Clin Orthop Relat Res (2013) 471:3543–3553
DOI 10.1007/s11999-013-3183-4

Clinical Orthopaedics and Related Research®
A Publication of The Association of Bone and Joint Surgeons®

CLINICAL RESEARCH

Trabecular Metal in Total Knee Arthroplasty Associated with Higher Knee Scores: A Randomized Controlled Trial

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Received: 12 March 2013 / Accepted: 10 July 2013 / Published online: 25 July 2013

Abstract

Background Porous tantalum is an option of cementless fixation for TKA, but there is no randomized comparison with a cemented implant in a mid-term followup.

Questions/purposes We asked whether a tibial component fixed by a porous tantalum system might achieve (1) better clinical outcome as reflected by the Knee Society Score (KSS) and WOMAC Osteoarthritis Index, (2) fewer complications and reoperations, and (3) improved radiographic results with respect to aseptic loosening compared with a conventional cemented implant.

Methods We randomized 145 patients into two groups, either a porous tantalum cementless tibial component group (Group 1) or cemented conventional tibial component in posterior cruciate retaining TKA group (Group 2). Patients were evaluated preoperatively and 15 days, 6 months, and 5 years after surgery, using the KSS and the WOMAC index. Complications, reoperations, and radiographic failures were tallied.

Results At 5-year followup the KSS mean was 90.4 (range, 68–100; 95% CI, ± 1.6) for Group 1, and 86.5 (range, 56–99; 95% CI, ± 2.4) for Group 2. The effect size, at 95% CI for the difference between means, was 3.88 ± 2.87. The WOMAC mean was 15.1 (range, 0–51; 95% CI, ± 2.6) for the Group 1, and 19.1 (range, 4–61; 95% CI, ± 2.9) for Group 2. The effect size for WOMAC was −4.0 ± 3.9. There were no differences in the frequency of complications or in aseptic loosening between the two groups.

Conclusions Our data suggest there are small differences between the uncemented porous tantalum tibial component and the conventional cemented tibial component. It currently is undetermined whether the differences outweigh the cost of the implant and the results of their long-term performance.

One of the authors (MF-F) has received research funding from Zimmer GmbH, Winterthur, Switzerland.
All ICMJE Conflict of Interest Forms for authors and Clinical Orthopaedics and Related Research editors and board members are on file with the publication and can be viewed on request.
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Each author certifies that his or her institution approved the human protocol for this investigation, that all investigations were conducted in conformity with ethical principles of research, and that informed consent for participation in the study was obtained.
This work was performed at Instituto de Cirugía Ortopédica y Traumatología de Barcelona, Barcelona, Spain.

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Level of Evidence Level I, therapeutic study. See Instructions to Authors for a complete description of levels of evidence.

Introduction

A TKA is an effective and widely accepted procedure to decrease pain and improve function in patients who are experiencing significant physical limitations [31, 57]. To date, a cemented TKA has been considered the accepted standard [11, 37, 40], with predictable and durable results [12, 17, 21, 35, 48, 53, 54]. The survivorship of a well-designed and properly positioned cemented TKA at 10 to 20 years exceeds 90%, resulting in stability, increased mobility, and reduction of pain for many patients [38, 49].

Despite this, new designs, materials, and fixation techniques have been introduced. Cementless fixation is an option that seeks to address the issue of aseptic failure of cemented fixation, especially in younger patients [13, 39]. Cementless fixation may result in durable biological fixation with more physiologic transfer of stresses to underlying bone and, therefore, perhaps preservation of bone mineral density. Earlier cementless implants showed the possibility of achieving these goals, but they experienced a high rate of complications and failures, particularly of the patellar and tibial components [26, 37, 47, 52, 65]. For this reason, some authors recommended a hybrid technique using a cemented tibial component and uncemented femoral component [26, 47]. However, with time, problems with cementless implants have been overcome by better designs and new fixation systems, reducing the risk of early migration [62] and loosening of the tibial component [18], and resulting in clinical results and survivorship rates comparable to those achieved with cemented implants [5, 7, 8, 18, 19, 24, 25, 33, 40, 46, 51, 65, 66]. However, given the similarity of results, some of these authors have concluded that the lack of advantages of uncemented over cemented components would not support the use of more expensive implants [19, 33].

Tantalum is a newer biomaterial, purported to be similar in porosity [36, 68] to cancellous bone (Trabecular Metal™; Zimmer Inc, Warsaw, IN, USA). It has excellent mechanical and biological properties [6, 36, 68], including primary stability and osseointegration. As reported in clinical studies, this has resulted in excellent early performance of primary implants of this material [14, 20, 22, 23, 30, 41, 45, 59, 63, 67]. However, there are only two randomized trials comparing tantalum TKA implants with cemented devices in small series of patients with 2-year [14] and 5-year [67] followups, and only one other controlled study that is beyond 5 years of followup [30].

Accordingly, we sought to test, in the context of a randomized controlled trial, whether a tantalum tibial component in a cementless TKA would provide (1) better clinical outcomes as reflected by the KSS and the WOMAC index, (2) fewer complications and reoperations, and (3) improved radiographic results with respect to aseptic loosening compared with a conventional cemented implant.

Patients and Methods

To evaluate the benefits of this emerging technology, we conducted a randomized controlled trial comparing outcomes of an uncemented, PCL-retaining Trabecular Metal™ monoblock tibial component and a cemented stemmed PCL-retaining modular tibial component in TKAs without patellar resurfacing. The study was done at the Instituto de Cirugía Ortopédica y Traumatología de Barcelona. One hundred seventy-one consecutive patients who met the inclusion criteria were judged as eligible for this study between June 2002 and December 2005 (Fig. 1).

Inclusion criteria for patients in this study were: (1) admitted for primary TKA; (2) moderate to severe femorotibial gonarthrosis following the classification of Altman et al. [1] and the scale of Kellgren and Lawrence [32]; (3) between 50 and 70 years of age; (4) living in the Barcelona area; and (5) expressing willingness to participate without difficulty in returning for followups.

Local ethical committee approval was obtained before the start of this study. All patients were informed of the nature of the study by an independent research assistant (VQ), and after accepting the study protocol, written informed consent was obtained from all patients. Nine patients expressed unwillingness to participate or anticipated difficulty in returning for followups, therefore, they were not included (Fig. 1).

We excluded patients with (1) previous knee surgery, with the exception of arthroscopy; (2) a history of infection; (3) axial deformities greater than 10°; (4) preoperative knee flexion less than 90°; (5) an unstable knee requiring a constrained or semiconstrained prosthesis; (6) posttraumatic or inflammatory arthritis; (7) contralateral moderate to severe gonarthrosis or contralateral TKA; (8) factors causing difficulties with normal locomotion and function such as polyarticular, cardiovascular, or respiratory disability; (9) morbid obesity (BMI > 40 kg/m^2); (10) radiographic osteopenia or bone loss in the affected knee; (11) known metabolic bone disease; and patients (12) prescribed medications affecting bone mineral density such as bisphosphonates, calcitonin, steroids, or hormone therapy. Seventeen patients met some of the exclusion criteria and were omitted from this study.

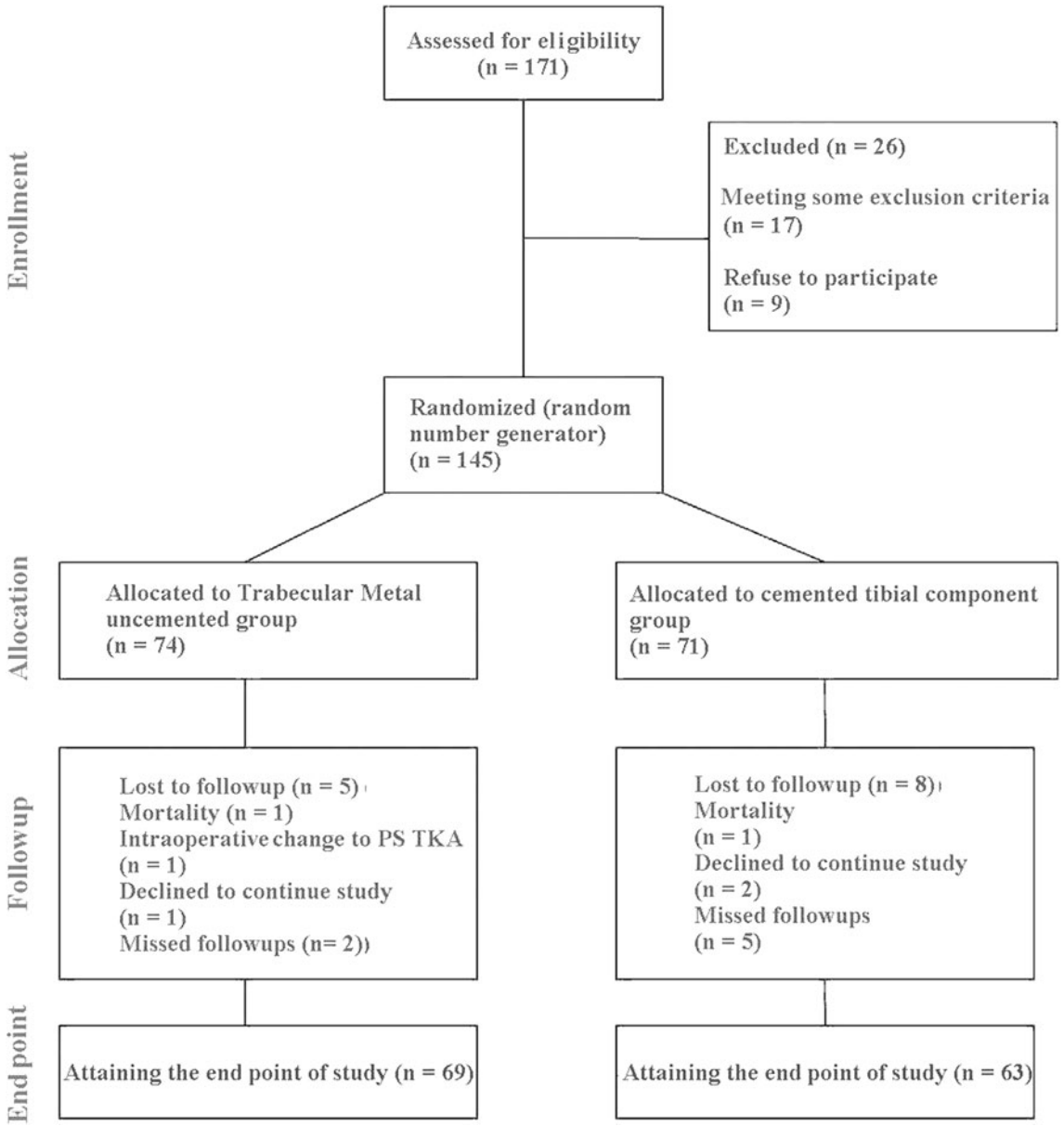

Fig. 1 The CONSORT flow diagram shows the progression of the study through patients' enrollment, allocation, followup, and analysis at the end point. PS = posterior stabilized.

The sample size was calculated using a two-sided test of difference between two means (alpha risk of 0.05; beta risk of 0.20) to detect a difference of at least seven points in the normalized WOMAC scale (0–100) assuming a SD of baseline scores of 20 [2]. The sample size was estimated to be 61 participants for each group, but it was overestimated by 20% to allow for patients lost to followup while maintaining the 80% level of statistical power.

One hundred forty-five patients (109 women and 36 men with a total of 145 diseased knees) were recruited, randomized, and blinded. Patients received either the cementless Trabecular Metal™ tibial component (NexGen®; Zimmer Inc, Warsaw, IN, USA) (Group 1) or a conventional cemented tibial component (Group 2). Randomization was conducted with a computer-generated random list (Randlist Software; Datainf GmbH, Tübingen, Germany), administered by a statistician (AL), with a 1:1 allocation using random block sizes of 10. Seventy-four patients, 55 women and 19 men, ranging in age from 51 to 69 years (mean ± SD, 61 ± 5.0 years), were allocated to Group 1 and 71 patients, 54 women and 17 men, ranging in age from 50 to 69 years (mean ± SD, 60 ± 4.6 years), were allocated to Group 2.

Sealed, sequentially numbered envelopes containing assignment to one of the two treatment groups were given

to the assisting nurse (NG), who was blinded to the content and opened the envelopes in numerical order as the patients were admitted to the operating room. The surgeon knew the group assignment just before to initiate preparation to insert the tibial trial prosthesis. Clinical staff involved in rehabilitation, followup, and outcome assessment was blinded to which surgical procedure was performed; and radiologists involved in image assessment did not know the patients' clinical outcome. Patients were informed about the implant they had received only after the study was completed, as was established at the time informed consent was given.

Demographic data, height, weight, BMI, work status, comorbidities, American Society of Anesthesiologists class, and degree of articular damage were recorded preoperatively. All comorbid conditions in our patients had a Charlson integer weight of 1 or 2 [10] with a Charlson Index 1 to 2 (low) in all cases. There were no significant differences between the two groups concerning demographic, anthropometric, or preoperative clinical data (Table 1). Patients were assessed using the Knee Society (KS) objective rating system [27], and as a primary outcome measure, the Spanish adaptation of the WOMAC questionnaire [15] as a disease-specific, self-administered health assessment normalized to the 0 to 100 scale, with 0 as the best quality of life and 100 the worst. There were no statistically significant differences in scores between the Groups 1 and 2 at the time of the preoperative examination ($p > 0.05$; (Table 2).

Standardized AP standing long radiographs of both extremities and lateral views in extension and in 30° knee flexion were taken.

All procedures were done by one surgeon (MF-F). For Group 1 (the cementless group), the surgeon used an uncemented fiber metal femoral component (NexGen®; Zimmer Inc) and uncemented Trabecular Metal™ monoblock tibial component, approved by the FDA for that use. Patients in Group 2 received a hybrid TKA using the same uncemented femoral component and cemented NexGen® stemmed tibial component.

The uncemented porous tantalum tibial component monoblock design has the polyethylene intruded directly into the porous tantalum tray with two Trabecular Metal™ hexagonal-shaped pegs on its undersurface to be press-fit into the tibial spongiosa.

The cemented tibial tray used in Group 2 was made of titanium alloy with a 50-mm central stem with small posterolateral flanges. The undersurface was grit-blasted and had a peripheral lip to increase penetration of cement in bone and prevent escape of cement at the margins. Cementation was performed following a conventional technique [50] by using high-volume, high-pressure lavage (Pulsavac®; Zimmer Inc) and a pack of low-viscosity polymethylmethacrylate bone cement (Palacos® LV-40; Schering-Plough Europe, Brussels, Belgium), without antibiotics, vacuum-mixed, and applied to the undersurface of the tibial tray and pressurized into the tibial bone by a bone cement injector. The polyethylene insert was held to the base tray by a peripheral capture mechanism.

The articular surface was similar for both designs using a minimum polyethylene thickness of 10 mm. A PCL-retaining prosthesis was implanted in all but one patient in Group 1 whose implant was converted to a PCL-substituting prosthesis as a result of intraoperative laceration of the PCL. This patient subsequently was withdrawn from the study. The patella was not resurfaced in any case. The wound was closed over a 10-gauge drain that was removed 24 hours postoperatively. Transfusion was administered based on the transfusion criteria of patients with hemoglobin levels of 8.0 g/dL.

Table 1. Demographic, anthropometric, and preoperative clinical data

Subject preoperative data	Group 1 (n = 74) Uncemented (Trabecular Metal™)	Group 2 (n = 71) Cemented (PMMA)	p value
Age, mean ± SD years	61 ± 5.0	60 ± 4.6	0.46
50–60	n = 27	n = 22	
60–70	n = 47	n = 49	
Sex			
Women	55 (74)	54 (76)	0.80
Men	19 (26)	17 (24)	
BMI, mean ± SD kg/m^2	29.1 ± 5.2	30.5 ± 4.9	0.20
< 25	10 (14)	10 (14)	0.23
25–30	38 (51)	27 (38)	
30–40	26 (35)	34 (48)	
Work status			
White collar	14 (19)	12 (17)	0.86
Blue collar	23 (31)	22 (31)	
Housekeeping	26 (35)	29 (41)	
Retired/unemployed	11 (15)	8 (11)	
Osteoarthrosis grade			
Moderate	11 (15)	14 (20)	0.43
Severe	63 (85)	57 (80)	
Comorbidities	8 (11)	6 (8)	0.7
Arrhythmia	0	1 (1.4)	
Hypertension	2 (2.7)	1 (1.4)	
Diabetes	1 (1.3)	2 (2.8)	
Gastric disease	3 (4.0)	2 (2.8)	
Liver dysfunction	1 (1.3)	0	
Renal dysfunction	1 (1.3)	0	

Values are the number (percentage) unless otherwise indicated; PMMA = polymethylmethacrylate.

Table 2. Baseline and postoperative scores at 5-year followup

Outcome measure	Evaluation interval	Group 1 (cementless) n = 69		Group 2 (cemented) n = 63		Group 1 versus Group 2	
		Mean scores (± SD)	p value preoperative versus 5-year followup	Mean scores (± SD)	p value preoperative versus 5-year followup	Effect size (95% CI) at 5-year followup	p value
The Knee Society Score	Preoperative	36.7 ± 11.4	< 0.0001	33.3 ± 9.8	< 0.0001		0.21
	5-year followup	90.4 ± 6.9		86.5 ± 9.6		3.88 (1.00 to .75)	0.02
WOMAC	Preoperative	58.3 ± 7.4	< 0.0001	60.0 ± 7.7	< 0.0001		0.20
	5-year followup	15.1 ± 10.9		19.1 ± 11.7		−4.00 (−7.91 to −0.09)	0.02

The Knee Society Score = 100 as the best score and 0 the worst; WOMAC = 0 as the best quality of life and 100 the worst; effect size of all scores: difference of means.

Table 3. Perioperative data

Perioperative data	Group 1 (n = 73)	Group 2 (n = 71)	Group 1 versus Group 2	
	Uncemented (Trabecular Metal™)	Cemented(PMMA)	Effect size (95% CI)	p value
Duration of operation (minutes)	60.3 ± 4.4	77.5 ± 4.6	−17.20 (−18.70 to −15.70)	< 0.0001
Blood loss (cc)	908 ± 177	889 ± 81	19.06 (−26.52 to 64.65)	0.4
Patients requiring transfusion, number (%)	57 (77)	60 (84)	−6.42% (−19.35 to 6.56)	0.3
			0.92 (0.78 to 1.08)	
Transfusion PRBC units	1.4 ± 1.0	1.5 ± 0.8	−0.05 (−0.38 to 0.27)	0.9
Hospital length of stay (days)	3.2 ± 0.6	3.2 ± 0.6	0.059 (−0.21 to 0.22)	0.8

Effect size of duration of operation, blood loss, transfusion units, and length of stay: difference in means; effect size of patients requiring transfusion: absolute (risk difference) and relative (risk ratio); PMMA = polymethylmethacrylate; PRBC = pack red blood cells.

Perioperative management, antibiotic and antithrombotic prophylaxis, anesthetic and analgesic protocols, tourniquet use, a standard surgical technique for approach, alignment, bone cuts, and component implantation were identical in all patients, except for insertion of the tibial component, logically different in each of the two groups.

Average operative time between incision and closure, intraoperative blood loss and postoperative blood collected in the closed suction drainage, transfusion rate, and length of stay in the hospital were recorded (Table 3).

The postoperative physical therapy protocol was the same in both groups. Continuous passive motion (CPM) was started immediately after surgery, and all patients were allowed full weightbearing and progressed from using assistive devices as tolerated. After hospital discharge, they continued to use a CPM machine at home and performed five sessions of physical therapy each week for 3 weeks and then three visits per week for an additional 3 weeks. If gains of at least 90° flexion and full extension were not achieved after 6 weeks of postoperative physiotherapy, the patient was readmitted for closed knee manipulation under anesthesia.

Patients were seen at 15 days, 3 months, 6 months, and each year after surgery, with the 5-year followup as the end point of the study. Outcome questionnaires were completed and radiographic studies were repeated at the 15-day, 6-month, and 5-year followups. Complications and reoperations were recorded.

Thirteen patients were lost to followup. At the last followup, one patient in Group 1 and one in Group 2 had died, three patients declined to continue the study (n = 1 Group 1, n = 2 Group 2), and seven patients did not return for the final followup (n = 2 Group 1, n = 5 Group 2). At the conclusion of the study, 69 patients in Group 1 and 63

patients in Group 2 attained the end point of study at 5 years of followup and were included in the per-protocol analysis.

Clinical outcomes were assessed by two independent investigators not involved in surgery (AM, AT), with each observer blinded to the other observer. Interobserver agreement had kappa values greater than 0.90 for all parameters assessed.

Serial radiographs were compared with the first postoperative radiograph to determine whether there had been changes of implant position, progression of radiolucent lines, or osteolysis. Radiographs were reviewed by two independent radiologists (AM, NL) having no knowledge of the clinical outcome and not having taken part in any other stage of this work. The alignment of the arthroplasty was measured as described by Nilsson et al. [44]. Any migration or change in the position of components was considered indicative of loosening [8, 9, 44]. The presence, localization, and size of radiolucent lines were analyzed following the KS criteria [16] and the modification proposed for uncemented pegged tibial components [45] (Fig. 2). Radiolucency was classified as progressive when an increase in length or width was observed on sequential films, and was predictive of potential implant loosening [8, 9]. Kappa values for interobserver agreement were greater than 0.7 for all parameters assessed.

Descriptive analysis of variables was performed using univariate statistics. To analyze differences, a t-test for continuous data normally distributed, the Mann-Whitney U test and Wilcoxon signed rank test for values not normally distributed, and the chi-square test and Fisher's exact test for categorical data were used. The effect size was estimated assuming the difference in means for continuous data and the risk difference (absolute effect size) and risk ratio (relative effect size) for categorical data. We calculated all variable and modeling statistics using 95% CI. Statistical significance was evaluated at alpha = 0.05 and the analysis was performed using SAS, Version 9.2 (SAS Institute Inc, Cary, NC, USA).

Results

Patients who received the cementless tibia had improved KSS and WOMAC scores compared with patients who received the cemented tibial component. When comparing clinical outcomes between groups, at the 5-year followup, the KSS mean score was 90.4 (range, 68–100; 95% CI, ± 1.6) for Group 1 (uncemented tibia), and 86.5 (range, 56–99; 95% CI, ± 2.4) for Group 2 (cemented tibia), with a significant difference ($p = 0.02$). The effect size, at 95% CI for the difference between means, was 3.88 ± 2.87 for the KSS. At 5-year followup the WOMAC mean was 15.1 (range, 0–51; 95% CI, ± 2.6) for Group 1, and 19.1 (range, 4–61; 95% CI ± 2.9) for Group 2, with a significant difference ($p = 0.02$). The effect size for the WOMAC was −4.0 ± 3.9 (Table 2).

Mean KSS and WOMAC scores reported at 6 months and 5 years postoperatively showed significant ($p < 0.001$) improvement over preoperative levels for both patient cohorts (Table 2).

There were no differences between the groups in terms of the frequency of complications or reoperations (Table 4). The patients with deep vein thrombosis were treated satisfactorily with initial heparin followed by

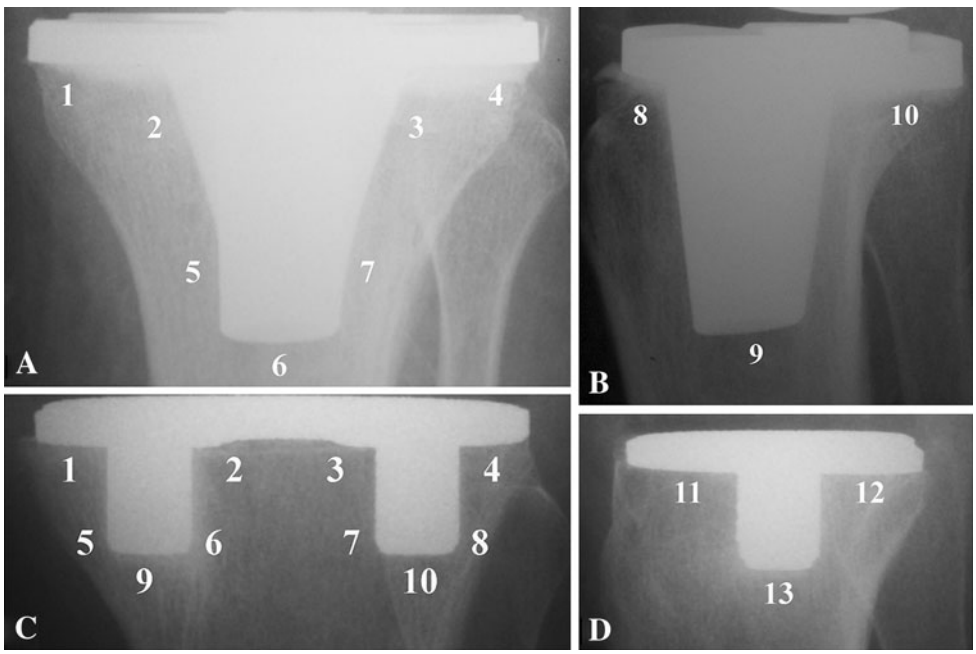

Fig. 2A–D Radiolucencies were analyzed following the KS criteria [26] and the modification proposed for uncemented pegged tibial components [66]. (**A**) The implant-bone interface zones are shown in this AP view of a stemmed cemented tibial component used in our study. (**B**) The zones are shown in this lateral view of the stemmed cemented tibial component. (**C**) The implant-bone interface zones are shown in the AP view of the uncemented tibial component used our study. (**D**) The implant-bone interface zones are shown in this lateral view of the uncemented tibial component.

acenocoumarol. All the patients readmitted for manipulation under general anesthesia achieved greater than 100° flexion with full extension, were discharged with a CPM machine for in-home use, and were prescribed a physical therapy program. Patients reporting patellar pain were treated successfully by patellar resurfacing. The patient with the infected arthroplasty was treated and underwent two revision surgeries, and the infection resolved but with an unsatisfactory functional result. In total, 10% of Group 1 patients and 14% of Group 2 patients underwent additional procedures (Table 4), most of which were the manipulations under anesthesia mentioned above.

Radiographic analysis showed no differences in radiologic alignment at 5 years between groups. Additionally, no changes in component position or osteolysis were observed during this time. Two patients in the Group 1 had progressive radiolucent lines under the anterior flange of the femoral component, but no patients in either group had progressive radiolucent lines around the tibial component or radiographically loose components.

Discussion

TKA fixation is a controversial issue with insufficient evidence to recommend one or another method of fixation [3]. Although some high-quality studies support the use of cemented implants [29, 49, 60, 61], others show that clinical and functional results and survivorship of uncemented prostheses are similar to those of cemented implants [3–5, 19, 33, 42, 43, 46, 62, 64]. New porous metal uncemented designs have the potential for greater osseous integration, which could reduce the rate of early aseptic loosening and provide a more durable biological fixation. However, potential drawbacks are the lack of experience with these implants and cost. In this study, we sought to evaluate pain, function, complications, and radiographic findings in a randomized trial that compared cementless with hybrid (cemented tibia, cementless femoral components) fixation in TKA. We attempted to obtain a relatively homogeneous study population, enroll a representative study population, and eliminate confounding variables as much as possible. We recruited only patients categorized "A" (unilateral disease) following the KS criteria proposed by Diduch et al. [12], excluding patients with bilateral and multiple-joint arthritis to limit the variables that may influence outcomes.

However, this also is one of the limitations of our study, impeding the generalization of results by excluding patients with bilateral involvement, with severe deformities, or alteration of bone density. Therefore it is not possible to extend the results to a population with knee osteoarthrosis. Another limitation of this study is the short-term 5-year followup of our series. Because most arthroplasty failures, and specifically those related to fixation, tend to begin near the 10-year mark, one must interpret our findings cautiously. We plan to follow this cohort of patients for 10 years and thus should be able to address this question. Another limitation may be the different design of the tibial components used in this study. The uncemented monoblock component is a two-peg design, whereas the cemented implant has a short, central stem. We chose the cemented stemmed design to obtain maximum stability and assure fixation of the tibial component [58]. Pegs could be less effective to counterweigh the forces of flexion and extension [23], and their placement requires much precision [30]. The monoblock component lacks the easy ability to adjust tension of ligaments by exchanging the polyethylene with different thicknesses [30]. Another limitation is the loss to followup of five patients in Group 1 (6%) and eight patients

Table 4. Complications and additional procedures

Complications and additional procedures	Group 1 Uncemented (Trabecular Metal™) (n = 71; %)	Group 2 Cemented (PMMA) (n = 64; %)	Group 1 versus Group 2	
			Effect size (95% CI)	p value
Complications	9 (12.6)	11 (17.1)	−4.51% (−17.26 to 7.73) 0.73 (0.32 to 1.66)	0.4
Deep vein thrombosis	2 (2.8)	2 (3.1)		
Postoperative stiffness	6 (8.4)	7 (10.9)		
Infection	0	1 (1.5)		
Patellar pain	1 (1.4)	1 (1.5)		
Additional procedures	7 (9.8)	9 (14.0)	−4.20% (−16.13 to 7.06) 0.70 (0.27 to 1.77)	0.4

n = patients attaining end point of study plus patients with complications or additional procedures during the controlled course and leaving the study before the end point; effect size = absolute (risk difference) and relative (risk ratio); PMMA = polymethylmethacrylate.

Table 5. Literature comparison between cemented and uncemented tibial components in TKA

Study	Design of study	Number of patients	Followup (years)	Results
Bassett [7]	Retrospective study comparing cemented versus uncemented Performance prosthesis (Biomet, Warsaw, IN, USA)	416 cemented versus 584 uncemented	5	Slightly higher KSS average cementless versus cemented
Nilsson et al. [44]	PRCT comparing cemented versus uncemented Tricon-M TKA (Smith & Nephew, Memphis, TN, USA)	25 cemented tibial component versus 20 uncemented	2	No significant difference in micromotion
Parker et al. [47]	PRCT comparing hybrid versus uncemented PCLR Miller-Galante I TKA (Zimmer, Warsaw, IN, USa)	48 cemented tibial component versus 52 uncemented	12.8	No significant difference in survivorship
Bertin [8]	Cohort study comparing stemmed cemented versus pegged cemented NexGen® tibial component (Zimmer, Warsaw, IN, USa)	84 stemmed versus 141 pegged	7	No significant differences in KSS and SF-12 scores, radiographic and survivorship results
Park and Kim [46]	Cohort study comparing stemmed cemented versus pegged uncemented NexGen® tibial component (Zimmer, Warsaw, IN, USA)	50 stemmed cemented in one side versus 50 pegged uncemented in the other side	14	No significant differences in WOMAC, radiographic results, complications, and survivorship
Henricson et al. [23]	Cohort study comparing stemmed cemented versus Trabecular Metal™ monoblock uncemented NexGen® tibial component (Zimmer, Warsaw, IN, USA)	21 stemmed cemented versus 26 Trabecular Metal™ monoblock uncemented, patients < 60 years	2	No significant differences in KSS score, radiographic results, and RSA migration
Dunbar et al. [14]	PRCT comparing stemmed cemented versus Trabecular Metal™ monoblock uncemented NexGen® tibial component (Zimmer, Warsaw, IN, USA)	21 stemmed cemented versus 28 Trabecular Metal™ monoblock uncemented	2	No difference in WOMAC. Trabecular Metal™ component at lower risk of loosening than cemented component
Minoda et al. [41]	CCS comparing BMD cemented PFC Sigma® RP versus Trabecular Metal™ monoblock uncemented NexGen® tibial component (Zimmer, Warsaw, IN, USA)	28 PFC Sigma® cemented versus Trabecular Metal™ 28 NexGen® uncemented	2	No differences in KS score. Lower decrease in BMD using Trabecular Metal™ component in comparison to cemented component ($p = 0.002$)
Kamath et al. [30]	Cohort study comparing stemmed cemented versus Trabecular Metal™ monoblock uncemented NexGen® tibial component (Zimmer, Warsaw, IN, USA)	312 stemmed cemented versus 100 Trabecular Metal™ monoblock uncemented, patients < 55 years	5–7	No significant differences in clinical or radiographic results, complications, and cost
Wilson et al. [67]	PCRT comparing stemmed cemented versus Trabecular Metal™ monoblock uncemented NexGen® tibial component (Zimmer, Warsaw, IN, USA)	18 stemmed cemented versus 27 Trabecular Metal™ monoblock uncemented	5	No difference in WOMAC. Inducible displacement Trabecular Metal™ significant higher than cemented. No difference in proportion at risk for aseptic loosening
Current study	PRCT comparing stemmed cemented versus Trabecular Metal™ monoblock uncemented NexGen® tibial component (Zimmer, Warsaw, IN, USA)	63 stemmed cemented versus 69 Trabecular Metal™ monoblock uncemented	5	Significant difference in clinical results

PRCT = prospective randomized control trial; PCLR = posterior cruciate ligament-retaining; CCS = case-control study; RSA = radiostereometric analysis; BMD = bone mineral density; KSS = Knee Society Score; KS = The Knee Society.

in Group 2 (11%). For this reason, we did not apply the intention-to-treat approach to this analysis, as it is possible only when complete outcome data are available for all randomized subjects. Clinical effectiveness may be overestimated if only available data analysis is included. Although Joshi et al. [28] did not give significance to the patients who missed followups, assuming they do not necessarily have poor results, in our study we generally observed poor results at the last evaluation the patients attended before they were lost to followup. Finally, an important limitation of this study is the small magnitude of differences between the two groups in the scores we used and the effect size achieved.

These small differences observed in the KSS and the WOMAC score seem to give a slight advantage to the group that received the cementless tibia. This tendency favoring cementless components has been observed by some authors in studies comparing cemented versus cementless implants (Table 5), although none of the differences observed in the comparison of these two types of implants attained statistical significance [7, 8, 14, 23, 30, 42, 46, 67]. In the same sense, the minor differences observed in our study, although being statistically significant, raise the question of their clinical significance and the relevance of using such expensive technology. To answer this question, we are doing a cost-effectiveness study of this population.

In terms of complications and reoperations, the rates we observed were all within the ranges suggested by Gandhi et al. in a meta-analysis [19]. There were a similar number of manipulations under anesthesia in both groups, therefore, one implant was not favored over the other.

Radiologically, the behavior of the uncemented porous tantalum tibial component has been as good as the conventional cemented component, as it has been shown by the radiostereometric analyses already performed [14, 23, 67]. The cementless porous tantalum component attains good and durable stability [67], with no progressive radiolucencies at the bone-implant interface observed on postoperative radiographs [20, 23, 30, 63], and a smaller risk of early aseptic loosening than that of cemented components [14, 67]. Fixation by osseointegration has been reported in the few reported revision cases of this implant [34, 55, 56]. We think that the absence of differences in radiologic data of our two groups, at a mid-term followup, agrees well with the small differences observed in the clinical outcomes, with an inconclusive clinical significance.

Based on our results with respect to pain, function, and fixation, we believe the uncemented monoblock porous tantalum tibial component may be a good alternative to a conventional cemented tibial component in cases similar to those included in our series. However, although the differences currently detected in our results are statistically significant, they were small and of uncertain clinical value to justify the choice of this type of implant in a TKA. We are continuing the study to determine whether these differences outweigh the cost of the implant and how they will be perform in the long-term.

Acknowledgments We thank A. Manchón MD, N. Lavilla MD, and J. Faixat MD, for performing the independent radiographic analysis, A. Labayen MA, for generating the randomization list and for help with the statistical analysis, and V. Querales MD, and N. Grau MSN, for assistance with management of patient documentation.

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