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Good mid-term outcome of the rotating hinge knee in primary total knee arthroplasty – Results of a single center cohort of 106 knees with a median follow-up of 6.3 years



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ABSTRACT

Background: The prognosis of complex primary total knee arthroplasty (TKA) with severe deformity and ligament deficiency is not clear. There is a paucity of evidence in the current literature on treatment outcomes of the rotating hinge knee implants in primary TKA. The aim of this study was to determine the mid-term clinical, radiographic, and health-related quality of life (HRQoL) outcomes in patients who had undergone complex primary TKA using single hinged knee replacement.

Methods: In total, 106 complex primary TKAs (101 patients) were performed using the single rotating hinged knee (RHK) implant design at our institution between January 2004 and December 2013. We conducted a retrospective analysis of prospectively collected outcome data of these patients, obtaining also information on all possible revision surgeries from the Finnish Arthroplasty Register, and conducted a prospective follow-up study of all living patients.

Results: The 10-year Kaplan-Meier survival rate of the RHK knees was 91.6% (95% CI 86.0% to 97.2%) with revision for any reason as the endpoint. Overall, eight knees (7.5%) underwent revision surgery during the follow-up. None of the unrevised RHK knees were radiographically loose. The majority of patients evinced good clinical outcome and quality of life as measured with patient reported outcome measures.

Conclusion: The hinge knee replacement which was assessed current study can be regarded as a suitable option in complex primary TKA, provided adequate attention is paid to the correct indications and patient selection.

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1. Introduction

Primary total knee arthroplasty (TKA) is an effective treatment of end-stage knee osteoarthritis (OA) [1]. According to data from national arthroplasty registries, the 10-year survival rate of contemporary TKA implants exceeds 90% [2–4]. Most primary TKAs are performed using cruciate-retaining or posterior stabilizing primary components, with cemented fixation and fixed-type polyethylene insert without stems and/or augments [2–4]. A minority of primary TKAs are, however, complex. Such knees may have severe preoperative deformities as well as bony and/or ligament deficiencies. TKA implants with varying levels of prosthesis constraint are available to help surgeons deal with these difficult situations.

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A few previous studies have proposed that highly-constrained TKA designs are prone to early implant loosening and increased polyethylene wear [5,6]. There seems to be a clear association between the level of constraint and the risk for revision, i.e., the higher the level of constraint, the higher the revision rate [2–4]. Thus, in primary TKA, the least level of constraint necessary to gain stability and to reconstruct adjacent bone loss should be used [5,6]. There are, however, clinical situations that require the use of hinged knee implants to achieve adequate stability. Hinged TKAs are most commonly used in knees with extensor mechanism failure, absence of the collateral ligament, large bone defects, or in patients undergoing tumor surgery [5–7]. Hinged knee implants are stabilized with a mechanical axle that creates a link between the femoral and the tibial components. This axle restricts movement in the coronal and sagittal planes, but it allows the rotating movement. The range of rotation and how weight-bearing is transmitted through the knee depends on the type of hinged knee implant [6,8]. Surprisingly, little is known at present on the mid- to long-term outcomes of complex primary TKAs using hinged implants [5,9–12].

The purpose of this study was to determine the mid-term clinical, radiographic, and health-related quality of life (HRQoL) outcomes in patients who had undergone complex primary TKA using single hinged knee replacement design between January 2004 and December 2013 at our institution.

2. Methods

Between January 2004 and December 2013, 106 complex primary TKAs (101 patients) were performed at our institution using the NexGen® RHK rotating hinge knee implant. The NexGen® Rotating Hinged Knee (RHK) is a single design manufactured by Zimmer Biomet (Warsaw, Indiana, USA). The implant uses condylar loading and allows up to 25 degrees of internal-external rotation [13]. The study site is an academic high-volume tertiary referral center with an annual volume of approximately 2500 primary TKAs.

This study comprised three phases: first, a prospective follow-up study of all the surviving patients of this cohort was conducted. Second, a retrospective analysis of prospectively collected outcome data recorded into the electronic joint replacement database at our institution. Third, information on possible revision surgeries that might have been performed elsewhere and thus not recorded into our own database, were cross-checked from the Finnish Arthroplasty Register.

All RHK knee arthroplasties were performed using the medial parapatellar approach and a tourniquet was also routinely used. Mechanical alignment [14] technique was utilized. TKAs were carried out under spinal anesthesia in combination with intravenous sedation. General anesthesia was used only if there was a contraindication to spinal anesthesia. Immediate, full weight-bearing was allowed, and all patients were mobilized on the first postoperative day. An antithrombotic prophylaxis with low-molecular-weight heparin, enoxaparin, was administered for 4 weeks postoperatively. All details of perioperative care and possible complications were recorded in the hospital's electronic database in a routine manner. In 39 knees (36.8%), the patella was resurfaced in the index TKA. Cemented femoral and tibial stems were used in all operations.

At baseline of the study, there were 101 patients (106 knees) who were included in the retrospective analysis, where all the demographics, surgery reports, first post-operative visits (at 2–3 months), possible post-operative complications and adverse events as well as reasons for revisions were obtained from the medical records and the hospital's electronic clinical database.

In the prospective study phase, an extra follow-up visit was scheduled between 4 and 14 years post-operatively, depending on the year of the index operation. All of the 46 living and unrevised patients (48 knees) were recruited by telephone for an extra follow-up visit at our outpatient clinic (Figure 1). Information on possible revision surgeries performed on patients elsewhere who were lost to follow-up (18 patients, 19 knees), was cross-checked from the Finnish Arthroplasty Register [2]. One handicapped patient was excluded from the study for ethical reasons. In total, 26 patients (27 knees) agreed to participate in the follow-up phase of this study. Those patients who were unable to attend the extra follow-up visit received the set of PROM questionnaires by surface mail and were asked to visit their nearest health care provider for plain radiographs to be taken. The extra follow-up visit included plain radiographs of the operated joint, clinical assessment by a physiotherapist, and the use of PROMs, i.e., the Oxford Knee Score (OKS), the Knee Injury and Osteoarthritis Outcome Score (KOOS), the 15D (generic measure of health-related quality of life), and the Forgotten Joint Score (FJS).

2.1. Radiographic evaluation

2.1.1. Pre-operative

Radiographic findings, such as mechanical axis, Kellgren-Lawrence grade [15], and Krackow [16] scale, were measured or evaluated from the pre-operative radiographs. The degree of deformity (varus/valgus alignment) was measured from the long-axis weight-bearing anterior-posterior radiographs. The stability of the patella was examined from the skyline patellar radiographs. All patient records and pre-operative radiographs were examined by the first author who had not been involved in the primary surgeries and had not met the patients during the follow-up visits. A sample (n = 20) of the pre-operative radiographs was later reviewed by an experienced orthopaedic surgeon, who was blinded to the original measurements, to estimate the reliability of the measurements.

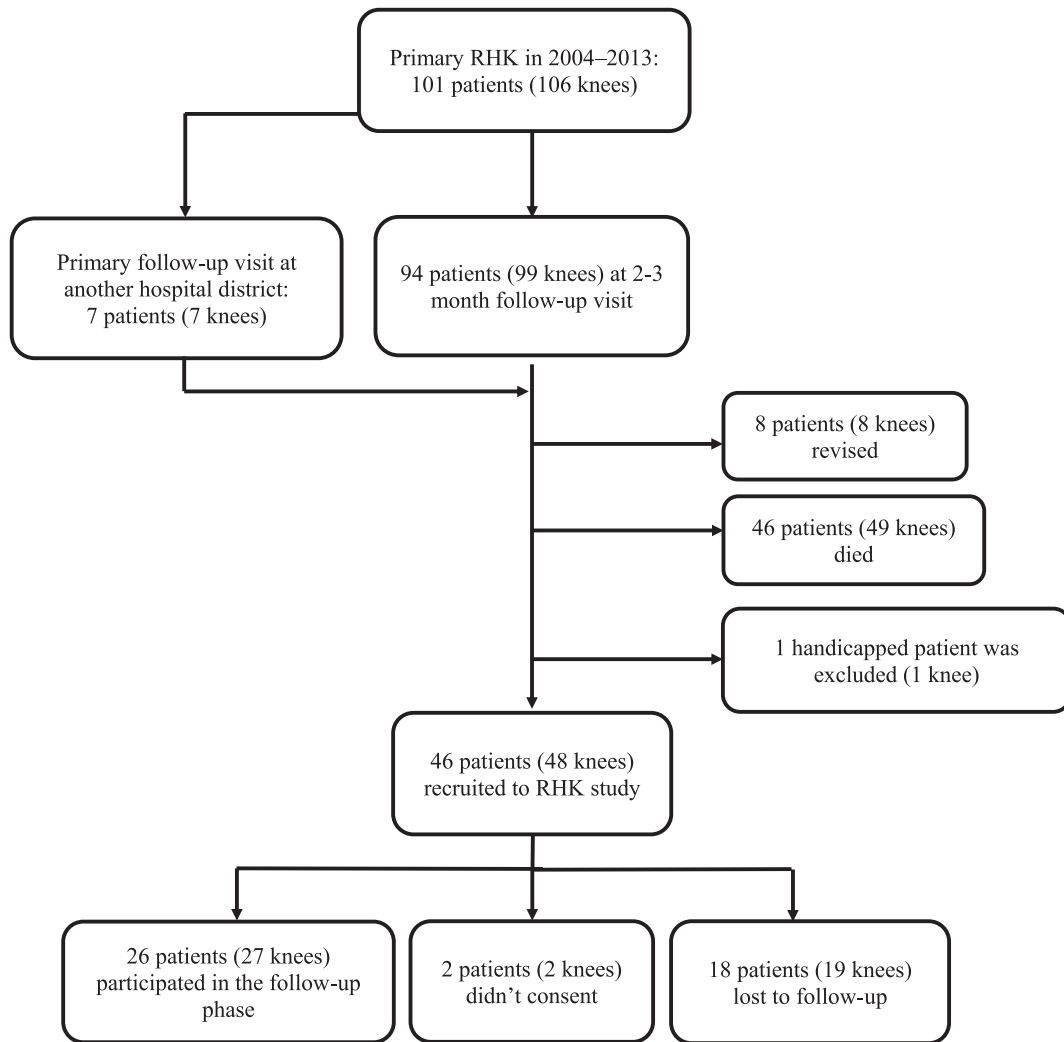


Figure 1. Flowchart describing the selection and loss to follow-up of study participants.

2.1.2. Postoperative

All postoperative plain radiographs taken at the time of final follow-up were evaluated by two senior orthopaedic surgeons (co-authors JN and AE). Radiographic evaluation was performed from standardized weight-bearing antero-posterior (AP), lateral, and skyline patellar views. Radiographs were assessed for the presence of radiolucent lines or osteolytic defects.

2.2. Patient reported outcome measures

Health-related quality of life (HRQoL) was measured using the comprehensive generic 15D instrument. The instrument combines the advantages of a profile and a preference-based single index measure. The 15D instrument includes the following 15 dimensions: mobility, vision, hearing, breathing, sleeping, eating, speech, excretion, usual activities, mental function, discomfort and symptoms, depression, distress, vitality, and sexual activity. For each dimension, the respondents choose one of the five ordinal levels best describing their state of health at the time (best = 1; worst = 5). The single index score (15D score) represents the overall HRQoL on a 0 to 1 scale (1 = full health, 0 = being dead). The dimension level values reflect the goodness of the levels relative to no problems on the dimension (=1) and to being dead (=0). These are then calculated from the health state descriptive system (questionnaire) by using a set of population-based preferences or utility weights. Mean dimension level values are then used to draw 15D profiles for the groups [17,18]. The minimum clinically important change or difference in the 15D score has been estimated to be ± 0.015 on the basis that people can on average feel such a difference [19].

We compared our study population's 15D results to those of an age- and gender-standardized sample of the general Finnish population ($n = 4052$) taken from the Health 2011 Survey carried out by the Finnish National Institute for Health and Welfare [20].

The OKS and KOOS have been widely used to assess the outcomes of knee replacements [21,22]. In this study, the OKS was categorized into four different grades: poor (0–26), fair (27–33), good (34–41), and excellent (42–48) [21].

The KOOS is an extension to the WOMAC Osteoarthritis index and includes five separately scored subscales. The subscales are Pain, other Symptoms, Function in daily living (ADL), Function in sport, and recreation and knee related quality of life [22].

Behrend et al. introduced the Forgotten Joint Score (FJS) PROM in 2012 [23]. The FJS assesses the patient's ability to forget the replaced joint while performing recreational activities and in daily life. A higher degree of forgetting the joint indicates a better outcome of surgery.

The Kaplan-Meier (K-M) analysis was performed to assess survival rates of the RHK implant. Both survival rates and 95% confidence intervals (CI) were derived from K-M models. The independent samples t-test was used to test the statistical significance of the differences in the mean 15D results between the groups. Statistical significance was set at $p < 0.05$. The statistical analysis was performed with SPSS Statistics for Mac (version 24.0). Competing risk analysis was performed with R (version 4.0.2). The study was funded by an institutional grant from Zimmer Biomet Inc. (Warsaw, IN, USA). The study was approved by the local ethical committee (R17010).

3. Results

The baseline study group included 79 women (84 knees) and 22 men (22 knees) with a median age of 76.5 years (range, 18–90 years) at the time of the primary TKA. Five female patients underwent bilateral TKA (RHK on both sides). The demographics of these patients are summarized in Table 1. The vast majority ($n = 74$, 69.8%) of the knees evinced severe varus-valgus instability in preoperative physical examination.

In the final follow-up group, most of the patients were women (96%, $n = 25/26$). The median age of these patients was 69.7 years (range, 37–82 years) and the median follow-up was 7.0 years (range, 4.0–13.8 years) at the time of the final follow-up.

3.1. Clinical outcome and PROMs in the final follow-up group

The median KOOS for Pain was 97 ($n = 19$, range 56–100), Symptoms 89 ($n = 21$, range 50–100), ADL 93 ($n = 20$, range 40–100), Sport/Rec 80 ($n = 17$, range 0–100), and QOL 81 ($n = 21$, range 25–100) at the time of final follow-up. The median FJS was 75 ($n = 16$, range 23–100) and the median OKS 38 ($n = 20$, range 14–47) at the time of final follow-up. The OKS was good or excellent in the majority of the patients (75%; 15 knees), moderate in 2 knees, and poor in only 3 knees, respectively.

The mean 15D score of the patients was 0.831 ($n = 22$, range 0.443–1.000) at the final follow-up. The age- and gender-standardized control population average was 0.862 (range, 0.778–0.943). The difference between the groups was not statistically significant ($p = 0.312$). The mean level values of the dimensions of the patients compared to those of the age- and the gender-standardized general population are shown in Figure 2. On average, the RHK patients scored statistically significantly better than the control population on the dimensions of mental function ($p < 0.001$) and sexual activity ($p = 0.010$). On the rest of the dimensions (except speech), the patients scored on average worse. However, the difference was only statistically significant ($p = 0.016$) on the dimension of mobility (Figure 2).

In the plain radiographs taken at the time of the final follow-up, there were non-progressive mild radiolucencies around the proximal part of the femoral stem in 14% (3/21) of the knees; all of these femoral components were stable and no osteolysis was seen. On the tibial side, bone-cement junctions were clear in all knees.

During the follow-up, fourteen postoperative complications were recorded. Later on, three of these patients underwent knee revision surgery. Overall, revision surgery was performed on eight knees (7.5%) during the follow-up. The reasons for the revisions were patellar problems in three cases and prosthetic joint infections (PJI) in five cases (See Table 2). The 10-year K-M survival rate for the RHK implant was 91.6% (95% CI 86.0%–97.2%) with revision for any reason as the endpoint. However, when those revisions in which only patellar resurfacing was performed were excluded, the 10-year K-M survival rate was 94.5% (95% CI 89.8%–99.2%). Competing risk analysis for overall survival probability of arthroplasty (34.0% at 10 years) and probability of revision (7.5% at 10 years) and death (40.6% at 10 years) as competing events is shown in Figure 3.

4. Discussion

The most important finding of the present study was that RHK TKA provided a good mid-term clinical outcome for patients undergoing complex primary TKA, as 75% of the patients reported a good or excellent OKS at the time of the final follow-up. Further, general quality of life was comparable to that of the age- and the gender-standardized general population in Finland. The 10-year implant survival rate of 91.6% can also be regarded as acceptable for this challenging patient group.

Table 1
Patient demographic and preoperative data.

Demographics of RHK group	The baseline		Final follow-up	
No. of knees (patients)	106	(101)	27	(26)
Age (median, range)	76.5	18–90	69.7	37–82
Body mass index (median, range)	26.4	17.1–50.7	26.8	19.1–50.7
Follow-up, years (median, range)	6.3	0.1–13.8	7.0	4.0–13.8
Females (knees, %)	84	79.2%	26	96.3%
History of previous knee surgeries (yes, %)	13	12.3%	8	29.6%
Indications for RHK (knees), No. (%)				
Primary OA	50	47.2%	9	33.3%
Posttraumatic OA	28	26.4%	9	33.3%
Rheumatoid Arthritis	9	8.5%	4	14.8%
Secondary OA	9	8.5%	4	14.8%
Malignancy	4	3.8%	1	3.7%
Tibial Fracture	3	2.8%	–	–
Avascular necrosis	3	2.8%	–	–
Stability of patella, No. (%)				
Stable	59	55.7%	16	59.3%
Subluxation	29	27.4%	8	29.6%
Chronic dislocation	10	9.4%	1	3.7%
Sequela of patellectomy	2	1.9%	1	3.7%
Unknown	6	5.7%	1	3.7%
Instability of knee, No. (%)				
Antero-Posterior	46	43.4%	14	51.9%
Medio-Lateral	74	69.8%	17	63.0%
Deformity, No. (%)				
Valgus > 20°	35	33.0%	12	44.4%
Valgus 10°–20°	17	16.0%	4	14.8%
Valgus 3°–9°	4	3.8%	1	3.7%
Neutral ± 2	4	3.8%	1	3.7%
Varus 3°–9°	11	10.4%	3	11.1%
Varus 10°–20°	11	10.4%	4	14.8%
Varus > 20°	12	11.3%	1	3.7%
Missing (fracture or no x-ray)*	12	11.3%	1	3.7%
Krackow^ No. (%)				
Scale 1	20	32.3%	6	22.2%
Scale 2	41	66.1%	12	44.4%
Scale 3	1	1.6%	–	–
Kellgren-Lawrence radiographic classification No. (%)				
Grade 1	1	0.9%	–	–
Grade 2	3	2.8%	1	3.7%
Grade 3	9	8.5%	3	11.1%
Grade 4	88	83.0%	23	85.2%
Fracture or no x-ray	5	4.7%	–	–

*=no mechanical axis radiographs

^=Krackow scale for valgus deformity (% of valgus knees)

This survival rate is comparable with the rates of other similar implant designs [11,24]. It must also note that there were no mechanical complications related to the prosthesis reported during the follow-up.

We acknowledge a few limitations in our study. First, the implant selection between the RHK and the other constrained condylar knee implants was not always clear perioperatively, and the indications were variable for the rotating hinge knee [7]. Second, the number of participants was low in the final clinical follow-up visit, which is reflected in a lack of statistical power. Medical comorbidities and the inability to participate in this kind of mid-term clinical follow-up study were the main reasons for the low participation rate. However, this is an obvious universal problem when conducting research on these frail, elderly patients: previous follow-up studies have also reported difficulties to achieve a complete follow-up for this challenging patient group [25–28].

However, by cross-checking the patient’s revisions from the Finnish Arthroplasty Register, we could be sure that we had captured all the revisions performed on these patients, and also those performed outside our hospital district on patients who were lost to our clinical follow-up. We performed competing risk analysis (revision and death as competing events), because of high mortality rate during the follow-up. 16 patients had follow-up of less than two years, because five of these patients underwent revision before the two-year follow-up, and 11 patients died before the two-year follow-up. Overall, 90 (85 %) knees had a minimum two-year follow-up.

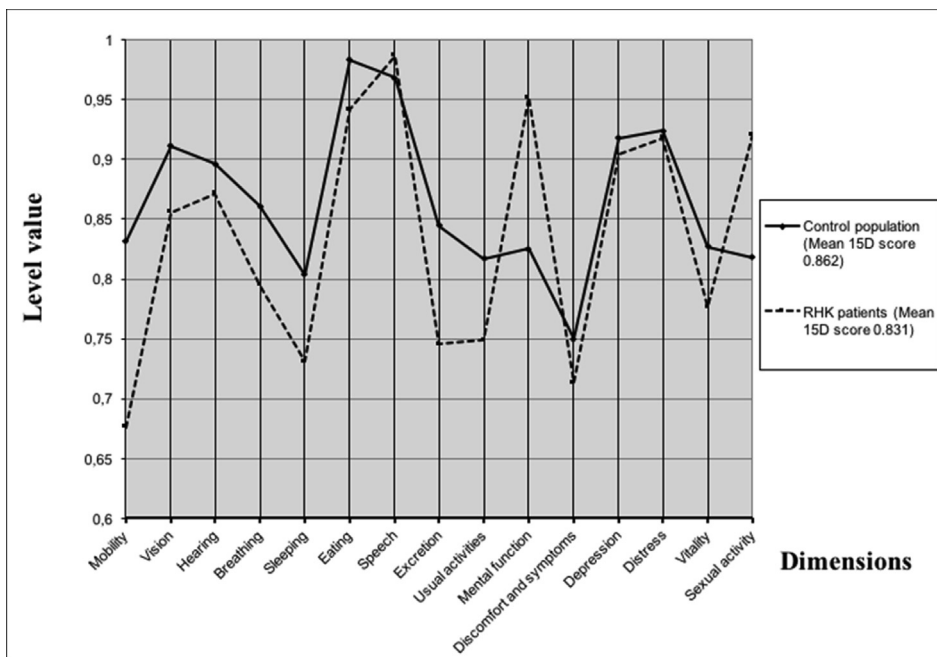


Figure 2. Comparison of mean 15D profiles between control population and RHK group.

Thirdly, the preoperative PROMs were unavailable, which makes it difficult to evaluate the influence of RHK arthroplasty on symptoms, ability to act or quality of life. Fourthly, there was lack for information of stem lengths and the use of augments. Moreover, postoperative cardiovascular complications were not registered.

Rotating hinge knees are mainly used for the treatment of more complex knees, and it is therefore unlikely that the clinical outcome would be as good as that of unconstrained TKA designs. Because of this obvious selection bias, the results should not be directly compared with those of uncomplicated primary TKA. In our study, the main indications for RHK were primary or posttraumatic osteoarthritis. It must be noted, however, that four patients were treated for malignancies: three of them had bone metastases (two from renal and one from prostate cancer) and one was a primary tumor (chondrosarcoma). The mean follow-up time was only 3.6 years for these patients due to the high mortality rate associated with the underlying disease. Patients with malignancies add complexity into the study cohort, as their failure patterns may markedly differ from other patients (e.g. graft resorption, recurrence of the underlying disease). In the current study, however, these patients did not encounter any postoperative complications.

It should be noted that the majority of the follow-up patients reported excellent or good OKS at the time of the final follow-up. As many as 11 knees (55%) were reported painless on the first question of the OKS questionnaire. The 15D scores can also be regarded as good for this follow-up group. The scores were better than the control population scores in mental and sexual activity dimensions, although this might be related to selection bias – from the group of elderly, frail patients, usually only the healthiest ones are candidates for complex knee replacement surgery. Moreover, among those patients that were lost to follow-up, many had neurodegenerative disease and this could have biased the functional results in our study.

Previous studies have reported variable implant survival rates or incidence of complications for rotating hinge knees [5,11,12,24–30]. However, it should be noted that some of these studies have included both primary and revision patients, which may have had an impact on the rate of complications and revisions [5,25,27–29]. A few earlier studies have reported a considerable risk for revision when the rotating hinged implant is used for primary arthroplasty due to periprosthetic fractures [9], deep infections [11,12], and extensor apparatus complications [26]. In our study, we did not encounter any implant-related complications during the follow-up.

However, a high incidence (7.5%) of extensor apparatus complications appeared in our cohort of patients, even though insufficiency of the extensor apparatus was not reported preoperatively in any of them. Of the fourteen reported complications, six (5.7%) were related to the extensor apparatus and three resulted in revision arthroplasty. Of these, one was revised for secondary patellar resurfacing and two were revised for PJI. In addition, one patient with dislocation of the patella and one patient with anterior knee pain with mild extensor insufficiency were revised for secondary patellar resurfacing.

The extensor apparatus complication rate is in line with the findings of two recent studies on the outcome of rotating hinge TKAs [24,26]. In these two studies, however, the patella was not resurfaced and most of the patellar problems were related to incorrect patellofemoral alignment and anterior knee pain [24,26]. Yang et al. [11] did not report any postoperative complications that were related to the extensor apparatus in their 62 primary RHK knees. In their study, patellar resurfacing

Table 2
Postoperative complications and revision surgeries.

Complications and revisions		Complication/failure		Time to failure
Treatment	Outcome/Remarks			
14 complications (13.2% of all)				Early complications
1	Cardiac arrest at the OR	0 days	Successful resuscitation	Full recovery
2	Peroneal nerve palsy	0 days	Watchful waiting	Full recovery
3	Peroneal nerve palsy	1 days	Watchful waiting	Partial recovery
4	Peroneal nerve palsy	1 days	Neurolysis of peroneal nerve	Full recovery
5	Periprosthetic femoral fracture	14 days	Conservative	Fair
6	Superficial wound infection (s. aureus)	18 days	Antibiotics	Wound healed without surgery
7	Patella fracture	28 days	Operative with tension band wiring ^A	Followed by PJI that was treated with debridement and gastrocnemius flap; did not heal and major amputation was performed
8	Periprosthetic femoral fracture	33 days	Osteosynthesis with plating	Fair
9	Patella fracture	51 days	Operative with tension band wiring	Despite pseudoarthrosis satisfactory extensor function
10	Patellar tendon rupture	91 days	Operative treatment; augmentation with hamstring graft and Dall-Miles cable	Complicated recovery with fracture of patella
11	Avulsion of the patellar tendon	91 days	Orthosis and physiotherapy	Satisfactory extensor function achieved
		Late complications		
12	Avulsion of the patellar tendon	283 days	Operative treatment twice; in the first operation, secondary patellar resurfacing in addition to fracture fixation ^C	Satisfactory extensor function achieved
13	Pseudoarthrosis in proximal tibia (below tibial stem)	350 days	Debridement, bone grafting and plating	Healed well
14	Quadriceps tendon rupture	370 days	Conservative ^B	Poor outcome
8 revisions (7.5% of all)				
1	Prosthetic joint infection	49 days	Debridement ^A	Did not heal and later major amputation was performed
2	Dislocation of patella (unresurfaced)	236 days	Secondary patellar resurfacing, medial tightttening and lateral release	Fair
3	Dislocation of patella (unresurfaced) and patellar tendon avulsion fracture (distal patella)	391 days	Secondary patellar resurfacing in addition to fracture fixation ^C	Satisfactory extensor function achieved
4	Prosthetic joint infection	1.4 years	Debridement and exchange of tibial insert	Good outcome
5	Prosthetic joint infection	1.5 years	1-Stage revision	Good outcome
6	Anterior knee pain and mild extensor insufficiency (sequela of open distal femoral fracture and patellectomia)	2.9 years	Secondary patellar resurfacing with tantalum patellar component	Fair
7	Prosthetic joint infection	3.4 years	Treated elsewhere ^B	No information on outcome
8	Prosthetic joint infection	4.15 years	2-Stage revision	Good outcome

^{A,B,C} = Are each the same patient

was performed selectively for 44% of the TKAs. In our study, there were only two postoperative patellar dislocations and both of them occurred in knees with un-resurfaced patellas.

It is clear that more research on RHK prosthetic designs for primary TKA patients is needed. Further studies should concentrate on the role of patellar resurfacing in rotating hinge TKAs. Patellar maltracking may be over expressed because of the mobile bearing mechanism of the RHK implant. However, it remains unclear whether resurfacing the patella already in the primary RHK TKA would reduce the incidence of extensor apparatus-related complications and re-operations. Patellar resurfacing may, on the other hand, increase the risk for periprosthetic patellar fractures or ruptures of the patellar ligament [31].

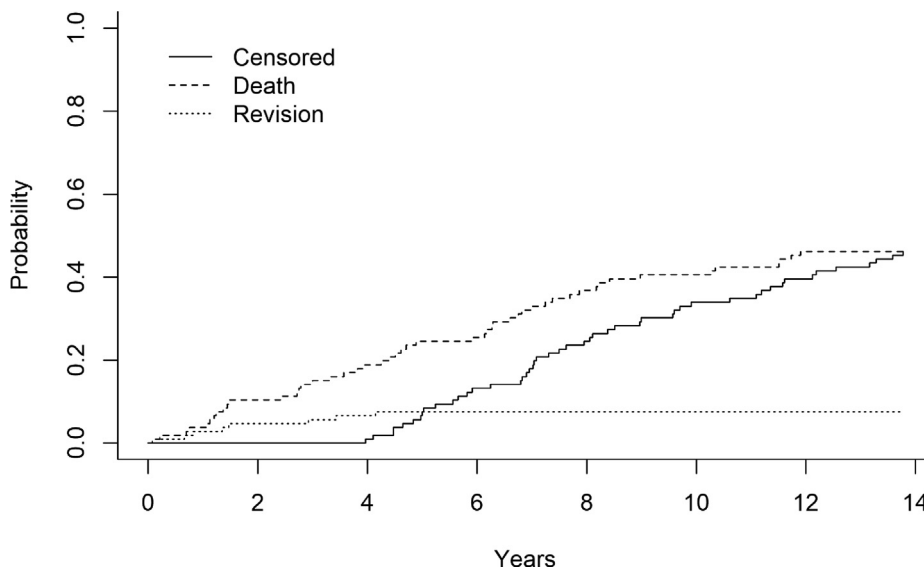


Figure 3. Cause-specific probability and overall survival probability of arthroplasty revision and death as competing events.

5. Conclusion

In conclusion, the NexGen[®] RHK design can be regarded as a suitable option in complex primary TKA. Moreover, it seems to provide these patients with a fairly good functional outcome, quality of life, and also acceptable implant survival rate in mid-term follow-up. Further research is warranted to see whether these results endure the test of time, and also to clarify the role of patellar resurfacing in these knees.

Ethics committee letter

The permission to perform this study (Good Mid-Term Outcome of The Rotating Hinge Knee in Primary Total Knee Arthroplasty – Results of A Single Center Cohort of 106 Knees With A Median Follow-up of 6.3 Years) was obtained from the local ethical committee (R17010) with informed consent from the patients.

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Declaration of Competing Interest

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