Total knee arthroplasty in patients with joint fracture sequela: Mid-term follow-up outcomes

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ABSTRACT

Introduction: Knee joint fractures are common in Orthopedics, and may evolve to post-traumatic Osteoarthritis (PTOA). Total Knee Arthroplasty (TKA) is an effective treatment for the end-stage of this process. When indicated, orthopedic surgeons face many situations that may cause unsatisfactory results and affect prosthesis survival. The purpose of our study was to evaluate TKA outcomes on Osteoarthritis secondary to distal femoral and proximal tibial joint fractures, in cases with a minimum follow-up period of 4 years. **Materials and Methods:** We carried out an observational, retrospective study on TKA patients treated between May 1999 and January 2013. We evaluated 25 TKAs, performed on 24 patients, with knee fracture sequela, with an average follow-up of 6.1 years and an average age of 67.1 years. Three cases (12%) had required additional surgeries before TKA. Eight cases (32%) were 2-stage surgeries. Constrained implants were used in four cases (16%). The Knee Society Score (KSS), the Functional KSS (KSSf) and the Range of Motion (ROM) were evaluated preoperatively and at the last follow-up. Prosthesis survival evaluation was documented. **Results:** KSS increased from a preoperative average of 38.5 to a postoperative average of 82.8. Postoperative KSSf increased on average from 48 to 85. ROM increased on average from 7.5°-76° to 1°-102.4°. Four patients required a second surgical procedure. Prosthesis survival was 92% at a 6.1-year average follow-up. **Conclusion:** TKA is an appropriate treatment for advanced PTOA, with good mid-term outcomes. If adequate postoperative alignment and correct component positioning is achieved, expected outcomes are satisfactory and similar to those with TKA in primary Osteoarthritis.

Key words: Total knee replacement; fracture; arthroplasty

Level of Evidence: IV (case series)

Artroplastia total de rodilla en pacientes con secuela de fracturas articulares. Resultados del seguimiento a mediano plazo

RESUMEN

Introducción: Las fracturas articulares de rodilla son frecuentes y pueden evolucionar a gonartrosis postraumática. El tratamiento en su estadio final es el reemplazo total de rodilla (RTR). Cuando se indica, el especialista se enfrenta a situaciones que predisponen a resultados menos satisfactorios. El objetivo de este estudio fue evaluar los resultados del RTR en pacientes con secuela de fracturas articulares de rodilla, con un seguimiento mínimo de 4 años. **Materiales y Métodos:** Estudio retrospectivo observacional, entre mayo de 1999 y enero de 2013. Se evaluaron 25 RTR en 24 pacientes (edad promedio 67.1 años) con secuela de fractura articular de rodilla y un seguimiento promedio de 6.1 años. Tres (12%) tenían cirugías anteriores al RTR. Ocho se resolvieron en dos tiempos. Se empleó un implante constreñido en 4 pacientes (16%). Se determinaron el KSS, el KSSf y el rango de movilidad preoperatorios y del último control. Se documentó la supervivencia del implante. **Resultados:** El KSS se incrementó de 38,5 en el preoperatorio a 82,8 en promedio. El KSSf posoperatorio mejoró de 48 a 85. El rango de movilidad aumentó de un promedio de 7,5-76° a 1-102,4° en el posoperatorio. Cuatro casos fueron reoperados. La supervivencia de la prótesis fue del 92% a los 6.1 años. **Conclusiones:** El RTR es adecuado para la gonartrosis postraumática en su estadio final, con buenos resultados a mediano plazo. Si se logran una adecuada alineación posoperatoria y un correcto posicionamiento de los componentes, los resultados son satisfactorios y se asemejan a los del RTR por gonartrosis idiopática.

Palabras clave: Reemplazo total de rodilla; fractura; artroplastia.

Nivel de Evidencia: IV (Serie de casos)

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INTRODUCTION

Distal femoral and proximal tibial fractures with joint involvement may develop post-traumatic or secondary Osteoarthritis, regardless of treatment, which incidence may rise up to 20-46% according to several authors.[1-4]

Predisposing factors include cartilage damage as part of the initial injury, residual malalignment and the presence of subchondral that may damage the joint surface, old age, and pre-existing degenerative joint disease or meniscectomy.[5]

TKA is an appropriate treatment for advanced PTOA. Malunions, nonunions, bone defects, prior internal fixation devices, latent infections, arthrofibrosis, and compromise of the soft tissue envelope constitute surgical challenges, increase the procedure complexity and usually require the use of bone graft or revision implant.[6-8]

Early papers on TKA outcomes in patients with joint fracture sequela reported disheartening values, with a high complication rate.[2,9]

The purpose of our study was to analyze TKA outcomes in patients with sequelae from joint fractures (distal femoral and proximal tibial) that had been operated on in our Department and had had a minimum follow-up period of 4 years. We focused on describing the technical difficulties and complications experienced in the cases under study.

MATERIALS AND METHODS

Following the retrospective study of our Center database, we identify TKA patients who had sustained a knee fracture. Between May 1999 and January 2013, our Department performed 1019 primary cemented TKAs, 25 (2.45%) of them in 24 patients who had knee fracture sequelae (1 simultaneous bilateral case). Two patients died of conditions unrelated to the TKA 10 and 12 years after the procedure. As they had had an adequate evolution at last follow-up, they were included in the study.

Study inclusion criteria were: patients with advanced knee Osteoarthritis, associated or not with nonunion, who had undergone TKA, with a history of knee fracture (distal femoral or proximal tibial) and a minimum follow-up period of 4 years. Study exclusion criteria included: patients who had a history of inflammatory disorders, such as rheumatoid arthritis, or who were receiving treatment that could affect bone mineral density, such as chemotherapeutic agents, radiotherapy, methotrexate or high-dose corticosteroids.

The series had an average follow-up of 6.1 years (range, 4.3-16.2). The population was composed of 7 males and 17 females, with an average age at TKA of 67.1 years (range, 26-87), 12 right TKAs and 13 left TKAs. The time period between fracture/osteosynthesis and TKA averaged 9.4 years, with a significant difference between cases (range, 4 moths-32 years). Table 1 shows the preoperative diagnoses and prior treatments.

One of the studied patients that had sustained a distal femoral articular fracture and was treated with a DSC plate, underwent TKA 4 months after internal fixation due to early implant failure. Two patients presented pseudarthrosis (medial tibial plateau and lateral femoral condyle). The rest of the patients developed PTOA.

Three patients (12%) had undergone other prior surgical procedures prior to the TKA. Arthroscopy-assisted manipulation under anesthesia was carried out in 1 patient, at our Center, due to the development of stiffness (ROM, 30°-60°) at 4.5 months after the internal fixation of the medial tibial plateau; at TKA, the ROM was 15°-110°. A second patient, with a similar fracture, had a surgical infection and so required multiple debridement procedures and antibiotic therapy. He then underwent another surgery with a pseudarthrosis diagnosis, a locked plate and a bone-bank allograft, and soft-tissue coverage (medial gastrocnemius muscle flap); all these procedures were performed at another center. The third patient, who had a supraintercondylar fracture, required a second surgery due to pseudarthrosis in the distal third of the extra-articular femur, 4 years after the primary surgery (conversion from DCS plate to retrograde intramedullary nail), at another center.

Only 8 (32%) of the 25 cases were planned to be resolved in a two-stage procedure. In one case, the patient underwent manipulation under anesthesia, which was done simultaneously with implant removal (internal plate fixator) and sample collection of joint fluid, peri-articular soft tissues and bone, obtaining negative results for infection. Another of these patients was the one who had undergone multiple procedures with infection and pseudarthrosis diagnoses, who underwent hardware removal and bone sample collection, with negative results. The other 6 cases also included hardware removal and sample collection (negative for infection) during the surgery prior to TKA.

Table 1. Type of fracture and prior treatment

Type	Patient	Fracture	Treatment
Closed	1	Medial tibial plateau	Cast immobilization
	2	Medial tibial plateau	Cast immobilization
	3	Medial tibial plateau	ORIF
	4	Lateral tibial plateau	Cannulated screw + allograft
	5	Lateral tibial plateau	Cast immobilization
	6	Lateral tibial plateau	Cast immobilization
	7	Lateral tibial plateau	ORIF
	8	Lateral tibial plateau	ORIF
	9	Lateral tibial plateau	Cast immobilization
	10	Lateral tibial plateau	ORIF
	11	Both tibial plateaus	ORIF
	12	Both tibial plateaus	ORIF
	13	Both tibial plateaus	ORIF
	14	Both tibial plateaus	ORIF
	15	Supraintercondylar	Retrograde intramedullary nails + cannulated screws
	16	Supraintercondylar	Retrograde intramedullary nails + cannulated screws
	17	Supraintercondylar	Retrograde intramedullary nails + cannulated screws
	18	Supraintercondylar	ORIF
	19	Supraintercondylar	ORIF
	20	Supraintercondylar	ORIF
	21	Supraintercondylar	ORIF
	22	Supraintercondylar	ORIF
	23	Lateral condyle	Cast immobilization
	24	Medial tibial plateau + supraintercondylar	ORIF
Open	25	Medial tibial plateau	Traction and cast immobilization

ORIF: open reduction and internal fixation.

In order to rule out latent infections, all patients had physical and laboratory evaluations. The sample collection of joint fluid, peri-articular soft tissues and bone were not routine practices and were only performed in patients with suspected infection (12 patients). Six patients underwent serial joint fluid sampling (fine needle aspiration), and, in the other 6 patients, samples (fluid, bone and soft tissues) were collected during the hardware removal, prior to the TKA.

All surgeries were performed at a laminar flow operating room with hypotensive spinal anesthesia. Antibiotic prophylaxis was with first-generation cephalosporin, and prophylaxis for deep vein thrombosis and pulmonary thromboembolism was performed by using low molecular weight heparin.

The operation was carried out through an anterior skin incision and a parapatellar arthrotomy. A skin bridge of 5-7cm was preserved between the TKA approach and any prior surgery incision. Previous approaches were only used in some patients. Ligament balancing was performed before any bone cut in the 25 cases, because all cases presented *genu varum* or *genu valgum*.

In relation to the detachment of the extensor apparatus, proximal approaches included snip incision of rectus femoris muscle in 12 cases (48%) and the Coonse-Adams approach in 1 case), and the distal approach was an osteotomy of the anterior tibial tuberosity in 2 cases.[10]

These last 3 patients required postoperative immobilization for 45 days. Lateral patellar retinacular releases were performed in 2 cases to improve alignment.

All patients underwent cemented posterior-stabilized TKA with posterior cruciate sacrificing and patellar replacement. Twenty patients (80%) received primary, posterior-stabilized prostheses (8 PFC All-Poly and 12 Sigma, DePuy® J&J, Warsaw, IN, USA), 4 patients (16%) received varus-valgus constrained prostheses (PFC Sigma TC3, DePuy® J&J, Warsaw, IN, USA), and 1 patient (4%) received a stabilized plus implant (Sigma Plus, DePuy® J&J, Warsaw, IN, USA). Prosthesis selection was based on physical and imaging examination (standard and, in unstable cases alone, stress radiography) and was decided during surgery (trial component measurement). Fully cemented femoral or tibial stems were used in 9 cases (36%).

In twelve cases (48%), patients had bone defects at the time of replacement. In 8 cases, defects were filled with cement because they were contained defects of less than 5mm; 2 cases required structural allograft with screw stabilization; and in the remaining 2 cases a metal femoral component was used.

Analysis

The clinical and radiographic courses of patients were assessed through their medical records and the radiographic file kept by our Center. We studied the follow-up controls at 3 weeks, 3 months, 6 months, 1 year and every other year after surgery.

We used the KSS to perform the objective evaluation and the KSSf for the functional evaluation. Additionally, we compared the ROM at last follow-up to the preoperative ROM.

We used the best quality anteroposterior and lateral radiographs available from the last follow-up control to assess components position and alignment, postoperative anatomical axis and prosthesis loosening, defined as the presence of a complete radiolucent line or femoral or tibial subsidence of 2mm or more.[6]

Survival analysis considered the need to perform revision surgery for any reason. We carried out a second assessment that included only revision for mechanical reasons.

RESULTS

The average preoperative KSS was 38.5 (range, 15-55). At last follow-up, the KSS had risen to an average of 82.8 (range, 40-95). Likewise, the average KSSf changed from 48 (range, 25-60) prior to surgery to 85 (range, 55-100) (Table 2). The outcome was considered "good-excellent" (KSS>80) in 16 cases (64%), "acceptable" in 6 cases (24%), and "poor" in the remaining 3 cases (12%).

The average ROM increased from 7.5°-76° (range, 0°-15° and 10°-110°) before surgery to 1°-102.4° (range, 0°-5 and 85°-115°) at last follow-up. Three patients had a <5° flexion contracture and 1 patient had an extension deficit of 5º, none of whom required manipulation under anesthesia.

The femorotibial anatomical axis (4º-7º) was restored in all cases.

Radiographic evaluation evidenced the adequate position of the prosthetic components in all patients (Figure). Demarcation lines were found in three knees at tibial level, which proved to be non-progressive in subsequent controls during their 13.2 and 14.5-year follow-up; patients were asymptomatic until the last follow-up control.

We found no cases of skin necrosis/integument defects, extensor apparatus injuries, patellar fracture or necrosis, femoro-patellar misalignment, clinical instability, deep venous thrombosis/pulmonary thromboembolism, neurovascular injuries or reflex sympathetic dystrophy during the postoperative period.

Four patients underwent new surgeries after their TKAs, 2 of which were revision surgeries. One patient suffered superficial infection at the surgical wound site, which was detected at the 3-week follow-up control. Treatment consisted in superficial debridement and antibiotic therapy, and the patient had a favorable course.

Another patient had an acute hematogenous infection 3 years after TKA, following an abscess in the proximal third of the ipsilateral thigh. Treatment consisted of arthroscopic debridement and antibiotic therapy, and the patient had a favorable course until the last follow-up control.

Table 2. Demographics

Patient	Sex	Age	Fracture	Preoperative KSS	Postoperative KSS	Complications
1	M	74	Left lateral tibial plateau	40	90	
2	F	87	Right lateral tibial plateau	15	75	
3	F	82	Right supraintercondylar	25	80	
4	M	78	Left medial tibial plateau	30	95	
5	F	69	Left lateral tibial plateau	35	80	
6	M	67	Left lateral tibial plateau	35	80	Superficial debridement + antibiotic therapy
7	M	38	Left lateral tibial plateau + left supraintercondylar	40	90	
8	F	69	Both left tibial plateaus	40	90	
9	M	28	Left medial tibial plateau (open)	50	80	Infection, arthroscopic debridement
10	M	26	Left supraintercondylar	50	95	
11	F	76	Right lateral femoral condyle	55	80	
12	F	65	Right supraintercondylar	30	40	Peri-prosthetic fracture, stem revision
13	F	71	Left lateral tibial plateau	45	95	
14	F	80	Right tibial plateaus	30	55	
15	M	75	Right medial tibial plateau	35	85	
16	F	65	Right medial tibial plateau	35	85	Infection, two-stage spacer revision
17	F	48	Right lateral tibial plateau	40	80	
18	F	49	Right supraintercondylar	45	95	
19	F	63	Left supraintercondylar	45	90	
20	F	71	Right tibial plateaus	40	90	
21	F	71	Right supraintercondylar	40	80	
22	F	67	Left lateral tibial plateau	45	90	
23	F	85	Left supraintercondylar	35	80	
24	F	38	Right tibial plateaus	45	85	
25	F	69	Right supraintercondylar	40	85	

KSS = Knee Society Score.

Figure. **A.** Woman with a lateral tibial plateau fracture treated with internal fixation. **B.** Distal tibial fracture, a year later. **C.** Tibial internal fixation with anterograde intramedullary nail

Figure. D. Cannulated screw removal and sample collection, 4 months later. **E.** Total left knee arthroplasty, with tibial stem.

Figure. F. Evolution 7 years after arthroplasty, no evidence of loosening.

A third patient sustained a femoral periprosthetic fracture 2 years after TKA. In spite of the use of prophylactic cerclage wire on the distal femoral (nonunion of a lateral femoral condyle fracture), the patient sustained a fracture that resulted from a standing-height fall. The subsequent TKA revision surgery included the implantation of a larger cemented femoral stem.

The fourth patient, who had undergone nonunion treatment, soft-tissue coverage and several debridement procedures due to an infection at the surgical wound site following the surgery of a medial tibial plateau fracture, suffered a subacute prosthetic infection (negative preoperative cultures) and tested positive for methicillin-resistant *Staphylococcus*. The patient underwent a two-stage revision with prefabricated spacer implantation 35 days after TKA and converted to a new prosthesis 4.5 months thereafter. The patient attended the last control with culture and laboratory tests negative for infection; however, the patient reported pain and limited function 5 years and 3 months after the knee revision. Infection is suspected to persist (patient history includes intravenous drug dependency).

This analysis indicates that the prosthesis average survival rate was of 92% at 6.1- year postoperative follow-up, considering all revisions, irrespective of their causes. Prosthesis survival rises to 96% if mechanical causes are not considered.

DISCUSSION

Our series of 25 TKA patients with sequelae from joint fractures produced the following results: a considerable KSS and ROM increase, realignment of the anatomical axis in all cases, a second surgery rate of 16% and a prosthesis survival of 92% at an average follow-up of 6.1 years.

According to literature studies, the outcomes for TKA patients with knee Osteoarthritis as joint fracture sequela are inferior to those from patients who undergo routine primary TKA due to idiopathic Osteoarthritis (90-95%, at 10-15 years).[11,12]

There is a paucity of information in the literature regarding mid- and long-term prosthesis survival. Among the early studies on this subject, we consider noteworthy the works of Roffi and Merritt, who obtained poor outcomes in patients who they treated for knee fracture sequelae, with an average follow-up period of 27 months (range, 1-4 years) and poor outcome rate of 38.5%.[7]

Likewise, Lonner *et al*. found a higher complication rate in TKA patients treated for PTOA; they reported a successful outcome rate of only 71%.[9]

Among more recent papers, Saleh *et al*. conducted a retrospective study and found an 80% rate of good-excellent outcomes in 15-TKA patients with a minimum of 5-year follow-up. However, 3 patients (20%) had deep infection and so underwent knee arthrodesis (2 patients) and a two-stage revision TKA (1 patient), with a prosthesis survival of 80% at an average of 6.2-year follow-up period.[4]

Weiss *et al*. conducted a prospective study on 62-TKA patients who underwent surgery due to Osteoarthritis and had had a previous fracture of the tibial plateau. They reported a second surgery rate of 21% (5 revisions due to infection or mechanical problems) and a prosthesis survival of 91.1% at an average follow-up of 4.7 years.[5]

In their multicenter, retrospective study, Salcedo Zunino *et al*.[13] analyzed 29 TKA knees that had been intervened due to Osteoarthritis as a sequela to a joint trauma between 2008 and 2015, with an average follow-up of 45 months. The complication rate was 21% and the prosthesis survival rate was 93.1%. Lizaur *et al*. have recently published a prospective cohort study comparing the outcomes between TKA patients with idiopathic Osteoarthritis and TKA with PTOA. Although there were no statistically significant differences regarding function and mobility, the group that underwent surgery due to PTOA had a higher complication rate.

Our series results are consistent with modern studies, with an adequate mid-term prosthesis survival despite a high second surgery rate (Table 3).

Table 3. Comparison of studies variables

Series	Follow-up period	Complication rate	Prosthesis survival	ROM	
				Pre-operative	Post-operative
Roffi *et al*. (1990)	27 months (12-48)	38.4%	-	-	-
Lonner[9] (1999)	46 months (28-114)	57.0%	71%	94° (20°-120°)	100° (0°-135°)
Saleh *et al*.[4] (2001)	6.2 years (5.4-11.1)	53.3%	80%	87° (20°-125°)	105° (70°-135°)
Weiss *et al*.[5] (2003)	4.7 years	36%	79%	-	-
Salcedo Zunino *et al*.[13] (2015)	45 months (6-104)	21%	93.1%	60° (45°-90°)	112 (60°-140°)
Our series (2017)	6.1 years (4.3-16.2)	16%	92%	76° (10°-110°)	102,4° (85°-115°)

The reasons that are likely to cause these cases to produce inferior outcomes and a higher complication rate following a TKA may include: knee replacement in young patients with higher functional demands (premature Osteoarthritis due to the joint involvement of the fracture), retained internal fixations devices, nonunion, latent infection, intra-articular osseous defects and residual malalignment, prolonged surgical time, surgeries prior to the TKA that may affect the soft tissue envelope and may predispose to skin complications, and intra-articular scar fibrosis associated with the original trauma that may complicate exposure during surgery, hinder achieving ligamentous balance and affect the ROM.[8,15,16]

Although TKA in these cases is a technically demanding procedure, we agree with other authors[17,18] who claim that an adequate postoperative alignment and implant positioning appear to be the most important predictors of a satisfactory surgical outcome.

Malpositioning has been shown to have a negative effect on the long-term survival of TKA. Weiss *et al*.[5] reported that patients with suboptimal component positioning or residual deformity have a poorer outcome than patients with and acceptable realignment. In our study, prosthetic components positioning and alignment were adequate in all patients.

The infection rate in these patients is higher than the rates reported by other authors regarding TKA patients with idiopathic Osteoarthritis, with a rate ranging from 1% to 2% (Table 4).[19-21]

Table 4. Population sizes and infection rates of the series in chronological order

Authors	Population size	Infection rate
Lonner (1999)	25	10%
Saleh *et al.* (2001)	15	15%
Weiss *et al.* (2003)	26	3%
Civinini *et al.* (2009)	30	4%
Massin (2011)	40	5%
Our series	25	4%

Similarly to the prosthetic infection rates obtained by Weiss *et al*.[11] (3.2%) and Civinini *et al*.[22] (4%), our rate was relatively low (4%) in comparison to the series of Lonner *et al*.[9] and Saleh *et al*.,[4] 10% y 15%, respectively. It should be noted that we had 2 other infection cases, but of different origin: a superficial infection without implant involvement and an acute hematogenous infection. A possible explanation for our lower infection rate may be found in that our series included knee joint fractures treated with conservative management.

Our daily practice includes using an algorithm for preoperative testing meant to rule out any hidden infection in these patients. After a thorough physical examination, a routine blood test is performed (WBC count, erythrocyte sedimentation, and quantitative C-reactive protein). In patients with suspected infection, we perform a fine needle aspiration of joint fluid and a sample collection of bone tissue (this procedure is conducted when a two-stage TKA is to be performed, having previously removed the internal fixation device). Despite these protective measures, our only case of deep infection (patients who had undergone multiple surgeries and diagnosed with infection, nonunion, and coverage defect), which required a two-stage revision, had negative culture and biopsy results before the TKA.

Delayed scarring and surgical wound infection constitute common complications. Similarly to Weiss *et al*. study,[5] which reported three superficial infections (4.8%) treated with debridement and antibiotic therapy, 1 of our patients (4%) developed a complication 3 weeks after the TKA, with identical resolution.

Due to the number of variables that may adversely affect the outcome of TKAs, this procedure involves a high technical demand. Thus, preoperative planning is key in these cases. Physical examination must include the assessment of skin state (previous incisions), neurovascular state, ROM, and the stability level of the knee. Choosing the skin entry site requires careful and thorough evaluation. A skin bridge of 5-7cm should be preserved between the TKA approach and any previous scars. The patellar preoperative evaluation may provide insight into the approach difficulties: an immovable patella in extension with limited flexion of <90° indicates high chances of requiring an additional procedure to achieve adequate exposure. Standard radiography may show previous internal fixation

hardware, residual alignment and the presence of osseous defects, which may be obscured by retained internal fixation devices. Thus, CT imaging may befit the preoperative planning. Clinical instability requires varus-valgus stress X-rays in order to establish the level of joint stability and to decide the degree of prosthetic constraint to use. In this planning stage, we should also establish if there is a need for augmentation (cement, bone, or metal augmentation) and femoral or tibial stems. We advise using stems that exceed the defect from the most distal tibial screw or more proximal femoral screw in patients who undergo internal fixation hardware removal.

The limitations of this study include its retrospective design, an extended period for data collection, a lack of an adequate number of study patients, the different types of fractures undergoing different treatments. The strengths of our study include a considerable postoperative follow-up period.

CONCLUSIONS

TKA is an appropriate treatment for advanced PTOA, with good mid-term outcomes. However, the orthopedic surgeon should be aware of the higher complication rate in comparison with that of primary TKA due to idiopathic Osteoarthritis. The complexity of these cases requires detailed preoperative planning. Some patients may require prosthesis with greater constraint degree, metal augmentation and tibial/femoral stems, implant devices sometimes reserved for complex knee revisions. If adequate postoperative alignment and correct positioning of the components is achieved, expected outcomes are satisfactory and similar to those obtained with routine TKAs. Finally, long-term outcomes should be addressed by further studies, as TKA revisions sometimes involve young patients, with high functional demands and long life expectancy, and may require further revisions.

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