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Original Article

Rotating-Hinge Prosthesis for Aseptic Revision Knee Arthroplasty: A Multicentre Retrospective Study of 127 Cases with a Mean Follow-up of Five Years

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*This study was conducted within the framework of the SoFCOT symposium: Outcomes after more than 5 years of hinged vs. non-hinged prostheses in total knee arthroplasty.

92th SoFCOT meeting, Paris, November 2017.

Abstract

Background: The use of third-generation rotating-hinge knee prostheses has increased considerably in recent years. The more anatomical design of these prostheses, together with their controlled rotation system that reduces constraints generated by the single degree of liberty, have produced better outcomes. The objective of this study was to evaluate the clinical and radiological outcomes of revision knee arthroplasty for aseptic failure using rotating-hinge prostheses.

Hypothesis: The rotating-hinge knee prostheses currently used in France provide significant improvements in function and self-sufficiency of patients undergoing revision knee arthroplasty, with outcomes comparable to those reported with constrained condylar knees.

Material and Methods: A multicentre retrospective study was conducted in 17 centres, under the auspices of the SoFCOT. The cohort consisted of 127 patients (127 knees) operated on before 2013. The main reasons for knee revision were aseptic loosening, major instability, mechanical failure, and extensor apparatus failure. Function and self-sufficiency were assessed using the International Knee Society (IKS) score and the Devane score, respectively. Survival was defined with all-cause surgical revision as the end point.

Results: Mean follow-up was 67.3±11.8 months (range, 13-180 months). Significant improvements ($p<0.001$) were seen in the total IKS score (+42 points), the IKS function score (+12 points), and the knee IKS score (+30 points). Paradoxically, the Devane score decreased by 0.44 point. The 5-year survival rate was 77% (95% confidence interval, 0.70-

0.85). Post-operative complications developed in 29% of patients (infection, n=12; aseptic loosening, n=11; and fracture, n=7).

Discussion: Rotating-hinge prostheses provide satisfactory outcomes of knee arthroplasty revision and remain an effective option for complex cases, confirming our working hypothesis. Self-sufficiency diminished slightly. The long-term outcomes obtained using rotating-hinge prostheses were, however, less good than those seen with constrained condylar knees for aseptic TKA revision, and the complication rate was higher, although the population and local circumstances were different. Discernment is therefore in order when determining the indications of rotating-hinge prostheses.

Level of evidence: IV; retrospective cohort study.

Key Words: Knee arthroplasty. Revision surgery. Hinged prosthesis. Rotating-hinge prosthesis. Survival. Complications.

1. Introduction

The good outcomes currently provided by total knee arthroplasty (TKA) [1] explain the sharp rise in TKA procedures [2,3], which are being performed at increasingly younger ages. This success has led inevitably to an increased number of revision TKAs in the medium and long terms [4,5] and to an increase in repeated revisions [6,7].

The main reasons for TKA revision, apart from prosthetic joint infection and peri-prosthetic fractures, are aseptic loosening (19-40%), instability (6-26%), polyethylene wear (0-25%), extensor apparatus failure, and material failure [8–12]. In France, the 2000 SoFCOT symposium on aseptic TKA revision found the following reasons in a cohort of 473 patients: loosening, 35.9%; patellar complications and tendon ruptures, 18.8%; stiffness, 15.2%; tibio-femoral laxity, 13.7%; mechanical failure, 6.9%; and unexplained pain, 6.5% [13]. Non-hinged knee prostheses (posterior-stabilized, semi-constrained) also produce

satisfactory outcomes when used for revision arthroplasty [14,15]. However, patients with severe instability due to failure of the capsule and ligaments require a greater level of constraint[16–19]. Increased constraint does not seem to diminish the functional improvements. The constrained condylar knee prosthesis, which is the most widely used design in patients with instability or deformity, produces excellent long-term outcomes [20], but has limitations in patients with severe instability. Although much has been written about TKA revision, few studies have focussed on aseptic TKA revision using a rotating-hinge prosthesis [21–23].

The objective of the multicentre retrospective* study reported here was to evaluate the clinical and radiological outcomes of aseptic knee arthroplasty revision performed using a rotating-hinge prosthesis. Our working hypothesis was that the rotating-hinge knee prostheses currently used in France provide significant improvements in function and self-sufficiency of patients undergoing revision TKA, with outcomes comparable to those reported with constrained condylar knees.

2. Patients and methods

2.1 Study design

We conducted a multicentre retrospective study under the auspices of the SoFCOT and within the framework of the 2017 symposium on the place of rotating-hinge prostheses in France. The 17 centres were located in Amiens, Bordeaux, Clamart, Dijon, Fort de France, Grenoble, Lille, Lyon, Nancy, Nantes, Nîmes, Paris, Poitiers, Saint Etienne, Strasbourg, Toulouse, and Tours. We included all patients who had had revision of total knee arthroplasty or unicompartmental arthroplasty using a rotating-hinge prosthesis, for any of

the following aseptic reasons: (a) aseptic loosening, (b) major instability; (c) severe bone loss, (d) failure of the extensor apparatus; (e) bulkiness of the prosthesis, (f) polyethylene wear, and (g) failure of the material. Failure, and therefore the survival rate, was defined as surgical revision for any reason. We included 127 patients (127 knees). One patient with missing clinical and radiological data was excluded (Figure 1).

2.2 Methods

We recorded the usual data: age, sex, age at revision surgery, body mass index (BMI), American Society of Anesthesiologists (ASA) score [24], hip-knee-ankle (HKA) angle, mechanical axis before revision (varus or valgus knee), surgical approach, whether a procedure was performed on the anterior tibial tuberosity, and previous surgical procedures on the knee.

The clinical assessments before surgery and at last follow-up included an evaluation of self-sufficiency by the Devane score [25] and of function by the International Knee Society (IKS) score [26]. Intra-operative and post-operative clinical complications were recorded.

The radiographic assessment consisted in standing coronal and lateral views, a skyline view, and a long-leg view. These views were obtained before surgery and at last follow-up. Bone loss was assessed by determining the class in the Anderson Orthopedic Research Institute (AORI) classification [27].

2.3 Statistical analysis

The anonymised data were entered into a server. The statistical analyses were done at the Lille university hospital.

The first step consisted in a descriptive analysis of the parameters. Continuous variables were described as mean, standard deviation, and range and categorical variables as

percentages. Then, changes in the functional scores were evaluated by applying Student's test, with values of p less than 0.05 taken to indicate significant differences. Survival curves were plotted according to Kaplan-Meier.

3. Results

3.1 Description of the cohort

We included 127 patients (127 knees). There were 79 females and 48 males. Mean age at revision was 69.5 ± 11.8 years (range, 23-89 years). The mean BMI was 29.3 (range, 17.9-47.6) and the mean ASA score was 2.38 ± 0.6 (range, 1-4). Mean follow-up was 67.3 ± 36.9 months (range, 13-180 months) (Table 1 and Figure 2).

Mean time from primary TKA to revision was 85 months (range, 2-302 months). Aseptic loosening was the most common reason for revision (Figure 3), with 59% of patients, followed by instability (39%), mechanical failure (17%) (material breakage, wear and luxation of the polyethylene), and extensor apparatus rupture (6%).

The mean preoperative values were 91 for the IKS score and 2.7 ± 1 (range, 1-5) for the Devane score. Tables 2 and 3 report details on the intraoperative data and on the implants used for TKA exchange.

At inclusion, 12 (9%) patients had died, after a mean time since surgery of 69 months (range, 26-151 months). As their follow-up duration was deemed sufficient and they had no missing clinical or radiological data, these 12 patients were included.

3.2 Clinical outcomes

After the mean follow-up of 67.3 months, significant improvements were seen in the total IKS score (from 91 to 133; $p < 0.0001$), IKS function score (from 44 to 56; $p = 0.0007$),

IKS knee score (from 47 to 77; $p<0.0001$), and pain score (from 17 to 37; $p<0.0001$) (Figure 4). Mean flexion was also improved, from 92° to 96° ($p=0.03$).

Despite the overall improvement in the function of the operated knee, some loss of self-sufficiency was noted, with a decline in the Devane score from 2.7 to 2.26 ($p=0.0003$). The numbers of patients in the Devane groups 1 and 2 (with low self-sufficiency) increased, from 12 to 28 and from 55 to 57, respectively; whereas the numbers in the Devane groups 3, 4, and 5 (with a higher level of activity) decreased, from 36 to 24, from 10 to 4, and from 15 to 9, respectively.

3.3 Complications

Of the 127 patients, 37 (29%) experienced one complication (29%) (Table 4).

- Infection developed in 12 (9.4%) patients and consistently required surgery. The treatment consisted in single-stage exchange in 1 patient and two-stage exchange in 4 patients; none of these 5 patients experienced recurrent infection. Arthrodesis was performed in 2 patients, transfemoral amputation in 3 patients, and joint lavage with suppressive antibiotic therapy in 2 patients.
- Aseptic loosening occurred in 11 (8.6%) patients at a mean of 40.7 months (range, 3-96 months) after revision surgery. Eight of these patients required surgery, which consisted in removal and repositioning of the same prosthesis in 4 patients, a change of the tibial component in 3 patients, and a change of the femoral component in 1 patient. The remaining 3 patients did not undergo surgery.
- Peri-prosthetic fractures developed in 7 (5.5%) patients, who were managed by internal fixation.
- Rupture of the extensor apparatus occurred in 6 (4.7%) patients.

- Rupture of the femoral extension stem occurred in 1 (0.8%) patient and was managed by replacement of the component.

In sum:

- 106 (83.4%) prostheses were still in place with no evidence of loosening at last follow-up, including 2 (1.6%) infected sealed prostheses.
- 18 (14.2%) prostheses were no longer present as they had been exchanged due to septic or aseptic loosening, removed to perform arthrodesis, or removed during transfemoral amputation.
- 3 (2.4%) loosened prostheses were not treated surgically, due either to a contraindication to anaesthesia or to complete absence of pain and functional repercussions.

3.4 Survival rate

When failure of the rotating-hinge prosthesis was defined as all-cause surgical revision the survival rate was 87% (95% confidence interval [95%CI], 0.81-0.93) after 1 year, 77% (95%CI, 0.70-0.85] after 5 years, and 73% at last follow-up (95%CI, 0.65-0.81) (Figure 5).

4. Discussion

TKA revision surgery often raises technical challenges, particularly as the patients may have had multiple knee surgeries and are frequently elderly and frail. The hinged knee prosthesis was typically reserved for elderly patients with low functional demands, given the very high complication rates seen with the first-generation implants [28]. However, recent reports show that hinged prostheses are no longer reserved for salvage procedures [29]. The

latest report issued by the French Drug and Healthcare Product Safety Agency (ANSM)[30] states that, in 2013, hinged prostheses were used in 573 (0.7%) of 80 819 TKA procedures, a 21% increase over 2008. In 2017, a survey conducted by the SoFCOT symposium among prosthesis manufacturers demonstrated that about 3000 hinged prostheses were implanted in France. Hinged prostheses thus accounted for 3% of all TKA procedures, and most were rotating-hinge prostheses. These data confirm the place held by the rotating-hinge prosthesis in our therapeutic armamentarium. In 2018, the Swedish TKA register recorded 14 957 primary TKAs in 2017, including 51 (0.3%) hinge prostheses. From 2007 to 2016, primary hinged-prosthesis TKA was performed for 598 (0.5%) knees. Over the same period, hinged prostheses were used for 7.35% of first TKA revisions [31]. The total number of hinged prostheses used, including repeat revisions, was not recorded in this register.

Our hypothesis was confirmed in that knee function improved significantly. The functional outcomes in our cohort were satisfactory. Marked improvements were seen after surgery compared to the preoperative values, with a mean 30-point increase in the IKS knee score ($p<0.001$) and a 12-point increase in the IKS function score ($p<0.001$). Despite these functional improvements, self-sufficiency did not increase, as shown by the 0.44-point decrease in the Devane score. This loss of self-sufficiency is undoubtedly ascribable to the age of the patients (mean age, 69.5 years) and to their many comorbidities, some of which impaired the ability to walk. However, we found no supporting statistical correlation in our study. The Devane score is probably not relevant for assessing the activity of patients after revision arthroplasty, as the progression of comorbidities and presence of other prostheses decrease the Devane score.

Although statistically significant, the clinical improvement in our population was less marked than in other studies of rotating-hinge prostheses used for aseptic TKA revision. In a study of 24 patients, Neumann et al. [22] reported a 50-point increase in the IKS function

score after 56 months, while Joshi et al. [21] obtained a 28-point increase after 94 months in 78 patients and Merchan et al. [23] a 20-point increase after 87 months in 96 patients. These differences are ascribable to the higher pre-operative IKS scores in our population than on average in the literature: the IKS knee scores ranged from 25 to 38 and the IKS function scores from 33 to 35 in the studies by Merchan, Joshi, and Neumann compared to 47 and 44, respectively, for our study (14-16) (Table 5). On the other hand, our clinical outcomes are comparable to those observed for other causes of TKA revision, such as infection and aseptic trauma [32].

The complication rate in the literature varies from 4% to 36% [21,33–35] and was 29% in our cohort. Joshi et al.[21] report comparable results with 27% of complications. In their meta-analysis, Sheng et al. [33] found a mean complication rate of 19%. This lower rate compared to our study may be ascribable to the inclusion in the meta-analysis of cohorts treated by revision with posterior-stabilized or constrained condylar knees. This complication rate is higher than for primary TKA [5,36] and for revision with less constrained prostheses [37,38]. No case of intra-prosthetic dislocation was recorded in our study. This rare complication is typical of rotating-hinge prostheses and is dependent on their design [39].

Infection remains a common cause of failure and revision after TKA exchange by a rotating-hinge prosthesis [36]. The rate was 9.4% in our study, with 12 patients (including 5 in whom the unfavourable course required either transfemoral amputation [n=3] or arthrodesis [n=2]). These numbers are higher than in the studies of aseptic TKA revision by Merchan, Joshi, and Neuman in which there was 1 case of infection managed by two-stage exchange, 2 cases of septic loosening managed by arthrodesis, and no cases of post-operative infection, respectively. The high rate of infection in our study is ascribable to the characteristics of our population, with numerous comorbidities associated with a high risk of

infection (high ASA score, diabetes, obesity) and often with a history of multiple surgeries on the knee (23). Severe infection required amputation in 3 of our patients. In the studies of hinged prostheses for knee tumours or trauma done at the 2017 SoFCOT symposium, the rates of infection were 16% and 15%, respectively [40,41]. However, the high rate of infection after hinged prosthesis implantation is not related only to multiple surgeries to treat a tumour or traumatic injury. Abdulkarim et al. performed a meta-analysis of primary TKA with a rotating-hinge knee prosthesis, from which they excluded tumours and trauma, and found an infection rate of up to 14% [42]. Infection was the cause of 31.5% of treatment failures in this meta-analysis. These data indicate that the longer operative time and greater aggressiveness for the tissues increase the risk of infection.

Five-year survival rates vary in the literature from 52% to 90% [34,43–46] irrespective of the type of hinged prosthesis used and of the reason for revision. With our severe definition of failure as all-cause revision surgery, the survival rate was 77%, which is toward the lower middle of previously reported values. However, when failure is defined as septic or aseptic loosening, the survival rate at last follow-up (mean, 67.3 months) is 82%. In another study, when failure was defined as revision for aseptic loosening, the 10-year survival rate was nearly 90%, whereas it was 65% when failure was defined as all-cause revision [43].

Our study shows that some surgeons prefer the rotating-hinge prosthesis over constrained prostheses such as the constrained condylar prosthesis, even for knees without marked hyperlaxity, which is theoretically the indication for rotating-hinge prostheses used for the first TKA revision. The SoFCOT symposium held in 2000 on TKA revision had already found that hinged prostheses were sometimes chosen routinely for TKA revision [13].

The best type of implant for TKA revision remains a matter of debate. The rotating-hinge prosthesis has the main advantage of requiring no support from the ligaments.

Hermans et al. [47] compared the rotating-hinge prosthesis to the constrained condylar knee in patients undergoing TKA revision for stiffness requiring extensive joint release. The functional outcomes were better with the rotating-hinge prosthesis. However, in a study by Rhöner et al.[48] of primary TKA for laxity, the rotating-hinge prosthesis and the constrained condylar knee produced comparable results in terms of laxity, mobility, and satisfaction. The meta-analysis by Yoon et al.[49] on TKA revision found a higher survival rate with the rotating-hinge prosthesis than with the constrained condylar knee after less than 5 years (87.4% vs. 75%) contrasting with better survival of the constrained condylar knee after 5 to 10 years (81.3% vs. 83.8%). The complication rate was higher with the rotating-hinge knee (Table 6).

In our study, prosthetic wedges were generally used to handle minor epiphyseal and metaphyseal bone defects, whereas bone grafts were used for larger defects. No preformed tantalum cones were used, although they have been reported to provide good outcomes [51,52]. Their recent introduction in France and high cost explain that they were not used in our study.

Our study has several limitations. The retrospective and multicentre design should be borne in mind, although it allowed us to obtain one of the largest cohorts in the literature. The use of different rotating-hinge knee models in the study centres may make comparisons difficult. To date, 16 models of rotating-hinge prosthesis are available on the French market. Finally, comparisons of our results to those reported previously are hindered by the heterogeneous surgical indications in most studies. We were unable to analyse the results and complications for each reason for TKA revision because, at patient inclusion, the surgeon could give one or more reasons for revision of the same knee. Such an analysis would enable the identification, before surgery, of the ideal indication for the rotating-hinge prosthesis and the required level of constraint [53].

Despite these limitations, this study provides an overview of the use of rotating-hinge prostheses in France and shows that this type of prosthesis is increasingly used with ever better outcomes.

5. Conclusion

The rotating-hinge prosthesis is an indispensable component of the therapeutic armamentarium to treat patients with major ligament failure, certain comminuted fractures of osteoporotic bone, and of course tumours [54,55]. TKA revision using a rotating-hinge prosthesis is technically challenging and was historically reserved for salvage surgery. The outcomes obtained with the more recent generations of rotating-hinge prosthesis have resulted in greater use outside the typical indications.

Data in the literature clearly demonstrate that outcomes of aseptic TKA using a rotating-hinge prosthesis are satisfactory overall. The good functional outcomes obtained in our study confirm these data but should be considered in the light of the high rate of mechanical and septic complications (29%) and of the absence of gains in self-sufficiency. In addition, revising rotating-hinge TKA often raises complex technical challenges [56] associated with complications. The medium-term survival rate is lower than with constrained condylar prostheses in earlier studies, although we used a very broad definition of failure. Patients must be selected with discernment and informed of the risk of complications.

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FH, DM, GP, ME: drafted the manuscript

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FIGURE LEGENDS

Figure 1. Flow diagram

Figure 2. AORI score: pre-operatively, femoral bone defects in 45% of patients and tibial bone defects in 47% of patients

Figure 3. 93-year-old male patient who underwent total knee arthroplasty in 1985: mechanical loosening and laxity in the coronal plane

(a) pre-operative radiographs

(b) radiograph taken in 2015 after revision in 2010 using a rotating-hinge prosthesis

Figure 4. IKS scores before revision surgery and at last follow-up

Figure 5. Survival curve. At 1 year, 87% (95%CI, 0.81-0.93] and at 5 years, 77% (95% confidence interval, 0.70-0.85)

Table 1. Main features in the study population

Sex (F/M)	79 (62%)/48 (38%)
Mean age, years	69.5±12 (42-89)
ASA score [24] mean 2.38	
ASA 1	3 (2.4%)
ASA 2	69 (54.3%)
ASA 3	46 (36.2%)
ASA 4	1 (0.8%)
missing	8 (6.3%)
Morphotype before revision	
HKA, mean	174°
Varus Knee	68 (63%)
Valgus Knee	20 (19%)
Normal alignment	19 (18%)
Mean flexion before revision	92°±25 (0-130)
IKS Total	91
IKS function	44
IKS knee	47
IKS pain	17
Devane score [25] mean before revision: 2.7	
Devane 1	12 (9.4%)
Devane 2	55 (43.3%)
Devane 3	35 (27.6%)
Devane 4	10 (7.9%)
Devane 5	15 (11.8%)

Table 2: Intra-operative data from the study cohort

Medial approach		90%								
Procedure on the anterior tibial tuberosity		23%								
85 months (2-302) on average between the primary knee arthroplasty ^a and the revision										
50 % of patients had had a single operation on the knee before implantation of the rotating-hinge prosthesis										
Number of operations before the revision	1	2	3	4	5	6	7	8	9	>10
Patient (n)	63	36	17	5	3	1	0	1	0	1
Type of primary prosthesis before revision										
- Total knee arthroplasty		120 (94.5%)								
- Unicompartmental knee arthroplasty		7 (5.5%)								
Other procedure on the knee										
- Meniscectomy		8 (6%)								
- Valgus high tibial osteotomy		12 (9%)								
Implant fixation modality (cemented /cementless)										
- Cemented component: 112 femoral components (88 %) and 108 tibial plateaux (85 %)										
- Cemented stem extension: 66 tibial and 66 femoral (52 %)										
Filling of bone defects										
wedges femoral	30 (24%)									
tibial	27 (21%)									
both	10 (8%)									
allograft	14 (11%)									
autograft	2 (1.5%)									

^aeither total knee arthroplasty or unicompartmental knee arthroplasty

Table 3. Rotating-hinge prostheses used for the revision

Manufacturer	Prosthesis	N	%
ZIMMER	RHK NexGen	40	31.5
STRYKER	MRH	40	31.5
LINK	Endomodel	18	14.2
STANMORE	METS	7	5.5
SMITH & N	RT PLUS	4	3.1
BBRAUN	AXEL	3	2.4
	Enduro	2	1.6
IMPLANTCAST	MUTARS KRI	1	0.8
Other		1	0.8
Missing		11	8.6

Table 4. Post-operative complications

Complications	n	%
Infections	12	9.4
Aseptic loosening	11	8.6
Peri-prosthetic fracture	7	5.5
Rupture of the extensor apparatus	6	4.7
Hardware failure	1	0.8
Total	37	29

Table 5. Revision using rotating-hinge prostheses: review of the literature

	Number of patients	Mean age (years)	Mean follow-up	IKS Knee (pts)	IKS function (pts)	Range of Motion Extension - Flexion
Joshi (2008) Endomodell (Link)	78	72	5 years	38 -> 86	33 -> 61	- 4° -> -1° 103° -> 97°
Neumann (2012) RHK Nexgen (Zimmer)	24	67	4.6 years	25 -> 91	35 -> 85	0° 72 -> 116°
Rodriguez-Merchan (2015) Endomodell (Link)	96	79	7.3 years	33 -> 79	34 -> 54	- 15° -> - 5° 80° -> 120°
Sofcot (2017)	127	69.5	5.8 years	47 -> 77	44 -> 56	- 4° -> 0° 91.6 -> 96°

Table 6. Comparison to revision using constrained condylar prostheses

	Our study	Sanz-Ruiz 2015 [50] (BMC)	Kim 2009 [38] (JBJS-Am)
Revisions (n)	127	47	114
Mean follow-up (months)	67.3	98.4	86.4
Mean age (years)	69,5	73	65
Post-op. complications	37	11	10
- Infections	12	2	2
- Aseptic loosening	11	2	4
- Fracture	7	2	0
- Rupture of the extensor apparatus	6	0	3
- Implant failure	1	0	1
- Instability	0	1	0
Progression IKS knee	47 -> 78	40 -> 80	35 -> 90
Progression IKS function	44 -> 56	32 -> 56	16 -> 64
Progression Flexion	92 -> 96	90 ->106	95 -> 106
Survival rate	77 % at 5 years	80 % at 6.5 years	96 % at 10 years

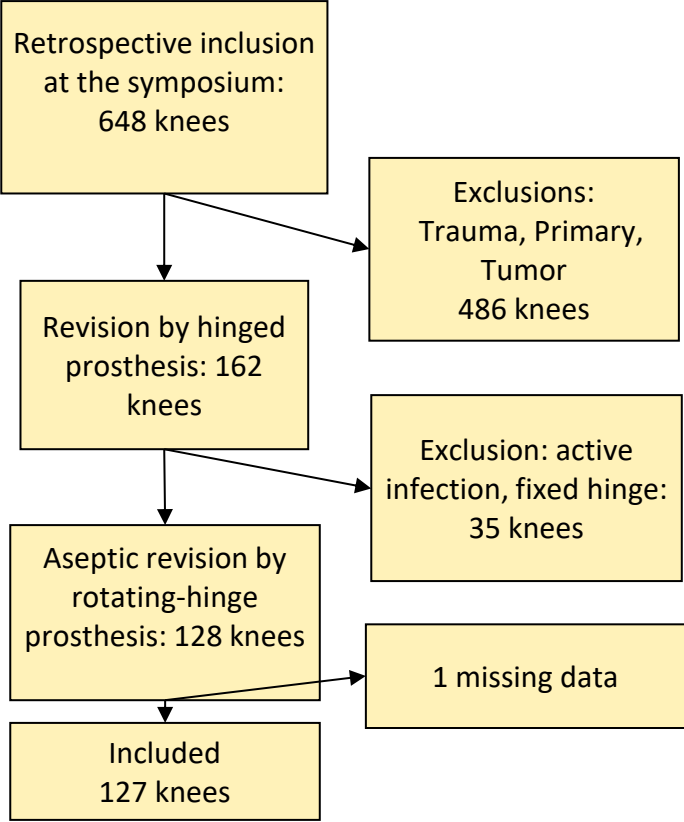


Figure 2.

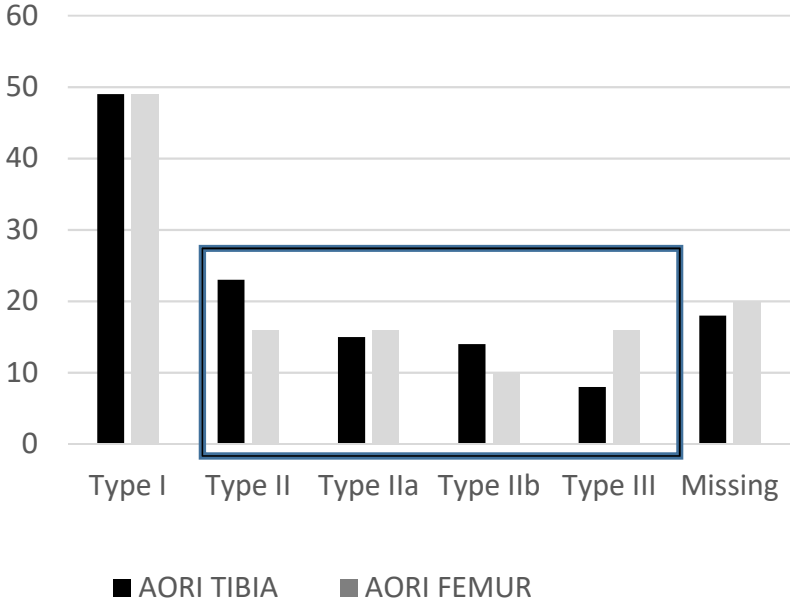


Figure 3.

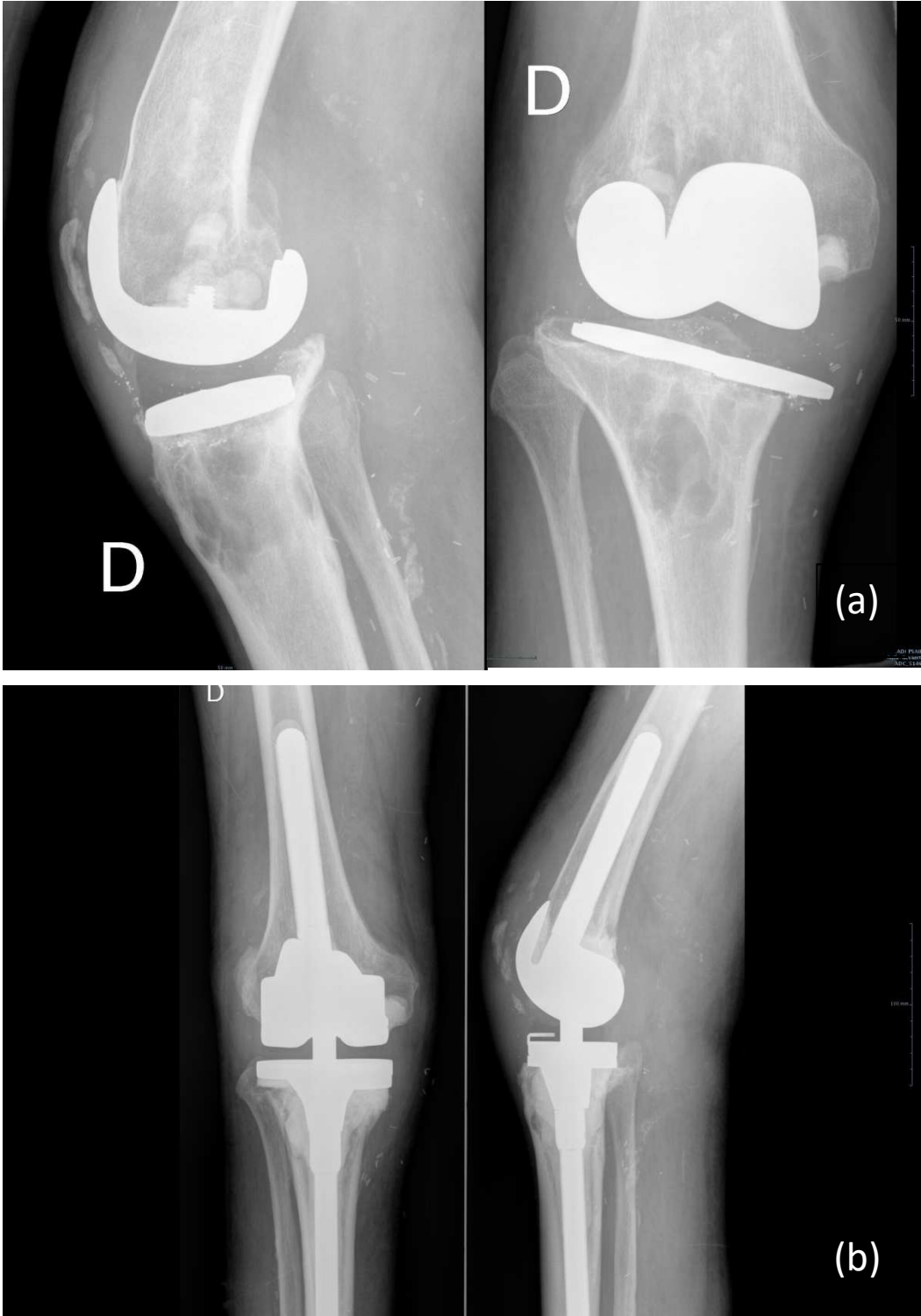


Figure 4.

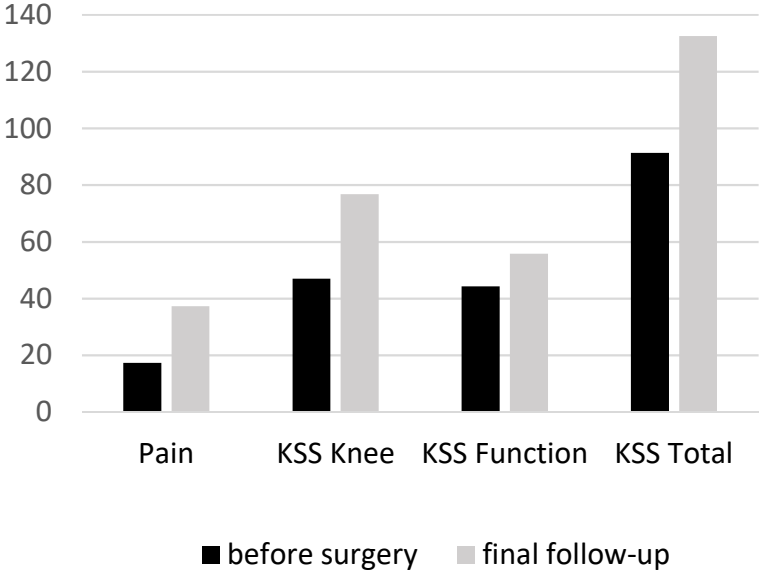


Figure 5.

