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ORIGINAL PAPER

Revision knee arthroplasty with rotating hinge systems in patients with gross ligament instability

Sebastian P. Boelch[1] · Joerg Arnholdt[1] · Boris M. Holzapfel[1,2] · Axel Jakuscheit[1] · Maximilian Rudert[1] · Maik Hoberg[1]

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Abstract

Purpose The clinical and radiographic outcomes after revision total knee arthroplasty (TKA) for instability with two rotating hinge knee prostheses were compared.

Methods Fifty-one patients revised for TKA instability were prospectively randomized to either the Link Endo-Model ($N = 26$) or the EnduRo ($N = 25$). Clinical and radiographic outcome scores were compared pre-operatively and at 12 months' follow-up. Failure mechanisms were recorded.

Results Age, BMI, operation, and tourniquet-time did not differ significantly between groups. Radiographic evaluation demonstrated correct implant alignment. The Endo-Model was implanted with a higher slope ($p = 0.0001$) and the mechanical lower extremity axis was straighter ($p = 0.0323$). Except for the patient function Knee Society Score and the Physical Health Component Summary Score in the EnduRo group, all clinical scores (range of motion/knee function Knee Society Score/ Oxford Knee Score/Visual Analog Scale/Mental Health Component Summary Score) improved significantly for both prosthesis designs during the follow-up period. The Visual Analog Scale and Mental Health Component Summary score were significantly better ($p = 0.045$ and $p = 0.0148$) in the Endo-Model group at the 12 months' follow-up. In the EnduRo group 2 patients (8%) and in the Endo-Model group 1 patient (3.8%) had to be revised for infection.

Conclusion Both prosthetic designs provide significant improvement in pain and function scores after TKA revision for gross instability. We found slight advantages in favor of the Endo-Model; however, no design yielded superior results throughout the study.

Keywords Total knee arthroplasty · Link Endo-Model · EnduRo · Revision · Instability · Rotating hinge

Introduction

Primary total knee arthroplasty (TKA) is the treatment of choice for end-stage osteoarthritis. Patient satisfaction with TKA has been improving continuously over the last decades [1] and survivorship of cruciate retaining primary TKA has been reported as good as 97% after 14 years [2]. However, due to the aging society and the increasing numbers of TKAs, the absolute numbers of TKA revisions are on the rise [3]. Next to aseptic loosening and periprosthetic infection, instability is one of the major reasons for these TKA revisions [4, 5].

For the treatment of instability after TKA, a diagnostic algorithm to evaluate the surgical therapeutic options from isolated poly-exchange to complete component revision is mandatory. However, ligament deficiency and bone loss may require a certain degree of constraint and alternate component fixation strategy [3, 6]. Hinged knee prostheses have been developed for these situations [3]. Fixed hinged prostheses have shown high failure rates due to increased rotational forces at the implant-bone interface. This has led to the design of rotating hinge knee (RHK) prostheses allowing a certain degree of internal and external rotation with knee flexion, thereby reducing peak forces at the bone-implant interface [7]. At the study institution, two different RHK designs, the

Sebastian P. Boelch and Joerg Arnholdt have equally contributed as first author to this article.

✉ Sebastian P. Boelch
s-boelch.klh@uni-wuerzburg.de

[1] Department of Orthopaedic Surgery, König-Ludwig-Haus, Julius-Maximilians-University Würzburg, Brettreichstraße 11, 97074 Würzburg, Germany

[2] Centre for Regenerative Medicine, Institute of Health and Biomedical Innovation, Queensland University of Technology, 60 Musk Avenue, Brisbane, QLD 4059, Australia

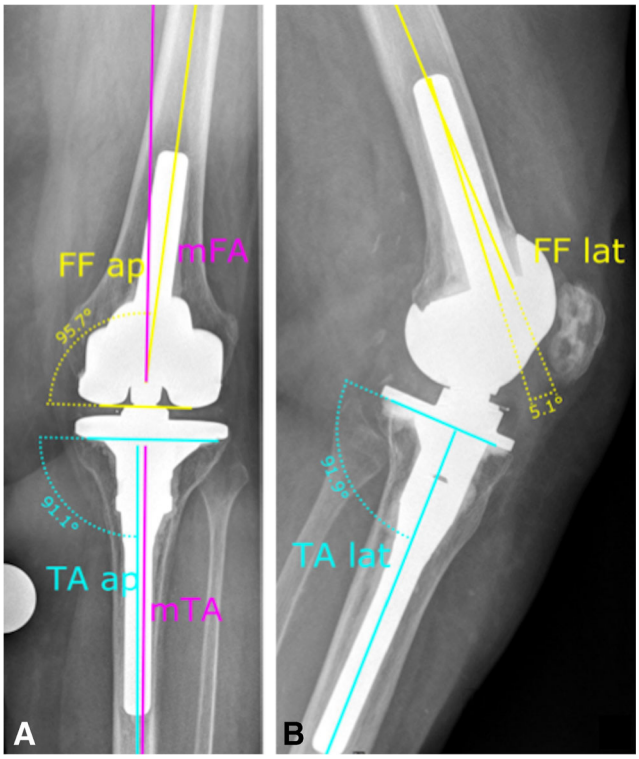

Fig. 1 Radiographic outcome parameters after TKA revision: EnduRo prosthesis 1 year post-operatively anterioposterior (ap) (**a**) and lateral (lat) (**b**); FF, femoral flexion angle; TA, tibial angle; mFA, mechanical femur axis; mTA, mechanical tibia axis. Mechanical femoro-tibial angle is the angle between mFA and mTA

Link Endo-Model SL™ (Waldemar Link GmbH & Co. KG, Hamburg, Germany) and the EnduRo RHK (Aesculap AG, Tuttlingen, Germany), are used for these indications. The Link Endo-Model, whose initial design was introduced in 1979, has been modified up to the currently available third-generation model. Its design limits rotation in flexion by a particular congruency of the tibial and femoral components [7]. It can be used as a monoblock or modular implant with the option of cemented or cementless stems and polyethylene tibial and femoral augments [7]. The EnduRo RHK was introduced in 2008 and is characterized by high modularity with femoral and tibial off-set couplers as well as metal wedges for augmentation and the opportunity of cemented and cementless stem fixation. Rotation is guided by the lift technology of the yoke [8]. For both RHKs, the data on clinical results in revision TKA is scarce. The current short- and mid-term survivorship for these designs ranges between 65% and 98.7% and an improvement of function scores has been described for both implants [7–12]. However, to date, there are no comparative, prospective studies. Additionally, the plethora of indications for revisions included in previously published retrospective study designs only allows very limited conclusions about the benefit for patients suffering from one specific condition such as gross ligament insufficiency. With this randomized prospective study, we compared postoperative leg axis alignment, functioning scores, and patient-reported outcome measurements one year after revision for TKA instability. Failure rate and mechanisms were also analyzed for both RHKs.

Patients and methods

For this study protocol, we received institutional review board approval (approval no. 195/10) from the University. It was conducted according to the principles of the World Medical Association Declaration of Helsinki.

Patient inclusion and randomization

Inclusion criterion was TKA revision for gross ligament insufficiency. Instability was assessed by both clinical examination and radiographic analyses as described elsewhere [3]. Patients with any other indication for this TKA revision such as infection, periprosthetic fracture, and implant failure and patients not able to participate at the follow-ups and patients younger than 18 years were excluded. Between 07/2012 and 12/2013, 52 patients were included after patient informed consent. The patients were randomized by envelope to either group EnduRo or Endo-Model. From the 52 patients included, one died of reasons unrelated to the procedure leaving 51 patients for follow-up.

Surgical technique

Surgery was performed via standard medial arthrotomy. Cefazolin was administered as single shot. After removal of the indwelling prosthesis, the tibial and femoral osseous defect was assessed according to the Anderson Orthopaedic Research Institute (AORI) classification by the operating surgeon [6]. Depending on the size and morphology of the bony defects, augments were applied or cement was used as a filler. In the EnduRo group, short-stem extensions were used in all but one patient at the femur and in all patients but three at the tibia. All stem extensions were cemented with gentamicin premixed Palacos (Palacos® R+G) and the patellae resurfaced. A tourniquet was applied for cementing. Postoperatively, patients were mobilized with 20-kg partial weight bearing fort two weeks and half the body weight for further two weeks. Range of motion (ROM) was not restricted.

Outcome parameters

Clinical scores (Knee Society Score separated into knee function (kKSS) and patient function (pKSS), Oxford Knee Score (OKS), Visual Analog Scale (VAS), and the SF-36 separated into Mental Health Component Summary Score (MCS) and Physical Health Component Summary Score (PCS)) and

Fig. 2 A 75-year-old female with severe knee instability: preoperative radiographs (**a**, **b**) with ap view (**b**) demonstrating extension gap asymmetry during weight bearing. The patient was managed with the EnduRo revision system with distally placed 4-mm medial and lateral wedges (AORI type IIb) and a short (77 mm) cemented femoral stem. At the tibia (AORI type IIb), a long (92 mm) cemented stem was implanted. **c**–**f** Lateral and ap radiographs directly (**c**, **d**) and 1 year (**e**, **f**) post-operatively

ROM were evaluated pre-operatively, at the fifth postoperative day, at discharge as well as at three and 12 months postoperatively. At these time points, radiographs of the knee were taken and evaluated for radiolucency lines, over- or underhang of the tibial component and mechanical alignment according to the Knee Society Total Knee Arthroplasty Roentgenographic Evaluation and Scoring System as depicted in Fig. 1.

Statistics

Statistical analyses were performed using SAS Institute Inc. software, Cary, NC, USA. Comparisons between the groups were conducted with the pooled *t* test, comparisons within the groups with the paired *t* test. $p < 0.05$ was set statistically significant.

Results

In the EnduRo group, including 9 males and 16 females, the mean age was 69.52 years (51 – 85) and the mean BMI was 31.60 kg/cm^2 (21.00 – 42.00). The revised TKAs were two condylar constrained and 23 bicondylar unconstrained. Figure 2 illustrates a case of severe knee

Fig. 3 A 63-year-old female with massive knee instability: pre-operative radiographs (**a**, **b**) with ap view (**b**) demonstrating extension gap asymmetry during weight bearing. The patient was managed with the Endo-Model using a cemented (AORI type IIa) modular component with a short (100 mm) cemented femoral stem. At the tibia (AORI type IIa), a monoblock component was cemented. **c**–**f** Lateral and ap radiographs directly (**c**, **d**) and 1 year (**e**, **f**) post-operatively

instability during weight bearing managed with the EnduRo.

For those patients treated with the Endo-Model, including six males and 20 females, the mean age was 70.85 years (58 – 84) and the mean BMI was 30.54 kg/cm^2 (20.00 – 42.00). In this group, the revised prostheses were one medial unicondylar prosthesis, one condylar constrained prosthesis, and 24 bicondylar unconstrained TKAs. Figure 3 shows a patient with massive knee instability during weight bearing managed with the Endo-Model.

Patient age and BMI did not differ significantly between groups. Revision was performed on average 56.4 months (3 – 121) after previous surgery. In 42 cases, this was the first TKA revision and in 10 cases, previous revisions had been performed. In the EnduRo group, osseous defects at the tibia and at the femur were classified as type 2 in 88%. In the Endo-Model, a type 2 defect at the tibia occurred in 81% and in 92% at the femur. No type 3 defects were observed. Wedges were used three times at the femur and twice at the tibia for the EnduRo. A tibial spacer was implanted once for the Endo-Model. One of the most

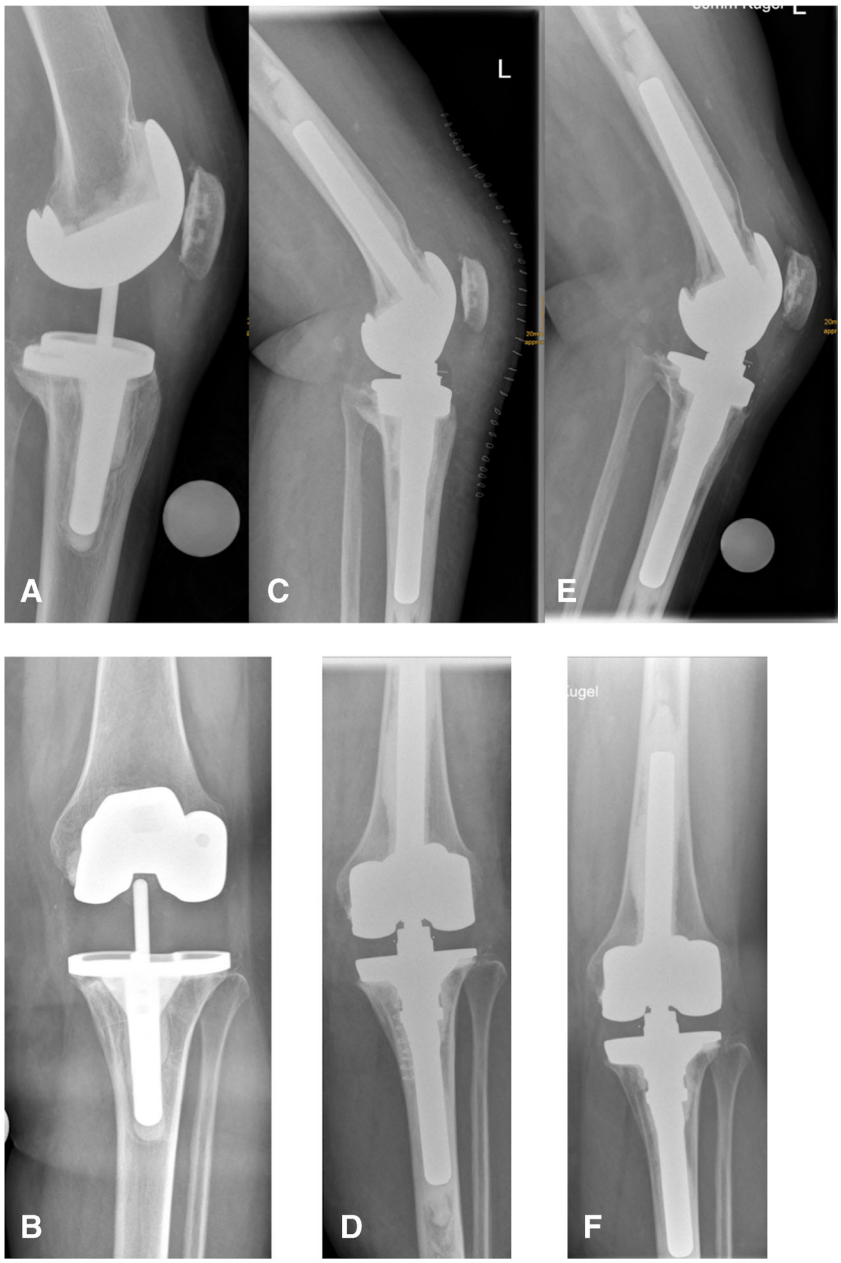

Fig. 4 A 65-year-old female with collateral ligament insufficiency: the pre-operative lateral radiograph (**a**) demonstrating an iatrogenic patella baja. The pre-operative ap weight bearing radiograph (**b**) showing severe elevation of the joint line and radiolucency lines around the tibial component. The patient was managed with the EnduRo revision system with distal medial and lateral 8-mm wedges (AORI type IIb) and a long (157 mm) cemented femoral stem. After removal of the distally fixed tibial implant, the newly implanted component was cemented using an additional 4-mm medial wedge (AORI type IIa) and a long (92 mm) cemented stem. **c**–**f** Lateral and ap radiographs directly (**c**, **d**) and 1 year (**e**, **f**) post-operatively

complex cases in our series was a patient with collateral ligament insufficiency as depicted in Fig. 4.

In the EnduRo group, the mean operation time was 96.88 minutes (66.00 – 148.00) with a tourniquet duration of 30.80 minutes (11.00 – 95.00) compared to 100.08 minutes (64.00 – 142.00) and 29.27 (14.00 – 90.00) in the Endo-Model group. Operation time and tourniquet-time did not differ significantly.

Both prosthesis designs were reproducibly implantable as shown by the post-operative roentgenographic evaluation in Table 1. However, the Endo-Model was implanted with a higher slope ($p = 0.0001$) and the mechanical lower extremity axis was reconstructed better ($p = 0.0323$). Tables 1 and 2 contain values/numbers with italic emphasis. Please indicate the significance of these values in a form of a table note. Otherwise, kindly consider removing emphasis.emphasis was removed

No radiolucency lines were seen at 12-month post-operatively in the Endo-Model group. In the EnduRo group, two patients showed radiolucency lines without clinical relevance. No difference between the groups regarding over- or underhang of the tibial component was found. There were no intra-operative complications or post-operative implant failures.

As exemplified for the kKSS in Fig. 5, both prostheses led to significant improvement in function and patient-reported outcome measurements. Only the pKSS and the PCS in the EnduRo group did not improve significantly (Table 2).

Table 1 Mechanical evaluation before and 12 months after revision categorized by revision model

	EnduRo		Endo-Model SL		*p*	
	Preop	Postop	Preop	Postop	Preop	Postop
mFTA ap	5.88 (1.00–19.00)	3.05 (1.00–6.00)	6.50 (1.00–29.00)	2.09 (0.00–6.00)	0.7051	0.0323
FF lat	1.68 (1.00–2.00)	0.67 (0.00–1.00)	1.50 (1.00–2.00)	0.39 (0.00–1.00)	0.1991	0.0704
FF ap	92.6 (87.00–100.00)	91.1 (86.00–96.00)	91.23 (81.00–97.00)	91.39 (87.00–96.00)	0.1341	0.6961
TA ap	88.40 (83.00–91.00)	89.76 (87.00–92.00)	88.27 (82.00–91.00)	89.65 (87.00–93.00)	0.9642	0.7897
TA lat	84.76 (76.00–90.00)	89.05 (83.00–95)	83.92 (75.00–90.00)	85.04 (80.00–88.00)	0.4338	0.0001

p p value for comparison of EnduRo vs. Endo-Model, *mFTA* mechanical femoro-tibial angle, *ap* anterior-posterior, *FF* femoral flexion, *lat* lateral, *TA* tibial angle

Except for a significantly lower VAS ($p = 0.0450$) and significantly higher MCS ($p = 0.0148$) at last follow-up in the Endo-Model group, we found no other significant differences in the outcome scores between both the RHK designs, neither pre-operatively nor post-operatively.

The total revision rate one year post-operatively for the EnduRo was 8.0% (1 acute post-operative, 1 chronic infection) and for the Endo-Model, the total revision rate was 3.8% (1 acute post-operative infection).

Discussion

To our knowledge, this is the first prospective, randomized study comparing the EnduRo with the Endo-Model. We found both RHK designs to provide good clinical results; however, no design performed in a superior way. Implant positioning and leg axis alignment were reproducibly correct for both RHK designs. Although in our study the ranges suggest isolated alignment outliers, we achieved results comparable to the results described by Ochs et al. for TKA revision with navigated EnduRo implantation [8]. Thus, intramedullary referencing is a reliable approach to achieve post-operative alignment, an observation confirmed by studies comparing navigated and conventional TKA revisions [13]. Comparing the RHK designs, the Endo-Model yielded straighter legs. This may be due to the use of short cemented stems for the EnduRo, while the Endo-Model stems are significantly longer and have the option of a centralizer. However, the difference of the mFTA was less than 1° and thus clinical relevance is highly questionable. Under the aspect of the necessity, to remove one of either implanting shorter cemented stems seem favorable.

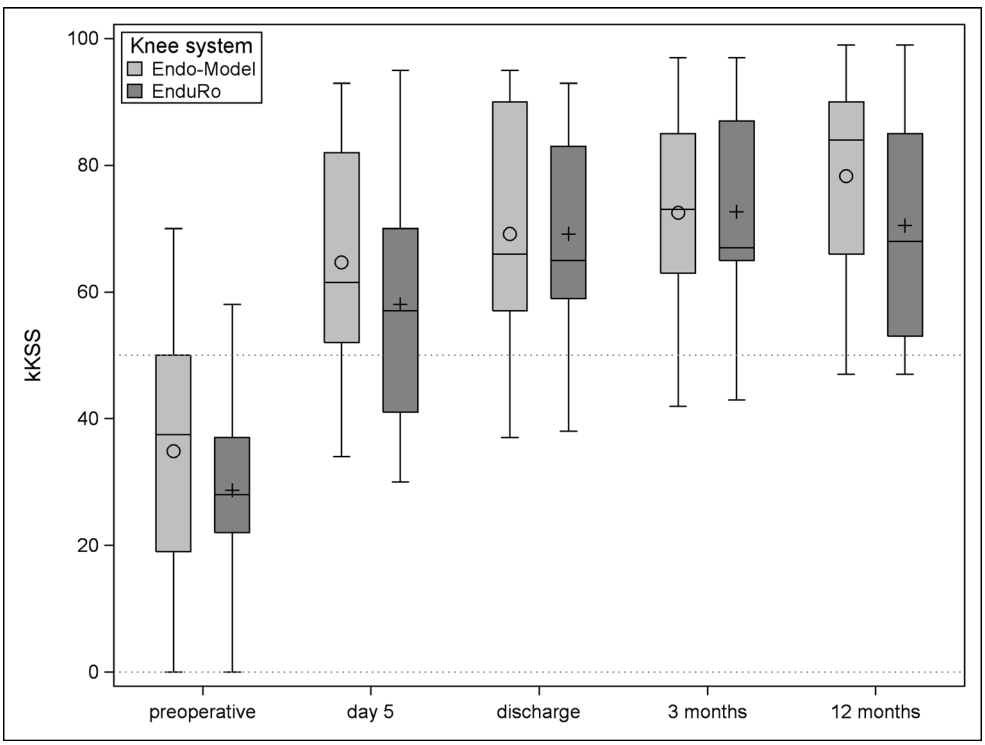

Fig. 5 Boxplots of kKSS categorized by revision model at time points of evaluation: kKSS knee function Knee Society Score

Table 2 Comparison of the outcome scores within the study groups

	EnduRo			Endo-Model		
	Preop	12-month postop	*p*	Preop	12-month postop	*p*
ROM	88.40 (30.00–120.00)	104.09 (80–140)	0.0028	90.38 (30.00–125.00)	106.74 (90.00–130.00)	0.0095
pKSS	44.60 (0.00–80)	57.73 (20.00–100.00)	0.1102	37.50 (0.00–70.00)	67.61 (30.00–10.00)	0.0002
kKSS	28.68 (0.00–58.00)	70.50 (47.00–99.00)	0.0000	34.88 (0.00–70.00)	78.26 (47.00–99.00)	0.0000
OKS	14.52 (4.00–28.00)	26.95 (10.00–46.00)	0.0002	17.54 (7.00–29.00)	32.74 (18.00–48.00)	0.0000
VAS	5.44 (3.00–8.00)	1.86 (0.00–5.00)	0.0000	5.19 (0.00–9.00)	1.09 (0.00–4.00)	0.0000
PCS	26.38 (17.32–35.75)	30.80 (3.42–54.21)	0.0563	25.02 (14.90–34.58)	35.15 (16.38–57.23)	0.0006
MCS	40.76 (17.10–64.18)	50.85 (32.14–65.07)	0.0132	47.20 (27.12–68.51)	56.76 (45.63–68.51)	0.0460

ROM range of motion, *kKSS* knee function Knee Society Score, *pKSS* patient function Knee Society Score, *OKS* Oxford Knee Score, *VAS* Visual Analog Scale, *PCS* Physical Health Component Summary Score, *MCS* Mental Health Component Summary Score

Our failure rates are in accordance with the ones reported by other authors. For the EnduRo, Giuera et al. found a survivorship of 85.4% after two years in 152 primary and revision cases [11]. Better results were reported by Ochs et al., who had a failure rate of only 3.2% at a mean of 21.9 months after 31 navigated TKA revisions [8]. Our results with the Endo-Model seem to be better than the ones published by Efe et al., who found a rather high implant failure rate of 34.1% in 44 cases after 12 months, of which 18.2% were due to infection [9]. Comparable results were published by Guenuon et al. with septic failure in 10.6% and in further 17.6% related to other reasons in 85 TKA revisions at a mean follow-up of 36 months [7]. However, these results derive from retrospective studies with various revision indications within the studies. We had no implant-related failures neither in the EnduRo nor in the Endo-Model group after 12 months. Thus, we could confirm infection as the major threat after TKA revision, even in aseptically revised cases [14, 15]. Of the two patients with septic failure in the EnduRo group, one patient had a history of prior culture-negative infection after TKA due to post-traumatic arthritis. This patient underwent TKA aspiration prior to revision. Intra-operative microbiologic and histologic samples of both patients in the EnduRo group did not indicate periprosthetic infection at RHK implantation. One patient was treated with debridement and irrigation, and the other with a two-stage exchange. In contrast, the only patient with septic failure in the Endo-Model group had no history of infection but intra-operative histologic samples at RHK implantation showed acute inflammation. Although this patient also underwent aspiration with normal white blood cell count, this case can be considered a missed periprosthetic infection at revision [16], which was finally treated with a two-stage exchange.

We found good clinical results for pain, stability, alignment, and range of motion for both RHKs. A result that is supported by the radiologic evaluation and the low post-operative pain, as reported in other studies, too [10, 17, 18]. However, patient-reported outcome measurements that quantify patient satisfaction, perception, and subjective impairment are crucial for evaluation of the outcome. The activity-related results for walking and stair climbing, as indicated by the pKSS, were not as satisfying. Still, these scores lie in the upper third compared to those in other studies with these RHK designs as depicted in Table 3. The best results have been reported by Sanguineti et al. with a pKSS of 77.6 and a kKSS of 92 after a five year follow-up. However, in their study, the drop-out rate of 64.4% was high [10]. According to our results, the outcome is not related to the RHK design. This conclusion is underlined by comparable outcomes reported for other RHK designs such as the S-ROM (Fa Johnson and Johnson) [19], the Stryker Rotating Hinge Prosthesis (Fa. Stryker) [20], or the RHK OSS salvage system (Fa. Biomet) [21].

Although a significant increase of the OKS was noted for both RHKs, the low final points of 26.95 for the EnduRo and 32.74 for the Endo-Model SL are striking [11]. This negative perception of the knee's function by the patient has been reported by other authors and is underlined by a physical health component score that remained severely reduced at follow-up in comparison to the average population [11, 24].

The major limitation of this study is its rather short follow-up. Thus, no conclusion on the clinical relevance of the radiolucency lines in the EnduRo group can be derived. Compared to the three months' follow-up, they were not progressive. Jiang et al. demonstrated only small decreases of the OKS from year one to year ten after primary TKA [25]. However, mid- and long-term results may deteriorate and thus need to be investigated in future studies.

Second, this study is based on a rather small number of patients. Larger sample sizes might identify significant radiologic and clinical differences. The sample size was restricted by the specific treatment indication in this study. But still, it adds a comparable high number to the literature as shown in Table 3. So far, results on outcome were based on retrospective studies. Additionally, data for a specific revision

Table 3 Results of pKSS, kKSS, and failure rates reported in the literature for the Endo-Model and EnduRo after TKA revision sorted by year of publication

Author	RHK	Number of indications	Follow-up	pKSS	kKSS	Failure rate (at duration after revision)	Study type
Joshi 2008 [22]	Endo	57 aseptic failures	56–130 m	–	73% > 80; 9% 61–80; 5% 40–60, 13% < 60	24.4% (–)	Retrospective
Gudnason 2011 [23]	Endo	13 aseptic loosening	6–18 y	29	85	34.9% (120 m)	Retrospective
Giurea 2014 [11]	EnduRo	62 various	24 m	56.0	81.4	14.6% (24 m)	Retrospective
Efe 2012 [9]	Endo	26 not specified	10–133 m	47	80	34.1% (12 m)	Retrospective
Sanguineti 2014 [10]	Endo	13 aseptic loosening; 5 infection; 2 periprosthetic fracture	Mean 42.2 m	77.6	92	5.0% (60 m)	Retrospective
Rodriguez-Merchan 2015 [12]	Endo	96 instability	5–10 y	53	79	1.3% (60 m)	Retrospective
Ochs 2016 [8]	EnduRo	11 instability; 6 aseptic loosening; 1 arthrofibrosis	21.9 m	65.6	58.4	3.2% (21.9 m)	Retrospective
This study	Endo	25 instability	12 m	67.61	78.2	3.8% (12 m)	Prospective
This study	EnduRo	26 instability	12 m	57.73	70.50	8% (12 m)	Prospective

RHK rotating hinge prosthesis, *kKSS* knee function Knee Society Score, *pKSS* patient function Knee Society Score, *m* months, *y* years

indication are scarce. We focused on one of the most frequent failure mechanism after TKA in this randomized prospective study and found comparable performance of the investigated RHK prostheses.

Conclusion

Both RHK designs proved to be reliable options for TKA revision due to instability and provided good clinical results concerning knee function and pain reduction. Although the patients' overall status is significantly improved with these RHKs, revision remains a salvage procedure with a high risk of persistent impairment in daily activities and unsatisfying physical health perception. Infection remains to be the major threat to those surgical procedures.

Compliance with ethical standards

For this study protocol, we received institutional review board approval (approval no. 195/10) from the University. It was conducted according to the principles of the World Medical Association Declaration of Helsinki.

Conflict of interest The authors declare that they have no conflict of interest.

Informed consent Informed consent was obtained from all individual participants included in the study.

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