CLINICAL ARTICLE

Cementless Porous-Coated Metaphyseal Sleeves Used for Bone Defects in Revision Total Knee Arthroplasty: Short- to Mid-Term Outcomes

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Objectives: While many studies have presented excellent short-term outcomes of the metaphyseal sleeves used in revision total knee arthroplasty (TKA), currently published mid-term results remain limited and some controversial issues remain unresolved. The purpose of this study was to investigate clinical and radiographic mid-term outcomes of the sleeves for the management of metaphyseal bone defects in revision TKAs.

Methods: From 2015 to 2019, 44 patients (45 knees) who were operated with cementless porous-coated metaphyseal sleeve in revision TKA were included in this study. Bone defects were assessed according to Anderson Orthopaedic Research Institute Classification. On the tibial side, there were 37 type II and six type III, and with regards to the femur, 15 were type II, and four were type III. Through reviewing electronic records, data were collected, including baseline demographics, operative details, information of prothesis, and complications. Clinical and radiographic evaluations were performed, including Knee Society Scores (KSS), Western Ontario and McMaster Universities Osteoarthritis Index (WOMAC), range of motion (ROM), the radiolucent line, level of joint line, and implant survival rate. Statistical analysis was performed by paired *t*-test for clinical and radiographic indexes.

Results: The mean follow-up time was 4.4 ± 1.4 years. During surgery, sleeve-related fractures were encountered in four (8.9%) knees, including incomplete tibial fracture of lateral cortex in one knee and of medial cortex in two knees, and longitudinal femoral metaphyseal fracture in one knee. Unions were achieved in all cases at the final follow-up. Significant improvements in KSS and WOMAC scores were found at the final follow-up, respectively, from 83.8 ± 29.1 to 152.9 ± 31.0 ($t = -12.146$, $p < 0.001$) and from 148.4 ± 42.3 to 88.1 ± 52.5 ($t = 6.025$, $p < 0.001$). The mean ROM improved from $88.7 \pm 31.9^\circ$ to $113.7 \pm 13.7^\circ$ ($t = -5.370$, $p < 0.001$). A 75 mm length of cementless stem was used in all patients and only one patient was identified as tibial end-of-stem pain. No sleeve-related revision occurred, and one patient was diagnosed with early postoperative infection and was treated with irrigation and debridement, polyethylene liner exchange, and appropriate antibiotic treatment. The overall implant survival was 97.8% with the endpoint reoperation and 100% with the endpoint revision. Osseointegration at the bone-sleeve interface was found in all patients and no loosening happened. Satisfactory alignment between 3° varus and 3° valgus was achieved in all but not in three patients.

Conclusion: The use of metaphyseal sleeves in the treatment of bone defects in rTKAs can provide stable fixation and significantly improve the clinical scores at the midterm follow-up. In addition, the rare occurrence of end-of-stem pain suggests routine use of cementless stems. Although there are chances of intraoperative fractures, it has no negative effect on outcome when managed properly.

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Introduction

In recent decades, the number of total knee arthroplasty (TKA) has increased dramatically, and patients younger than 65 years will exceed 50% of the population in need of TKA in the future.[1,2] Consequently, the demand for revision TKA will inevitably increase. In revision TKAs, bone defects are one of the most common problems, which can be caused by aseptic loosening, subsidence, and periprosthetic osteolysis, and are commonly classified using the Anderson Orthopaedic Research Institute (AORI) Classification.[3]

Several reconstruction strategies have been utilized to address bone loss. Small, contained defects, such as AORI types I and IIa, can be managed by morcellized or structural autografts, cement, and modular augment blocks and wedges, while large bone defects, such as types IIb and III, may require bulk allografts or allograft prosthetic composites, highly porous metal cones, porous-coated metaphyseal sleeves, and custom-made prostheses.[4–13] Relying on the capability of providing stable metaphyseal biologic fixation, the use of cones and sleeves has grown in popularity in recent years.[14] In comparison with the porous metal cone, the metaphyseal sleeve has some potential advantages including simplified bone preparation with the broaching technique, additional rotation stability, and superior biomechanical properties provided by the stepped structure. Moreover, the surface's porous coating of sleeves directly in contact with the host bone can facilitate bone ingrowth to improve the long-term implant survival rate.[15]

Some authors have described excellent short- to mid-term results of metaphyseal sleeves in rTKA.[16–20] In a recent study, Klim *et al.*[21] performed a clinical and radiological follow-up of a mean of 6.3 years in 92 patients with rTKA using cementless sleeves and stems, and reported osseointegration at the sleeve-bone interface in 96.1% of cases. It is well-known that early results of metaphyseal sleeves have been encouraging; however, the results of sleeve in large midterm cohorts are still limited. In addition, whether the sleeve should be utilized in combination with the stem remains unclear. Some authors have suggested the use of sleeve without stem to avoid end-of-stem pain and satisfactory results with no stem used have been reported. In contrary, Gøttsche *et al.*[22] thought the stem was essential to achieve optimal alignment. Thus, more evidence about the use of sleeves is required to make definitive clinical decisions.

In this study, we aimed to (i) investigate clinical and radiographic short- to mid-term outcomes of the sleeves for the management of metaphyseal bone defects in revision TKAs; (ii) analyze the role of cementless stems in rTKA with sleeves; and (iii) report intraoperative and postoperative sleeve-related complications.

Patients and Methods

Inclusion and Exclusion Criteria

The inclusion criteria were: (i) adult patients who were operated on with a cementless porous-coated metaphyseal sleeve; (ii) patients who received revision TKA by one single surgeon at our institution between March 2015 to July 2019; (iii) the bone defects were type II or III according to the AORI classification; (iv) the follow-up period was at least 2 years; (v) outcome measures included Knee Society Scores (KSS), Western Ontario and McMaster Universities Osteoarthritis Index (WOMAC), range of motion (ROM), the radiolucent line, level of joint line and implant survival rate; and (vi) retrospective study. The exclusion criteria included: the medical records and radiographs were incomplete or missing. This retrospective study was approved by the Ethics Committee of General Hospital of Chinese People's Liberation Army (S2018-018-01).

Patients

From March 1 2015 to July 31 2019, 49 patients who were operated on with a cementless porous-coated metaphyseal sleeve in revision TKA were identified. There were three patients who did not have minimum 2 years complete clinical and radiographic follow-up, and two patients had missing radiographic records, leaving 44 patients available. Of the 44 patients (45 knees), the indications included infection, aseptic loosening, instability, knee pain or stiffness, prothesis fracture, and recurvation (Table 1).

Bone defects were assessed according to AORI classification at the time of surgery following removal of previous components. On the tibial side, there were 37 type II and six type III cases, and with regards to the femur, 15 were type II and four were type III (Table 2). We used DePuy Synthes Metaphyseal sleeves in all patients, in conjunction with M.B.T Revision Tibia-trays with varus/valgus constrained (VVC) inlays (SIGMA TC3 RP, DePuy Synthes, Warsaw, IN). All tibial trays were rotating platform and no fixed bearing component was used. The sleeve was used combined with cementless stem in all cases.

Surgical Technique

A medial parapatellar arthrotomy was performed. To achieve adequate exposure, extended tibial tuberosity osteotomy (ETTO) was used in four patients, and quadriceps snip was used in one patient. After a complete synovectomy, the previous components were removed. Then, the medullary canal was reamed until adequate endosteal contact was detected. The preparation of the metaphysis was performed *via* sequential broaching with progressive increase in size until rigid rotational and axial stability is achieved. The

TABLE 1 Characteristics of patients included in the study

Demographic	Values
Number of patients/knees	44/45
Operated side (right/%)	51.1%
Gender (female/male)	33/11
Age at time of surgery (years)*	66.7 ± 9.0 (38–85)
BMI (kg/m^2)*	27.2 ± 4.1 (21.3–40.2)
Follow-up period (years)	4.4 ± 1.4 (2.2–6.5)
Time from primary to revision surgery (years)*	4.7 ± 3.6 (0.7–13.9)
Mean duration of surgery (minutes)*	154 ± 44 (96–240)
Intraoperative blood loss (ml)*	703 ± 287 (100–1600)
Indication for surgery	
PJI	21
Aseptic loosening	14
Instability	4
Knee pain or stiffness	4
Prothesis fracture	1
Recurvation	1

Abbreviations: BMI, body mass index; PJI, periprosthetic joint infection
* The values are given as the mean and standard deviation (range).

appropriately sized tibial component was chosen to allow the most coverage of viable tibial bone. Trial implants were then assembled and inserted, and flexion and extension gaps were assessed to estimate the need for distal and posterior femoral condylar augmentation. On the femoral side, the similar bone preparation was done to establish a stable femoral platform. Then, we performed the final insert trialing to determine stability, alignment, and level of the joint line. Final implants were completely assembled prior to implantation. Cement was utilized on the undersurface of the tibial tray and the distal undersurface of the femoral component.

Clinical Assessment

All patients underwent clinical and radiographic assessment before surgery and 3 months, 6 months, 1 year, and yearly thereafter. Clinical evaluation included the KSS, WOMAC, and ROM.[23,24]

TABLE 2 Bone defect types and details of the components used

Parameters	Number
Type of bone defects	
Tibia (I/II/III)	0/37/6
Femur (I/II/III)	0/15/4
Prosthesis type at the surgery	
Tibial component ($n = 45$)	
Sleeve (yes/no)	43/2
MBT	45
Femoral component ($n = 45$)	
Sleeve (yes/no)	19/26
TC3	45
Length of stems	
75 mm	59
115 mm	3

Knee Society Score

The KSS scoring system was applied to assess the outcomes of rTKAs. It was divided into the functional and clinical sections, respectively, ranging from 0 to 100 points with the maximum value for the best result. The values were graded according to the following classification: 80–100, excellent; 70–79, good; 60–69, fair; below 60, poor.

Western Ontario and McMaster Universities Arthritis Index

The WOMAC index was used to assess patients using 24 parameters, ranging from 0 (good clinical result) to 10 points (poor clinical result). It can be used to monitor the course of the disease or to determine the effectiveness of revision TKA. The WOMAC index assessed domains including pain, stiffness, and physical function.

Radiographic Evaluation

Radiographic evaluation was accomplished by two independent experienced observers based on the knee X-ray in anterior–posterior (AP) and lateral view and full-length weight-bearing X-ray in the standing position.

Radiolucent Lines, Osseointegration, and Loosening

The zone assessment of implant fixation was performed by measuring the width of the radiolucent lines based on the criteria developed by the Knee Society.[24] Radiolucency with >1 mm periprosthetic distance was recorded, and all radiolucent distances in the respective zones were cumulated. Osseointegration of sleeves was determined according to the criteria described by Engh *et al.*[25] Loosening was defined as implant migration or a ≥2 mm radiolucency around the metaphyseal sleeve.[10]

The Joint Line and Hip-Knee-Ankle Angle

The trans-epicondylar axis width ratio (TEAW), which was defined as the distance between the lateral and medial epicondyle of the distal femur, was utilized to measure the level of joint line, and the optimal level was placed at 1/3 TEAW distal of the lateral epicondyle.[26] An acceptable joint line was defined as ±4 mm from the measured anatomic level.[27] The hip–knee–ankle (HKA) angle was calculated as the angle between the line drawn from the center of the femoral head to the center of the knee joint and the line drawn from the center of the knee to the center of the ankle joint, and a satisfactory alignment was defined between 3° varus and 3° valgus.[28]

Statistical Analysis

Statistical analysis was performed using SPSS for Windows Version 25 (IBM, Armonk, NY, USA). Continuous variables were expressed as mean and standard deviation (range). The difference in clinical scores and range of motion between

TABLE 3 Preoperative and final follow-up clinical outcomes for all patients

Parameters	Preoperative	Final follow-up	t-value	P-value
KSS	83.8 ± 29.1	152.9 ± 31.0	−12.146	<0.001
Functional score	40.7 ± 21.9	64.1 ± 23.2	−5.168	<0.001
Clinical score	43.2 ± 10.9	88.8 ± 15.4	−18.455	<0.001
WOMAC	148.4 ± 42.3	88.1 ± 52.5	6.025	<0.001
ROM (°)	88.7 ± 31.9	113.7 ± 13.7	−5.370	<0.001

Abbreviations: KSS, Knee Society Scores; ROM, range of motion; WOMAC, Western Ontario and McMaster Universities Osteoarthritis Index.

pre- and post-operation were assessed by paired *t*-test. Significance was set at $p < 0.05$.

Results

Follow-Up and General Results

Forty-four patients (45 knees) were finally included in this study, which consisted of 11 males (25%) and 33 females (75%) with a mean age of 66.7 ± 9.0 years (range, 38–85 years). The mean follow-up time was 4.4 ± 1.4 years (range, 2.2–6.5). The mean body mass index (BMI) before surgery was 27.2 ± 4.1 kg/m^2 (range, 21.3–40.2 kg/m^2). The indications for rTKA included infection (21 knees), aseptic loosening (14 knees), instability (four knees), knee pain or stiffness (four knees), prothesis fracture (one knee), and recurvation (one knee) (Table 1).

Intra-Operative Complications

Sleeve-related intraoperative fractures were encountered in four patients during broaching of the metaphysis or implantation of final components, including incomplete tibial fracture of the lateral cortex in one patient and of the medial cortex in two patients, and longitudinal femoral metaphyseal fracture in one patient. Nevertheless, as the constructions were considered stable, no additional fixation was required. In addition, one patient sustained medial femoral condylar comminuted fracture by the reason of the osteoporosis, and then was treated with screw fixation. One patient had a pre-operative medial tibial plateau fracture, and was treated with wire fixation. At the final follow-up, union were achieved in all cases.

KSS, WOMAC, and ROM Improvement

Clinical results are summarized in Table 3. Significant improvements in WOMAC and KSS were found at the final follow-up. The mean preoperative WOMAC was 148.4 ± 42.3, which improved to 88.1 ± 52.5 at the last follow-up ($t = 6.025$, $p < 0.001$). The KSS increased from a mean of 83.8 ± 29.1 to 152.9 ± 31.0 ($t = -12.146$, $p < 0.001$) with functional scores from 40.7 ± 21.9 to 64.1 ± 23.2 ($t = -5.168$, $p < 0.001$) and clinical scores from 43.2 ± 10.9 to 88.8 ± 15.4 ($t = -18.455$, $p < 0.001$). All the patients achieved full extension except one

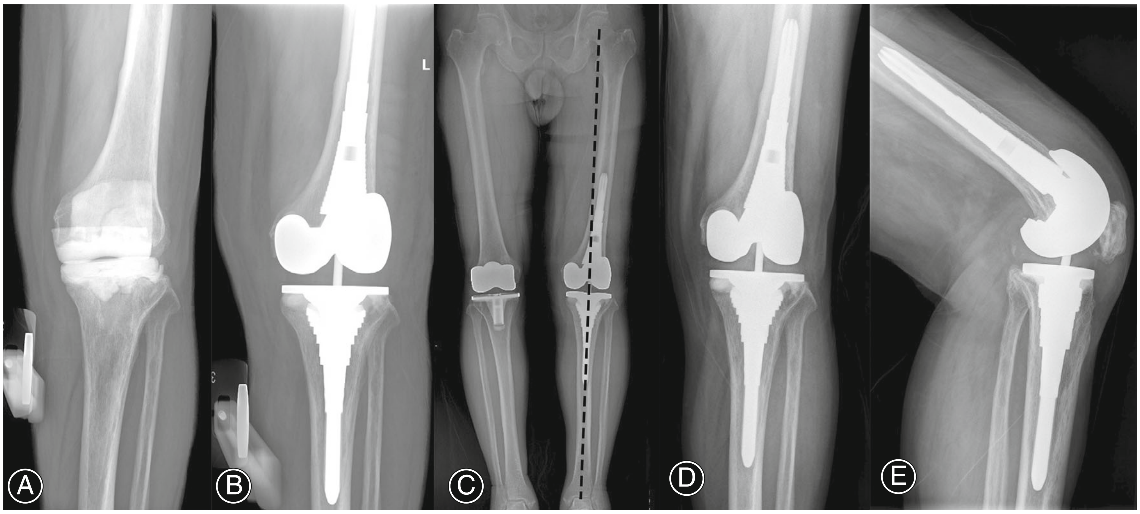

Fig. 1 Radiographs of a 71-year-old male who underwent two-stage revision TKA with tibial and femoral metaphyseal sleeves for infection. Preoperative (a) and postoperative (b) radiographs from the AP view; The postoperative full-length X-ray (c) showed satisfactory alignment. After a follow-up of 5.1 years, the AP (d) and lateral (e) radiographs demonstrated stable fixation

TABLE 4 Radiolucent lines on the knee X-ray in AP and lateral view

Region	Zones	Sum of radiolucent lines (mm)
Femur	1	1
	2	0
	3	0
	4	1
	5	1
	6	1
	7	1
Tibia-AP	1	3
	2	0
	3	0
	4	1
	5	3
	6	5
	7	2
Tibia-lateral	1	0
	2	0
	3	5

Abbreviation: AP, anterior–posterior.

having a residual fixed flexion deformity of 10°. The mean range of motion was significantly improved from 88.7° ± 31.9° to 113.7° ± 13.7° ($t = -5.370$, $p < 0.001$).

Radiographic Evaluations

Osseointegration at the bone-sleeve interface was found in all patients, and no loosening was observed (Fig.1). The radiolucent lines were observed in eight patients mainly in the Zone 5, 6, and 7 of the tibias from the AP view and Zone 3 of the tibia from the lateral view (Table 4). Mean postoperative HKA angle was 179.1 ± 2.5° (170.6–186.0°). Satisfactory alignment between 3° varus and 3° valgus was achieved in all but three patients. One of them was aligned in 9.4° of varus on account of extra-articular deformity. Of the 40 patients with preserved epicondyles for TEAW, an acceptable joint line was achieved in 38 patients.

Postoperative Complications

One patient was identified as tibial end-of-stem pain, which was described as mild to moderate and localized at the tibial diaphysis. Due to the inadequate fixation of medial tibial plateau fracture, a significant migration of stem was observed in the early time after surgery, thus leading to the direct contact between the tip of stem and the cortical bone, and resulting in the tibial end-of-stem pain (Fig.2). In spite of no further migration found after 1 year, the patient was still plagued by continuous end-of-stem pain until the last follow-up. One patient had continuous diffuse pain all over the knee. Although analgesics were used, the symptom persisted until the last follow-up. In addition, one patient was diagnosed with minimally symptomatic patellar clunk that did not require surgical intervention.

Re-Revision and Survival Rate

During the study period, no sleeve-related revision occurred and only one patient required reoperation. On the 24th day after surgery, this patient was diagnosed with early postoperative infection and was successfully treated with irrigation and debridement, polyethylene liner exchange, and appropriate

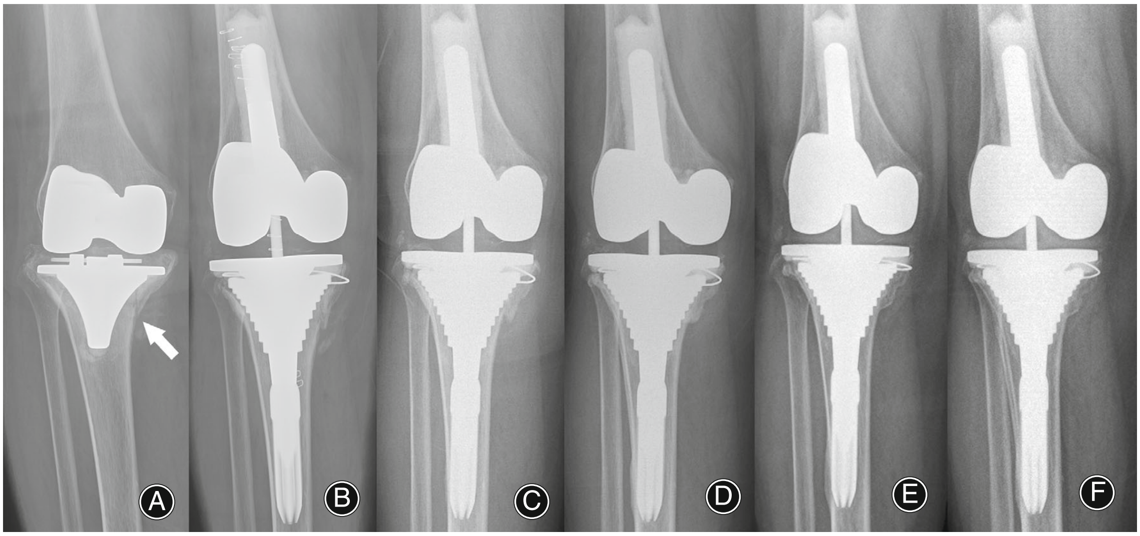

Fig. 2 Radiographs of a 78-year-old female who underwent revision TKA with tibial metaphyseal sleeves for aseptic loosening. Preoperative (a) radiograph showed a medial tibial plateau fracture which was treated with wire fixation during surgery (b). From the films of 3 months (c), 6 months (d), and 1 year (e) after surgery, a progressive migration of protheses was observed. At the final follow-up, stable fixation of the protheses was achieved and no further migration was found (f). The white arrow refers to preoperative medial tibial plateau fracture

antibiotic treatment. Thus, the overall implant survival was 97.8% with the endpoint reoperation and 100% with the endpoint revision.

Discussion

In our study, the main finding was the excellent short- to mid-term results of the metaphyseal sleeves in combination with cementless stems in rTKAs. According to the clinical and radiographic evaluation, the metaphyseal sleeves are a promising option in management of bone defects in rTKAs, providing mechanical support for the implant and promoting biological fixation.

Improvement of Clinical and Radiographic Outcomes

In accordance with previous reported results, our study provided favorable outcomes after a mean follow-up of 4.4 years, with significant improvement on all clinical scores. The WOMAC score improved from 148.4 ± 42.3 preoperatively to 88.1 ± 52.5 at the final follow-up. Wirries *et al.*[29] revealed a similarly significant improvement of WOMAC in 62 cementless sleeves after a mean of 5 years follow-up. Additionally, the KSS significantly improved as well, and our results were comparable to those previously published studies. Similar increases in KSS were found by Watters *et al.*,[30] who described an increase of 65 points in 108 patients with the mean 5.3-year follow-up. At the final evaluation, the ROM improved from 88.7° ± 31.9° to 113.7° ± 13.7°. In analogy to the present study, Barnett *et al.*[31] showed a restoration of ROM from 98.9° to 112.1°, and Graichen *et al.*[32] presented an improvement from 89° to 114°.

The radiographic outcomes of our study were excellent with satisfactory alignment in 42 (93.3%) knees and an acceptable joint line in 38 (84.4%) knees. Despite a slight migration of one tibial sleeve at the early period after surgery, stable metaphyseal fixation was achieved in all sleeves after 1 year. Radiolucent lines were found mainly around the cementless stems. These findings were in accord with the results by Wirries *et al.*[29] The author evaluated 47 cases with sleeve-fixed revision knee system and reported the most radiolucent lines in the zone 5 and 7. They analyzed that there is a possibility of pivoting with the use of long diaphyseal stems. In term of this issue, our data were insufficient to establish valuable comparison because we used 75 mm length stems in almost all patients.

The Role of Stems in rTKAs with Sleeve

All sleeves in this study were used in combination with cementless stems. Whereas, there was still controversy on this issue. Some authors argued the use of stems may give rise to postoperative end-of-stem pain. In a study reported by Alexander *et al.*,[10] of 30 patients, seven (23.3%) complained of mild to moderate tibial end-of-stem pain when using the non-slotted, long stems with small diameters. By contrast, Martin-Hernandez *et al.*[33] found a significantly lower frequency of pain at the tip of the stem (2.2%) in a large series of 134 patients. In order to eliminate stem-related pain, Gøttsche *et al.*[22] performed 71 rTKAs with sleeves without stem and 63 patients were finally evaluated. Unfortunately, 56% of the patients were plagued by moderate-to-severe knee pain. Poor results in rTKAs without stems were also manifested by Agarwal *et al.*,[34] which showed that all five patients whose sleeves were not attached to a stem had issues of aseptic loosening or significant knee pain. The end-of-stem pain was found in only one patient in our study. The rate of 2.3% was comparable to the findings of Klim *et al.*[21] (tibial 3.2%) and Martin-Hernandez *et al.*[33] (tibial 2.2%). In our opinion, compared with end-of-stem pain, potential aseptic loosening caused by no stem used was more devastating to patients. Therefore, we suggested routine use of stems in all patients. There was evidence that stems have the capability to reduce some stress concentrations generated at bone-sleeve interfaces, thus supporting osseointegration of sleeves and preventing aseptic loosening in the early period after surgery.[35] Especially when we encouraged weight bearing as tolerated and rehabilitation of range of motion in the early stage, the usage of stems was of great significance. Another important role of stems was the guidance for implant alignment. With the assistance of stems, satisfactory alignment between 3° varus and 3° valgus was achieved in 42 (93.3%) knees.

Sleeve-Related Intraoperative Fracture

In this series, sleeve-related intraoperative fracture occurred in four (8.9%) knees during preparation of the metaphysis for sleeve or final component implantation. Due to the demand for broaching technique against sclerotic bone, the intraoperative fractures have become one of the most common complications. In a review of 928 revisions with 888 tibial sleeves and 525 femoral sleeves, Bonanzinga *et al.*[36] reported an overall intraoperative fracture rate of 3.1%. In our study, all the sleeve-related fractures occurred in two-stage reimplantation for PJI. We speculated that the fracture was caused by severe cortical sclerosis and cancellous bone loss in the proximal tibia after the retention of cement spacer. Thus, we recommended to remove all the scleroses or perform wire fixation for protection before broaching. Moreover, when intraoperative fractures have no effect on the stability of the prosthesis, no additional fixation was required.

Comparison between Sleeves and Cones

As an alternative reconstruction technique, the highly porous cones can achieve a metaphyseal fixation as well. However, different methods of bony preparation and fixation with protheses may lead to differing results. In a comparative meta-analysis of cones *vs* sleeves, the cones showed a higher rate of PJI, which may be caused by different material properties.[14] In another systematic review, Zanirato *et al.*[37] reported the mean rate of intraoperative fractures was 1.2% in cone group and 0.54% in sleeve group. The second-generation cones included a cannulated reaming technique, which is superior to previous high-speed burr and may contribute to reduce cone-related fracture.[38] However, further prospective, randomized studies are need to clarify complications, clinical and radiological results of metaphyseal sleeves and cones.

Limitations and Strengths

There are several limitations of our study. This is a retrospective study with relatively small sample size, and the follow-up is short to medium term, ranging from 2.2 to 6.5 years. Also, no comparative cohort is included in the study. Due to the lack of contrary analysis with porous metal cone, it is not convictive enough to compare these two reconstruction methods. Moreover, our cohort is heterogeneous with varying indications. Various degrees of bone defect from grade II to III were both included.

Strengths of this study include a relatively comprehensive assessment of the metaphyseal sleeves for bone defect management in rTKAs, including functional assessment with the KSS, WOMAC, and range of motion, and the radiographic evaluation with joint line, HKA angle and radiolucent lines. In addition, all patients received the same type of knee system and 75 mm length of cementless stem. The consistency of implants made our data valuable for further research on the use of stems.

Conclusion

The use of metaphyseal sleeves in the treatment of bone defects in rTKAs can provide stable fixation and significantly improve the clinical scores at the midterm follow-up. On account of the relatively low rate of end-of-stem pain in this study, the cementless stems are recommended for routine use. Although there are chances of intraoperative fractures, it has no negative effect on outcome when managed properly. However, extended follow-up is evidently required to determine long-term survivorship of metaphyseal sleeves.

Acknowledgments

Not applicable.

Authors' Contributions

JMS and TZ: Designing the study, Collecting the data, Analyzing the data, Writing the manuscript; LFG and YGZ: Designing the study, Editing the manuscript; YCZ and YD: Collecting the data, Analyzing the data, Reviewing the manuscript, Reviewing the literature. All authors have read and approved the final version of this manuscript.

Conflict of Interest

The authors declare that they have no conflict of interest.

Ethics Approval and Consent to Participate

The Ethics Committee of our hospital, General Hospital of Chinese People's Liberation Army, approved the study protocol. A certificate of approval has been provided. The requirement of informed consent was exempted due to the retrospective nature of the study.

Authorship Declaration

All authors listed meet the authorship criteria according to the latest guidelines of the International Committee of Medical Journal Editors. All authors are in agreement with the manuscript.

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