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ORIGINAL ARTICLE

Complications following rotating hinge Endo-Modell (Link[®]) knee arthroplasty

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KEYWORDS

Total knee arthroplasty;
Complication;
Hinge Prosthesis;
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Summary

Background: Rotating hinge knee prostheses are indicated in revisions especially when major ligament laxity or substantial AP deformities are present. These situations make ligament balancing difficult with less constrained design implants. Despite its use for nearly 50 years, this type of prosthesis continues to have a poor reputation due to a high complication rate.

Hypothesis: Complications are frequent after this type of arthroplasty and the complication rate is similar in primary or revision arthroplasties. The objective of this study is to report the medium-term results of these implants and determine the eventual predictive factors of complications in order to refine operative indications.

Material and methods: In this retrospective study of patients operated on between 1998 and 2006, 85 Endo-Modell (Link[®]) rotating hinge knee prostheses had been used in 61 females and 24 males. The mean age at surgery was 72.4 years (range, 32–92 years). Fifty-two arthroplasties were primary and 33 were revisions either for loosening (24) or deep infections (9). The mean follow-up was 36 months \pm 22 (range, 0–75 months).

Results: Complications were observed in 24 patients (28.2%): nine deep infections, four patellar complications, and three cases of aseptic loosening. No significant difference was found between the primary arthroplasties and the revisions regarding all complication types. A significant relation was established between the occurrence of a complication and presence of several associated comorbidity factors (obesity, heart disease, diabetes, etc.).

Discussion: The use of this type of implant carries a high risk of complications, higher than the one pertaining to unconstrained design prostheses; this fact is noted irrespective of the surgical indication and other comparison elements. The leading criteria to poor functional results appear to be the indication (gonarthrosis with substantial ligament laxity at primary surgery) and the

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number of associated comorbidities. These prostheses should therefore be restricted to selected indications, notably in view of the fact that less constrained prostheses give superior outcomes.

Level of evidence: Level IV. Retrospective therapeutic study.

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Introduction

Implanting a rotating hinge knee prosthesis is an alternative in total knee arthroplasty. The first hinge prosthesis designed in the 1950s by Judet and by Walldius and Shiers [1] developed a considerable number of complications (loosening, infection) [2,3]. The initial joint mechanism consisted in a fixed hinge with no rotational motion. Very quickly, it was observed that normal external rotation on a healthy knee during walking was between 9 and 13°, which produced an excessive torsional stress on the bone–cement interface with this type of implant.

A second generation of prostheses was therefore designed, modifying different aspects (rotational axis with a stop, new design of the patello femoral joint to facilitate the patella's displacement, appearance of a metallic tibial base-plate to reduce polyethylene wear, and improvements in the stems to facilitate osteofixation). These improvements led to the progressive appearance of several models, with the main models being the GUEPAR implant in 1970 (with the rotational axis shifted backward and upward) [4,5], the Stanmore [6] prosthesis in 1971, and the Saint Georg by Engelbrecht, Nieder, Keller, and Strickel prosthesis in 1979 (ancestor of the Endo-Modell (Link®)) [7,8]. Despite these important changes, an unacceptable complication rate for total knee prostheses persists today. For the Rotaflex® (used between 1980 and 1984), David et al. [9] reported a complication rate near 80%, with material fractures or rupture of the extensor apparatus. In the 1980s, new modifications therefore had to be made (antidislocation feature, etc.) so that this type of implant could evolve toward third-

generation models such as the Endo-Modell (Link®) rotating hinge knee prosthesis, which functions as a flexion around an axis with no change in the center of rotation (Fig. 1). By studying the curves reproducing the knee's natural motion, the compromise axis of the center of rotation was determined by Nieder [10] to be 22.5 mm from the lowest point of the tibial plateau and 16 mm behind the tibial axis.

During extreme rotational movements, the components abruptly transmit the torque force to the bone–cement interface, theoretically increasing the risk of loosening. On a healthy knee, rotation is increased with flexion particularly between 0° and 30° of flexion. The joint's freedom of rotation submitted to a load is limited by the compression of the cartilage, the increase in the adaptation of the joint surfaces, and finally the increase in the kinetic energy of the body mass related to the tightening/loosening mechanism corresponding to the automatic rotation in flexion. It was therefore necessary to limit the amount of rotation to reduce the risk of loosening. The Endo-Modell (Link®) rotating hinge knee prosthesis attempts to reproduce this phenomenon using ramps shaped like the tibial component to command flexion, with a limitation on rotation depending on the flexion. In full extension, the knee has limited rotation, which increases by 15–20° from 50° of flexion.

Despite these consequential improvements in the implants [11,13], the rotating hinge knee prosthesis continues to suffer from a bad reputation, contrary to gliding implants whose results have become the norm (2–6% complication rate). Nevertheless, these hinge prostheses can be useful in certain specific indications such as gonarthrosis associated with major ligament instability, a distal femoral

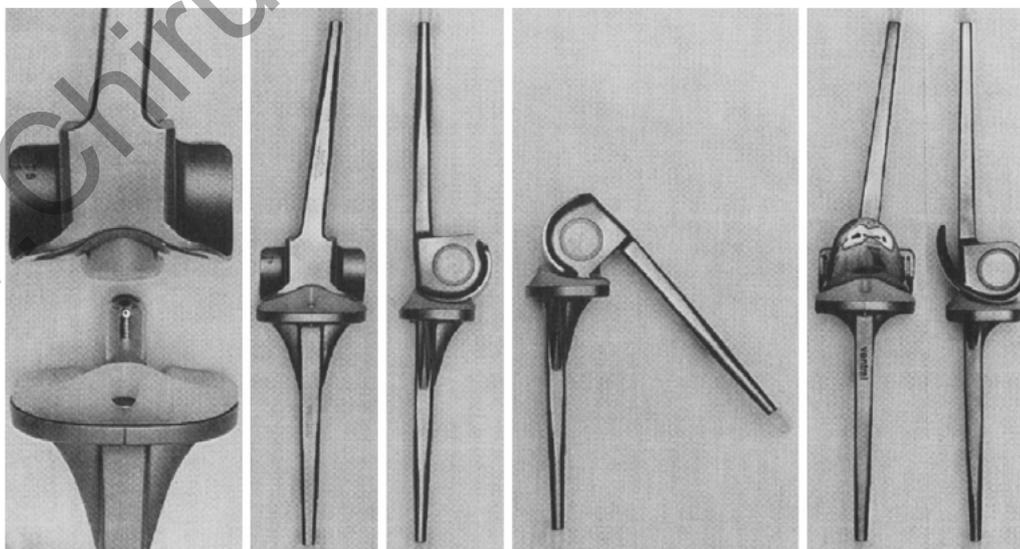


Figure 1 Rotating hinge knee prosthesis with and without patellar flange [6].

or proximal tibial bone defect resulting from tumor or injury, or in revisions for reasons of aseptic or septic loosening with major bone defect or insufficiency or destruction of the collateral ligaments.

The objective of this study was therefore to evaluate the complication rate after implanting Endo-Modell (Link®) rotating hinge knee prostheses and to define the predictive factors of complication.

We hypothesize that complications are frequent but that the complication rate is identical for primary and revision knee arthroplasty.

Material and methods

Patients

Between June 1998 and July 2006, 85 patients underwent surgery. Only unilateral arthroplasties were retained for study to eliminate the factors that were not independent of the patients who underwent a bilateral intervention. Since this was a study on complications, all the patients were retained, including the 39 patients lost to follow-up because the documents from the last revision were available. In the same period, 364 gliding total knee prostheses were implanted by the department's staff.

At surgery, the patients' mean age was 72.4 years \pm 9.2 (range, 31.9–92.6 years). The mean follow-up was 36 months \pm 22.0 (range, 0–99 months) with 60.0% followed up for more than two years. There were 61 females and 24 males. The patients' mean American Society of Anesthesiologists (ASA) score was 2 and 39% of the patients presented at least two comorbidities (obesity, diabetes, heart disease, lung disease, cancer, etc.).

In 52 cases, the patients underwent primary surgery, and in 33 cases they had revision total knee arthroplasty. The surgical indications for primary and revision arthroplasties are summarized in Table 1.

Table 1 Surgical indications (primary and revision).

	Number of patients	Percentage
Primary	52	61.2
Primary gonarthrosis	37	43.5
Primary gonarthrosis with ligament laxity	9	10.6
Substantial varus	21	24.7
Substantial valgus	7	8.2
Tumor	1	1.2
Secondary gonarthrosis	14	16.5
Posttraumatic	8	9.4
Rheumatoid arthritis	6	7.1
Revision	33	38.8
Sepsis	9	10.6
Aseptic loosening	24	28.2

Operative technique

The operative technique was identical in all cases. The incision was median with a medial parapatellar arthrotomy and lateral dislocation of the extensor apparatus. The collateral ligaments were disinserted tangentially to the femoral bone subperiosteally, then the posterior capsule and the ligaments were released. The distal femur and the proximal tibia were prepared using the oscillating saw and the specific Link® ancillary instruments designed to place the cemented implants (two doses of cement with gentamicin). The implant was adapted to the bony defect, with or without the patellar flange. No ligament balancing was required. The patella joint area was trimmed using the oscillating saw for reduction facing the prosthetic trochlea. A patella prosthesis was never implanted. The polyethylene tray was then placed and fixed using a screw antidislocation system (Fig. 2). The surgery lasted a mean 126.4 min \pm 49.1 (range, 60–260 min).

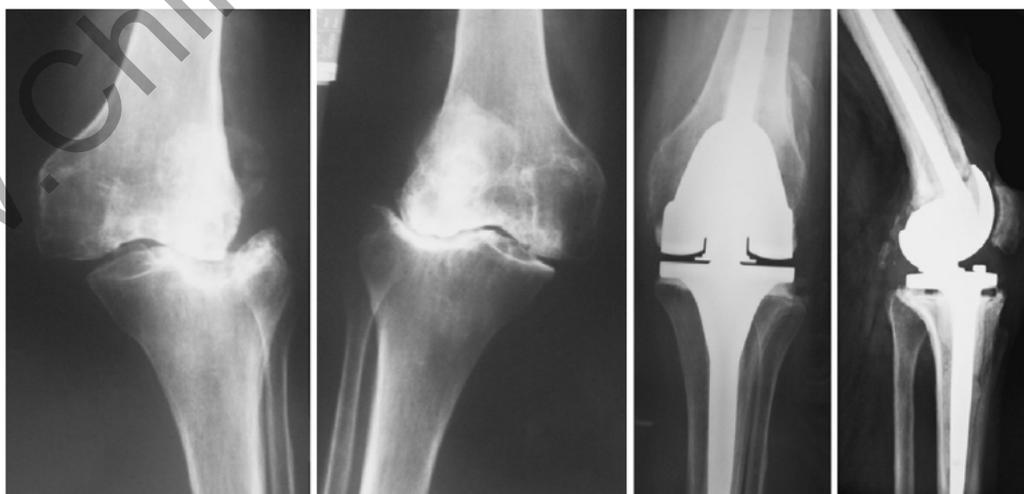


Figure 2 Preoperative and postoperative X-rays from 79-year-old woman with a 22° genu valgum.

An antibiotic therapy protocol was used in all cases, but in 16 cases (18.8%), it was not scrupulously respected.

Weight bearing and walking were resumed after the second day associated with passive mobilization on the arthromotor starting on Day 0.

Method

The medical files were reviewed by a single independent examiner. The correlations between the appearance of complications and the different relevant clinical factors were sought.

A radiological analysis was carried out on plain AP and lateral views of the operated knee and on a patello femoral horizontal view, to look for signs of bone fracture, material fracture, and evolving radiolucent lines or osteolyses, and signs of loosening. The patella's position on the lateral X-ray was evaluated using the Insall criteria [14,15].

Statistical analysis

The statistical analysis was done using Windows SAS version 9.0 software.

The results are presented in numbers and percentages for the qualitative variables, and in mean \pm standard deviation and range for the quantitative variables. The percentages for the qualitative variables were compared using the Pearson χ^2 test (Fisher's exact test for small groups). Means were compared for the quantitative variables using the Student *t*-test or the nonparametric Mann-Whitney test for comparing two means, and using the Kruskal-Wallis test for comparing three means (abnormal distributions, nonhomogeneous variances). The correlation between two quantitative variables was studied by means of the Pearson correlation coefficient. The significance threshold was set at 0.05.

Results

Complications

A single intraoperative complication was noted: a shock reaction to the cement leading to the patient's death 48 h after the intervention.

In the early postoperative period (<1 month), five complications were reported. There were two infections requiring revision surgery for joint lavage, two peripheral nerve lesions with partially resolving involvement of the common fibular nerve, and acute ischemia of the lower limb requiring emergency arterial surgery (Table 2).

At the longest follow-up, in addition to the acute complications, 21 complications were observed. Seven deep infections were observed. In four cases, the infections required surgical revision to remove the prosthesis, with a new implant in two cases and arthrodesis in two other cases, with satisfactory results. In the other cases of infection (3), surgical revision was performed, associating abundant lavage, debridement, and changing the polyethylene without changing the implant. Only one of these three cases presented a deep infection at 46 months of follow-up, requiring surgical revision.

Table 2 Complications.

Complications	n	%
Sepsis	9	10.6
Patellar complications	4	4.7
Rupture of extensor apparatus	1	1.2
Clunk syndrome	1	1.2
Patellar dislocation	2	2.4
Other complications	11	12.9
Chronic synovitis	3	3.5
Shock reaction to cement	1	1.2
Acute ischemia, lower limb	1	1.2
Common fibular nerve involvement	2	2.4
Cutaneous complications	4	4.7
Aseptic loosening	3	3.5

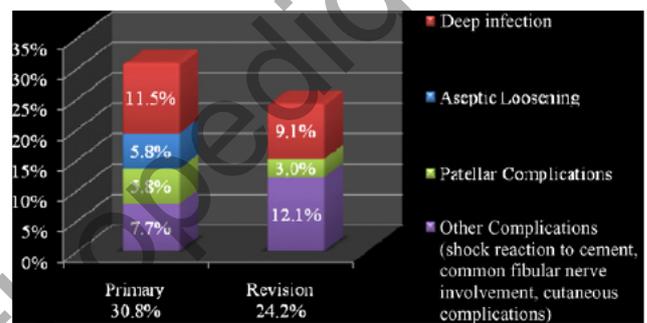


Figure 3 Distribution of complications according to indications.

Three cases of aseptic loosening were observed. Four patellar complications were observed, two of which were patella dislocations, one rupture of the extensor apparatus, and one case of patellar clunk syndrome. Only the rupture of the extensor apparatus led to surgical tendon suture revision.

This gives an overall complication rate of 28.4%, with a 30.8% rate in the primary surgery group and 24.2% in the revision surgery group (no significant difference, $p=0.31$) (Fig. 3). Implant survival, if failure is defined as implant removal for any cause, was 89.4% at three years. However, if failure took into account the appearance of a complication, for any reason, implant survival was 75.1% at one year and 65.2% at three years.

Predictive factors

Correlations were sought between the appearance of a complication (aseptic loosening, deep infection, patellar complications, or other complications) and certain factors such as indication, presence of diabetes, presence of at least two comorbidities, and finally operative duration greater than 120 min.

The factors that increased the overall complication rate were primary gonarthrosis with ligament laxity (66.7%; $p=0.018$), the presence of diabetes (57.1%; $p=0.07$), the presence of at least two comorbidities (36.4%; $p=0.017$), and surgical duration greater than 120 min (42.3%; $p=0.05$).

The only protective factor found was the indication for varus axial deviation greater than 10° (14.3%; $p=0.05$).

Examining each type of complication specifically, no statistically significant factor of appearance or protection of any complication could be retained, probably because of the small numbers of patients.

Overall, the statistical tests, the ASA index, the type of antibiotic therapy, and even errors in applying protocols did not seem to be factors favoring the appearance of complications, whether or not they were septic.

Twenty-five evolving radiolucent lines were noted in 16 patients. More than 50% of them only presented a single radiolucent line. The seat and number of radiolucent lines were not found to be significant predictive factors of onset of a complication and more particularly of aseptic loosening.

Analysis of patella height showed 73.5% high patellas, 11.8% low patellas, and 14.7% normally positioned patellas. The postoperative position of the patella influenced the appearance of a complication: 16% of the high patellas and 50% of the low patellas presented a complication ($p=0.04$). No specific complication was dependent on patella height, and more particularly on patellar complications.

Discussion

The series

This series of 85 Endo-Modell (Link®) knee prostheses, evaluated with a mean follow-up of 36 months, is comparable to a recent series reported in the literature in terms of age (72 years), sex ratio (with a predominance of females), and number of subjects. Only the designers' series [11] presented much higher patient numbers (respectively, 1074 and 1937 patients) (Table 3). The variability of our etiologies differs from the literature with a predominance of revisions for Utting et al. [16] and a predominance of primary surgeries for most of the other studies [11,17–19].

Despite the large number of patients lost to follow-up, all of the medical files could be analyzed for the study of complications.

Our overall follow-up period for the implant was 89.4% at 36 months. Nieder et al. reported a 95% survival rate at seven years, Petrou et al. [20], on a series of 100 TKAs, had a 96.1% survival rate at two years and 80.3% at 12 years.

Complications

The complication rate was high, but not unexpected in a series including a majority of patients requiring salvage knee surgery. Infection was the most frequent complication (10.6%), corresponding to the data usually found in the literature [19,20] (Table 3). For example, Shaw et al. [21] had 16% deep infection. Only Nieder et al. [13], Zinck et al. [17], and Reignier [19] found an overall complication rate of approximately 6%, with only 2% septic complications.

In our series, we observed a 30.8% complication rate for primary surgery and 24.2% for revisions, without the difference being statistically significant ($p=0.31$). Our primary surgery complication rate was higher than the series reported in the literature (between 2 and 6%) (Table 3), whereas it was similar in the revision group [22,23].

To explain these results, it seems relevant to detail the inclusion criteria for each group. Our population presents a high percentage of patients with several risk factors for complications: high mean age, association of comorbidities (obesity, diabetes, cardiological or pulmonary disease), and a low rate of "native knees." Similar rates were found in the series reported by Utting et al. [16], Inglis et al. [24], and Springer et al. [22], all of them with similar inclusion criteria.

Our study therefore reports less favourable results than the specific studies (exclusively primary surgery, young patients, etc.) because recruitment was extended to a vaster population [28].

Like Reignier [19] and Utting et al. [16], we observed a very low aseptic loosening rate, 3.5% but with a short follow-up period (36 months). This low rate was also found in series with longer follow-up periods (2–10 years), thus allowing us to validate axial rotation as being protective of intramedullary stem cementing.

No axis dislocation was found in our series, even though this has already been described by Wang et al. [25], probably related to the systematic use of an antidislocation feature with screws used in the third-generation implants.

The only protective factor found in our series is the indication for varus axial deviation greater than 10° (14.3%; $p=0.05$), an indication whose best results in the literature were reported by Hulet et al. [26]. Patella position is the radiological predictive factor of appearance of a complication found in our series: the lower the patella is, the higher the risk of complications. In a series of 43 post-tumor reconstructions using a rotating hinge prosthesis, Schawb et al. [15] reported the same conclusions. Maintaining patellar height and the joint space level is therefore an essential objective.

Indications

The complication rate was higher in rotating hinge prostheses than in less constraining implants. In view of these results, we believe it is preferable to use a less constraining prosthesis whenever possible.

The rotating hinge implant can only be placed in certain specific indications. In primary surgery [22,27–29] these are functional loss of lateral ligaments [6,30], ligaments that cannot be balanced in flexion or extension during surgery, major valgus or varus deformity, a distal femoral or proximal tibial defect resulting from a tumor lesion or mechanical problems, or a comminuted fracture or malunion of the distal femur in the elderly subject [4]. In revision surgery, these indications are aseptic loosening with a major bone defect or ligament insufficiency in the frontal planes, septic revision with major bone defect [31], a supracondylar fracture of the femur with a TKA and no possibility of osteosynthesis [5].

All authors agree that one must study all the specific preoperative clinical and radiological criteria to determine the relevance of using this type of implant [26,29,32]. In this type of complicated example, completing all the steps of preoperative planning is important: the clinical exam (ligament balance), plain radiographs (knee X-rays, stress views) to determine the

Table 3 Rotating hinge knee prosthesis in the literature.

	Our series	Springer [24]	Zinck [19]	Nieder [5]	Argenson [20]	Engelbrecht [4]	Rinta-Kiikka [26]	Reignier [21]
Type of implant	Endo-Modell	Modular segmental kinematic Rotating hinge	Endo-Modell	Endo-Modell	Endo-Modell	Endo-Modell	Endo-Modell	Axel
Indications	Primary/revision	Primary/revision	Primary	Primary	Primary	Primary	Primary revision	Primary
Number of cases	85	69	2682	1837	194	1074	48	210
Mean age	72.4 years		69 years	66 years	68 years		68.5 years	71 years
Mean follow-up	36 months	75.2 months	64 months	78 months	75 months		66 months	105 months
Mechanical problems	0%	10%	1.7%	1.3%				2.8%
Aseptic loosening	3.5%		1.0%	0.8%	1.5%	6.0%	2.0%	1.9%
Sepsis	10.6%	14.5%	1.6%	1.9%	2.5%	1.3%	20.0%	1.9%
Neurological complications (common fibular nerve)	2.4%		0.8%					0.5%
Patellar complications	4.7%	13%	3.9%	1.8%	5.0%		5.2%	1.9%
Patellectomy	0%		1.4%					0.5%
Axis dislocation	0%		0.8%		1.0%	4.0%		
Femur fractures	0%		0.2%	0.3%	1.0%		2.0%	0.9%
Scores	IKS, flexion, SF36, Charnley, X-rays	IKS, flexion, Charnley		Flexion, Satisfaction questionnaire, Survival rate	IKS, Flexion, X-rays			
Statistical test	Chi ² , Fisher	Wilcoxon signed rank						

extent of the bone defect [33] and ligament insufficiency.

Reignier [19] proposed using, after studying his series of AXEL models, this type of implant in complex cases of gonarthrosis and even to extend the habitual indications of rotating hinge prostheses to certain cases of less severe gonarthrosis for patients older than 80 years with a low functional demand presenting laxity or an additional extra-articular factor. This is what we have done and reported in this study in the indications of primary gonarthrosis with ligament laxity. However, after a specific study of these patients, an unacceptable complication rate appears (66.7%, with 33.3% deep infection). This high complication rate should be compared to the type of patient undergoing surgery (mean age, 80 years, ASA > 2, number of comorbidities > 2), but this type of indication can nevertheless be challenged. The severity of the deformity is not in itself an indication for a hinge prosthesis, because it can be remedied by a certain number of procedures such as an osteotomy associated with a posterostabilized prosthesis with satisfactory results, with no recourse to ligament release of collateral ligaments or cruciate ligaments [26]. Lachiewicz et al. [8] obtained highly satisfactory results (> 87% good or very good results at five years) with a posterostabilized prosthesis in indications of gonarthrosis with isolated ligament laxity.

Conclusion

Rotating hinge knee prostheses have, in our hands, a higher complication rate than those observed with sliding prostheses [34] with both primary arthroplasties and revisions.

Given these results, the indication should be selective after confirming that a less constraining prosthesis is impossible. The posterostabilized prosthesis remains the reference.

However, some indications remain for this type of implant when the patient has substantial bone defects (reconstruction impossible) resulting from tumor or injury or with very large axial deviations. A favorable situation for placing this implant must also be associated: an elderly patient with a low functional demand presenting few comorbidities.

Conflicts of interest

None.

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