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High rate of tibial debonding and failure in a popular knee replacement

A FOLLOW-UP REVIEW

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Aims

Total knee arthroplasty (TKA) is a common and safe orthopaedic procedure. Zimmer Biomet's NexGen is the second most popular brand of implant used in the UK. The primary cause of revision after the first year is aseptic loosening. We present our experience of using this implant, with significant concerns around its performance with regards early aseptic loosening of the tibial component.

Methods

A retrospective, single-surgeon review was carried out of all of the NexGen Legacy Posterior Stabilized (LPS) TKAs performed in this institute. The specific model used for the index procedures was the NexGen Complete Knee System (Legacy Knee-Posterior Stabilized LPS-Flex Articular Surface, LPS-Flex Femoral Component Option, and Stemmed Nonaugmentable Tibial Component Option).

Results

Between 2013 and 2016, 352 NexGen TKAs were carried out on 331 patients. A total of 62 TKAs have been revised to date, giving an all-cause revision rate of 17.6% at a minimum of five years. Three of these revisions were due to infection. Overall, 59 of the revisions were performed for aseptic loosening (16.7%) of the tibial component. The tibial component was removed intraoperatively without instrumentation due to significant tibial debonding between the implant-cement interface.

Conclusion

While overall, we believe that early aseptic loosening is multi-factorial in nature, the significantly high aseptic revision rate, as seen by an experienced fellowship-trained arthroplasty surgeon, has led us to believe that there is a fundamental issue with this NexGen implant design. Continued implant surveillance and rigorous review across all regions using this particular implant is warranted based on the concerning findings described here.

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Keywords: NexGen, Zimmer, Total Knee Arthroplasty, Aseptic Loosening, Tibial Tray Failure, Early Implant Failure

Introduction

Total knee arthroplasty (TKA) is a common and safe orthopaedic procedure. According to the 2020 UK National Joint Registry (NJR), between 1 April 2003 and 31 December 2019, a total of 1,300,987 primary knee joint arthroplasty procedures were carried out. Overall, NexGen (Zimmer Biomet, USA) is the second most popular brand of implant used. The system used in this study – the NexGen Legacy Posterior Stabilized (LPS) knee system – only made up 3,205 of the 176,295 (1.82%) NexGen knees implanted.[1]

A total of 37,794 first revisions of a knee prosthesis have been identified in the NJR. The overall revision rates at one year, three years and five years were reported as 0.50%, 1.82%, and 2.65%, respectively, for all knee prosthetics. The revision rates for the NexGen LPS at one, three, and five years

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Table I. Descriptive statistics for primary patient cohort.

Variable	Number	TKAs
Sex, n (%)		
Male	153 (46)	159 (45)
Female	178 (54)	193 (55)
Side, n (%)		
Left	172 (49)	
Right	176 (50)	
Bilateral	2 (1)	
Mean age at operation, yrs (SD)	67 (10.2)	

SD, standard deviation; TKAs, total knee arthroplasties.

Table II. Descriptive statistics for revision patient cohort.

Variable	Total	TKAs
Sex, n		
Male	29	29
Female	31	33
Side, n		
Left	36	
Right	25	
Bilateral	1	
Mean age at index operation, yrs (SD)	63 (7.5)	
Mean age at revision operation, yrs (SD)	67 (7.9)	
Mean months from primary to revision (SD)	43.8 (17.1)	

SD, standard deviation; TKAs, total knee arthroplasties.

were reported as 0.47%, 1.94%, 2.67%, respectively.[1] It is forecast that the rates of TKA revision in England and Wales will increase by 332% from the 2012 figures by the year 2030.[2] The type of revision procedure performed is informed by several factors including time from primary surgery and indication for revision. The cost of revision surgery is significant – a 2006 study, using 2004 data, estimated that the cost of a revision TKA in England and Wales was £5,868.[3] More recent reports from the USA calculate the cost of revision TKA as $23,130 to $75,028.[4,5]

The most common reasons reported in the NJR for revision of cemented TKAs were aseptic loosening/lysis, infection, instability, pain, and 'other'. Infection is the most common cause of revision in the first year; however, in years one to three, aseptic loosening is the most common reason for revision. A posterior-stabilized fixed knee without patellar resurfacing had a reported all-cause revision rate of 5.22 per 1,000 prosthesis years. The revision rates for infection and aseptic loosening were reported as 1.12 and 1.66 per 1,000 prosthesis years, respectively.[1]

We originally published our results of using the NexGen Complete Knee System LPS-Flex in early 2020.[6] The high failure rate was of significant concern and led to the discontinuation of the use of this implant in this unit. This original paper generated significant interest in the orthopaedic community and led to requests from the UK NJR and ODEP to publish a follow-up paper with updated results. The primary aim of this study is: 1) to assess the all-cause revision rate for this cohort of patients; and 2) to identify cases of aseptic loosening of the tibial component.[2]

Methods

Study design. A retrospective, single-surgeon review was carried out of all NexGen LPS TKAs performed between April 2013 and January 2016. In order to identify patients who underwent a revision of their primary TKA, a manual review of the National Imaging Management Information System (NIMIS) was conducted in June 2021. The end point for the study was defined as either the date of the revision operation, or the last date that images were available on NIMIS. As this research is a radiological audit, formal IRB ethical approval was not required.

Surgical technique. All index cases were performed by, or under the direct supervision of, a single fellowship-trained arthroplasty surgeon (DK, GAS, EM) in a high-volume centre for TKA. The specific model used was the NexGen Complete Knee System (Legacy Knee-Posterior Stabilized LPS-Flex Articular Surface, LPS-Flex Femoral Component Option, and Stemmed Nonaugmentable Tibial Component Option). This tibial component is not compatible with a stem extension and does not have a polymethyl methacrylate (PMMA) pre-coat. It is made from wrought titanium (Ti-6Al-4V) alloy with a dovetail locking mechanism for the polyethylene. Patellar resurfacing was not performed routinely; however, the 'All Poly Patella Standard' implant was used when it was carried out.

Technique. All procedures were done under tourniquet via a sub-vastus approach. The tibia was prepared with a 16.7 mm stemmed tibial drill and tibial broach impactor as per the manufacturers recommended surgical technique. High-viscosity Palacos cement (Zimmer Biomet) was used in all cases. The cementing technique employed involved applying cement to the cut surface of the tibia and digital pressurization of cement into the intra-medullary canal. No cement was applied directly to the undersurface of either component. The original surgical guidelines for the NexGen knee gave no specific instructions as to the preferred cementing technique for the tibia. At a later stage, the cementing guidelines were updated to recommend the application of cement to the undersurface of the tibial component, as well as to the cut tibial surface itself.

Post-operation. A standardized postoperative care pathway for knee arthroplasty was followed for all patients. Plain film radiographs were obtained and reviewed by the lead surgeon on postoperative day one to allow for assessment of prosthesis position and to out-rule occult periprosthetic fractures. The patient was brought back

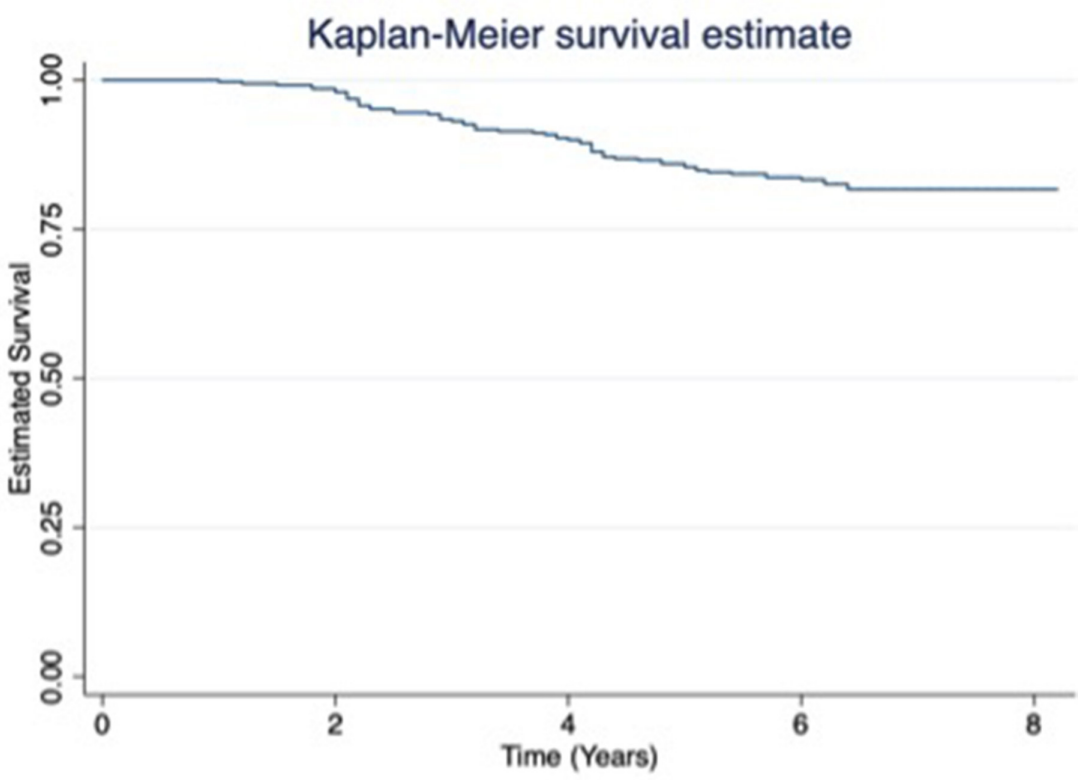

Fig. 1
Kaplan-Meier estimate of survivorship.

for clinical review six weeks postoperatively. If no issues were identified, patients were discharged to their GP.

Statistical analysis. Demographic data was described with descriptive statistics. A Kaplan-Meier graph was produced to illustrate survivorship. The total time period of analysis was from 17 April 2013 to 30 June 2021. Statistical analysis was performed using Stata/IC13.1 for Mac (64-bit Intel; StataCorp, USA).

Results

In total, between 17 April 2013 and 19 January 2016, 352 NexGen TKAs were carried out on 331 patients. In all, 19 patients had bilateral staged TKAs. The demographics of the TKAs are given in Table I below.

Demographics of the patients who underwent revision are given in Table II.

Typically, patients started to experience symptoms of medial knee pain with a supra-patellar effusion between 12 and 24 months postoperatively. Radiographs of symptomatic knee arthroplasties initially showed subtle bone loss on the medial tibia with a tilt of the tibial component into a varus alignment which became more obvious as time progressed. The cement mantle surrounding the stem of the tibial implant remained firmly bonded to bone in all cases. Small fractures were noted in the cement on the medial side of the stem, which allowed it to tilt into varus malalignment.

Of these 352 TKAs, 62 have been revised to date, giving an all-cause revision rate of 17.6%. These 62 revisions were performed on 60 patients with a mean time from primary to revision of 44 months (12 to 78). The minimum time from primary procedure to revision was 12 months, and the maximum time was 78 months. Several suspicious x-rays were identified during this review, and we anticipate the number of revisions to increase in the future.

Three revisions were due to confirmed infection and required either a one- or two-stage revision. In all, 59 revisions were performed for aseptic loosening (16.7%) of the tibial component; the femoral component was revised in two cases. Most of these patients had a preoperative CT SPECT scan, which has shown to be superior to other imaging methods for detecting aseptic loosening.[7] This scan demonstrated loosening of the tibial component. Infective blood parameters were normal in all cases. Intraoperative deep tissue samples were sent for these patients and all returned negative results, thus ruling out infection as the cause for loosening of the component.

NexGen implant survival analysis. Figure 1 demonstrates NexGen survival rate over time, with all-cause revision as the failure point. By the time that usage of

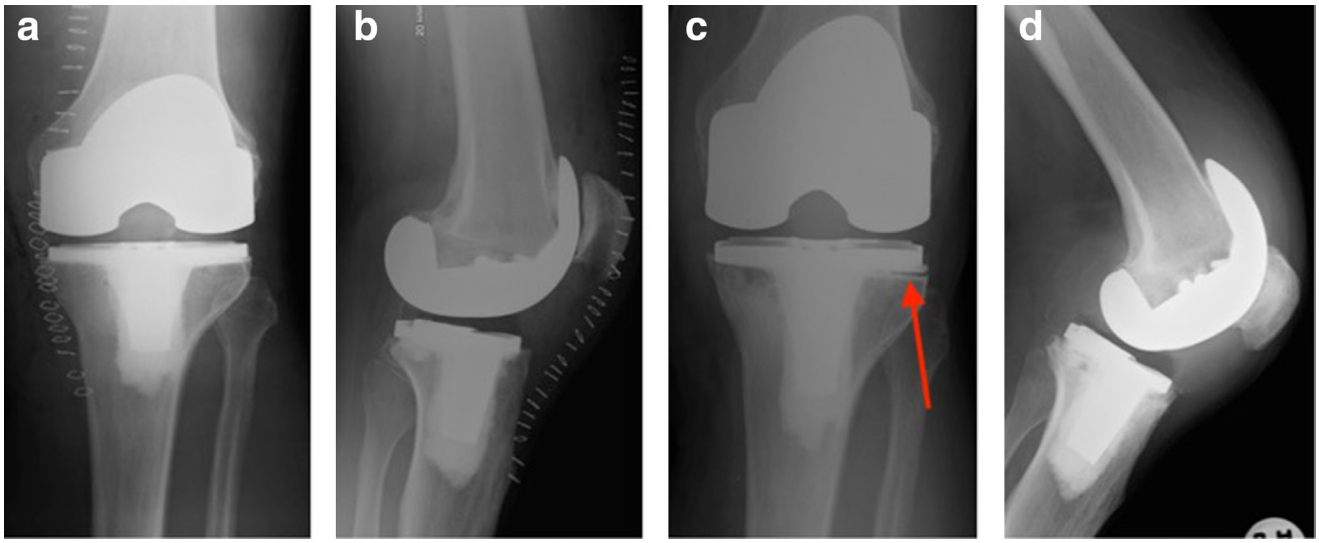

Fig. 2

Day one postoperative a) anteroposterior (AP), and b) lateral images of NexGen total knee arthroplasty (TKA); pre-revision c) AP, and d) lateral images of same TKA.

the implant was discontinued in January 2016, two revisions had already been performed; however, many other patients had re-presented with suspicious symptoms.

Radiological findings. Figure 2 contains a set of four images for the same patient. Parts a and b illustrates day-one postoperative anteroposterior and lateral images of a typical NexGen TKA which subsequently developed aseptic loosening of the tibial component. This radiograph demonstrates an intact cement mantle, neutral coronal alignment and no positioning issue. Parts c and d illustrates the same knee pre-revision. An obvious varus deformity of the tibial component is appreciated.

Intraoperative revision findings. In all cases, the tibial component was loose and could be removed without instrumentation. This is illustrated in Figure 3. The second image in Figure 3 illustrates an intact cement mantle after removal of the tibial component. In a subset of cases, a small volume of cement was still attached to some aspect of the under-surface of the tibial component.

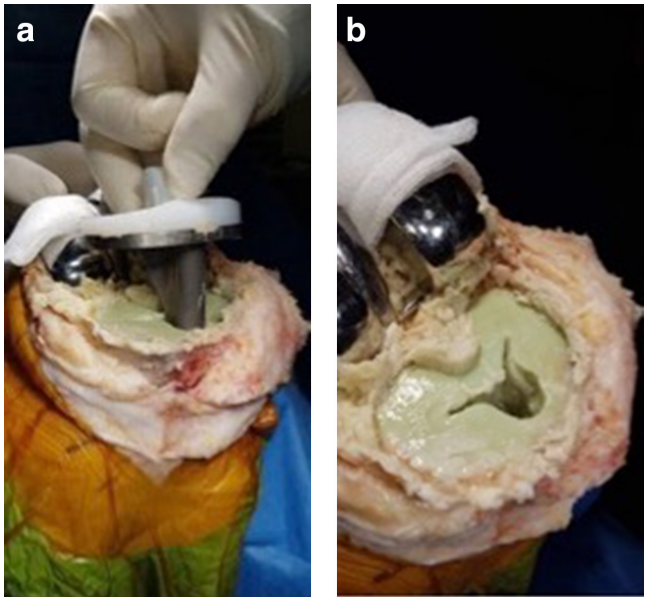

Fig. 3

Intraoperative images of the removal of the tibial baseplate with an intact cement mantle remaining.

Discussion

Using all-cause revision as our end point, we identified 62 NexGen TKAs which required revision, giving an all-cause revision rate of 17.6%, with a mean time to revision of 44 months. Three of these revision TKAs were indicated for infection, but 59 were revised for early aseptic loosening of the tibial component, giving an aseptic revision rate of 16.7%. This figure is significantly at odds with the UK NJR, which reports revision rates for the NexGen LPS TKA of 0.47%, 1.94% and 2.67% at one year, three years and five years respectively.[1] There are other reports in the literature of early aseptic loosening of NexGen tibial components. Brown et al[8] reported a five-year aseptic revision rate of 1.42% with the NexGen non-augmentable Option tibial component. Foran et al[9] report an early aseptic loosening rate of 1.5% using the NexGen pre-coated MIS tibial component with a mean time to failure of 17 months. Arsoy et al[10] identified early tibial debonding as a cause for early revision in 1.9% of NexGen TKAs, which were performed using the NexGen LPS 3° tibial tray with a median time to revision of 39 months.

Nearly all of the patients revised in these publications presented in a similar manner to our patients.[8-10] Clinically, they reported painful weightbearing (after a period of postoperative pain-free weightbearing), and a knee effusion. Radiologically, a lucent line was noted between the under surface of the tibial component and the cement mantle with a tilting of the tibial tray into varus. Intraoperatively, the tibial component which was removed by hand was noted to have an intact cement mantle underneath.

Identifying a single cause for aseptic loosening is not straightforward. The literature has identified multiple factors which have been shown to contribute to early aseptic loosening of tibial components. Overall, these causes can be stratified into surgical-, patient-, cementing-, and implant-related factors.

Surgical factors. While operative technique can contribute towards early aseptic loosening, the same lead surgeon who experienced the high rate of aseptic loosening with the NexGen knee had a previous revision rate for aseptic loosening of 0.5% between 1999 and 2017 using the PFC Sigma (DePuy Synthes, USA) implant.[6] While the learning curve may explain a slightly higher revision rate as the surgeon needs to familiarize themselves with new implants and equipment, we would expect to see the cases requiring aseptic revision to be front-loaded over the period that the new implant was used. This was not the case with the revisions split relatively evenly throughout, with 12 in 2013, 23 in 2014, 24 in 2015, and three in 2016. On that basis, we do not think that poor surgical technique was a major contributing factor towards our high revision rate. An independent consultant radiologist (see Acknowledgements) retrospectively reviewed the index day-one postoperative images of our patients who required revision for aseptic loosening, and reported that there was no issue with malalignment of the implants.

Patient factors. According to the UK NJR, the median age at the primary surgery for the NexGen LPS knee was 67 years (interquartile range 59 to 74).[1] This is consistent with the mean age of the total NexGen cohort in the current study of 67 years (standard deviation (SD) 10.2) for their index procedure. However, the mean age at the time of the index procedure for the cohort of patients who required revision surgery was age 63 years (SD 7.5). This younger age group experiencing aseptic loosening is consistent with the literature.[1,11]

Garceau et al[12] demonstrated that obese patients undergoing TKA had a higher rate of aseptic loosening than non-obese patients. The BMI was not recorded for our patient cohort; however, we think it is unlikely to have played a significant role in the aseptic loosening experienced here. We would expect to have seen an equal rate of aseptic loosening in the PFC Sigma cohort, who were previously operated on by the lead surgeon, but this was not the case.[6]

Cementing factors. All of the NexGen TKAs in our study were implanted with high-viscosity Palacos cement. The literature is indeterminate when trying to determine whether or not the use of high viscosity cement (HVC) or low viscosity cement (LVC) increases the risk of early aseptic loosening. Several published studies have claimed that the use of HVC was the cause of early aseptic loosening in their patient cohort,[13,14] and that it is an independent risk factor associated with a higher rate of revision for aseptic loosening.[15] Recent in vitro studies have determined that the use of LVC resulted in a significantly higher failure force compared to HVC.[16,17] However, a 2021 large cohort study examined over 76,000 knees using HVC and LVC and found no difference in the risk of aseptic loosening between the two.[18] We do not believe that use of HVC explains the high revision rate in our patient cohort.

Cementing technique has been shown to be important for long-term implant survival.[19] In vitro studies have shown that applying cement to both the under-surface of the tibial tray and onto the tibial bone leads to optimal cement penetration.[20] Other in vitro studies have demonstrated that cement applied to the tibia and the keel increases pull-out strength compared to cementing the tibial baseplate alone.[16] As documented above, the lead surgeon only applied cement to the tibia itself and did not apply cement to the under-surface of the tibial tray. The manufacturer cementing guidelines changed to include adding cement to the under-surface of the tibial tray. We did not change our practice to reflect this update, and should acknowledge that this may have led to small increase in the rates of aseptic loosening for our patient cohort.

Implant factors. The design of the implant and how the various options for components that make up a TKA interact may have an effect on its longevity. For example, registry data from Australia has demonstrated a higher revision rate due to aseptic loosening for rotating platform TKAs than fixed-bearing TKAs;[21] our patients received a fixed-bearing TKA.

Another variable which can affect longevity is having a PMMA pre-coat on the implant. Pre-coating tibial trays with PMMA has been shown to be an independent risk factor for early aseptic loosening.[22] In vitro studies testing pull-off strength have demonstrated that coated implants had a lower pull-off strength than non-coated implants.[17] The tibial baseplate in our patient cohort did not have a PMMA pre-coat, and neither did the NexGen tibial trays that failed early in the Arsoy et al paper;[10] however, Foran et al have demonstrated early aseptic loosening of PMMA coated NexGen tibial components.[9] From personal communication with a NexGen representative, we know that 81% of NexGen tibial components have a pre-coat, with the remaining 19% not having a pre-coat. The UK NJR does not record whether an implant has a pre-coat

of PMMA or not. As our patient cohort would fall within the 19% of NexGen implants that do not have a PMMA pre-coat, we think that the NJR data may be somewhat incomplete and possibly misleading.

The method of stablization of the tibial baseplate in the tibia can also influence the longevity of the implant. Swedish registry data reports a higher 15-year all-cause revision rate in the NexGen pre-coat four-pegged tibial baseplate (5.8%) than the Option stemmed tibial baseplate (3%),[23] which was the one used in our study. A potential confounding factor in this study is the pre-coat on the pegged stem. Katetanek et al[24] reported a significantly higher rate of aseptic loosening of the tibial component when comparing the NexGen MIS Tibial Component using a mini-keel (5.7%) versus the standard keel (1.6%). Brown et al[8] reported a five-year all-cause revision rate of 3.4% with the NexGen non-augmentable Option tibial component. The modular tibial stem extension had a lower five-year all-cause revision rate of 1.84%. These findings are in keeping with research from Hinman et al,[25] who reported lower revision rates with modular tibial stem extensions.

A recent paper by Bhalekar et al[26] examined explanted NexGen components and identified a pattern of deformation in the polyethylene insert which they thought was likely a manufacturing issue which was exacerbated in vivo. They believe that the problem was related to the polyethylene component and the central locking mechanism used to sit it into the tray, not the tibial tray itself. This polyethylene deformity causes increased frictional torque between the insert and the tray. This is linked to excessive micromotion between the tibial tray and cement mantle. Unstable components result in increased wear and the release of excessive amounts of particulate debris. Gallo et al[27] have linked the excessive wear of polyethylene particles to the generation of wear particles which triggers peri-prosthetic osteolysis, which is a precursor for aseptic loosening. We think that this is a potential cause for the issues we encountered with this implant.

After publishing our original paper in 2020, we were contacted by other institutions who were experiencing the same issue with this implant. It has led these institutes re-auditing all of their NexGen revisions, and the discovery of many more cases of aseptic loosening than previously thought. There are some limitations to this paper. Some national public and private hospitals do not use the NIMIS system; therefore patients followed up in those institutes would not be included in our study. If no current imaging was available on NIMIS, it was assumed that the patient did not have their TKA revised.

While overall, we believe in conclusion that early aseptic loosening is multi-factorial in nature, the significantly high aseptic revision rate, as seen by an experienced fellowship-trained arthroplasty surgeon, has led us to believe that there is a fundamental issue with this NexGen implant design. Continued implant surveillance and rigorous review across all regions using this particular implant is warranted based on the concerning findings described here. If universally alarming findings are noted in future, an implant recall may be necessary in future.

Take home message

- Early aseptic loosening is complex and multi-factorial.
- We believe we have identified an issue with this specific NexGen implant, which has been masked in the UK National Joint Registry by the overall good NexGen dataset.
- Extreme caution is urged if usage of this implant (LPS Flexion with Option Tibia) is to continue.

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- G. A. Sheridan: Formal analysis, Writing - review & editing.
- E. Masterson: Conceptualization, Supervision, Writing - review & editing.

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