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Clinical Results in Posterior-Stabilized Total Knee Arthroplasty with Cementless Tibial Component in Porous Tantalum: Comparison between Monoblock and Two Pegs vs. Modular and Three Pegs

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Abstract: Nowadays, total knee arthroplasty (TKA) is widely considered to be the gold standard for treatment of end-stage knee osteoarthritis. Although the optimal mode of fixation in TKA continues to be an important area of investigation, cementless fixation offers the possibility to gain biologic fixation, preserve bone stock and mineral density, and potentially improve survivorship. The purpose of this retrospective study was to evaluate the clinical results of a posterior-stabilized total knee arthroplasty with cementless tibial component in porous tantalum, comparing two groups: Group A (30 patients), TKA with a monoblock component and two pegs, and Group B (22 patients), with a modular component and three pegs. Knee Society Score (KSS) and the Knee Injury and Osteoarthritis Outcome Score (KOOS) were submitted to the patients, and radiographs were collected at the last follow-up. The mean follow-up was 26.32 (20–40) months. Significant differences were not detected between the postoperative KSS values in the two groups ($p = 0.44$). Evaluating KOOS outcomes, we found in Group A that the rating system showed a statistically significant improvement from a preoperative average rating of 51.4 (SD ± 15) to an average of 72.66 (SD ± 19) at final follow-up ($p < 0.05$). In Group B, the KOOS rating system showed a statistically significant improvement from a preoperative average rating of 48.3 (SD ± 18) to an average of 79.54 (SD ± 17) postoperatively ($p < 0.05$). Comparing KOOS final outcomes between groups, we found no statistically significant difference at the mean final follow-up ($p = 0.20$), with the exception of the sport-related section ($p < 0.05$). Radiological evaluation at the final follow-up did not show any sign of polyethylene wear, radiolucency, septic or aseptic loosening, or change in alignment in either group. The current study demonstrates an excellent survivorship of cementless tibial components in porous tantalum and the possibility of osseous integration, without significant differences between the two groups under investigation.

Keywords: knee; total knee arthroplasty; tantalum; trabecular metal

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1. Introduction

Total knee arthroplasty (TKA) has become the procedure of choice in knee arthritis nonresponsive to conservative treatment, with an anticipated increase in demand over time [1]; to this end, survivorship of these constructs is the goal of most recent studies. Furthermore, TKA is increasing in prevalence among younger and more active patients with longer life expectancy, and this projection likely will continue in the coming years. Therefore, maximizing the survivorship of the prosthesis is nowadays a firm point of emphasis, and reconstructive surgeons are handling the problem to provide long-lasting implants to this high-demanding population [2]. Currently, cemented fixation for TKA is considered as the gold standard, due to the optimal clinical outcomes and prosthesis survivorship in long-term follow-up. Despite this, recent studies have demonstrated that the increasing number of TKAs implanted worldwide is associated with a concomitant increase in procedures of revisions, with mechanical loosening still considered the leading cause of aseptic failure, catalyzing the need for further surgery from primary to revision TKA. Cemented TKA is thought to be at increased risk of this complication due to a lack of biologic fixation, leading to loosening in the implant cement and at the cement–bone interfaces over time [1–4].

Biological fixation using uncemented components has the theoretical capability to tackle some of these challenges [3]. In fact, the introduction of modern biomaterials and new designs has led to a reemerged interest in uncemented fixation: porous tantalum monoblock tibial components were proposed, mostly for young and active patients, as components for TKAs some years ago, with the goal to improve the survivorship of the prosthesis and to decrease the percentage of biomechanical failures due to the presence of two interfaces in cemented implants [5]. The use of porous metals, such as titanium and tantalum, has led to greater coefficient of friction and a reduction in Young's modulus mismatch of the surface between the host bone and the implant [6]. Tantalum shows excellent compatibility from a biological perspective: its ability to form a self-passivating surface oxide layer leads to the formation of a bone-like apatite coating, resulting in excellent bony ingrowth, allowing rapid and substantial bone attachment, and avoiding the unsatisfactory results of first-generation designs [5–7].

The purpose of this study is to evaluate the short-term functional results of patients and the survivorship of the prosthesis after primary TKA, comparing two different cementless tibial components, both in tantalum.

2. Material and Methods

We retrospectively evaluated the records of patients who underwent primary TKA using a tantalum tibial component, totaling 52 consecutive patients between January 2017 and April 2018. Two groups were identified based on the different tibial component implanted. In 30 patients (Group A), a three-peg modular trabecular metal technology (TMT) component was implanted, and in 22 patients (Group B), a two-peg monoblock TMT component was chosen. The choice of implant depended on surgeon preferences. In Group A, the ultrahigh-molecular-weight polyethylene (UHMWPE) is mechanically locked into the tibial metal baseplate, and the inferior side of the baseplate reveals the presence of two hexagonal pegs that engage the area of highest tibial bone density (in line with the condylar loading), plus a central boss for the lock down screw (Figure 1). In Group B, there is a direct compression molding of the UHMWPE into the tibial metal baseplate, and the central boss is not present (Figure 2). The two cohorts were homogeneous in terms of diagnosis (all primary osteoarthritis), sex (all women), mean age, side of the involved knee, size of the tibial component, and thickness of the UHMWPE. Exclusion criteria were rheumatoid/inflammatory arthritis, TKA revision, post-traumatic arthritis, previous osteotomies, age > 80 years old, severe osteoporosis, and severe varus/valgus deformities (overall limb alignment more than 20°). The study protocol was in accordance with the Declaration of Helsinki for human research. Informed consent was obtained from all patients.

Figure 1. Three-peg modular TMT tibial component.

Figure 2. Two-peg monoblock TMT tibial component.

Preoperative planning was made in all cases on plain radiographs with different views: anteroposterior and lateral of the knee, weight-bearing telemetry of the affected limb, and skyline of the patella. Preoperatively, the Knee Society Score (KSS) and the Knee Injury and Osteoarthritis Outcome Score (KOOS) were submitted to the patients. All the knee arthroplasty surgeries were performed only by experienced orthopedic surgeons. In all patients, a tourniquet was inflated before skin incision, and it was released before the suture; the chosen approach was the medial parapatellar. Resections of the proximal tibia and the distal femur were performed according to the mechanical alignment concept, which aims to place the femoral and tibial component perpendicular to their mechanical axis. After establishment of the tibial cutting platform and resection of the proximal tibia, the appropriate size (i.e., the one that provides the desired bony coverage) was selected with respect to the anatomical landmarks, the holes were drilled in straight (an angulation of the holes may prevent from proper seating), and the definitive component was inserted by hammering firmly with the knee fully flexed and the tibia advanced forward. The femoral component was cemented in all cases; patellar resurfacing was never performed. Before closure in layers, one closed suction drainage was used and removed after 36 h in all the procedures. Two boluses of 10 mg/kg of tranexamic acid were administrated intraoperatively and two hours after surgery; postoperatively, all patients were given mechanical and pharmacological prophylaxis for deep vein thrombosis and underwent the same postoperative rehabilitation protocol. Weight-bearing as tolerated was permitted from day 1 after surgery. Postoperative clinical evaluations with the above-mentioned scores were performed at 1, 3, 6, and 12 months follow-up and annually thereafter; radiographs were collected at the last follow-up to identify any signs of polyethylene wear, radiolucency, septic or aseptic loosening, and change in alignment (Figures 3 and 4).

Figure 3. Radiographic image of a TKA using a three-peg modular TMT tibial component.

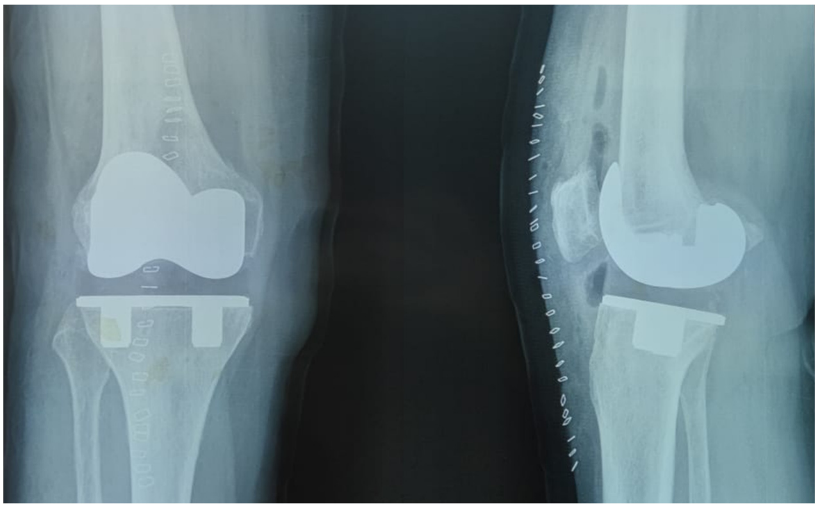

Figure 4. Radiographic image of a TKA using a two-peg monoblock TMT tibial component.

All statistical analyses were performed using MedCalc Version 18.2.1. The quantitative variables were analyzed using Student's *t*-test and the qualitative variables were compared by univariate analysis using the chi-squared test. A *p*-value of less than 0.05 was considered statistically significant.

3. Results

The mean age was 68.14 for Group A and 70.09 for Group B (p = 0.54). The tibial component size ranged from 3 to 5 (size 3 in eighteen cases, size 4 in ten cases, size 5 in two cases) in Group A and from 3 to 5 in Group B (size 3 in fourteen cases, size 4 in two cases, and size 5 in four cases) (p = 0.09). The UHMWPE insert size ranged from 10 mm to 12 mm in both groups: in Group A, we choose 10 mm in 20 cases and 12 mm in the remaining 10 cases; in Group B, we used a 10 mm insert in 20 cases and a 12 mm insert in the remaining two cases (p = 0.04). The right side was involved in 16 cases in Group A and in 14 cases in Group B; the left side was involved in the remaining 14 cases in Group A and in eight patients of Group B (p = 0.45). The mean follow-up was 26.32 months (20–42), with 28.4 months (SD ± 4) for Group A and 23.1 months (SD ± 4) for Group B (p = 0.04). The mean surgical time was 102′ (SD ± 26) in Group A and 100′ (SD ± 12) in Group B (p = 0.81). The KSS in Group A improved from 45.25 (SD ± 3) preoperatively to 73.66 (SD ± 17) postoperatively (p < 0.05). In Group B, the improvement was from 47.29

(SD ± 6) preoperatively to 76.9 (SD ± 9) postoperatively ($p < 0.05$). Significant differences were not detected between the postoperative KSS values in the two groups ($p = 0.44$). Evaluating KOOS outcomes, we found in the group using a three-peg modular TMT tibial component that the rating system showed a statistically significant improvement from a preoperative average rating of 51.4 (SD ± 15) to an average of 72.66 (SD ± 19) at final follow-up ($p < 0.05$). In the group using a two-peg monoblock TMT tibial component, the KOOS rating system showed a statistically significant improvement from a preoperative average rating of 48.3 (SD ± 18) to an average of 79.54 (SD ± 17) postoperatively ($p < 0.05$). Comparing KOOS final outcomes between groups, we found no statistically significant difference in the mean final follow-up ($p = 0.20$), with the exception of the sport-related section ($p < 0.05$). Radiological evaluation at the final follow-up did not show any sign of polyethylene wear, radiolucency, septic or aseptic loosening, or change in alignment in either group. Two cases with minor complications were registered in Group A, one case of delayed wound healing and one case of lymphangitis ($p = 0.21$). Demographic and clinical information are summarized in Table 1, and KOOS results in Table 2.

Table 1. Demographic and clinical information.

	Group A	Group B	*p*-Value
Age (n)	68.1 ± 5	70.8 ±7	0.28
Follow up (months)	28.4 ± 7	23.1 ± 4	<0.05
Surgical time (minutes)	102 ± 26	100 ± 12	0.81
Preoperative KSS	45.06 ± 3	47.29 ± 6	0.12
Postoperative KSS	73.66 ± 17	76.9 ± 9	0.44
Preoperative KOOS	51.4 ± 15	48.3 ± 18	0.31
Postoperative KOOS	72.66 ± 19	79.54 ± 17	0.20
Complications (n)	2	0	0.21

Table 2. Postoperative assessment of KOOS values.

	Group A	Group B	*p*-Value
KOOS symptoms	78.26 ± 20	79.6 ± 16	0.84
KOOS pain	80.53 ± 18	85 ± 19	0.40
KOOS ADL	79.73 ± 19	83.63 ± 19	0.47
KOOS sport	61.4 ± 28	78 ± 26	<0.05
KOOS QOL	65.8 ± 28	73.27 ± 19	0.29
KOOS total	72.66 ± 19	79.54 ± 17	0.20

4. Discussion

TKA is considered a cost-effective surgical procedure that can lead to a significant improvement in performing daily activities among patients affected by knee osteoarthritis in whom conservative treatments had previously failed. As surgeons, we are aware that TKA in high-demanding patients will continue to increase in numbers and that we must focus our attention to use long-lasting and well-performing joint replacements. Several factors are associated with longevity of knee implants; the design of the implant and the method of fixation to the bone are among the most relevant from a mechanical point of view. The components of the prosthesis should allow mobility and grant stability with respect to the normal kinematics and without peaks of stress on the polyethylene surface and constraint forces on the tibial baseplate [2].

The results of our study demonstrate mid-term longevity of both groups of tibial components without loosening signs on radiographs or clinical instability. Cemented fixation in TKA has excellent long-term results and is the most-used technique worldwide, but the longevity of cemented fixation also depends on an accurate technique and factors related to the patient. The bone–cement interface lacks the ability to remodel and becomes vulnerable to mechanical debonding with cyclical loading; the aseptic loosening of cemented components is strictly dependent on these two factors [3]. On the other hand, cementless fixation offers the possibility to obtain a direct and biologic fixation, contributes to preserve more bone stock, and eventually positively influences the survivorship of the implant. In fact, in clinical practice, the surgeon's preference and experience play the most important roles in the final decision to use TKAs with cemented or cementless fixation [8,9].

Other theoretical advantages of cementless fixation include shorter surgical time and the absence of debris from loose cement particles that may act as a foreign third body [3]. The cementless porous metal component, promoting osseous integration while interlocking with the surrounding bone, should consequently reduce the risk of periprosthetic osteolysis. This was not observed in our patients in the present study, due to the hypothesis that direct contact between the component and the host bone might be a superior barrier to particle migration compared with cement fixation, eventually also with an additional contribution given by a monoblock implant design (with the advantages of no risk of backside wear) [10].

In the past, poor designs of the uncemented baseplates have shown high rates of mechanical aseptic loosening and subsequent failure of the tibial component due to frequent and progressive radiolucencies at the implant–bone interface. The first-generation cementless prostheses revealed some problems related to their ineffective osteoconductive surfaces, inaccurate geometry, and inadequate properties for an early metal-to-bone interlocking, thus leading to the appearance in radiological images of the characteristic lines below the tibial component, indicative of an inadequate and unstable immediate fixation [11]. It is evident that these initial implant designs were not able to immediately provide adequate stability of the cementless tibial baseplate, a factor that is crucial for subsequent biologic ingrowth [12]. Recent advances in cementless TKA designs have shown successful results at mid- to long-term follow-up, demonstrating percentages of survivorship of more than 90%. Salem et al. [2], in a recent metanalysis of the literature, reported that cementless TKA had a better survivorship compared with cemented fixation when all causes of failure were considered.

Porous tantalum is a biomaterial with outstanding biomechanical properties in orthopedics fields that was introduced to clinical practice several years ago; thank to its high coefficient of friction (μ = 0.88), this porous material has the capability to enhance the desired initial fixation and to reduce micromotion and stresses at the interface between the implant and the host bone. Its structure in fully interconnected pores (550 μm) provides a high volumetric porosity (average 80%), and its modulus of elasticity (2.5–3.9 GPa) appears similar to cancellous bone: both peculiarities permit an enhancement of the potential for bone ingrowth and produce a physiologic load transfer and diminished stress shielding. It allows a stable mechanical surface between implant and surrounding bone in the short term (primary stability) and supports osseointegration in the medium and long term. These enhanced bioactive characteristics optimized for bone ingrowth have led to excellent clinical and radiographic results in both primary and revision total hip and knee arthroplasty [5].

Last but not least, cutaneous and systemic hypersensitivity reactions to metals have been identified as emerging concerns in patients with knee arthroplasties, even if allergies against implant materials are still a rare and not well-known problem; thus, TMT, together with alumina ceramic composites, have been proposed as prosthetic knee components due to their excellent immunochemical biocompatibility [13].

Harwin et al. reviewed a modern TKA design, cementless with screws and where a coating of hydroxyapatite is applied to enhance the potential for immediate biologic rigid fixation of the tibial baseplate, which has shown a survivorship of 99% at a mean follow-up of 4 years [14]. In a randomized control trial, Beaupre et al. evaluated the same modern design comparing different tibial components, one cementless coated with hydroxyapatite versus one cemented baseplate, demonstrating equivalent outcomes at 5 years [15]. Nowadays, with more advanced technologies than in the past, the development of new implants using highly porous components has avoided the need for additional screws in the tibial baseplate fixation and has proven to allow immediate implant stability [12].

One of the exclusion criteria was the presence of rheumatoid arthritis, due to the fact that the bone density could be compromised [16]. However, Patel et al., evaluating 126 cementless TKAs in a retrospective case series at a mean follow-up of 4 years in patients affected by rheumatoid arthritis, reported that implant survivorship—the primary outcome of interest—was 99.2%, with one aseptic failure. Clinical outcomes, postoperative complications, and radiographic evaluations, performed annually, were also recorded: mean extension was 2 degrees and mean flexion was 124 degrees; pain and function scores were 92 and 84 points, respectively, on average. There were no surgical complications in any patients. In addition, no evidence of progressive radiolucency, loosening, or subsidence was noted, with the exception of the single aseptic failure. Such interesting results from this scientific report demonstrate outstanding survivorship and excellent clinical and radiographic outcomes of cementless TKAs also in patients with rheumatoid arthritis [17].

Another exclusion criterion was age over 80 years old, because elderly people often suffer severe osteoporosis. Nevertheless, two different studies conducted in patients over 75 years old demonstrated favorable clinical and radiographic outcomes of cementless TKA even in this population. In fact, according to a retrospective review by Dixon et al., where 135 patients operated on by a single surgeon and aged 75 years or greater had been included, elderly patients who underwent TKA with a cementless implant performed just as well as their younger counterparts, whether a hydroxyapatite-coated, posterior cruciate-retaining, or stemless prosthesis was used [18]. The study of Newman et al. also retrospectively revealed no cases of implant loosening, subsidence, or progressive radiolucency at the radiographic evaluation at the final follow-up of 8 years in 134 patients over 75 years of age who underwent cementless TKA. Additionally, the mean pain score was 93 points (range, 80–100) and the mean function score was 84 points (range, 70–90) [19].

The present study has some limitations: first, it is a report of a small sample size and with a short follow-up, in the absence of a control group of patients with cemented TKA. However, this has ensured that all the patients were eligible at the final follow-up. Second, on radiographs, we have not measured biomechanical parameters such as vertical hip–knee–ankle alignment and tibial mechanical angle in the coronal plane, and posterior femoral condylar offset and tibial slope in the sagittal plane.

Our results clearly support findings reported in other recent studies, with satisfactory functional scores, especially given our young patient population with high functional demands, activity levels, and possibly different expectations surrounding surgery. In both groups of our study, there was a significant postoperative increase in KOOS and KSS compared to the preoperative scores, without statistically significant differences between the two groups. Our findings confirm that implant design processes and manufacturing technologies have advanced significantly, improving biologic fixation and facilitating durable osseointegration through ingrowth.

Two cases with minor complications were registered in our study in Group A, one case of delayed wound healing and one case of lymphangitis ($p = 0.21$), while radiological evaluation at the final follow-up did not show any signs of polyethylene wear, radiolucency, septic or aseptic loosening, or change in alignment in both groups. Periprosthetic joint infection remains one of the most devastating complications of joint replacement surgery, and it constitutes an economic burden, both on patients and on society; the potential of using antibiotic-infused bone cement in primary cemented fixation may be an argument for its clinical superiority, but it must be underlined that tantalum components are associated with a lower incidence of infection [7,20]. In fact, in our experience, we have not found cases of periprosthetic infection; nevertheless, a recent review has demonstrated no significant difference in infection rates between cemented and cementless fixation, a finding supported by other systematic reviews [11].

A limitation of our study is the short follow-up and its significant difference between the two groups. However, aseptic loosening due to lack of immediate fixation is typically an early complication that was not observed in any of our patients. Therefore, we think that the difference in follow-up between the two groups, although significant, does not have any influence on our results.

In conclusion, the current study showed excellent mid-term survivorship, consistent with previous findings, and the possibility of metal-to-bone integration may indeed make cementless porous tibial implants preferable for active patients, with a clear improvement in the quality of life in subjects suffering from degenerative diseases such as osteoarthritis, even if the need for a more individualized approach in TKA should be pursued. Further studies with larger cohorts and longer follow-up are needed to demonstrate the superiority of this implant compared to conventional ones.

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Informed Consent Statement: Informed consent was obtained from all subjects involved in the study.

Data Availability Statement: The data presented in this study are available on request from the corresponding author.

Conflicts of Interest: The authors declare no conflict of interest.

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