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Endo-Modell Rotating-hinge Total Knee for Revision Total Knee Arthroplasty

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Abstract

The goal of this study was to analyze the clinical and radiographic results and the survival rate of a series of rotating-hinge implants used for revision total knee arthroplasties in mild and severe instability.

Between December 1991 and June 2004, fifty-three revision total knee arthroplasties were performed using the Endo-Modell (Waldemar LINK GmbH and Co, Hamburg, Germany) rotating-hinge prosthesis; 7 (13.2%) patients underwent partial revision of a previous Endo-Modell. All patients were evaluated preoperatively, 3 and 6 months postoperatively, and annually thereafter using the Hospital for Special Surgery (HSS) knee score and the Knee Society Roentgenographic Evaluation System (KS-RES). Mean follow-up was 155.2±40.1 months (range, 78–240 months), with 32 patients examined at the final follow-up. All HSS knee scores increased from preoperatively to last follow-up. No statistically significance differences were found in the HSS knee scores between septic and aseptic revisions and between total or partial revisions. Progressive radiolucent lines were detected in 8 (25%) patients. Implant failure occurred in 11 (20.7%) patients; the cumulative survival of the implants was 80.4% at 150 months for the final 32 patients.

The authors recommend use of this implant for revision total knee arthroplasty, especially in patients with severe instability and bone loss.

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The need for revision total knee arthroplasty (TKA), which accounted for no more than 5% of all implants until recently, has increased recently to more than 10% of all TKAs.[1–3] However, it is a complex surgery and often has worse results and a higher complication rate compared with the first implants. An accurate diagnosis and correct preoperative planning are necessary to obtain good results, as is the identification of the causes of the failure.[4–6]

The first goal of the revision TKA is to achieve a functionally effective, painless, properly aligned, and stable joint with a good range of motion and good patellar tracking. Several techniques are described in the literature to achieve these objectives, with a different implant available with variable constraints. In general, a less hinged model should be used in the presence of ligamentous stability and good bone stock. However, in patients with mild or severe instability and bone stock deficiencies, it is necessary to use more hinged and stemmed implants. The choice of the implant model and the degree of the hinge are the surgeon's choice.[7] Rotating-hinge implants may increase transmission of the bone-implant forces compared with that of the condylar constrained implants. Some articles have indicated that this would be associated with a higher risk of aseptic loosening and mobilization.[8–11]

The current study analyzes the clinical and radiographic results and the survival rate of a series of rotating-hinge implants used for revision TKA in mild and severe instability. The hypothesis is that hinged implants have good functional results, acceptable complication rates, and a reasonably long survivorship.

Materials and Methods

Prosthesis Model

The Endo-Modell (Waldemar LINK GmbH and Co, Hamburg, Germany) prosthesis, which was designed in 1979 and produced by Link, was used for patients in this study. It is characterized by a metal hinge that allows for flexion-extension and axial rotation, and it has long cemented stems. The prosthesis tie is a tibial metallic hinge that lodges in the femoral component, which is covered by an ultra-high-molecular-weight polyethylene girdle approximately 2 mm thick. A model with an antidislocation device is also available. The implant, as declared by Link and according to its design, allows for physiological rotation. An outer rotation of 50° and an inner rotation of 35° occur at 120° of flexion, and a virtual flexion up to 165° also occurs.

Patients

Between December 1991 and June 2004, fifty-three revision TKAs in 50 patients (3 bilateral patients) were performed using the Endo-Modell implant. Seven (13.2%) patients required partial revision of an Endo-Modell used for the first implant (to replace the femoral component in 5 and to replace the tibial component in 2), whereas the remaining 46 (86.8%) patients underwent total revision of a different implant. All bilateral patients underwent total implant revision.

The 50 patients included 33 (66%) women and 17 (34%) men with an average age at surgery of 69.7±6.5 years (range, 45–85 years). In the 46 patients who underwent total revision, 20 (43.5%) had aseptic loosening, 14 (30.4%) had septic loosening, 5 (10.9%) had implant wear, 3 (6.5%) had a polyethylene fracture, 2 (4.3%) had femorotibial instability, 1 (2.2%) had a periprosthetic fracture, and 1 (2.2%) had a femorotibial dislocation. In the 7 patients who underwent partial revision, 2 (28.6%) had an implant dislocation, 2 (28.6%) had a polyethylenic hinge rupture, 1 (14.2%) had a femoral component rupture, and 2 (28.6%) had a polyethylenic component rupture. All patients were included in the survival rate evaluation.

Preoperative Evaluation

All patients underwent a careful clinical evaluation of local and general health conditions. All patients also underwent standard radiographic evaluation, with anteroposterior, laterolateral, skyline, and long-leg views obtained in bipodalic suppor. In addition, all patients were examined for the presence of radiolucent lines according to the method described by Ewald[11] (the Knee Society Roentgenographic Evaluation System) and evaluated for periprosthetic bone loss.[12,13] If septic loosening was suspected, a 3-phase scintigraphy with technetium and a monophase scintigraphy with marked granulocytes cells were performed.[14]

Surgical Technique

In all patients, the previous surgical incision was followed, continuing with a medial parapatellar capsulotomy. In 1 (1.9%) patient, a tibial tuberosity detachment was necessary to improve exposure, with the protection of the extensor apparatus; in all other patients, a staple in the tibial tuberosity through the patellar tendon was applied to protect it intraoperatively.

After the implant exposition, it was removed with all of the remaining cement and necrotic tissues, and the Engh classification was used to evaluate bone loss.[15] The reconstruction followed assessing for bone loss, balancing the soft tissues, and evaluating knee stability and alignment.

The reconstruction of the bone loss was performed using cement (also armed with screws), autologous and homologous bone grafts, metal and polyethylenic spacers, wedges, and a custom-made prosthesis.[16–19] Fixation of the prosthesis was provided in all patients by diaphyseal cemented stems and metaepiphyseal cementation. In this series, the antidislocation device was used in 43 (81.1%) of 53 revisions. In 2 (3.8%) patients, the use of a custom-made prosthesis was necessary. Patients with septic loosening are treated using a 2-stage technique, followed by intravenous antibiotic therapy for approximately 4 to 6 months, according to the literature.[20,21] Among the 14 patients with septic loosening, the 2-stage technique was possible in 10 (71.4%) patients, whereas the remaining 4 (28.6%) patients the underwent 1-step revision because of the severity of their comorbidities.

Patella revision was not performed in the presence of good tracking of the native patella or of the patellar component (when present) or if the patellar component was stable and had no sign of loosening. Therefore, patella replacement was performed in 11 (20.7%) of 53 revisions, but all patients underwent thermal denervation of the patella.

Prophylaxis and Rehabilitative Protocols

All patients received antibiotic prophylaxis 1 hour preoperatively and anti-thromboembolic prophylaxis with low-molecular-weight heparin until full recovery of the load. The rehabilitative protocol depended on the concomitant procedure performed intraoperatively. For example, in instances in which an osteotomy of the tibial tuberosity was performed, the patient used a fixed-extension brace for 1 month to protect the extensor apparatus.

Clinical Evaluation

The Hospital for Special Surgery (HSS) knee score was used for clinical evaluations[22,23] preoperatively, 3 and 6 months postoperatively, and annually thereafter at the outpatient clinic. The

clinical evaluations were performed by the investigators and by different orthopedic surgeons with casual rotation. In addition, the patient's demographic data, body weight, concomitant diseases, and postoperative complications were recorded. These data were prospectively collected via a form. When a patient could not reach the hospital for the evaluations due to his or her impaired health or distance from the hospital, he or she answered a telephone questionnaire, in accordance with the literature supporting the stacking of the data obtained using this method.[24]

Radiological Evaluation

The Knee Society Roentgenographic Evaluation System (KS-RES), developed by Ewald,[11] was used for radiological evaluations at the same time as the clinical evaluations. All patients had anteroposterior, laterolateral, and skyline radiographs obtained. The radiographs were evaluated for implant position, signs of periprosthetic fracture, mobilization or loosening, and the presence of osteolysis. Radiolucent lines were considered relevant when larger than 2 mm and progressive (indicating they were most likely linked to the loosening of the implant).

Statistical Analysis

Clinical and radiological data were analyzed using arithmetic averages related to confidence intervals and SDs. Statistical significance was evaluated for all of the collected and compared data by calculating the *P* value using Student's *t* test. The Kaplan-Meier method was used to calculate the cumulative survival rate.

Results

The study was completed in December 2010. Average follow-up period was 155.2±40.1 months (range, 78–240 months). Seven (14%) patients died during follow-up with no signs of implant failure. In addition, 11 (20.7%) patients were lost to follow-up. Therefore, 32 patients were included in the current study (64% of those undergoing surgery).

Bone Loss Classification and Treatment

After preparation of the femoral and tibial meta-epiphysis, the bone loss was classified according to the Engh classification[15] and treated as reported in Tables 1 and 2.

Table 1

Bone Loss Evaluation in All Cases of Total Revision and Relative Method of Treatment

Patient No.	Femur Defect	Treatment	Tibia Defect	Treatment	Cause of Implant Failure After Revision
1	2A	CEM	2A	CEM	
2	2A	CEM	2A	CEM	
3	2B	CEM	2A	CEM	Amputation
4	2B	CEM	2A	CEM	
5	3	CEM	3	SPAC	Septic
6	3	CEM	3	SPAC	Amputation
7	2A	CEM	2A	CEM	
8	2B	CEM	2B	CEM	
9	2B	CEM	2B	CEM	
10	2B	CEM	2A	CEM	
11	2A	CEM	2A	CEM	
12	2B	CEM	2B	SPAC	
13	2A	CEM	2A	CEM	
14	2B	CEM	2A	CEM	
15	2B	CEM	2B	CEM	Septic
16	3	CEM	2B	CEM	Arhrodesis
17	2B	CEM	3	SPAC	
18	2B	CEM	2B	SPAC	
19	3	CEM	3	SPAC	
20	2A	CEM	2A	CEM	
21	3	CEM	3	SPAC	
22	2B	CEM	2B	CEM	
23	2B	CEM	2B	CEM	
24	3	CEM	3	SPAC	
25	2B	CEM	2B	CEM	
26	2A	CEM	2A	CEM	
27	2B	SPAC	3	SPAC	
28	2B	CEM	3	SPAC	
29	2B	CEM	3	SPAC	
30	2B	CEM	2B	CEM	
31	2B	CEM	3	SPAC	Peripristhetic fracture
32	2A	CEM	2A	CEM	
33	3	CEM	3	SPAC	
34	3	CM	3	CM	Estensor apparatus rupture
35	3	CEM	3	SPAC	
36	2A	CEM	2A	CEM	
37	3	CEM	3	SPAC	
38	3	CM	3	CM	Hinge rupture
39	2B	CEM	2B	SPAC	Hinge rupture
40	2B	CEM	3	SPAC	
41	3	CEM	3	SPAC	
42	2B	CEM	2B	SPAC	
43	2B	CEM	2B	SPAC	
44	3	CEM	2B	SPAC	Aseptic
45	3	CEM	3	SPAC	Septic
46	3	BONE+CEM	2B	BONE+CEM	

Abbreviations: CEM, cementation; SPAC, spacers; CM, custom-made prosthesis; BONE, morselized bone.

Table 1:

Bone Loss Evaluation in All Cases of Total Revision and Relative Method of Treatment

Table 2

Bone Loss Evaluation

Classification	No. (%) Femur	Tibia
1	0	0
2A	9 (16.9)	13 (24.5)
2B	25 (47.2)	16 (30.2)
3	17 (32.1)	18 (33.9)

Table 2:

Bone Loss Evaluation

Immediate Complications

Immediate complications were detected in 8 (15%) revisions. In 4 of these revisions, surgical wound revision due to a delayed healing was performed. In 2 revisions, a hematoma drainage was necessary. In 2 revisions, early infection of the prosthesis was suspected and a surgical knee lavage with a polyethylene exchange was performed and followed by prolonged antibiotic therapy. All patients were successfully treated.

Late Complications

In 9 (17.0%) revisions, rupture of the polyethylenic hinge occurred. In 3 of these revisions, the implant revision was performed because of the consequent instability. In 3 revisions, the wear and rupture of the hinge was found due to dislocation (n=2) and septic loosening (n=1). In the remaining 3 revisions, the damage of the plastic hinge was asymptomatic, with mild clinical varus-valgus instability. This instability was attributed to the wear-rupture of the plastic hinge, but because the functionally of the implant was not affected and the patients had no pain, no further treatments were performed and the patients were observed.

Two (3.8%) patients with extremely poor results are included in this series. One had rupture of the extensor apparatus, and the other had aseptic loosening of the implant. Both were treated nonoperatively because of their poor general condition and consequent unacceptable surgical and anesthetic risks; they were allowed to walk with a rigid knee brace fixed in extension.

Clinical Results

All HSS knee scores increased from preoperatively to last follow-up. In particular, the pain component score (maximum score, 30 points) improved from an average of 12.6 points (classified as moderate; 95% confidence interval [CI], 10.4–14.8) to 26.6 points at last follow-up (classified as absent; 95% CI, 20.4–30) ($P<.05$). Range of motion increased from an average of 81.3° (95% CI, 77.8°–84.8°) preoperatively to 102.6° (95% CI, 97.2°–107.9°) at last follow-up ($P<.05$). In addition, the total score increased from an average of 58.4 points (equivalent to a poor condition; 95% CI, 55.1–61.8) to 85.5 points at last follow-up (equivalent to a good result; 95% CI 79.6–87.5) ($P<.05$). Table 3 compares the average HSS knee scores preoperatively and at final follow-up.

Table 3

Specific Items of the Hospital for Special Surgery Score Before and After Revision TKA

	Mean±SD (95% CI)		
Item	**Preop**	**Postop**	***P***
Pain score	12.6±3.5 (10.4-4.8)	26.6±2.5 (20.4-30)	.000002
Range of motion	81.3°±11.2° (77.8°-84.8°)	102.6°±14.3° (97.2°-107.9°)	.00001
Functionality	6.7±2.9 (7.5-5.8)	9.5±2.4 (10.2-8.8)	.0001
Stairs	2.23±0.8 (2.5-2)	2.7±1.3 (3.1-2.4)	.0369
Crutches	2.5±1.1 (2.8-2.1)	3.1±1.5 (3.5-2.7)	.1596
Quadricipital force	7.3±2.3 (8-6.7)	9.1±1.3 (9.5-8.7)	.0001
Flexion deformity	8.7±1.5 (9.1-8.2)	9.7±0.7 (9.9-9.5)	.0029
Instability	7.7±2.1 (8.3-7.1)	9.2±2.3 (9.8-8.5)	.0001
Total score	58.4±10.8 (55.1-61.8)	85.5±10.1 (79.6-87.5)	.0000002

Abbreviations: CI, confidence interval; postop, postoperative; preop, preoperative; TKA, total knee arthroplasty.

Comparing the results between septic and aseptic patients, no statistically significant differences were found for all of the HSS knee score values. However, patients who had revision for an aseptic loosening showed slightly better results in all scores compared with those with a septic loosening in terms of pain, range of morion, and functionality. Similarly, no statistically significant differences were found in the results obtained from patients undergoing revision of the entire prosthesis compared with those undergoing revision of a single component. Nevertheless, the patients who had a partial revision showed better results in all of the HSS knee score items and in terms of total score.

Radiographic Results

Radiograph evaluation was possible for 32 patients. Implant revision was performed in 8 (25%) patients with progressive radiolucent lines and 6 (18.7%) with nonprogressive radiolucent lines (Figure 1). No radiolucent lines were observed in the remaining 18 (56.3%) patients (Figure 2). Polyethylenic wear and damage and massive osteolysis were not detectable on radiographs.

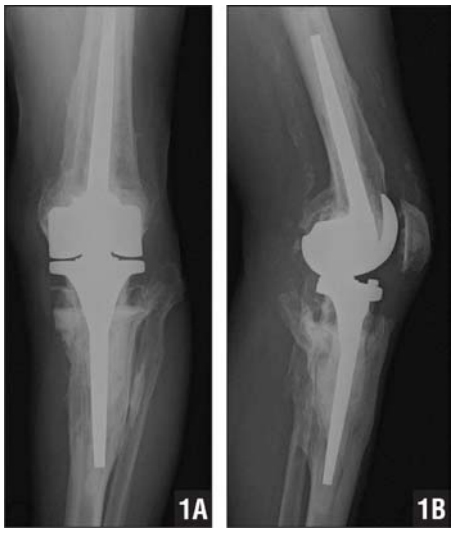

Figure 1:

A 65-year-old man underwent left revision total knee arthroplasty for massive septic loosening with diffuse osteomyelitis using the Endo-Modell (Waldemar LINK GmbH and Co, Hamburg, Germany) rotating-hinge prostheses. Anteroposterior (A) and laterolateral (B) radiographs taken at 10-year follow-up showing well-fixed implants with no evidence of progressive radiolucent lines or loosening. Clinical results were good according to the Hospital for Special Surgery knee score.

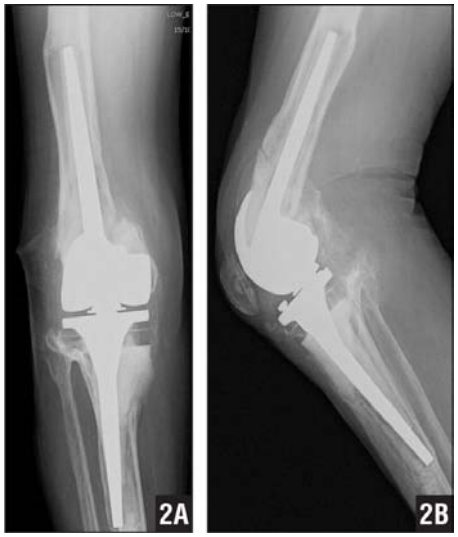

Figure 2:

A 77-year-old man underwent right revision total knee arthroplasty for septic loosening using the Endo-Modell (Waldemar LINK GmbH and Co, Hamburg, Germany) rotating-hinge prostheses. Anteroposterior (A) and laterolateral (B) radiographs taken at 3-year follow-up showing persistence of infection and associated fractures. The patient could not be operated on for a new revision, and 2 years later a diaphyseal femoral fracture at the tip of the stem resulted in the need for amputation.

Survival Analysis Results

Implant failure occurred in 11 (20.7%) of the 53 revisions, 5 of which were a rerevision of the femoral component alone (3 due to rupture of the polyethylenic hinge, 1 due to implant dislocation, and 1 due to periprosthetic fracture) and 4 of which were re-revision of the entire implant (all of these patients had septic loosening). In addition, knee arthrodesis was performed during the third surgery because of the resumption of septic phenomenon in 1 patient, and amputation for osteomyelitis was performed for 2 patients (in both patients, the indication for revision was septic loosening) (Figure 3). The cumulative survival rate calculated with the Kaplan-Maier method, using removal of implant as the endpoint, was 80.4% at 150 months (Figure 4).

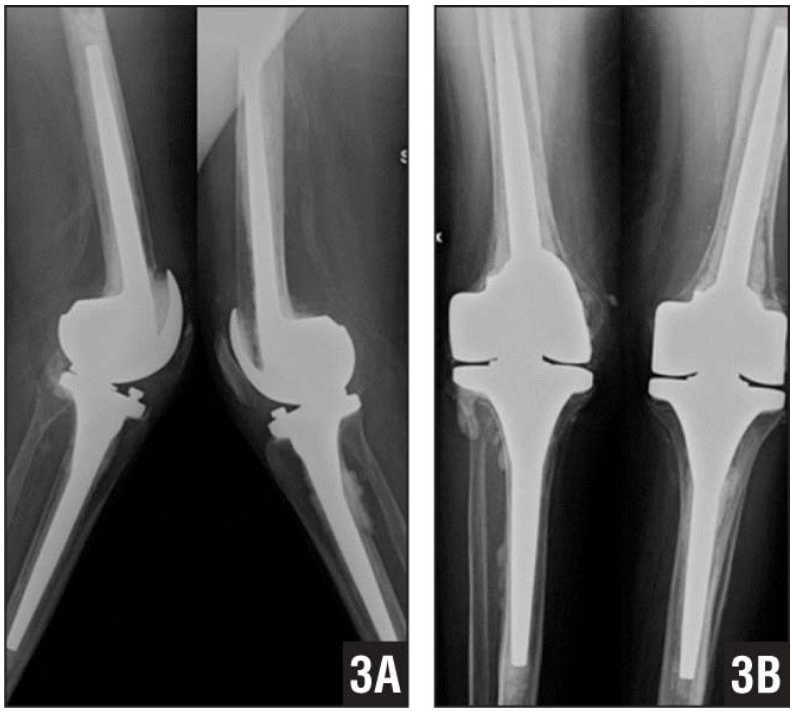

Figure 3:

A 61-year-old woman underwent bilateral revision total knee arthroplasty with the Endo-Modell (Waldemar LINK GmbH and Co, Hamburg, Germany) rotating-hinge prostheses. Laterolateral radiograph at 14 years (A) and anteroposterior radiograph at 13 years (B) postoperatively showing well-fixed implants with no evidence of progressive radiolucent lines or loosening. Nonprogressive radiolucent lines appear below the tibial plateau.

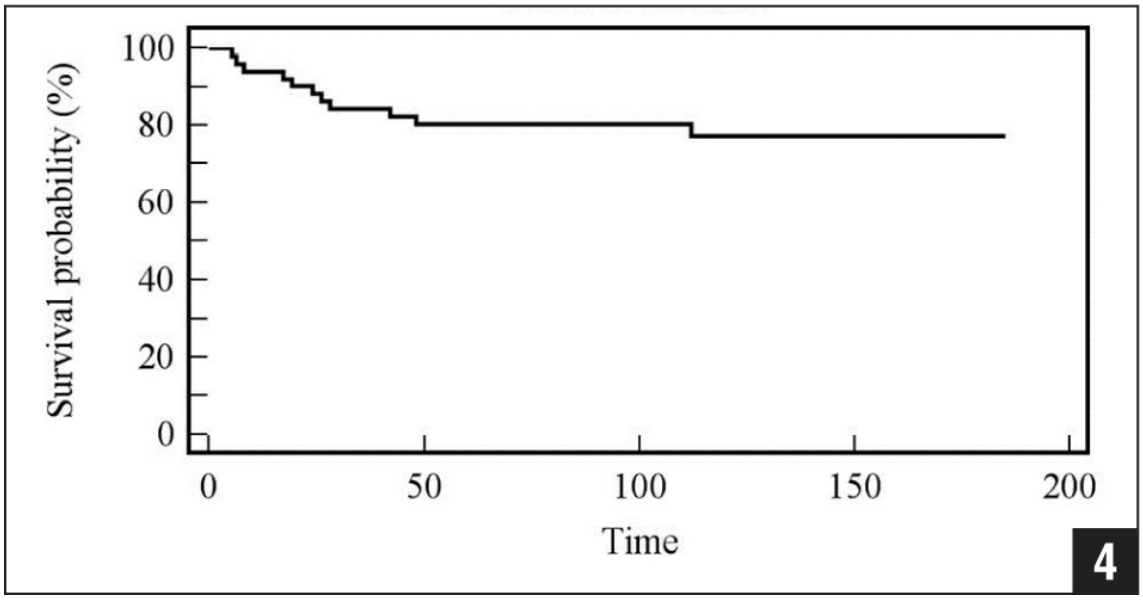

Figure 4:

Survival analysis according to the Kaplan-Maier curve.

Discussion

This study represents an unselected sample of revision TKAs that used the Endo-Modell hinged implant. It is based on patients' clinical assessment and radiological evaluation.

To the authors' knowledge, no series similar to this one has been reported because condylar constrained knee implants are preferred for revision TKA.[25] The current study's hypothesis was that the Endo-Modell hinged implants would have good functional results, an acceptable complication rate, and a reasonably long survivorship rate.

The first hypothesis was confirmed. A statistically significant increase in the HSS knee score from preoperatively to last follow-up examination was observed in addition to stable impants. As expected, less improvement was observed in patients with septic loosening. All of the results, as well as the percentage of failures, are similar to those reported in the literature regarding revision TKAs with similar implants or condylar constrained knee implants.[26,27] According to some authors, the hinge might involve severe stress transmission to the bone-prosthesis interface, and this may be correlated with a higher failure rate.[28] In the current series, the hinged implant did not correspond with early dramatic loosening, massive failures, or ruptures due to abnormal stress transfer. Finally, in the current series, the hinged implants did not have a worse survival rate compared with other less constrained models.

The high failure and complication rates in the current study are probably due to the complexity of the surgery, and they are similar to other results reported in the literature.[29] The early complications were immediately treated with complete resolutions without further effect on the implant results. However, the presence of an adequate extensor mechanism and the absence of neurovascular deficits are basic requirements to obtain good results. In fact, in the 2 patients in which they were not present, a significant improvement in quality of life after surgery was not obtained. Finally, considering that these implants had reasonable survivorship at 10 years of follow-up, the third goal—a reasonably long survivorship rate—was also achieved.

Implant dislocation is another concern because it is difficult and often requires a new revision surgery (usually to implant the antidislocation model). Therefore, the authors recommend using the antidislocation device and reserving the standard model for patients with proven intraoperative stability. Another concern regards the long cemented stems because they may transmit significant stress forces at the bone-cement-prosthesis interface.[30] The radiolucent line rate in the current study corresponds with the literature and confirms the ability to tolerate the forces on the bone-cement-prosthesis interface without increasing the aseptic loosening rate. However, removal of the diaphyseal cementation may be a problem in new implant revisions. For these reasons, new uncemented, press-fit femoral and tibial stems have been developed.

To treat the bone loss, the current authors used cement only, with or without screws, to fill them because they believe that this technique is safe and easier when compared with the use of spacers and wedges. Their results support this choice.

It is known that the fragility of the polyethylenic component may be an issue, especially when the material is subjected to significant forces. Nevertheless, new cross-linked vitamin E–added polyethylenes promise long-term duration and improved mechanical and chemical characteristics, including an increased resistance to bacterial adhesion.[31–33] In the current study, the polyethylenic hinge was recognized as the weak point of the implant; it is used to lock the 2 pitons between them, and its rupture can cause considerable instability and may require revision. This event occurred in 9 patients, and revision surgery was performed for 3 patients due to severe instability. In the authors' opinion, replacement of the femoral component is indicated only when rupture of the hinge causes relevant clinical involvements.

Partial implant revision is another issue. In this series, 7 patients had only 1 component of the Endo-Modell revised. In 5 patients, the femoral component was removed because of dislocation or hinge rupture; in the other 2 patients, the tibial component was revised for aseptic loosening. Although a questionable procedure, the partial revision of a failed Endo-Modell can be performed when the other component is fixed and well implanted, and it is less invasive and has acceptable clinical and radiological results.

According to the current results, the hinged prosthesis can be indicated in revision for patients with ligamentous instability or bone loss.[34,35] Advantages of this model are its adaptability to the majority of the anatomic and clinical situations (with thin stems) and the relative ease of the surgical technique due to the simplicity of the instrumentations compared with the second-generation rotating-hinge knees. In the authors' opinion, this implant allows for accurate reproduction of the joint line, especially if revision starts at the femoral component.

This study has several imitations, such as the number of patients lost to follow-up, the percentage of patients evaluated without radiographs, and the lack of a control group.

Conclusion

The authors used a rotating-hinge model for unselected revision of TKA. Although a high complication rate was observed, the long-term results were similar to those with other revision implants with less constraints, and the surgical technique is easier. Therefore, the authors recommend use of this implant for revision TKA, especially if instability and bone loss are severe.

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