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No difference between fixed- and mobile-bearing total knee arthroplasty in activities of daily living and pain: a randomized clinical trial

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Abstract
Purpose Until now, there are no definitive conclusions regarding functional differences related to middle- and long-term everyday activities and patient pain following implantation of mobile- and fixed-platform tibial prostheses. The aim of this study was to determine whether there are middle-term differences in knee function and pain in patients undergoing fixed- and mobile-bearing total knee arthroplasty (TKA).
Methods Eligible patients were randomized into two groups: the first group received TKA implantation with a fixed tibial platform (group A); the second group received TKA with a mobile tibial platform (group B). Patients were followed up (2 years), and their symptoms and limitations in daily living activities were evaluated using the Knee Outcome Survey—Activities of Daily Living Scale (ADLS), in addition to pain evaluation assessed using the pain visual analogue scale (VAS).
Results There were no significant differences in function and symptoms in the ADLS and VAS between the study groups.
Conclusion The type of platform used in TKA (fixed vs. mobile) does not change the symptoms, function or pain of patients 2 years post-surgery. Although mobile TKAs may have better short-term results, at medium- and long-term follow-up they do not present important clinical differences compared with fixed-platform TKAs. This information is important so that surgeons can choose the most suitable implant for each patient.
Level of evidence Randomized clinical trial, Level I.

Keywords Arthroplasty · Replacement · Knee · Pain · Clinical trial

Introduction

The good results of total knee arthroplasty (TKA), along with ageing populations due to longer life expectancy, have led to a sharp increase in the number of TKA procedures performed in recent years worldwide [5]. Improvements in patient's pain and function after TKA are the primary objective because these outcomes are key in improving the patient's quality of life.

A large number of knee prosthesis designs are currently available on the market. Although the long-term results of TKA with a fixed tibial platform show a high level of clinical success [2], there is constant concern regarding problems related to polyethylene wear, patellar tracking, joint and osteolysis around the implants, especially in younger patients [7]. TKAs with mobile tibial platforms have been proposed as the solution to many of these problems and were developed with the primary objective of reducing polyethylene wear and decreasing the post-operative osteolysis and pain observed with some fixed-platform prosthesis designs [18].

Several studies have been also conducted to determine the kinematics of the knees undergoing TKA [3, 8–10, 17, 19, 20].

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However, as yet, there are no definitive conclusions regarding functional differences related to middle- and long-term everyday activities and patient pain following the implantation of mobile- and fixed-platform tibial prostheses [4, 11, 15].

The aim of this study is to determine whether there are middle-term differences in knee function and pain in patients undergoing these two types of TKA. The hypothesis is that there are no differences in these variables when TKA is performed with a fixed tibial platform compared to a mobile tibial platform.

Materials and methods

Inclusion criteria

The study included patients of both genders, between 55 and 70 years old, presenting with signs and symptoms consistent with osteoarthritis of the knee and with indications of TKA; signs of tricompartmental osteoarthritis (involvement of the medial, lateral and patellofemoral compartments) of the knee on plain posterior–anterior with load, profile and axial patellar radiographs; and grade IV or V arthrosis of the knee according to Alhback et al. [1] evaluated using radiographs.

Non-inclusion criteria

Patients with the following conditions were excluded: infection (local or systemic); bilateral osteoarthritis that required bilateral arthroplasty; fixed flexion deformity $\geq 10°$; angular deviation in varus/valgus $\geq 25°$; focal defect from a tumour; previous joint replacement; physical conditions that tend to eliminate the appropriate implant support, such as insufficient bone quality or quantity (resulting from cancer, congenital displacement or osteoporosis), neuromuscular impairment, morbid obesity, vascular deficiency in the affected limb, lack of muscle strength supporting the joint structures and neuropathy; the presence of rheumatic and orthopaedic diseases in another joint that interfere with gait; and having undergone orthopaedic surgery on the spine, hips, knees, ankles or feet in the 6 months prior to knee surgery that could interfere with gait.

Exclusion criteria

Patients were excluded if were unable to return for follow-up or if were uncertain as to whether they would return for follow-up visits.

Randomization and blinding

Eligible patients were randomized into two groups: the first group received TKA implantation with a fixed tibial platform (group A); the second group received TKA with a mobile tibial platform (group B). Permuted block randomization was used to maintain a similar distribution in the number of patients in each study group. Blocks of eight patients were created with different combinations. Sealed, opaque envelopes numbered 1–64 were generated and contained the group to which each patient wallocated (group A or B).

Surgical technique

All prostheses were implanted using the same surgical technique. All surgeries were performed under spinal anaesthesia. Arthroplasty was performed by a single expert orthopaedic surgeon (JTA) via an anterior midline approach with a 20-cm longitudinal skin incision. Both cruciate ligaments were sacrificed during the surgical procedure. At the end of surgery, the tourniquet was deflated, and haemostasis was obtained. In all patients, 1 g cefazolin was used as the prophylactic antibiotic. Antibiotic therapy was continued for 24 h after surgery. All patients underwent the same rehabilitation protocol. Patients were encouraged to start active flexion and extension as soon as possible. Partial weight bearing was allowed within the first week of surgery based on patient's pain. After being discharged from the hospital, patients were followed up, and their symptoms and limitations in daily living activities were evaluated using the Knee Outcome Survey—Activities of Daily Living Scale (ADLS), in addition to pain evaluation assessed using the pain visual analogue scale (VAS).

Outcomes

The primary outcome was the functional evaluation of patients using the ADLS after 24 months. A single blinded evaluator (GGA) performed this evaluation. Secondary outcomes were pain assessment using the pain VAS before surgery and then at 12 and 24 months post-surgery and ADLS prior to surgery and at 12 months post-surgery.

Statistical analyses

The sample size was calculated using a 95 % confidence interval and 80 % power. Expecting a difference of seven points on the ADLS, which based on previous studies was considered a clinically significant improvement, the sample necessary for each group in this study would have to include a minimum of eight patients. The qualitative characteristics of the patients were described according to type of prosthesis with the use of absolute and relative frequencies, and associations between the types of prosthesis and characteristics were determined using the Chi-square test [13]. The quantitative characteristics of patients were

described according to the types of prosthesis using summary measures (means, standard deviations, medians and quartiles [P25 and P75], and comparisons between the groups were performed using Student's *t* test. The functions, symptoms and pain VAS scores were described according to the type of prosthesis at each assessment time point and were compared between the different types of prosthesis and time points using generalized estimating equations with normal marginal distribution and logarithmic link function due to the asymmetric distribution of the scores, assuming a first-order autoregressive correlation between time points [14]. The analyses were followed by Bonferroni multiple comparisons to compare the groups and time points when the scores were significantly different. Statistical analysis was performed using statistical software (SPSS, Inc., Chicago, IL, USA, version 18). A p value of less than 0.05 was considered statistically significant.

Ethics

This study was a prospective double-blinded randomized clinical trial performed at Vila Nova Cachoeirinha General Hospital (hospital in São Paulo, Brazil) from November 2011 to December 2012. All study procedures were approved by the Research Ethics Committee of the Federal University of São Paulo (Universidade Federal de São Paulo—UNIFESP/EPM) (number 195.817).

Results

During the study, 328 patients were eligible and enrolled. Of these patients, 264 patients were excluded. Thus, 64 patients were randomized, including 32 allocated to group A and 32 to group B. None of the patients withdrew from the study during the follow-up period.

The flow chart below (Fig. 1) shows the study design and the patient distribution.

There were no significant differences in the demographic variables between the two groups, including age, gender, height, weight, body mass index (BMI) and the side of surgery (Table 1).

The ADLS was applied three times during the study period: before the surgery, 12 and 24 months after surgery. The pain VAS was also applied before surgery and at 12 and 24 months after surgery. There were no significant differences in function and symptoms in the ADLS and VAS between the study groups (Table 2). There were no complications during the study period.

Discussion

The main result of this study is that the type of platform used in TKA (fixed vs. mobile) did not change the symptoms, function or pain of patients 2 years post-surgery.

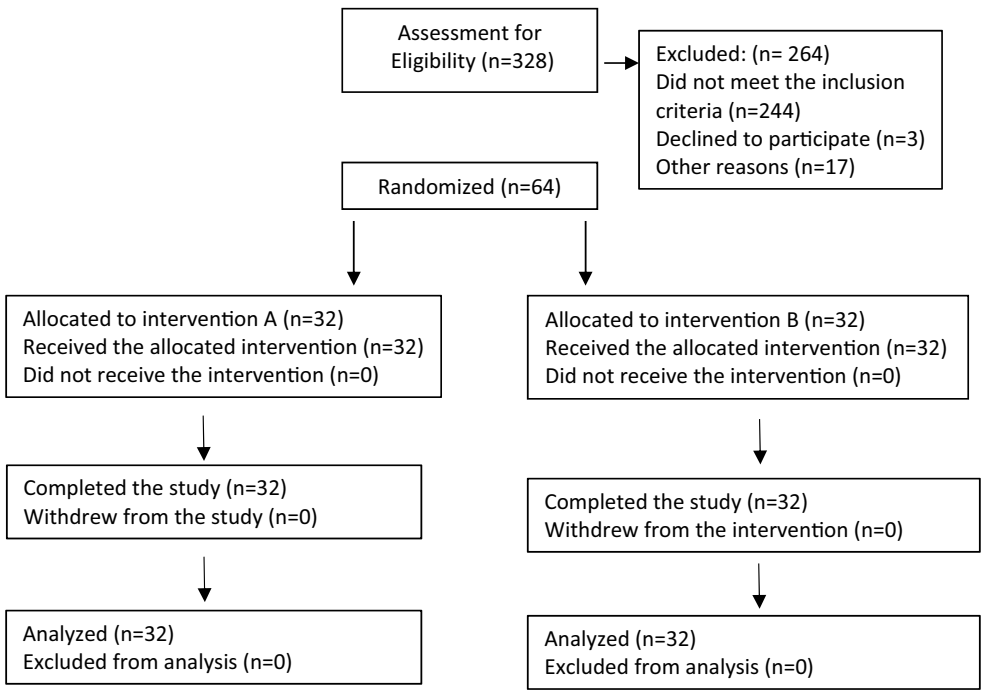

Fig. 1 Flow chart of the stages

Table 1 Demographic characteristics of the patients

Variable	Type of prothesis		Total ($N = 64$)	p
	Fixed ($N = 32$)	Rotating ($N = 32$)		
Gender n (%)				
Female	22 (68.8)	24 (75)	46 (71.9)	n.s.
Male	10 (31.2)	8 (25)	18 (28.1)	
Side operated n (%)				
Right	19 (59.4)	13 (40.6)	32 (50)	n.s.
Left	13 (40.6)	19 (59.4)	32 (50)	
Age (years)				
Mean (SD)	66.2 (4)	65.2 (3.2)	65.7 (3.6)	n.s.
Median (P25; P75)	68 (63; 70)	65.5 (63.3; 68)	66 (63; 69)	
Weight (kg)				
Mean (SD)	80.4 (17)	81.9 (13.7)	81.2 (15.3)	n.s.
Median (P25; P75)	78 (70; 83)	80 (70; 92)	78.5 (70; 90)	
Height (m)				
Mean (SD)	1.64 (0.09)	1.62 (0.07)	1.63 (0.08)	n.s.
Median (P25; P75)	1.64 (1.58; 1.68)	1.63 (1.6; 1.68)	1.63 (1.6; 1.68)	
BMI (kg/m^2)				
Mean (SD)	29.8 (4.8)	31.1 (4.1)	30.5 (4.5)	n.s.
Median	29.2 (26.1; 32.6)	32.1 (27.7; 33.3)	29.9 (27.2; 33.2)	

Student's *t* test; Chi-square test

There were no differences in the ADLS and VAS scores between groups.

To be considered a success, TKA should leave the patient without pain and with improved function, and these results should be maintained over time. Many articles have discussed the potential benefits of TKA with a rotating tibial platform compared to designs with a fixed tibial platform. The ultimate goal of these manuscripts was to determine whether the theoretical advantages of arthroplasties using a mobile platform resulted in superior clinical outcomes. Kinematic and in vitro studies have suggested certain theoretical benefits of TKA with a mobile platform. However, most clinical studies were inconsistent in demonstrating the functional superiority of TKA with a mobile platform.

KIM et al. [12] compared fixed and mobile TKA in a population with a mean age of 65 years and found no differences between groups with respect to pain, function, joint range of motion and satisfaction scores between groups.

Watanabe et al. [23, 24] randomized 22 patients with simultaneous bilateral TKA where one knee received TKA with a fixed platform and the other knee received a mobile platform. The mean follow-up was 8 years. They found no significant differences with respect to either range of motion or clinical outcomes. Another randomized clinical trial comparing knee arthroplasties with fixed and mobile platforms also found no clinical differences or differences in post-operative pain after 4 years of follow-up. However, Thienpont et al. [21] in a retrospective study showed superior clinical outcomes of prostheses with fixed tibial platforms compared to mobile tibial platforms using the Forgotten Joint Score (FJS-12).

Moskal et al. [16] in a recently published meta-analysis found no differences between these two designs of prostheses in terms of clinical results, component alignment, adverse event frequencies or survivorship. However, in most studies included in this meta-analysis the authors used different methods of evaluation compared to the present study. Thus, this study is important as it confirms and adds more information about these issues.

Breugem et al. [6] also found no differences between a fixed and a mobile posterior stabilized total knee arthroplasty after 7.9 years in ROM, VAS, Oxford 12-item knee questionnaire and SF-36.

Table 2 ADLS (function and symptoms) and VAS results in both study groups during the study period

Variable	Time point	Type of prothesis						p
		Fixed			Rotating			
		Mean	SD	N	Mean	SD	N	
Function	Pre	14.7	5.9	32	13.9	5.3	32	n.s.
	1 year	27.7	8.5	32	32.0	6.2	32	
	2 years	32.4	5.1	32	32.1	5.4	32	
Symptoms	Pre	13.7	6.7	32	13.2	4.4	32	n.s.
	1 year	24.7	4.5	32	26.8	4.5	32	
	2 years	26.8	4.3	32	28.8	2.2	32	
VAS	Pre	84.4	19.1	32	80.7	15.6	32	n.s.
	1 year	14.5	21.3	32	12.1	14.3	32	
	2 years	5.6	9.9	32	7.9	10.9	32	

Van Stralen et al. [22] found different tibiofemoral contact points in patients with fixed and mobile TKAs, but that was not correlated with a different clinical outcome and higher incidence of anterior knee pain.

In the present study with 2 years of follow-up, our results were similar to those reported in other studies in that we observed that the mean scores for function, symptoms and pain did not differ significantly between the two groups. It is important to note that many different prosthesis designs with mobile tibial platforms have been evaluated in various published studies, making it very difficult to standardize the results.

Although mobile TKAs may have better short-term results, at medium- and long-term follow-up they do not present important clinical differences compared with fixed-platform TKAs. This information is important so that surgeons can choose the most suitable implant for each patient.

This study had some limitations, such as a short follow-up period and a small sample size for subgroup analyses. This study did not address other variables, such as range of motion, polyethylene wear and quality of life due to the focus given to function, symptoms and post-operative pain. However, this study is significant in that it had a larger sample size than previous studies on the subject, and its study design was prospective and randomized.

Conclusion

The type of platform used in TKA (fixed vs. mobile) does not change the symptoms, function or pain of patients 2 years post-surgery.

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