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Cementless total knee arthroplasty in young patients using tantalum trabecular implants results in significantly lower rates of aseptic loosening

a series of 454 total knee arthroplasties with a mean follow-up of ten years

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Aims

The mean age of patients undergoing total knee arthroplasty (TKA) has reduced with time. Younger patients have increased expectations following TKA. Aseptic loosening of the tibial component is the most common cause of failure of TKA in the UK. Interest in cementless TKA has re-emerged due to its encouraging results in the younger patient population. We review a large series of tantalum trabecular metal cementless implants in patients who are at the highest risk of revision surgery.

Methods

A total of 454 consecutive patients who underwent cementless TKA between August 2004 and December 2021 were reviewed. The mean follow-up was ten years. Plain radiographs were analyzed for radiolucent lines. Patients who underwent revision TKA were recorded, and the cause for revision was determined. Data from the National Joint Registry for England, Wales, Northern Island, the Isle of Man and the States of Guernsey (NJR) were compared with our series.

Results

No patients in our series had evidence of radiolucent lines on their latest radiological assessment. Only eight patients out of 454 required revision arthroplasty, and none of these revisions were indicated for aseptic loosening of the tibial baseplate. When compared to data from the NJR annual report, Kaplan-Meier estimates from our series (2.94 (95% confidence interval (Cl) 1.24 to 5.87)) show a significant reduction in cumulative estimates of revision compared to all cemented (4.82 (95% Cl 4.69 to 4.96)) or cementless TKA (5.65 (95% Cl 5.23 to 6.10)). Our data (2.94 (95% Cl 1.24 to 5.87)) also show lower cumulative revision rates compared to the most popular implant (PFC Sigma Cemented Knee implant fixation, 4.03 (95% Cl 3.75 to 4.33)). The prosthesis time revision rate (PTIR) estimates for our series (2.07 (95% Cl 0.95 to 3.83)) were lower than those of cemented cases (4.53 (95% Cl 4.49 to 4.57)) from NJR.



Conclusion

The NexGen trabecular (tantalum) cementless implant has lower revision rates in our series compared to all cemented implants and other types of cementless implants, and its use in younger patients should be encouraged.

Take home message

 The use of a uncemented trabecular metal total knee arthroplasty should be considered in younger patients who have an increased lifetime risk of revision surgery, as it significantly reduces the chance of aseptic loosening versus cemented implants, thereby improving implant longevity.

Introduction

Total knee arthroplasty (TKA) is a well-established procedure for end-stage osteoarthritis (OA) of the knee joint.^{1,2} Failure after TKA may be for a variety of different reasons, with the most common indications including aseptic loosening, periprosthetic joint infection, pain, and instability.^{3,4} Aseptic loosening has become the most common failure mode and indication for revision surgery in the UK.⁵ Aseptic loosening of the tibial component is seen more frequently than femoral loosening, and has been linked to poor cementing technique and a lack of cement bonding to the tibial component.⁶

Cementless TKA was thought to be a solution to this problem, but unfortunately outcomes did not replicate the early enthusiasm. Failures were multifactorial and differed depending on implant design. The first-generation polyethylene was vulnerable to wear with subsequent osteolysis.⁷ Some cementless implant designs had a high failure rate secondary to poor fixation, leading to early implant migration and loosening of the tibial component.^{8,9} Modern polyethylene manufacturing and design have greatly reduced the concerns about polyethylene wear, and therefore concerns are rightly now more focused on implant fixation.

The mean age of patients undergoing TKA has reduced with time.¹⁰ Analysis of the National Joint Registry for England, Wales, Northern Ireland, and the Isle of Man (NJR) shows a significantly increased risk of revision in younger patients receiving TKA.⁵ Given the increased costs, morbidity, and poorer outcomes of revision TKA compared to primary TKA, every effort should be made to reduce the risk of revision in this challenging group of patients.¹¹⁻¹³

The NexGen Cementless Implant (Trabecular Metal Monoblock Tibia; Zimmer Biomet, USA) has been in use for almost two decades. It incorporates a tantalum trabecular mesh that has a modulus of elasticity comparable to the cancellous bone.¹⁴ Enhanced osseointegration seen with the tantalum implant results in decreased stress shielding, higher resistance against shear forces, and improved implant fixation.^{15,16} These properties potentially reduce the risk of aseptic loosening, making this implant an attractive choice in younger, higher-demand patients. The femoral component is porous-coated, and does not incorporate trabecular metal; previous studies have demonstrated that femoral component loosening is much less of a concern compared to tibial component loosening with both cemented and cementless TKA designs.¹⁷

The aim of this study was to review a large consecutive case series of NexGen tantalum trabecular metal cementless TKA. We investigate the modes of failure, particularly aseptic loosening of the tibial baseplate. We compared our series with conventional cemented and cementless TKA performed in the UK by using existing data from the NJR. We hypothesize that the use of trabecular metal uncemented implants would reduce the revision rates, specifically in younger population.

Methods

We performed a retrospective review of a prospectively kept database, including all cementless TKA procedures performed at a single district general hospital and the senior authors' independent practice within the UK. All consecutive cementless NexGen TKA performed between August 2004 and December 2021 were included in the study.

We sourced NJR data and followed their guidelines. Patient data for our database had been recorded as a part of

Tab	le I.	Se	lection	criteria.

Inclusion criteria	Exclusion criteria
Patient consent obtained	Patients who underwent TKA for other diagnoses except OA
Patient diagnosed with OA including traumatic OA	Patients mistakenly registered as cementless, originally cemented TKA
Patient undergoing primary TKA	Mobile-bearing cementless prostheses with various modes of fixation, or other brands or designs
Cementless NexGen implant used (cruciate-retaining type and posterior-stabilizing type)	Patients who declined to be registered on the NJR
Ongoing engagement and traceability for revisions on the NJR	Patients without notes or radiographs
	Complex bilateral primary knee arthroplasty

NJR, National Joint Registry; OA, osteoarthritis; TKA, total knee arthroplasty.



Fig. 1

Flowchart depicting the selection of cases for the study. NJR, National Joint Registry; TKA, total knee arthroplasty.



Age distribution of cementless primary knee arthroplasty patients.

routine hospital practice over the years. While the data were collected, the patients gave consent for its use for research purpose. We did not collect new data from the patients.

Inclusion and exclusion criteria for the study are shown in Table I and patient selection is depicted in the

flowchart (Figure 1). A cementless implant was preferred over a cemented implant in young, high-demand patients with good bone stock on the radiographs, and pre-menopausal women with no concerns about osteoporosis.

Surgery was performed using a standard medial parapatellar approach. The NexGen (Zimmer Biomet, USA) tantalum trabecular-mesh monoblock tibial implant was used in all patients, combined with the cementless NexGenporous coated femoral component. Patellar resurfacing was not performed as part of the primary procedure in any patients. Patients were encouraged to mobilize from day one postoperatively, and full range of motion was allowed as tolerated. All patients had regular outpatient surveillance in an arthroplasty nurse specialist-led clinic with routine five-yearly radiographs.

All patients underwent radiological evaluation of their TKA at time of final follow-up. The presence of radiolucent lines around the femoral and tibial components was assessed using a zone specific American Knee Society radiological evaluation score recommendation, which has been modified specifically for the pegged tibial baseplate design used in this study.¹⁸⁻²⁰

Electronic patient records in conjunction with radiographs and surgeons' individual NJR data were used to identify any reoperations or revision of components. Individual NJR surgeon reports were reviewed to ensure completeness of Table II. Reasons for revising the uncemented total knee arthroplasty.

Cause of revision	Number of cases	Age at primary surgery, yrs	Year of primary procedure	Implant survival, yrs
		53	2005	11.4
Femoral component loosening	2	68	2009	3.5
		45	2009	9.5
		57	2004	7.6
		62	2015	1.38
Instability*	4	66	2012	5.6
Stiffness	2	54	2008	1.3
		56	2005	1.2

*Instability was defined clinically, and there was no evidence of component loosening or malalignment on radiological evaluations.

data, and all index linked revisions were viewed to establish cause of revision. The NJR tracks all patients regardless of where the subsequent revision surgery is performed, and therefore we were able to identify patients who underwent revision of the primary TKA in other units across the UK.

Our revision rate was defined as revision of TKA due to implant-related causes for any reason. Secondary patella resurfacing was classed as a reoperation rather than a revision, due to implant failure for the purpose of this study.

Statistical analysis

Patients' data was anonymized to protect identity. Statistical analysis was performed by a senior statistician (AS) associated with the University using SAS Version 9.4 of the SAS System for Windows (SAS Institute Inc. 2016. Base SAS 9.4 Procedures Guide, USA). Kaplan-Meier (KM) estimates of cumulative survival and revision of knee implants were calculated. Prosthesis time incidence rate (PTIR) in terms of the number of revisions per 1,000 prosthesis years was also calculated. Due to the small size of the dataset, and particularly the small number of revisions observed, skewness-corrected asymptotic score method (SCAS) was used to calculate the PTIR estimates and their confidence intervals.²¹ Data were split by patient age at original arthroplasty, looking primarily at those aged 64 years and under, and those aged 65 years and over.

Results

Complete datasets were available for analysis in 454 patients (389 male, 65 female) who underwent TKA using the NexGen tantalum trabecular mesh implants between August 2004 and December 2021. The mean age was 59 years (22 to 78) with the majority of patients falling between 54 and 64 years (Figure 2).

In total, 41 patients received a cruciate-retaining (CR) implant while the rest (n = 413) had a posterior-stabilizing (PS) prosthesis.

Only eight patients required revision arthroplasty (Table II). Overall, the revision rate was 1.76% and the cumulative revision rate was 2.94% (1.24 to 5.87) at 17 years. Most importantly, no patients required revision for aseptic loosening of the tibial baseplate. There was no evidence of radiolucent lines in any patients on latest radiological assessment.

There was a single patient who required a secondary patella resurfacing due to persistent postoperative anterior knee pain, but there was no evidence of femoral or tibial component loosening both radiologically and intraoperatively.

KM estimates for implant survival (Figure 3) and separate curves for age distribution (\leq 64 years, and \geq 65 years) (Figure 4) showed similar trends. KM estimates of cumulative revision are comparable in both age groups (Table III). Table IV shows the overall follow-up duration for all patients.

Our data shows a significant reduction in cumulative estimates of revision compared to all cemented or cementless TKA from the NJR (Table V). This is despite a mean age of 58.6 years in our dataset in comparison to a mean national age for primary TKA of 69.7 years (cemented) and 68.2 years (cementless).

When comparing the KM estimates of the cumulative revision rate by implant brand (implanted on at least 2,500 occasions), our data show lower rates when compared to the most popular cemented implant (PFC Sigma Cemented Knee implant fixation) and when compared to other cementless implants (Tables VI and VII). We have excellent outcomes compared to the national data for the NexGen Tibia Monoblock (Table VII).

PTIR is defined as the number of revisions per population at risk in a given time period, and expressed as the number of revisions per 100 patient years at risk.²² The PTIR estimates with SCAS for our series is lower than the national rate for both uncemented and cemented TKA (Table VIII).

Discussion

For patients with end-stage OA, TKA remains the gold-standard method of treatment.^{1,2} The mean age of the patients who undergo TKA has decreased over time.^{10,23} Early cementless TKA implants were often associated with increased failures, largely due to poor implant designs.²⁴ Aseptic loosening of the tibial component and inadequate bone ingrowth were common causes of failure.^{2,17} Studies using titanium alloybased porous implants published in the 1990s and early 2000 showed poor results, with high implant failure, inferior clinical outcomes, and poor osseointegration.^{17,2526}

Data from the NJR show that the preference for cementless fixation has been decreasing since 2004. The 20th





Fig. 3

Kaplan-Meier estimates of cumulative survival in cementless primary knee arthroplasties.

Fig. 4



Table III. Kaplan-Meier estimates of cumulative revision (95% confidence interval) by age group in primary knee arthroplasties.

Age at primary knee		Time since primary knee arthroplasty, yrs						
arthroplasty, yrs	Ν	1	3	5	10	15	17	
		0.00	0.89	0.89	2.15	3.27	3.27	
≤ 64	350	(N/A)	(0.25 to 2.42)	(0.25 to 2.42)	(0.74 to 4.96)	(1.15 to 7.28)	(1.15 to 7.28)	
		0.00	0.00	1.03	2.24	2.24	2.24	
≥ 65	104	(N/A)	(N/A)	(0.09 to 5.08)	(0.42 to 7.13)	(0.42 to 7.13)	(0.42 to 7.13)	

Where there are patients at risk, but no events, the absolute risk is estimated as 0 and the confidence interval cannot be estimated. It is denoted by "(N/A)".

N/A, not applicable.

Table IV. Number of patients as per follow-up duration.								
Age at primary knee arthroplasty, yrs	1 yr 3 yrs	5 yrs	10 yrs	15 yrs	17 yrs			
≤ 64	350 319	280	135	37	16			
≥ 65	104 99	92	43	19	12			

annual NJR report shows that 95.47% of all TKAs performed in the UK are fully cemented.⁵ This is despite studies with smaller cohorts showing comparable results between cementless tibial component and fully cemented TKA, with no significant differences between the porous femoral component and cemented femoral component. Studies focusing on patients below the age of 65 years have shown superior results for cementless implants in terms of implant failure and revision rates compared to cemented TKA, while conventional implants have higher failure rates in the younger population compared to older population.²⁷ A single-blinded randomized controlled trial published in 2020 by one of our authors in a different unit compared the cementless tantalum monoblock tibia fixation device (NexGen TMT, Zimmer Biomet) against a conventional cemented tibial component (Option Tibia, Zimmer Biomet) for a mean follow-up of 13.2 years.²⁸ They found that while there was a significant improvement in Knee Society Score and Oxford Knee Score after TKA in both groups, there was a gradual decrease in scores in the cemented group over time. Radiological analysis also demonstrated a marked difference in both groups, with significantly more radiolucency seen beneath tibial trays in the cemented group.

Despite the more recent encouraging data, surgeons remain hesitant to adopt the use of cementless implant fixation for younger patients. This could be due to higher implant costs compared to cheaper, dependable cemented implants. However, evidence shows that the cost difference is not significant when shorter operating time and reduced expendables are taken into consideration.^{20,24,29} Our data suggest that the use of cementless TKA may significantly reduce the risk of revision TKA in a high-risk group of patients, and therefore the high costs associated with revision TKA should also be taken into consideration.

In the cohort presented here, cementless TKA was performed predominately in male patients with a mean age below 59 years. Both male sex and young age are directly related to an increased risk of revision TKA.⁵ Increased levels of activity of in younger patients places more stress on the bone implant interface, which can lead to premature loosening of the components, which may be the reason aseptic loosening is the major cause for revision in this age group.³⁰ Despite

Table V. Kaplan-Meier estimates of cumulative revision (95% confidence interval) by fixation in primary knee arthroplasties.

	Mean age, yrs			Time since primary knee arthroplasty, yrs					
Data source	(SD)	Fixation	Ν	1	3	5	10	15	17
NJR									6.43
	68.9			0.49	1.75	2.54	4.13	5.84	(6.29 to
	(9.6)	All types	1,357,077	(0.48 to 0.51)	(1.73 to 1.77)	(2.51 to 2.57)	(4.08 to 4.17)	(5.75 to 5.93)	6.57)
									4.82
	69.7			0.42	1.48	2.11	3.23	4.14	(4.69 to
	(9.3)	All cemented	1,136,212	(0.41 to 0.43)	(1.45 to 1.50)	(2.08 to 2.14)	(3.19 to 3.27)	(4.33 to 4.50)	4.96)
									5.65
	68.2	All uncemen-		0.56	2.09	2.84	4.06	5.35	(5.23 to
	(9.6)	ted	47,061	(0.50 to 0.64)	(1.96 to 2.23)	(2.68 to 3.00)	(3.86 to 4.27)	(5.05 to 5.86)	6.10)
Our series									2.94
	58.6	All uncemen-		0.00	0.68	0.93	2.17	2.94	(1.24 to
	(8.07)	ted	454	(N/A)	(0.19 to 1.87)	(0.31 to 2.24)	(0.91 to 4.40)	(1.24 to 5.87)	5.87)

Where there are patients at risk, but no events, the absolute risk is estimated as 0 and the confidence interval cannot be estimated. It is denoted by "(N/A)".

N/A, not applicable; NJR, National Joint Registry; SD, standard deviation.

Table VI. Kaplan-Meier estimates of cumulative revision (95% confidence interval) in primary knee arthroplasties using PFC Sigma (cemented) vs our series.

			Time since pri	mary knee arthro	plasty, yrs			
Data source	Brand	Ν	1	3	5	10	15	17
NJR	PFC Sigma Bicondylar Knee (femoral) PFC Bicondylar (tibial)							
	Cemented		0.39	1.23	1.70	2.36	3.02	3.19
	unconstrained, fixed	132,331	(0.36 to 0.42)	(1.17 to 1.29)	(1.62 to 1.77)	(2.26 to 2.45)	(2.88 to 3.17)	(3.01 to 3.37)
			0.40	1.49	2.05	2.99	4.03	4.54
	Cemented, PS, fixed	36,344	(0.34 to 0.47)	(1.37 to 1.62)	(1.91 to 2.21)	(2.80 to 3.19)	(3.75 to 4.33)	(4.02 to 5.13)
	PFC Sigma Bicondylar Knee (femoral) PFC Sigma Bicondylar (tibial)							
	Cemented		0.35	1.34	1.87	2.50		
	unconstrained, fixed	122,269	(0.32 to 0.38)	(1.27 to 1.41)	(1.79 to 1.95)	(2.39 to 2.62)		
Our series			0.00	0.68	0.93	2.17	2.94	2.94
	All uncemented	454	(N/A)	(0.19 to 1.87)	(0.31 to 2.24)	(0.91 to 4.40)	(1.24 to 5.87)	(1.24 to 5.87)

Where there are patients at risk, but no events, the absolute risk is estimated as 0 and the confidence interval cannot be estimated. It is denoted by "(N/A)". Where fewer than ten patients are at risk, the cell is left blank.

N/A, not applicable; NJR, National Joint Registry.

this, we experienced no cases of aseptic loosening of tibial component, and a very modest revision rate of 1.76% in the whole cohort.

The 18th annual NJR report shows comparable revision rates between cemented and cementless implants in patients below the age of 65 years. This is contrary to the results in our study, with significantly better revision rates than those reported in the NJR (Table V). The NexGen implant has a higher reported failure rate (4.98) versus our data (2.94). We believe this is due to being selective over the patients who receive a cementless implant, specifically young male, pre-menopausal women, and non-smokers, who will have better bone biology compared to the routine cohort.

We almost exclusively used PS implants in our reported cohort, despite the NJR showing an increased revision rate for PS versus CR cemented implants.³¹ The senior author (AJA) concludes that poor cementing technique in a PS implant will result in a higher failure rate. Considering that our series Table VII. Kaplan-Meier estimates of cumulative revision (95% confidence interval) by brand, in primary knee arthroplasties.

	Brand		Time since primary knee arthroplasty, yrs					
Data source		Ν	1	3	5	10	15	17
NJR	LCS Complete (femoral) M.B.T. (tibial)							
			0.42	1.83	2.53	3.43	4.11	
	Uncemented, unconstrained, mobile	15,831	(0.33 to 0.54)	(1.63 to 2.06)	(2.28 to 2.80)	(3.12 to 3.77)	(3.67 to 4.61)	
	Nexgen (femoral) TM Monoblock (tibial)							
			0.61	2.62	3.33	4.39	4.98	4.98
	Uncemented, unconstrained, fixed	4,002	(0.41 to 0.90)	(2.16 to 3.17)	(2.81 to 3.96)	(3.76 to 5.12)	(4.24 to 5.84)	(4.24 to 5.84)
	Scorpio (femoral) Scorpio NRG (tibial)							
			0.62	1.93	2.61	3.93	4.74	4.74
	Uncemented, unconstrained, fixed	3,733	(0.41 to 0.93)	(1.53 to 2.43)	(2.14 to 3.18)	(3.33 to 4.63)	(4.02 to 5.58)	(4.02 to 5.58)
	Triathlon (femoral; tibial)							
			0.61	1.70	2.15	3.07		
	Uncemented, unconstrained, fixed	4,190	(0.41 to 0.91)	(1.30 to 2.23)	(1.64 to 2.82)	(2.07 to 4.54)		
Our series	All uncemented (NexGen		0.00	0.68	0.93	2.17	2.94	2.94
	(femoral; tibial))	454	(N/A)	(0.19 to 1.87)	(0.31 to 2.24)	(0.91 to 4.40)	(1.24 to 5.87)	(1.24 to 5.87)

Where there are patients at risk, but no events, the absolute risk is estimated as 0 and the confidence interval cannot be estimated. It is denoted by "(N/A)". Where fewer than ten patients are at risk, the cell is left blank. N/A, not applicable.

Table VIII. Prosthesis time incident rate estimates of indications for revision (95% confidence interval) by fixation, constraint, bearing type, and whether a patella component was recorded.

Data source	Fixation, constraint, and bearing subgroups	Mean age, yrs	Prosthesis years at risk (× 1,000)	Total revisions	Number of revisions per 1,000 prosthesis years (all causes) with SCAS CI*
NJR	All cases	70	8,921.4	40,414	4.53 (4.49 to 4.57)
	All cemented	70	7,353.0	26,618	3.62 (3.58 to 3.66)
	Cemented: PS, fixed, with patella	All ages	900.3	3,259	3.62 (3.50 to 3.75)
	Cemented: PS, fixed, without patella	All ages	887.6	4,385	4.94 (4.80 to 5.09)
	All uncemented	All ages	386.8		
Our series	All uncemented	59	4.0	8	2.07 (0.95 to 3.83)
	Uncemented	≤ 64	3.0	6	2.09 (0.83 to 4.21)
	Uncemented	≥ 65	1.0	2	2.19 (0.36 to 6.60)

*This CI method takes into account the skewed distribution of the number of revisions, resulting in a narrower interval.

Cl, confidence interval; NJR, National Joint Registry; PS, posterior-stabilizing; SCAS, skewness-corrected asymptotic score.

involves uncemented fixation, we are able to avoid this problem. The tantalum metal osseointegrates excellently with native bone, resulting in a stable and long-lasting fixation.

Cementless implants aid in preserving the native bone stock, and incorporate the physiological healing process, thus delivering superior osseointegration. The surgical time is shortened, which could be advantageous in reducing the pneumatic tourniquet time for surgeons who perform surgery using a tourniquet. The initial stability and fixation of trabecular metal is excellent, which allows for the twin pegged design of the tibial baseplate, when compared to the keel required for rotational stability in cemented baseplates; this potentially allows for an easier bone-sparing revision in the event of failure.²⁹ Avoiding cement also prevents cement-related complications both perioperatively and later due to cement debris. Cementless implants can withstand higher shearing forces compared to cemented implants, as they transmit the stress onto native bone, encouraging bone growth and remodelling, whereas the cement-bone interface wears out over time. Once osseointegrated, the concern about shear stress and increased constrained becomes irrelevant.³² Tantalum has low rates of infection compared to other metallic components. The porous metal results in decreased bacterial adherence and reduction in biofilm production.³³

Despite the advantages of cementless implants, there is paucity of data about its long-term survival in large centre studies. Currently available studies focus mainly on the older generation of cementless implants, which experienced high rates of failure.⁷⁻⁹ The common causes for revision of cementless TKA knees include pain, aseptic loosening/lysis, and wear. Nevertheless, compared to cemented implants, the rates of revision due to implant infection are lower.

The tibial monoblock carries the risk of instability and stiffness due to its design, lacking modularity once the femoral and tibial components are in place, and does not allow for an isolated exchange of polyethylene insert in case of instability that requires revision surgery.² Four of our patients experienced instability, and one patient had stiffness for which they underwent revision TKA. In our case series, we encountered only two cases of aseptic loosening of the femoral component. The radiographs were normal in each case and showed no implant migration, but the femoral components were thought to be loose intraoperatively at the time of revision surgery. In our study, 41 patients were implanted with the CR type of NexGen implant, while the rest were implanted with the PS type. Studies have shown that both varieties have similar outcomes.³⁴

This study does have limitations. Its retrospective nature means that datasets may not be complete, however we used a prospective database and carefully analyzed individual surgeons' NJR data, and therefore believe our dataset to be complete. This study specifically investigates the outcomes of a Tantalum trabecular metal tibial component, and our results may not be applicable to other cementless designs. We did not collect functional outcome scores in this study that would have been of interest; however, the aim of this study was to determine if revision and aseptic loosing rates were reduced by the use of this specific implant and, most importantly, we seem to have addressed the problem of tibial aseptic loosening.

In conclusion, cementless TKA is an attractive choice for younger (< 65 years), more active patients, and has excellent survivorship. The NexGen trabecular (tantalum) cementless implant has lower revision rates in our series compared to all cemented implants and other types of cementless implants, and its use in younger patients should be encouraged.

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