Midterm Outcomes of Tantalum Metal Cones for Severe Bone Loss in Complex Primary and Revision Total Knee Arthroplasty

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Abstract

Background: Managing severe periarticular bone loss poses a major challenge in complex primary and revision total knee arthroplasty (TKA). Impaction bone graft, structural allografts, metal augments, and mega prosthesis are some of the methods used to address major bone loss. Tantalum metal (TM) Cones (Zimmer, Warsaw, IN) were introduced as an alternative to address this cohort of patients. The advantages of these cones include excellent biocompatibility, high porosity with osteoconductive potential, and a modulus of elasticity between cortical and cancellous bone. In addition, it is bioactive and offers an intrinsically high friction fit.

Methods: A cohort of 62 patients with severe distal femoral and proximal tibial bone loss were operated for primary and revision TKA between January 2007 and December 2014 and followed up for a mean period of 108.5 months (range: 60-156 months). Preoperative and postoperative range of motion and Knee Society score were documented. Postoperatively long leg X-rays were performed at each follow-up visit to determine osteointegration, evidence of loosening, and migration.

Results: The range of motion and Knee Society score improved considerably from preoperative a value of 63.9 ± 13.9° and 52 ± 14.9 to 102.1 ± 9.9° and 76.1 ± 10.03, respectively, at the final follow-up visit in the primary cohort and 52.14 ± 13.3° and 38.1 ± 9.1 to 92 ± 8° and 68.5 ± 4.3, respectively, in the revision cohort. Serial radiographs demonstrated complete osteointegration of the TM cones at the final follow-up.

Conclusions: Our study demonstrates excellent midterm survivorship of TM cones with predictable osteointegration and good outcomes (clinical and radiological) in treatment of severe femoral and tibial metaphyseal bone defects in complex primary and revision TKAs.

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Introduction

Significant metaphyseal and meta-diaphyseal bone loss is usually a challenge in revision and some complex primary total knee arthroplasty (TKA). In the primary setting, significant metaphyseal or meta-diaphyseal bone loss may be due to long-standing degeneration, inflammatory arthritis, instability, or previous failed surgeries for either fractures or tumor resection. In the revision setting, bone loss is more common and may be attributable to polyethylene wear, third body debris, mechanical loosening, infection, or tumor. Metaphyseal and meta-diaphyseal bone loss may compromise component fixation and stability in total knee arthroplasty. The ideal strategy for addressing major bone loss has not been determined, with options such as structural allografts reporting failure rates of up to 20% at 5 years [1].

Surgical strategies currently available to address bone loss include the use of cement, screw in cement, impaction bone grafting, metal augments, structural allografts, and tumor implants [2,3]. Tantalum metal (TM) cones and sleeves (Zimmer, Warsaw, IN) have been introduced as an option to address all major bone defects in TKA [4]. TM has a high-volume porosity [5], modulus of elasticity between cortical and cancellous bone, and a high coefficient of friction [6]. Early in vitro studies reported high potential for rapid bony ingrowth within the TM structure [7,8]. The intrinsic porous nature of the TM cone has been shown to have some resistance to bacterial adherence and infection compared with other materials.
Multiple studies have shown that TM cones provide stable fixation and rotational stability in the treatment of severe bone deficiencies in revision TKAs in the short-term with documented osteointegration [10–17]. However, a longer follow-up is needed to determine the durability of these reconstructions.

Our hypothesis in this study is that the use of TM cones in severe tibial and femoral metaphyseal and meta-diaphyseal defects provides stable metaphyseal fixation ensuring stability of the construct and long-term survivorship.

The aim of this study was to evaluate midterm survival of TM cones used for femoral and tibial bone deficiencies in complex primary and revision TKA using clinical and radiological outcomes. This single-center study evaluates the clinical scores, radiological evidence of osteointegration, complications, component migration, and survivorship at a mean follow-up duration of 108.5 months and median of 110 months.

Material and methods

After obtaining formal institutional review board approval, we retrospectively evaluated the records of 65 consecutive patients who had undergone complex primary or revision TKA using TM cones, operated by the senior author between January 2007 and December 2014. During the course of the study, 3 patients expired from unrelated causes and were excluded. Our cohort included 62 patients who underwent complex primary (14 patients) and revision (48 patients) TKA procedures in which porous TM cones were used for reconstruction of femoral and tibial metaphyseal or meta-diaphyseal bone loss (Anderson Orthopedic Research Institute [AORI] type 2B and 3). The need for use in primary knees was decided on the basis of the size and location of the femoral and tibial bone loss. Inclusion criteria for use of TM cones included large cavitary defects (in excess of 3 cm) in the distal femur and proximal tibia and periarticular loss of bone seen in periarticular fractures and benign tumors. The revision cohort included patients who had prosthetic joint infections, aseptic loosening with osteolysis, polymetal wear, and periprosthetic fractures. All patients were followed up clinically and radiologically for a median period of 110 months (range: 60–156 months). The clinical records of these patients were analyzed, and the demographic data, etiology, indication for surgery, duration of symptoms, and comorbidities along with surgical findings were noted. Preoperative and postoperative range of motion (ROM), radiographic analysis with alignment, and component positioning were similarly documented. The preoperative and postoperative Knee Society scores [18] (KSS) were recorded by a senior physiotherapist at each follow-up visit at 6 weeks and bimonthly thereafter. At each follow-up visit, long leg weight-bearing X-rays were performed to determine bony integration, to determine alignment of the components, and to look for evidence of aseptic loosening. We evaluated the X-rays to assess radiolucent or sclerotic lines under the tibial and femoral components, around the stem, and evidence of shift or subsidence of the implant. The statistical analysis included profiling of patients on different demographic and clinical outcomes. Quantitative parameters used in the descriptive analysis were expressed as means and standard deviation and the data expressed as absolute numbers and percentages. Independent Student t-test was used for testing of mean difference between 2 independent groups, whereas paired Student t-test was used for testing of paired difference in mean value. Analysis of variance test was used for testing of mean difference for more than 2 independent groups.

Table 1

| Type of surgery | Diagnosis, number of patients | Isolated femoral cones | Dual stacked femoral cones | Single tibial cones | Tibial + femoral cones | No. of patients | No. of cones |
|----------------|-------------------------------|------------------------|--------------------------|-------------------|----------------------|----------------|-------------|
| Primary        | Complex primary total knee replacement | 1 (1 cone) | 1 (2 cones) | 2 (2 cones) | 2 (4 cones) | 6 | 9 |
|                | Periarticular # | 2 (2 cones) | 2 (4 cones) | 1 (1 cone) | 5 | 7 |
|                | Tumors | 1 (1 cone) | 2 (4 cones) | 3 | 5 |
| Revision       | Loosening + periprosthetic joint infection + polymetal wear | 8 (8 cones) | 8 (16 cones) | 16 (16 cones) | 6 (12 cones) | 38 | 52 |
|                | Periprosthetic # | 3 (3 cones) | 3 (6 cones) | 1 (1 cone) | 3 (6 cones) | 10 | 16 |
| Total          |                               |                       |                         |                   |                     | 62 | 89 |
Test applied: Mann-Whitney
* represents P value

Median duration of follow-up was not statistically different in both primary and revision patients (P = .155).
Test applied: Mann-Whitney U Test.

A P value < .05 was considered statistically significant. All analyses were performed using SPSS software, version 24.0 (IBM India).

Surgical technique

All surgeries were performed by the senior author using a midline incision under tourniquet control. After adequate exposure, in both the primary cohort and revision situation, bony defects were assessed for their size and location and classified as per AORI classification. TM cones were only considered for those patients with type 2 B and 3 defects. Starting with the smallest size of the TM cone trials, progressively increasing sizes were used by broaching till scratch interference fit was obtained, with optimal coverage of the defect. In some cases, a high-speed burr was used to ensure adequate seating of the trial component. Type 3 femoral defects with severe metaphyseal and meta-diaphyseal bone loss extending up to 6-7 cm from the articular surface, often seen in comminuted periprosthetic fractures, were treated using a “stacked cone” technique. This technique uses a larger distal and a smaller proximal cone threaded over a long stem (length 155 mm) extension and is used as a bridging interface to maintain length and achieve a stable construct. This option also makes use of a constrained articulation. In both single and stacked cones, all residual defects were packed with bone chips and fragments. Correct rotational alignment of both the femoral and tibial components with restoration of limb length and alignment of the extensor mechanism was ensured. The components were cemented using a hybrid stem fixation option (cementation of the proximal two-third of the stem), and the wound was closed in layers (Fig. 1).

Results

Patient demography

In our cohort of 62 knees (62 patients), 21 were male and 41 female. Cones were used in 14 primary and 48 revision knee arthroplasties. A single tibial cone was used in 19 knees (3 primary and 16 revision), single femoral cone was used in 16 knees (4 primary and 12 revision), dual stacked cones for severe distal femoral defects were used in 16 knees (5 primary and 11 revision), and both tibial and femoral cones were used concomitantly in 11 knees (2 primary and 9 revision) making up a total of 89 cones. Rotating hinge knee was used in 52 knees, and legacy constrained condylar knee (Zimmer, Warsaw, IN) in 10 knees. In the primary cohort, 64.2% of the patients needed femoral cones, 21.5% needed tibial cones, and 14.3% needed both femoral and tibial cones. In the revision cohort, 45.8% of the patients needed femoral cones, 35.4% needed tibial cones, and 18.8% needed both femoral and tibial cones.

The distribution of the femoral and tibial cones is described in Table 1.

The median age of this study group was 65 years (range: 62-71 years). The median age of patients in the primary group was 59 years (range: 52-67 years), and 66 years (range: 64-72 years) in the revision cohort. The average basal metabolic index was 28.6. The median follow-up duration was 110 months, with follow-up for the primary group being 121 months and the revision cohort being 107 months. Demographic parameters are summarized in Table 2.

Clinical and functional outcomes

While all patients were clinically evaluated preoperatively, in 14 patients, assessing ROM and functional scores was not possible on account of severity of the disease process and presence of periarticular fractures. In both primary and revision groups, improvement in KSS and ROM was observed at the last follow-up visit compared with the preoperative values (P < .05). Improvement in KSS was significantly higher in the revision group than that in the primary group (revision vs primary: [30.6 ± 8.2 vs 24.4 ± 8.4]; P = .049), whereas improvement in ROM was comparable in both primary and revision knee groups (revision vs primary: [39.3 ± 11.0 vs 40.5 ± 9.2]; P = .764) (Table 3).

Radiological outcomes

The postoperative average hip-knee-ankle angle was 180.5° ± 3.2°. While evidence of osteointegration was difficult to evaluate when using single cones, stability of the construct was evaluated by absence of change in the position of the cone and lack of evidence of progressive radiolucent lines. When stacked cones were used, evidence of periosteal reaction was visible at 3 months and matured fully between 12 and 14 months. The progression of osteointegration was satisfactory during each visit on serial radiographs, and at the final follow-up visit, there was evidence of integration of the TM cones (Figs. 2 and 3).

Three patients showed nonprogressive radiolucent lines within the first 6 months postoperatively, but subsequent follow-up and radiographic analysis did not reveal any component loosening, migration, or progression of radiolucency (Fig. 4).

Table 3
Clinical and functional outcomes.

| Type of surgery | KSS          | P value | ROM          | P value |
|-----------------|--------------|---------|--------------|---------|
|                 | Preoperative, mean ± SD | At last follow-up, mean ± SD | Difference, mean ± SD | Preoperative, mean ± SD | At last follow-up, mean ± SD | Difference, mean ± SD |
| Primary         | 52 ± 14.9    | 76.1 ± 10.3 | 24.4 ± 8.4  | .0001* | 63.9 ± 13.9 | 102.1 ± 9.9 | 40.5 ± 9.2 | 0.0001* |
| P value         | 0.001*       | 0.0001*   | 0.045* | .0001* | 0.025* | 0.0001* | 0.764 | 0.0001* |
| Revision        | 38.1 ± 9.1   | 68.5 ± 4.3  | 30.6 ± 8.2  | .0001* | 52.4 ± 13.3 | 92 ± 8 | 39.3 ± 11.0 | 0.0001* |

* represents P value <0.05 to be significant.
Complications/revision surgeries

Three out of 62 knees (5%) developed complications necessitating further surgical intervention. These were however unrelated to the TM cones. A patient operated for giant cell tumor distal femur using dual stacked cones had a malignant recurrence of the tumor 3.4 years after his primary surgery requiring en bloc resection and tumor mega-prosthesis reconstruction. During explantation, the TM cones were found to be well integrated into the host bone (Fig. 5).

Two patients developed superficial surgical site infection and were treated by extracapsular debridement, irrigation, secondary closure, and antibiotics. The patient requiring revision surgery was treated as a failure. In this study, our mean survival rate at 108.5 months was 98%.

Discussion

Addressing severe distal femoral and proximal tibial bone loss (AORI type 2B and type 3) can pose a challenge in complex primary and revision TKA. While current available options to address massive bone loss include structural allografts, megaprosthesis, and metal augments, there is no consensus on the ideal solution to address this difficult issue [19]. Availability of the porous tantalum sleeves and cones has offered an alternative promising option for the management of this problem.

Interest in the TM cone has increased in recent years because of the purported limitations and high failure rates of the structural allograft [20]. Advantages of TM cones include a high coefficient of friction facilitating a scratch interference fit providing immediate

Figure 2. (a) Preoperative X-ray showing osteolysis. (b) Intraoperative measurement of distal femur defect. (c) Postoperative X-rays anteroposterior and lateral views.
stability and allowing for early weight-bearing [21]. The ultra-porosity of the TM cone additionally facilitates good osteointegration and metaphyseal fixation, thereby minimizing component migration and subsidence [22]. The osteoconductive and osteoinductive properties of TM cones allow for good bony ingrowth as seen by the formation of bridging callus across the site of the defect aiding in the restoration of bone mass. The advantage of supposed low bacterial adherence and shorter operating time using TM cones may also decrease the infection rate [23].

Beckmann et al. [3] in a systematic review comparing outcomes using structural allografts and TM cones to address massive bone loss found a significantly higher incidence of failure in terms of prosthetic loosening, fractures, and infections in the allograft cohort. They reported a significant reduction in loosening and failures in the TM cohort by up to 75% and 50%, respectively.

Backstein et al. [24] reported a 21.3% failure rate at 5.4 years using structural allograft. Pala et al. [25] reported a 29.1% failure (72 out of 247 patients) using megaprostheses, with soft tissue failure and aseptic revisions being the most frequent indications for revision.

Capanna et al. [26] in a study of 200 megaprostheses implanted in 199 patients reported an overall survival of 66.2% at 10 years with infection and structural failures being the most frequent modes of failure.

Patel et al. [27] reported good outcomes and survivorship using metal augments to address bone loss inspite of the purported risks

Figure 3. (a) X-ray showing implant loosening secondary to infection. (b) Postoperative X-ray after stage I revision total knee replacement showing cement spacer. (c) Postoperative X-ray after stage II revision showing implant with tibial cone.

Figure 4. (a) X-ray showing radiolucency under the tibial component at 6 months postoperatively. (b) X-Ray showing non progression of radiolucency at 24-month follow-up.
of fretting, corrosion, stress shielding, and dissociation of the modular components reported in literature.

Panni et al. [28] reported comparable outcomes in 2 cohorts of patients using TM cones and metal augments to address major bone loss in revision TKA at a 7-year follow-up.

Brown et al. [16] reported an overall revision rate of 12% (10 out of 83) in their series of 83 cases using TM cones. Only one revision was however attributed to loosening of the TM cone.

Bonanzinga et al. [29] reviewed 16 studies published from 2006 to 2015 using TM cones for management of metaphyseal bone loss in complex primary and revision TKA. They reported a loosening rate of 1.15% of the 523 implanted TM cones at a mean follow-up of 42 months.

Kamath et al. [30] used porous TM metaphyseal cones for severe tibial bone loss in revision TKA in 66 knees with type 2A, 2B, or 3 defects and reported an overall revision-free survival of 93.9% at the last follow-up visit (>95% survival of tibial metaphyseal cones).

Panda et al. [21] in their study of 79 cases (20 primary and 59 revision surgeries) reported complete osteointegration of TM cones in all the cases at a mean follow-up of 6.6 years as did De Martino et al. at a 6-year follow-up [31].

Zanirato et al. [32] reported comparable clinical and radiological outcomes and survivorship in 2 cohorts of patients with severe bone loss using porous cones and sleeves at a mean follow-up of 3.6 ± 1.4 years and 4.5 ± 1.6 years, respectively.

Schmitz et al. [10] in their study of 44 patients also showed favorable clinical and radiological outcomes using TM cones in managing major bone loss in revision TKA at a follow-up of 3 years.

Jensen et al. [33] measured bone mineral density (BMD) changes after revision TKA using dual energy X-ray absorptiometry (DEXA scan) in 36 patients and reported no differences in the BMD in patients undergoing revision with and without TM cones. This demonstrates that despite stable metaphyseal fixation, the use of TM cones did not lead to significant variation in BMD.

Girerd et al. [17] recommended using combined diaphyseal and metaphyseal cones to address massive diaphyseal and metaphyseal defects. They recommend this to minimize the use of megaprosthetic implants. They reported excellent osteointegration at a mean follow-up of 34 months (range: 24-52 months).

Rajgopal et al. [34] reported excellent stability with evidence of good osteointegration in their selected cohort of patients using

Figure 5. (a) Anteroposterior and lateral preoperative X-rays of patient with distal femur giant cell tumor. (b) Postoperative X-rays with tantalum cones. (c) X-ray taken 3.4 years postoperatively showing a malignant recurrence. (d) Intraoperative image, after implant extraction, showing good osteointegration.
stacked cones for severe distal femoral bone loss at a mean follow-up period of 57 months.

Cherry et al. [35] too recommended using diaphyseal and metaphyseal cones fixed by bone cement as a promising option when the bone defect extended into the diaphysis.

Outcomes, follow-up, and complications reported in other studies [11,13,10,15,21,36] are summarized in Table 4.

Our results using femoral and tibial cones compare favorably with those reported in literature demonstrating excellent osteointegration in cases with severe bone loss. This is well documented in cases of severe periprosthetic fractures.

In our experience, TM cones offer an excellent option in the management of large metaphyseal and diaphyseal defects demonstrating evidence of osteointegration and providing for a stable construct.

Limitations

The limitations of our study include the retrospective design though the data were collected in a prospective manner. The small size of the cohort, especially primary TKA, is another limitation even though the numbers are comparable to those of other studies reported in literature. Another limitation is the heterogenous nature of the cohort in terms of the indications for surgery.

Conclusions

Our study demonstrates that TM cones are an effective option for treating severe bone defects during TKA (both primary and revision). At a midterm follow-up, TM cones demonstrate good osteointegration and implant stability by providing a stable metaphyseal fixation.

Conflict of interest

The authors declare there are no conflicts of interest.

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