Optimising Clinical Outcome and Survival in Revision Knee Arthroplasty

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Colofon

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– Voor Corrie –

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Chapter 1

General Introduction

Total knee arthroplasty (TKA) is recognised as a highly successful treatment for osteoarthritis in terms of pain relief and improved quality of life.[1,2] Due to an ageing population and an increase in unfavourable societal factors such as obesity, over the next decades there will be a substantial increase in the number of people with knee osteoarthritis and the number of TKAs performed.[3,4] Although the treatment of knee osteoarthritis by a TKA is successful in many cases, a significant number of patients still remain unsatisfied after surgery and will have persistent complaints or functional limitations in daily activities.[5–7] Many factors contribute to dissatisfaction after surgery, such as unmet expectations after the operation, surgery at a younger age, and persistent knee pain and/or stiffness of the operated knee.[6,8] While some complaints might be related to a malfunctioning knee implant, the majority of the dissatisfied patients have unmet expectations and persistent pain, which are correlated with patient characteristics rather than implant or surgical factors.[2,9,10] Therefore, finding the underlying cause of these complaints is one of the most important aspects to select those patients who will not benefit from revision total knee arthroplasty (rTKA). Numerous studies have shown the relationship between the reason for revision and outcome measures, including patient-reported outcome measures (PROMS), survival and mortality.[11–14] For example, revision for aseptic loosening is thought to be a fair indication for rTKA, while revision for unexplained pain has worse outcomes.[15] In addition to the reason for revision, many other predictive factors have been described that play a significant role in patient selection.[16] So, the process of rTKA starts with the workup of a patient with complaints after a TKA and then selecting those patients who would have a reasonably predictable outcome after an rTKA.

Revision TKA is the replacement of one or more components of the original knee implant; therefore, it can be a partial or a total revision. Around 3000 revision knee procedures are performed in the Netherlands each year, half of which are total revisions that replace all parts of the implant [17] The most frequent indications for rTKA are instability (24.6%), patellar pain (23.9%), infection (22.4%) and aseptic loosening of the tibial component (18.7%).[18] Due to an increasing demand in primary TKA, especially in younger, highly demanding patients with a prolonged life expectancy, the number of rTKAs will rise steeply in the next decades.[3,19] In addition to the impact of an rTKA for each patient, this continuous rise in the number of rTKAs will have a significant consequence on the health care systems in the future.

Revision TKA is a technically demanding procedure with an inferior functional outcome, a lower survival rate and a higher complication rate compared with primary TKA.[14,20–22] Preoperative planning is crucial and simplifies the surgery: it allows clinicians to anticipate the often seen bone defects during surgery and to choose the

most suited knee implant for these revisions.[23] Revision knee implants can be non-constrained, condylar constrained or (rotating) hinge-type implants. Rotating hinge knee implant are the most constrained and are used in cases with gross ligament insufficiency and/or extensive bone loss.[24]

During revision surgery, the components first have to be removed with the least possible amount of bone loss. Second, bone cement, if present, fibrous tissue and mechanically unstable bone should be debrided before the full extent of bone loss can be determined. Third, the ligament status needs to critically examined during surgery. Based on this, a final selection of revision implants with the appropriate level of constraint, implant fixation technique and techniques regarding how to manage concomitant bony defect can be made. The next step is to align the cutting guides, which are part of the used knee revision system, to make adequate and mechanically stable flat bone surfaces perpendicular to the mechanical axes. Due to the loss of anatomical reference points, determination of implant alignment and the level of the joint line can be difficult during revision surgery. After alignment and reconstruction of the level of the joint line with trial implants, the definitive components can be implanted. Fixation of those components is one of the challenges of rTKA, especially in patients with extensive bone loss and inferior bone quality. Implant fixation is crucial for implant survival, and aseptic loosening is unfortunately still one of the main reasons for failure of an rTKA.[25–27] However, it is still unclear which factors influence later aseptic loosening and how to achieve the most appropriate fixation in an rTKA.

Optimising the clinical outcome and survival of rTKA is crucial for patients as well as the future health care burden due to the expected rise in the number of rTKAs. In this thesis, we explore these knowledge gaps in patient selection, the type of implant fixation and implant performance in rTKAs. **Specifically, this thesis aims to investigate:**

- The functional outcome of patients who have had a rTKA for the diagnosis of malalignment and to determine the most influencing factors for the outcome;
- The association between the zonal fixation of a rTKA and later aseptic loosening;
- The optimal fixation technique for hinge knee implants in terms of survival;
- The micromotion, assessed with radiostereometric analysis (RSA), of a fully cemented hinge knee implant over time;
- The short- to midterm survival and outcome of a novel hinge knee implant.

Outline of this Thesis

Functional Outcome and Patient Selection in Revision Total Knee Arthroplasty for Malalignment

Malalignment is one of the reasons for malfunctioning of a TKA and accounts for 7%–14% of all rTKAs.[18,27] From a technical perspective, malalignment is a malrotation of the femoral or/and tibial component about one or more of the three-dimensional axes. Malrotation in a certain plane and direction will lead to specific component deviations and complaints. For example, malrotation in the coronal plane will lead to varus or valgus malalignment, depending on the direction of the rotation. While slight deviations due to undercorrection of an existing constitutional alignment in new (restricted) kinematic alignment techniques might be favourable in terms of the clinical outcome, higher degrees of malalignment have been associated with inferior outcomes.[28,29] Moreover, varus malalignment has been associated with a higher aseptic loosening rate, while valgus malalignment is associated with failure due to instability.[30,31] On the other hand, malrotation in the axial plane results in an internal or external malrotation of the femoral or tibial component, or leads to a combined femoral-tibial malrotation; these abnormalities have been associated with patellar maltracking, pain and stiffness.[32,33] Although definitions of malalignment have been described in literature, only a limited number of patients with aligned TKAs outside these reported values will develop complaints or inferior outcomes.[34] Therefore, malalignment of a TKA is a clinical diagnosis in which complaints and clinical signs can be addressed to the malaligned component(s). Based on the current literature, very little is known about the clinical outcome after rTKA for malalignment and which factors influence the outcome. Some cohort studies have described the clinical outcome without any description of the malalignment of the component(s).[11,35,36] Other studies have focused on malrotation in the axial plane only.[37–40] So, it is still unclear who will benefit most after rTKA for malalignment.

In **Chapter 2** of this thesis, we studied a prospective cohort of patients who have had an rTKA for malalignment. Our aim was to determine the functional outcome after revision and to determine the factors that influence the outcome.

Optimising Fixation and Prevention of Aseptic Loosening in Revision Total Knee Arthroplasty

Appropriate implant fixation is one of the main challenges in rTKA. There is bone loss and decreased bone quality in each knee revision, and these factors play a significant role in the fixation of the next implant.[41–43] Many treatment options exist to overcome these bony impairments and to achieve an appropriate fixation for satisfactory long-term survival of the revision knee implant.[41–43] The available modular rTKA

systems consist of a stemmed component with fixation in the three anatomical bone zones: the epiphysis, metaphysis and diaphysis (Figure 1). One commonly used option is the hybrid fixation technique, where the femoral and tibial components are cemented to the surrounding bone (epiphysis and metaphasis), while the stems are fixed in the diaphysis with a press-fit (uncemented) technique. Morgan-Jones et al.[41] introduced the zonal fixation concept in which they describe how to achieve appropriate fixation in those three anatomical zones with different treatment modalities. To ensure optimal implant survival, the authors suggested to obtain appropriate fixation in at least two out of three anatomical zones. Although this paper has been referred to frequently, so far, no clinical evidence has been published.

In **Chapter 3**, we investigate whether there is an association between the quality of fixation in the three anatomical zones of a hybrid tibial component in rTKA and later aseptic loosening.

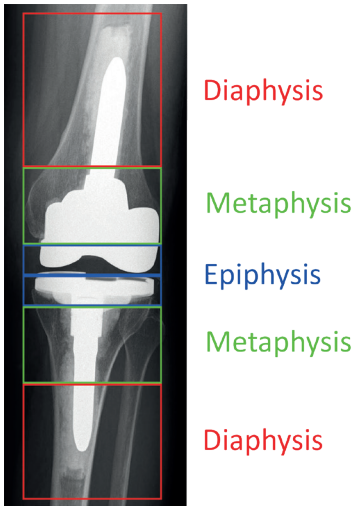

Figure 1: Radiograph of a revision knee implant with the three anatomical zones highlighted.

A rotating hinge knee implant is an example of a highly constrained implant design. It is mostly used in complex rTKA or re-revision surgery where intrinsic stability is mandatory.[24,44] Because of the highly constrained nature of the knee implant, large forces will be directed through the hinge mechanism onto the bone-(cement)-implant interface. Hence, in combination with the use in complex rTKA in which substantial bone loss and decreased bone quality is frequently seen, a higher rate of aseptic loosening has been described for these hinge-type implants.[24,44] So, optimal

fixation in these implants is mandatory for satisfactory long-term survival. Like modular rTKA systems, most hinge systems provide a fully cemented option (cemented tibia or femur component with a cemented stem) or a hybrid fixation option (cemented tibia or femur component with a press-fit stem) (Figure 2). For condylar rTKA systems, both fixation options seem appropriate with a comparable outcome.[45–47] However, the results of finite element analysis[48] and observations reported in the literature[49] and in our own clinical practice hint towards superior survival of the fully cemented hinge implants.

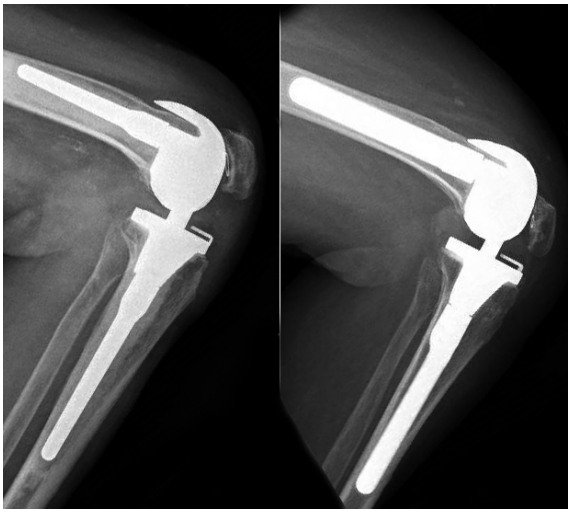

Figure 2: Radiographs of a fully cemented rotating hinge knee implant with bone cement fixation of both the component and the stem (left) and a hybrid fixed rotating hinge knee implant with bone cement fixation of the component and a press fit stem (right).

In **Chapter 4**, we compare a retrospective cohort of fully cemented and hybrid fixed rotating hinge knee implants to investigate whether one is superior to another in terms of implant survival.

A well-established method that is able to predict later aseptic loosening is radiostereometric analysis (RSA). With this accurate technique, three-dimensional micromotion of an implant can be determined over time.[50,51] With postoperative biplanar radiographs, the position of an implant can be calculated relative to intraoperatively placed beads in the surrounding bone and tracked over time (Figure 3). Previous studies have shown a relationship between early micromotion and later aseptic loosening in primary TKA, and threshold values have been reported for implants

that are at risk for aseptic loosening.[52,53] Although these values cannot directly be translated to rTKA implants, micromotion patterns over time can be indicative of stable or unstable implants. Thus, detecting early micromotion with RSA in a hinge-type knee implant can be helpful to confirm adequate fixation or whether specific failure patterns appear.

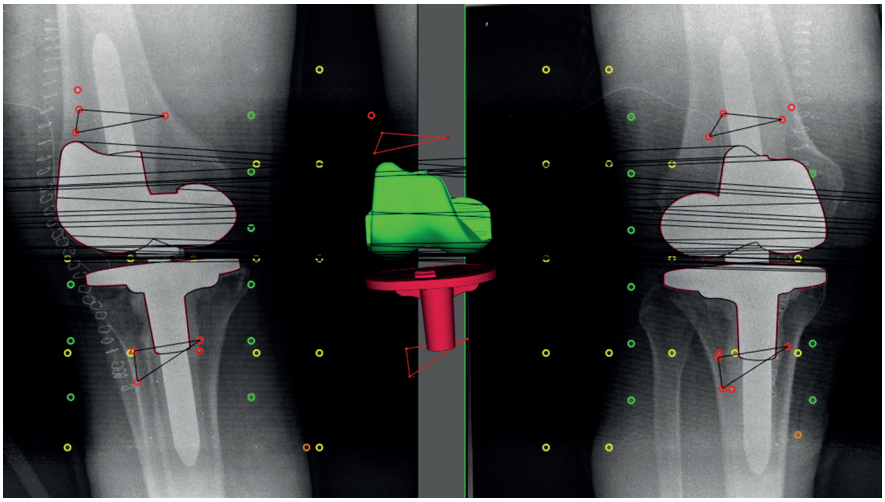

Figure 3: RSA radiographs (left and right) with RSA bone markers (red) and calibration box markers (green and yellow) and a computer-aided design (CAD) model of the implant (red and green) in the centre.

In **Chapter 5**, we describe the micromotion of a fully cemented rotating hinge knee implant in rTKA determined with RSA.

A Novel Rotating Hinge Knee Implant: Short- to Midterm Performance and Unforeseen Instability Cases

Implant survival, the revision-free rate of implants at a certain time, is a commonly used measure of implant performance. In the last decades, national joint registries have become a valuable resource providing important survival data of a large number of longitudinally followed knee implants. However, joint registries have their limitations in revision surgery, especially for hinge knee implants. First, the number of cases is markedly smaller compared with primary and condylar rTKA. Second, revisions can vary extensively from simple cases with minimal bone loss to complex revisions that require multiple augmentations, a phenomenon that might explain why hinge knee implants, which are commonly used in the most complex revision

cases, have significantly lower survival rates compared with other revision knee implants.[27] This might be more the result of patient and perioperative conditions rather than implant performance. Third, because of the high threshold for re-revision, or even no additional options for re-revision surgery, patients can experience implant complications that are not recorded in a registry. From this perspective, cohort studies may be the preferred study design to reveal clinical performance and specific implant drawbacks in those small numbers of heterogeneous cases of hinged knees versus implant registry data and the resulting studies.

In **Chapter 6**, we describe the short- to midterm survival and clinical outcomes of a consecutive multicentre cohort of a novel guided-motion rotating hinged implant.

A rotating hinge knee implant is a highly constrained implant. It allows flexion and extension by a hinge mechanism and permits axial free rotation to diminish rotational forces onto the hinge mechanism and implant fixation interface. Although a hinge knee implant is considered to be the highest levels of constraint in knee implants, extensive varus and valgus deviation can emerge.[54] One explanation is distraction and tilting of the tapered rotational peg.[55,56] Other case series have reported instability by failure of the mechanism.[57–60] With the introduction of a new rotation hinge knee system, we have encountered several patients with instability complaints.

In **Chapter 7**, we investigate a group of patients with instability complaints after a specific rotating hinge knee implant and describe our treatment algorithm.

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1

Chapter 2

Revision for Coronal Malalignment Will Improve Functional Outcome up to 5 Years Postoperatively

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Abstract

Introduction

Revision of a total knee arthroplasty (TKA) for the diagnosis of malalignment is widely performed. However, very little is known about the functional outcome in revision TKA surgery for malalignment. The aim of this study was to assess the functional outcome and to identify factors influencing the functional outcome of patients who have had a revision of a TKA for the diagnosis of malalignment at 5 years follow-up.

Methods

All patients with a revision of a TKA for malalignment as the primary reason were selected from a prospective database. The diagnosis of symptomatic malalignment was made by the surgeon and quantified by radiologic examination. Functional outcome was scored by the functional score of the Knee Society Clinical Rating System (fKSS) at 0, 12, 24 and 60 months. Multiple imputation for missing data and multivariable analysis were performed to identify factors influencing functional outcome.

Results

After selection, 105 patients (age: 65.1 ± 9.1 years, gender M:F 30:75) were eligible for outcome analysis. Functional outcome significantly improved from the preoperative (fKSS: 44.1 ± 22.0) to 5 years postoperative (64.7 ± 24.0, $p < 0.001$) time frames. Higher degree of coronal deviation, younger age and lower preoperative KSS were found to be strongest positive influencing factors for the change in fKSS.

Conclusion

Revision of TKA for malalignment appears to be an effective treatment to improve functional outcome up to 5 years postoperatively. Higher degree of coronal deviation, younger age and lower preoperative KSS are the strongest contributing factors for functional improvement.

Introduction

Malalignment in total knee arthroplasty (TKA) represents malposition of the femoral or tibial component in the coronal, sagittal or transversal plane.
Definitions for alignment/malalignment have been described in the literature;[1] however, a certain degree of malalignment will not cause complaints in every patient. So, the diagnosis of malalignment is a complex match of complaints, clinical and radiological investigations, and exclusion of other reasons for malfunction. Functional outcome and identification of influencing factors for revision TKA surgery for malalignment could help surgeons to identify patients who might benefit the most and inform them about the expected outcome.
Revision of malalignment accounts for 7.6-14% of all revisions.[2,3] Nevertheless, very little is known about the outcome after revision surgery for malalignment.[4–10] Few cohort studies have shown improvement of functional outcome scores in revision TKA for malalignment but without any descriptive definitions.[4,9,11] Others have shown improvement after revision for malrotation in the transversal plane only.[5–8] To this date, it is unclear who will and who will not benefit from revision surgery in patients with malalignment, in one or more planes.
The goal of this analysis of a prospective database was to assess the functional outcome at 5 years follow-up of patients who have had a revision of a TKA for the diagnosis of malalignment and to identify factors influencing functional outcome after revision. It was hypothesized that revision for malalignment is an effective treatment to improve functional outcome up to 5 years postoperatively.

Material and Methods

Patients

All patients with a revision for malalignment as the primary reason were selected from a prospective database consisting of data from patients with a full revision TKA who were operated on between 2004 and 2013. In total, 123 patients were eligible for analysis. Malalignment was defined as the presence of clear malalignment or malrotation of one or both components causing pain, instability or patella maltracking.[4] The diagnosis of symptomatic malalignment was made by the surgeon based on complaints, clinical investigation, preoperative plain radiographs (antero-posterior, lateral and axial patellar and long leg standing X-rays) and computed tomography (CT) scans. Infection was ruled out with the use of laboratory testing, aspiration, or open biopsies. Work-up was standardized among all orthopaedic surgeons. Eighteen patients were excluded for the following reasons: malsizing of components (n = 10), malunion after periprosthetic fracture (n = 2), use of an outdated

nonmodular revision system other than the ones described in the methods section (n = 2), incorrect allocation to the diagnosis of malalignment (instability by ligament insufficiency (n = 3), and fixed flexion contracture (n = 1) (Figure 1). On average, patients were 65.1 ± 9.1 years old; 75 (71%) patients were female and 30 (29%) patients were male.

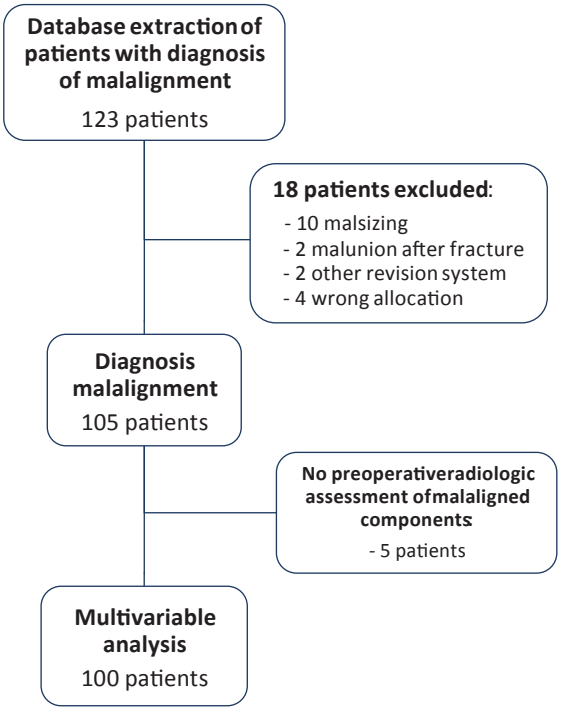

Figure 1: Flowchart of patient selection.

All patients were operated by five experienced orthopaedic surgeons who specialized in knee revision surgery in a high-volume orthopaedic centre (Sint Maartenskliniek, Nijmegen, the Netherlands). Patients were treated with the Genesis II® revision system (2004-2006), the Legion® revision system, or the RT-PLUS® modular rotating hinge system (2006-2013) (Smith & Nephew, Memphis, TN, USA). When needed, tibial and femoral augments were used to fill bony defects and to restore neutral alignment per Gromov et al.[1]

Radiological measurements of preoperative alignment

Coronal alignment was assessed on a long leg weight-bearing anteroposterior radiograph. The angle between the femoral and tibial mechanical axis and the distal or proximal portion of the femoral component (DFA) and tibial component (PTA), respectively, were measured as shown in Figure 2. The mechanical hip-knee-ankle angle was calculated from those two angles. Sagittal alignment was assessed on the short leg lateral knee radiograph as described in the paper by Gromov et al. and shown in Figure 3.[1] Rotational alignment of the femur and tibia was assessed according to the method of Berger et al.[12] All radiologic measurements were done by one physician (SvL) and within an accuracy of 1°. Long leg standing X-rays were available in 99 patients (94%), and a CT scan was performed in 59 patients (56%). In five patients, malrotation of the femoral component was diagnosed by clinical investigation and stress radiographs in flexion for the assessment of lateral flexion laxity without the use of a CT scan. These five patients were excluded for the multivariate analysis, and the remaining 100 patients were categorized by the criteria specified by Gromov et al. (Table 1).[1]

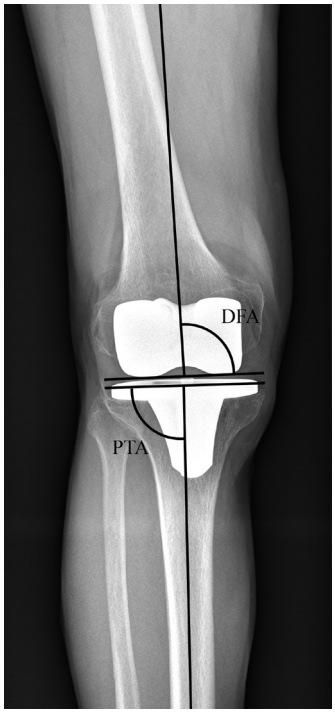

Figure 2: Part of a long leg radiograph with assessment of the coronal alignment. Distal femoral angle (DFA) and proximal tibial angle (PTA).

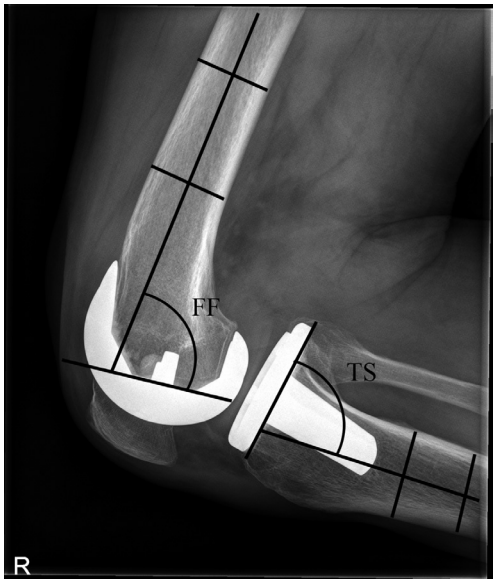

Figure 3: Radiograph with assessment of sagittal alignment. Flexion of the femoral component (FF) and tibial slope (TS) of the tibial component.

Table 1. Radiologic categorization of malaligned components by the criteria of Gromov et al.[1]

Malalignment criteria (Gromov):	Number of outliers:	
HKA (0° ± 3°)	Varus (N = 14) Median 6° (4° to 12°)	Valgus (N = 28) Median 6° (4° to 11°)
FF (0° to 3°)	Flexion (N = 44) Median 6° (4° to 17°)	Extension (N = 12) Median -2° (-1° to -8°)
TS (0° to 7°)	Downslope (N = 36) Median 10.5° (8° to 19°)	Upslope (N = 6) Median -1.5° (-1° to -4°)
sTEA (2° to 5° ER)	Internal rotation (N = 50) Median -2° (1° to -10°)	External rotation (N = 1) Median 6° (6°)
TCA (-18° IR)	Internal rotation (N = 46) Median -28.5° (-19° to -52°)	External rotation (N = 11) Median -11° (-17° to 6°)

Values are expressed as numbers (N) and medians (range). Components can have outliers in multiple planes. HKA: hip-knee angle, FF: femoral flexion, TS: tibial slope, sTEA: surgical transepicondylar axis, ER: external rotation, TCA: tibial component angle, IR: internal rotation.

Outcome scores

For functional outcomes, we used the functional score of the Knee Society Clinical Rating System (fKSS) ranging from -20 to 100, the latter being the best outcome.[13] The fKSS was scored preoperatively and at 12, 24 and 60 months postoperatively. Other outcome scores were the clinical score of the KSS, VAS pain and VAS satisfaction ranging from 0 to 100, with the latter representing the highest satisfaction rate. Range of motion (ROM) was extracted from the clinical part of the KSS ranging from 0 to 25, with every point representing 5° of flexion.

This analysis of a prospective knee revision cohort was approved by the Institutional Review Board of the Sint Maartenskliniek and the Medical Review Ethics Committee (CMO-nr: 2003/173).

Statistical analysis

The preoperative characteristics and outcome scores were described as means ± standard deviations. Differences between pre- and postoperative outcome scores were analysed using paired t-tests.

Individual trajectories of change from baseline in functional outcomes exhibited nearly linear trajectories and were therefore used as dependent variables. Univariate association of preoperative characteristics with functional outcome trajectory was assessed using box and scatter plots. For most alignment parameters, the influence of positive and negative deviations was similar, which was in line with clinical expectation. Also, most associations had a linear and/or quadratic shape. Therefore, our model included coronal deviation, femoral and tibial sagittal deviation and femoral and tibial axial deviation both as absolute value (ABS) and quadratic (SQR) function from the optimum given by Gromov et al..[1] Age, gender, preoperative ROM and preoperative pain score and time (12, 24, 60 months) were included as linear functions. Backward selection down to $p < 0.05$ was performed on 20 imputed datasets, where the p-values of remaining variables in each step were calculated using Rubin's rules. Time was retained in all models because of the repeated measurement design of the study. The fit of the final model was assessed using residual plots and by comparing the model predictions with the observed data. Statistical analysis was performed with SAS 9.4 (SAS Institute Inc., Cary, USA).

Results

Mean follow-up was 4.1 ± 1.6 years. In all, 27% (n = 28) of patients were lost to follow-up at 5-year follow-up for the following reasons: 10 patients by request (e.g., distance and age), five patients died due to unrelated causes, four patients had a re-revision (three for aseptic loosening and one insert exchange for instability), two patients due to other medical issues (carcinoma and Parkinson's), and seven patients for unknown reasons.

Average functional outcome showed a significant improvement from a mean preoperative fKSS of 44.1 ± 22.0 points to 64.7 ± 24.0 points ($p < 0.001$) at 60 months postoperatively (Figure 4). Individual patient trajectories showed a large change from preoperative to 12 months in most patients and afterwards a relatively stable trend. In line with this, change from baseline (i.e., preoperative score) to 12, 24 and 60 months showed a linear trend and was reasonably normally distributed. A higher preoperative functional outcome was associated with a smaller increase in functional outcome at 12, 24 and 60 months, which is in line with the ceiling effect observed in individual profiles. Outcome scores are summarized in Table 2.

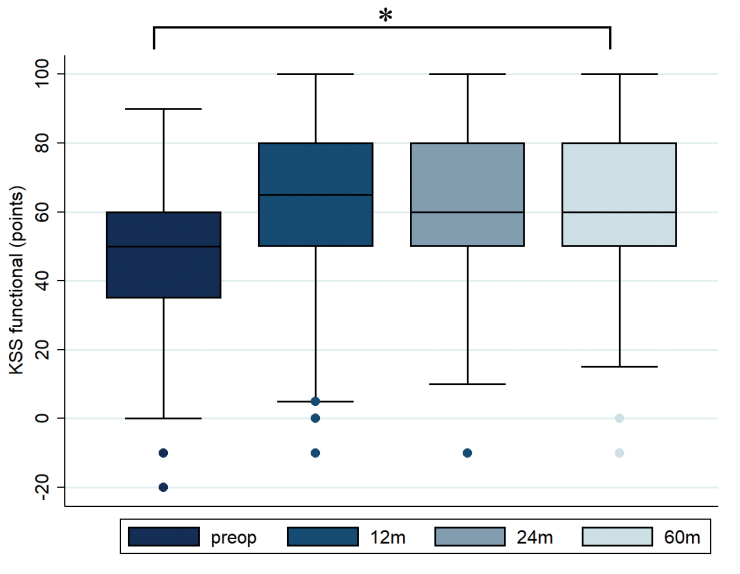

Figure 4: The KSS functional scores at different time points. * = $p < 0.001$.

Table 2. Outcome scores on different time points.

Outcome score	Preoperative	12 months	24 months	60 months
fKSS	44.1 (±22.0)	62.5 (±24.9)	63.9 (±22.4)	64.7 (±24.0)
cKSS	50.5 (±17.2)	78.1 (±19.6)	73.5 (±19.3)	77.6 (±16.2)
VAS pain	61.0 (±19.8)	31.8 (±27.8)	40.4 (±27.4)	37.1 (±31.0)
VAS satisfaction	-	70.2 (±24.6)	69.4 (±25.3)	70.9 (±27.8)

Values are expressed as mean ± standard deviation. fKSS: functional score of the KSS, cKSS: clinical score of the KSS, VAS: visual analogue scale.

After backward selection, factors influencing the change of functional outcome after revision were age, preoperative fKSS, coronal deviation ABS and SQR (Figure 5), tibial malrotation ABS (Figure 6), VAS pain and KSS ROM (Table 3). Higher coronal deviation (5.06; 95% CI 1.26 to 8.86; p = 0.01), younger age (-0.82; 95% CI -1.22 to -0.42, p < 0.001) and lower preoperative fKSS (-0.71; 95% CI -0.88 to -0.53, p < 0.001) were the strongest positive influencing factors for the change in functional outcome based on their estimates.

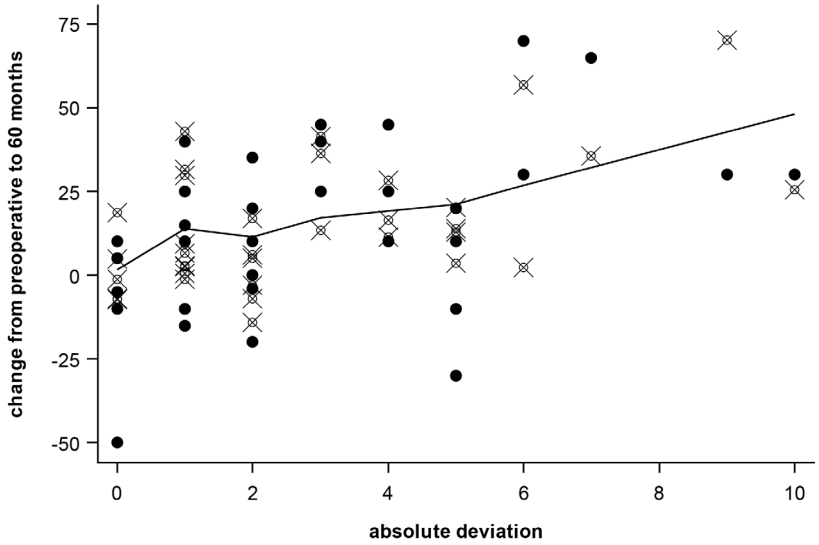

Figure 5: Change in fKSS after 60 months compared to the coronal deviation. Black dots represent observed data. Cross dots represent the predicted data from the model. The line represents a Loess fit to the predicted data. Mixing of the predicted and observed data is reflective of a good model fit.

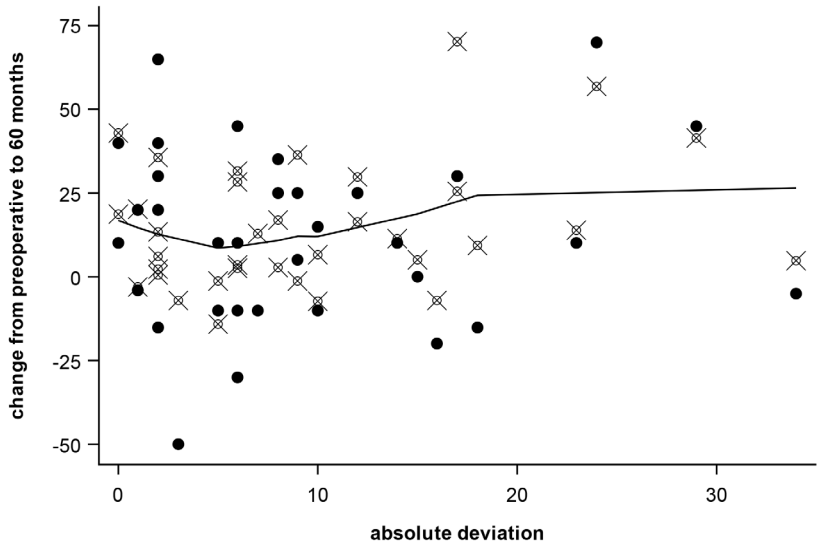

Figure 6: Change in fKSS after 60 months compared to the tibial malrotation. Black dots represent observed data. Cross dots represent the predicted data from the model. The line represents a Loess fit to the predicted data. Mixing of the predicted and observed data is reflective of a good model fit.

Table 3. Outcome of multivariable analysis after backward selection.

	Parameter	Estimate	95% CI		p
1	intercept	83	51	115	<0.001
2	preop fKSS (pts)	-0.71	-0.88	-0.53	<0.001
3	KSS ROM (pts)	0.94	0.23	1.66	0.01
4	coronal dev. ABS (°)	5.1	1.3	8.9	0.01
5	coronal dev. SQR (°)	-0.47	-0.84	-0.10	0.01
6	tibial malrot. ABS (°)	0.49	0.10	0.89	0.01
7	age (yrs)	-0.82	-1.22	-0.42	<0.001
8	time (yrs)	-0.02	-0.15	0.10	n.s.
9	VAS pain (pts)	-0.16	-0.32	-0.01	0.04

CI: confidence interval, preop: preoperative, pts: points, dev: deviation, ABS: absolute value, SQR: square function, malrot: malrotation, yrs: years.

Discussion

This is the first study to evaluate the functional outcome of revision for the diagnosis of symptomatic malalignment with 5-year follow-up results. The fKSS showed a steep improvement from the preoperative to 12 months postoperative time points and remained stable up to 5 years postoperatively. With a mean improvement of 20.6 points on the fKSS, patients increased on average two categories (e.g., from poor to good) on the fKSS scale, which has been stated as a beneficial outcome.[14] Higher coronal deviation, younger age and lower preoperative fKSS are the strongest positive influencing factors for the change in functional outcome based on their estimates. Low VAS pain, higher ROM, and higher degree of malrotation of the tibial component were less strong positive factors.

Coronal deviation appears to be the strongest alignment factor influencing the change in functional outcome. Patients with a higher degree of coronal deviation from the mechanical axis showed a greater improvement of the fKSS after revision. To our knowledge, this is the first study that shows a correlation between the degree of coronal deviation and the effect on functional outcome after revision. Although new insights of constitutional alignment and the development of kinematic alignment have changed the aim for neutral alignment in TKA,[15–17] revision for higher degrees of coronal deviation outside the constitutional range seems a valid option with significant functional improvement.

Age and preoperative fKSS were found to be other strong factors in our explorative model, influencing the change in functional outcome negatively. With an estimate for age of -0.82, the change of fKSS will on average decrease 0.82 points for every increasing year of age (with all other variables unchanged). Preoperative fKSS was inversely related to the change of fKSS and can be explained by the ceiling effect of the fKSS, where patients with a high preoperative functional score cannot improve as much as patients with a low preoperative functional score. Both older age and higher preoperative fKSS have been previously described as negative influencing factors of functional outcome in revision TKA.[14]

In the literature, there is limited data regarding outcomes after revision for malalignment. Some revision cohorts reported improvement of outcome scores but lack a clear description and quantification of malalignment.[4,9,11] The present study is an extension of a part of the cohort of van Kempen et al. and showed similar functional outcome results.[4] Baker et al. and Ghomrawi et al. showed improved functional outcomes but with different outcome measures.[9,11] A small series of papers has shown favourable results on the functional outcome after revision for malrotation of the femoral and tibial components.[5–8] This is in contrast with the present study, in which no clear relation was found between malrotation and functional outcome, with only a small estimate for malrotation of the tibial component. In the previous

studies, the amount of femoral malrotation was different,[6] preoperative fKSS was lower [7,8] and functional improvement was less[5] as compared to those in the present study. Moreover, the effect of revision for malrotation might be overestimated by the effect of correction in the coronal plane,[7,8] since the role of malrotation in primary TKA on functional outcome has been questioned by other authors.[18,19]

Pain has not been determined as an influencing factor in revision surgery before.[14,20] It might be possible that patients with unexplained pain after TKA were incorrectly diagnosed as having malalignment with a bad result as a consequence. Although statistically significant, the estimate for VAS pain was small, indicating no strong influence on functional outcome. Stiffness in TKA has previously been shown to result in a worse functional outcome after revision, which is in line with the positive estimate of the KSS ROM in our model.[14]

We are aware of the limitations of this study. Although this is the largest prospective malalignment group in literature, it is still relatively small. Loss to follow-up is substantial in this elderly population (27%), and missing data for the assessment of malrotation had to be imputed for the multivariable analysis. Therefore, we decided not to build a prediction model, but investigate the most influential factors via multivariable analysis. The model fit, assessed by comparing predicted trends by the model versus the observed data, seemed reasonable. Together with the mechanistical plausibility of the results, this lends credibility to the findings. However, validation in new patients with full assessment of pre- and postoperative alignment would be warranted before firm conclusions can be made. Other previously identified factors for worse outcome after revision (BMI and bone loss) were not recorded in our prospective database and are therefore absent in the analysis.[14,20]

Conclusion

Revision of TKA for malalignment appears to be an effective treatment to improve functional outcome up to 5 years postoperatively. Higher coronal deviation, younger age and lower preoperative fKSS are the strongest contributing factors for functional improvement. This may help surgeons identify patients who might benefit the most and inform them about expected outcomes from revision TKA surgery for malalignment.

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Chapter 3

Association Between Postoperative Zonal Fixation of Hybrid Tibial Components in Revision Total Knee Arthroplasty and Subsequent Aseptic Loosening: Appropriate Metaphyseal Fixation is Key

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Abstract

Introduction

Tibial fixation in revision total knee arthroplasty (rTKA) can present surgical challenges. It has been suggested that appropriate fixation in at least two of the three anatomic zones (epiphysis, metaphysis, and diaphysis) is essential for implant survival. However, supporting clinical data are lacking. In this retrospective case-control study, we investigated the relationship between zonal fixation of hybrid rTKA tibial components and re-revision total knee arthroplasty for aseptic loosening (rrTKA-AL).

Methods

All consecutive rTKAs with hybrid tibial components (May 2006 to Dec 2020) were screened for subsequent rrTKA-AL. A control group was randomly selected from the remaining cohort. Postoperative radiographs of rTKAs were scored in random order by three blinded observers for zonal fixation in the epiphysis (bone resection level below, at, or above fibular head; 0 to 2), metaphysis (number of sufficiently cemented zones; 0 to 4) and diaphysis (canal filling ratio [CFR]; %). The intraclass correlation coefficient (ICC) was calculated to quantify the agreement between observers. Multivariate logistic regression analysis was performed to assess the relationship between zonal fixation and rrTKA-AL.

Results

Overall, 33 patients underwent a further rrTKA-AL from a total of 1,173 hybrid tibial components (2.8%). Patients requiring rrTKA-AL had a significantly lower epiphyseal bone resection level (OR 0.43; 95%CI 0.23 to 0.76; p=0.006), lower number of adequately cemented zones (OR 0.50; 95%CI 0.30 to 0.79; p=0.004), but no difference in CFR (p=0.86). Furthermore, patients needing rrTKA-AL had more frequently previous revisions (p=0.047), a higher rate of a prior use of a stemmed tibial component (p=0.011) and a higher Anderson Orthopaedic Research Institute classification (p<0.001). Agreements of zonal fixation between observers was good (ICC 0.79 to 0.87).

Conclusion

Patients in need of subsequent rrTKA-AL had lower epiphyseal bone resection levels and a lower number of sufficiently metaphyseal cemented zones following rTKA. These results emphasize the importance of appropriate metaphyseal fixation at rTKA. With this information, orthopaedic surgeons can identify patients at greater risk for rrTKA-AL and optimise their surgical technique in revision knee arthroplasty surgery.

Introduction

The number of patients undergoing total knee arthroplasty (TKA) is increasing worldwide. Due to the increasing life expectancy of patients in general and the increase in younger, more active patients in need of TKA, the incidence of revision total knee arthroplasty (rTKA) is likely to increase considerably in the coming decades.[1,2]

A revision TKA is a demanding procedure with poorer outcomes and rates of survival compared to primary TKA.[2,3] One of the main reasons for rTKA failure is aseptic loosening.[4–7] Good fixation for optimal implant survival is therefore crucial for better longterm outcomes in rTKA. Durable fixation can be impaired by bone loss or poor bone quality in the three tibial anatomical zones (epiphysis, metaphysis, and diaphysis) and it is suggested that to achieve the best outcomes, adequate fixation is required in at least two of the three anatomical zones.[8] Many treatment strategies have been proposed to obtain this goal.[8–10] Although newer innovations such as highly porous metaphyseal cones or sleeves have shown to be successful in providing additional fixation, including complex cases,[11,12] excessive use may have negative consequences, as they are expensive and hard to remove in re-revision cases. Identification of patients who are at higher risk of further loosening may help to optimize and personalize fixation strategies at rTKA.

One method to achieve tibial fixation in rTKA is the hybrid technique consisting of a cemented proximal component with a cementless diaphyseal engaging stem. For these hybrid components, the diaphyseal canal filling ratio has been described clinically as having predictive value for aseptic loosening.[13,14] However, supporting clinical data are lacking to answer the questions: what is the most appropriate zonal fixation in rTKA, and how should zonal fixation be assessed? The goal of this study was to investigate the relationship between postoperative zonal fixation in the three tibial anatomical zones when using hybrid components in rTKA and subsequent need for re-revision total knee arthroplasty for aseptic loosening (rrTKA-AL).

Methods

Design

This study was designed as a retrospective case-control study, and the study protocol was approved by the hospital's institutional review board. This study was conducted in accordance with the Declaration of Helsinki.[15]

Patients

All consecutive patients treated at our institution with a full rTKA using the Legion Revision Knee System (Smith and Nephew, USA) and underwent surgery between

2006 and 2020 were screened for the modes of fixation (hybrid fixation or fully cemented fixation), the use of additional fixation techniques (e.g. extensive bone impaction grafting or metaphyseal cones/sleeves), and the subsequent need for further re-revision surgery. Patients who required additional fixation techniques were excluded. Patients requiring rrTKA-AL (cases) were defined as those with clinical symptoms, radiological signs, and clinical findings of poor fixation of the implant at re-revision surgery indicative of aseptic loosening. Septic loosening was excluded by the use of six intraoperative cultures obtained at every rTKA. The controls were defined as rTKA patients who did not require rrTKA AL, no clear radiolucent lines on plane radiographs, and sufficient follow-up. We defined sufficient follow-up as a minimum of six years, as the majority of rrTKA-AL all occurred within six years of the previous rTKA. We therefore excluded patients who were operated on after 2017, patients with a re-revision surgery for any other reason within six years, and patients who died within six years of rTKA. From this cohort, a control group was defined based on sorted randomly generated numbers in a ratio of 1:2 to rrTKA-AL patients.

Radiological evaluation

Radiological assessment of the zonal fixation of the rTKA was performed on the first weightbearing anteroposterior (AP) and lateral radiograph at six weeks post-operatively. Radiological rating scores for zonal fixation in the three anatomical zones were determined. Epiphyseal fixation was scored by the height of the bone resection level above (2), at (1), or below (0) the tip of the fibular head and was measured on the lateral radiograph (Figure 1). Metaphyseal fixation was scored by the number of adequately cemented zones (0 to 4) at the level of the roughened grit-blasted titanium taper of the tibial stem on both the AP and lateral radiographs. Adequate cementing was defined as ≥ 2 mm cement interdigitation at ≥ 50% of the taper length (Figure 1). Diaphyseal fixation was scored as the canal filling ratio (CFR) at the widest, most distal part of the stem and was calculated using the method described by Fleischman et al.[13] All radiographs were assessed in random order by three independent observers, who were blinded to group allocation.

Statistical analysis

Parametric tests or alternative non-parametric equivalents were used to compare the demographics between the rrTKA-AL group and the control group. Intraclass correlation coefficient (ICC) was calculated to quantify the agreement between observers. For the radiological evaluation in further analyses, the modus of the three observers was used for the epiphyseal and metaphyseal zonal fixation scores and the mean value of the CFR. Univariate analysis was performed to investigate the association between a variable and rrTKA-AL. Multivariate logistic regression analysis was performed to determine the association between the zonal fixation scores and

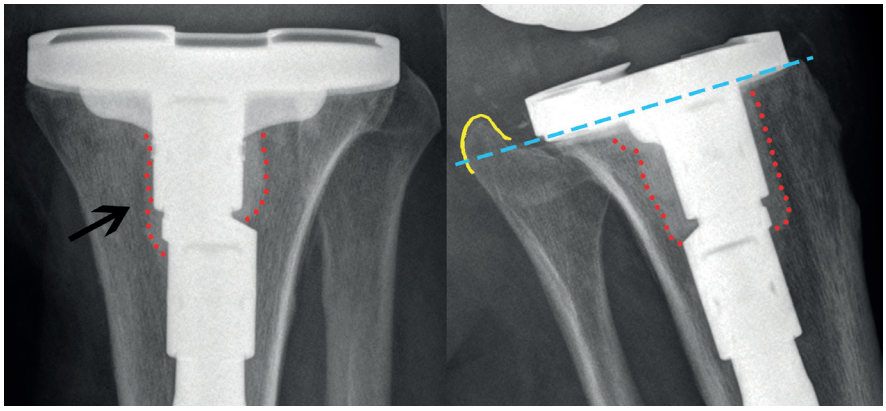

Figure 1: Anteroposterior (AP) and lateral radiographs of the proximal tibial revision total knee arthroplasty (rTKA) component. On the left, the AP radiograph is shown with the cemented zones of the metaphysis indicated by the red dotted line. The medial cement mantel (black arrow) is insufficient (< 2 mm). On the right, the lateral radiograph is shown with a bone resection level (blue dashed line) below the fibular head (yellow) and sufficient cement mantle on both the anterior and posterior part of the taper. In total, three out of four metaphyseal zones are sufficiently cemented in this example.

rrTKA-AL. The area under the curve (AUC) was calculated to determine the discriminative ability of the model between rrTKA-AL and control cases. Normally distributed data were presented using the mean and SD, and non-normally distributed data using the median and IQR. Statistical analysis was performed using STATA (Stata/IC 13.1, StataCorp, USA) and R version 4.1.3 (R Foundation for Statistical Computing, Austria, 2022).

Results

In total, 1,366 full rTKA in 1,348 patients were performed with the Legion Revision Knee System. Of these, 1,173 (85.9%) revision tibial components were fixed with the hybrid technique. rrTKA-AL was required in 35 knees of which two were excluded for further analysis: one had a perioperative periprosthetic fracture during rTKA which eventually resulted in rrTKA-AL, and the other required rrTKA-AL due to insufficient cementing within a metaphyseal cone, which was retained during rrTKA-AL.
The control group was derived from the 1,138 rTKAs that were not revised for aseptic loosening. Of those, a total of 344 knees were excluded. There were 280 knees excluded due to having inadequate follow-up and surgery after 2017; 44 knees having

re-revision for any other reason within six years of rTKA; the use of additional fixation methods (n = 35); death within six years of rTKA (n = 27); or clear radiolucent lines on radiographs (n = 16). Of those patients with clear radiolucent lines, ten had no or minor clinical complaints with stable radiolucent lines on serial radiographs. Six patients had suspected loosening, of whom two had minor complaints, two had a high index of suspicion of a periprosthetic joint infection following joint aspiration, one patient had suspected loosening but refused a re-revision, and one patient was scheduled and awaiting re-revision. Patients could have had more than one exclusion criterion; a flowchart is shown in Figure 2.

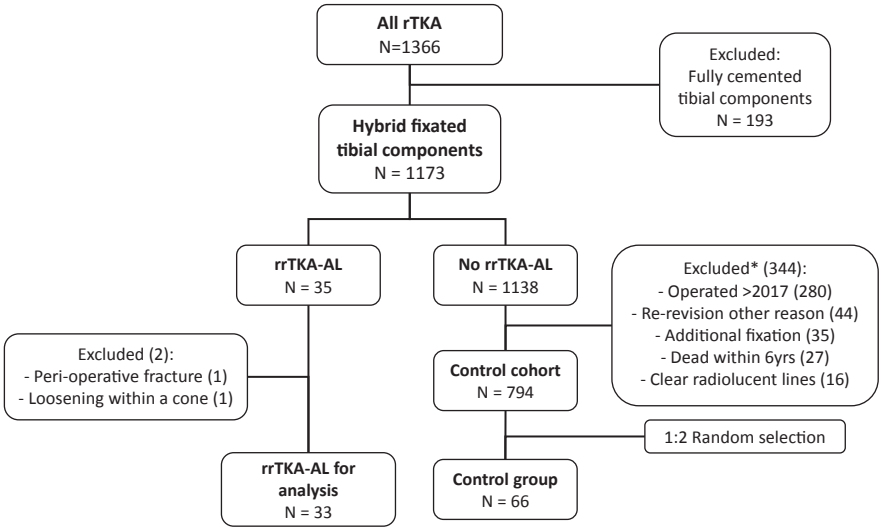

Figure 2: Flowchart of revision total knee arthroplasty (rTKA) components. *Patients could have had more than one exclusion criterion. rrTKA-AL, re-revision total knee arthroplasty for aseptic loosening.

Patient characteristics of the two groups are shown in Table 1. Patients with rrTKA-AL had had significantly more previous arthroplasty surgeries, had a higher Anderson Orthopaedic Research Institute (AORI) classification, and a higher incidence of prior use of a tibial diaphyseal stem component. Radiological zonal fixation scores showed a significantly lower epiphyseal bone resection level and fewer satisfactory cemented metaphyseal zones in patients with rrTKA-AL. The CFR did not differ between the two groups (Table 2). Multivariate logistic regression showed an association between rrTKA-AL and the zonal fixation scores of the epiphysis

Table 1. Demographic data of re-revision total knee arthroplasty for aseptic loosening and control patients.

	rrTKA-AL	control group	p-value
Number (N)	33	66	
Age yrs (mean ± SD)	62.4 ± 9.0	64.5 ± 8.6	0.13
Gender (Female : Male)	23:10	40:26	0.38
BMI (kg/m2, median ± IQR)	30 (26.9-33)	29.5 (26.1-33)	0.73
ASA - 1 - 2 - 3	6 24 3	11 41 6	1.00
Smoking	5/32	4/56	0.28
DM %	2/33	10/60	0.20
Previous surgeries (N) - 1 - 2 - 3	27 5 1	63 3 0	**0.047**
AORI - T1 - T2A - T2B	 16 7 4	 53 3 0	**<0.001**
Prior stem	4/33	0/66	**0.011**
Reason (revision) - Aseptic - Septic - Instability - Malposition - Stiffness - Other	 15 6 7 2 2 1	 18 6 25 12 4 1	0.11
OR time (min, median ± IQR)	99 (90-108)	100 (88-112)	0.93
Stem length (N, 120mm/160mm)	27/6	52/14	0.80
Stem diameter (mm, median ± IQR)	16 (14-16)	16 (14-18)	0.34
Full augment	5/33	4/66	0.16
Liner thickness (mm, median ± IQR)	13 (11-15)	13 (11-15)	0.84
Liner constrained	10/33	25/66	0.51
Tibial tuberosity osteotomy	2/33	2/66	0.60
Time to rrTKA-AL (yrs, median ± IQR)	2.9 (1.8-4.1)		
Follow-up time (yrs, median ± IQR)		8.6 (7.3-10.2)	

AORI, Anderson Orthopaedic Research Institute classification; ASA, American Society of Anesthesiologists; DM, diabetes mellitus; rrTKA-AL, re-revision total knee arthroplasty for aseptic loosening.

(OR 0.43; 95% CI 0.23 to 0.76; p = 0.006) and the metaphysis (OR 0.50; 95% CI 0.30 to 0.79; p = 0.004). The AUC of this model was 0.74 (Figure 3) and additional variables (CRF, prior stem, previous surgeries) did not improve the model fit (all p > 0.185).

Table 2. Assessment of radiological fixation of the epiphysis, metaphysis, and diaphysis.

	rrTKA-AL	control group	p value
Epiphysis (modus)			
- 0	14	12	**0.018**
- 1	12	25	
- 2	7	29	
Metaphysis (modus)			
- 0	2	0	**0.031**
- 1	4	5	
- 2	12	14	
- 3	10	22	
- 4	5	25	
Diaphysis (mean)			
- CFR (%, median ± IQR)	0.82 (0.76-0.86)	0.83 (0.77-0.88)	0.74

CFR, canal filling ratio; rrTKA-AL, re-revision total knee arthroplasty for aseptic loosening.

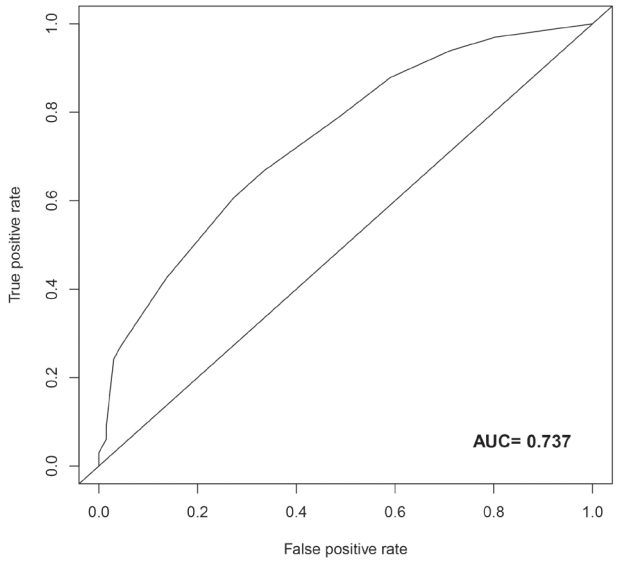

Figure 3: Area under the curve (AUC) analysis of the epiphyseal and metaphyseal fixation assessment in relation with re-revision total knee arthroplasty for aseptic loosening.

Interobserver agreement was good with an ICC of 0.79 (95% CI 0.72 to 0.85) for epiphyseal assessment, ICC 0.87 (95% CI 0.81 to 0.91) for metaphyseal assessment, and ICC 0.79 (95% CI 0.70 to 0.86) for diaphyseal assessment.

Discussion

This is the first study in which zonal fixation of all three anatomical zones has been assessed and related clinically to the subsequent need for rrTKA-AL. The results showed an association between the epiphyseal bone resection level and the number of adequately cemented metaphyseal zones, and a higher risk of rrTKA-AL in hybrid tibial revision components. Other predicting factors for rrTKA-AL were multiple previous rTKAs, a higher AORI score, and the previous use of a tibial diaphyseal stem component. The interobserver agreement of radiological assessments of zonal fixation was good.

The association between the epiphyseal and metaphyseal zonal fixation has been previously described for primary TKA. In a study by Hampton et al,[16] an association was found between the number of inadequate cemented zones (< 2 mm cement penetration) at primary TKA and later revision for aseptic loosening. This is similar to our findings on the metaphyseal zonal fixation in rTKA. For the epiphyseal zonal fixation, we decided to score the height of the bone resection level as an indicator of zonal fixation. In contrast to primary TKA, the bone of the epiphysis is compromised in the vast majority of rTKAs and to allow and achieve good fixation in rTKA, a stable, flat, and clean surface needs to be prepared following removal of compromised bone and/or cement as necessary.[8] This results in a lower bone resection level and a reduced fixation surface area because of the anatomy of the proximal tibia. This may explain the association between the height of the bone resection level and the risk of rrTKA-AL.

For the diaphyseal zonal fixation we found no association between the CFR and the risk of rrTKA-AL; unlike previous studies.[13,14] The mean CFR reported by Fleischman et al.[13] was significantly lower than that in the present study (53.3% vs 81.8%), which may explain this difference. In the study by Lee et al.,[14] aseptic loosening was defined by radiological assessment while only four of 17 loose knees were revised, which may represent an overestimation of the diagnosis of aseptic loosening. The results of the present study may indicate either that the diaphyseal zonal fixation with the hybrid fixation method is of lesser value compared to the epiphyseal and metaphyseal zonal fixation, or that the diaphyseal fixation measured by the CRF is not the best way to evaluate diaphyseal fixation.

Besides the fixation in the epiphyseal and metaphyseal zones, multiple revision surgeries in the past, a higher AORI score, and the presence of a prior tibial diaphyseal

stem were the observed differences between the two groups. This is in line with the previous literature and all these factors relate to bone loss and, as a consequence, less bone being available for zonal fixation.[17]

The results of this study therefore do not fully support the zonal fixation hypothesis of Morgan-Jones et al.,[8] as the three zones do not seem to be of equal importance when hybrid fixation methods are used in rTKA. We believe that in a substantial number of the rTKAs, the epiphyseal and metaphyseal zonal fixation is of greater importance than the diaphyseal zonal fixation. In patients with limited epiphyseal and metaphyseal bone loss and with sufficient or adequate fixation in those two zones, then the diaphyseal fixation may be of less value. Previous studies provide support to this theory, with good survival for stemless rTKA and with additional metaphyseal fixation and sufficient stability as assessed by finite element analysis.[18–20] Furthermore, in cases with substantial epiphyseal bone loss and a resulting lower epiphyseal bone cut, additional metaphyseal fixation may be preferred to diaphyseal fixation with a press-fit stem; an example of this fixation method is shown in Figure 4. Finally, in those cases with compromised epiphyseal, metaphyseal, and diaphyseal zones caused by the presence of a prior stem, fixation may depend on (additional) metaphyseal fixation only. This makes the metaphyseal fixation essential in every rTKA case.[21]

A strength of the current study is the large number of uniformly fixed tibial components, which makes it possible to establish the association between zonal fixation and the risk of rrTKA-AL. This study also, however, has potential limitations. First, we did not evaluate epiphyseal fixation directly, but assessed the height of the epiphyseal bone resection level and not the implant-cement-bone interface. We chose this method as the bone of the epiphysis is compromised in the majority of rTKAs, and cement fixation may not be as sufficient within the compromised bone. Moreover, it is difficult to assess the interface as the component can obscure the interfaces when a radiograph is not obtained perfectly perpendicular to the axis of the component. We are not aware of a superior alternative method of assessment. Second, although we believe bone quality is important for implant fixation, it was not assessed or recorded at operation. Third, we defined revision for loosening as the endpoint, and some unrevised but loose implants may have been excluded in the analysis. Therefore, the true rate of aseptic loosening may be higher than the re-revision rate for aseptic loosening. Nevertheless, we decided to include only those knees with confirmed loosening at re-revision and no evidence of infection following negative intraoperative cultures.

The results of this study may be helpful for surgeons to optimize their pre- or intraoperative decision-making for appropriate tibial implant fixation. Additional fixation devices can be considered in patients who are at risk for a future rrTKA-AL with a previous low tibial bone resection level, a previous stem, or evidence of

extensive bone loss. Additional metaphyseal fixation devices such as cones and sleeves have proven their value in the outcomes of rTKA in severe bone defects,[11,12] but also the use of highly porous wedges or augments may help in achieving good fixation in the epiphyseal zone where there has been a previous low tibial bone resection level. For every patient with metaphyseal cement fixation, achieving interdigitation of cement is essential. To obtain this, we apply cement to both the component as well as in the metaphysis by the finger-packing technique as described by Vanlommel et al.[22]

In conclusion, this is the first study that has shown a clinical association between the zonal fixation achieved and subsequent risk of re-revision surgery for aseptic loosening of the tibial component in hybrid rTKA. The height of the epiphyseal bone resection level and the cementing quality in the metaphyseal zone appear to be crucial for preventing rrTKA-AL. These results can help orthopaedic surgeons to optimize their surgical technique at revision knee arthroplasty surgery.

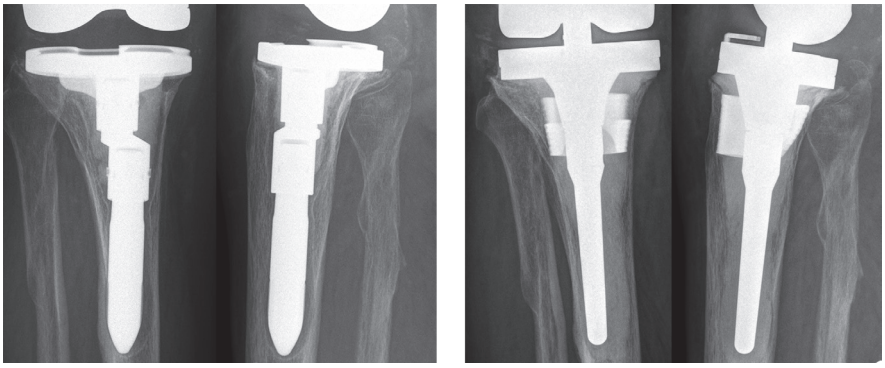

Figure 4: Anteroposterior (AP) and lateral X-rays of a rTKA with radiologic sign of loosening with clear radiolucent lines and migration (left). The bone resection level is at the level of the fibular head (lateral Xray). On the right, the postoperative X-rays (AP and lateral) of the re-revised implant with a full augment, additional metaphyseal fixation with a cone, and a fully cemented stem.

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Chapter 4

Superior Survival of Fully Cemented Fixation Compared to Hybrid Fixation in a Single Design Rotating Hinge Knee Implant

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Abstract

Introduction

Clinical observations revealed higher rates of aseptic loosening for hybrid fixated rotating hinge knee implants compared to fully cemented ones. We hypothesize that the use of a fully cemented fixation technique had a higher survival rate for aseptic loosening compared to a hybrid fixation technique in a rotating hinge knee implant.

Methods

All procedures of patients who were treated with the RT-PLUS® rotating hinge knee implant (Smith & Nephew, Memphis, TN, USA) between 2010 and 2018 were included. Primary outcome was revision for aseptic loosening. Kaplan-Meier survivorship and Cox proportional hazard regression analysis were performed to calculate survival rates and hazard ratios.

Results

A total of 275 hinge knee implants were placed in 269 patients (60 primary procedures, 215 revisions). Median follow-up was 7.3 ± 3.9 years. In total, 24 components (16 hybrid femur, 2 fully cemented femur, 6 hybrid tibia; all revision procedures) in 19 patients were revised for aseptic loosening. Kaplan-Meier survivorship analysis showed superior survival rates of fully cemented components (femur 97.1%; tibia 100%) compared to hybrid fixated components (femur 89.5%; tibia 95.9%) at the 10-year follow-up. Multivariate Cox hazard analysis showed a significantly higher risk of aseptic loosening for hybrid fixated components, a prior stemmed component and the femoral component.

Conclusion

Fully cemented fixation showed superior survival rates for aseptic loosening compared to hybrid fixation in a single design rotating hinge knee implant. A prior stemmed component appears to be a risk factor for aseptic loosening and the femoral component seems to be more prone to loosening.

Introduction

Rotating hinge knee implants are highly constrained knee prostheses used in cases with ligament insufficiency and/or extensive bone loss.[1] Due to the constraint nature of the implant, multidirectional stresses are directed through the bone-(cement-) stem interface and hinge mechanism. Together with the complexity of these cases, this leads to relatively high reported rates of aseptic loosening up to 15%.[2]

Rotating hinge knee implants are mainly fixated with either a cemented component in combination with a cemented stem (fully cemented) or with a cemented component with an uncemented press-fit stem (hybrid fixation). Both fixation techniques have shown comparable outcomes in less constrained implants.[3–6] However, no evident clinical data are available about the preferred method of fixation in relation to implant survival in hinge knee implants. Using a bone model and finite element analysis, El Zayat et al. showed lower stresses and micromotion in long cemented tibial stems compared to uncemented ones.[7] Guttowski et al. found higher pull-out forces in fully cemented femoral components compared to hybrid fixated femoral components in a cadaver study.[8] In the discussion of the paper by Farid et al. [9], the authors reported higher rates of aseptic loosening when using a hybrid fixation with an uncemented stem and therefore abandoned this technique.

After the introduction of a hybrid fixated rotating hinge knee implant with a press-fit stem, we encountered several cases of early aseptic loosening in our clinic and changed our fixation strategy to a fully cemented technique in every case with this implant. The goal of this study was to investigate these two cohorts and compare the rate of aseptic loosening. We hypothesize that the survival rate for aseptic loosening in a specific rotating hinge knee implant was higher with the use of a fully cemented technique compared to a hybrid fixation technique.

Material and Methods

Patients

For this retrospective cohort study, all procedures of patients who were treated with the RT-PLUS® rotating hinge knee implant (Smith and Nephew, Memphis, TN, USA) between January 2010 and December 2018 were included. All procedures were performed by high-volume arthroplasty surgeons in a tertiary orthopedic center. This study was approved by the institutional review board of the Sint Maartenskliniek.

Intervention

A medial parapatellar approach was used in every case. In revision cases, six cultures were taken routinely for exclusion of infection. Bone defects were classified by the

Anderson Orthopedic Research Institute classification (AORI)[10] and were treated with augments, (solid) bone grafting or additional metaphyseal cones. The modular hinge system consists of femoral and tibial components in combination with a straight conical cemented stem or a straight uncemented press-fit stem. The uncemented stems did have an option for 3.75 mm offset on the tibial side only. In the hybrid fixation technique, the intramedullary canal was reamed to expose cortical bone to achieve press-fit anchoring. Vacuum-mixed antibiotic-impregnated polymethyl methacrylate (PMMA) cement was loaded onto the epiphyseal and metaphyseal parts of the components and bone surface before placement by the use of a cement gun. In the fully cemented technique, the bone surface was prepared and after the insertion of a cement plug cleaned with pulse lavage irrigation. PMMA cement was loaded onto the components and pressure injected into the intramedullary canal by the use of a cement gun before placement. Radiographs of the two fixation techniques are shown in Figure 1. We started to use the hinge knee implant with uncemented stems predominantly and changed to the nearly exclusive use of cemented stems in 2014 (Fig. 2). Decisions regarding the mode of stem fixation and stem length were made by the operating surgeon.

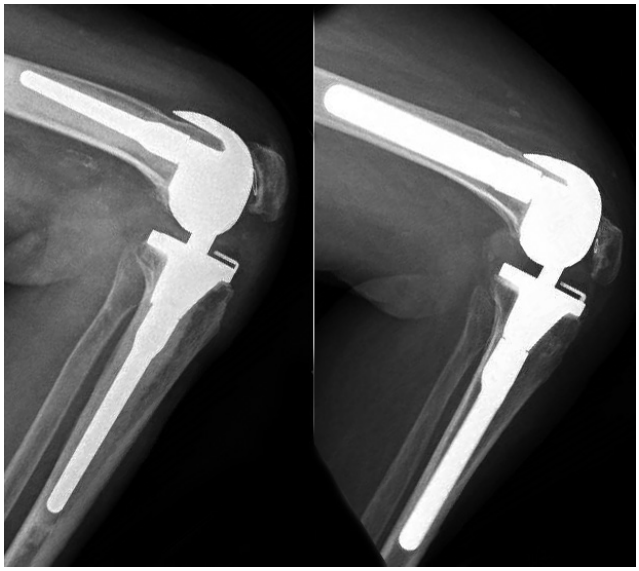

Figure 1: Radiographs of a fully cemented implant (left) and a hybrid fixated implant (right).

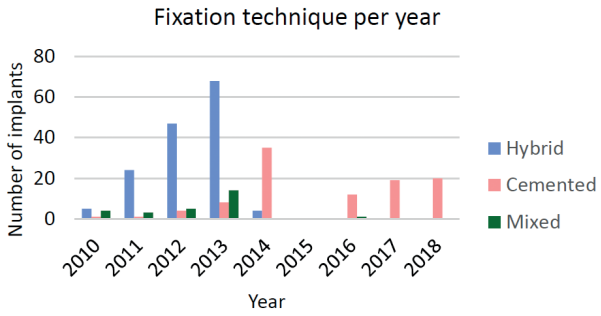

Figure 2: The use of fixation technique over time (years). In the second half of 2014 we started to use another type of a fully cemented hinge in parallel which explained the lower number of implants from 2015. Outcome and survival of the other hinge system was published previously. [20]

Outcomes

Patient demographics (e.g., gender, age), surgical data (e.g., reason for revision, AORI classification) and postoperative outcome data (reoperations, Knee Society Score (KSS)) were collected from the electronic medical record system. For uncemented stems, the canal filling ratio (CFR) was calculated by the method of Fleischman et al.[5] The reason for revision surgery was classified as described earlier.[11]

Primary outcome was the time to revision for aseptic loosening of a major component (femur and/or tibia). Aseptic loosening was defined as a loose component observed during revision surgery without the presence of a periprosthetic joint infection according to the definition of Parvizi et al.[12] Secondary outcome measures were component revision for any reason and reoperation. A reoperation was defined as any additional surgery performed on the same knee. The Dutch Arthroplasty Register (LROI) was contacted to double check for missed revisions of our cohort that had been performed in other Dutch hospitals.

Statistical analysis

Descriptive statistics were used to summarize the data. Parametric tests or non-parametric equivalents were used to compare the demographics between patient groups. Kaplan-Meier survivorship analysis for aseptic loosening was performed per component since fixation techniques could be different between the femoral and tibial component (mixed fixation) and aseptic loose components could have been revised partially. Survival rates were calculated for revision for any reason and reoperation were performed per patient. Failure was defined as revision for aseptic loosening of a component, revision for any reason or reoperation on the same

knee, respectively. Patients who died, who had revision for any other reason (femur and/or tibia) of a component and who were lost to follow-up (last date of follow-up) were considered censored. Log-Rank tests were performed for testing equality of survivor functions. To assess the association between fixation technique and aseptic loosening, a multivariable Cox proportional hazard regression analysis was performed to calculate hazard ratios (HR) and adjust for potential confounders. Proportional hazards assumptions were tested. Statistical analysis was performed using STATA (Stata/IC 13.1, StataCorp LP, USA). The level of statistical significance was set at $p < 0.05$.

Results

In total, 275 RT-PLUS® rotating hinge knee implants were placed in 269 patients (60 primary procedures, 215 revisions). The cohort was predominantly female (69%), with a mean age of 65.5 ± 14.9 years. Of the 275 implants, 248 had a uniform fixation technique for both components (148 fully hybrid, 100 fully cemented), while 27 implants had a mixed fixation technique for the components (15 hybrid femur and fully cemented tibia, 12 fully cemented femur and hybrid tibia). The median follow-up was 7.3 ± 3.9 years, with a minimum of 2 years for non-failed implants. Characteristics of the total cohort and the groups are shown in Table 1. In the fully cemented group, a relatively higher number of primary procedures were performed and more additional cones were used, but the follow-up was shorter. Thirty-six patients died at a median time from operation of 6.2 ± 2.7 years, all due to unrelated causes.

In total, 24 components (16 hybrid femur, 2 fully cemented femur, 6 hybrid tibia; all revision procedures) in 19 patients were revised for aseptic loosening at a median time from operation of 2.7 ± 3.2 years. Kaplan-Meier survivorship analysis for aseptic loosening of the femoral component showed a survival rate of 89.5% (95% CI 83.4–93.4) for the hybrid fixated components and 97.1% (95% CI 88.1–99.3) for fully cemented components at the 10-year follow-up, which was statistically significantly different ($p=0.03$) (Fig. 3). For the tibial component, the survival rate was 95.9% (95% CI 91.1–98.1) for hybrid fixated components and 100% for fully cemented components at the 10-year follow-up ($p=0.08$) (Fig. 4). Multivariate Cox hazard analysis showed a significantly higher risk of aseptic loosening for hybrid fixated components (HR 6.7; 95% CI 1.6–28.4; $p<0.01$), a prior stemmed component (HR 6.0; 95% CI 2.6–14.2; $p<0.01$) and for the femoral component (HR 4.1; 95% CI 1.9–8.8; $p<0.01$).

Kaplan-Meier survivorship analysis with revision for any reason as an end point showed a survival rate of component revision of 84.1% (95% CI 78.6–88.3) at the 10-year follow-up. Survival rate for reoperation was 72.5% (95% CI 66.5–77.7) at the 10-year follow-up and reasons for reoperation are shown in Table 2. Canal filling ratio

Table 1. Demographics of all cases and different fixation groups.

	All cases	Hybrid fixation	Fully cemented fixation	Mixed fixation	p value
Amount (N)	275	148	100	27	N/A
Female/Male	191/84	98/50	69/31	24/3	0.06
Age (yrs, median±IQR)	65.5 ± 14.9	64.6 ± 13.5	66.5 ± 15.8	66.6 ± 20.6	0.71
BMI (kg/m^2, median±IQR)	29.1 ± 7.6	29.3 ± 6.9	29.1 ± 8.2	28.1 ± 8.8	0.61
ASA (%)					
- 1	12.4	15.8	8.3	8.7	0.44
- 2	74.9	71.9	79.4	73.9	
- 3	12.7	12.2	12.4	17.4	
Diabetes (%)	14.0	13.1	14.3	17.4	0.77
Revision procedure (%)	78.2	83.8	71.0	74.1	**0.05**
Previous stem (%)					
- Femur/Tibia	14.5/25.1	12.8/25.0	18.0/26.0	11.1/22.2	0.50/0.96
Reason (primary) (%)					
- Deformity	58.3	66.7	48.3	71.4	0.74
- Post-trauma	25.0	16.7	31.0	28.6	
- Instability	10.0	12.5	10.3	-	
- Stiffness	6.7	4.2	10.3	-	
Reason (revision)					
- Instability	31.2	33.9	28.2	25.0	0.53
- Stiffness	28.4	26.6	32.4	25.0	
- Septic	15.3	15.3	16.9	10.0	
- Aseptic	12.6	11.3	12.7	20.0	
- Malposition	10.7	12.1	8.5	10.0	
- Fracture	1.9	0.8	1.4	10.0	
AORI (%) Femur/Tibia					
- 1	49.3/72.6	54.8/76.6	46.5/67.6	25.0/65.0	0.06/0.13
- 2A	23.3/7.9	23.4/7.3	19.7/8.5	35.0/10.0	
- 2B	17.7/11.2	12.9/12.1	25.4/8.5	20.0/15.0	
- 3	9.8/8.4	8.9/4.0	8.5/15.5	20.0/10.0	
Allograft (%) Femur/Tibia	2.9/2.9	2.7/2.7	2.0/3.0	7.4/3.7	0.29/0.88
Cones (%) Femur/Tibia	1.5/3.3	0/0	4.0/8.0	0/3.8	**0.04/<0.01**
Follow-up (yrs, median±IQR) Femur/Tibia	7.2 ± 3.9/ 7.3 ± 3.8	7.7 ± 1.5/ 7.8 ± 1.5	4.2 ± 3.9/ 4.2 ± 3.8	7.4 ± 3.0/ 7.5 ± 1.3	**<0.01/ <0.01**
KSS (preoperative) Clinical/Functional	49.5 ± 22/ 37.5 ± 25.5	51 ± 21/ 40 ± 20	60 ± 40/ 30 ± 15	43 ± 25/ 30 ± 25	0.10/ 0.05

Bold numbers represents significant differences. N: number, IQR: interquartile range, ASA: American Society of Anesthesiologists, AORI: Anderson Orthopedic Research Institute classification; KSS: Knee Society Score; N/A: not applicable.

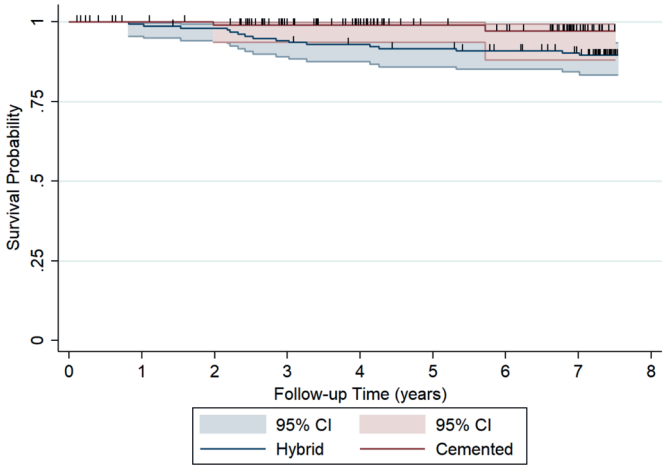

Figure 3: Kaplan Meier survivorship curves for aseptic loosening of the femoral component. Vertical spikes represent censored data.

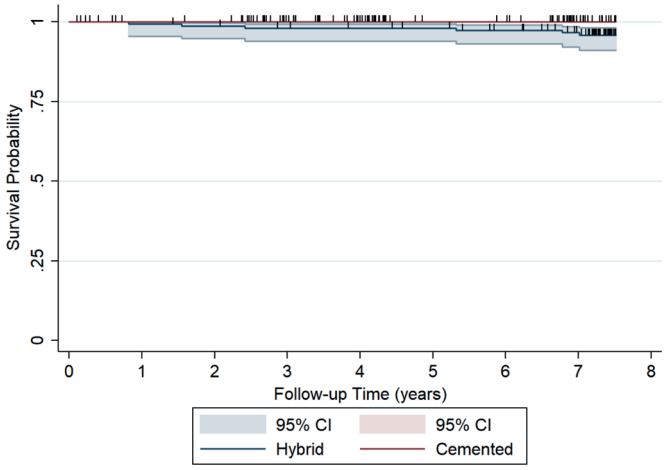

Figure 4: Kaplan Meier survivorship curves for aseptic loosening of the tibial component. Vertical spikes represent censored data.

was significantly lower on the femoral side compared to the tibial side (55.6% vs 64.7, p<0.01), but did not differ between aseptic failed uncemented stems and non-failed uncemented stems, both for the femoral (p=0.11) and tibia component (p=0.17).

Table 2. Reasons for reoperation and number of patients.

Reoperations	Number of patients
Infection	
- DAIR	5
- 1 or 2 stage reimplantation	5
- Amputation	6
- Arthrodesis	2
- Prolonged wound leakage (negative cultures)	5
Aseptic loosening	
- Revision	18
- Arthrodesis	1
Extensor apparatus	
- Patellar maltracking	8
- Patellar component placement	2
- Extensor apparatus reconstruction	1
- ITB release	1
Stiffness	
- MUA	5
- Scopic or open arthrolysis	6
- Arthrodesis	1
Other	
- Periprosthetic fracture	4
- Malposition	1
- Mechanism failure	1
- Pain	3

NB: one patient can have multiple reoperations. In case of multiple operations for one indication only the major one was counted (e.g., multiple DAIRs before amputation, only amputation was counted). DAIR: debridement, antibiotics and implant retention, ITB: iliotibial band, MUA: manipulation under anesthesia.

Discussion

The results of this study showed superior survival for aseptic loosening for fully cemented fixation compared to hybrid fixation in a single design rotating hinge knee implant. This is a confirmation of our hypothesis and the clinical observations which formed the basis for the shift towards the use of cemented stem fixation only. Having had a prior stemmed component appeared to be a risk factor for aseptic loosening, and the femoral component is more prone to loosening.

No comparable clinical studies between hybrid fixation and fully cemented fixation have been performed on rotating hinge knee implants. Preclinical experiments with finite element analysis and cadaver studies showed favourable results for the use of cemented stems,[7,8] which was in line with our observations. Most clinical studies on hinge knee implant cohorts consist of fully cemented implants and report aseptic loosening rates of 0–10.0%; however, different follow-up periods make comparisons difficult.[9,13–20] Some have performed a survival analysis for aseptic loosening and showed rates of around 90% at the 10-year follow-up.[21,22] For hybrid fixated rotating hinged implants, less literature is available. Farid et al.[9] described a high rate of aseptic loosening with the use of an uncemented grid-blasted stem (27%) and abandoned this fixation technique. A cohort of hybrid fixated hinge implants described by Giurea et al.[23] showed aseptic loosening in 1.3% of their patients, but in predominantly primary procedures and after a short-term follow-up. The current study showed a significantly higher risk of aseptic loosening for hybrid fixated rotating hinge implants at 10-year follow-up. We think it is easier to achieve an adequate fixation with a fully cemented technique compared to the hybrid fixated technique in cases with extensive bone loss as we described below.

The femoral component was more prone to loosening compared to the tibial component. This is similar to the observations by Farid et al.[9] in which 20 femoral components (15%) and only 2 tibial components (1.5%) were revised for aseptic loosening. They believed that the femoral component is subject to more bending and torsion stresses due to the natural deviation of the femoral anatomic axis from the mechanical axis of the lower extremity. Another explanation for higher torsion stresses of the femoral component lies within the design of the rotation hinge mechanism. The rotational free axis of the tibial component is always parallel to the longitudinal axis of the tibial stem, which diminishes torsion stresses. For the femoral component, this axis changes direction, while the knee flexes and varus or valgus stresses will convert to torsion stresses acting on the femoral component and stem.

The anatomical shape of the distal femur and its variations in antecurvation and anatomical axis compared to the mechanical axis could be another explanation for the higher rate of aseptic loosening of the femoral component. A large femoral canal diameter in the anteroposterior direction appeared to be an increased risk factor for

aseptic loosening in cemented stems.[24] For uncemented stems like the ones of the RT-PLUS implant, it can be difficult to align and achieve press fit anchorage with the straight cylindrical profile and no-offset femoral stem. In cases of femoral loosening, cortical erosion at the distal end of the uncemented stem was often seen as a first sign. A limited contact area due to the relatively blunt tip of the stem could cause high stresses, which could explain this localized osteolysis. In our cohort, we found a significantly lower CFR on the femoral side compared to the tibial side, which may support this theory. However, no differences in CFR were found between aseptic failed uncemented stems and non-failed uncemented stems, and the median CFR was higher compared to reports in the literature on revision knee implants.[5] Further development of more anatomically designed stems might solve this disadvantage of the uncemented option.

Sufficient component fixation can be challenging in complex cases with additional bone loss. The AORI classification is the most commonly accepted and widely used classification for bone loss assessment.[10] In the present cohort, the degree of bone loss by the AORI classification was not associated with aseptic loosening in the Cox model, while a prior stemmed implant was strongly associated with aseptic loosening. It is likely that aseptic loosening could be the result of impaired metaphyseal and diaphyseal bone as a consequence of the prior stem, which is only partially quantified in the AORI classification. In revision knee surgery, adequate fixation in the metaphyseal and diaphyseal area is strongly advised to obtain fixation in at least two of the three zones since the epiphyseal area is impaired in most revision cases.[25] New classifications that assess bone loss in all three zones might have more clinical implications in knee revision surgery.[26]

Previous clinical observations and the results of this study have changed our approach towards fixation for hinge knee implants. We currently use cemented fixation for all of our hinge implants and pay more attention to appropriate fixation of the femoral component, especially in cases with a prior stemmed component. With the recent introduction of more anatomically designed cones, we started to use them more commonly in metaphyseal and diaphyseal bone defects of both the femur and tibia.

Overall revision rates for any reason and reoperation rates are comparable with previous cohorts.[9,21,27,28] Only one mechanical failure of the hinge mechanism occurred because of a jammed hinge mechanism.

This study has several limitations due to its retrospective design. Since we started this cohort with the hybrid fixation technique, the follow-up period was longer in this group, which may have led to more cases of aseptic loosening. Although this difference in follow-up exists, most cases of aseptic loosening occur within the first 3 years after implantation. Therefore, we do not think that the shorter follow-up in the fully cemented group has influenced our findings.

Another difference between the two groups was the use of additional cones. Since cones were introduced later on in the cohort, they were used in the fully cemented group only. Although cones might have a positive effect on the fixation of the implant, we were not able to assess the effect on survival due to the small numbers (N=13) that were used. Because most of the loosenings were femoral components and the number of cones used on the femoral side was small (N=4), the effect of cones on the overall survival of the fully cemented group will be negligible. In addition, the use of cones was not found to be one of the influencing factors in the Cox proportional hazard regression analysis.
A third dissimilarity was the higher percentage of revision procedures in the hybrid fixation group. This difference might have influenced the survival of the hybrid group negatively. We believe that not the revision itself, but the amount of concomitant bone loss is an influencing factor for aseptic loosening, as a prior stemmed implant was a strong predictive factor.
Finally, the mode of stem fixation was decided upon by the operating surgeon, which could have led to selection bias. We cannot exclude this type of bias, however, due to the abrupt change in mode of fixation in our clinic and the correction of possible influencing factors by analyzing this effect was minimized.

Conclusion

A fully cemented fixation showed superior survival rates for aseptic loosening compared to a hybrid fixation using a single design rotating hinge implant. A prior stemmed component is a risk factor for aseptic loosening and the femoral component appears to be more prone to loosening.

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Chapter 5

Micromotion of a Cemented Hinge-type Knee Revision System, Measured with Model-based RSA

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Abstract

Introduction

Rotating hinged knee implants are highly constrained prostheses used in cases in which adequate stability is mandatory. Due to their constraint nature, multi-directional stresses are directed through the bone–cement–implant interface, which might affect fixation and survival. The goal of this study was to assess micromotion of a fully cemented rotating hinged implant using radiostereometric analysis (RSA).

Methods

20 patients requiring a fully cemented rotating hinge-type implant were included. RSA images were taken at baseline, 6 weeks, and 3, 6, 12, and 24 months post-operatively. Micromotion of femoral and tibial components referenced to markers in the bone was assessed with model-based RSA software, using implant CAD models. Total translation (TT), total rotation (TR) and maximal total point motion (MTPM) were calculated (median and range).

Results

At 2 years, TT_{femur} was 0.38 mm (0.15–1.5), TR_{femur} was 0.71° (0.37–2.2), TT_{tibia} was 0.40 mm (0.08–0.66), TR_{tibia} was 0.53° (0.30–2.4), $MTPM_{femur}$ was 0.87 mm (0.54–2.8) and $MTPM_{tibia}$ was 0.66mm (0.29–1.6). Femoral components showed more outliers (> 1 mm, > 1°) compared with tibial components.

Conclusion

Fixation of this fully cemented rotating hinge-type revision implant seems adequate in the first 2 years after surgery. Femoral components showed more outliers, in contrast to previous RSA studies on condylar revision total knee implants.

Introduction

Rotating hinged knee implants are the most constrained type of knee prosthesis. They are mostly used in complex revision knee surgery with insufficient ligaments or extensive bone loss. Due to the hinge mechanism, relatively high multidirectional stresses will be transferred across the bone–implant interface. These forces, in combination with impaired bone, make appropriate fixation of hinge implants in revision knee surgery challenging.

Radiostereometric analysis (RSA) can be used to evaluate the stability of an implant, with early detection of micromotion between the implant and the surrounding bone.[1] The degree of micromotion assessed by RSA in the first 2 years after surgery is associated with late revision for aseptic loosening in primary total knee arthroplasty (TKA).[2,3] From the sparse data available on condylar revision knee implants, it can be observed that higher degrees of micromotion do not result in aseptic loosening later on.[4–6]

For rotating hinged knee implants, no RSA data are currently available. This information is required to determine the acceptable limit of micromotion for the long-term survival of a stable implant. Furthermore, RSA data can aid in evaluating the pattern of migration and potential failure modes which might be different to primary or condylar revision implants due to forces directed through the rigid hinge mechanism.

The primary objective of our study was to investigate the stability of the fixation of a fully cemented rotating hinged knee implant in revision surgery within the first 2 years postoperative. The secondary objective was to assess clinical and functional performance in these patients.

Patients and Methods

Design and patients

We conducted a single-center, cohort study from 2017 to 2021 at the Sint Maartenskliniek, Nijmegen, the Netherlands. 20 patients requiring a revision total knee replacement with a hinged type knee system were included in this study. Exclusion criteria were BMI > 40, active infection (systemic/local), disorders that could compromise compliance with the follow-up period, known sensitivity to materials in the device, and no visible markers in both the femoral and tibial components on the first postoperative RSA radiograph.

The present study was reported according to STROBE guidelines.

Intervention

All patients received the Legion Hinge Knee (HK) System (Smith & Nephew, TN, USA) and were operated on by orthopedic surgeons specialized in knee revision surgery. We used a medial approach and a fully cemented technique for all patients. Previous implants were carefully removed, and 6 interface cultures were taken as per routine care. Realigned refresh cuts were performed, and the bone canal was prepared for stem fixation. The canal was reamed until cortical contact was obtained and a 2-mm downsized stem was chosen for a sufficient cement mantle. Stem length (120 or 160mm) was dependent on the surgeon's preference to obtain sufficient fixation. Bone loss was assessed by the Anderson Orthopaedic Research Institute (AORI) bone stock classification and defects were treated with metal augments, cones, and/or bone grafting. The bone surface was cleaned with pulse lavage irrigation after placement of a polyethylene cement plug. Vacuum-mixed antibiotic-impregnated polymethyl methacrylate (Copal® G+C, Biomet Merck, Darmstadt, Germany) was loaded onto the components and retrogradely injected into the canal after tantalum beads for RSA were placed in the femur and tibia. The final components (tibia, femur) were cemented sequentially. All patellae were resurfaced or revised. A standard postoperative care protocol with direct full weight-bearing and 5-day antibiotic treatment was followed for all patients.

Primary outcome

The primary outcome parameter was micromotion of both the femoral and tibial components, measured with model-based RSA using a uniplanar setup with 1 ceiling-mounted X-ray tube and 1 mobile device. Patients were lying in a supine position, with standardized foot rotation to enable marker visibility throughout the follow-up period. Micromotion of the implant component was evaluated at predetermined time points (6 weeks, 3 months, 6 months, 1 year, and 2 years postoperatively) compared with the baseline RSA radiograph taken after initial weight-bearing shortly after surgery. At 6 weeks, double RSA radiographs were performed in all patients to assess the precision with measurement error statistics (mean with standard deviation).[7] Accuracy was determined with a phantom study prior to patient inclusion. Model-based RSA (MBRSA) measurements with CAD models were performed with MBRSA software (Model-based RSA 4.2, RSAcore, Leiden, The Netherlands) to calculate translation (T) and rotation (R) of the component with reference to the bone markers. Translation was expressed in millimeters and rotation in degrees along or around the transverse (x), longitudinal (y), and sagittal (z) axes. Total translation (TT) was calculated as $TT = \sqrt{Tx^2 + Ty^2 + Tz^2}$ and total rotation (TR) was calculated as $TR = \sqrt{Rx^2 + Ry^2 + Rz^2}$. [8] Outliers in relation to TT and TR were defined as components moving > 1 mm or > 1° as described by Heesterbeek et al.[5] Maximum total point motion (MTPM) was the length of the translation vector of

the (virtual) marker on the implant that showed the greatest migration. All measurements were evaluated according to the condition number and rigid body error. ISO 16087:2013 was followed, which recommends a maximum condition number of 150 and a rigid body error < 0.35 to have reliable results.

Other outcome scores

During follow-up visits, clinical and functional outcome measures were collected in a standardized way by a research nurse. Outcome measures were the Knee Society Score (KSS), Knee injury and Osteoarthritis Outcome Score – Physical Function Short form (KOOS-PS), Oxford Knee Score (OKS), Oxford Knee Score – Activity and Participation (OKS-APQ), and visual analog scales (VASs) for pain and satisfaction. VAS scores ranged from 0 (no pain or dissatisfied) to 100 (worst pain or satisfied). Additionally, knee flexion was measured with a long-arm goniometer and all (severe) adverse device-related events were registered.

Statistics

Descriptive statistics were used to present patient characteristics. Micromotion and outcome measures were given as medians with ranges and presented graphically to demonstrate micromotion patterns over time. Data were analyzed using STATA 13.0 (StataCorp, College Station, TX, USA).

Ethics, registration, funding, and disclosures

The study protocol was approved by the hospital's investigational review board and the Medical Ethical Review Board of Slotervaart and Reade (NL58887.048.16). This study was conducted in accordance with the Declaration of Helsinki and RSA guidelines.[1] Written informed consent was obtained from all participating patients. The hospital receives funding from Smith & Nephew to pay for staff and materials for conducting this study. Smith & Nephew had no role in the design or conduct of the study, the collection, management, analyses and interpretation of the data, or the preparation of the manuscript. Completed disclosure forms for this article following the ICMJE template are available on the article page, doi: 10.2340/17453674.2023.12305

Results

Preoperative patient characteristics such as age, sex, and surgical details can be found in Table 1.

At final follow-up, 3 patients were lost to follow-up. 1 patient died due to an unrelated cause and 2 refused further participation (1 due to dementia, 1 due to pain). Micromotion could not be assessed in 2 femoral components and 7 tibial components due to insufficient RSA marker visibility and distribution. This resulted in complete RSA measurements of 16 femoral components and 11 tibial components at 2-year follow-up (Figure 1). The median number of matching markers was 4 (3–9) and in 8 femur and 8 tibias marker configuration models were used. In 1 femoral and 3 tibial components, the markers were found to be in an equilateral triangle which led to a higher condition number (> 150) which is beyond the ISO guideline recommendations. The analyses were reviewed by independent RSA experts (RSAcore, Leiden, The Netherlands) and found to be reliable to use. Measurement error statistics of the 6 degrees of freedom, TT, and TR are shown in Table 2.

Table 1. Patient characteristics and surgical details. Values are count unless otherwise specified.

Patient characteristics		Surgical details	
N	20	**Surgery time (min), (range)**	124 (85–193)
Age, (range)	71.6 (55–81)	**Bone loss (AORI)**	
Female/male	14/6	- F1/T1	10/15
		- F2A/T2A	5/2
BMI, (range)	28 (20–38)	- F2B/T2B	4/3
Right/Left	8/12	- F3/T3	1/0
No. of revision		**Cones**	
- 1st	15	- Femur/tibia	5/5
- 2nd	5		
Reason for revision		**Bone grafting**	
- Instability	10	- Femur/tibia	0/1
- Loosening	2	**Additional surgery**	
- Infection	1	- Extensor apparatus repair	1
- Severe arthrofibrosis	7	**Admission (days), (range)**	5 (4–12)

AORI = Anderson Orthopaedic Research Institute bone stock classification.

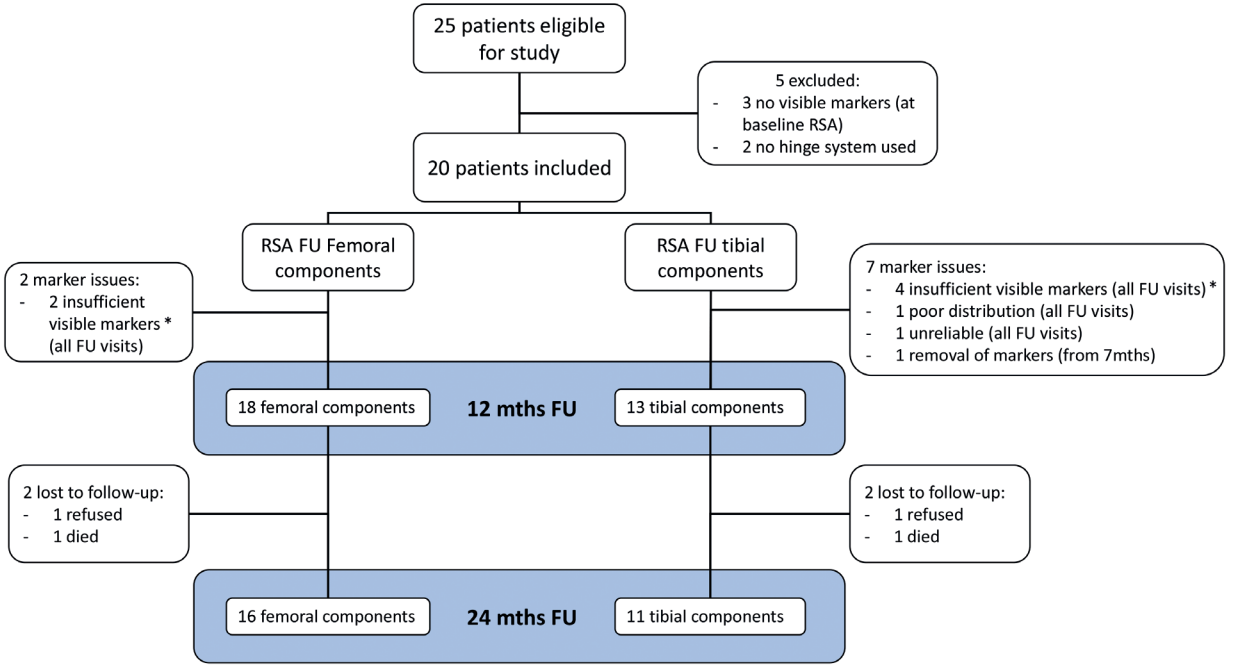

Figure 1: Flowchart of patients and components. At final follow-up clinical data was available for 17 patients (2 patients refused, 1 died).
***** In 1 patient also lost to follow up > 12 months.

Table 2. Precision limits based on double examinations and calculated with measurement error statistics.

	Medial translation (Tx)	Proximal translation (Ty)	Anterior translation (Tz)	Flexion (Rx)	Internal rotation (Ry)	Varus rotation (Rz)	TT	TR	MTPM
Femur									
Mean	0.03	0.02	−0.04	0.11	−0.05	0.05	0.18	0.34	0.38
SD	0.08	0.07	0.19	0.27	0.20	0.13	0.14	0.15	0.17
Tibia									
Mean	0.03	−0.01	0.00	0.02	0.00	−0.05	0.09	0.32	0.28
SD	0.04	0.06	0.08	0.18	0.36	0.10	0.06	0.26	0.19

Tx: translation along the transverse axis; Ty: translation along the longitudinal axis; Tz: translation along the sagittal axis; Rx: rotation around the transverse axis; Ry: rotation around the longitudinal axis; Rz: rotation around the sagittal axis; TT: total translation; TR: total rotation; MTPM: maximum total point motion; SD: standard deviation.

At 2-year follow-up, median TT_{femur}, TR_{femur}, and $MTPM_{femur}$ were 0.38 mm (0.15–1.5), 0.71° (0.37–2.2) and 0.87 mm (0.54–2.8), respectively. Median TT_{tibia}, TR_{tibia}, and $MTPM_{tibia}$ were 0.40 mm (0.08–0.66), 0.53° (0.30–2.4) and 0.66 mm (0.29–1.6), respectively (Figures 2 and 3). The majority of micromotion occurred from baseline to 6 weeks postoperative followed by stabilization of micromotion (Figure 2).

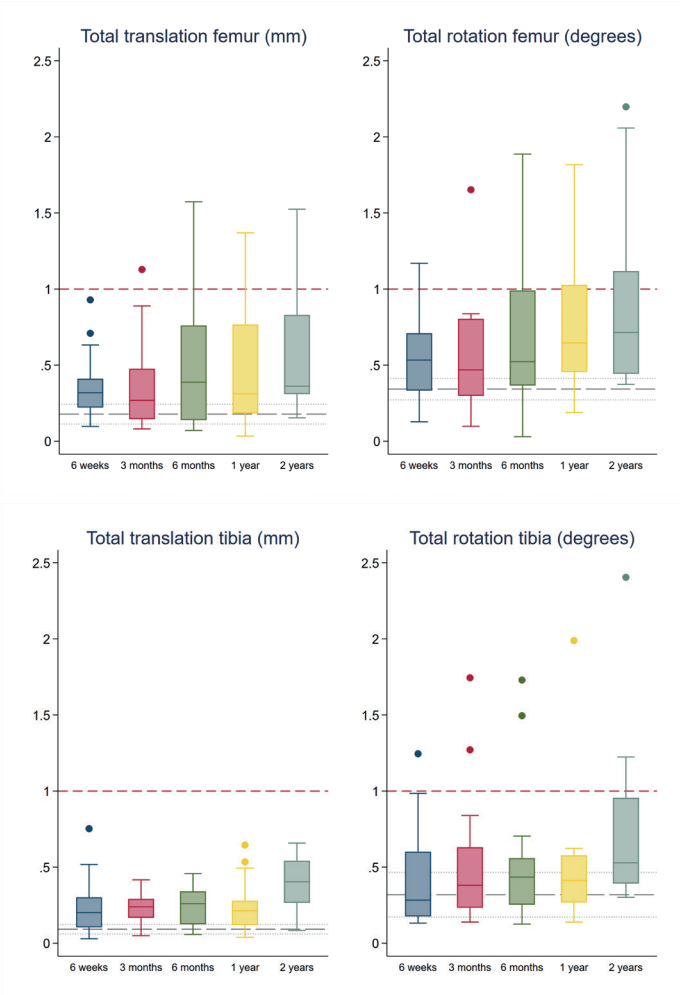

Figure 2: Total translation (top panel) and total rotation (bottom panel) of the femoral and tibial components at follow-up intervals. Top and bottom of box are the 25th and 75th percentiles, horizontal line within box is the median, whiskers are the lower and upper adjacent values (1.5x IQR), and markers are outside values. Grey dashed lines are the measurement error statistics (mean ± 95%CI).

Individual translation and rotation trajectories did not show uniform migration patterns (towards a specific direction), with median translation and rotation values close to zero. However, individual outliers with higher migrations were most prominent in the anterior-posterior translation, flexion-extension and internal-external rotation in femoral components and in the flexion-extension rotation of tibial components (Table 3). At 2 years, 5 femoral components translated with a TT > 1 mm and 5 femoral components rotated with a TR > 1° whereas no tibial components translated with a TT > 1 mm and 2 tibial components rotated with a TR > 1°. Moreover, MTPM trajectories of the femur component showed more continuous migration over time compared with tibial components (Figure 3). Translation and rotation of the femoral and tibial components in all 6 degrees of freedom throughout the entire follow-up are presented in Table 3.

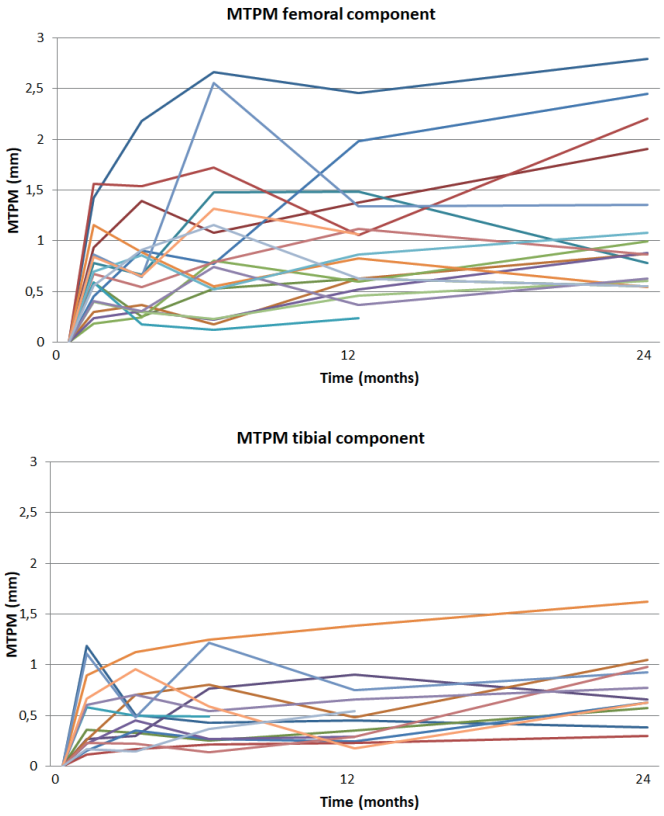

Figure 3: Individual RSA trajectories of the MTPM of the femoral (left panel) and tibial components (right panel).

Table 3. Translation and rotation of the femoral and tibial components on all axes at all follow-up time points. Values are median (range).

	Femoral component					Tibial component				
	6 wk	3 mo	6 mo	12 mo	24 mo	6 wk	3 mo	6 mo	12 mo	24 mo
Medial translation (Tx) (mm)										
N	18	18	18	18	16	14	14	14	13	11
Median	−0.01	0.11	−0.01	0.03	0.03	0	0.02	0.01	−0.03	−0.04
Min.	−0.49	−0.44	−0.51	−0.52	−0.63	−0.27	−0.21	−0.18	−0.16	−0.41
Max.	0.39	0.49	0.44	0.53	0.97	0.49	0.24	0.24	0.43	0.59
Proximal translation (Ty) (mm)										
N	18	18	18	18	16	14	14	14	13	11
Median	0.03	−0.04	−0.02	0.03	0.06	0.02	0.08	0.04	0.09	0.03
Min.	−0.28	−0.19	−0.31	−0.14	−0.21	−0.05	−0.14	−0.03	−0.09	−0.24
Max.	0.19	0.28	0.37	0.49	0.81	0.19	0.26	0.3	0.2	0.23
Anterior translation (Tz) (mm)										
N	18	18	18	18	16	14	14	14	13	11
Median	0.08	0.08	0.14	0.1	0.15	−0.01	−0.02	0.02	0.02	0.12
Min.	−0.90	−1.1	−1.1	−0.86	−1.3	−0.68	−0.38	−0.39	−0.62	−0.62
Max.	0.64	1.0	1.5	1.3	1.4	0.5	0.27	0.44	0.53	0.4
Flexion (Rx) (°)										
N	18	18	18	18	16	14	14	14	13	11
Median	−0.03	0.02	−0.02	0.06	0.1	−0.07	0.02	0.08	−0.09	−0.06
Min.	−0.82	−0.89	−1.26	−1.18	−1.24	−1.2	−1.7	−1.7	−2.0	−2.4
Max.	0.65	0.8	0.9	1.65	2.1	0.22	0.28	0.43	0.43	0.52

Table 3. Continued.

	Femoral component					Tibial component				
	6 wk	3 mo	6 mo	12 mo	24 mo	6 wk	3 mo	6 mo	12 mo	24 mo
Internal rotation (Ry) (°)										
N	18	18	18	18	16	14	14	14	13	11
Median	−0.1	−0.1	−0.03	−0.18	−0.36	0.02	0.07	0.15	0.06	0.09
Min.	−0.64	−0.83	−1.07	−1.12	−0.99	−0.71	−0.33	−0.17	−0.33	−0.21
Max.	1.1	1.4	1.6	1.4	1.6	0.45	1.2	1.5	0.57	0.82
Varus rotation (Rz) (°)										
N	18	18	18	18	16	14	14	14	13	11
Median	0.01	0.07	0.01	0.01	−0.01	−0.01	−0.01	0	0.03	0.03
Min.	−0.25	−0.26	−0.46	−0.25	−0.66	−0.68	−0.34	−0.33	−0.49	−0.52
Max.	0.22	0.26	0.35	0.37	0.68	0.23	0.24	0.28	0.46	0.48

Tx: translation along the transverse axis; Ty: translation along the longitudinal axis; Tz: translation along the sagittal axis; Rx: rotation around the transverse axis; Ry: rotation around the longitudinal axis; Rz: rotation around the sagittal axis.

Most outcome scores at 2 years showed an improvement from baseline (Table 4). Pain scores decreased significantly over time in both the subscore of the OKS as well as in the VAS pain score (Table 4). 11 patients encountered a complication (recurrence of arthrofibrosis (4), (neuropathic) pain (5, of whom 3 with worsening of pre-existing pain), deep venous thrombosis (1), recurrence of quadriceps tendon rupture (1), pneumonia (1), extended wound leakage (1)) with only 1 patient requiring a reoperation (full allograft extensor mechanism reconstruction). None of the implants were revised nor suspected of loosening at 2-year follow-up.

Table 4. Clinical outcome scores given in median (range) at 1 and 2 years follow-up.

Total score median (range)	Baseline	12 months	24 months
No. of patients	20	20	17
Knee Society Score			
- Total	111 (35–174)	131 (53–179)	125 (58–170)
- Clinical	52 (29–94)	82 (42–100)	65 (38–100)
- Functional	55 (–10–80)	50 (0–80)	50 (0–80)
Oxford Knee Score			
- Total	21 (11–40)	33 (10–44)	31 (12–48)
- Pain	43 (21–86)	73 (18–96)	68 (25–100)
- Function	38 (25–80)	60 (25–100)	50 (25–100)
APQ	8 (0–38)	20 (0–75)	13 (0–100)
KOOS-PS	51 (30–92)	39 (0–100)	44 (0–84)
VAS pain	63 (10–83)	36 (0–91)	49 (0–90)
VAS satisfaction		58 (0–100)	45 (1–100)

Scores given as median (range). APQ: Oxford Knee Score – Activity and Participation; KOOS-PS: Knee injury and Osteoarthritis Outcome Score – Physical Function Short form; VAS: visual analog scale.

Discussion

This is the first RSA study to investigate the stability of a revision rotating hinged-knee implant. Most implants showed some degree of early micromotion followed by stabilization of micromotion between 6 weeks and 2 years. At 2 years, a significant number of components showed a TT > 1 mm or TR > 1°, especially on the femoral side. However, none of the implants failed or showed radiological signs of loosening. Most clinical and functional scores showed an improvement from baseline, and pain decreased.

Implant stability has been studied widely for tibial components in primary TKA.[3] Acceptable migration has been defined as MTPM < 0.5 mm in the first 6 months and MTPM < 0.2 mm from 6–12 months and 12–24 months. Although these values cannot be applied to complex knee revision surgery with rotating hinged implants, the micromotion results of the current study are within or close to these safe zones, with a median MTPM of 0.46 mm at 6 months and an increase of 0.21 mm between 12 and 24 months. For femoral components, there are no reference data for acceptable micromotion. Although there was higher early migration, with an MTPM of 0.78 mm at 6 months, this was followed by satisfactory stabilization up to 2 years (0.06 mm 6–12 months, 0.03 mm 12–24 months). A possible explanation for higher early migration in revision TKA compared to primary TKA might be existing bone loss with compromised primary fixation and subsequent remodeling in stemmed revision TKA.[9] No difference in migration was found between the groups AORI F1/T1 and AORI >F1/>T1.

While on group level acceptable levels of micromotion were observed, individual RSA trajectories did show outliers outside the previously mentioned safe zones. 4 femoral components could be identified having continuous migration (Figure 3). Further analysis showed mainly anterior-posterior translation and, rotation around the transverse (flexion-extension) and (to a lesser extent) longitudinal (internal-external rotation) axis. 1 tibial component showed increasing rotation around the transverse (flexion-extension) axis. This particular migration for both the femoral and tibial components might be due to increased momentum in the sagittal plane caused by the fixed hinged mechanism and extension stop of the implant system.

In literature there are limited RSA data for revision TKA: Heesterbeek et al. reported median TT (TT_{femur} 0.31 mm, TT_{tibia} 0.40 mm) and median TR (TR_{femur} 0.62°, TR_{tibia} 0.86°) for fully cemented revision TKA with condylar revision implants at 2 years, which are comparable with the current findings.[5] In contrast to this, the number of outliers (TT > 1 mm or TR > 1°) seems higher for femoral components compared with the tibial components in the current study (7/16 vs 2/11) and in contrast to the study of Heesterbeek et al. with cemented condylar revision TKA (4/15 vs 5/14).[5] Higher rates of aseptic loosening of femoral components in rotating hinged knee implants have been reported, for which different explanations have been provided.[10,11] Farid et al. believed that the femoral component in rotating hinged knee implants is subject to more torsion and bending stresses due to differences in the anatomic femoral and mechanical axis.[10] We presumed that the femoral component and stem are subject to higher torsional stresses due to the design of the rotating hinge mechanism. The tibial component is relatively free from these stresses since the rotational free axis is always in line with the longitudinal axis of the tibial component and stem. Due to these findings, our previous focus on tibial fixation in revision knee surgery with rotating hinged implants has been changed into increased attention to fixation of the femoral component.

Although a significant number of implants showed an continuous migration or a high degree of micromotion (> 1 mm or > 1°), longer follow-up RSA in revision knee surgery with condylar implants did not show signs of aseptic loosening for this potential group at risk.[4,6] In addition, a retrospective analysis of a fully cemented Legion HK cohort showed only 1 femoral component loosening in 147 cases with a mean follow-up of 3.8 years.[12] This might confirm appropriate stability of the present fully cemented rotating hinged implants and might indicate that higher degrees of micromotion are acceptable in revision TKA along with the use of hinged implants. Moreover, long-term survival data of fully cemented rotating hinged implants showed excellent and superior survival over hybrid fixated implants.[11] Extended clinical follow-up of the current patients will be needed to ascertain whether the degree of migration will lead to early re-revisions and, if so, to investigate a relationship with the migration patterns.

Most clinical and functional scores showed a significant improvement at 24 months (OKS, KSS clinical, OKS-APQ, and KOOS-PS) and this improvement is of clinical importance in knee revision surgery.[13,14] However, a slight decrease was seen for most of the scores after 12 months. This was especially true for patients with recurrent arthrofibrosis and increased (neuropathic) pain. This is in line with previous studies on revision knee surgery for arthrofibrosis which showed clinical deterioration after 12 months.[15] Recurrence of arthrofibrosis was the most frequent complication, which is similar to previous reports and moderate outcomes after revision surgery.[15,16] Nevertheless, a total of 8 patients had a preoperative stiff knee (range of motion < 90°) and improved at least 20° in range of motion at 2 years follow up. Only 1 reoperation occurred (full allograft extensor mechanism reconstruction), which is very reasonable compared to previous studies on revision knee surgery with hinged implants.[11,12]

The main limitation of the present study is the substantial loss of analyzable tibial components due to marker invisibility. Because of the extensive size of the implant and the limited cancellous bone for marker placement, RSA measurements were not possible in 4 tibial components and 2 femoral components. This could not be solved with marker-configuration models. Furthermore, poor distribution of markers and unreliable measurements in another 2 tibial components resulted in failure to analyze the micromotion in these patients. In 1 tibial component, some markers were removed during a full allograft reconstruction of the extensor apparatus which made analysis impossible at 12 and 24 months. In 4 components, the condition number was> 150 which may have impeded the quality of the RSA measurements.

Conclusion

Micromotion in fully cemented rotating hinged knee implants was comparable to previous findings in decent fixated condylar revision knee implants with long-term follow-up. Therefore, fixation of this implants seems adequate in the first 2 years after surgery. Femoral components showed more outliers, in contrast to previous RSA studies.

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Chapter 6

Short to Midterm Outcomes of a Novel Guided-Motion Rotational Hinged Total Knee Arthroplasty

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Abstract

Introduction

Hinged prostheses have been increasingly utilized in complex and revision total knee arthroplasty (TKA) cases requiring additional mechanical support and global stability. However, there is limited data detailing the outcomes of modern hinge designs in these procedures. The aim of this study is to report a minimum 2-year functional outcomes and survivorship of a novel guided-motion hinged-knee TKA system.

Methods

A multicenter, retrospective cohort study was conducted on consecutive TKA patients between March 2013 and August 2017 with a novel guided-motion hinged-knee system. Demographics, change in range of motion (ΔROM), quality metrics, and implant survivorship were collected with a minimum of two-year follow-up. Implant survival was analyzed using the Kaplan-Meier method.

Results

Overall, 147 hinged-knee cases (18 complex primaries and 129 revisions) were identified with an average follow-up duration of 3.8 ± 1.2 years. Patients presented with an average of 2.4 ± 1.6 prior knee surgeries, and 51 (34.7%) had a history of knee infections. ROM improved post-operatively: Δextension = 2 ± 1°, Δflexion = 7 ± 3°, Δtotal ROM = 9 ± 4°. Kaplan-Meier survivorship analysis for implant revision at 2- and 5-year follow-up showed a survival rate of 100 and 98.5% (95% confidence interval: 94.3-99.6%), respectively, with one patient undergoing total revision for infection and another undergoing femoral revision for aseptic loosening. Survivorship for aseptic all-cause reoperation at 2- and 5-year follow-up was 93.2% (87.7-96.3%) and 88.2% (80.0-93.2%), respectively. Fourteen patients underwent aseptic reoperation (patellar complications: n = 7 (4.8%); instability: n=2 (1.4%); hinge bolt loosening: n=2 (1.4%); aseptic loosening: n=1 (0.7%); tuberosity fixation: n=1 (0.7%); extensor mechanism failure: n=1 (0.7%)). Survivorship for all-cause reoperation at 2- and 5-year follow-up were 85% (78.2-90.0%) and 77.7% (68.8-84.3%), respectively. Fifteen patients underwent reoperation for infection (DAIR: n = 14 (9.5%); two-stage revision: n=1 (0.7%)).

Conclusions

Despite some reoperations, this guided-motion hinged-knee TKA system demonstrates excellent survivorship for component revision compared to other modern hinged knee implants reported in the literature. Patients also displayed an improvement in knee ROM at their latest follow-up.

Introduction

The hinged prothesis is a highly constrained implant that provides additional mechanical support and global stability via a hinge mechanism that links the femoral and tibial components.[1] Hinged knee protheses are traditionally reserved for highly complex, revision or salvage cases of total knee arthroplasty (TKA) in which unconstrained implants are less likely to provide adequate stability and proper function.[2] These cases are commonly seen in revision surgery in which there is excessive bone loss, ligamentous instability, extensive soft-tissue deficiency, or extensor mechanism dysfunction that require higher levels of implant constraint.[2–4] Hinged protheses have also been used in primary TKA in cases of severe degenerative deformity and/or inflammatory arthritis, and complex fractures or neoplasms.[4] As hinge knee systems are infrequently used, previous studies on the survivorship and functional outcomes of these designs are limited by small sample sizes and inconsistent results among users.[4–6] Early hinge implants have reportedly high rates of aseptic loosening and mechanical failure ranging from <60% to >90% within a short and medium-term follow-up compared to less constrained implants.[5] These failure rates may be attributed to the high amounts of shear and rotational stress on the prothesis due to earlier designs using a fixed hinge with severe rotational constraint.[1] Newer hinge implants are designed to closely replicate normal knee kinematics via a rotating hinge mechanism, which reduces torque stress on the implant bone interface and provides inherent stability. The hinged prothesis that was evaluated in this study uses a rotating guided-motion hinge with a medial pivot and is designed with a lateral rollback mechanism to closely replicate natural knee kinematics. One unique aspect of the prothesis lies in its guided-motion insert, which enable a screw home rotation of the knee during full extension and provides inherent stability during the stance phase. [7] This design is constructed such that most of the joint load is placed on the condylar surfaces, thereby removing stressors on the hinge mechanism and, theoretically, improving wear and failure rates of the device.[8,9] Additionally, the anatomic asymmetric tibial construct facilitates customization of the tibial component for each patient's unique anatomic requirements. The modular component and augment design also allows for compatibility between designs from the same manufacturer.[8] To our knowledge, there is currently only one study published on this design system, demonstrating this prosthesis to have similar survivorship to other hinged knee devices, in addition to substantial improvement in post-operative functional outcomes. However, this study is limited by a small sample size of 31 cases with 2 year follow-up and was conducted at a single center.[6] As such, we devised a multicenter study to add onto the existing literature and to assess the short- to midterm functional outcomes and survivorship following implantation of a novel guided-motion rotational hinged-knee TKA system.

Materials and Methods

The present study is a multi-institution, multi-surgeon, retrospective study that analyzes patients who underwent complex primary and revision TKA between March 2013 and August 2017 using the LEGION HK Hinge Knee System (Fig. 1). All procedures were performed by fellowship-trained, high-volume arthroplasty surgeons at their respective institutions. Surgical decision-making (i.e. the use of cones, grafts, augments, and fixation strategies) was left to the surgeon's discretion. Throughout the entire study period, a multitude of implant systems were employed for TKAs, but only patients receiving this specific hinged system were included in this study. In addition, this study only included patients with a minimum of 2-year follow-up in order to evaluate short- to midterm outcomes.

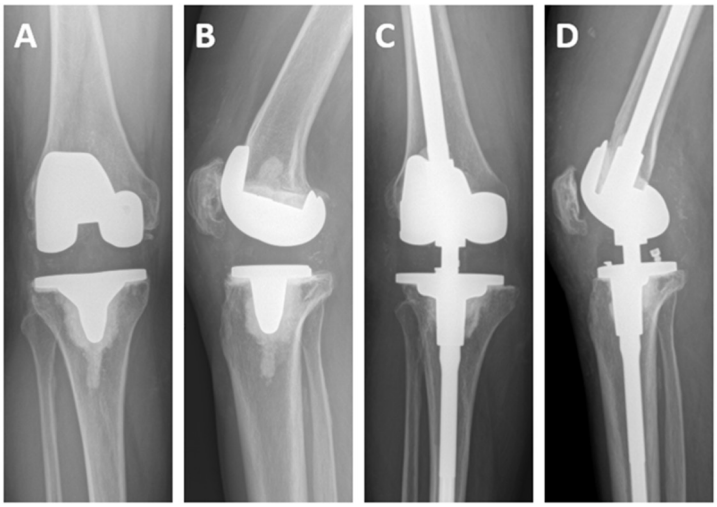

Figure 1: Pre- and Post-Operative Hinged Total Knee Arthroplasty Implant Case Example of Patient Revised for Recurrent Instability. (A) Pre-Operative Anteroposterior Radiograph. (B) Pre-Operative Lateral Radiograph. (C) Post-Operative Anteroposterior Radiograph. (D) Post-Operative Lateral Radiograph.

In general, a standard medial parapatellar arthrotomy was used when feasible. Following prior implant removal, bony preparation for this implant involved the same technique used for a standard revision implant. However, three extra steps were needed beyond the standard revision technique; a 10mm posterior femoral condylar resection was needed, the intracondylar box cut was larger, and the tibial component required additional reaming depth to accept the larger tibial keel.

Patient demographics and surgical data were reviewed from each institution's respective electronic medical record system, Epic (Verona,WI), Chipsoft HiX (Amsterdam, The Netherlands), and the Dutch Arthroplasty Register. Baseline patient demographics (i.e. age, gender, body mass index (BMI), American Society of Anesthesiologists (ASA) score, smoking status, prior knee surgeries and infections) and surgical data (i.e. indication for index procedure, procedure type, surgical laterality, anesthesia type) were collected from the date of surgery (Table 1). Patient outcomes were collected at routine follow-up appointments of 2 to 3 weeks, 4 to 6 weeks, 3 to 6 months, 12 months, and every year thereafter. Assessed outcomes include ambulatory status, lengths of stay, complications, readmissions, reoperations, revisions, infections, and mortality. Reoperation was deemed any case in which the indexed knee was taken back to the operating room and reopened for a postoperative complication. Revision surgery included cases in which the femoral, tibial, or both components of the implant were explanted or exchanged. Revision of any major components was cross referenced with the implant registry, in order not to miss any of the revisions performed elsewhere. All-cause reoperation included any case taken back to the operating room and had surgery performed on the same knee (e.g. debridement, antibiotics, and implant retention; extensor mechanism repair; patellar removal; etc.), whereas aseptic reoperation excluded cases performed for infectious causes. Survivorship was analyzed and presented graphically by using the Kaplan–Meier method. Outcomes and survivorship data were calculated by using time of latest follow-up. Patients who died with the implant in situ and patients lost to follow-up were considered censored at the date of death and last follow-up, respectively. Range of motion (ROM) data were collected preoperatively and at latest follow-up to calculate change in range of motion (DROM). All data was analyzed with descriptive statistics using SPSS v.25.0 (IBM Corp., Armonk, NY).

Table 1. Baseline Patient Demographics and Surgical Characteristics.

Characteristic	Count (%) or Mean (SD)
Age (years)	67.93 (10.04)
Gender	
- Female	92 (62.6)
- Male	55 (37.4)
Laterality	
- Left	75 (51.0)
- Right	72 (49.0)
BMI (kg/m^2)	30.59 (5.95)
ASA	
- 1	15 (10.2)
- 2	109 (74.1)
- 3	22 (15.0)
- 4	1 (0.7)
- Median	2
Smoking Status	
- Current Smoker	14 (9.5)
- Former Smoker	3 (2.0)
- Non-Smoker	130 (88.4)
Indication for Index Procedure	
- Arthrofibrosis	19 (12.9)
- Failure/dislocation	4 (2.7)
- Infection	34 (23.1)
- Instability	39 (26.5)
- Loosening	29 (19.7)
- OA/deformity	19 (12.9)
- Patellar subluxation	2 (1.4)
- Periprosthetic fracture	1 (0.7)
Procedure Type	
- Primary TKA	18 (12.2)
- Revision TKA	129 (87.8)
Surgical Time (minutes)	135.10 (36.53)
Anesthesia Type	
- General	112 (76.2)
- Regional	35 (23.8)
Prior Knee Surgeries (n)	2.39 (1.62)
Previous Knee Infections	51 (34.7)

Abbreviations: ASA, American Society of Anesthesiologists; BMI, body mass index; OA, osteoarthritis; SD, standard deviation; TKA, total knee arthroplasty.

Results

Overall, there were 147 knees identified to be eligible for this study, having undergone hinged TKA throughout the study period using the evaluated hinge knee system. On average, there was 3.8 ± 1.2 years of follow-up. The cohort was predominately female (62.6%) with a mean age of 67.9 ± 10.0 years, BMI of 30.6 ± 6.0 kg/m^2, a median ASA score of 2, and were mostly nonsmokers (88.4%). Patients also presented with on average 2.4 ± 1.6 prior knee surgeries and 51 (34.7%) had a prior history of knee infection. Of the 147 cases, 18 (12.2%) were complex primary cases and 129 (88.0%) were revision TKAs. The indications for implantation of the guided-motion hinge were arthrofibrosis (12.9%), failure/dislocation (2.7%), infection (23.1%), instability (26.5%), loosening (19.7%), osteoarthritis/deformity (12.9%), patellar subluxation (1.4%), and periprosthetic fracture (0.7%).

This series demonstrated a mean surgical time of 135.1 ± 36.5 minutes and were performed primarily under general anesthesia (76.2%). All cases underwent full femur, tibia, and liner implantation, except for one which underwent only femur and liner implantation. Overall, 124 (84.4%) utilized a retained or revised patella. In terms of the femoral component, cones were used in 13 (8.8%) cases, screw-on augments in 86 (58.5%) cases, impaction grafts in 5 (3.4%) cases, and structural bone grafts in 5 (3.4%) cases. On the tibial side, cones were used in 26 (17.7%) cases, screw-on augments in 33 (22.4%) cases, impaction grafts in 8 (5.4%) cases, and no structural grafts. Fully cemented femoral and tibial stems were used in all but two cases. One case used hybrid tibial fixation and two used hybrid tibial and femoral fixation with long press-fit uncemented stems in order to bypass bony defects.

At latest follow-up, ROM had improved in all domains: Δextension = 2 ± 1 degrees, Δflexion = 7 ± 3 degrees, Δtotal ROM = 9 ± 4 degrees (Table 2). Patients shifted from a predominant ambulatory status of unassisted (36.7%) preoperatively to cane or crutches (63.3%) upon discharge to again unassisted (48.3%) at latest follow-up. On average, length of stay was 7.1 ± 5.4 days. Ten patients experienced intraoperative complications including patellar tendon rupture (n=2, 1.4%), peroneus nerve damage (n=1, 0.7%), cement leakage (n=3, 2.0%), tibial fracture (n=3, 2.0%), and femoral canal

Table 2. Knee Range of Motion.

Time	Extension	Flexion	Total ROM
Baseline	4±11°	95±26°	91±32°
Last Follow-Up	2±8°	102±23°	100±25°
Δ	-2±1°	7±3°	9±4°

Abbreviation: ROM, range of motion.

perforation (n=1, 0.7%). Twenty-one patients experienced inpatient complications, most commonly for draining wound (n=4, 2.7%) or urinary retention (n=6, 4.1%). The 90-day readmissions occurred in 11 (7.5%) cases for infection (n=8, 5.4%), periprosthetic femur fracture (n=1, 0.7%), tuberosity osteotomy fragment dislocation (n=1, 0.7%), and postprocedural hemorrhage (n=1, 0.7%) (Table 3).

Table 3. Quality Outcomes.

Outcome	Count (%) or Mean (SD)
Preoperative Ambulatory Status	
Cane/Crutches	33 (22.4)
Rolling Walker	18 (12.2)
Wheelchair	11 (7.5)
Unassisted	54 (36.7)
Unknown	31 (21.1)
Discharge Ambulatory Status	
Cane/Crutches	93 (63.3)
Rolling Walker	42 (28.6)
Wheelchair	8 (5.4)
Unassisted	2 (1.4)
Unknown	2 (1.4)
Latest Follow-up Ambulatory Status	
Cane/Crutches	22 (15.0)
Rolling Walker	13 (8.8)
Wheelchair	3 (2.0)
Unassisted	71 (48.3)
Unknown	38 (25.9)
Length of Stay (days)	7.07 (5.35)
Complications/Readmission	
Intraoperative Complications	11 (7.5)
Inpatient Complications	21 (14.3)
90-day ED Visits	4 (2.7)
90-day Readmissions	11 (7.5)
Reoperation Surgery	
Infection	15 (10.2)
Patellar Complication	7 (4.8)
Aseptic loosening/Instability	5 (3.4)
Tuberosity Fixation	1 (0.7)
Extensor Mechanism Failure	1 (0.7)
Mortality	2 (1.4)

Abbreviations: ED, emergency department; SD, standard deviation.

Overall, 2 out of 147 (1.4%) cases required revision surgery was of the most recent follow-up visit, having undergone two-stage revision for infection and femoral revision for aseptic loosening. Kaplan–Meier survivorship analysis for implant revision at 2- and 5-year follow-up showed a survival rate of 100 and 98.5% (95% confidence interval [CI]: 94.3–99.6%), respectively (Fig. 2). Mean time to implant failure was 585 days. Fourteen patients underwent aseptic reoperation due to patellar complications (n=7, 4.8%), instability (n=2, 1.4%), hinge bolt loosening (n=2, 1.4%); aseptic loosening (n=1, 0.7%), tuberosity fixation (n=1, 0.7%), and extensor mechanism failure (n=1, 0.7%). Kaplan–Meier survivorship analysis for aseptic reoperation at 2- and 5-year follow-up showed a survival rate of 93.2% (87.7–96.3%) and 88.2% (80.0–93.2%), respectively (Fig. 3). Mean time to aseptic reoperation was 579 (range: 57–1,660) days. Fifteen patients underwent reoperation for the infection with DAIR (n=14, 10.2%) and full two-stage revision (n=1, 0.7%). Kaplan–Meier Survivorship analysis for all cause reoperation at 2- and 5-year follow-up showed a survival rate of 85.0% (78.2–90.0%) and 77.7% (68.8–84.3%), respectively (Fig. 4). Mean time to all-cause reoperation was 426 (range: 10–1,134) days. Overall mortality at latest follow-up was 1.4%.

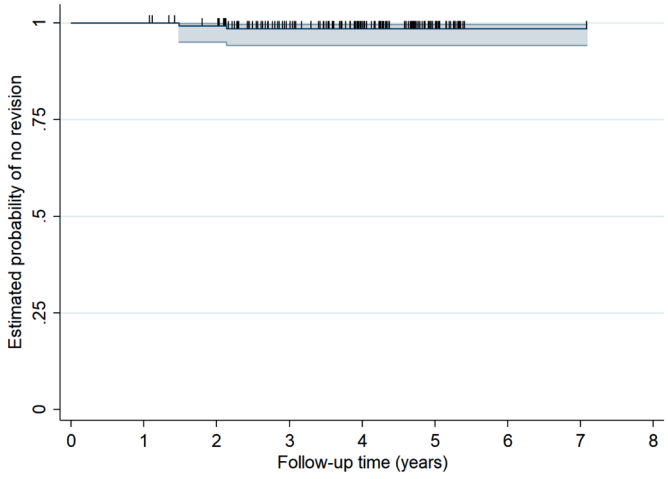

Figure 2: Kaplan-Meier survivorship curve for implant revision.

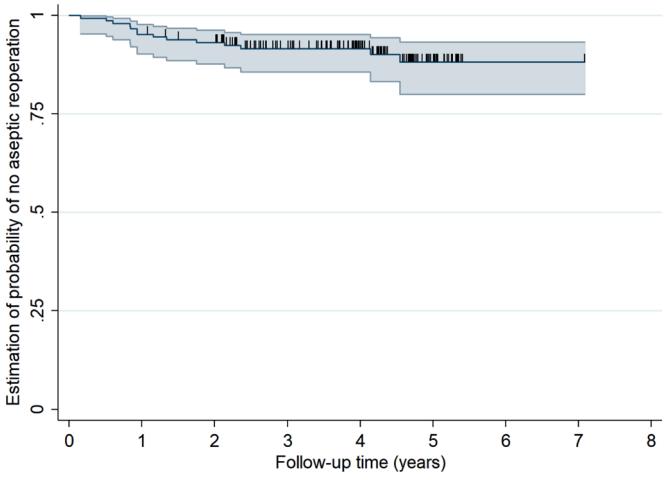

Figure 3: Kaplan-Meier survivorship curve for aseptic reoperation.

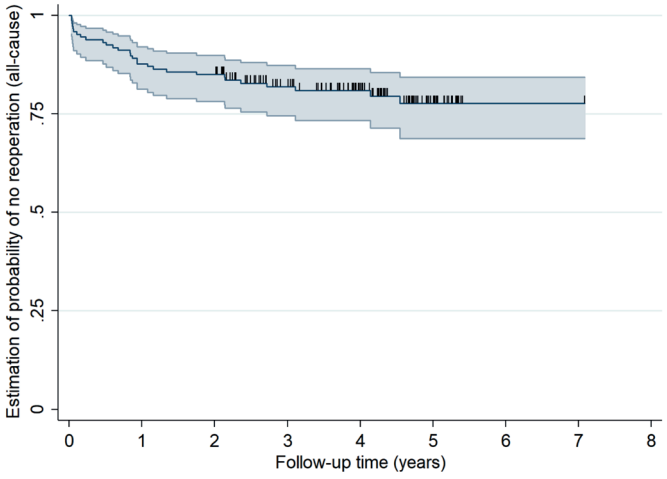

Figure 4: Kaplan-Meier survivorship curve for all-cause reoperation.

Discussion

Hinge knee prostheses were first introduced to the market almost a half century ago.[10] Originally, their application was limited to use in elderly patients with severe instability due to ligamentous insufficiency or substantial bony deformity, they are becoming more commonly utilized for complex and revision TKA cases.[10–13] The hinged TKA system evaluated in this study features a rotating hinge mechanism and novel-guided motion inserts, aimed to maintain native knee motion, and combat common complication of wear and dislocation.[8,9]

Survivorship analysis for implant revision revealed this hinge TKA system to be extremely robust when examining short- to midterm outcomes, with at 2- and 5-year implant survival rate of 100 and 98.5%. This is in line with, if not superior to, recent reports of other hinge knee survivorship studies. At 2-year follow-up, Giurea et al. reports 92.1% implant survivorship of a rotating hinge TKA.[14] In 2017, Cottino et al. performed one of the largest studies to date on a cohort of 408 rotating hinge implants.[15] At 2 years, the cumulative incidence of revision for any reason was 9.7% (95% CI: 6.7–12.6%). Farid et al. reported outcomes on 142 rotating-hinge arthroplasty devices with 73% implant survival probability at 5-year follow-up.[16] Similarly, Guenoun et al. reported 89% implant survival at a mean of 36 months, and Bistolfi et al reported 2- and 5-year survival rates of 93 and 79%, respectively.[17,18] Our study reports higher survivorship, with a much larger sample size than most reports in the literature.

One similar study out of the University of Manitoba in Canada published on a series of 39 cases, of which only 31 had a minimum of 2-year follow-up.[6] They reported the 2- year survivorship of the same hinge knee system to be 90.7%, notable lower than what we report at 5 years. The three revisions reported in their series were due to periprosthetic joint infection, undersizing of the femoral component, and a mechanical fall. As reported, the latter two mechanical failures were unlikely due to device failure. Likewise, in our study, one failure was due to surgical site infection on postoperative day (POD) 392, leading to full two-stage revision. The second failure was of a revision of an aseptic failed femoral cemented component to a femoral component with a cone. Postoperative radiographs of the failed implant showed an insufficient cement interdigitation and a small amount of cement in the metaphysis and diaphysis. Within 1 year, a radiolucent line was observed, and loosening was confirmed later by CT. Femoral revision with a cone was performed on POD 778.

The 14 aseptic reoperations in this series were most commonly performed due to patellar complications (4.8%) and aseptic loosening or instability (3.4%), frequent complications of earlier hinge designs.[13,19] More modern designs utilize a rotating hinge mechanism, which adds axial rotation to the existing flexion-extension motion, thereby reducing peak forces at the bone-implant interface.[13,20] Consequently, this

feature is hypothesized to reduce the risk of these frequent complications. The rates of loosening observed in the literature for rotating hinge designs report 2- and 10-year cumulative incidences of 1.7 and 4.5%, respectively.[15] Guenoun et al. reported on a rotating hinge design, with a mean 3-year follow-up, to have 4.7% patellar complications and 3.5% aseptic loosening events.[17]

Limitations

The authors acknowledge that there may be limitations to the results presented in the current study. One such limitation is the retrospective study design and manual chart review, which predisposes our results to data collection error. Furthermore, we may have inadequately controlled for confounding variables due to the lack of a control group, although this is an inherent bias in a case series study such as this one. Finally, given that this novel design has only recently come to market, extensive follow-up data are currently unavailable to assess long-term performance of this hinged knee design. Yet, our follow-up time still provides the longest term follow-up of this implant in the literature.

Conclusion

Our study establishes this novel-guided motion-hinged knee TKA system to be a highly robust and efficacious implant choice for complex and revision TKA. Only two cases of implant revision were noted in the postoperative period due to infection and aseptic loosening. These results support the use of this device in a multitude of complex and revision cases, yet long-term outcomes will ultimately determine this device's durability.

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Chapter 7

Instability, an Unforeseen Diagnosis of the Legion™ Hinge Knee System

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Abstract

Introduction

Instability is an infrequently encountered diagnosis in rotating hinge knee (rHK) implants. With the introduction of a new rHK implant, we encountered multiple patients who complained of instability. This article presents its prevalence while describing our diagnostic and treatment algorithms.

Methods

retrospective analysis of a cohort of all consecutive patients treated with the Legion™ Hinge Knee System (Smith & Nephew, Memphis, Tennessee) as primary or revision procedure between July 2014 and December 2018 was performed. All patients reporting a sense of instability or having recurrent joint effusion after activity were suspected of experiencing instability. Stress X-rays were performed and brace treatment was started. In patients with insufficient effect of brace treatment, a liner exchange to a thicker liner was performed. Prevalence of instability and the effect of treatment was analysed descriptively.

Results

In total, six patients were categorized as patients having instability problems (prevalence 3.5%; male:female ratio 5:1; median age 69.5 years; all revision procedures). Indication for revision to the Legion rHK implant was infection (three), instability (two) and aseptic loosening (one). In two patients, a prior rHK implant was revised. All patients showed tilting beyond the tolerance on stress X-ray examination. Brace treatment was adequate in three patients; in the other three patients a liner exchange was performed, two of which were satisfied.

Conclusion

Instability is an infrequently encountered diagnosis in rHK implants. The design of the Legion rHK implant seems prone to this problem with a prevalence of 3.5%. If brace treatment is insufficient a liner exchange might be considered.

Introduction

Hinged knee implants play an important role in both complex primary and revision total knee arthroplasty. They are the most constrained type of knee implants. Indications for the use of HK implants include collateral ligament insufficiency, severe deformity and bone loss, gross flexion-extension gap imbalance, stiffness, and tumor and septic cases.[1,2]

First generation HK implants had only one degree of freedom incorporated and were subject to high force transmission at the bone-implant interface and on the hinge mechanism itself. In some designs , this led to substantial rates of mechanical failure, aseptic loosening and patellar (sub-) luxation. With the introduction of rotating hinge knee (rHK) implants the force transmission was lowered and the patellofemoral articulation was improved. Ten-year survivorship of rHK implants ranges from 51% to 92.5%.[1–3] Even so, the complication rate remained high, up to 63% in some series and is considered the price paid for its constrained design.[2,3]

Against expectations, instability can still occur in rHK implants. Although the rHK implant is the most constrained type of knee implant, varus and valgus tilting is possible if there is some built-in tolerance of the mechanism or by distraction and tilting of the tapered rotational peg.[4,5] This has been described in patients with grossly unbalanced flexion-extension gaps following multiple revision procedures of resection of the capsule in oncology surgery.[6,7]

With the introduction of a new rHK knee system we encountered multiple patients who complained of this type of instability. In this article we presented its prevalence in our tertiary arthroplasty centre, described our diagnostic work-up and treatment algorithm and illustrated the mode of failure.

Materials and Methods

Design

This retrospective analysis of a cohort was approved by the Institutional Review Board of the Sint Maartenskliniek. The primary aim was to establish the prevalence of symptomatic instability. The secondary aim was to describe the results of our diagnostic and treatment algorithms.

Patients

All patients treated with the Legion™ Hinge Knee System (Smith & Nephew, Memphis, TN, USA) between July 2014 and December 2018 were eligible for inclusion into the study. During this period in total 173 consecutive Legion rHK implants (16 as primary, 157 as revision) were placed in 169 patients by dedicated arthroplasty surgeons in

our tertiary arthroplasty centre. Full details of all consecutive Legion rHK implants can be found in Table 1.

Table 1. Details of all consecutive patients with a Legion rHK implant.

	HK implant
Number of implants	173
Number of patients	169
M:F	63:106
Age years (SDV)	69.0 (9.1)
BMI kg/m^2 (SDV)	30.1 (5.4)
ASA (SDV)	2.1 (0.5)
Indication for Legion rHK implant	
Primary	16 (9%)
- Deformity	13
- Stiffness	2
- Instability	1
Revision	157 (91%)
- Instability	51
- Septic	42
- Aseptic loosening	36
- Stiffness	22
- Malposition	3
- Failure of hinge	2
- Periprosthetic fracture	1
Complications (rate)	
- Infection	10 (6%)
- Extensor apparatus	10 (6%)
- Instability	6 (3.5%)
- Bolt loosening	2 (1.2%)
- Aseptic loosening	1 (0.6%)

M: male, F: female, SDV: standard deviation of the dependent variable, BMI: body mass index, ASA: American Society of Anesthesiologists, Extensor apparatus (e.g. patellar complaints or (sub) luxation).

Implant

The Legion rHK implant is a relatively new system as an extension of the Legion Knee System (Smith & Nephew, Memphis, TN, USA). This modularity allows the surgeon to convert from a less constrained implant to a rHK implant with relative ease. The unique mechanism consists of a bush rotating around and moving up and down a

sleeve which is fixed to the tibial component (Figure 1). The built-in tolerance of the Legion system is 2° of varus and 2° of valgus motion and 0.8 cm of distraction of the bush around a sleeve before an anti-luxation feature will stop further movement.[8]

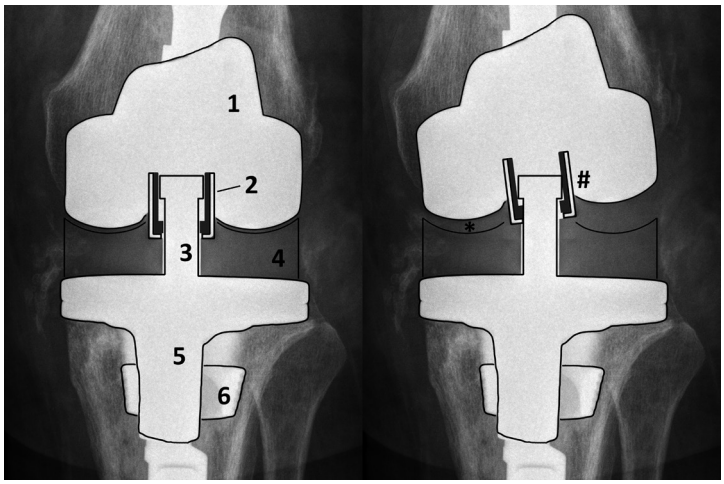

Figure 1: X-Ray with a schematic representation of the link-bush and sleeve mechanism. Left: 1. Femoral component, 2. Link-bush with polyethylene liner, 3. Sleeve with bolt, 4. Polyethylene liner, 5. Tibial component, 6. Trabecular cone. Right: distraction and tilting of the link-bush around the sleeve (#). Abolishment of condylar support in the distracted position (*).

Surgical procedure

Prophylactic antibiotics were administered in all patients 15-30 minutes before incision. A tourniquet was used on the surgeon's preference. A medial parapatellar approach was used and in every revision case six cultures were taken for exclusion of bacterial infection. Bone defects were treated with augments or bone grafting and all protheses were fixated using fully cemented stems on both sides. Additional cones were used in case of metaphyseal bone loss. Antibiotics were continued postoperatively until the cultures were negative. Physiotherapy was started the day after surgery and weightbearing regime depended on the primary stability of the construct.

Diagnostic and treatment algorithm

Standard follow-up schedule included visits at 6 weeks, 3 months and 1 year after surgery. Instability was suspected in patients reporting a sense of instability or having recurrent joint effusion after activity as previous described by Schwab et al.[9]

In these patients stress X-rays were performed in extension and 70° of flexion with a 15Nm load by the technique previously described by te Molder et al. and Heesterbeek et al.[10,11] (Figures 2 and 3)

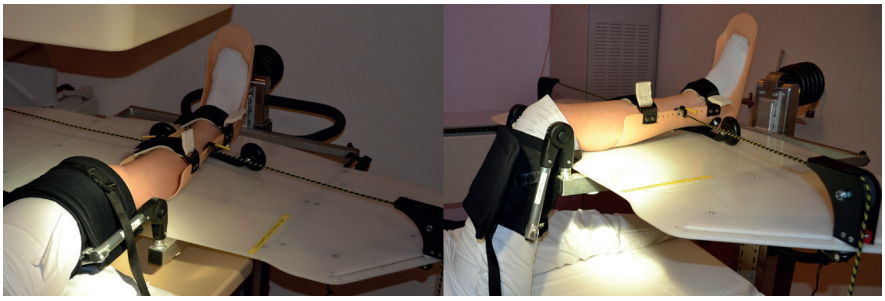

Figure 2: Custom-made stress device
Assessment of varus and valgus laxity of the knee in 0° (left), 70° (right) of flexion.[10]

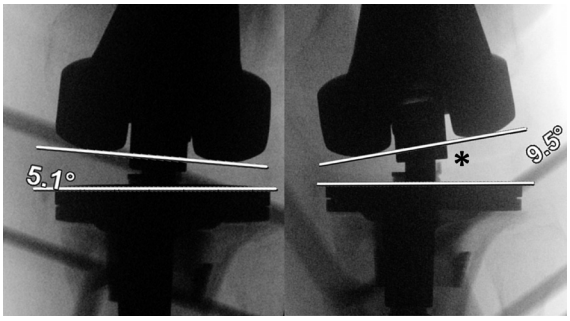

Figure 3: Stress X-ray
Stress X-ray with valgus and varus stress in 70° of flexion. Angle between the femoral and tibial component is given in degrees. Near the asterix distraction and tilting of the link-bush is noticed.

Hinge brace treatment (Donjoy Playmaker II, DJO Global, Lewisville, TX, USA) was started to objectify if instability was the main complaint for 6 weeks. If brace treatment was effective and the patient was satisfied a custom made brace was manufactured and regular follow-up was scheduled. In patients with insufficient reduction of complaints or a temporarily effect of brace treatment aspiration or biopsy was carried out to rule out periprosthetic joint infection (PJI). A liner exchange to a thicker liner was performed if PJI test was negative. A flowchart of the patient selection and algorithm is shown in Figure 4.

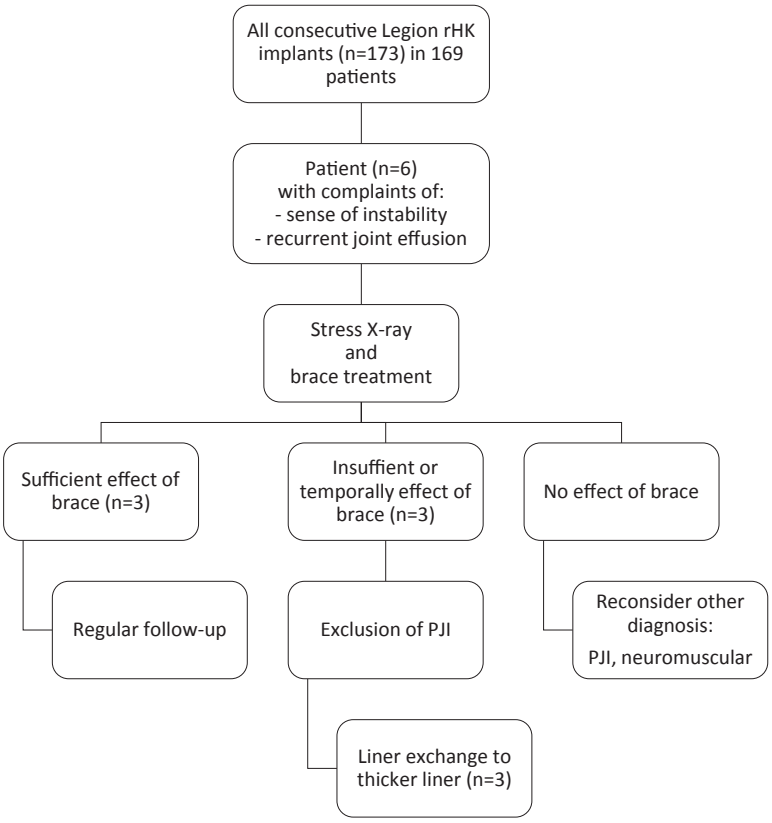

Figure 4: Flowchart
Flowchart of patient flow and the diagnostic workup and treatment algorithm.

Statistical analysis

Descriptive analyses of population and outcome parameters were performed using SPSS Statistics for Windows, version 20 (IBM Corp., Armonk, NY, USA). As the group is small, medians and interquartile ranges (IQR) were reported.

Results

In the total cohort of 169 patients with 173 rHK implants, six were categorized as patients having instability problems (prevalence 3.5%, M:F 5:1, all revision procedures). Of the six patients with instability, median age at the time of rHK implantation surgery was 69.5 years (IQR 16.3) with a median body mass index of 27.4 kg/m^2 (IQR 7.8). Reason for revision with a rHK implant was infection (three), instability (two) and aseptic loosening (one). In two patients a prior rHK implant (RT-modular, Smith & Nephew, Memphis, TN, USA) was revised. All characteristics are shown in Table 2. Four patients had both a sense of instability and recurrent joint effusions after activity. In four out of five, patient complaints started gradually during the first year after surgery.

Table 2. Characteristics of patients with instability.

No	Age (yrs)	G	BMI (kg/m^2)	Indication for hinge	Revision No	Bone loss (AORI)	Complaints
1	72	F	22.1	Instability	1st	F1, T1	Sense of instability, recurrent joint effusion
2	68	M	25.8	2-stage infection	1st	F2A, T1	Sense of instability, recurrent joint effusion
3	58	M	29.0	2-stage infection	2nd	F2A, T1	Sense of instability, recurrent joint effusion
4	75	M	25.6	Aseptic loosening	2nd	F2B, T2B	Recurrent joint effusion
5	52	M	31.8	Instability	2nd	F1, T1	Sense of instability, recurrent joint effusion
6	71	M	34.6	2-stage infection	2rd	F2A, T2B	Sense of instability

No: number, yrs: years, G: gender, M: male, F: female, AORI: Anderson Orthopedic Research Institute, LLR: long leg radiograph, postop: postoperative, n/a: not available, HPE: histopathological examination.

Stress X-rays of the six patients with instability showed a median varus and valgus tilting of 4.8 (IQR 5.8) and 4.0 (IQR 2.2) degrees in extension and 6.0 (IQR 5.2) and 4.6 (IQR 2.8) degrees in flexion. Radiological follow up showed signs of osteolysis in two patients without signs of loosening of the implant. Infection was excluded by biopsy in four patients and additional histopathological examination showed signs of foreign tissue reaction with the presence of giant cells in two patients.

All patients with instability reported a decrease of complaints after hinge brace treatment. No further treatment was necessary in three patients while they continue to wear a custom-made hinge brace. The effect of brace treatment was temporary in two patients and one had brace discomfort. Eventually these three patients had surgery in which exchange to a thicker liner (median +7mm) was performed. No visual damage to the rHK mechanism or liner was noticed. At final follow up (median 13.6

Varus or valgus joint opening on stress X-ray (degrees)				Alignment LLR (degrees)	Exclusion infection by method	Treatment and outcome	Comments/ complications
Extension:		Flexion:					
varus valgus postop: varus valgus	3.1 3.2 4.2 4.6	varus valgus varus valgus	1.8 3.2 3.6 5.4	5° valgus	Open biopsy +aspiration	Brace with temporary effect Liner exchange with temporary effect Scheduled for total revision	HPE: Foreign body reaction
varus valgus	3.7 4.1	n/a		n/a	n/a	Brace with good effect	
varus valgus	5.8 3.9	varus valgus	6.8 4.6	n/a	Open biopsy +aspiration	Brace with temporary effect Liner exchange with good effect	Osteolysis on X-Ray HPE: Foreign body reaction
varus valgus	8.9 2.6	varus valgus	6.0 3.0	5° valgus	Open biopsy +aspiration	Brace with good effect	Osteolysis on X-ray
varus valgus	8.5 6.4	varus valgus	4.1 6.7	n/a	n/a	Brace with good effect	Previous bolt loosening of the hinge mechanism
varus valgus	1.8 4.8	varus valgus	9.5 5.1	2° varus	Open biopsy	Brace with good effect but discomfort Liner exchange with good effect	

months) two patients had less complaints of instability and were able to mobilize without their brace. One patient had reoccurrence of complaints after several months. New stress X-rays showed further tilting of the system and the patient is scheduled for a total revision to an RT-PLUS (Smith & Nephew, Memphis, TN, USA) rHK implant.

Discussion

In this cohort of 173 Legion rHK implants we encountered six patients with instability, all after revision procedures. Patients were predominantly male and four patients had a prior revision procedure. Because we were unfamiliar with instability in rHK implants we were surprised by the remarkable prevalence of 3.5%. Stress X-rays confirmed tilting of the mechanism beyond the 2° of build-in tolerance provided by the manufacturer. Hinge brace treatment had an adequate effect in half of the patients. In the remaining patients liner exchange might have a role in decreasing complaints although it was not sufficient in each patient and longer follow-up is needed.

Instability in rHK implants has been occasionally reported in the literature, e.g. by Joshi et al. who found a prevalence of approximately 5% in 78 implants.[6] It seems to occur most often in patients with grossly unbalanced flexion and extension gaps.[6,7] In these patients, distraction of the tapered rotation peg cannot be withstood by the soft tissues and leads to tilting of the mechanism.[4,5] Treatment exists of revision with balancing the flexion and extension gaps or conversion to knee arthrodesis.[6] Ward et al. described one patient who had instability complaints before dislocation of the rHK mechanism.[7] This patient had a prior fixed-HK implant and multiple revision procedures before. Another group of patients at risk of dislocation consists of those who underwent extensive capsular resection in oncology surgery.

Closer investigation of the stress X-rays confirms tilting of the link bush around the sleeve when varus or valgus stress is applied (Figure 2). The sleeve is not tapered and therefore tilting as result of distraction as previously described should be marginal.[4,5] However, in the distracted position the condyles of the rHK are no longer supported by the liner and stresses are only resisted by the relatively short link bush system. Distraction is possible when axial forces on the hinge system are diminished e.g. during the swing phase of walking or in unloaded activities. In these situations tilting beyond 2° of varus or valgus seems tolerated by the rHK system (Figure 1). Another explanation for further tilting might be wear or deformation of the polyethylene liner in the link-bush. Although no visible damage of the mechanism was observed in our revision cases, osteolysis and histopathological examination showed foreign tissue reaction, which both can be the result of polyethylene wear. Minor tilting between

the link bush and femoral component is also noticeable and its effect accumulates.
In our series, two patients had a revision for multidirectional instability and two patients had a prior, more rigid, rHK system (RT-PLUS, Smith & Nephew, Memphis, TN, USA) before revision to the Legion rHK implant. In accordance with the instability cases described by Joshi et al. and Ward et al., we do not recommend the less rigid Legion rHK implant in patients with a poor soft tissue envelop (e.g. multidirectional instability or posterior capsule insufficiency), extensor mechanism insufficiency, gross unbalanced flexion-extension gaps or a prior more rigid rHK system. For these cases we have now switched to the more constrained RT-PLUS system. In a biomechanical study by Friesenbichler et al. this system has been shown to be angular stable even in higher degrees of distraction.[4] As far as we know, no data are present on the angular stability in relation to distraction of the Legion hinge system.

In our clinic we start hinge brace treatment in all suspected cases of instability. Although there is no evidence available, in our experience brace treatment can be of diagnostic value in objectifying instability. In this study all patients reported a decrease of instability, less joint effusion after activity and/or decreased pain with the use of a brace. Because half of the patients were satisfied, hinge brace treatment is a worthwhile conservative option for treatment of instability in rHK implants. Until the exact cause and progress of instability is known regular follow-up with X-ray assessment is mandatory to evaluate the hinge mechanism. Liner exchange to a thicker liner was performed in the patients who had only a temporary effect of brace treatment, or brace discomfort. By increasing the height of the liner we obtained more tension on the soft tissue envelope which prevented distraction of the mechanism. At final follow-up two patients had less complaints of instability and were able to mobilize without their brace. One patient had reoccurrence of complaints after several months. New stress X-rays showed further tilting of the system and the patient is scheduled for a total revision to a RT-PLUS rHK system. Whether increasing the height of the liner is an effective solution for the instability problem by decreasing the possibility of joint distraction, longer follow up is needed to ensure instability will not reoccur in the other patients. A prospective study with standardized postoperative clinical and radiological (stress X-rays) assessment of instability after Legion rHK implants is needed.
A limitation of the present study is its retrospective design. Instability was confirmed in six patients; however, patients might have been missed because of nonspecific complaints or the unfamiliarity of instability in hinge implants by the surgeon leading to underreporting. Furthermore, rotational movement of the rHK system might cause instability complaints but could not be assessed.

Conclusion

Instability is an infrequently encountered diagnosis in rHK implants. The relative new design of the Legion rHK implant seems prone to this problem as we found a prevalence of 3.5% in our group. Stress X-rays and hinge brace treatment can be helpful in the diagnostic workup for instability. If hinge brace treatment is ineffective a, liner exchange might be considered.

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Chapter 8

General Discussion and Future Perspectives

The aim of this thesis was to evaluate and optimise clinical outcome and survival of rTKA. Several insights in patient selection for rTKA, implant fixation and implant performance have been investigated. This information can be helpful for orthopaedic surgeons in selecting the most appropriate patient with the highest success rate for knee revision surgery and to optimise the surgical technique for each patient. Moreover, by improving the survival and outcome of rTKAs, the future health care burden could be diminished. In this chapter, I will summarise the main results of this thesis, discuss the findings methodologically and provide clinical implications and future research perspectives.

Functional Outcome and Patient Selection in Revision Total Knee Arthroplasty for Malalignment

In **Chapter 2**, we investigated the functional outcome of a prospective cohort of patients with a revision for malalignment. On average, the patients showed a clinically significant functional improvement of 20.6 points on the functional Knee Society Score up to 5 years after surgery. A higher deviation of pre-revision varus or valgus malalignment, a younger age and a lower pre-revision functional score were the strongest factors predicting a positive gain in the functional outcome. Other, less strong, pre-revision factors with a positive influence on outcome were a lower Visual Analogue Score on pain, a higher range of motion and a higher degree of malrotation of the tibial component.

Based on the current literature, very little is known about the clinical outcome after an rTKA for malalignment and its influencing factors. Previous cohort studies have only presented clinical outcomes at the group level but without any description or quantification of the malaligned component(s).[1–3] Other smaller series on rTKAs for malrotation have only shown favourable results in terms of the clinical outcome.[4–7] This is the first study that evaluated a prospective cohort of patients with an rTKA for malalignment in all three-dimensional planes and that determined the factors that had the greatest influence on the functional outcome. Although the average patient showed a clinically significant functional improvement after revision, only patients with a revision for varus or valgus malalignment showed a correlation between the degree of malalignment and the change in functional improvement after revision. This may implicate that higher deviation of coronal malalignment will lead to functional incapabilities and correction of these coronal malaligned component(s) by rTKA may restore these impairments. On the other hand, finding no clinically significant correlations of malalignment in other planes (sagittal or axial) with functional improvement after rTKA does not necessarily mean that revision is of a

negligible value in those patients. It implicates that the absolute degree of malalignment is not related to the functional outcome of the revision.

Although definitions for malalignment have been described in literature, only a limited number of patients with malaligned components outside these limits will have complaints and functional limitations.[8] Therefore, the diagnosis of malalignment seems to be a complex patient-specific match of complaints, clinical observations and radiological measurable malrotation of the component(s), and conclusions cannot be drawn based on the absolute radiologically measured values alone. This might be the reason why several studies have not shown a clear relationship between absolute radiologically measured values and PROMs after primary TKA.[9–12] Therefore, a more patient-specific approach can be proposed for the diagnosis of malalignment. First, malalignment definitions as described by Gromov et al. [8] are derived from mechanically aligned TKAs. With this alignment technique, the coronal bone resection cuts of both the femur and tibia are planned perpendicular to the mechanical axis. The femoral component rotation is positioned on average in three degrees of external rotation to compensate for the perpendicular cut in a naturally oblique tibial joint line. Recent developments of a more anatomical approach for TKA placement (e.g. kinematic alignment) with the implant positioned as close to the native anatomy as possible might shed new light on the diagnosis of malalignment.[13] From this perspective, we should consider the patient's constitutional alignment before TKA when evaluating malalignment. For example, patients with a constitutional varus alignment might benefit from residual varus after a TKA.[14] This kinematic approach requires further investigation regarding the clinical outcome, implant survival and alignment target limits, given that previous studies have reported early implant loosening in patients with extensive varus alignment.[15,16] Second, a certain degree of malalignment may cause complaints in one patient but may be clinically unnoticed in another patient. Some patients might be able to compensate for some degrees of malalignment by increased muscle strength or adjusted gait patterns. Furthermore, from our clinical observations, we observed that particular combinations of (minor) malrotations can easily result in complaints and functional impairments. One example is a slight valgus malalignment in combination with some degree of internal rotation of the femoral component, weak hip abductor muscles and pes planus with hindfoot valgus. In those patients, the overall valgus will be aggravated by kneeing in and hindfoot valgus during weightbearing. Moreover, those patients will experience an unstable knee because they cannot compensate the kneeing in by muscle weakness. However, treatment of those patients will start with hip muscle strengthening and hindfoot correction instead of planning an rTKA.

In patients with persistent complaints and a clear relationship between the complaints and the malaligned implant, surgical treatment can be considered. Although we were not able to construct a prediction model because of the limited number of patients in the current study, with the results described in Chapter 2, we are now able to provide a better estimation of the functional improvement to the patient after rTKA for coronal malalignment and manage the patient's expectations better. When proceeding with surgical treatment, revision and correction of the malaligned component(s) will be needed. After exposure and removal of the component(s), with bony recuts, and wedge augmentation the correction will be achieved. Figure 1 shows an example a malaligned TKA and the correction after revision.

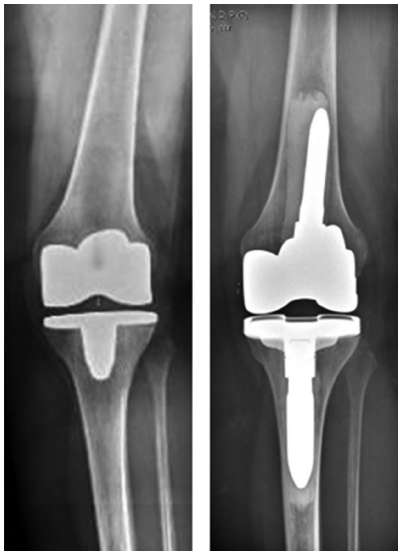

Figure 1: TKA in valgus (mal-)alignment (left) and after an rTKA with correction of the malalignment (right).

Optimising Fixation and Prevention of Aseptic Loosening in Revision Total Knee Arthroplasty

Appropriate implant fixation is one of the main challenges to overcome in rTKA, especially true for those cases with extensive bone loss or poor bone quality.[17,18] This might be one of the reasons why aseptic loosening is one of the most common reasons for re-revision surgery.[19–21]

Appropriate fixation of an rTKA in the three anatomical zones can be achieved by a numerous techniques.[17,18,22,23] Stems are commonly used to augment the fixation of the components in an rTKA and have shown to be beneficial in most revision cases.[24–26] They come in two main fixation types: cemented and press-fit (uncemented), and in a variety of dimensions. Moreover, there are additional techniques and augmentations for fixation such as bone impaction grafting,[27] highly porous trabecular metal wedges,[28] highly porous metaphyseal cones and sleeves,[29,30] or combinations of those.[31] Given the numerous treatment options and the lack of sufficient clinical evidence regarding what to use, the decision on a fixation technique is based on the surgeon's experience, perioperative findings and the availability of treatment options to achieve appropriate fixation. [17]

In **Chapter 3**, we investigated the relationship between the quality of the fixation in the three anatomical zones of a hybrid fixed tibial component in rTKA and subsequent re-revision for aseptic loosening (rrTKA-AL). The results showed an association between the height of the epiphyseal bone resection level and the number of sufficiently cemented metaphyseal zones and rrTKA-AL. The canal filling ratio (CFR) of the uncemented press-fit diaphyseal engaging stem was not associated with rrTKA-AL. Other predictive factors for rrTKA-AL were multiple revision surgeries in the past, a higher Anderson Orthopaedic Research Institute (AORI) score and the presence of a prior diaphyseal stem, all of which might be related to bone loss and poor bone quality.

In the literature, very little has been published about the zonal fixation in relation to rrTKA-AL. Morgan-Jones et al.[18] suggested appropriate fixation in at least two of the three anatomical zones was sufficient for optimal survival for an rTKA based on their experience. However, there is a lack of clinical evidence to confirm this view and considering the results of Chapter 3, appropriate fixation in the metaphyseal zone (zone 2) seems to be more important than that of the diaphyseal zone (zone 3) in hybrid fixed tibial components. In contrast to our finding of no association between diaphyseal fixation and rrTKA-AL, two previous studies have found a relation between the CFR and aseptic loosening.[32,33] However, the mean CFR reported by Fleischman

et al.[32] was significantly lower compared with the current study, and Lee et al.[33] defined aseptic loosening based on radiological assessment, and only a minor proportion of the cases were revised and intraoperatively tested and found to be 'really' loose. These differences, along with the lack of assessment of the epiphyseal and metaphyseal zones in both studies, might explain these different findings.

With the results of Chapter 3, we are able to identify those patients at risk for aseptic loosening after rTKA, allowing the surgeon to adapt the fixation strategy in those specific cases. In patients with an rTKA and limited epiphyseal and metaphyseal bone loss, three-zone-augmentation might not be needed. It is questionable whether diaphyseal fixation is necessary in these patients given that the results of the Chapter 3 showed no correlation between the diaphyseal CRF and later rrTKA-AL. This is supported by previous studies that showed good survival and sufficient stability in finite element analysis for stemless rTKAs with additional metaphyseal fixation.[34–36] In cases with substantial epiphyseal bone loss and, subsequently, a low epiphyseal bone cut, metaphyseal fixation becomes increasingly important. A lower epiphyseal cut results in a smaller surface area for fixation due to the tapered shape of the proximal tibia. Moreover, because the epiphyseal bone quality is presumed to be impaired in the majority of revision cases, fixation in this zone may always be compromised to a certain extent.[18,37] Although porous epiphyseal wedges for bone ingrowth exist, the availability and clinical evidence of these augmentations is scarce.[28] In those cases with extended epiphyseal bone loss, it becomes even more important for the surgeon to achieve sufficient metaphyseal fixation of the revision knee implant. This is emphasised by the association between the quality of cementation in the metaphyseal zone and later rrTKA-AL in Chapter 3. Surgeons should ensure sufficient metaphyseal interdigitation of cement; one way to achieve this is by using the 'finger packing technique'.[38] If for some reason this is not possible – for example, due to sclerosis or extensive bone loss – then we advise the use of additional metaphyseal augmentation in this zone by using a cone or a sleeve. In addition, the association between increased bone loss and decreased bone quality with higher rates of aseptic loosening seems quite evident based on the results of Chapter 3: the presence of a prior stem (metaphyseal and diaphyseal bone loss), multiple previous arthroplasties (increased bone loss and decreased bone quality) and a higher AORI classification are all related to rrTKA-AL.

In **Chapter 4**, we compared a retrospective cohort of fully cemented rotating hinge knee implants with a cohort of hybrid fixed rotating hinge knee implants to investigate whether one fixation technique is superior to the other in terms of survival. The results showed superior survival for fully cemented fixation compared with hybrid fixation. Although a study with finite element analyses[39] and clinical

observations of a previously published cohort study[40] provided evidence regarding the benefits of fully cemented fixation, this is the first clinical evidence of the superiority of fully cemented fixation compared with hybrid fixation in rotating hinge knee implants. The femoral component showed a higher risk for aseptic loosening compared with the tibial component. Prior use of a stemmed component appeared to be a risk factor for re-revision for aseptic loosening, a finding which is in line with the results of Chapter 3.

A rotating hinge knee is a highly constrained implant design; thus, forces are directed through the hinge mechanism onto the fixation interface. These forces make these implants more vulnerable to aseptic loosening.[41,42] In contrast to the results of Chapter 4, previous studies on stem fixation have found no differences in survival or micromotion measured with RSA between hybrid and fully cemented stems in rTKAs with non-hinge implants.[43–45] In addition, the femoral component seems to be more prone to loosening compared with the tibial component, a phenomenon that is in contrast to registry data of primary TKAs and rTKAs in which the tibial component is more at risk of aseptic loosening.[46] So, rotating hinge knee implants seem to behave differently compared with rTKAs with non-hinge implants. There are several explanations. First, the cases in which rotating hinge knee implants are used are quite complex: in these (re)revision cases, bone loss can be extensive, which makes fixation even more challenging. Usually, femoral fixation is uncomplicated: the femoral component grabs onto the distal femur with the help of fixation of the intercondylar box of the implant between the condyles. When bone loss extends and wedge augmentations are needed, the femoral component has less bone to grab onto and the intercondylar box surface is diminished, fixation might become more problematic, resulting in a higher risk of loosening.[17,37] Second, the anatomical shape of the distal femur and its variations in antecurvation make it hard to align and to fix a press-fit stem properly. This possibly makes diaphyseal fixation with cemented stems more reliable and easier to perform in the more demanding fixation interface of a hinge knee implant. Moreover, Farid et al.[40] stated that the femoral component is subject to more bending and torsion stresses due to the natural deviation of the femoral anatomic axis from the mechanical axis of the lower extremity. Third, the design of the hinge mechanism itself exerts an influence: the rotational free axis of the tibial component is always parallel to the longitudinal axis of the tibial stem, which diminishes torsional stresses. For the femoral component, this axis changes direction while the knee flexes, and varus or valgus stresses will convert to torsional stresses acting on the femoral component and its stem.

Considering the results of Chapter 4, we advise the use of fully cemented stems in hinge knee arthroplasty. A recently published study showed similar findings with superior survival for fully cemented hinge knee implants.[47] In contrast to primary and rTKA with non-hinge implants, special attention should be paid to the fixation of the femoral component because it seems more prone to loosening in hinge-type implants (Chapters 4 and 5). This finding has decreased the threshold for the use of additional metaphyseal femoral cones in rotating hinge knee implants in our clinical practice today.

In **Chapter 5** we assessed the micromotion of a fully cemented hinge knee implant with the use of RSA. Although there were some degrees of micromotion, especially in the first six weeks following surgery, most implants showed a subsequent stabilisation of micromotion. In the literature, this stabilisation is thought to be a sign of adequate fixation and a predictor of good survival later on in primary TKA.[48] However, at the same time, greater micromotion (>1 mm/degree) does not indicate loosening after an rTKA in long follow-up rTKA RSA studies.[45,49] Combining this knowledge with the absence of radiological signs of loosening of these hinge knee implants, we conclude that fully cemented fixation in this hinge-type rTKA seems adequate during the first two years after surgery. The femoral components showed more micromotion outliers, a finding that seems to be in line with the higher risk of loosening of femoral components in hinged knee implants found in Chapter 4. Most clinical outcome scores improved over time despite the fact that a notable number of patients encountered a complication, and one patient even required a reoperation (extensor apparatus reconstruction). Complications and reoperations are unfortunately frequent in revision surgery with hinge knee implants (see also the findings reported in Chapter 6). The main limitation of this study was the loss of analysable tibial components due to marker issues. The extensive size of the implant and the limited cancellous bone for marker placement makes RSA marker visibility challenging.

A Novel Rotating Hinge Knee Implant: Short- to Midterm Performance and Unforeseen Instability Cases

In **Chapter 6**, we described the clinical outcome and survival of 147 consecutive hinge knee implants from two institutions. Short- to midterm follow-up at 2 and 5 years showed a survival rate of 100% and 98.5% (95% CI 94.3%–99.6%). Overall, two cases required a revision, one for infection and one for aseptic loosening of the femoral component. Survivorship for the endpoint reoperation at 2 and 5 years was 85% (95% CI 78.2%–90%) and 77.7% (95% CI 68.8%–84.4%), respectively. Reoperations were mainly performed for infection with debridement, antibiotics and implant retention

(n = 14) and patellar or extensor mechanism complications (n = 12). Although hinge knee implant cohorts are difficult to compare due to the heterogeneous nature of the groups and patients (e.g. different implant systems, primary vs revision, differences in complexity, additional procedures), the short- and midterm implant survival rates seem to be comparable.[40–42,50] Complications and reoperations are known to be high in rTKAs with any hinge knee implant and can occur in up to 50% of the patients after 10 years of follow-up.[50] Infection, aseptic loosening, extensor mechanism failure and patellar instability are the most frequently mentioned complications.[42,50] Because of differences in the rotating hinged mechanism designs, specific complications can occur with regard to the mechanical failure type of the system.[51–54] In the cohort described in Chapter 6, we encountered two loosenings of the hinge bolt which connects the femoral hinge to the tibial base plate. Two more patients had complaints of extensive varus/valgus instability and have had a revision with liner and bolt exchange. This latter complication is rather unusual in hinge knee implants. To gain more knowledge about this complication, we investigated a group of patients with instability complaints after this specific hinge knee implant (Chapter 7).

In **Chapter 7**, we presented six patients, from a total cohort of 173 hinge knee implants, who had complaints of instability of their knee (a feeling of instability or recurrent joint effusion during activity). Investigation with stress radiographs showed varus and valgus tilting beyond the built-in tolerance of the hinge mechanism (±2 degrees). All patients noticed some relief of their complaints with brace treatment; at the time of publication, three patients have had a liner exchange to a thicker one to obtain more tension of the soft tissue envelope to prevent distraction of the mechanism. As time passed by, only one of four patients is still satisfied with the liner exchange. Eventually, three patients had a re-revision to another type of hinge knee implant, of whom one is now satisfied (one had no improvement and one developed a chronic infection). With these new insights, we are more reluctant to offer surgical treatment to patients for instability complaints caused by this specific hinge knee implant.

Two of the re-revisions and extracted hinge knee implants were sent to the London Implant Retrieval Centre (LIRC) for further analysis. The inner polyethylene (PE) sleeve of the link system showed signs of fractures and deformation close to the apex in both implants (Figure 2). The clearance between the inner (metal) and outer (plastic) sleeve was 0.14 and 0.22 mm, respectively. This could potentially contribute to 0.6–1.2 degrees and 0.9–1.8 degrees of varus/valgus angulation, depending on the inner and outer shaft contact points. The tolerance of the hinge between the link bush and the femoral component was not investigated. The experts from the LIRC concluded that the noticed instability cannot be confirmed with the data from the analysis. To date, we cannot fully explain the extensive varus and valgus deviation of the system in those six patients.

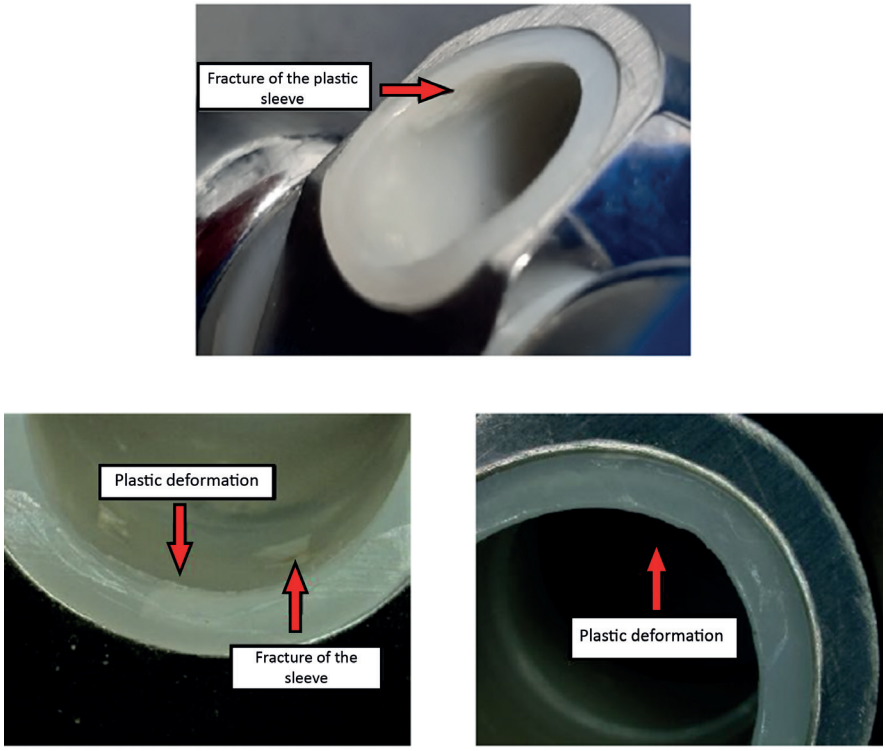

Figure 2: Close-up photographs of the damaged PE sleeves in the link bush systems of the two retrieved hinge knee implants.

Overall Conclusion

Based on the results of the studies presented in this thesis, we provide new insights into the outcome of revision total knee arthroplasty and factors influencing the functional outcome and survival. Revision of a total knee arthroplasty for malalignment appears to be an effective treatment with improved functional outcome up to 5 years postoperative and a higher prerevision coronal deviation is associated with a higher gain in functional recovery. We found an association between the zonal fixation and subsequent re-revision for aseptic loosening in hybrid fixated tibial components in revision knee arthroplasty. The height of the epiphyseal bone resection level and the cementing quality in the metaphyseal zone appear to be crucial for preventing re-revision. In rotating hinge knee implants a fully cemented fixation of the components was found to be superior compared to hybrid fixation and the femoral

component might be more prone to loosening. In addition, radiostereometric analysis of a fully cemented rotating hinge knee implant showed adequate fixation in the first 2 years after surgery with more outliers of micromotion of the femoral components. At last, short and mid-term results of a novel rotating hinge knee implant showed good survival although some patients experienced unforeseen instability complaints with noticeable laxity on examination. All this information may help orthopaedic surgeons to select and inform patients, and to choose the best treatment options for optimal survival in revision total knee arthroplasty.

Future Perspectives

We have to gain a better understanding of the complaints and functional impairments caused by malalignment of primary TKA implants. As stated above, we need a more individual approach in which the constitutional alignment and dynamic functional assessment play a role in the diagnosis of malalignment. Therefore, we need objective and dynamic instruments to determine the relationship between the malaligned component(s) and complaints or functional impairments in each patient. Dynamic fluoroscopic TKA analysis during daily tasks performed by the patient might reveal abnormal motion patterns in patients with malalignment.[55] Further development of four-dimensional computed tomography (CT) might be able to show patellar maltracking in malaligned TKAs.[56] Moreover, accurate and precise alignment measurements and ligament laxity patterns with robot-assisted knee surgery might reveal associations between TKA alignment, ligament laxity and the outcome in each patient. This approach might help to achieve a better understanding of malalignment at an individual level, to decrease the rate of malalignment in primary TKA and to realign the revision knee implant in an rTKA for malalignment. Ultimately, given the predicted rise in TKAs, information regarding personal alignment, ligament laxity patterns, joint kinematics and patient factors might lead to an individual treatment algorithm with the most optimal alignment, fixation type and implant design selected based on the patient's desires, while keeping the health care costs and burden low.

In rTKA, we should aim for an optimal fixation strategy. Here, too, an individual approach is needed. Pre-operative planning, bone loss, bone quality and risk factors for later aseptic loosening should be assessed. As bone can be lost during extraction of an implant, the true bone loss should be evaluated during surgery, and real-life adjustment of the fixation strategy is a future goal for improvement. Augmentation should only be used when it adds value, as overuse will have a negative impact on health care costs and will make future revisions more complex.[57] All this information

could be combined to create a patient-specific fixation algorithm for an rTKA. Although clinical data are the best input for building a fixation algorithm, sufficient data will require large prospective cohorts of patients with long-term follow-up and might appear unfeasible. Pre-clinical studies such as rTKA loading cadaver experiments and finite element analysis will be able to compare augmentation strategies over a wide range of different bone defects and patient characteristics. To validate the results of these studies, clinical implementation with assessment of micromotion with RSA can help to further develop adequate fixation techniques within 2 years instead of long-term follow-up.

To confirm the adequate performance of the novel hinge knee implant mentioned in Chapters 5, 6 and 7, a longer follow-up is needed. Although we found gross instability of this specific hinge knee implant in some patients, the overall clinical outcome and survival may still be adequate. As stated, due to the complexity of the cases and high forces transmitted through the hinge mechanism complications and failure of the mechanism and fixation are frequently encountered and the price to be paid in every hinge knee case. From now on, a patient specific decision has to be made on which type of hinge knee system should be used to reduce implant related complications and new hinge knee designs should undergo extensive mechanical testing before they are used in vivo. As a first clinical step, prospective studies with assessment of implant fixation by the use of RSA and clinical observations should be performed to guarantee a well-performing and safe implant introduction before widespread clinical use.[58]

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8

Chapter 9

Nederlandse Samenvatting

Het doel van dit proefschrift was het evalueren en optimaliseren van de klinische uitkomsten en de overleving van revisie totale knieprothesiologie (rTKP). Verschillende kennislacunes in patiëntselectie voor rTKP, implantaatfixatiemethoden en implantaat functioneren zijn onderzocht. Deze nieuwe informatie kan orthopedisch chirurgen helpen bij het selecteren en informeren van patiënten voor een rTKP en het patient-specifiek optimaliseren van de operatietechniek. Bovendien kan door het verbeteren van de overleving en de functionele uitkomst van rTKP's de toekomstige zorglast worden verminderd.

In **Hoofdstuk 2** van dit proefschrift is de functionele uitkomst van een prospectief cohort van patiënten met een rTKP vanwege malalignement onderzocht. Gemiddeld vertoonden patiënten een klinisch significante functionele verbetering op de functionele Knee Society Score tot vijf jaar na de operatie. Een hogere afwijking van pre-revisie varus- of valgusmalalignement, een jongere leeftijd en een lagere pre-revisie functionele score waren de sterkste positief beïnvloedende factoren voor de verandering in de functionele uitkomst. Andere, minder sterke en minder klinisch relevante positieve pre-revisie factoren waren een lagere Visuele Analoge Score voor pijn, een groter bewegingsbereik van de knie en hogere mate van malrotatie van de tibia component.

De relatie tussen de implantaatfixatie in de drie anatomische zones (epifyse, metafyse en diafyse) van een hybride gefixeerde tibia component van een rTKP en re-revisie voor aseptische loslating (rrTKA-AL) werd onderzocht in **Hoofdstuk 3** van dit proefschrift. De resultaten van deze studie toonden een associatie aan tussen de hoogte van het epifysaire botresectieniveau en het aantal adequaat gecementeerde metafysaire zones en het risico op rrTKA-AL. Andere voorspellende factoren voor rrTKA-AL waren meerdere revisies in het verleden, een hogere mate van botverlies (Anderson Orthopaedic Research Institute-score) en de aanwezigheid van een eerdere diafysaire steel, die allemaal gerelateerd kunnen worden aan botverlies en verminderde botkwaliteit. De kanaalvullingsratio (canal filling ratio; CFR) van de ongecementeerde press-fit diafysaire stelen was niet geassocieerd met rrTKA-AL.

In **Hoofdstuk 4** vergeleken we een retrospectief cohort van volledig gecementeerde scharnierknie-implantaten met een cohort van hybride gefixeerde scharnierknie-implantaten om te onderzoeken of de ene fixatietechniek superieur is aan de andere in termen van overleving. De resultaten van de studie toonden een superieure overleving voor volledig gecementeerde fixatie in vergelijking met hybride fixatie. Bovendien vertoonde de femur component een hoger risico op aseptische loslating in vergelijking met de tibia component. Daarnaast was de aanwezigheid van een eerdere diafysaire steel een risicofactor voor rrTKA-AL.

Het meten van microbewegingen van een volledig gecementeerd scharnierknie-implant in het bot met behulp van radiostereometrische analyse (RSA) werd uitgevoerd in **Hoofdstuk 5.** Hoewel er enige mate van microbewegingen werden waargenomen, vooral in de eerste zes weken na de operatie, toonden de meeste implantaten daaropvolgend een stabilisatie van microbewegingen. Een significant aantal componenten vertoonde een totale translatie > 1 mm of een totale rotatie > 1 graad ten tijde van twee jaar follow-up, met meer uitschieters van de femurcomponenten in vergelijking met de tibiacomponenten. De meeste klinische uitkomstscores verbeterden in de loop van de tijd, maar een aanzienlijk aantal patiënten ondervond een complicatie en één patiënt werd opnieuw geopereerd. De belangrijkste beperking van deze studie was het verlies van analyseerbare tibia componenten door RSA-marker gerelateerde problemen. De grote omvang van het implantaat en het beperkte spongieuze bot voor markerplaatsing bemoeilijkte de zichtbaarheid van RSA-markers.

In **Hoofdstuk 6** beschreven we de overleving en klinische uitkomst van 147 opeenvolgende scharnierknie-implantaten. Korte- tot middellange termijn follow-up na twee en vijf jaar toonde een overleving van 100% en 98,5% (95% CI 94,3 – 99,6%). De heroperatievrije overleving na twee en vijf jaar waren respectievelijk 85% (95% CI 78,2 – 90%) en 77,7% (95% CI 68,8 – 84,4%). Revisies werden uitgevoerd voor infectie en aseptische loslating van de femur component. Heroperaties waren voornamelijk voor infectie met debridement, antibiotica en implantaatbehoud en problemen van de knieschijf of strekapparaat. Twee patiënten waren overleden bij de laatste follow-up.

Zes patiënten, uit een totaal cohort van 173 scharnierknie-implantaten, die klachten hadden van instabiliteit (gevoel van instabiliteit of terugkerende gewrichtseffusie tijdens activiteit) werden beschreven en geanalyseerd in **Hoofdstuk 7**. Verdere onderzoeken met stress-röntgenopname toonden een toegenomen varus- en valgusopening in zowel extensie als in flexie van de knie. Alle patiënten merkten enige verlichting van klachten met scharnierbracebehandeling. Op het moment van publicatie hadden drie patiënten een vervanging van de insert ondergaan naar een dikkere maat om zo meer stabiliteit te verkrijgen. Op korte termijn leek dit voor twee van de drie patiënten tot een verbetering van de klachten te leiden, maar bij langere follow-up bleek het resultaat teleurstellend te zijn.

Met de resultaten van de studies dit proefschrift geven we nieuwe inzichten in de uitkomsten van revisie totale knieprothesiologie en de factoren die de functionele uitkomsten en de overleving beïnvloeden. Deze informatie kan orthopedisch chirurgen helpen bij het selecteren en informeren van patiënten en het kiezen van de meest optimale behandeling.

9

Research Data Management

PhD Portfolio

List of Publications

Dankwoord

About the author

Theses Sint Maartenskliniek

Research Data Management

Ethics and privacy

This thesis is based on the results of medical-scientific studies with human participants, which were conducted in accordance with the principles of the Declaration of Helsinki. All studies were approved by the institutional review board of the Sint Maartenskliniek. The medical ethical review committee (METC Slotervaart-ziekenhuis en Reade, NL58887.048.16) has given approval to conduct the study of Chapter 5. Written informed consent was obtained from participants of this study for the collection, processing, and publication of their data. For the studies of Chapter 3, 4, 6 and 7 informed consent and medical ethical review was not required according to the Dutch Medical Research Involving Human Subjects Act. The privacy of the participants was warranted by the use of pseudonymization.

Data collection and storage

The data of Chapter 2 was collected from a prospective database at the Sint Maartenskliniek. Relevant data were selected, analyzed, stored pseudonymized and accessible only to project members on a secured server of the Sint Maartenskliniek. The data of Chapters 3, 4 and 7 were retrospectively collected form the electronic patient files, analyzed, stored pseudonymized and accessible only to project members on a secured server of the Sint Maartenskliniek. The data from Chapter 5 was prospectively collected, analyzed, stored pseudonymized and accessible only to project members on a secured server of the Sint Maartenskliniek. Hardcopy paper data (Case Report Forms) are stored in file cabinets within the department and only accessible to project members.

The data form Chapter 6 was collected and pseudonymized transferred for data analyzation to Lagone Medical Centre NYU, New York, USA, after fulfilling a data sharing agreement. Data was stored of our own subjects only on a secured server of the Sint Maartenskliniek.

Data sharing

The data from Chapter 2 was not suitable for reuse by the absence of patients permission to share. The anonymized dataset of Chapter 3 and 4 is findable and published online on Zenodo.org (**10.5281/zenodo.13907050 and 10.5281/zenodo.14039474**). The data of Chapter 5 was not suitable for reuse as patients did not give permission for sharing within the informed consent. Moreover due to the very specific surgical interventions with radiologically visible markers, type of implants used and characteristics of the patients there is a risk of traceable identities and that anonymity cannot be guaranteed. The comprehensive dataset of Chapter 6 was analyzed by the coauthors of the collaborating institute and is not owned by our

institute. The subset of data of Chapter 7 could not be published and shared because the small number of patients with very specific complaints is at risk to be linked to specific identities and anonymization cannot be guaranteed.
All data not suitable for reuse will be archived for 15 years after termination of the studies.

PhD Portfolio of Simon Nurettin van Laarhoven

Department: Orthopedic Surgery, Sint Maartenskliniek
PhD period: **01-12-2020 – 01-06-2025**
PhD Supervisor(s): **Prof. dr. B.W. Schreurs**
PhD Co-supervisor(s): **dr. P.J.C. Heesterbeek, dr. A.B. Wymenga**

Training activities	Hours
Courses	
- EKS online course, New technologies and robotics in TKA (2020)	9.00
- RIHS - Introduction course for PhD candidates (2021)	15.00
- Radboudumc - eBROK course (for Radboudumc researchers working with human subjects) (2021)	26.00
- Radboudumc - Scientific integrity (2022)	20.00
Seminars	
- Webinar 'How to recognize fake news in orthopaedics?' (2020)	2.00
- VMS avond: research van dromen naar doen (2022)	2.00
- Masterclass Knee Revision course, SMK, faculty (2024) (oral presentations)	10.00
Conferences	
- WAC (2021)	24.00
- IRSA (2021), oral presentation	24.00
- NOV (2021), oral presentation	16.00
- DKS (2022), oral presentation	4.00
- EKS congress (2022)	16.00
- EKS Kitzbudel (2023)	16.00
- IRSA 2023 (2023), oral presentation and moderator	16.00
- TOTBID 2023 (2023), oral presentation	32.00
- EKS 2023 Bordeaux (2023), oral presentation	16.00
- WAC Madrid (2024), oral presentation	16.00
- NOV najaarscongres (2024), oral presentation	6.00
Other	
- EKS travelling fellowship, 14 clinics around Europe (2022)	30.00
- Clinical research lead (2022)	140.00
- Visiting Surgeon program, NYC, USA (2024)	8.00

Teaching activities	
Lecturing	
- Opleiden AIS in de praktijk (2022)	8.00
- Mentor PA in opleiding (2024 - 2025)	16.00
Supervision of internships / other	
- Supervisor of 2 junior researchers and master student (2023)	48.00
- Supervisor of 2 junior researchers (2024)	60.00
Total	**580.00**

List of Publications

van Laarhoven SN, Nota SPFT, van Hellemondt G.G, Scheurs BW, Wymenga AB, Heesterbeek PJC. Association between postoperative zonal fixation of hybrid tibial components in revision total knee arthroplasty and subsequent aseptic loosening: Appropriate metaphyseal fixation is key. *Bone & Joint Journal* 2025 Jan 1;107-B(1):65-71. doi: 10.1302/0301-620X.107B1.BJJ-2024-0241.R1

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About the Author

Simon van Laarhoven was born on April 14th, 1985, in Wageningen, The Netherlands. After graduating from secondary school (VWO, Pantarijn, Wageningen) in 2003, he moved to Eindhoven to study Biomedical Engineering at the Eindhoven University of Technology. However, after one year, he decided to change his career and was selected to begin medical school at Maastricht University. Upon completing his bachelor's degree, he undertook his final internship at the Department of Orthopaedics at Zuyderland Medisch Centrum, Heerlen. He graduated with his medical degree in 2010.

As a resident (not in training), he worked at the Department of Orthopaedics and the Intensive Care Unit at Zuyderland Medisch Centrum (Heerlen), as well as at the Department of Orthopaedics at Kasturba Medical College (Manipal, Karnataka, India). In 2013, he began his residency training under the supervision of Prof. dr. I.C. Heyligers, working at Zuyderland Medisch Centrum (Heerlen-Sittard), Maastricht UMC+ (Maastricht), and Maxima Medisch Centrum (Veldhoven).

After completing his training, Simon began a fellowship in primary and revision knee and hip arthroplasty at the Sint Maartenskliniek, under the supervision of G.G. van Hellemondt. With a particular interest in revision surgery and several research projects, the framework for his thesis was founded.

Since 2020, Simon has been working as a staff member at the Knee Reconstruction Unit at the Sint Maartenskliniek. In 2022, he was selected for the European Knee Society Travelling Fellowship, visiting 14 specialized knee surgery hospitals across Europe. He has a particular interest in revision knee surgery and is the clinical research leads of surgical innovations.

Simon lives with his wife Floortje and their two daughters, Iep and Kees, in Lent. In his free time, he enjoys running and making wooden furniture.

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