKPs.
- Verwachtingen van chirurgen voorspellen het resultaat van een TKP niet.
- Een glijdend steel mechanisme bij revisie TKPs verschafde adequate stabiliteit en stress shielding.

Door de verbeterde resultaten van TKPs en de toegenomen aantallen TKPs is er meer aandacht voor de kwaliteit van de uitkomsten. Traditionele beoordelingen door middel van revisie aantallen en op de chirurg gebaseerde score systemen zijn niet sensitief genoeg. De subtiele verschillen in de huidige praktijk vereisen selectivering instrumenten. Objectieve, functionele testen en op de patiënt gebaseerde uitkomsten zijn waardevolle aanvullende middelen.
Het voldoen aan de verwachtingen van de patiënt is het allerbelangrijkste bij het bereiken van patiënt tevredenheid na een TKP. Het zou verstandig zijn voor orthopedisch chirurgen en patiënten om de verwachtingen voorafgaand aan de TKP operatie te bespreken en te zorgen dat deze realistisch zijn. Ondanks de aanzienlijke vooruitgang in chirurgische techniek en het ontwerp van de implantaten, bestaat er nog steeds een gedeelte van de TKP populatie bij wie er geen of weinig verbetering van de operatie wordt ervaren. Omdat het resultaat van een TKP afhankelijk is van multiple factoren, vereist een verdere verbetering van de kwaliteit van TKPs een multifactoriële benadering.
Het Promotieteam

Tacticus Albert van Kampen was primair de veldtrainer (opleider). Met een scherpe blik behoudt hij het overzicht en bewaakt hij het samenspel tussen de linies (onderwerpen). Bovendien heeft hij het aangedurf om (het knikkende knietje van) zijn instabiele vedette eigenhandig aan te pakken.

Technicus Nico Verdonschot heeft telkens weer oog voor elk detail. Geeft zorgvuldige coaching en is oprecht geïnteresseerd in zijn pupillen. Bewonderenswaardig hoe hij steeds de juiste aanpassingen/omzettingen wist te maken om de strijd met de tegenstander (reviewer) te winnen.

Laatste man Maarten de Waal Malefijt is eigenlijk de eerste man geweest; de aanval begon in feite bij hem, later speelde hij als ‘ausputzer’ een stukje achter de verdediging, om wat meer overzicht te houden.

Centrale rol voor Corné van Loon; hij is echt overal te vinden, nooit te beroerd om eens wat extra meters (vanuit Arnhem) af te leggen en structureel is hij er als eerste bij om adequaat te reageren en openingen te creëren.

Op nummer 1 staat natuurlijk Marit; betrouwbaar, ondersteunend en relativerend. Altijd op de achtergrond aanwezig, maar wel de voorpagina halen. Een betere beschermert van het thuisfront (en partner…) is er niet.

Tim olde Hartman links op het middenveld. Als (niet twee-benig) duizendpoot weet hij overal zijn bijdrage aan te leveren. Ligt altijd goed in de groep en zorgt zo voor mentale balans in de ploeg, waardoor onverklaarbare ‘schwalbes’ significant afnamen.

Voorstopper Arjen Meijerink staat voor een degelijk fundament. Vervuld een voorbeeld functie en is daarbij terecht kritisch. Kiest binnen het veld voor de vrije ruimte (behalve voor z’n tegenstander), biedt buiten het veld juist meer structuur.

In de spits Roy Brokelman, hij heeft namelijk een neusje voor het scoren. Met zijn aanstekelijke enthousiasme bepaalt hij ieders (VAS) tevredenheid.

Op de rechter flank kun je op het ruimtelijke inzicht van Marco Barink rekenen. Door goed positiespel en correcte richting zorgt hij voor de juiste (patella) sporing in de groep.

Marieke Ploegmakers als moderne linksback; heeft van tevoren de tegenstander uitgebreid in beeld gebracht en doorlicht, maar heeft vooral zelf veel technisch vermogen.

Een Gerjon Hannink heb je gewoon nodig in je team. Zijn acties zijn steeds weer onberekenbaar, niet alleen voor de statistieken, en zeker significant.

Willem van de Wijdeven komt in ieders favoriete opstelling voor. Weet als geen ander de technische gedachten van de trainer in de praktijk te brengen. Maar het beëindigen van zijn carrière zal niet alleen op technisch vlak een aderlating blijken te zijn.

Huub Meijerink bleek eens te meer een flegmatieke aanvaller; lange periodes onzichtbaar, en dan opeens een paar mooie acties. Zodoende heeft hij toch weten te scoren, en heeft hij met dit team de promotie bereikt.

Op de tribunes – hetzij skybox, meestal onoverdekt staan – natuurlijk vele bekende en minder bekende supportersons. Soms een fluitconcert, maar meestal fanatiek meelevend... Bedankt!
Huub Johannes Meijerink werd geboren op 25 mei 1977 in Heeten (Raalte). In 1995 behaalde hij het VWO diploma aan het Florens Radewijns College te Raalte. Aansluitend werd hij ingeloot voor de studie geneeskunde aan de Erasmus Universiteit in Rotterdam, alwaar het artsexamen in 2001 werd afgelegd. Na een keuze co-schap op de afdeling orthopedie van het UMC St Radboud, mocht hij in Nijmegen blijven, eerst als arts-onderzoeker op het Klinisch Score Station, later als AGNIO op de afdeling. In deze periode werd gestart met divers onderzoek betreffende knie prothesiologie, initieel bedoeld om in opleiding te komen, later bleek het de basis van dit proefschrift.

Vervolgens werd in 2004 gestart met de opleiding tot orthopedisch chirurg. De vooropleiding werd genoten bij de heelkunde van het Canisius Wilhelmina Ziekenhuis te Nijmegen (opleider Dr. W.B. Barendregt). De orthopedische specialisatie werd in de St Maartenskliniek Nijmegen (opleider Dr. A.B. Wymenga) en het UMC St Radboud (opleiders Prof. dr. R.P.H. Veth en Prof. dr. A. van Kampen) volbracht. Hierna werkte hij een jaar als chef de clinique in het Canisius Wilhelmina Ziekenhuis te Nijmegen. Per 1-11-2011 is hij werkzaam in de maatschap orthopedie van Tjongerschans Ziekenhuis Heerenveen.