



Cementless Highly Porous Titanium Tibial Base Plate in Total Knee Arthroplasty – 5-year Survivorship

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Abstract

Background: TKA in more active and young patients has prompted the interest in more durable and biological methods of Osteo-integration with cementless components. With the emergence of improved biomaterials like porous titanium the search for a cementless TKA with long-term durability may have ended. This is a retrospective study of 492 consecutive TKAs using cementless tibial fixation with a comprehensive ANJRR review for failure at 5.9 years and clinical and radiological results in a subgroup.

Method: We studied 492 TKAs performed consecutively by a single surgeon between 1st Jan. 2010 and 31st Dec. 2015 using a cementless, fixed bearing tibial tray (porous–Regenerex, Vanguard, Zimmer-Biomet) and a cementless femoral component (Vanguard) with no exclusion criteria. A joint registry review through the Australian National Joint Replacement Registry (ANJRR) was performed on the whole cohort. The surviving patients were followed up for clinical outcomes and radiological assessment completed on a subgroup of patients accessible during the study period (Level II evidence).

Results: The average Knee Society Score at final follow-up was 89.33, average pre-op being 42.06. Average post-op WOMAC score was 43.45 and average pre-op was 77.78. On radiological examination, only one patient had osteolysis and subsidence of the tibial base plate. In our series 9 patients were revised, out of which only 4 patients had the tibial tray and femoral component revised and 5

patients had patella resurfacing or liner exchange. Overall survivorship of the cementless tibial component is excellent with a survivorship of 99.4% at 5.9 years based on the ANJRR analysis.

Conclusions; Cementless tibial fixation using a porous titanium tray can provide stable bone ingrowth fixation on the tibial side with excellent and predictable medium-term outcomes.

Background

Cemented and cementless tibial components are two different options for tibial fixation in Total Knee Arthroplasty. Cemented tibial fixation is common and proven durable in long term studies [1]. Cementless tibial components were introduced over the last 30 years with some variable results with the main concerns being aseptic loosening and long-term survival. Several radiostereometric studies have shown migration of cemented tibial trays due to bone resorption at cement-bone interface, which is of concern in young active patients [2]. With the favorable outcome from cementless hip arthroplasty, there has been resurgence in interest around cement-less fixation in TKA [3]. Hybrid fixation like cementless femur and cemented tibia in TKA has shown equivalent results in terms of du-

Keywords: cementless tibia; Regenerex; cementless total knee arthroplasty; Vanguard

Level of Evidence: II

rability and survival to cemented TKA. Clinical outcomes and histological evidence have shown porous surfaces provide the ideal scaffold for bone ingrowth [4]. Highly porous metals have been used successfully in revision TKA and so may be an attractive fixation option for primary tibial trays. Regenerex® is a highly porous titanium construct with large pore size and interconnecting porous structure with good biomechanical properties including compressive strength and modulus of elasticity very similar to normal trabecular bone. Material biomechanical properties like roughness help in friction fit and initial stability and high porosity enhances bone ingrowth, thus increasing implant survival [5].

While there are several studies demonstrating favorable outcomes with cementless tibial components in TKA, many have strict inclusion criteria and rely on careful patient selection to achieve these outcomes. Our study had no exclusion criteria and aimed to examine and report on the early clinical and radiologic outcomes as well as mid-term survivorship of the cementless porous titanium tibial tray in a cohort of 492 consecutive cases (492 patients).

Our hypothesis was that this cementless tibial tray would demonstrate excellent early durability and survivorship, as well as excellent clinical and radiological outcomes.

Materials and Methods

Retrospective analysis of 492 patients comprised 295 females (60.0%) and 197 males (40.0%). The average age of patients was 66.5, range 42-91 years. The average pre-operative mechanical axis measured 3.9o varus (23o varus – 17o valgus).

All TKA cases operated by single surgeon from the 1st January 2010 to the 31st December 2015 were included in this study (N=492 cases). Institutional ethics approval was sought and granted for this project (Ref. H11998). The clinical data set is incomplete, with only 477 patients having a complete pre-operative assessment and 318 with a minimum 6-month post-operative assessment or greater data set. The reasons for this include failure to collect data at time of consultation (15 cases) or patient's election not to participate or return for follow up after 6 weeks for logistic reasons (159 cases).

All the patients who underwent primary total knee arthroplasty are included in data collection. There were no exclusion criteria based on patient characteristics including age, BMI, indication for TKA, type of arthritis, metabolic bone disease or previous osteotomy. All the surgeries were performed at two centers (Macquarie University

Hospital and Nepean Private Hospital, NSW, Australia).

Submission to National Joint Replacement Registry

A submission was made to the Australian National Joint Replacement Registry (ANJRR) for the whole cohort of patients, to review the revision rates and reasons for revision for each patient whether performed by the senior author or performed at another facility. A comparison of the revision rates of the cementless tray with all TKAs using other cementless tibial trays and all TKAs using a cemented tibial tray.

The Australian National Joint Replacement Registry (ANJRR) report included data of all 492 cases in its analysis. This is viewed as a benefit of the registry review as it ensures inclusion of all patients in the analysis who had the index surgery including those who elected not to return for further follow up and who may have had revision surgery at an alternate institution

The ANJRR has an over 99% data compliance, allows analysis of surgeon's performance including full demographics of the surgeon's practice, reasons and types of revisions, a list of prostheses they use, hospitals where they treat their patients and revisions by year of implantation [7].

Patient Assessment

All 492 patients are assessed pre-operatively and then routinely seen at 6 weeks, 6 months, and 5 years post-operatively or at any interim time they elect to return for an assessment and clinical evaluation. The American Knee Society (AKS) score, Western Ontario and McMaster Universities Osteoarthritis Index (WOMAC) and Flexion score is collected for each patient. The most recent or current scores are derived from their most recent follow-up appointments and/or score sheet mail out. For both Knee and Function AKS scores, a score of >80 was considered excellent, 70-79 good, 60-69 fair, and <60 poor.

Radiological Assessment

X-rays were done for all 492 patients pre-operatively, post-operatively, at 6 months and at 5-year follow-up. Radiological evaluation was performed on the 297 patients who either returned follow-up x-rays following mail out request or attended for follow-up during the time of the study period with routine x-rays between August 2016 to July 2017 using Knee Society Radiological evaluation and scoring system for TKA [6]. Each X-ray was examined for radiolucent lines, osteolysis and subsidence of the implant (fig.1, 2, 3). Radiolucent lines were measured in millimeters. Lucent lines of 1mm or more were recorded. Osteolysis is any progressive lesion of bone loss beneath the

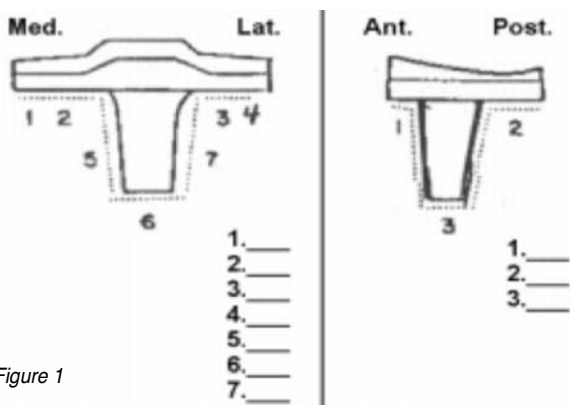


Figure 1

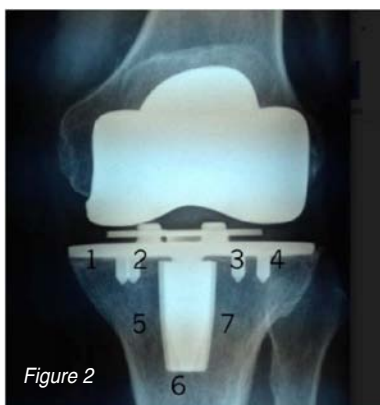


Figure 2



Figure 3

Figures 1, 2 and 3: showing zones around Tibia for radiological evaluation after TKA. (From Knee Society Radiological Evaluation)

implant (tibial base plate). Subsidence can be defined as a change in position of an implant (tibial base plate) due to bone loss at implant bone interface.

Implants

The implant used is the Regenerex ® Cementless Tibial tray, part of Vanguard Total Knee system manufactured by Zimmer-Biomet, Warsaw, Indiana, USA. It has highly porous titanium undersurface with an average porosity of 67% and average pore size of 300 microns (fig. 4,5). It

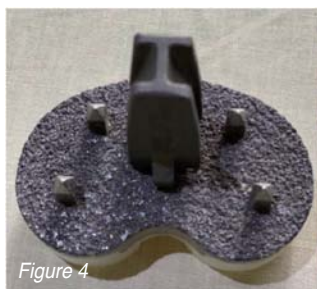


Figure 4



Figure 5

Figure 4 and 5: showing highly porous titanium under surface and implant bone interface

is not coated with hydroxyapatite unlike some other cementless total knee systems [8]. The tray has central stem and 4 square non-porous peripheral pegs to improve fixation (fig. 6). The polyethylene insert used was posterior cruciate retaining in most of the patients. The ultracongruent insert was used in a small number of patients where the PCL was deficient or was sacrificed for balance.

The Vanguard Porous Hydroxyapatite coated cementless femoral component was inserted for all cases and a ce-



Figure 6: X-ray showing stable interface with Regenerex tibial tray.

mented polyethylene patella button was used to resurface the patella only in selected cases of advanced patella wear.

Surgical Technique

A standard medial para-patella approach was used in all cases and tibial base plate was inserted in accordance with the manufacturer’s recommended technique. The first 260 cases were implanted using a tourniquet. The remaining cases were implanted without tourniquet due to a change in surgical protocol with the introduction of tranexamic acid. One gram of tranexamic acid was given intravenously immediately prior to the incision, as well as 3 grams in 30mls normal saline placed topically after implantation. It is of advantage to perform whole surgery without tourniquet, as it gives chance to achieve accurate haemostasis prior to implantation given the best visibility of posterior capsule. Also, it prevents post-operative swelling, bruising and delayed articular recovery [9]. In addition, studies have failed to demonstrate any relationship between tourniquet use and implant survivorship in TKA [10].

Statistical Analysis

AKS scores, WOMAC index and flexion range were recorded pre-operatively, at 6 weeks and 6-months post-operatively and at their most recent follow up. All patients were included regardless of the completeness of their data set to provide the best representation of the cohort and avoid selection bias. Mean and standard deviation values were calculated for WOMAC index, AKS and flexion scores at each follow-up interval. Pre-operative values were compared separately with both the post-operative values and current follow-up using paired samples T-tests. Kaplan-Meier curves were calculated using the data from the ANJRR to compare the relative survival (defined as revision of any kind) of our study cementless tibial trays and other cemented TKAs. All statistical analysis was conducted using SPSS. The permissible upper limit of significance accepted is at 0.05 (5%) probability level.

Results

Clinical Parameters

The average follow-up time for all patients was 4 years, with a range of 1 year 4 months to 7 years 1 month. At each assessment interval the AKS (Knee and function) scores, WOMAC index and Flexion scores were recorded for each of the patients seen. The following table illustrates this data, comparing the pre-operative, post-operative and current values. The first p value indicates the statistical significance between pre-operative and post-operative scores, the second p value the significance between the post-operative and current values.

Table 1. Clinical results

Clinical Parameter	Follow-up point	Mean \pm Std. Dev	p value
WOMAC	Pre-op	77.78 \pm 14.37	-
	Post-op	43.45 \pm 16.56	<0.001
	Current	38.43 \pm 15.08	0.005
AKS Knee Score	Pre-op	42.06 \pm 17.86	-
	Post-op	82.53 \pm 16.60	<0.001
	Current	89.33 \pm 15.48	<0.001
AKS Function Score	Pre-op	45.65 \pm 18.34	-
	Post-op	75.73 \pm 22.77	<0.001
	Current	75.85 \pm 23.95	0.953
Flexion range	Pre-op	104.08 \pm 13.84	-
	Post-op	116.89 \pm 10.55	<0.001
	Current	118.10 \pm 13.22	0.144

At each follow-up interval there was a significant improvement from baseline in all-clinical parameters and notably there was a statistically significant improvement between the 6-month post-operative and current follow-up scores for both the WOMAC index and AKS Knee scores. At current follow-up 85% of knees were rated excellent, 5% good, 4% fair and 6% poor. Therefore 90% of TKAs were rated as good/excellent and the flexion range also significantly improved to an average of 118 degrees.

Radiological Results

Radiographs of 297 patients who submitted their x-rays during the study period were analysed. Lucent zones around the tibial tray were documented in 13 patients (5%). A summary of the lucent zones as measured, and their location is shown in Table 2.

One patient had radiologic evidence of significant subsidence, shown in figure 7,8. This patient had lucent lines totalling 9mm across the different zones and was clinically loose. The femoral component also demonstrated sig-

Table 2. Lucent zones around the tibial implant

AP zones	1.0mm	1.5mm	2.0mm	2.5mm	3.0mm
1	5	-	-	-	-
2	2	-	-	-	-
3	2	-	-	-	-
4	6	2	1	-	-
5	-	-	-	-	-
6	-	-	-	-	-
Lateral					
1	4	-	1	-	-
2	2	-	1	-	-
3	1	-	-	-	1

nificant osteolysis below the implant and was loose. This patient was not reporting any significant pain and was still functional without support and has to date declined proposed revision surgery. No other patient X-rays demonstrated lucent zones sufficient to suggest implant loosening. Note that the routine knee x-rays of the remaining patients have all been reviewed by the senior author during routine follow-up outside the study period and documented to be stable, but this was not used for reporting here.

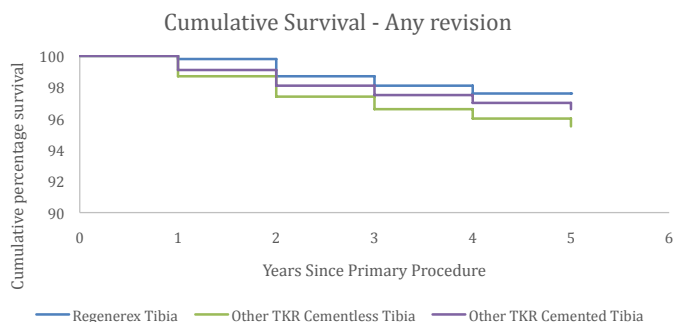
Registry Results

The Australian National Joint Replacement Registry (ANJRR) data reported that of the 492 cases submitted, only 9 patients (1.7%) required revision of their knee replacement and all had their revision surgery between 12 and 36 months following the index procedure. The revision procedures in these 9 patients were identified as 2 patients who had only their polyethylene insert revised, 2 patients who had their patella resurfaced, 1 patient who had both the polyethylene insert and patella resurfaced, 1 patient who had a cement spacer and 3 patients who had full revision of their total knee replacement (tibial & femoral components). The reasons for revision in these 9 patients included 1 for infection, 1 for loosening/lysis, 2 for patella pain, 1 for instability, 3 for arthrofibrosis and 1 other (reason not provided). At 5 years follow-up there was a cumulative revision rate of 0.6% (CI 0.1, 2.4) for all tibial implant revisions.

Kaplan-Meier Analysis

Survivorship with tibial revision as the end point was 99.4% (CI 97.6, 99.9) at 5 years. Survivorship for the tibial implant with aseptic loosening requiring revision, as an endpoint was 99.8%. This is illustrated in figures 2 and 3, respectively.

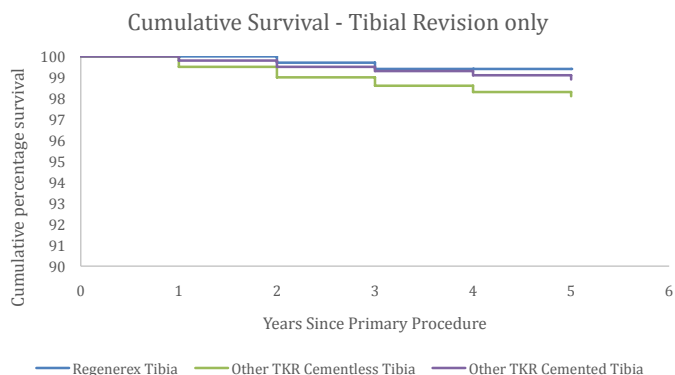
Curve 1 Kaplan Meier Curve – Survival of entire implant



In comparison to other cementless implants using any revision procedure as an end point our series showed slightly higher survival (Hazard ratio =1.68, CI 0.87-3.22, P=0.121), but this was not statistically significant. The absolute difference in favour of our study tibial component is 2.1% (95.5% vs. 97.6%). Similarly, comparison of our cementless tibial component with other cemented tibial implants showed higher survival but no significant difference at 5 years (HR=1.42, CI 0.74-2.73, P=0.293).

Hazard Ratio - In survival analysis the hazard ratio (HR) is the ratio of the hazard rates corresponding to the conditions described by two levels of an explanatory variable.

Curve 2 Kaplan Meier Curve – Survival of Tibial Implant

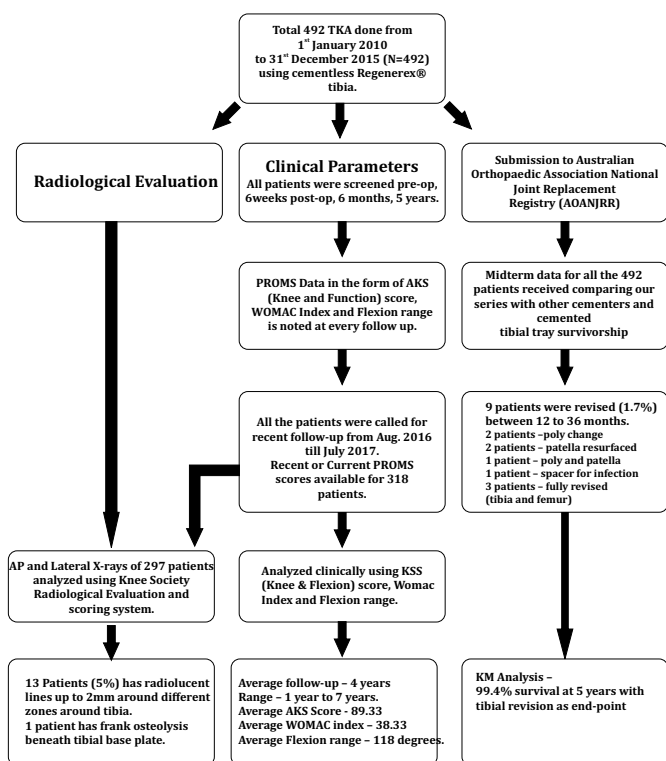


With revision of the tibial implant as an endpoint there is an absolute but non-significant difference in favour of our cementless tibial implant at 5 years. Other cementless implants compared to the Regenerex tibia produces a hazard ratio of 1.92 (CI 0.62-5.96, P=0.258). Cemented tibias compared to the Regenerex tibia yields a hazard ratio of 1.27 (CI 0.41-3.94, P=0.679).

Discussion

Our retrospective study of 492 cementless TKAs drew on comprehensive data from an ANJRR analysis and combined with a clinical review of patients returning for follow up during the study period. At most recent follow-up

Flow Chart of the Study



patients reported an average AKS knee score of 89, with 85% of knees being rated as excellent. This is consistent with the previous study comparing it to the PPS implant where it demonstrated excellent clinical outcomes in the short term. These results demonstrate a high rate of patient satisfaction with the study implant and are comparable to other implants with excellent survival rates [11].

Radiologic analysis of 297 patients demonstrated some evidence of lucent lines in only 5% of cases, most commonly in zone 4. One case demonstrated radiologically significant change with extensive osteolysis and subsidence at 12 months (fig. 7 and 8) but despite radiographic evidence of implant failure this patient had few symptoms and declined revision surgery.

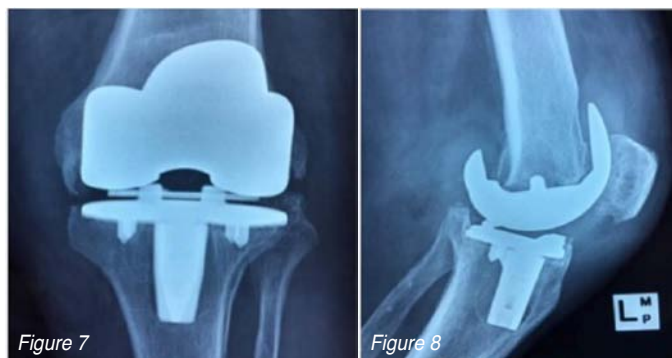


Figure 7 and 8: showing tibial subsidence due to early failure of biological ingrowth

The failure of early cementless implants is multifactorial, however can be largely attributed to early designs not achieving sufficient early fixation and the implant interface not adequately replicating trabecular bone structure to encourage long term bony ingrowth. These early implants were designed with beaded technology or fibre-mesh technology for their implant-bone interface, which had low-porosity. They also used screws to achieve early fixation. The first fully cementless implant using porous bead technology was the PCA TKA (Howmedica Corporation, Rutherford, New Jersey). It suffered from a high failure rate, most commonly due to tibial implant related failures. Moran et al reported a 19% failure rate at 5 years, predominantly due to collapse of the anteromedial portion of the tibial plateau [12]. Another study looking at the fibre-mesh technology in the Miller-Galante-I implant (Zimmer Inc, Warsaw, Indiana, USA), demonstrated aseptic loosening of the tibial component in 8% of cases, partial lucency around the tibial component in 53% of cases and 12% osteolysis rate around screws used for adjuvant fixation [13]. As well as aseptic loosening and osteolysis, stress shielding and polyethylene wears and patellar failures all plagued early implant designs [14,15].

After catastrophic failure of earlier cementless designs, screw-based fixation has been replaced by pegged tibial designs, eliminating screw-holes and providing an increased surface area for implant fixation, while simultaneously removing potential points where osteolysis can occur due to polyethylene debris entering cancellous bone surfaces [16,17].

Improved surface design, and the addition of Hydroxyapatite coating have yielded excellent results with several cementless designs [18]. The Natural Knee (Zimmer Inc., Warsaw, Indiana, USA) with a cancellous-structured titanium implant yielded a 95.1% survival rate for the tibial implant [19]. More recently, there has been the introduction of highly porous titanium and tantalum-based implant interfaces, which replicate both the porosity and compressive strength of cancellous bone.

Dunbar et al. [20] reported on early clinical and radiostereometric (RSA) analysis results comparing cementless trabecular metal tibia with conventional cemented tibia. They reported no revisions or failure at 2years. RSA helped in measuring the migration of the tibial component. It suggested migration of trabecular metal group during initial post-operative period and stabilised by one-year period.

Niemelainen et al. [21] of the Finnish Registry reported on revision and re-operation data for cementless trabecular metal tibia by patient age. Three categories i.e. age <55, 55 to 65 and age >65 showed 97% survival, revision for aseptic loosening being the end point.

Minoda et al. [22] reported 6-year follow-up in a matched cohort comparing cementless trabecular metal tibia with conventional cemented tibia. They have used Dual Energy X-ray absorptiometry in conjunction with plain radiographs for assessment of bone density and implant migration. They reported bone density in proximal tibia well preserved in trabecular metal group and same durability as cemented tibia.

The implant examined in our study represents another new baseplate technology, using highly porous titanium. Porous titanium offers benefits of a high coefficient of friction to stop early movement and a high porosity and biocompatible scaffold to encourage early bone growth. This is supported by a recent paper, evaluating the bone remodelling around this implant, demonstrating an increase in bone mineral density below the lateral plateau, and no change below the medial plateau [23].

There is limited published data examining the outcomes of this prosthesis specifically and include a RCT comparing the Vanguard Regenerex implant to a Vanguard Porous Plasma Sprayed (PPS) implant [24] in 61 patients with follow-up including RSA up to 24 months. The Regenerex implant had a statistically significant higher subsidence rate at 24 months on RSA, but lower migration rate between 12 and 24 months. There was no difference in clinical outcomes scores at 4 years and no implants in either arm required revision. This study suggests the tibial prosthesis provides a stable migration pattern with good clinical outcomes scores in the short term but did not perform any better than an older established implant [25]. The study was also slightly underpowered as only 21 patients in the PPS group and 22 in the Regenerex group completed follow-up.

In these series, survivorship of the tibial Implant is excellent with a survivorship of 99.4% at 5.9 years based on a comprehensive ANJRR data analysis. Three revisions of the tibial implant were performed, in each case part of revision of the entire TKA (femoral and tibial implants). One revision was for infection (fig. 9, 10), one for pain and one



Figure 9 and 10 showing osteolysis on medial side under tibia (zone 1, 2) and retrieval of same tibia for infection showing good ingrowth on lateral side

for loosening/lysis. Survivorship with tibial aseptic loosening as an endpoint is 99.8%.

Comparison of this cohort with ANJRR data demonstrates excellent survivorship, comparable to cemented TKA which still remains the gold standard. Time-matched comparisons with revision for any reason as an endpoint between TKR with cemented tibias and this cohort produced a Hazard Ratio (HR) of 1.42 (CI 0.74-2.73, P=0.293), demonstrating a non-significant trend in favour of the study tibial tray. Comparison with other cementless tibial TKA vs. this cohort had an HR of 1.68 (CI 0.87-3.22, P=0.121) again demonstrating a non-significant trend favouring this implant. Comparison using tibial revision as an endpoint demonstrated similar non-significant trends in favour of this implant with hazard ratios of 1.27 (0.41-3.94, P=0.679), 1.92 (0.62-5.96, P=0.258) for cemented tibias and cementless tibias.

There are very few studies reporting on clinical outcome and survivorship of the Regenerex implant and most of them are underpowered. This study combines clinical outcome, radiological assessment along with registry-analysed data for the enrolled cohort with no exclusion criteria.

Limitations of the study

Being a retrospective study with data collected prospectively, there is a potential for confounding bias due to -

- Incomplete data set due to difficulties in having patients return for clinical follow up or return to have follow up x-rays particularly if they have no symptoms. A more complete data set of outcome scores and radiographic analysis was aimed for to match the complete ANJRR analysis.
- Radiographic evaluation of whole cohort was not done as all patients did not attend follow-up during study period or failure to respond to mailout request.
- Patient selection criteria might be different for other series or in data provided by ANJRR.

Conclusion

In conclusion, this is an early to mid-term follow up study reporting on survivorship for a highly porous titanium tibial cementless implant used consecutively in all patients without exclusion criteria. It provided reliable results (clinical and radiological) and durable fixation with PROMS data reflecting a 90% good/excellent result and a 5.9-year tibial tray survivorship of 99.4% as per the ANJRR analysis. It is too early to predict that this highly porous coating of tibial implant will contribute to a long-term survivorship in cementless TKA. Another study is under-

way aiming to answer the questions whether these results are maintained at over 10 years.

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AUTHOR DISCLOSURES

- The authors declare that there is no conflict of interest in connection with this submitted article.

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