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Research Article

Rotating-Hinge Total Knee Arthroplasty: Clinical and Radiographic Results from a Medium-Term, Multi-Center Study in a Latin American Population

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Abstract

Background: Hinged prostheses are a good choice in the setting of complex knee arthroplasty. Nevertheless, the results could be different in the Latin-American people.

Methods: A retrospective follow-up was performed. Seventy-six patients underwent pTKA using hinged prosthesis from 2012 to 2017. Survival analysis was performed with the Kaplan-Meier method. Functional results were assessed using Oxford Knee Score (OKS), OKS-APQ (Activity and Participation Questionnaire) and KOOS-12. Radiologic assessment was performed at each follow-up. In all the surgeries the rotating-hinge prosthesis solved the cases of complex knee surgery.

Results: Seventy-six patients underwent pTKA using hinged prosthesis from 2012 to 2017. Survival analysis was performed with the Kaplan-Meier method. Functional results were assessed using Oxford Knee Score (OKS), OKS-APQ (Activity and Participation Questionnaire) and KOOS-12. Radiologic assessment was performed at each follow-up. In all the surgeries the rotating-hinge prosthesis solved the cases of complex knee surgery. Hinge prostheses for complex knee arthroplasty in Latin-American people have a 10-year survivorship of 90.8% which is within the range of 51% to 92.5%, shown in a recent literature review of non-Latin American world population.

Conclusions: Rotating Hinge prostheses are a good option for patients with major deformities, grade 3 ligament instability, neurological sequalae that compromises the knee joint and severe bone loss. The Latin-American population shows a similar behavior in terms of survivorship in comparison with the literature from the rest of the world. However, comparative studies with greater statistical power are needed to show more accurate conclusions.

Level of Evidence: Level III

***Keywords:** Knee, Hinged, Prosthesis, Clinical.*

What Are the New Findings?

- The functional results and survivorship of the primary total knee arthroplasty with hinge prosthesis in Latin-American population are consistently with the world population.
- Hinge prostheses have excellent results when are used in people with Sequelae of neurological diseases.
- Hinge prostheses associated with collateral ligament and posterior capsular release in patients with fixed flexion deformity of the knee (>20º), can extend the knee and help the patients with gait return. This improves the quality of life of patients that cannot walk.

Introduction

Rotating-hinge knee prostheses are usually used in complex knee revision surgery. Several authors consider such devices to be useful in salvage procedures after numerous failed revisions. Nevertheless, evidence suggest that third generation rotating-hinge devices in the setting of pTKA should be considered in limited indications in which ligamentous tibiofemoral instability is the core indication[1]. Potential indications for a rotating hinge or pure hinge implant in pTKA include collateral ligament insufficiency, severe varus or valgus deformity (> 20°) with relevant soft-tissue release and relevant bone loss, as well as insertions of collateral ligaments, gross flexion-extension gap imbalance, ankylosis and hyper- laxity[2]. The use of unconstrained prosthesis in this cases has been associated with an increased incidence of complications including poor soft-tissue balance and instability[3]. The EndoModel Rotating Hinge Design (Waldemar Link, Hamburg, Germany) has been used extensively in cases in which a hinged prosthesis was required for pTKA[4,5]. However, these results have not been yet reported in Latin American population.

The aim of this study is to show the results of rotating hinge implants when used for pTKA in osteoarthritic knees; postraumatic, inflamatory and infectious knee arthritis; osteonecrosis of the knee; sequelae of neurological diseases and peri-prosthetic fractures around the knee; with severe deformity or third grade collateral instability. The hypothesis is that the hinged implants in Latin American people may have good functional and radiographic results, a reasonable complication rate, and acceptable survivorship, consistent with world literature.

Material and Methods

Study Design and Ethical considerations

We conducted an observational analytical cohort study.

IRB approval was obtained from our institution (IRB00007736 minutes No. 22-2021).

Patients' selection

We conducted an observational analytical cohort study. A total of 75 pTKA were performed in 75 patients, information from all patients could be recruited from 2012 to 2017. An average follow-up of 8 years was achieved with a minimum of 5 years and a maximum follow-up period of 10 years. The sample size was calculated taking as a reference proportion of 85%, a precision of 11%, with a statistical power of 85%, at an alpha level of significance of 5%, an approximate loss of 5% of the cases was assumed after 10 years after the implantation of the prosthesis. Between 2012 and 2017, seventy-five pTKA were performed with the Rotating Hinge Knee prosthesis. The diagnoses included 55 patients with osteoarthritis, 11 with inflammatory arthritis, 7 with post-traumatic arthritis, 1 with septic arthritis sequelae and 2 with neurologic disease sequelae. The specific indications were the mainstay of the treatment. Forty-one patients had a severe valgus deformity (>20°) and 13 patients a severe varus deformity (>20°), associated with third-grade instability of the collateral ligaments; 9 patients had a fixed flexion deformity (>20°), none of these patients walked before surgery; 11 patients had a fixed extension deformity; and 2 patients had a recurvatum deformity.

Prosthesis Model

The EndoModel Rotating Hinge Knee prosthesis was designed in 1979. This is characterized by a metal hinge, which allows flexion-extension and axial rotations and has cemented stems. The prosthesis tie is a tibial metallic hinge that lodges in a femoral site covered by an ultra-high-molecular- weight polyethylene girdle approximately 2 mm thick. Two models exist: a standard model without a trochlear component and a trochlear-provided model for patients with serious patellofemoral joint degeneration. In addition, a model that has an antidislocation device is available with or without the trochlear component (Fig. 1). The implant, as declared by the manufacturer according to the design, allows physiological rotation with control. Virtually no rotation occurs in extension. At 120° of flexion, an outer rotation of 50°, an inner rotation of 35°, and virtual flexion of up to 165° occur[6].

Surgical Procedures

A tourniquet was used in all cases. It was only inflated during cementation. A midline para-patellar approach was used in all cases. The patella was resurfaced in indicated cases. The femoral attachments of the collateral ligaments were released during the surgical exposure.

This was performed to optimize surgical exposure while minimizing iatrogenic damage to the ligaments and surrounding bone. If necessary, the popliteus tendon and/or the lateral head of the gastrocnemius were divided in large, fixed valgus deformities. One dose of prophylactic antibiotics was administered, and low-molecular-weight heparin was used for thromboprophylaxis. Patients could fully weight bear and mobilize on day 1 after surgery. The cemented long- stemmed Rotating Hinge prosthesis with an anterior femoral flange (Fig. 2) was used in all cases. Patients were assessed preoperatively as well as 2 weeks, 6 weeks, 3 months, 6 months and annually thereafter.

Evaluation

Survivorship was calculated using the Kaplan-Meier method[7]. Patients who were lost to follow-up were censored.

Clinical Assessment and Functional Scales

Clinical outcome was evaluated using the Oxford Knee score (OKS), Oxford Knee score–Activity and Participation Questionnaire (OKS-APQ) and 12-item short form Knee Injury and Osteoarthritis Outcome (KOOS-12). These three PROMs met the Consensus- based Standards for the selection of health Measurement Instruments (COSMIN) standard for recommendation of use for assessing pTKA outcomes in the three main evaluation areas: pain, function and quality of life[8–12].

Radiographic assessment

Radiographic assessment was performed preoperatively and at each follow-up visit. Each radiographic image was reviewed by the two authors looking for signs of loosening at the cement-bone and prosthesis-cement interface as well as alignment of the prosthesis. Signs of loosening were present if there was a radiolucent line at the cement-bone interface or the prosthesis-cement interface of the femoral or tibial components, which was greater than 2 mm, or if there were progressive radiolucent lines on serial radiographic examinations[13,14].

Statistical analysis

Qualitative variables were described with frequencies and proportions. Quantitative variables were described in terms of mean with interquartile ranges. Because the statistical distribution of the clinical evaluations was non-gaussian (tested by Shapiro-Wilk test), non-parametric tests (Wilcoxon matched-pairs signed-rank test) were used to compare the pre- and postoperative surgical evaluations. The time elapsed between the date of surgery and the date of failure or the date of the last clinical control were used to calculate the implant survival probability, assessed using the Kaplan-Meier product-limit estimates[7]. The Log-rank or Wilcoxon tests were used to test the statistical significance of the observed differences. All tests were 2-tailed. The data were processed in the IBM SPSS program version 14.0 (SPSS Inc., Chicago, Illinois). A significant P value of less than 0.05 was considered significant.

Results

Median age at surgery was 64 (58-71). All the surgeries were made at three hospitals. Four patients died due to causes unrelated to their knee surgeries, therefore seventy-two patients were available for clinical follow-up. Among the 76 patients, 55 were women. The clinical follow-up concluded in 2022, with a median follow-up of 94.8 (60-131) months (Table 1).

Clinical Analysis

PROMs showed a statistically significant improvement after pTKA. All the preoperative subjects of the scales were classified as poor (OKS: 3 (0-10.5); OKS-APQ: 0 (0-19); KOOS-12 pain: 6 (0-19), ADL: 0 (0-25), QoL: 0 (0-6)) whereas the postoperative was good-excellent (OKS: 39 (29.5-43), OKS-APQ: 69 (50-92.5), KOOS-12: pain: 88 (81-94), ADL: 81 (63-97), QoL: 75 (69-97)) (Table 2). Post-operative range of motion (ROM) average was: 100° (90°-110°).

Complications

One patient (1.5%) had a periprosthetic fracture of the femur that was managed with osteosynthesis. The prosthesis did not suffer of loosening at the time of final follow-up (Table 3).

Table 1: Demographic data	
Parameter	**Value**
BMI*	27.7 (25.3-28.8)
Prosthesis size	x-Small: 13.9%, Small: 54.2%, Medium: 27.8%, Large: 4.2%
Patellar resurfacing	Yes: 54.2%: No: 45.8%
Diagnoses	Osteoarthritis: 72.2%
	Posttraumatic arthritis: 9.7%
	Inflammatory arthritis: 15.3%
	Septic arthritis: 1.4%
	Sequelae of neurological diseases: 1.4%
Surgery indication	Valgus (>20º): 51.4%
	Varus (>20º): 18.1%
	Flexion (>20º): 12.5%
	Extension: 15.3%
	Recurvatum: 2.8%
Radiolucent lines	Yes: 2.8%: No: 97.2%
BMI, Body Mass Index * Mean, interquartile ranges	

Table 2: Patient- reported outcome measures (PROMs)			
Functional tests	**Preoperative**	**Postoperative**	**p**
OKS*	3 (0-10.5)	39 (29.5-43)	<0,001
OKS-APQ*	0 (0-19)	69 (50-92.5)	<0,001
KOOS-12 pain*	6 (0-19)	88 (81-94)	<0,001
KOOS-12 ADL*	0 (0-25)	81 (63-97)	<0,001
KOOS-12 QoL*	0 (0-6)	75 (69-97)	<0,001
OKS, Oxford Knee Score; APQ, Activity and Participation Questionnaire; ADL: Activities of Daily Living; QoL, Quality of Life * Mean, interquartile ranges			

Table 3: Complications and Treatments			
Patient No.	**Complication**	**Treatment**	**Date of Complication**
21	Periprosthetic Femur Fracture	Plate Osteosynthesis	06/10/2017

Radiographic Analysis

The radiographs of all patients were analyzed after a mean follow-up of 94.8 (60-131) months. Two patients (2.8%) had progressive radiolucent lines of 2 mm around tibial component; however, they were not revised because no pain or clinical signs of loosening were observed at the time of final follow-up. No radiographic evidence existed of polyethylene wear. Besides, no radiographic evidence existed of massive osteolysis.

Implant Survivorship

Survival analysis was performed with a minimum follow-up time of 5 years and a maximum follow-up time of 10 years; therefore, survival was evaluated on average during this time interval. The overall survivorship at a mean of 94.8 (60-131) months of follow-up was 90.8%, the estimate was 86.5, the typical error was 3.02 and, with a confidence interval of 95%, the inferior and superior limit was 80.6 and 92.4, respectively (Fig. 3). A failure was defined as a revision of the prosthesis or amputations for any reason related to the procedure. Above knee amputation was done in one patient that suffered a periprosthetic knee joint infection that did not respond to debridement and antibiotics.

Two patients required revision of the prosthesis, however, it was decided to carry out a conservative treatment due to the high risk in the case of surgery, until the follow-up evaluation (Table 4). The survivorship analysis was developed with the Kaplan-Meier method. The implant survivorship was the final event, seventy-six patients were included in the analysis. Four patients died during the follow-up. All deaths were secondary to factors unrelated to the prosthesis. A comparative analysis of the survivorship was done in patients < 50 years and > 50 years, based on the pre-operative alignment (varus or valgus), patellar resurfacing (yes or no), sex (male versus female), BMI (Body mass index (<25 versus >25), and the ROM of the knee. Nevertheless, there was no difference in terms of survivorship.

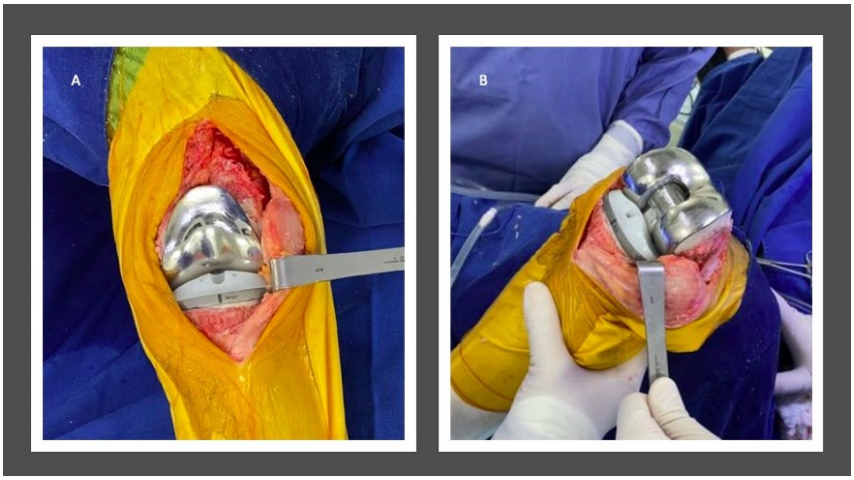

Figure 1. *EndoModel Rotating Hinge Prosthesis with trochlear component in flexion (A) and extension (B) of the knee.*

Figure 2. *Radiographic anteroposterior (A) and lateral view (B) of the EndoModel Rotating Hinge Prosthesis.*

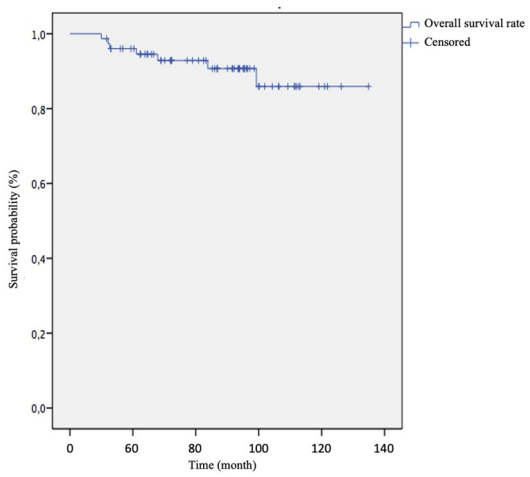

Figure 3. *Kaplan-Meier graph illustrating overall survivorship for the entire cohort. Patients who died or were lost to follow-up were censored. Survivorship at 131 months is 90.8%.*

Table 4: Causes of Failure and Treatments

Patient No.	Cause of Failure	Treatment	Date of Failure
11	Aseptic loosening	Conservative treatment (high risk in case of surgery)	02/05/2018
22	Aseptic loosening	Conservative treatment (high risk in case of surgery)	05/07/2019
52	Septic loosening	Above the knee amputation	26/04/2020

Discussion

The use of rotating-hinge prosthesis in pTKA remains unusual. There are specific indications for choosing this implant in primary surgery. If possible, the patients must be older than 60 years and have at least one of the following conditions: collateral ligament insufficiency, bony destruction of the tibial plateau or femoral condyles, hyperlaxity, fixed valgus/varus deformity > 20° and severe rheumatoid arthritis. We have found other indications for constrained implants in pTKA, such as the sequelae of neurological diseases associated with tibial-femoral ligament instability. Inconsistent results of the use of hinged implants in pTKA have been described[5], some authors show an unacceptably high complication rate of > 30% in primary cases and 24% in revisions using a rotating hinge design. In addition, reported infection rates were enormous with 11% in primary and 9% in revision cases and global survival of 65.2% at three years[15]. In contrast, previous reports of rotating-hinge implants in pTKA revealed more favorable results at a minimum of ten years follow-up[15–17].

The literature suggests that one of the contraindications for the use of hinge-type prosthesis in pTKA includes patients younger than 75 years, in whom stability can be obtained with non-constrained implants. This is based on the need to cement in tibial and femoral long stems, which makes further revisions and fixation techniques in the diaphyseal region problematic[17]. However, given that in our Latin American population we have seen highly complex cases in young adult patients (<50 years) with severe fixed deformities in flexion, varus, valgus and recurvatum (> 20º) or associated with inflammatory diseases or sequelae of neurological diseases, where poor muscle control can be a predictor of early failure of an unconstrained prosthesis, we show the clinical and radiographic results of a Latin American population that has undergone a pTKA with a hinge-type prosthesis. Our results are like world literature, with an overall survival rate of 90.8%. There were two cases of peri-prosthetic infection (2.6%), one of them underwent a prosthesis retention protocol and the second case led to a transfemoral amputation. A case of peri-prosthetic femoral fracture was reported, which underwent osteosynthesis with an anatomical femur plate (Table 3 and 4). Four patients died during the follow-up period and there were no cases of revision surgery associated with implant failure. In turn, it is necessary to highlight the great mobility that is achieved with this implant, which we attribute to the kinematics of the prosthesis design. Pain, quality of life and activities of daily living improved significantly after the surgical procedure.

Conclusions

Rotating Hinge prostheses are a good option for patients with major deformities, grade 3 ligament instability, neurological sequalae that compromises the knee joint and severe bone loss. The Latin-American population shows a similar behavior in terms of survivorship in comparison with the literature from the rest of the world.

Conflict of Interest

The authors have no conflict of interest to declare.

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