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Effects of personalized 3D-printed blocks in total knee arthroplasty and revision surgery for massive bone defects: a single-center retrospective study

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Abstract

Objective: To analyze the early- to mid-term clinical efficacy of personalized 3D-printed structural metal spacer technology in reconstructing massive bone defects during complex total knee arthroplasty (TKA) and revision surgery.

Methods: A single-center retrospective study was conducted on nine patients with severe bone defects who underwent TKA between 2018 and 2024. The general condition, surgical details, and clinical improvement of these patients were recorded and analyzed by clinical doctors.

Results: The average surgical duration was 183.9 minutes (range, 125–240 minutes), with intraoperative blood loss of 133.3 mL (range, 100–200 mL). The average hospital stay was 18.2 days (range, 10–42 days), and the follow-up duration was 13.2 months (range, 2–57 months). The preoperative average American Knee Society Score of 51.2 points (range, 15–74 points) improved significantly to 95.0 points (range, 81–106 points) at the last follow-up. No cases of vascular or nerve injury, infection, fracture, or prosthetic loosening were observed.

Conclusion: The precise manufacturing of customized spacers that seamlessly integrate with the patient's skeletal structure ensures stability, adaptability, and improved surgical outcomes.

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Introduction

Giant bone defects pose significant challenges for total knee arthroplasty (TKA), often requiring innovative solutions to achieve successful treatment outcomes. Conventional treatment methods may fail to address the complex anatomical variations and structural defects encountered in such cases.[1,2] In recent years, the emergence of 3D printing technology has revolutionized the field of orthopedic surgery, offering customized solutions for reconstruction procedures. The application of 3D-printed custom implants, particularly 3D-printed blocks, in knee arthroplasty to reconstruct giant bone defects has emerged as a promising approach. By leveraging advanced imaging techniques and computer-assisted design, these tailored implants can accurately replicate the patient's unique anatomical structure, ensuring optimal fit and functionality.[3,4] This personalized approach not only enhances surgical precision but also facilitates faster recovery and better long-term outcomes. In revision knee arthroplasty, patients may present with various degrees of bone loss or deformity, rendering traditional standardized blocks inadequate to fully meet surgical requirements. Through 3D printing technology, surgeons can design and manufacture custom blocks tailored to the patient's specific condition, better restoring the knee joint and improving both surgical outcomes and patient quality of life.[5,6] Overall, the application of 3D-printed blocks in TKA for giant bone defects and revision knee arthroplasty provides clinicians with personalized treatment options, promising improved surgical outcomes, reduced complications, and enhanced recovery speed and quality of life.

Since 2018, our institution has used 3D-printed structural metal blocks for initial TKA and knee arthroplasty revisions involving giant bone defects. We retrospectively analyzed this cohort of cases, aiming to explore the clinical applications and efficacy of 3D-printed blocks in TKA for treating giant bone defects, as well as to discuss the design principles and considerations for 3D-printed structural metal blocks.

Methods

Study design and participants

In this single-center retrospective study, we analyzed patients who underwent TKA in our orthopedic surgery department from 2018 to 2024. Patients were consecutively selected, and the two inclusion criteria were primary or revision total knee arthroplasty for severe bone defects (Anderson Orthopaedic Research Institute (AORI) type III) and use of 3D-printed structural metal spacers. The exclusion criteria were bilateral knee joint surgery during the same period, a history of ipsilateral hip joint surgery or spinal scoliosis, concurrent malignant bone tumors, and incomplete clinical data or follow-up duration of less than 1 month. Two patients were excluded because of intraoperative difficulties with placing the printed prostheses, which resulted in a change to the surgical plan. Consequently, data from nine patients were included for analysis. The research flowchart is shown in Figure 1.

Preoperative preparation

Design and printing of blocks

Based on the patients' preoperative knee joint computed tomography data (slice thickness of 1 mm), a reverse engineering process was employed to generate visual skeletal models. For revision surgery, the original prosthesis was separated by filtering through different thresholds in the software. The location and size of bone defects were clearly identified on the computer, and osteotomy lines were designed to maximize the preservation of autologous bone volume. XN-RHK-type knee joint prostheses of appropriate sizes were selected (Beijing Chunli Zhengda Medical Equipment Co., Ltd., Beijing, China), and fill components were designed based on the morphology of the defects and the planned prosthetic data for use during surgery. First, the size of the femoral condyle and platform was measured to determine the model of the prosthesis. The confirmed prosthesis was then virtually implanted into the skeletal model, and bone grafting was performed at the deficient area. The spacers were designed with the principle of maximizing bone preservation, and screw channels were pre-reserved on the spacers as needed. The printed components, host bone, and knee joint prostheses were integrated for fitting, simulating the surgical effect. The final result was generated by

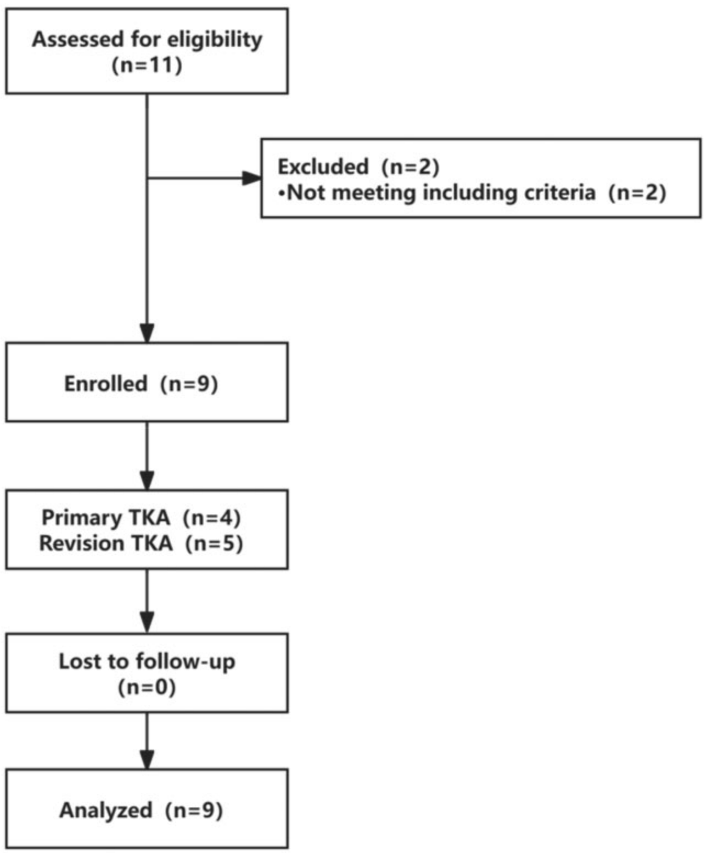

Figure 1. Consolidated Standards of Reporting Trials (CONSORT) diagram.

the engineer in the form of a graphical and video report. Throughout the process, the lead surgeon and the engineer maintained constant communication to ensure the rationality of the design plan. The final plan was reviewed and approved by the lead surgeon. Once the simulated effect was approved, the printing and manufacturing of prostheses and spacers commenced. The printing parameters for the metal spacers were as follows: aperture, $500 \pm 300\,\mu m$; wire diameter, $500 \pm 200\,\mu m$; porosity, 50% to 80%; and interconnected cubic-shaped pores to enhance tissue compatibility. Ti-6Al-4V powder with a particle size of 45 to 106 μm was used for printing, and the printing layer thickness parameter ranged from 50 to 200 μm. After printing, the outer surfaces of the prostheses and spacers were smoothed to reduce friction on soft tissues and were repeatedly cleaned in an ultrasonic cleaning machine.

Surgical procedure and perioperative management

Surgical procedure

The surgical technique was consistent across all patients. The patient was placed under general anesthesia in a supine position. The lower limbs were routinely disinfected and draped, and a pneumatic tourniquet was applied with a pressure of 50 kPa for hemostasis. A midline longitudinal incision was made in the anterior aspect of the knee to expose the joint cavity. According to the preoperative surgical plan, the original prosthesis was removed or excessive bone growth and scar tissue were cleared from the surgical site, and specimens were taken for intraoperative frozen section examination. Standard procedures included osteotomies anteriorly, posteriorly, and distally on the distal femur and proximally on the tibia. Irregular defects were smoothed using a high-speed burr to facilitate placement of the 3D-printed metal spacers. Trial prostheses were installed, and knee joint movement was adjusted to balance soft tissues. After the trial prostheses were removed, the surgical field was irrigated, bone cement was prepared, and appropriate total knee joint prostheses and 3D-printed spacers were inserted. Pressure was applied until the bone cement set to ensure intimate contact between the prosthesis, bone cement, and bone surface. Excess bone cement was removed, and joint flexion and extension were checked for any signs of active bleeding. The incisions were closed layer by layer, and compression bandages were applied.

Perioperative management

All patients followed the same postoperative rehabilitation plan. Specifically, all patients underwent multimodal pain management. Ankle pump training began on the first postoperative day, with the training period determined based on the soft tissue condition and the degree of prosthesis fixation. Passive lower limb exercises were initiated 2 to 3 days after removal of the drainage tubes.

Assessment of outcome

The patients' age, sex, body mass index (BMI), diagnosis, range of motion, and AORI bone defect classification were determined based on the preoperative imaging data and intraoperative assessment. Surgical details, including the operation time, total blood loss, postoperative transfusions, and complications, were also recorded. Patients were followed up in the outpatient clinic at 3 days and at 1, 3, 6, and 12 months postoperatively. Routine knee joint anteroposterior and lateral views, as well as full-length standing X-rays of both lower limbs, were taken within 1 week and 3 months postoperatively to measure the hip–knee–ankle (HKA) angles and assess the fit of 3D-printed metal spacers with the knee joint and for signs of prosthesis loosening. The American Knee Society Score (KSS) was recorded.[7]

Statistical analysis

IBM SPSS, Version 22.0 statistical software (IBM Corp., Armonk, NY, USA) was used for data analysis. Continuous data (age, BMI, operation time, blood loss, HKA angle, and KSS) were checked for normality and are presented as the mean along with the range. Paired-sample t-tests were used to compare data before and after surgery, with the significance level (α value) set at 0.01 for both sides.

Ethics statements

This research was approved by the Ethics Committee of the Second Affiliated Hospital, Zhejiang University School of Medicine (No. 2023-0512) on 20 June 2023. The study was conducted in accordance with the Helsinki Declaration of 1975 as revised in 2013, and the reporting of the study conforms to the STROBE guidelines.[8] All patient information that could identify individuals has been masked. This retrospective study exclusively used existing medical records or data without involving the participants' identities or privacy and poses no risk or harm to them. Consequently, informed consent was not required; the hospital's ethics committee granted an exemption during the ethical review process.

Results

General results

Of the nine patients included in the analysis, five were female and four were male. Their mean age was 61.3 years (range, 46–73 years), and their mean BMI was 24.92 kg/m^2 (range, 21.25–30.06 kg/m^2). One patient underwent primary TKA, four underwent first revision surgery, and one underwent prosthetic replacement after infection. Table 1 shows the demographic and preoperative characteristics of each patient.

Intraoperative results

All patients underwent surgery smoothly, with an average operation time of 183.9 minutes (range, 125–240 minutes) and intraoperative blood loss of 133.3 mL (range, 100–200 mL). Five patients' procedures used 3D-printed metal spacers, and two used integral tibial components. Two patients were excluded because of difficulties in placing the printed spacers intraoperatively; they were found to be oversized, necessitating a temporary change in the surgical approach.

Perioperative complications

All patients underwent follow-up for an average duration of 13.2 months (range, 2–57 months). The average hospital stay was 18.2 days, and there were no cases of poor wound healing, infection, fat liquefaction, nerve injury, deep vein thrombosis of the lower limb, knee joint stiffness, periprosthetic joint infection, loosening, or postoperative transfusions.

Clinical and radiologic outcomes of follow-up

At 3 months postoperatively, the mean KSS was 95.0 ± 8.1 points (range, 81–106), which was significantly higher than the preoperative score of 51.2 ± 16.5 points (range, 15–74) ($t = -8.906$, $P = 0.001$). For patients who did not reach the 3-month mark, the last follow-up point was used. At the last follow-up, the mean HKA angle was $181.0° \pm 3.5°$ (range, 177.9°–188.0°), which was significantly higher than the preoperative angle of $175.8° \pm 12.4°$ (range, 153.3°–

Table 1. Patients' demographics and preoperative characteristics

Patient No.	Age (years)	Sex	BMI (kg/m^2)	Diagnosis	Type of defect	Preoperative KSS	Preoperative HKA angle (°)
1	65	F	26.74	Aseptic loosening	Tibial, AORI III	65	167.0
2	59	F	21.50	Aseptic loosening	Tibial, AORI III	74	183.8
3	68	F	27.34	Prosthetic joint infection	Femoral and tibial, AORI III	51	178.9
4	64	F	24.40	Traumatic osteoarthritis	Tibial, AORI III	54	192.0
5	55	M	21.25	Traumatic osteoarthritis	Femoral, AORI III	47	153.3
6	46	M	27.47	Traumatic osteoarthritis	Femoral, AORI III	61	178.2
7	54	M	24.60	Traumatic osteoarthritis	Tibial, AORI III	46	177.3
8	68	M	20.96	Aseptic loosening	Tibial, AORI III	48	164.5
9	73	F	30.06	Aseptic loosening	Femoral and tibial, AORI III	15	156.8

F, female; M, male; BMI, body mass index; AORI, Anderson Orthopaedic Research Institute;
KSS, Knee Society Score; HKA, hip–knee–ankle.

Table 2. Surgical characteristics and follow-up data

Patient No.	Follow-up time (months)	Operating time (minutes)	Blood loss (mL)	Postoperative transfusion	Length of hospital stay (days)	Postoperative KSS	Postoperative HKA angle (°)
1	6	180	100	No	12	101	184.5
2	7	125	100	No	15	106	180.1
3	20	200	100	No	10	101	181.6
4	2	175	150	No	10	81	188.0
5	5	210	100	No	27	86	179.2
6	57	240	100	No	24	101	177.9
7	2	195	150	No	42	91	181.2
8	8	180	200	No	14	95	179.9
9	12	150	200	No	10	93	176.6

F, female; M, male; BMI, body mass index; KSS, Knee Society Score; HKA, hip–knee–ankle.

192.1°), indicating satisfactory correction of lower limb alignment ($t = -2.306$, $P = 0.05$). Table 2 shows the functional and radiographic scores of the follow-up patients. Figures 2 and 3 show the perioperative radiographs of Patients 4 and 6.

Discussion

AORI Type III bone defect is a complex condition in knee replacement surgery, typically involving extensive damage to the femur, tibia, and patella. The use of wedges to address AORI Type III bone defects in knee replacement surgery has been widely practiced.[9] This method can effectively fill bone defects, restore joint function and stability, improve surgical success rates, and enhance patients' quality of life. When managing AORI Type III bone defects, surgeons typically use various methods to apply wedges, including modular wedges, custom wedges, and fillers such as autogenous bone, allogeneic bone, bone cement, hydroxyapatite, and β-tricalcium phosphate.[10–14] These materials can create

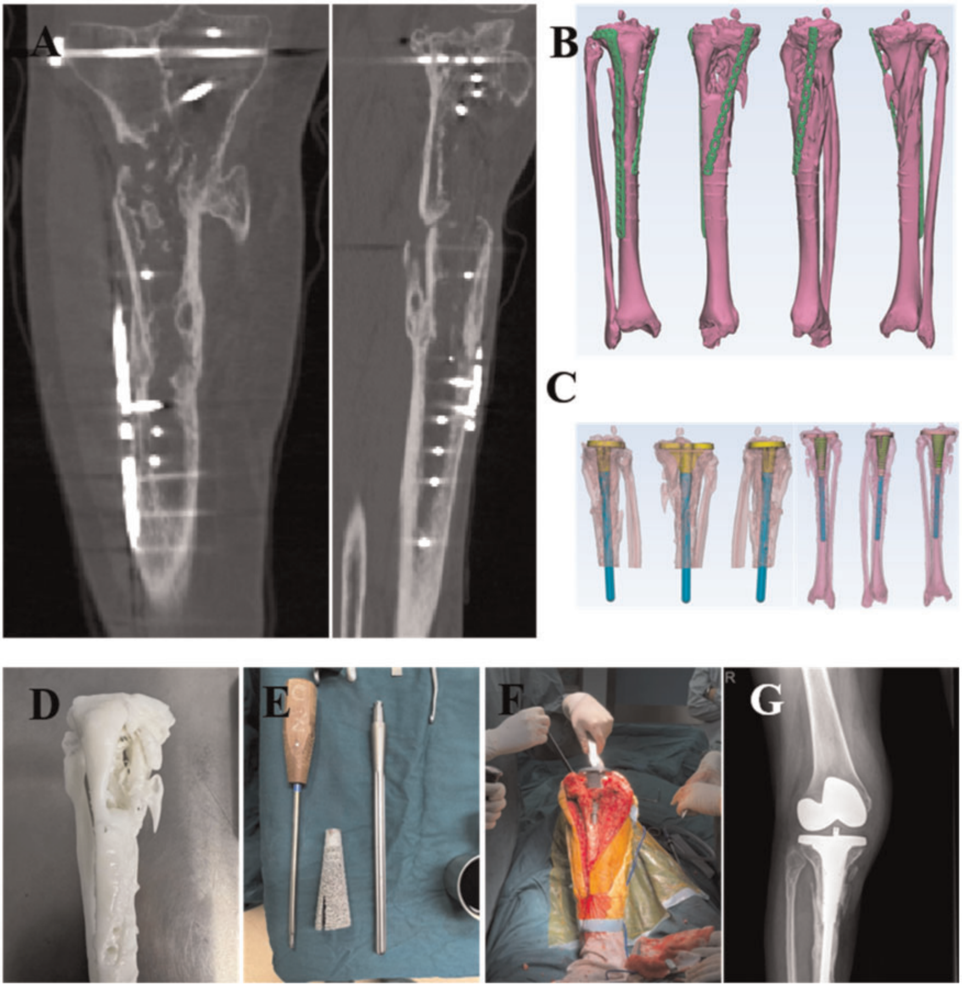

Figure 2. A 64-year-old woman with a 3-year history of traumatic arthritis underwent replacement surgery. (a) Preoperative knee joint imaging showed a massive tibial bone defect, AORI Type III. (b, c) Based on the patient's knee joint computed tomography data, a reverse-generated skeletal model was created, and a filling design was carried out according to the defect situation. The tibial component was printed, and a customized extension rod was assembled. (d, e) The 3D-printed skeletal model and physical component. (f) Installation of the 3D-printed components during surgery, showing satisfactory positioning and good stability and (g) postoperative X-ray images of the knee joint at 3 months, showing good integration of the 3D-printed component with the bone surface and stable prosthesis positioning.

a strong support structure in the bone defect area, aiding in prosthesis fixation and promoting bone tissue regeneration and healing. In particularly complex cases, surgeons may combine different types of wedges, such as custom wedges and fillers, to better meet the specific needs of the defect site and achieve more effective repair outcomes.[15]

Increasing research is showing significant progress in using 3D-printed wedges to address AORI Type III bone defects in knee replacement surgery,[16,17] which aligns with our findings, particularly regarding

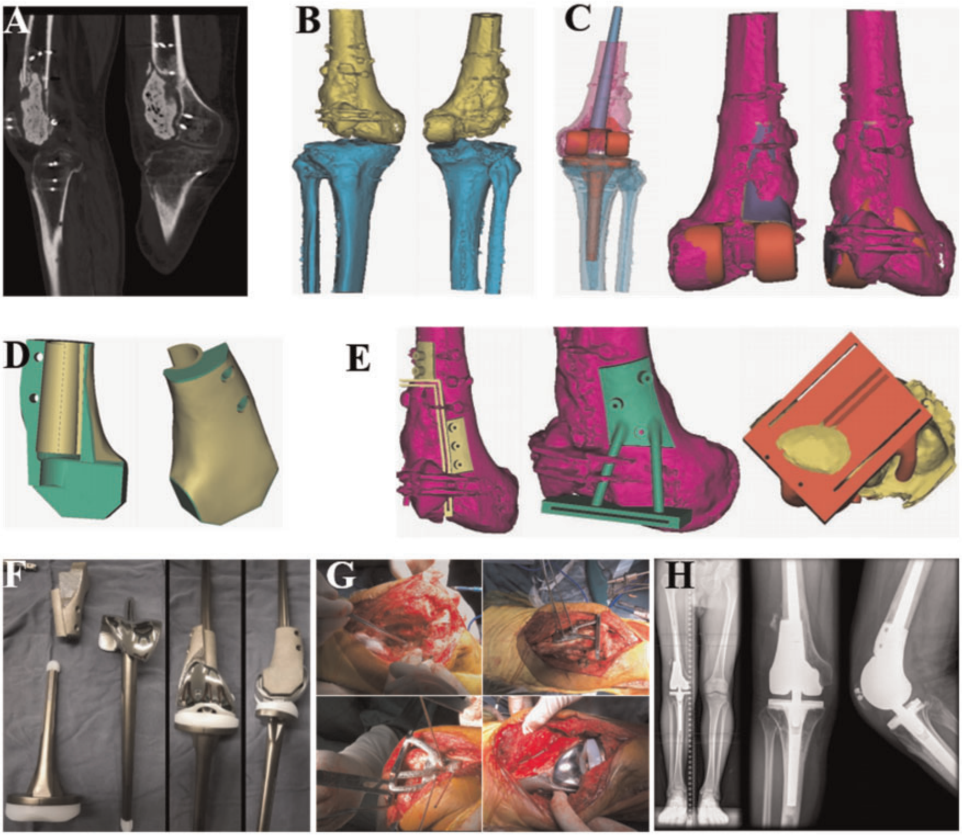

Figure 3. A 46-year-old man diagnosed with traumatic arthritis underwent revision surgery. (a) Preoperative knee joint imaging revealed a severe femoral bone defect, AORI Type III. (b, c) A reverse-generated skeletal model was created based on the patient's knee joint computed tomography data, and a filling design was conducted according to the defect situation. (d–f) The femoral component was 3D-printed, and a customized cutting guide was designed based on the patient's bone defect. (g) Installation of 3D-printed components during surgery, showing satisfactory positioning and good stability and (h) post-operative X-ray images of the knee joint at 3 months, including anteroposterior and lateral views as well as full-length standing images, demonstrating good integration of the 3D-printed component with the bone surface and stable prosthesis positioning.

improvements in the KSS. This technology offers more personalized and precise treatment options for patients while also addressing the technical aspects of its application.

First, the immediate stability of 3D-printed wedges requires careful consideration of fixation, including both physical and biological fixation. Among the many factors influencing immediate stability, the most critical and initial consideration is the direct contact fixation between the bone defect area and the wedge. The fixation area of the knee joint prosthesis is divided into three zones: Zone 1 for metaphyseal fixation, Zone 2 for diaphyseal fixation, and Zone 3 for distal bone shaft fixation. Stable fixation requires at least two-zone fixations.[18] If the bone quality in Zone 2 is good, using appropriate metal wedges can achieve secure Zone 2 fixation, which in turn enhances the stability of Zones 1 and 3. Consequently, many commercial products for diaphyseal fixation have been developed. The primary function of 3D-printed wedges is to fill and repair the bone defect area. To achieve this, the wedge must closely conform to the surrounding healthy bone tissue and ensure proper fixation within the defect area to provide stable support.

Second, the interface between the wedge and the surrounding bone tissue is a critical factor influencing its stability. Ensuring that the wedge bonds effectively with the patient's bone tissue and promoting bone tissue growth and wedge stability is essential.[19] Additionally, using appropriate methods to fix the wedge in the bone defect area during surgery is vital for immediate stability. Bone cement, bone screws, or other external fixators can be used to secure the wedge, ensuring it withstands postoperative forces and maintains stability. In some special cases, surgeons may consider using extension rods to enhance the stability and support of the artificial joint prosthesis.[20] If the patient's bone shaft is short or defective, the extension rod can provide additional length to ensure the prosthesis is properly implanted and adequately supported. This helps surgeons adjust joint alignment and stability more effectively.[21–23] In the cases shown in Figures 2 and 3, we also used an extension rod to ensure the stability of the tibial component. It is important to note that the decision to use an extension rod depends on multiple factors, such as the patient's bone structure, the severity of the condition, and the surgical plan. Decisions are made based on individual circumstances and require professional judgment and experience to ensure the success of the surgery and the patient's recovery.

In addition to bone tissue fixation, the surrounding soft tissues play a crucial role in the stability of the wedge. During surgery, care must be taken to protect the surrounding soft tissues to avoid damage or excessive stretching, ensuring that the fixed position of the wedge remains undisturbed. Considering these factors, effective fixation of these areas in the design and surgical operation of 3D-printed wedges can enhance the immediate stability of the wedge in knee replacement and revision surgeries for large bone defects, thereby promoting surgical success and patient recovery.

Although customization offers a viable solution for TKA surgeries with massive bone defects, the occurrence of an ill-fitting prosthetic component during surgery can impose significant psychological pressure on the lead surgeon, especially because of the lack of backup options. In our clinical practice, we prioritize using existing commercial prosthetics and modules for preoperative simulations. Personalized custom prosthetics are only employed when existing options fail to meet the patient's needs. Thus, customization is considered a final option, necessitating thorough preoperative planning, including the complete removal of metal artifacts and bone cement. Nevertheless, ill-fitting prosthetics may occasionally arise during surgery. If the prosthetic is too large, smaller commercial spacers can be used for trial simulations. Alternatively, the resection volume may be increased as appropriate, with bone cement used to fill any small gaps to ensure prosthetic stability. Because these surgeries are unconventional, often lack alternative options, and involve high costs, prolonged recovery, and limited case numbers (fewer than 10 cases per year in our hospital), it is essential to carefully evaluate the risks and benefits. We recommend strictly adhering to surgical indications, maintaining effective communication with patients and their families, and advising them to consider purchasing commercial insurance to alleviate financial pressure.

With the continuous development and improvement of technology, the use of personalized custom wedges to address AORI Type III bone defects is expected to become more mature and widespread. In practical applications, medical teams integrate these design principles and considerations to create personalized treatment plans tailored to each patient's specific situation. By leveraging the potential of 3D printing technology, the outcomes of knee replacement surgeries for large bone defects—whether initial or revision procedures—can be significantly improved. The personalized approach enabled by 3D printing is anticipated to enhance patient prognosis and drive advancements in the field of orthopedic surgery.

Limitations of the study

First, this was a single-center retrospective study with a small sample size and short follow-up duration. Second, there was no control group for a strict process design, limiting the ability to compare personalized 3D-printed metal spacer blocks with commonly used commercial implants in clinical practice. Thus, future multicenter, large-sample randomized controlled trials are needed to further validate the findings. Finally, patients who underwent primary and revision surgeries were grouped together in this study. In the future, as the sample size increases, conducting separate statistical analyses for these groups will provide more clinically meaningful insights.

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Author contributions

FL: Data curation, investigation, visualization, and writing of the original draft. CSL: Methodology. PFH: Data collection. BH: Funding acquisition. HBW: Writing and review. All authors read and approved the final manuscript.

Data availability statement

All data are available from the corresponding author upon reasonable request.

Declaration of conflicting interest

The authors declare that there are no conflicts of interest.

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