



Comparative Study of the Function and Quality of Life of Patients Submitted to Total Knee Arthroplasty with Fixed and Mobile Tibial Platforms

Estudo comparativo da função e qualidade de vida de pacientes submetidos à artroplastia total do joelho com plataformas tibiais fixa e móvel

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Abstract

Objective To compare the function and quality of life of patients undergoing total knee arthroplasty (TKA) with fixed tibial platform and mobile tibial platform.

Methods We evaluated 240 patients with knee osteoarthritis, randomized into two groups - Group A consisted of 120 patients who underwent TKA with fixed tibial platform, and the B group, consisting of 120 patients who underwent mobile platform arthroplasty. Patients were assessed according to the function and quality of life by the Western Ontario and McMaster Universities Arthritis Index (WOMAC) and the Short Form Health Survey (SF-36), and pain scores by visual analog scale (VAS) of pain, preoperatively and at 6 months, 1 year, 2 years, 4 years and 8 years of surgery.

Results Regarding the various domains of the SF-36, we observed that the average behavior of functional capacity scores, physical aspects, pain and emotional aspects in the patient groups were statistically different during follow-up. The other domains of quality of life showed no mean differences. Regarding the pain assessed by VAS and WOMAC pain scores, we can see that it showed a mean change in follow-up in both patient groups. However, at 2 years of follow-up, they were statistically worse in group A, equaling group B in the other moments.

Conclusion After 2 years of follow-up, we observed that pain scores and VAS were lower in the fixed platform group. However, these differences did not remain in the mid-term, suggesting that the mobile tibial platform arthroplasty has a short-term advantage, and may help in the rehabilitation process.

Keywords

- ▶ arthroplasty, replacement, knee
- ▶ quality of life
- ▶ osteoarthritis

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Resumo

Objetivo Comparar a função e qualidade de vida dos pacientes submetidos a artroplastia total de joelho (ATJ) com plataforma tibial fixa e plataforma tibial móvel.

Métodos Foram avaliados 240 pacientes com diagnóstico de osteoartrose de joelho, em um ensaio clínico, randomizados em dois grupos: grupo A, composto por 120 pacientes submetidos a ATJ com plataforma tibial fixa, e grupo B, formado por 120 pacientes com plataforma móvel. Todos foram avaliados de acordo com a função e qualidade de vida pelos questionários de Western Ontario and McMaster Universities Arthritis Index (WOMAC) e Short Form Health Survey (SF-36), e escores de dor, por meio da escala visual analógica (EVA) de dor, no pré-operatório e com 6 meses, 1 ano, 2 anos, 4 anos e 8 anos de cirurgia.

Resultados Com relação aos diversos domínios do SF-36, o comportamento médio dos escores de capacidade funcional, aspectos físicos, dor e aspectos emocionais foram estatisticamente diferentes ao longo do seguimento, em ambos os grupos. Os demais domínios de qualidade de vida não apresentaram diferenças. Assim como na EVA de dor, o escore médio do WOMAC de dor apresentou melhora ao longo do seguimento em ambos os grupos. Entretanto, com dois anos de seguimento, foram estatisticamente piores no grupo A, se igualando ao grupo B nos outros momentos de acompanhamento.

Conclusão Com 2 anos de pós-operatório, os escores de dor do WOMAC e da EVA foram piores no grupo submetido a ATJ com plataforma tibial fixa. Porém, as diferenças não permaneceram no médio prazo, sugerindo que a artroplastia com plataforma tibial móvel tem uma vantagem no curto prazo, podendo auxiliar no processo de reabilitação.

Palavras-chave

- ▶ artroplastia do joelho
- ▶ qualidade de vida
- ▶ osteoartrose

Introduction

In the last decades, with the ageing of the general population and the changes in the musculoskeletal system resulting from this process, osteoarthritis has become an important health problem.¹⁻³ The symptoms of this degenerative joint cartilage disease lead to functional disability and loss of quality of life for the elderly.⁴⁻⁹ These have been elements of evaluation of treatments, including total knee arthroplasty (TKA).^{10,11}

The methods for evaluating the results of TKA are mortality rates, morbidity, complications, and durability. However, with the rapid growth of improvements in procedures, these rates no longer reflect the real benefit in the quality of life of the individual.¹²⁻¹⁴ Thus, evaluations with generic or specific questionnaires regarding treatment have provided valuable information. Among them, the Western Ontario and McMaster Universities Arthritis Index (WOMAC) for TKA, and the Short Form Health Survey (SF-36) to assess quality of life, stand out.^{10,15} These questionnaires have shown the good results of TKA in improving the function and quality of life of elderly patients.

Total knee arthroplasty can be divided according to the tibial component into two types: TKA with fixed platform and with mobile platform. According to Wylde and Potter,¹⁶ the standard TKA - with fixed platform - can lead to an excessive load in the posterior region of the tibial component, increasing polyethylene wear, leading to a higher risk of

failure, and the need for revision. Thus, TKA with a mobile platform, as it allows greater rotational mobility and better congruence of the polyethylene component, has the theoretical advantage of self-aligning, reducing the incidence of anterior knee pain, producing better function.

In view of this, the theoretical advantages of TKA with a mobile platform must be confirmed clinically, since until now, there is no consensus regarding the best results, and previous studies were considered of low quality.¹⁷

The objective of the present study is to compare the function and quality of life of patients who underwent TKA with fixed and mobile platforms.

Methods

All procedures were approved by the research ethics committee of our university.

This is a randomized, double-blind clinical trial, conducted from January 2004 to January 2007. Inclusion criteria were: 1- age between 55 and 70 years old, 2-clinical signs and symptoms compatible with knee osteoarthritis, 3-radiographic signs of three-compartment osteoarthritis grades III, IV and V according to the Ahlbäck classification modified by Keyes and Goodfellow, 4-absence of associated diseases affecting the lower limbs, 5-absence of neurological disorder, 6-absence of nerve injuries or previous fractures in the lower limbs. The non inclusion criteria were: 1-infection, 2-flexion deformity > 10°, 3-angular deviations in varus and

valgus > 25°, 4–focal tumor defect, 5–physical conditions that would eliminate adequate implant support, 6–coexisting life-threatening disease in the year following the procedure. Patients who said that they were unable or unsure of returning for follow-up were excluded from the study.

After a complete clinical and radiological evaluation, patients with indication for TKA who met the criteria were invited to participate in the study. Those who confirmed their participation signed the free and informed consent form. The randomization method used was block exchange, with the aim of maintaining a similar distribution of the number of patients in each studied group. Eight patient blocks were created, with different combinations. Sealed, opaque envelopes numbered from 1 to 240 contained the group to which each patient belonged. The first group (group A), submitted to TKA with fixed tibial platform (Depuy Synthes, Warsaw, IN, USA), and the second group (group B), submitted to TKA with a mobile tibial platform (LCS, Depuy Synthes, Warsaw, IN, USA).

All of the patients were assessed with questionnaires in the preoperative and postoperative periods at 6, 24, 48 and 96 months regarding function (WOMAC), quality of life (SF-36) and subjective pain perception (visual analogue scale [VAS] for pain).

Sample Size

To accept an alpha risk of 0.05 and a β risk of 0.20, 98 patients were needed for each group to detect a ≥ 08 points difference between the average of pre- and postoperative scores for the dimensions of pain and function using the WOMAC questionnaire, deemed a clinically important difference.¹⁸ A common standard deviation (SD) of 20 was assumed. The sample was overestimated by 20% to allow for possible losses, so that each group should contain 120 patients.

Surgical Technique

All prostheses were implanted by the same surgeon. In all patients, spinal anesthetic block was performed. For 48 hours, prophylactic antibiotic therapy with sodium cefazolin was used. Pneumatic tourniquet was used routinely. The access route was the anterior one with medial parapatellar arthrotomy. The patella was everted and replaced in all cases. Both prostheses had a similar femoral component, and all were later stabilized. Both cruciate ligaments were extracted. Horizontal tibial bone cutting was performed first, using an extramedullary guide for the tibia and intramedullary for the femur. All of the components were cemented. A suction drain was used for 24 hours as a routine. For thromboembolic prophylaxis, for 14 days, patients received low molecular weight heparin.

Rehabilitation

Rapid mobilization was recommended, in which, on the first postoperative day, metabolic ankle exercises and isometric exercises for the quadriceps were performed. On the second postoperative day, after the suction drain was removed, gait training with a walker and weight unloading in both limbs began. Gait training was performed according to the tolerance of each patient (pain and clinical conditions). All of

them underwent one-hour sessions of continuous passive movement (CPM), twice a day (morning and afternoon), and the angle of movement varied according to the pain tolerance by each patient. Hospital discharge was given on average 5 days after the surgery, when the patient reached close to 90° of knee flexion and was able to walk independently with crutches or a walker. The outpatient physiotherapy sessions started 1 week after hospital discharge. The outpatient rehabilitation program lasted an average of 2 months, being similar for both groups.

Clinical Evaluation

The function was evaluated using the WOMAC, being composed of three domains: function, pain and stiffness. The sum of the points of each domain forms the result, varying from 0 to 68. To assess quality of life, the SF-36 was used, ranging from 0 to 100, presenting 36 response items, involving 8 concepts: functional capacity, physical aspect, pain, general health, vitality, social aspects, emotional aspects and mental health. The EVA was also applied, varying from 0 to 10.

Statistical Analysis

There was an association between the types of prosthesis and the characteristics using chi-squared tests.¹⁹ The quantitative characteristics of the patients were described according to the types of prosthesis using summary measures (mean, SD, median and quartiles, P25 and P75) and compared between the groups using the analysis of t-Student tests.¹⁹ The scores of the evaluated scales were described according to the types of prosthesis at each evaluation moment and compared between the types of prosthesis and moments using generalized estimation equation analyses with normal marginal distribution and logarithmic link function, due to the asymmetric distribution of scores, assuming a first-order autoregressive correlation between the moments of assessment.²⁰ The analyses were followed by multiple comparisons of Bonferroni²¹ to compare groups and times, when differences in scores were significant. The analyses were performed with the data evaluated in the patients, even considering losses during the follow-up. The results were illustrated with graphs of average profiles, with the respective standard errors, and the tests were performed with a significance level of 5%.

Results

Patients were recruited consecutively from November 2011 until December 2012. In total, 1,268 patients were evaluated and 1,028 were excluded, resulting in a final sample of 240 patients. Patients were randomized into 2 groups: 120 in the TKA with fixed platform and 120 in the TKA with mobile platform. From the fixed platform group, five patients died, and six did not adhere. From the mobile platform group, six died, four did not adhere, one had a cerebral vascular accident (CVA) and one had a rupture of the patellar ligament. All deaths occurred after >2 years of follow-up (► **Figure 1**).

Of the 240 randomized patients, 6 from the fixed platform group and 5 from the mobile platform group experienced

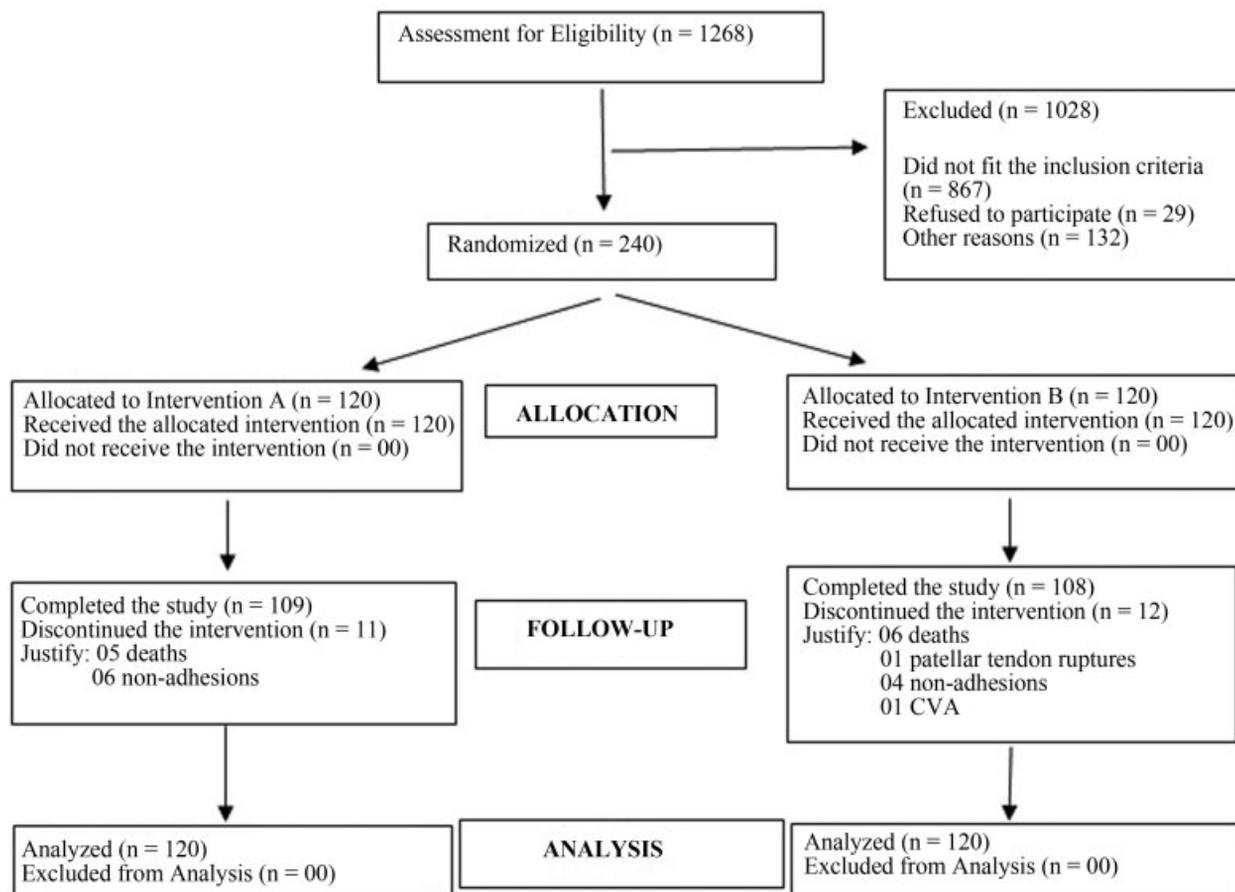


Fig. 1 Flowchart of Phases.

complications. In the fixed platform group, we had three cases of infection, two with embolism and one with deep venous thrombosis. In the mobile platform group, we had two cases of infection, one with deep venous thrombosis, one with CVA, and one with rupture of the patellar ligament.

The ages of the individuals in the sample were between 59 and 70 years old, with an average of 65.7 years old ($SD = 3.7$). A total of 81% were female, with a body mass index (BMI) of 30 ($SD = 4.7$). The personal characteristics evaluated did not show any association or statistically significant differences; therefore, the groups were homogeneous, as shown in **Table 1**.

Regarding the various domains of the SF-36 quality of life questionnaire, no difference was shown between groups regarding quality of life at the end of the follow-up. Only in some domains there is a difference between groups at certain times. An example is in the pain score in 1 and 2 years of follow-up, but they seem to equal each other in other moments.

Table 2 shows that the average behavior of the scores of functional capacity, pain and emotional aspects, were statistically different during the follow-up, in the groups of patients, according to the values highlighted in the table. The other domains of quality of life showed mean differences only during the follow-up, at different times of assessment, but with no difference between groups.

In **Table 3**, VAS for pain and WOMAC scores showed, on average, statistically different behavior between groups during follow-up ($p < 0.001$). In the WOMAC function and stiffness score, there was a statistically significant mean difference only during the follow-up, at different times of assessment, with no difference between groups ($p < 0.001$).

Discussion

The present prospective, randomized and controlled study found that, 8 years after the surgery, there were no significant differences in the clinical outcome of pain in the SF-36 and WOMAC quality of life questionnaires, as well as in the VAS scores, after knee prosthesis surgery with fixed tibial platform in relation to mobile platform implants. Recent prospective randomized studies^{16,22,23} also failed to find a difference in clinical evolution, radiological analysis or survival between fixed and mobile prostheses. These same authors compared the clinical results of the two types of implants in the same patient and found no differences in pain and range of motion (ROM) scores over 5 years of follow-up. Aglietti et al,²⁴ in their study of patients undergoing unilateral knee arthroplasty comparing the two types of prostheses, they also did not observe significant differences with 3 years of follow-up in pain scores, although greater flexion was pointed out in knees with fixed tibial platform. It is

Table 1 Description of personal characteristics of the patients according to types of prosthesis and results of statistical tests

Variable	Prosthesis type		Total (N = 240)	p Value
	Fixed (N = 120)	Mobile (N = 120)		
Gender, n (%)				
Female	96 (80)	100 (83.3)	196 (81.7)	0.505*
Male	24 (20)	20 (16.7)	44 (18.3)	
Operated side, n (%)				
Right	64 (53.3)	57 (47.5)	121 (50.4)	0.366*
Left	56 (46.7)	63 (52.5)	119 (49.6)	
Age (years)				
mean (SD)	65.9 (3.9)	65.4 (3.4)	65.7 (3.7)	0.369
median (P25; P75)	66 (63; 70)	65 (63; 68)	65 (63; 69)	
Weight (Kg)				
Mean (SD)	78.4 (12.1)	80.3 (13.5)	79.4 (12.8)	0.276
median (P25; P75)	78.5 (73; 85)	78.5 (71; 87)	78.5 (72; 86)	
Height (m)				
mean (SD)	1.62 (0.06)	1.62 (0.14)	1.62 (0.10)	0.320
median (P25; P75)	1.63 (1.6; 1.66)	1.63 (1.57; 1.67)	1.63 (1.59; 1.67)	
BMI (Kg/m²)				
mean (DP)	29.7 (4.2)	30.2 (5.1)	30 (4.7)	0.426
median (P25; P75)	29.5 (27.2; 32.3)	30.1 (27.2; 33.1)	29.7 (27.2; 32.9)	

Abbreviations: BMI, body mass index; SD, standard deviation.

t-Student test; * Chi-squared test.

Table 2 Description of quality of life scores according to types of prosthesis and moments of evaluation and statistical results

Variable	Moment	Prosthesis type						p Value Prosthesis type	p Value Moment	p Value Interaction
		Fixed			Mobile					
		Mean	SD	N	Mean	SD	N			
Functional capacity	Preoperative	20.22	18.10	120	17.17	14.79	120	0.219	<0.001	0.019
	6 months	57.54	19.47	120	62.79	19.39	120			
	1 year	65.46	15.38	120	74.42	17.32	120			
	2 years	68.37	16.76	120	73.88	16.71	120			
	4 years	61.63	15.46	120	63.88	15.14	120			
	8 years	51.46	16.72	120	55.46	16.09	120			
Physical aspects	Preoperative	13.48	26.58	120	17.23	25.76	120	0.910	<0.001	0.536
	6 months	71.68	28.24	120	67.86	37.68	120			
	1 year	77.08	24.38	120	73.96	31.49	120			
	2 years	88.27	65.30	120	82.75	29.13	120			
	4 years	84.77	23.00	120	75.43	35.65	120			
	8 years	78.93	25.52	120	78.34	28.06	120			
Pain	Preoperative	41.89	26.12	120	35.34	22.69	120	0.053	<0.001	0.004
	6 months	80.19	26.03	120	79.39	23.79	120			
	1 year	75.41	30.97	120	86.20	18.29	120			
	2 years	69.63	34.84	120	92.49	86.12	120			
	4 years	76.72	28.09	120	81.05	19.50	120			
	8 years	74.07	27.78	120	85.28	62.49	120			

(Continued)

Table 2 (Continued)

Variable	Moment	Prosthesis type						p Value Prosthesis type	p Value Moment	p Value Interaction
		Fixed			Mobile					
		Mean	SD	N	Mean	SD	N			
General Health Status	Preoperative	69.58	18.19	120	71.60	16.32	120	0.512	<0.001	0.167
	6 months	77.96	13.10	120	80.53	12.77	120			
	1 year	78.10	12.54	120	76.38	15.23	120			
	2 years	76.18	12.89	120	72.29	18.29	120			
	4 years	77.21	14.26	120	75.18	15.45	120			
	8 years	74.88	14.10	120	73.51	14.69	120			
Vitality	Preoperative	68.03	18.79	120	68.45	19.16	120	0.366	<0.001	0.779
	6 months	78.64	14.60	120	78.14	15.10	120			
	1 year	79.49	13.16	120	77.23	16.89	120			
	2 years	78.36	14.18	120	75.43	17.09	120			
	4 years	78.85	14.14	120	77.98	15.59	120			
	8 years	79.56	16.12	120	77.98	15.93	120			
Social Aspects	Preoperative	45.90	26.75	120	50.80	27.66	120	0.062	<0.001	0.080
	6 months	81.65	23.33	120	86.17	20.40	120			
	1 year	84.28	23.08	120	87.68	20.49	120			
	2 years	85.06	21.43	120	84.22	23.49	120			
	4 years	83.60	22.30	120	84.38	24.01	120			
	8 years	78.95	25.64	120	87.13	20.68	120			
Emotional Aspects	Preoperative	52.68	45.09	120	40.26	45.11	120	0.771	<0.001	0.036
	6 months	73.54	36.84	120	81.40	35.59	120			
	1 year	79.74	34.68	120	86.65	29.79	120			
	2 years	92.98	109.76	120	86.61	30.13	120			
	4 years	86.88	90.35	120	86.08	29.47	120			
	8 years	81.36	30.33	120	87.21	27.42	120			
Mental health	Preoperative	71.04	20.07	120	73.81	18.15	120	0.317	<0.001	0.484
	6 months	77.27	17.25	120	76.85	16.31	120			
	1 year	76.87	17.04	120	77.20	13.12	120			
	2 years	75.05	19.15	120	75.99	14.34	120			
	4 years	75.09	19.65	120	78.43	14.58	120			
	8 years	73.58	19.55	120	75.90	16.25	120			

Abbreviation: SD, standard deviation.

possible that the lack of difference in clinical results after 8 years of follow-up found in the present study, between implants with fixed platform and mobile platform, was due to the characteristics of the participants, especially regarding the age group.

In addition, the generic instrument for evaluating the SF-36 quality of life of patients in this age group contributes to confirm these results, but it seems insufficient when used separately to establish conclusions from the clinical point of view. When pain is analyzed, some patients are confused, because the issue is related to "pain in the body." All of the questions regarding pain, such as emotional aspects, disposition, and vitality, were often answered positively, but in

almost all cases it was difficult to relate the response directly to the knee, as they are questions of greater scope.

The average age of the participants in the present study was 65.7 (SD = 3.7) years old, and the majority did not perform recreational or sports physical activities that required a higher degree of joint movement. According to Wylde et al,¹⁶ the mobile tibial support prosthesis was designed to provide a greater range of joint movement and to allow participation in activities that require greater knee mobility in all planes. Therefore, it can be argued that the implantation of mobile tibial knee support did not reach its full potential in this group of patients because it is a study of an older population. A randomized clinical trial involving

Table 3 Visual analogue scale description of pain and functionality scores according to the types of prosthesis and moments of evaluation and statistical results

Variable	Moment	Prosthesis type						p Value Prosthesis type	p Value Moment	p Value Interaction
		Fixed			Mobile					
		Mean	SD	N	Mean	SD	N			
VAS for Pain	Preoperative	84.69	17.04	120	85.40	17.49	120	0.016	<0.001	<0.001
	6 months	26.43	22.13	120	24.70	22.43	120			
	1 year	25.63	15.08	120	20.53	20.85	120			
	2 years	28.83	19.40	120	16.57	18.97	120			
	4 years	14.06	17.39	120	13.04	18.07	120			
	8 years	13.78	16.37	120	10.56	16.59	120			
WOMAC for Pain	Preoperative	13.60	3.86	120	14.04	3.42	120	0.032	<0.001	<0.001
	6 months	3.46	3.53	120	3.42	3.82	120			
	1 year	3.86	3.30	120	2.67	3.91	120			
	2 years	5.11	3.97	120	2.86	4.01	120			
	4 years	2.91	3.06	120	2.24	3.92	120			
	8 years	2.31	3.21	120	1.77	3.72	120			
WOMAC function	Preoperative	43.64	13.91	120	45.36	12.60	120	0.037	<0.001	0.001
	6 months	14.11	11.78	120	10.94	9.45	120			
	1 year	9.62	9.81	120	8.53	7.79	120			
	2 years	8.83	9.81	120	7.11	7.39	120			
	4 years	13.12	9.81	120	10.13	7.96	120			
	8 years	21.37	10.90	120	18.31	8.47	120			
WOMAC stiffness	Preoperative	4.40	2.43	120	5.01	2.34	120	0.198	<0.001	0.203
	6 months	1.38	1.66	120	1.31	1.40	120			
	1 year	0.98	1.49	120	0.99	1.25	120			
	2 years	0.88	1.49	120	0.58	1.00	120			
	4 years	0.94	1.43	120	0.63	1.02	120			
	8 years	0.93	1.49	120	0.68	1.04	120			

Abbreviations: SD, standard deviation; VAS, visual analogue scale; WOMAC, Western Ontario and McMaster Universities Arthritis Index.

younger, more active patients, could reveal some functional advantage of one design over another.

An important finding of the present study that must be highlighted is the fact that, in a short period of time – 2 years after surgery – the VAS and WOMAC pain scores were significantly worse in the group with fixed tibial platform ($p < 0.05$ and $p < 0.001$, respectively). At that time, the worst pain scores had a negative influence on quality of life in patients undergoing TKA with a fixed tibial platform.

Concurrently, it is noted paradoxically that, exactly in this period with 2 years of follow-up, the groups had the best functional capacity scores, both in the SF-36 quality of life questionnaire assessments and in the WOMAC questionnaire functional assessments, with no statistically significant differences between the fixed and mobile groups.

Although TKA has already been shown to be a successful procedure for treating patients with osteoarthritis, a significant percentage can still experience pain after surgery.²⁵ Although the results of randomized controlled trials are

not yet conclusive to determine whether the type of implant can influence postoperative knee pain, the data obtained in the present study suggest that, in 2 years of follow-up, the SF-36 pain domain had less influence on quality of life in the group of patients submitted to TKA with a mobile tibial platform when compared to the group submitted to total prosthesis with fixed platform.

Aglietti et al²⁴ suggested that the advantages of a project with mobile tibial support may diminish over time. This is also observed in the present study, in which, after 2 years of surgery, it seems that the pain scores align again, with no statistically significant differences between the groups with 4 and 8 years in terms of pain levels. However, as anterior knee pain is relevant for patients even in the short term, it is not believed that this constitutes a limitation for the use of TKA with a mobile platform.

The highlight of the present study is the fact that all surgeries were performed by the same surgeon, with experience in both types of TKA, minimizing bias factors. In

addition, follow-up is medium to long term, with a larger sample size than most previous studies. In order to reduce the application bias, the questionnaires were completed by the patients themselves, with the help of the evaluator. Assessments were always performed by a physical therapist who did not know which group the patients had been randomized to.

As a limitation of this analysis, we can mention the nondivision of patients according to the ROM prior to the surgical and final procedure. Also, no radiological analysis was carried out in order to assess the advantages of one implant over the other in relation to the loosening aspect, which was not an objective of the present research.

When idealizing the present study, the focus was to find out if there were functional and quality of life differences in a group of elderly people with knee osteoarthritis who underwent both types of TKA. However, during its realization, some questions arose and remain unanswered, needing to be investigated.

Conclusion

The data from the present study demonstrate that 2 years after the surgery, pain scores in the questionnaires (SF-36, VAS and WOMAC) were worse in the fixed platform TKA group. However, individuals who underwent TKA with a fixed tibial platform did not present any functional and quality of life differences compared with those who underwent arthroplasty with a mobile tibial platform, with a medium-term follow-up.

Conflict of Interests

The authors have no conflict of interests to declare.

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