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Trabecular Metal Tibial Components Were Durable and Reliable in Primary Total Knee Arthroplasty: A Randomized Clinical Trial

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Abstract

Background Although highly porous metals have demonstrated excellent bone ingrowth properties and so are an intriguing option for fixation in total knee arthroplasty (TKA), some surgeons are skeptical about the durability of uncemented tibial fixation and the potential for soft tissues to adhere to these porous metals and perhaps cause knee stiffness or pain.

Questions/purposes The purpose of this study was to compare, in the context of a randomized clinical trial, a highly porous metal tibia compared with a traditional modular cemented tibia in terms of survivorship, Knee Society scores, range of motion (ROM), and complications.

Methods From 2003 to 2006, 397 patients (age 67.8 ± 8.7 years; 54% female) were randomized to three groups: (1) traditional modular cemented tibia; (2) cemented highly porous metal tibia; and (3) uncemented highly porous metal tibia. The same posterior-stabilized femoral component and patella component were cemented in every case. Stratified randomization was done for surgeon, patient's age, sex, and body mass index. Survivorship at 5 years was compared between the groups, as were Knee Society scores, ROM, and complications. Radiographic assessment included alignment, radiolucency, and implant migration/loosening. Patients were followed until death, revision, or for a minimum of 2 years (mean, 5 years; range, 2–9 years). Four patients were lost to followup before 2 years.

Results Highly porous metal tibias (both uncemented and cemented) were no different from traditional cemented modular tibial modular components in terms of survivorship at 5 years using a intention-to-treat analysis (96.8% [1]; 97.6% [2]; 96.7% [3]; $p = 0.59$). A per-protocol analysis revealed that no highly porous metal tibia was revised for aseptic loosening. Highly porous metal tibias performed comparably to traditional cemented modular tibias in terms of Knee Society scores, ROM, and the frequency of complications.

Conclusions At 5 years this randomized clinical trial demonstrated that highly porous metal tibias provided comparably durable fixation and reliable pain relief and restoration of function when compared with a traditional cemented modular tibia in TKA.

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

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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.

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Introduction

Cemented and uncemented tibial components are options for use in TKA. The use of cemented fixation in TKA is more common and has demonstrated durable long-term results [7]. Uncemented tibial components have been used over the last 30 years with some conflicting results regarding durability and reliability. In recent years uncemented fixation has become common for THA, and interest in uncemented fixation for TKA has reemerged among some surgeons. Highly porous metals have proved useful in complex revision TKA [9, 12] and are an attractive fixation option in primary TKA. The biomechanical properties of these materials (ie, lower modulus of elasticity similar to bone, possible decreased stress shielding, and higher porosity with improved friction fit, initial stability, and bone ingrowth) may help overcome shortcomings seen with previous uncemented tibial designs. Some surgeons, however, remain skeptical about the durability of uncemented tibial fixation, whereas others wonder whether soft tissues might adversely adhere to these porous metals and cause knee stiffness or pain [1, 7], and still others have voiced concerns with the use of highly porous metals in primary TKA pertaining to the possibility of difficult revisions and the cost of the implants.

This randomized clinical trial was done to assess the early durability and clinical reliability of a highly porous metal tibial component versus a traditional cemented modular tibial component in contemporary TKA. We specifically sought to answer the following questions: (1) Is TKA with an uncemented or cemented highly porous metal tibial component as durable as TKA with a standard cemented tibial component (as judged by 5-year survivorship)? (2) Is TKA with an uncemented or cemented highly porous metal tibial component as reliable clinically as TKA with a cemented tibial component (as judged by Knee Society pain scores, function scores, ROM, knee stiffness, complications, and reoperations)?

Patients and Methods

After institutional review board approval, we conducted a randomized clinical trial from August 2003 to May 2006. The sample size of the study was calculated to be 126 patients in each of the three arms of the trial to provide $> 80\%$ power to detect a difference in the proportion of significant lucent lines of 15% versus 30% between any two of the three groups ($\alpha = 0.05$, $\beta = 0.20$).

The inclusion criteria were patients aged 20 to 85 years who were candidates for unilateral TKA as treatment of end-stage knee disease secondary to degenerative or posttraumatic arthritis. The exclusion criteria included age < 20 years or > 85 years, severe deformity with $> 20°$ of varus, valgus or fixed flexion deformity, history of infection, significant neurological or musculoskeletal disorders, or disease that may adversely affect normal gait or weightbearing, metastatic disease, any congenital, developmental, or other bone disease or previous knee surgery that may interfere with total knee success (eg, Paget's disease, Charcot's disease), severe osteoporosis or previous high tibial osteotomy, presence of previous prosthetic knee replacement device, arthrodesis of the affected knee, and/or patients not undergoing patella resurfacing. During the period of this study, the overwhelming majority of patients at Mayo Clinic had the patella resurfaced at the time of TKA; on rare occasions, at the discretion of the operating surgeon, some young patients without patellofemoral arthritis did not receive patellofemoral resurfacing and those few patients were excluded from this study.

Four hundred eighty-three patients were assessed for eligibility during the study period, of whom 86 (18%) were excluded. Patients who met the inclusion criteria and agreed to participate in the study completed written informed consent. Three hundred ninety-seven were randomized into one of three groups: (1) traditional cemented modular tibia (n = 135 patients); (2) cemented nonmodular highly porous tibia (cement on baseplate, pegs uncemented as per original FDA approval) (n = 130 patients); or (3) uncemented nonmodular highly porous tibia (n = 132 patients) (Fig. 1).

Stratified randomization was performed using a computer program to dynamically balance the study groups for each surgeon on the basis of patient's age, sex, and body mass index. Eight patients were lost after randomization by postponing surgery or withdrawing participation. The final study group included 389 patients including 211 women and 178 men with a mean age of 68 years (range, 41–85 years). The mean body mass index was 31.8 kg/m^2 (range, 21.3–58.8 kg/m^2) (Table 1).

Of the 389 patients, 132 patients were allocated to the cemented traditional modular tibia component (Group 1), 128 to the cemented highly porous metal tibia (Group 2), and 129 to the uncemented highly porous metal tibia implant (Group 3). Some crossover after randomization did occur among the study groups and involved 10% of patients. The most common reason for crossover was an inventory problem related to a particular size of highly porous metal tibia being out of stock during surgery. With five surgeons operating on the same day occasionally, the hospital inventory of one size of porous metal tibia would be depleted. In keeping with contemporary guidelines for randomized clinical trial analysis, the effect of patient crossover was evaluated by a secondary review of our data using a per-protocol approach (Fig. 2).

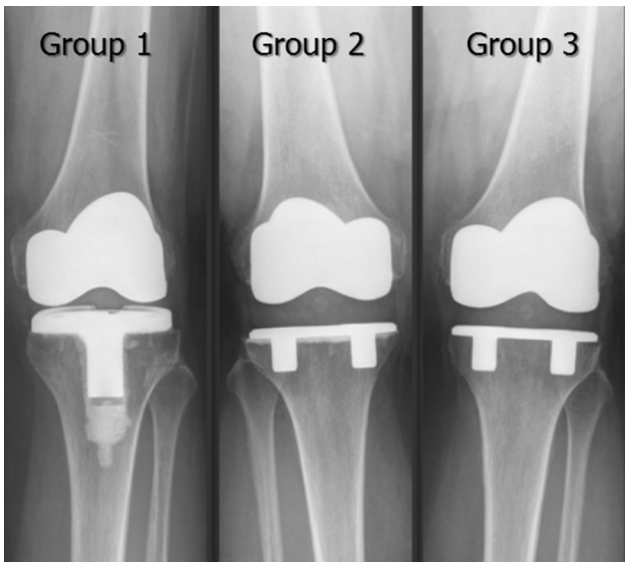

Fig. 1 Radiographic examples are shown of the three study groups: Group 1 (traditional cemented modular tibia); Group 2 (cemented nonmodular highly porous tibia, as per original FDA approval); Group 3 (uncemented nonmodular highly porous tibia).

Five surgeons with subspecialty training and interest in TKA (DGL, MJS, JS-S, ADH, MWP) performed all of the operative procedures. The NexGen® Legacy® Total Knee System (Zimmer, Warsaw, IN, USA) was used exclusively in this study. Legacy® posterior-stabilized femoral components and NexGen® all-polyethylene patella components were cemented in all patients. The tibial components used in this study were the NexGen® 3° modular fluted tibial tray in the traditional cemented modular group and a Trabecular Metal™ TM monoblock tibial component in the two highly porous metal groups. The patients in Group 2 (cemented highly porous metal nonmodular tibia) had the TM monoblock tibia fixed with cement under the tibial tray while the hexagonal tibial pegs were left uncemented; this combination of cemented undersurface-uncemented pegs conformed to the original FDA approval for the TM monoblock tray.

All TKAs were done with the tourniquet inflated using a standard paramedian incision, a medial parapatellar or subvastus surgical approach, tibial resection with an extramedullary guide, distal femoral resection with an intramedullary guide, and femoral rotation set parallel to the epicondylar axis. Intravenous antibiotic prophylaxis, mechanical and chemical prophylaxis for thromboembolic disease, antibiotics within the bone cement, and wound drains were used systematically. A comprehensive multimodal anesthesia and analgesia program based on peripheral nerve blocks was used in all groups. Structured physical therapy began with patients moved from the bed to the chair the day of surgery, progressed to walking weightbearing as tolerated the day after surgery (using a knee immobilizer if quadriceps weakness from the nerve block was present), and culminated with stairclimbing on Day 2.

Patients were asked to return for clinical examination and radiographs at 3 months, 1 year, 2 years, and 5 years after surgery. Preoperative and postoperative clinical function was assessed with the Knee Society Clinical Rating System with scores assigned for pain, function, and ROM. Preoperative and postoperative radiographs included standing weightbearing short AP films, lateral, and merchant views of the knee. Radiographic assessment was performed following the Knee Society Total Knee Arthroplasty Roentgenographic Evaluation and Scoring System. All radiographs were measured by one author (LP). For the evaluation of radiolucencies of the two-pegged trabecular metal tibial implants (Groups 2 and 3), we modified the Knee Society scoring system on the AP radiographs (Fig. 3).

Patients were followed until death, revision, or for a minimum of 2 years (mean, 5.2 years; range, 2–8.9 years). Four patients were lost before 2 years. The patients and surgeons were both blinded with regard to the group assignment before surgery. The patients were kept blinded to the type of prosthesis implanted for a minimum of 24 months after surgery.

Statistical Analysis

Data are summarized and reported using means (SD) for variables comprised of continuous data and count (percent) for categorical data. The analysis focused on comparing subjects in the three different study groups: traditional cemented modular tibia component (Group 1), cemented nonmodular highly porous metal tibia (Group 2), and the uncemented nonmodular trabecular metal tibia implant (Group 3). The primary analysis was performed based on the intent-to-treat principle in which subjects were analyzed according to the study groups in which they were randomized; patients who postponed surgery or withdrew participation were not included in this analysis, because their data were not available. A secondary analysis was performed using a per-protocol approach. Knee scores, ROM, and patient satisfaction were obtained from the 5-year followup; for those patients with < 5 years of followup, their most recent followup data were used. Outcomes based on continuous data (such as Knee Society scores and ROM) were compared using one-way analysis of variance. Categorical outcomes (including short-term perioperative complications) were compared using chi-square tests or Fisher's exact tests. Time to event outcomes, including long-term complications and revision, were evaluated using the method of Kaplan and Meier; groups were compared using log-rank tests. All statistical

Table 1. Demographic, functional, and surgical characteristics of study groups per protocol analysis

Demographics	Group 1 (N = 126)	Group 2 (N = 115)	Group 3 (N = 106)
Sex			
Female	71	58	51
Male	55	57	55
Age at surgery (years)			
Mean (SD)	68.4 (8.3)	67.6 (8.9)	68.1 (8.8)
Range	(42.0–85.0)	(42.0–85.0)	(41.0–84.0)
Height (cm)			
Mean (SD)	168.4 (10.6)	170.1 (10.1)	170.4 (9.1)
Median (range)	168 (141–195)	170 (148–195)	170 (145–193)
Weight (kg)			
Mean (SD)	90.5 (20.6)	93.5 (21.0)	91.3 (20.4)
Median (range)	86.5 (45–152)	90 (21–55)	89.5 (29–146)
Body mass index (kg/m^2)			
Mean (SD)	31.8 (6.5)	32.3 (6.6)	31.4 (6.3)
Median (range)	31.2 (21–54)	30.8 (21–55)	31.0 (10–52)
Preoperative function			
Knee Society pain score			
Mean (SD)	53.3 (14.8)	51.7 (16.4)	53.6 (14.5)
Median (range)	54 (10–80)	55 (3–94)	54 (2–80)
Knee Society function score			
Mean (SD)	49.9 (16.8)	54.4 (14.7)	54.9 (15.1)
Median (range)	50 (0–100)	50 (0–90)	50 (10–100)
Motion extension			
Mean (SD)	5 (10.8)	4.0 (9.5)	4.5 (4.6)
Motion flexion			
Mean (SD)	112.6 (14.9)	122 (9.5)	111.8 (12.7)
Surgical variables			
Tourniquet time (minutes)			
Mean (SD)	63.4 (31.9)	64.3 (30.5)	55.8 (30.4) p = 0.08
Operative time (minutes)			
Mean (SD)	129.7 (36.4)	125.3 (35.7)	123.8 (34.2) p = 0.40

Group 1 = traditional cemented modular tibia; Group 2 = cemented nonmodular highly porous tibia (as per original FDA approval); Group 3 = uncemented nonmodular highly porous tibia.

tests were two-sided and p values < 0.05 were considered significant. All analysis was conducted using SAS Version 9.2 (SAS Institute Inc, Cary, NC, USA).

Results

Survivorship at 5 years with revision for all causes as the endpoint was not different among the three groups (per-protocol analysis): 95.3% traditional modular cemented tibia, 96.5% cemented highly porous metal tibia, and 97.2% uncemented highly porous metal tibia; p = 0.552) (Fig. 4).

The 5-year cumulative risk of aseptic loosening of the tibial component was greater on the traditional cemented modular tibia group (3.1%) than in the highly porous metal tibia groups (0%) (p = 0.01) (Table 2). No highly porous metal tibia loosened during this study and fewer radiolucent lines were associated with highly porous metal tibial components than were associated with traditional cemented modular tibial components (p = 0.01) (Table 3).

Knee Society pain scores (p = 0.06), Knee Society function scores (p = 0.21), knee ROM (p = 0.09), and prevalence of knee stiffness (p = 0.5) were not different among the study groups (Table 3). The all-cause surgical

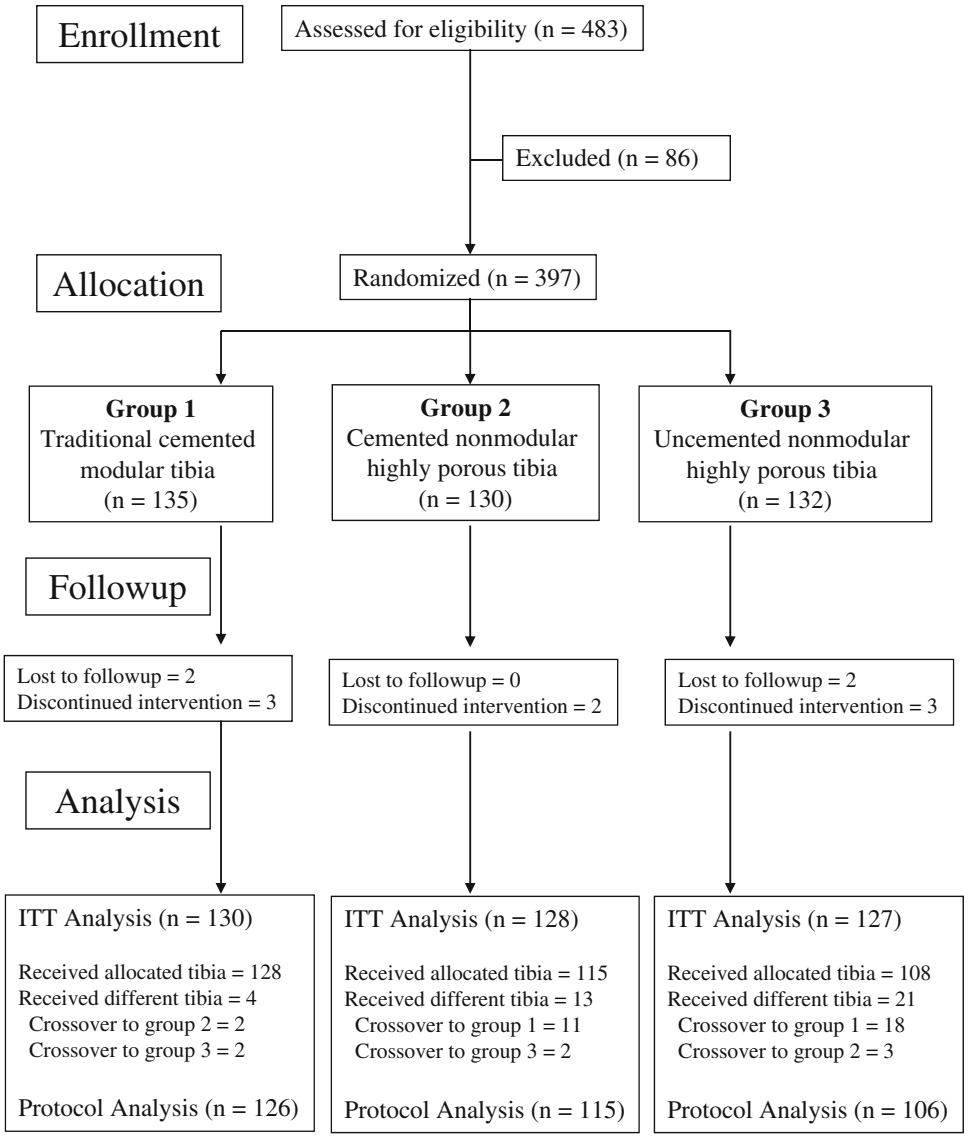

Fig. 2 Flowchart of the Consolidated Standards of Reporting Trials (CONSORT) 2010 is shown. ITT = intention to treat.

and medical complications and cumulative risk of reoperation were not different among these groups (Table 4).

Discussion

Over the last 30 years, cemented, cementless, and hybrid fixation options have been used with various TKA implant systems [7]. Cemented components are most widely used and are considered the most reliable method of fixation. With greater numbers of TKA being done in patients younger than 65 years of age, some surgeons may question whether those historically durable results with cement are widely applicable to today's patient undergoing TKA. Thus, some interest in cementless fixation in TKA has reemerged among surgeons in the last decade. It is notable that highly porous metals have found a useful role in the management of substantial bone loss in revision knee and hip arthroplasty [9, 12]. There is thus some logical basis for considering highly porous metal for fixation of the tibial component in primary TKA [5, 11]. This randomized clinical trial was done to answer the following questions: (1) Is TKA with an uncemented or cemented highly porous metal tibial component as durable as TKA with a standard cemented tibial component (as judged by 5-year survivorship)? (2) Is TKA with an uncemented or cemented highly porous metal tibial component as reliable clinically as TKA with a cemented tibial component (as judged by Knee

Society pain scores, function scores, ROM, knee stiffness, and all-cause complication and reoperation)? We found that survivorship, knee scores, ROM, complications, and reoperations were not different among the three study groups (traditional cemented tibial components, cemented tibial trays with cementless highly porous pegs, and entirely cementless highly porous tibial fixation) at a mean of 5 years.

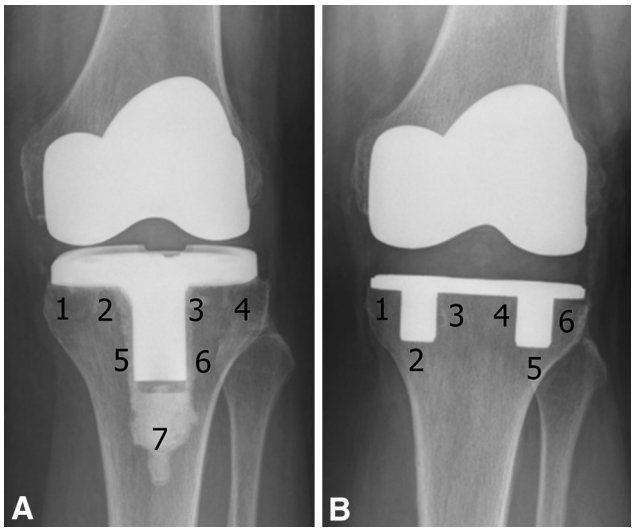

Fig. 3 A–B Radiographic assessment was performed following the Knee Society Total Knee Arthroplasty Roentgenographic Evaluation and Scoring System (**A**). For the evaluation of radiolucencies of the two-pegged trabecular metal tibial implants (**B**, Groups 2 and 3), we modified the Knee Society scoring system on the AP radiographs to assess for medial and/or lateral radiolucencies. The numbers represent the evaluation of radiolucent lines using the Knee Society Total Knee Arthroplasty Roentgenographic Evaluation and Scoring System.

This randomized clinical trial does have some limitations. First, despite the relatively large size of this trial, 389 patients, some events of interest including revision for all causes and revision or radiographic evidence of aseptic loosening are relatively uncommon. There is some risk that small differences between the groups thus might go undetected. With new implant designs, it is important to demonstrate safety and relative effectiveness in the early followup period and thus the trend in this study for the porous metal tibia groups to perform as well as the traditional cemented modular tibias is of value. Second, in any randomized clinical trial, there is the potential for crossover of patients from their assigned group to another group during the trial and that did occur in a subset of our patients, most often because a particular size porous metal tibial component was out of stock on the day of surgery. The porous metal tibial components are of a monoblock design and it is not difficult to envision the inventory issues that arose on days when all five of our surgeons were operating. The most commonly used porous metal tibia was in size 3 with a 10-mm polyethylene and the lack of availability of that implant was the source of most crossover in our study. We therefore analyzed data in this study using a contemporary intention-to-treat analysis and then followed that up with a secondary analysis of the groups per protocol to provide the reader with context in which to interpret our results.

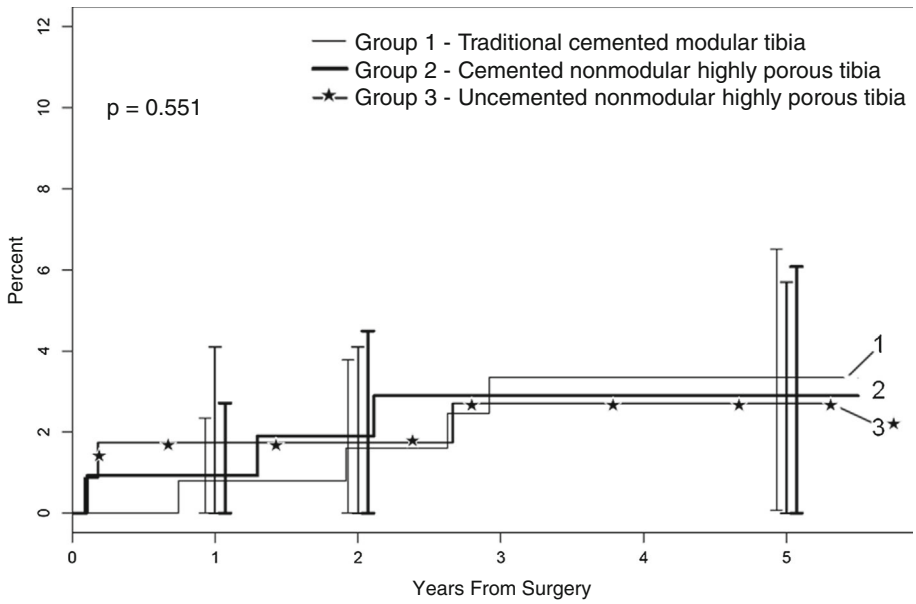

Fig. 4 Five-year cumulative probability for all-cause revision after primary TKA. Group 1 = traditional cemented modular tibia; Group 2 = cemented nonmodular highly porous tibia (as per original FDA approval); Group 3 = uncemented nonmodular highly porous tibia.

Table 2. Probability of reoperation and causes of failure after primary TKA

Reasons for revision	Group 1 (N = 126)	Group 2 (N = 115)	Group 3 (N = 106)
Femoral fracture	2 (1.6%)	0 (0%)	0 (0%)
Femoral loosening	2 (1.6%)	0 (0%)	0 (0%)
Tibial loosening	4 (3.1%)	0 (0%)	0 (0%)
Instability	1 (0.8%)	4 (3.5%)	1 (0.9%)
Deep infection	0 (0%)	2 (1.7%)	2 (1.9%)
Total	6 (4.7%)	4 (3.5%)	3 (2.8%)

Group 1 = traditional cemented modular tibia; Group 2 = cemented nonmodular highly porous tibia (as per original FDA approval); Group 3 = uncemented nonmodular highly porous tibia.

Our findings that a highly porous metal tibial component provided durable fixation at midterm followup is in agreement with most of the available data on this implant design at short- and midterm followup. Niemelainen et al. [13] reporting the registry-based data from Finland found that the uncemented trabecular metal tibial component was used in 1143 primary TKAs between 2003 and 2010 and had 7-year survivorship of 97% for all causes and 100% with aseptic loosening of the tibia as the endpoint. Neither patient age nor sex had an influence on durability of the trabecular metal tibia in that study from the Finnish Arthroplasty Registry. In a randomized clinical trial of 145 patients assigned to either an uncemented trabecular metal

Table 3. Clinical and radiographic results at the latest followup

	Group 1 (N = 126)	Group 2 (N = 115)	Group 3 (N = 106)	p value
Postoperative functional outcomes				
Knee Society pain score (points)				
Mean (SD)	88 (14)	92 (12)	89 (14)	0.06
Knee Society function score (points)				
Mean (SD)	67 (29)	72 (24)	72 (25)	0.21
Motion extension (degrees)				
Mean (SD)	0.0 (3.9)	0.1 (0.8)	0.3 (1.4)	0.69
Motion flexion (degrees)				
Mean (SD)	114.6 (14.1)	117.7 (11.4)	114.8 (10.9)	0.09
Change Knee Society pain score (points difference)				
Mean (SD)	35 (18)	41 (19)	36 (18)	0.02
Change Knee Society function score (points difference)				
Mean (SD)	16 (26)	19 (23)	18 (23)	0.61
Postoperative radiographic assessment				
Knee Society AP femur flexion (degrees)				
Mean (range)	95 (89.9–100.1)	94.7 (85.5–104.6)	94.9 (90.3–99.3)	
Knee Society AP tibia flexion (degrees)				
Mean (range)	89.9 (82.3–95.9)	89.7 (84.8–94.2)	90.0 (85.1–94.5)	
Knee Society total valgus angle (degrees)				
Mean (range)	4.9 (178–192.7)	4.4 (174.9–193.6)	4.9 (175.6–191.8)	
Knee Society lateral femur flexion (degrees)				
Mean (range)	4.7 (−5.0 to 14.7)	5.1 (0.0–0.5)	5.2 (0.0–11.9)	
Knee Society lateral AP tibia flexion (degrees)				
Mean (range)	84.9 (78.9–93.4)	84.5 (76.5–91.1)	83.6 (75.2–90.0)	
Nonprogressive medial radiolucent lines				
Yes	13 (11%)	4 (3%)	2 (2%)	0.01
No	113 (89%)	111 (97%)	104 (98%)	
Nonprogressive lateral radiolucent lines				
Yes	9 (8%)	2 (2%)	1 (1%)	0.01
No	117 (92%)	113 (98%)	105 (99%)	

Group 1 = traditional cemented modular tibia; Group 2 = cemented nonmodular highly porous tibia (as per original FDA approval); Group 3 = uncemented nonmodular highly porous tibia.

Table 4. Surgical and medical complications of all study groups

	Group 1 (N = 126)	Group 2 (N = 115)	Group 3 (N = 106)
Postoperative surgical complications			
Wound drainage or delayed healing	4 (3.1%)	8 (7.0%)	5 (4.6%)
Arthrofibrosis	4 (3.1%)	5 (4.3%)	5 (4.6%)
Patellar crepitus and Clunk syndrome	2 (1.6%	0 (0.0%)	1 (0.9%)
Contained hematoma	1 (0.8%)	3 (2.6%)	2 (1.9%)
Deep periprosthetic joint infection	0 (0.0%)	2 (1.7%)	2 (1.9%)
Femoral aseptic loosening	2 (1.6%)	0 (0.0%)	0 (0.0%)
Tibial loosening	4 (3.1%)	0 (0%)	0 (0%)
Instability	1 (0.8%)	4 (3.5%)	1 (0.9%)
Femoral periprosthetic fracture	2 (1.6%)	1 (0.9%)	0 (0.0%)
Patella periprosthetic fracture	1 (0.8%)	0 (0.0%)	0 (0.0%)
Postoperative medical complications			
Deep vein thrombosis	3 (2.3%)	8 (7.0%)	5 (4.6%)
Pulmonary embolism	3 (2.3%)	3 (2.6%)	1 (0.9%)
Myocardial infarction	0 (0.0%)	0 (0.0%)	1 (0.9%)
Atrial fibrillation	0 (0.0%)	1 (0.9%)	1 (0.9%)
Gastrointestinal bleeding	0 (0.0%)	0 (0.0%)	1 (0.9%)

Group 1 = traditional cemented modular tibia; Group 2 = cemented nonmodular highly porous tibia (as per original FDA approval); Group 3 = uncemented nonmodular highly porous tibia.

tibia or a traditional modular cemented tibia, Fernandez-Fairen et al. [3] found no difference in durability at 5 years. At a minimum 5 years followup, a prospective analysis of 100 patients aged < 55 years with an uncemented trabecular metal tibia by Kamath et al. [6] found 97% survival for all causes and 100% survival with aseptic loosening of the tibia as the endpoint. Also at 5 years followup, a matched-cohort study of uncemented trabecular metal tibia versus a traditional cemented modular tibia was done in Japan by Minoda et al. [10]. They used dual x-ray absorptiometry in addition to plain radiographs for assessment of implant migration and bone density. In that study, the bone density in the proximal tibia was better preserved in the trabecular metal group and the durability was the same at 5 years. Dunbar et al. [2] studied the early clinical and radiostereometric analysis (RSA) results in a randomized clinical trial comparing an uncemented trabecular metal tibial component versus a cemented implant. Complete followup and RSA analysis were available in 28 of the uncemented trabecular metal group and 21 of the cemented group. They reported no failure or revisions at 24 months postoperatively. The use of the RSA technique allowed them to measure migration of the implants with a high degree of accuracy. They showed that the TM group migrated slightly in the initial postoperative period and then stabilized at 1 year postoperatively. The TM group had no liftoff and zero risk of aseptic loosening (defined as the change in the maximum total point motion of > 0.2 mm between 12- and 24-month groups). In contrast, Meneghini and de Beaubien [8] reviewed 106 uncemented trabecular metal tibias done in 91 patients at a minimum of 2 years followup (mean, 3.4 years) and found nine failures, all of which followed a characteristic pattern. Those failures typically occurred in heavy, tall, male patients and involved the tibial component collapsing into varus at a mean of 18 months postoperatively. In some cases the trabecular metal component was well fixed in the lateral tibia and there was a fatigue fracture through the implant itself. In our randomized clinical trial, we had no failures of this highly porous metal tibia from migration or loosening and specifically did not observe the pattern reported by Meneghini and de Beaubien. It is of interest that our group of patients with an uncemented porous metal tibia did include patients across a wide age range (mean, 68 years; range, 41–84 years); a wide range of body mass index (mean, 31 kg/m^2; range, 21–52 kg/m^2); and a male over female predominance suggesting that our patient cohort likely included a substantial number of the types of patients that Meneghini and de Beaubien suggested were at risk.

We found that TKA with a highly porous metal tibial component provided reliable clinical outcomes as assessed by clinical outcomes scores, ROM, prevalence of stiffness, and prevalence of complications at 5 years when compared with a traditional cemented modular tibial component and that is in general agreement with the preponderance of data available at midterm followup from other centers. The randomized clinical trial done by Fernandez-Fairen and colleagues reported higher Knee Society scores and better WOMAC scores at 5 years with an uncemented trabecular metal tibial component versus a traditional cemented modular tibial component [3]. The magnitude of those reported differences was relatively small and the clinical implications of those small differences can be debated but are likely best characterized as trivial. Those authors found no difference in complications or reoperations. The prospective study of Kamath et al. found no difference in Knee Society scores between the patients in the uncemented trabecular metal group and a cohort of patients with a traditional cemented modular tibia with both groups reporting excellent pain relief and a high level of function consistent with the expectations for modern TKA [6]. There was no difference in the risk of knee stiffness, reoperation, or complications in that study. The report by Niemelainen et al. of the Finnish Registry data with uncemented trabecular metal tibias does not include clinical followup data but does stratify the revision and reoperation data by patient age [13]. In that analysis, there was no difference in the

reliability of the uncemented trabecular metal tibia at 1 year or 5 years based on patient age as stratified into three categories, namely age < 55 years, age 55 to 65 years, and age > 65 years with > 97% survival free of reoperation in each group. Minoda et al. from Japan performed a matched-pair cohort study of patients with an uncemented trabecular metal tibia compared with a group with a traditional cemented modular tibia using age, sex, weight, height, and diagnosis as the matching criteria [10]. At 5 years followup, there were no differences between the groups in terms of clinical scores as assessed by the Knee Society score, no differences in final ROM, and no differences in regard to component migration or the risk of periprosthetic fracture. The 6-year minimum followup results in 105 patients with an uncemented trabecular metal tibia was reported by Ghalayini et al. [4] and in that group, the clinical outcomes were assessed with the Oxford knee score, the Knee Society scores, and the SF-12 physical rating scale. Those authors characterized the clinical results at 6 years as performing as well as any TKA design at an equivalent length of followup. There were a total of three reoperations in that cohort including two deep prosthetic infections treated with débridement and component retention and one revision for unexplained pain.

In conclusion, most, but not all, available scientific literature at 5 years supports the contention that highly porous metal tibial components are reliable and durable in contemporary TKA. Further study is warranted to determine if the clinical and radiographic results in this study and the durability predicted through the RSA work of others [2] do prove true into the second decade of clinical use. In this randomized clinical trial, we did find that highly porous metal tibial components provided durable fixation and reliable clinical outcomes at 5 years when compared with a traditional cemented modular tibial component.

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