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KNEE ARTHROPLASTY

Epiphyseal fixation in revision total knee arthroplasty: a comparison between trabecular metal and titanium augments

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Abstract

Introduction The purpose of this retrospective study was to compare the medium-term clinical and radiographic outcomes of two series of patients treated for revision TKA: one implanted with trabecular metal (TM) augments and one implanted with classic titanium augments.

Materials and methods A total of 85 patients with a type 2 AORI defect underwent revision TKA and were treated either with TM epiphyseal augments directly screwed in the bone or with traditional titanium augments. There were 46 patients in the TM group and 39 patients in the titanium group included in the study. All the patients received the same varus-valgus constrained implant and no metaphyseal fixation devices were used.

Results After a mean follow-up of 66.4 months, no statistically significant difference was observed in terms of failure for aseptic loosening between the two groups (4% in the TM group and 7.8% in the titanium group, $p=0.35$). The ten-year survival using aseptic loosening as endpoint was 90.5% (95% CI 94.1–98.6) in the TM group and 85% (95% CI 101.9–119.3) in the titanium group ($p=0.26$). A statistically significant difference was detected for the presence of RLL. No RLL were found under the studied TM augments compared to 13.7% of the titanium augments ($p=0.01$).

Conclusion The use of TM augments directly screwed to the epiphysis of the femur and the tibia reduced the incidence of RLL compared to standard titanium augments during revision TKA with promising medium-term results.

Keywords Revision total knee arthroplasty · Trabecular metal · Augment · Aseptic loosening

Introduction

Revision total knee arthroplasty (TKA) is a complex surgical procedure which presents several technical challenges. In particular, the presence of bone loss can make reconstruction and fixation difficult to achieve [1]. Solid fixation of revision implants is essential to allow early post-operative mobilization and rehabilitation, and to improve the longevity of the construct [2, 3].

However, in most revision TKAs and in all re-revisions, the epiphyseal zone (zone 1) is usually compromised as the bone is deficient, sclerotic, and poorly vascularized [4].

Several techniques are available to address epiphyseal bone loss including cement augmented with screw fixation or impaction of morselized or structural bone graft. In the past 20 years modular metal augments attached to the revision implant has been the most common solution to address small to moderate epiphyseal bone defect which falls in the AORI classification of type 2 [1]. Each of these solutions have shown some drawbacks particularly when the surface of the bone defect is sclerotic or poorly vascularized. Cement filling or modular titanium augments cementation against a sclerotic bone of an uncontained femoral or tibial defect have been shown to produce a high rate of radiolucent lines (RLL) at follow up [6, 7] indicating suboptimal implant fixation in zone 1. Additionally, poor epiphyseal cement interdigitation

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coupled with uncemented stem extensions (namely "hybrid" fixation) may cause diaphyseal overload and implant micromotions, which may explain the rate of end-of-stem pain with this type of implant fixation [8].

Trabecular metal (TM®, ZimmerBiomet inc Warsaw, IN) tantalum augments have been available for cementless fixation of tibial and femoral implants. However, while the use of TM acetabular augments in revision hip arthroplasty has been extensively described, the use of TM epiphyseal augments for revision TKA have not been reported yet.

The purpose of this retrospective study was to compare the medium-term clinical and radiographic outcomes of 2 series of patients treated by the same surgeon for revision TKA: one implanted with porous TM augments and one implanted with classic titanium augments. It was hypothesized that porous TM epiphyseal augments directly fixed to sclerotic tibial or femoral bone would result in (1) a lower risk of loosening, (2) a lower rate of RLL compared to classic titanium augments.

Materials and methods

Ethical approval was obtained from the regional ethics committee (register number 15364_oss). A prospectively compiled arthroplasty database has been maintained at the study center since 2010, recording the demographics of the patients, preoperative, intraoperative, and postoperative data, clinical outcome, and x-rays.

Between September 2011 and July 2016, a total of 196 revision TKAs were performed by a single surgeon in two surgical centers. Bone deficiency encountered during the revision procedure was categorized according to the AORI bone defect classification system [1]. Of these patients, 105 presented with a type 2 AORI defect and were treated either with traditional modular titanium augments attached to the revision implant and cemented on the bone or with TM epiphyseal augments directly screwed in the bone. The choice between traditional augment and TM augment was based on the bone quality: in presence of sclerotic and poorly vascularized bone a TM augment was chosen. In order to reduce the variables that could affect the result and to focus on the management of epiphyseal fixation, strict inclusion and exclusion criteria were chosen for the study (Table 1). Indication and type of revision were reported in Table 2.

The NexGen Legacy Constrained Condylar Knee (LCCK, Zimmer, Warsaw, IN, USA) was used in all cases. The type of bone defect and its location is summarised in Table 3. The site and size of TM and titanium augments was recorded, as was the length of stems and length of surgery (Table 4 and Table 5). In the TM group, a total of 63 TM augments were implanted in 50 bones (41 augments in 32 femurs and

Table 2 Indication for revision and revision

Indication for revision	TM group	Titanium group
Aseptic loosening	24 (52.2%)	21 (53.8%)
Second-stage revision for deep infection	16 (34.8%)	10 (25.6%)
Instability	4 (8.6%)	4 (10.3%)
Implant failure	1 (2.2%)	None
Arthrofibrosis	1 (2.2%)	4 (10.3%)
Revision		
Primary TKA	28 (60.9%)	32 (82%)
Unicondylar prosthesis	2 (4.3%)	2 (5.1%)
Revisions of a revision implant	16 (34.8%)	5 (12.9%)

The values were reported as case frequencies (percentage)

Table 1 Materials and methods

Section	Description
Study design	Comparative retrospective cohort study
Population	46 patients who received TM augments (study group);
	39 patients treated with traditional titanium augments were included (control group)
Exclusion criteria	Additional procedures performed during surgery such as extensor mechanism allograft or any other bone allograft constructs;
	Use of a revision systems other than LCCK
Inclusion criteria	The presence of either a titanium augment or a TM augment in the tibial or femoral component;
	No additional metaphyseal trabecular fixation devices;
	Use of a varus-valgus constrained articulation with LCCK prosthesis (ZimmerBiomet inc Warsaw, IN);
	Minimum follow-up of 3 years
Follow-up	3 weeks;
	6 weeks;
	6 months;
	1 year

Table 3 Distribution of bone defects

	TM	Titanium
Tibia: AORI type 2A	14	16
AORI type 2B	4	1
Femur: AORI type 2A	23	26
AORI type 2B	9	8

22 augments in 18 tibias) (Table 5). In 11 patients two or more augments were used in the same bone. The size and the shape of the TM augment were chosen according to the defect type, shape, and location, in order to best fill the bone defect and to guarantee an intimate contact between bone and tantalum surface which is essential for bone ingrowth (Fig. 1A and Fig. 1B). All the TM augments used were directly fixed to the sclerotic epiphyseal bone using a self-threading medullary 6.5 mm screw (Fig. 2A and Fig. 2B). Tibial and femoral components were then cemented over the

Table 4 Demographics of the patients and baseline data

Variables	TM	Titanium	*p*-value
Gender, n (%)			0.38
Male	13 (28%)	9 (23%)	
Female	33 (72%)	30 (77%)	
Age at time of surgery (y)	71.5 (±11)	69.6 (±7.1)	0.35
BMI (kg/m^2)	31 (±4)	30.5 (±3.9)	0.61
Preoperative outcome scores			
Objective KSS	45.8 (±10.1)	46.2 (±11.6)	0.84
Functional KSS	30.5 (±13.05)	34.5 (±17.4)	0.2
Extension loss	4.1 (±9.9)	1.5 (±5.5)	0.87
Maximum flexion	85.4 (±26.6)	91.5(±26.6)	0.25
Previous surgeries	1.4 (1–3)	1.2 (1–3)	0.07
Operative variables			
Surgical time (min)	141 (±37.5)	123.3 (±28.8)	0.02
Augment			
Femoral	41 (65%)	77 (78.6%)	0.47
Tibial	22 (35%)	21 (21.4%)	0.47
Femoral cemented fixation (%)	6 (19%)	17 (50%)	0.01
Femoral hybrid fixation (%)	26 (81%)	17 (50%)	0.01
Tibial cemented fixation (%)	9 (50%)	7 (41.2%)	0.43
Tibial hybrid fixation (%)	9 (50%)	10 (58.8%)	0.43
Femoral stem length for HF (mm)	123.54 (±24.02)	116.25 (±20.53)	0.39
Tibial stem length for HF (mm)	106.67 (±13.23)	109.44 (±19.75)	0.93
Follow-up (mo)	71.8 (±16.2)	60.1 (±24.6)	0.01

TM Group N = 50 components (46 Patients); Titanium Group N = 51 components (39 Patients)

Age, BMI, Objective and Functional KSS, Extension, Flexion, Surgical time, Femoral and Tibial lenght HF (hybrid fixation) and Follow-up were reported as mean (±standard deviation). Gender, Femoral and tibial augments, Femoral and Tibial cones, Cemented and Hybrid Tibial fixation were indicated as frequencies (percentage). Previous surgeries were reported as mean (range). *p*-value considered as α = 0.05

Table 5 Thickness and distribution of the 63 epiphyseal tantalum augments used in 50 components

	Tibial		Femur			
			Distal		Posterior	
	5 mm	10 mm	5 mm	10 mm	5 mm	10 mm
Medial	8	9	13	6	1	0
Lateral	3	2	8	10	0	3
Total	11	11	21	16	1	3
	22		41			

Values were reported as number of cases

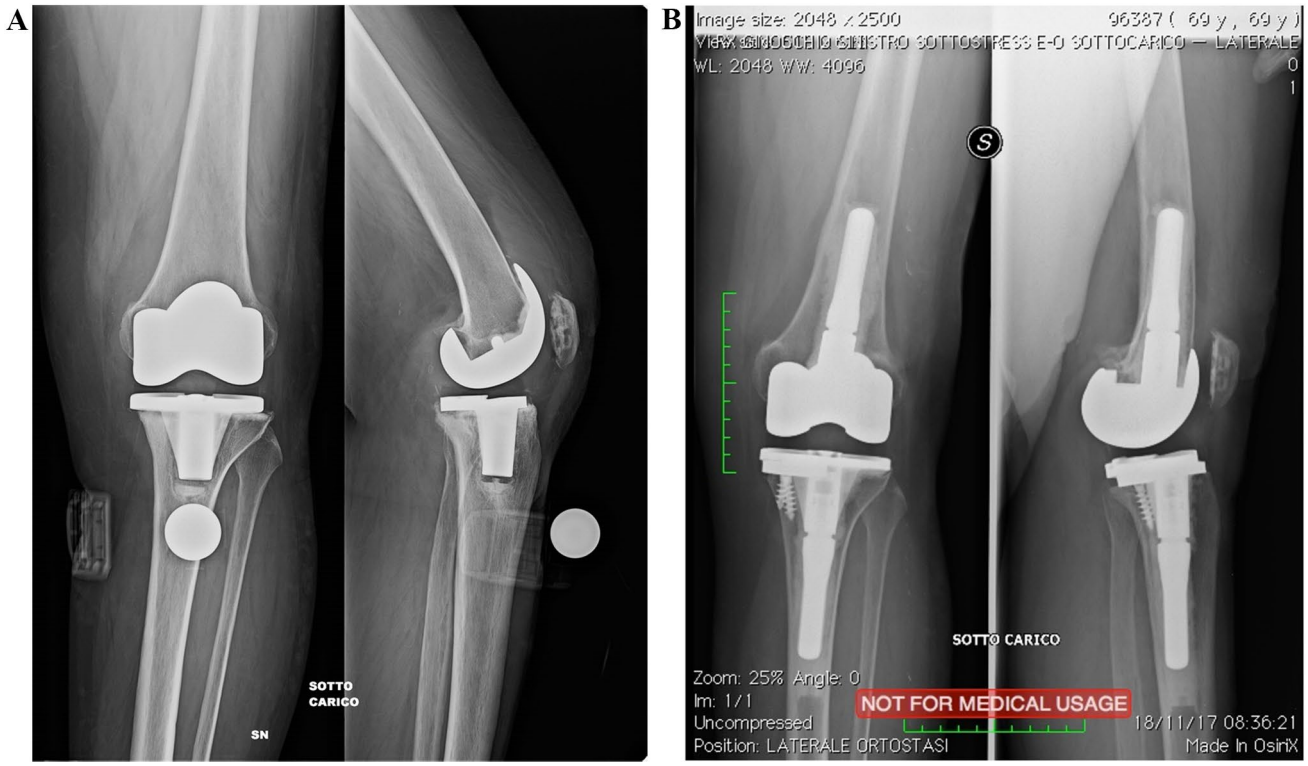

Fig. 1 **A**, **B** Preoperative and postoperative anteroposterior and lateral radiographs of the left knee of a 68-year-old woman that underwent revision total knee arthroplasty with the use of one tibial TM augment directly screwed to the epiphysis. Full-cemented stem extensions were also used in this case

augment (Fig. 2C and Fig. 2D) and the residual uncovered bone. In relation to the type of fixation chosen, in both group either hybrid press-fit diaphyseal engaging stems or short cemented stems (60 mm) were used (Table 4). Cemented or uncemented stems were chosen based on anatomical factors such as curved or narrow diaphysis. On the tibial side there was not a statistical difference in their usage for the two groups, while on the femoral side cemented stems were used more frequently in the titanium group (Table 4).

The primary endpoint measure was failure for aseptic loosening. Radiographs were reviewed at each follow-up visit (immediate postoperative, 6 months and every single year of follow-up) for signs of component loosening or subsidence. The secondary endpoint was the development of RLL. The presence of gaps or RLL as well as the new bone formation at interface were assessed according to a previously validated modification of the Knee Society total knee arthroplasty radiographic evaluation system for long stemmed revision prostheses [9].

Radiographs at the final follow up were independently evaluated by 2 independent observers, and a consensus decision was reached in a final common readout. All clinical and surgical complications, reoperations, and revisions were recorded. In particular, implant survival was assessed for all indications for revision and intention to treat, with revision surgery either undertaken or declined, or the patient being too frail to undergo further surgery. Patients were clinically followed-up using the Knee Society Scoring system (KSS) [10]. The onset and location of end of stem pain was also recorded. In order to assess the presence of end-of-stem pain, patients were specifically asked whether they experienced pain in the shin or in the thigh far from the knee joint [8].

Statistical analysis

Data were analysed in two groups. A power analysis with $\alpha = 0.05$ and $\beta = 0.80$ was performed [11]. The calculation is based on the failure rate for aseptic loosening in knee arthroplasty reviews estimated at 17% according to Wilke et al. [12], with a hypothesized standard deviation of 7% and a minimally clinically important difference of 5%. The sample size required the enrollment of a minimum of 31 participants for each group. Demographic variables were calculated with mean and standard deviation for continuous variables and with frequencies for dichotomous variables. Chi square test was used to assess differences between nominal variables in the two groups. Multivariate analysis was performed to identify clinical and demographic variables associated with RLL and failure for aseptic loosening. RLL differences between

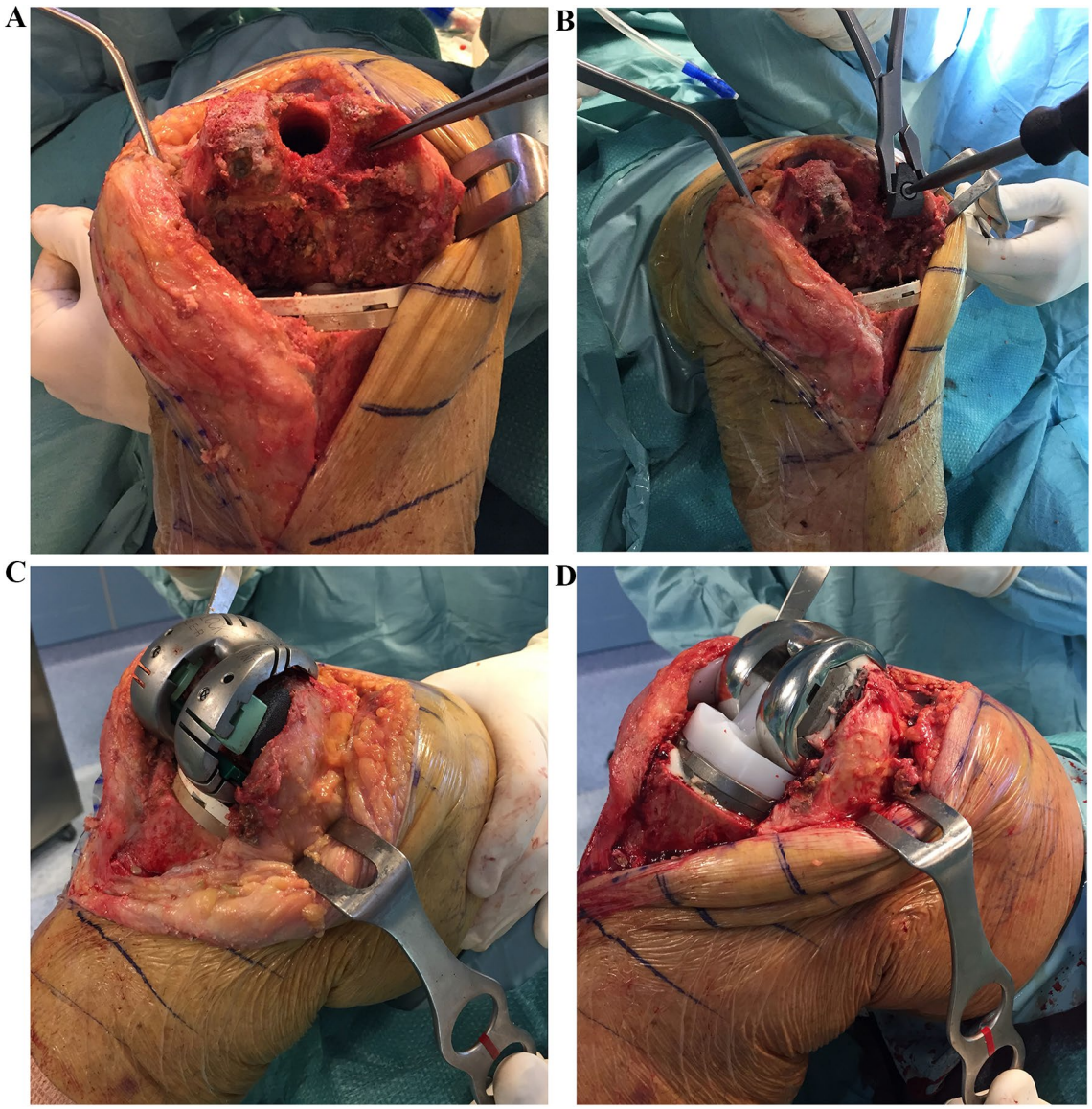

Fig. 2 **A**, **B** In this right knee, the medial femoral condyle defect (AORI 2) was managed with a 10 mm TM block fixed to the femoral epiphysis using a medullary acetabular 6.5 mm screw (**C**, **D**). After the trial, the femoral component was then cemented over the TM augment

the two groups were conducted with Fisher's exact test. Student t test for continuous variables were used. Survival function was determined using the Kaplan–Meier method. Log-rank (Mantel-Cox) test was used to compare the survival characteristics of the two groups. All analyses comparing the 2 groups (titanium and tantalum) were performed using SPSS software v. 26.0 (SPSS Inc., Chicago, 120 USA).

Results

A total of 85 patients were recruited in our study: 46 in TM group, and 39 in titanium group. The two groups shared comparable demographic and functional profiles (age, gender, body mass index (BMI), preoperative ROM and KSS) with the exception that the TM augment group had a longer follow up (Table 4). Regarding the surgical parameters the TM group had a longer surgical time which can be explained with the additional time needed to fix the screws into the bone.

After a mean follow-up of 66.4 ± 21.2 months, no statistically significant difference was observed between the two groups in terms of failure for aseptic loosening ($p = 0.35$). There was a total of 2 failures out of 50 components (4%) requiring revision surgery in the TM group (2 patients) vs 4 failures out of 51 components (7.8%) in the titanium group (3 patients) for aseptic loosening. Of the 2 failures of the TM group, 1 occurred in the femur and 1 in the tibia,

while in the titanium group 3 occurred in the femur and 1 in the tibia. In the titanium group an additional patient failed because of instability and was revised after 3 years. No other causes of failures were detected. The overall survivorship using aseptic loosening as the endpoint was 87.9% (95% CI 108.7–118.5) at 10 years (Fig. 3).

In the TM group, the survivorship considering aseptic loosening was 100% (95% CI 60–60) at 5 years and declined to 90.5% (95% CI 94.1–98.6) at 10 years. In the titanium group, the survivorship considering aseptic loosening decreased from 96.1% (95% CI 60–60) at 5 years to 85% (95% CI 101.9–119.3) at 10 years (Fig. 4).

No statistically significant difference was found for survivorship between the two groups at 5 years ($p=0.16$) and at 10 years ($p=0.26$) using aseptic loosening as the endpoint.

A statistically significant difference was detected for the presence of total RLL ($p=0.01$) and RLL under the studied augments ($p=0.01$) between titanium group and TM group at the time of final follow-up. In the TM group, RLL were found only in 3 components (6%, 2 femurs and 1 tibia) while in the titanium group, RLL were found in 17 components, (33.3%, 10 femurs and 7 tibias).

In 4 components of the titanium group (3 patients) RLL were found to be progressive even though not symptomatic yet. A statistically significant ($p=0.01$) difference was also found in the incidence of RLL under the studied augments among two groups. In the TM group no RLL or sign of loosening were observed under the tibial components and this finding was considered evidence of osseointegration. RLL on the femoral site could only be established for posterior augments. However, even for distal augments, no signs of osteolysis or micromotion were found in the TM group around the fixation screws. In the titanium group, RLL were found under the studied augments in 7 cases (13.7%) ($p=0.01$) (Table 6).

All failures in both groups demonstrated progressive RLL over time until the patient became symptomatic necessitating revision. However, in the 2 patients of TM group that required revision surgery, the TM augments were found to be solidly fixed to the bone while the above component was mobilized.

In relation to the type of fixation, a statistically significant association was found between hybrid fixation and failure for aseptic loosening in the overall population ($p=0.04$), and in the titanium group ($p=0.05$). In this group all failures occurred in patients with hybrid fixation. No statistically significant association was found between type of fixation and failure in the TM group ($p=0.48$).

A statistically significant association was observed in the titanium group between type of fixation and presence of RLL ($p=0.01$). In the titanium group components with hybrid pressfit diaphyseal engaging stems had an incidence

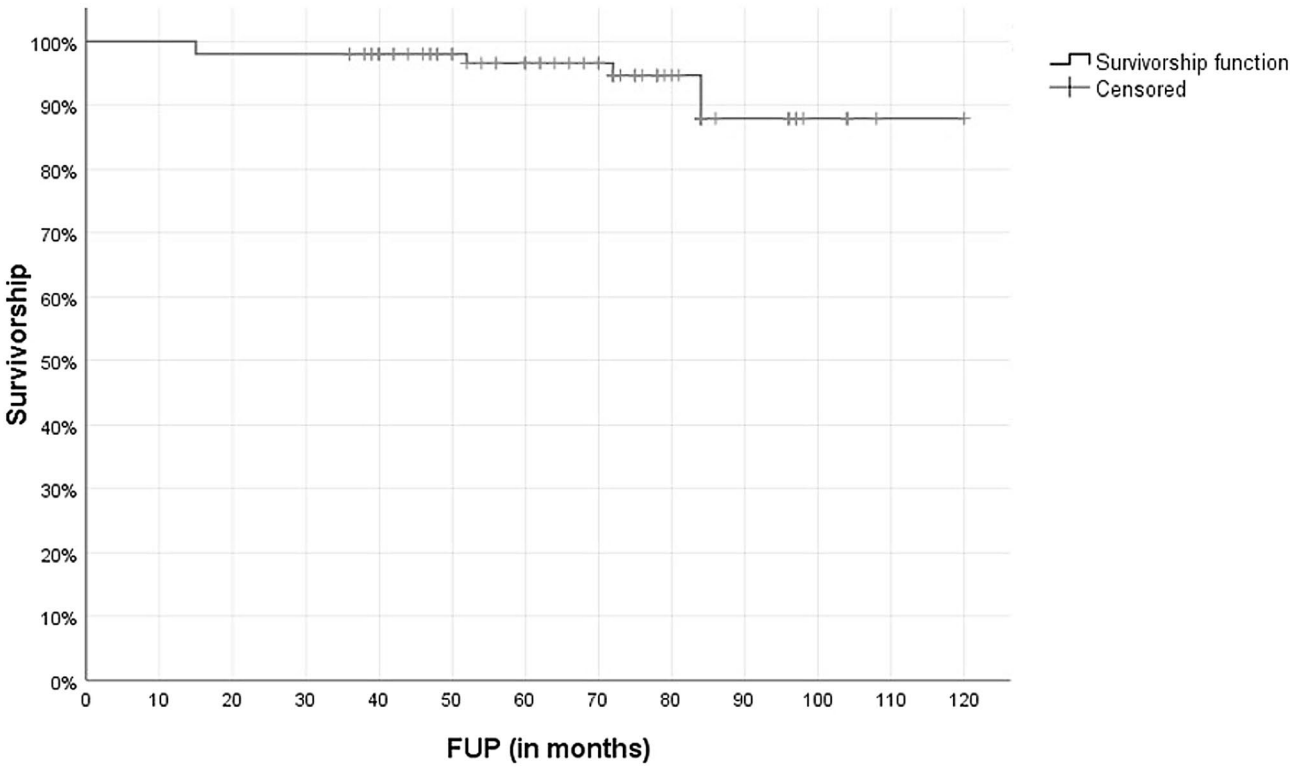

Fig. 3 Overall survivorship at 10 years with aseptic loosening as the endpoint

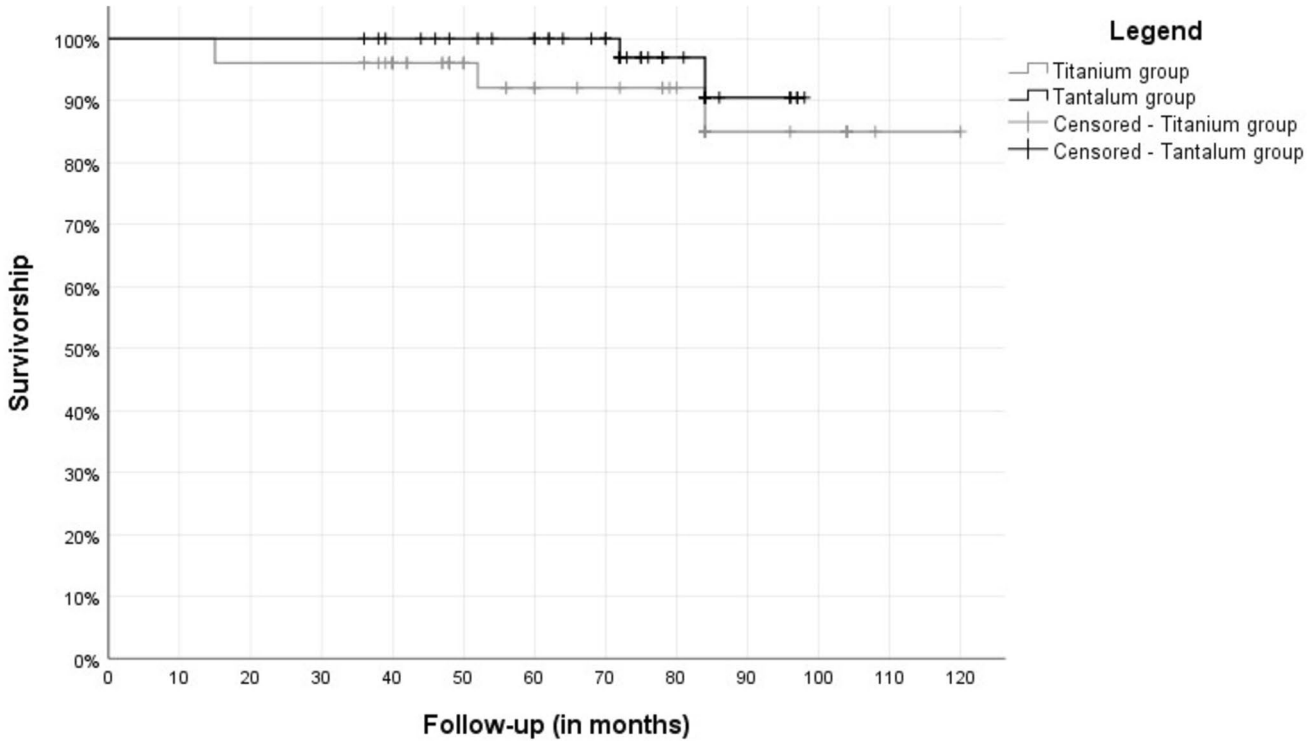

Fig. 4 Survivorship at 10 years with aseptic loosening as the endpoint in the TM and titanium groups

Table 6 Clinical and radiological results at final follow-up

Outcome measure	TM	Titanium	*p*-value
Objective KSS	84.56 (±9.8)	81.62 (±15.21)	0.53
Functional KSS	57.28 (±16.49)	63.87 (±21.7)	0.08
Extension	0.1 (±0.7)	0.0(±0.0)	0.30
Flexion	104.5 (±13.33)	103.45 (±20.79)	0.66
Total RLL	3 (6%)	17 (33.3%)	0.01
	1 tibia (5.6%), 2 femur (6.3%)	7 tibia (41.2%) 10 femur (29.4%)	
Augment RLL	0 (0%)	7 (13.7%)	0.01

TM Group N = 50 components (46 Patients); Titanium Group N = 51 components (39 Patients)

Objective KSS, Functional KSS, Extension, and Flexion were reported as mean (±standard deviation); Total and augment RLL were reported as frequencies (percentage)

of total RLL of 51.8% compared to 12.5% of the components with short-cemented stems. No association was found in the TM group between type of fixation and RLL ($p = 0.6$). No statistically significant association was observed between failure and BMI > 30 ($p = 0.92$) and between failure and age ($p = 0.43$).

In both groups, all patients showed a statistically significant improvement on the objective KSS, functional KSS and ROM ($p = 0.01$) at the latest follow-up. No statistically significant differences were observed when these parameters were compared between groups at final follow up (Table 6). At final follow-up, end of stem pain was present in one patient of the titanium group, and it was defined as mild. No patient reported this complaint in the TM group.

Discussion

This study demonstrates good clinical and radiological medium-term results with the use of TM augments directly screwed into the epiphyseal bone during revision TKA. Although no difference was found between TM and titanium augments in terms of survivorship and clinical outcomes, the results of our study demonstrated that the use of porous TM epiphyseal augments reduced the incidence of RLL compared to classic titanium augments. The hypothesis of this study was therefore accepted.

The radiographic analysis of RLL represents an established modality for the prediction of component loosening [11] and the presence of RLL under the augment indicates suboptimal implant fixation in the epiphyseal zone. No RLL were found under the TM augments after a mean follow-up of 6 years. Moreover, no mechanical failures related to TM augments were identified and no osteolysis or signs of micromotion around the fixation screws were observed.

Obtaining proper fixation in zone 1 is extremely difficult in revision TKA, particularly when the medullary cancellous bone is not available anymore [4].

In the last years the use of modular metal augments attached to the revision implant has become very popular to address epiphyseal bone loss. Most revision knee systems offer a variety of shapes and sizes of both tibial and femoral augments that can be screwed or cemented to the implant. Unfortunately, the currently available metal augments might not be sufficient to effectively address severe epiphyseal bone loss as they can only manage limited defects, up to 20 mm deep.

Other disadvantages of metal augments include the potential risk of debris creation from their modular attachment to the main component and the risk of loosening if the bone supporting the augment is poor [5]. Finally, the difference in elasticity between metal and bone may cause stress shielding with an increased potential for bone loss in the long-term: although non progressive, RLL are very common to find in augmented components after revision TKA [6, 7] and our current study is in line with these values (33.3% in the titanium group).

The recent introduction of porous tantalum has provided an alternative method for reconstruction of severe bone loss and fixation of the revision implant. Porous tantalum is attractive as a biomaterial because of its low stiffness, high porosity as well as high coefficient of friction [13]. In particular, the high degree of porosity has the potential for bone ingrowth and thus long-term biologic fixation [14].

To our knowledge, this is the first study that evaluated the results of revision TKA using TM augments directly screwed to the bone. Other studies have always focused on the use of TM metaphyseal cones reporting excellent medium and long-term results [15–17]. The modularity of TM cones allows an independent reconstruction of the methaphyseal zone [17]. The same concept described for metaphyseal fixation can also be applied to the epiphysis: the ability to obtain epiphyseal biologic fixation with these porous augments translates into durable fixation of the entire construct and may offload stresses on the stem, producing a long-term protective effect independently from stem fixation's strategy [15]. Moreover, TM augments are independents from the rest of the prosthesis and thus are flexible for eccentric bone defects compared to traditional titanium augments that often require to sacrifice more bone.

In the current study, the use of TM augments guaranteed a stable construct and reduced the incidence of RLL even when hybrid fixation was used, compared to the titanium group where hybrid fixation was associated with an increased risk of aseptic loosening and development of RLL.

In our study, the incidence of RLL in the TM was 6% after a mean follow up of 6 years. This result compares very favorably with other reported series of revision TKA.

In the literature, RLL occur adjacent to fully cemented stems in 32% to 61% [9, 18, 19]. Similarly, previous studies with hybrid fixation report RLL occurring in 19% to 64% [20–23].

In our series the survivorship in the TM group at 5 years was 95.2% and the revision rate was 4% after a mean follow up of 6 years, in line with other reported series of revision TKA. Wilke et al. [12] reported a 91% overall 5-year survival with 17% re-operation rate at a mean follow-up of 9 years while Gwam et al. [25] described a survivorship of 94% at 4 years and a 6.4% revision rate after 4 years of follow-up.

Limitations of the study

A limitation of the study is its retrospective nature with a control group with very similar characteristics but not fully matched. The inherent heterogeneity of revision constructs that were used is another limit. Even though several variables were excluded that could have affected the result, such as the presence of metaphyseal fixation devices, the augments in the two groups were used with short fully cemented stems as well as with uncemented diaphyseal filling stems. The use of the TM augments directly fixed to the bone is different from their official usage as described by the surgical technique, which was assuming their fixation to the femoral or tibial component. Another limitation is the relatively limited time length of follow-up.

Conclusions

Longer-term studies are needed to understand the durability of these construct, the fate of the RLL, and to confirm the promising results that were obtained after a mean follow-up of 6 years.

In summary, our study supports the evidence that the use of TM augments directly screwed to the epiphysis of the femur and the tibia represents an efficient and effective option to enhance fixation in zone 1 during revision TKA. The use of TM augments reduced the incidence of RLL compared to standard titanium augments with good medium-term results. The potential for improved survivorship using porous augments when indicated, should be explored at long term follow-up.

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Data availability All data of this study are available in the institutional database.

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