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Original research

# Early Survivorship of Newly Designed Highly Porous Metaphyseal Tibial Cones in Revision Total Knee Arthroplasty

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ABSTRACT

*Background:* Metaphyseal cones provide durable fixation in revision total knee arthroplasty (TKA). However, there is a paucity of data on the outcomes of a new porous cone design. As such, the goal of this study was to analyze the early survivorship in patients undergoing revision TKA with this cone.

*Methods:* We retrospectively reviewed 163 revision TKAs with a newly designed porous tibial cone from 2016 to 2018. Mean age was 67 years, and mean body mass index was 33 kg/m$^2$. Minimum follow-up duration was 2 years. Most patients were revised for aseptic loosening (46%), 2-stage periprosthetic joint infection (PJI) reimplantation (28%), or instability (15%). Most were varus-valgus constrained (65%) or hinged (32%) constructs. The majority had hybrid tibial stem fixation (74%). A multivariate Cox regression analysis was used to identify risk factors for reoperation.

*Results:* Survivorship free from re-revision for aseptic loosening, any nonmodular revision, and any reoperation was 100%, 96%, and 86% at 2 years, respectively. No patients were revised for aseptic loosening. Six (4%) tibial cones were removed for PJI, one of which was loose. There were 23 reoperations (14%), most commonly for PJI (10%). Multivariate analysis identified PJI reimplantation (hazard ratios [HR] = 4.2, $P = .002$), males (HR = 2.9, $P = .02$), and hinged constructs (HR = 2.7, $P = .02$) as significant risk factors for reoperation.

*Conclusions:* In a complex revision TKA cohort with a new highly porous tibial cone, in which most patients received hybrid stem fixation and nonlinked and linked constraint, there was 100% survival free from re-revision for aseptic loosening at 2 years. Longer term follow-up is required.



## Introduction

The incidence of revision total knee arthroplasty (TKA) has risen over the last decade and is projected to continue to steadily increase worldwide over the next several decades [1-3]. Revision TKA presents a number of challenges for arthroplasty surgeons, namely prevention of periprosthetic joint infection (PJI), achieving stability, and managing bone loss [4,5]. With epiphyseal bone largely absent, traditionally diaphyseal fixation alone with fully cemented or cementless stems has predominated [4,5]. However, metaphyseal fixation in the form of metaphyseal sleeves [6,7] and highly porous metaphyseal cones [8-15] has proven to be highly successful in providing durable mid- to long-term fixation in revision TKAs, even with moderate to severe bone loss [6-15].

As such, new designs of highly porous, additively manufactured, metaphyseal cones have been developed [14,15] to improve the surgical efficiency and ease of instrumentation. One such design is a 3D-printed, titanium (Stryker, Mahwah, NJ), highly porous metal with a ream-only instrumentation system that performed well in cadaveric testing [14]. However, there is only one other clinical study to the authors' knowledge analyzing the system's safety and short-term clinical efficacy [15].

The goal of the present study was to analyze the short-term outcomes of these novel metaphyseal cones with a reamer-only

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instrumentation system. Specifically, we analyzed (1) survivorship free from component aseptic loosening, any nonmodular revision, and any reoperation, (2) risk factors for any reoperation, (3) radiological outcomes at a minimum follow-up of 1 year, and (4) complications specific to cone preparation or insertion. We hypothesize that this newly designed porous tibial cone will have an excellent early survivorship free from aseptic loosening with a low rate of cone-related complications.

## Material and methods

Through our electronic medical record and chart review, patients who had undergone revision TKA at our institution from 2016 to 2018 with a specific tibial cone design (Stryker) were identified for retrospective review. A thorough chart review was performed to collect surgical and patient demographic details. Re-revisions, reoperations, and complications specific to the tibial cone were recorded. Patients were followed up until any reoperation or clinical follow-up at a minimum of 2 years; patients were excluded if they did not have at least 2 years of clinical follow-up. Mean follow-up duration was 2.5 years (range, 2-4 years). Preoperative radiographs were evaluated for preoperative bone loss as type 1, type 2a or 2b, or type 3 according to the Anderson Orthopedic Research Institute bone loss classification [16]. Furthermore, 140 of 157 patients (89%) who had not undergone a nonmodular component re-revision TKA during the study period had radiographic follow-up at a minimum of 1 year and a mean of 1.7 years. Postoperative radiographs were assessed for radiolucent lines and signs of implant and cone loosening as defined by 2 different classification systems [17,18]; the implant was considered loose if it met criteria for loosening in either system. Institutional review board approval was obtained before study initiation.

### *Patients*

We identified 178 revision TKAs (178 patients) performed at our institution from 2016 to 2018 with the specific tibial cone implanted. Fifteen revision TKAs (15 patients) were lost before 2 years of clinical follow-up. Therefore, 163 revision TKAs (163 patients) were included in the cohort. Eighty-eight patients (54%) were female. Mean age was 67 years (range, 48-86 years). Mean body mass index (BMI) was 33 kg/m$^2$ (range, 19-61 kg/m$^2$) (Table 1).

**Table 1**
Patient and surgical demographic data.

| Patient and surgical demographics | |
|---|---|
| Patients, no. | 163 |
| Revision TKAs with tibial cones, no. | 163 |
| Females, no. (%) | 88 (54%) |
| Mean age, years (range) | 67 (48-86) |
| Mean BMI, kg/m$^2$ (range) | 33 (19-61) |
| Indications for revision | |
| Aseptic loosening, no. (%) | 75 (46%) |
| Periprosthetic joint infection, no. (%) | 46 (28%) |
| Instability, no. (%) | 24 (15%) |
| Other, no. (%) | 18 (11%) |
| Symmetric tibial cone, no. (%) | 147 (90%) |
| Asymmetric tibial cone, no. (%) | 16 (10%) |
| Hybrid tibial stem fixation, no. (%) | 121 (74%) |
| Cemented tibial stem fixation, no. (%) | 42 (26%) |
| Constraint | |
| Posterior-stabilized (PS), no. (%) | 5 (3%) |
| Varus valgus constrained (VVC), no. (%) | 106 (65%) |
| Nonsegmental linked rotating hinges, no. (%) | 40 (25%) |
| Segmental linked rotating hinges, no. (%) | 12 (7%) |

BMI, body mass index; TKA, total knee arthroplasty.

### *Surgical technique*

All revision TKAs were performed by surgeons at a single tertiary care institution experienced in revision TKA. The surgical technique is similar to what has been described previously [14,15]. The decision for a fully cemented vs hybrid fixation of the tibial stem was based on the surgeon's preferred technique with most surgeons at our institution routinely using hybrid tibial fixation. For preparation and insertion of the highly porous, 3D-printed metaphyseal cone, sequential reaming of the tibial canal is first performed. Once a reasonable diaphyseal fit is achieved, a reamer is left in the diaphysis as an intramedullary guide for the conical reamer. For a symmetric cone, a single conical reamer is used over the intramedullary guide; reaming is performed until the defect is filled and an appropriate fit is achieved with grooves on the side of the reamer indicating the size reamed (size A, B, C, D, or E). For larger defects, an asymmetric cone is reamed with an instrumented system to fill a medial or lateral tibial plateau defect. A trial cone is placed to ensure proper seating height beneath the tibial tray. The rotation of the trial cone is marked with methylene blue, so during impaction of the real tibial cone, rotational alignment is achieved with the inserter. With hybrid stem fixation (cemented metaphysis, cementless diaphysis), the tibial plateau, proximal stem, and metaphyseal region are coated with cement, leaving the diaphyseal portion of the stem uncemented. In fully cemented stems, a cement restrictor is placed, and cement is pressurized throughout the length of the stem and metaphyseal region, including into the cone. With cemented or hybrid stem fixation, the construct is unitized with cement, and there is at minimum a thin layer of cement between the tibial tray (titanium in most systems) and the cone (also titanium); this in theory should prevent any potential for corrosion if the tray were to loosen and have motion at that interface.

### *Surgical details*

Revision TKA indications included aseptic loosening of one or more components in 75 (46%), reimplantation as part of a 2-stage exchange for chronic PJI in 46 (28%), instability in 24 (15%), periprosthetic fracture in 8 (5%), arthrofibrosis in 5 (3.0%), and suspected metal hypersensitivity in 5 (3.0%) cases. Preoperative Anderson Orthopedic Research Institute bone loss classification for the tibia was type 2A in 57 (35%), type 2B in 67 (41%), and type 3 in 39 (24%) TKAs; no patient had a type 1 defect. An asymmetric tibial cone was used in 16 (10%) TKAs, with the asymmetric lobe placed medially in 9 (Fig. 1A-D) and laterally in 7 patients. A symmetric tibial cone was used in 147 (90%) TKAs (Fig. 2A-B). Tibial stem fixation was hybrid in 121 (74%) TKAs and fully cemented in 42 (26%) TKAs (Table 1).

Prosthetic constraint included posterior stabilized (PS) in 5 (3%), nonlinked varus/valgus constrained (VVC) in 106 (65%), nonsegmental linked hinges in 40 (25%), segmental distal femoral replacements in 11 (6%), and a total femur in 1 (0.6%) patient. PS and VVC implant systems included the Legion revision system (Smith and Nephew, London, UK) in 51 (31%), the Stryker TS system (Stryker) in 28 (17%), the NexGen LCCK system (Zimmer-Biomet, Warsaw, IN) in 12 (8%), the Sigma TC3 Revision system (Depuy, Warsaw, IN) in 10 (6%), and the Optetrak LCCK system (Exactech, Gainesville, FL) in 10 (6%) cases. Nonsegmental hinge construct systems included the NexGen hinge (Zimmer-Biomet) in 19 (12%), the Legion Hinge in 17 (10%), the Modular Rotating Hinge (Stryker) in 2 (1%), and the S-ROM Noiles Hinge (Depuy) in 2 (1%) cases. Segmental DFR implant systems included the Global Modular Replacement System (Stryker) in 8 (5%) and the Orthopedic Salvage System (Zimmer-Biomet) in 3 (3%) cases. The total femoral replacement was also a Global Modular Replacement System.

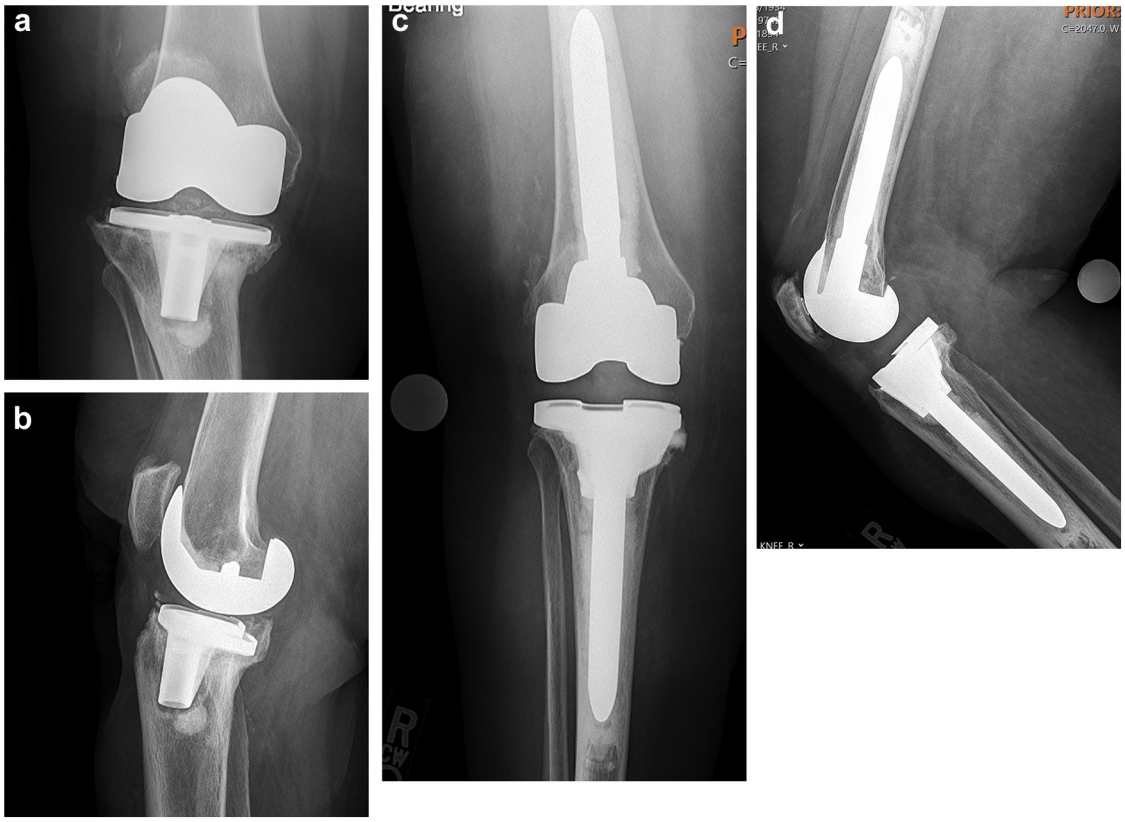


**Figure 1.** Preoperative antero-posterior (a) and lateral (b) radiographs of a patient with a loose, subsided tibial component with type 3 tibial bone loss according to the Anderson Orthopedic Research Institute classification. The patient underwent revision total knee arthroplasty with an asymmetric medially based tibial cone, cemented stems, and a varus-valgus constrained implant. The postoperative antero-posterior (c) and lateral (d) radiographs are stable without signs of implant loosening at 3-y follow-up.

*Statistical analysis*

Continuous variables are reported as means with ranges. Estimated survival free from re-revision for aseptic loosening, any nonmodular re-revision, and any reoperation were calculated with the Kaplan-Meier method [19] and presented with 95% confidence intervals (CI). A multivariate cox regression analysis was used to identify risk factors for reoperation, namely age, sex, BMI, revision indication, and prosthetic constraint; hazard ratios (HR) with 95% CIs were calculated. Statistical significance was defined as $P \leq .05$. All analyses were performed with JMP statistical software (SAS Institute, Cary, NC).

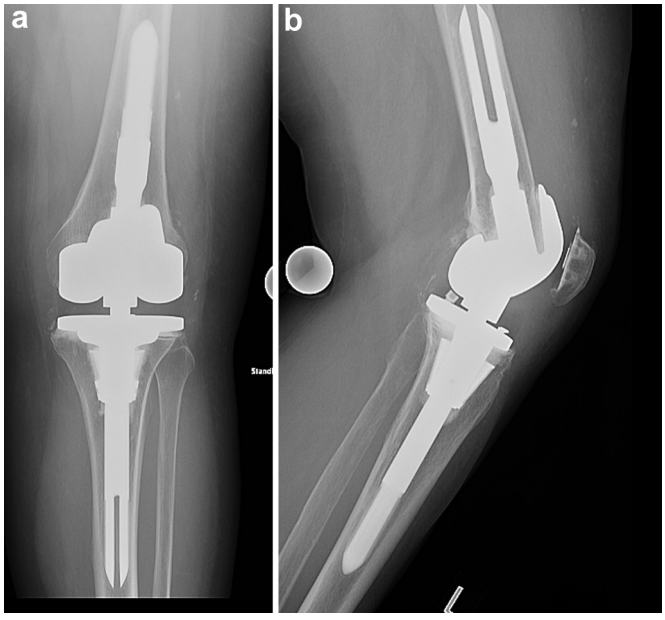


**Figure 2.** Postoperative antero-posterior (a) and lateral (b) radiographs of a linked revision hinged total knee arthroplasty with a symmetric tibial cone and hybrid tibial fixation; the construct is stable at 2-y follow-up.

## Results

*Survivorship free from re-revision for aseptic loosening, any nonmodular re-revision, and any reoperation*

Survivorship free from any re-revision for aseptic loosening of the cone or components was 100% (95% CI, 100%-100%) at 2 years. No tibial cones or tibial components were revised for aseptic loosening.

Survivorship free from any nonmodular re-revision was 96% (95% CI = 93%-99%) at 2 years (Fig. 3). Six (4%) TKAs underwent nonmodular revision during the study period with removal of the tibial cone, all for PJI. One tibial cone (0.5%) was loose at removal while the others were well fixed.

Survivorship free from any reoperation was 86% (95% CI = 82%-90%) at 2 years (Fig. 4). Overall, there were 23 reoperations, including the 6 patients that underwent nonmodular revision outlined previously. An additional 10 patients (6%) underwent irrigation, debridement, and modular exchange for acute or recurrent PJI postoperatively. Two patients (1%) underwent extensor mechanism reconstruction for an extensor disruption

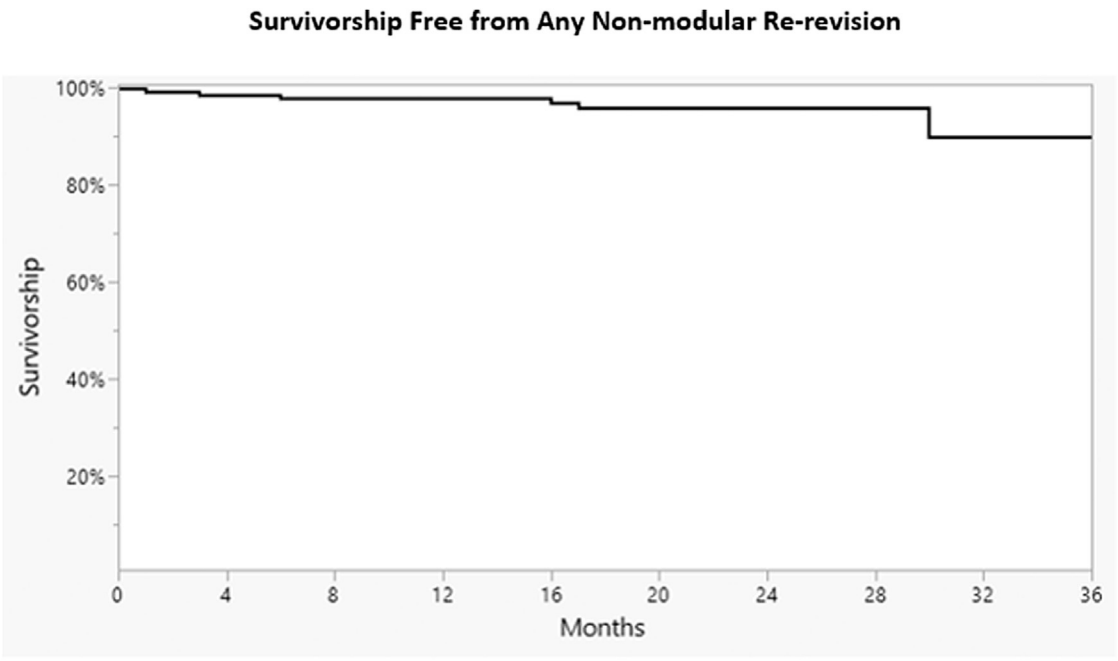


**Figure 3.** Kaplan-Meier curve depicting estimated survivorship free from any nonmodular re-revision of 96% (95% CI = 93%-99%) at 2 y.

postoperatively. Two patients (1%) underwent irrigation, debridement, and reclosure for arthrotomy dehiscence. Two patients (1%) underwent open reduction and internal fixation or periprosthetic femoral fractures. Finally, one patient underwent an arthroscopic synovectomy and lysis of adhesions at 9 months postoperatively for ongoing stiffness.

*Risk factors for any reoperation*

Multivariate regression analysis analyzing age, sex, BMI, revision indication, and level of constraint revealed that an indication of PJI (HR = 4.2, 95% CI = 3.1-5.3, $P = .002$), males (HR = 2.9, 95% CI = 1.3-4.5, $P = .02$), and hinged constructs (compared to VVC) (HR = 2.7, 95% CI = 1.2-4.2, $P = .02$) were independent risk factors for any reoperation. Age and BMI were not significant risk factors for poorer survival free from reoperation.

*Radiographic results*

Of the 157 patients without component revision at 2-year follow-up, 140 patients (89%) had radiographic follow-up at a minimum of 1 year postoperatively and at an average of 1.7 years. One cone (0.6%) in a patient with a VVC and a cementless tibial stem had circumferential radiolucent lines around the cone,

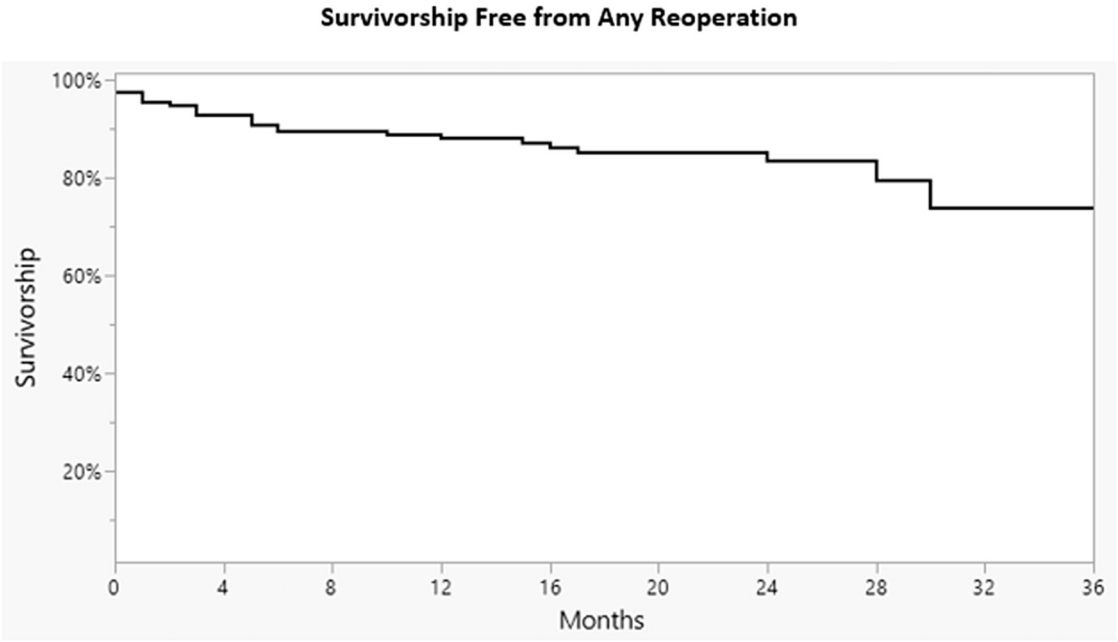


**Figure 4.** Kaplan-Meier curve depicting estimated survivorship free from any reoperation of 86% (95% CI = 82%-90%) at 2 y.

suggesting fibrous ingrowth, but there were no radiolucencies around the tibial component, and it had not migrated. Two cones (1.3%) and tibial components, one in a total femoral construct with a cemented stem and the other in a linked hinged construct with a cementless stem, had progressive radiolucent lines >50% of the cone-bone and tibial component interface suggestive of radiographic loosening.

*Complications*

Two patients (1.3%) had periprosthetic tibia fractures during cone preparation or insertion. One patient had a posterior medial longitudinal split during trialing that was fixated with one cable. The other patient had an anterior minimally displaced split during real cone insertion that was fixated with 2 cables. Symmetric cones were still used in each case; the components appeared unchanged, and the cones appeared ingrown at 18 and 24 months of radiographic follow-up and did not undergo re-revision.

## Discussion

With the incidence of revision TKA continuing to increase worldwide [1-3], efficient techniques and solutions to address the challenges in revision TKA are needed. Managing bone loss and providing durable long-term fixation continues to be a major challenge in revision TKA, with aseptic loosening continuing to account for a high percentage of re-revision TKA indications [20,21]. As metaphyseal fixation in the form of sleeves [6,7] and highly porous cones [8-15] has improved outcomes and fixation in revision TKA, new designs and materials are being introduced to the market [14] that should be monitored for safety and efficacy. A novel highly porous cone with a simple and efficient reamer-based system (Stryker) was introduced to the market in 2015 [14]. In the present study, there was a 100% survivorship free from re-revision for aseptic loosening at 2 years with the use of a novel, 3 dimensional, additively manufactured highly porous tibial cone used in complex revision TKAs. Furthermore, there was just a 1% rate of minimally displaced tibial fracture during cone preparation and/or insertion, lower than that in studies on other cone designs, and a low rate of radiologic loosening at short-term follow-up.

In the present study of 156 revision TKAs in which a symmetric or asymmetric novel tibial cone was used, no TKAs or tibial components were revised for aseptic loosening, resulting in a 100% survival free from re-revision for aseptic loosening at 2 years. Most TKAs revised had significant tibial bone loss in the type 2B (40%) or type 3 (24%) category, representing challenging bone loss cases. In addition, 31% of the revision TKAs in this series had linked segmental or non-segmental hinged constructs. While a cadaveric model confirmed the initial mechanical stability of these novel cones [14], there is only one other study to the authors' knowledge of their clinical outcomes [15]. In a similarly complex cohort with marked bone loss and a high level of constraint in the majority, Tetreault et al. [15] reported on a series of 134 of the same tibial cone. They similarly reported no re-revisions for aseptic loosening and a 100% 2-year survival free from re-revision for aseptic loosening [15]. In contrast to their study in which 77% of tibial stems were fully cemented [15], 75% of the tibial stems in the present study were hybrid fixation, suggesting that both approaches with this novel cone are durable in the short term. In support of this was a recent randomized controlled trial with radioisometric follow-up data of fully cemented vs hybridly fixed tibial cones that showed similar rates of micromotion at early follow-up with either fixation strategy [22].

We also found a low rate of radiographic signs of loosening at short-term follow-up; 2 tibial components and tibial cones with linked hinge constructs appeared radiographically loose but had not been revised. Similarly, Kamath et al. [8] found a >95% revision-free survival of tantalum tibial cones at a much longer follow-up at a mean of 6 years with similarly low rates of radiographic loosening in a complex revision TKA cohort. While these results are encouraging, continued follow-up is needed.

There were no complications noted during the reaming process for the tibial cone; however, there were 2 minimally displaced tibia fractures (1.3%) during cone trialing and/or cone insertion. Tetreault et al. [15] reported a similarly low rate of fracture (2%) during cone preparation and/or insertion for this system for both femoral and tibial cones. The potential advantage of a ream-only system is not only the efficiency but also the fact that it is potentially more safe as it avoids high impaction forces during cone preparation, particularly in sclerotic metaphyseal bone commonly encountered in revision TKA [14]. In a study of 393 metaphyseal broached sleeves used to manage bone loss in revision TKA, one study found a 6.5% rate of intraoperative femoral or tibial fractures with sleeve preparation and/or insertion [6]. Furthermore, the intraoperative fracture rate in this study is significantly lower than those reported in other cone systems with broach instrumentation [8,9,23]. Finally, we did not note any unique complications of this reaming or cone system. As such, this novel cone with a ream-only instrumentation system appears to be at least as safe as other metaphyseal fixation implants and their instrumentations.

As can be expected with a complex revision TKA cohort with severe bone loss and a history of PJI in one-third of patients, there was a modest survivorship free from any reoperation of 86% at 2 years. Most reoperations were secondary to PJI (70%). As such, it is expected that patients with a history of PJI had the highest independent risk of undergoing an early reoperation (HR = 4.2, $P = .002$). We also had a high rate of arthrotomy and extensor mechanism complications, almost exclusively in hinged and distal femoral constructs, which partially accounts for their poorer reoperation-free survival (HR = 2, $P = .02$). These results are similar to other series of complex patients undergoing revision TKA [6-8,20,21].

We acknowledge several limitations of the present study. First, this is a retrospective study of a relatively small group of patients. All the revision TKAs were performed at a single tertiary care institution by surgeons experienced in revision TKA which may limit the study's generalizability. The decision to use this specific cone rather than an alternative implant for metaphyseal fixation or no metaphyseal fixation at all was surgeon dependent and uncontrolled in this retrospective study. We did not have enough femoral cones of this design that were used during the study period to make a meaningful comment on their safety and durability. Finally, as this specific cone was not available until 2015, the follow-up is short in this study; continued follow-up is required.

## Conclusions

A novel 3-dimensional, additively manufactured, highly porous tibial cone with a reamer-only system and hybrid stem fixation in most cases proved to be effective and safe in managing bone loss in revision TKA at short-term follow-up. There was a 100% survivorship free from re-revision for aseptic loosening at 2 years and a low rate of radiographic loosening at short-term follow-up. Furthermore, there was a low rate of tibial fracture during cone preparation and/or insertion, and no unique complications were noted. Longer term follow-up with more patients is necessary to continue to monitor the safety and durability of this device.

## Conflict of interests

G. H. Westrich and S. A. Jerabek are consultants for Stryker that manufactures the metaphyseal cone discussed in this article. D. J.

Mayman and M. P. Bostrom are consultants for Smith & Nephew that also manufactures metaphyseal cones and/or sleeves. P. K. Sculco is a paid consultant for DePuy (Johnson and Johnson), EOS Imaging, Intellijoint, and Lima Corporate and received research support from Intellijoint Surgical.

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