3D-printed modular prostheses for reconstruction of intercalary bone defects after joint-sparing limb salvage surgery for femoral diaphyseal tumours

From Sun Yat-Sen University Cancer Center, Guangzhou, China

Correspondence should be sent to J. Wang wangjinbs@sysucc.org.cn

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X. Zhu,[1,2] J. Hu,[1,2] J. Lin,[1,2] G. Song,[1,2] H. Xu,[1,2] J. Lu,[1,2] Q. Tang,[1,2] J. Wang[1,2]

[1]Department of Musculoskeletal Oncology, Sun Yat-Sen University Cancer Center, Guangzhou, China
[2]State Key Laboratory of Oncology in South China, Guangdong Provincial Clinical Research Center for Cancer, Sun Yat-sen University Cancer Center, Guangzhou, China

Aims

The aim of this study was to investigate the safety and efficacy of 3D-printed modular prostheses in patients who underwent joint-sparing limb salvage surgery (JSLSS) for malignant femoral diaphyseal bone tumours.

Methods

We retrospectively reviewed 17 patients (13 males and four females) with femoral diaphyseal tumours who underwent JSLSS in our hospital.

Results

In all, 17 patients with locally aggressive bone tumours (Enneking stage IIB) located in the femoral shaft underwent JSLSS and reconstruction with 3D-printed modular prostheses between January 2020 and June 2022. The median surgical time was 153 minutes (interquartile range (IQR) 117 to 248), and the median estimated blood loss was 200ml (IQR 125 to 400). Osteosarcoma was the most common pathological type (n = 12; 70.6%). The mean osteotomy length was 197.53 mm (SD 12.34), and the median follow-up was 25 months (IQR 19 to 38). Two patients experienced local recurrence and three developed distant metastases. Postoperative complications included wound infection in one patient and screw loosening in another, both of which were treated successfully with revision surgery. The median Musculoskeletal Tumor Society score at the final follow-up was 28 (IQR 27 to 28).

Conclusion

The 3D-printed modular prosthesis is a reliable and feasible reconstruction option for patients with malignant femoral diaphyseal tumours. It helps to improve the limb salvage rate, restore limb function, and achieve better short-term effectiveness.

Take home message

- The 3D-printed modular prosthesis is a reliable and feasible reconstruction option for patients with malignant femoral diaphyseal tumours.
- It helps to improve the limb salvage rate, restore limb function, and achieve better short-term effectiveness.

Introduction

Primary bone malignancies often occur in the metaphysis of long tubular bones, among which the distal femur and upper tibia are the most commonly involved, resulting in overall functional disability and reduced quality of life.[1,2] The current therapeutic measures for malignant bone tumours of the limbs include neoadjuvant systemic chemotherapy and limb salvage surgery with en bloc

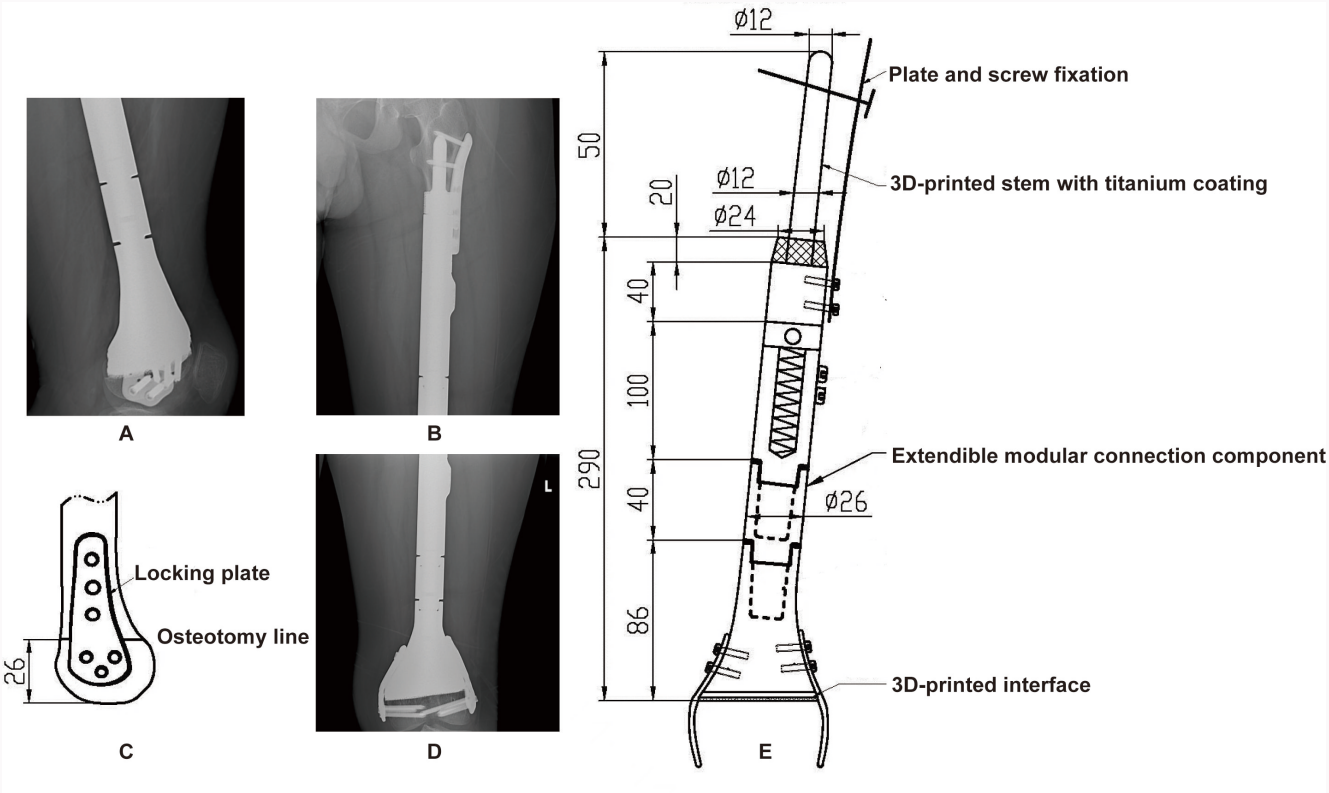

Fig. 1

Radiographs and design of the 3D-printed prosthesis of a ten-year old male. a) Lateral radiographs of the distal component 20 months postoperatively; b) anteroposterior radiographs of proximal stem; c) distal 3D-printed component on design proposal fixed by the locking screw and plate; d) anteroposterior radiographs of the distal component; and e) the gross view of the prosthesis on design proposal showing the proximal 3D-printed stem with a titanium coating, a modular connection component in the middle part, and a distal 3D-printed component.

resection.[3,4] Occasionally, the femoral shaft can be affected, and it is exceedingly difficult to replace only the midpart of the bone while preserving the joint above and below.[5,6] Joint-sparing limb salvage surgery (JSLSS) enables patients to retain the epiphyseal plate, preserve the growth potential, and provide better lower limb function, which is particularly important for growing children.[7-9]

Traditionally, reconstruction techniques for diaphyseal bone defects include vascularized fibular autografts, tumour-devitalized bone replantation, massive allografts, and prosthesis reconstruction.[10] These methods can provide durable mechanical strength and are valuable reconstruction strategies. Nevertheless, distinct concerns remain, including prolonged rehabilitation times, fractures, difficulty in matching, aseptic loosening, and immune rejection;[5,11] the optimal reconstruction method has not yet been determined. Technological advancements in 3D techniques allow the fabrication of metallic components with complex shapes and porous structures, simplifying the processing steps and reducing the fabrication time.[12] Theoretically, a 3D-printed modular prosthesis realizes the combined advantages of both a prosthesis and biological reconstruction, and is an ideal option for reconstruction. However, the reported clinical series of patients treated with JSLSS using 3D-printed prostheses is limited to a small retrospective series, and the efficacy of this material warrants further investigation.

In this study, we retrospectively analyzed the outcomes of 17 patients with malignant tumours of the mid-shaft femur treated at our department (Department of Musculoskeletal Oncology, Sun Yat-Sen University Cancer Center, China) with JSLSS, followed by reconstruction with 3D-printed modular prostheses, to clarify its treatment effectiveness.

Methods

Inclusion and exclusion criteria

The inclusion criteria were: 1) the treatment was conducted between 1 January 2020 and 30 June 2022; 2) a diagnosis of malignant tumours of the femoral diaphyseal confirmed by postoperative pathological examinations; 3) treatment with JSLSS; 4) reconstruction with 3D-printed modular prosthesis; and 5) a minimum 12-month follow-up period. The exclusion criteria were resection of the epiphyses, and reconstruction using other methods.

This study was approved by the ethics committee of our hospital. Informed consent was obtained from all patients.

Patients' medical records, operating room reports, histological results, and radiological findings were reviewed. The study parameters included patient age, sex, tumour histology, estimated blood loss, and surgical complications. The functional outcomes were assessed using the Musculoskeletal Tumor Society (MSTS) score[13] (ranges from 0 to 30, with higher scores indicating better function) and Toronto Extremity Salvage Score[14] (TESS; ranges from 0 to 100, with higher scores indicating lesser level of physical disability), and tumour stages were classified according to the Enneking staging system.[15]

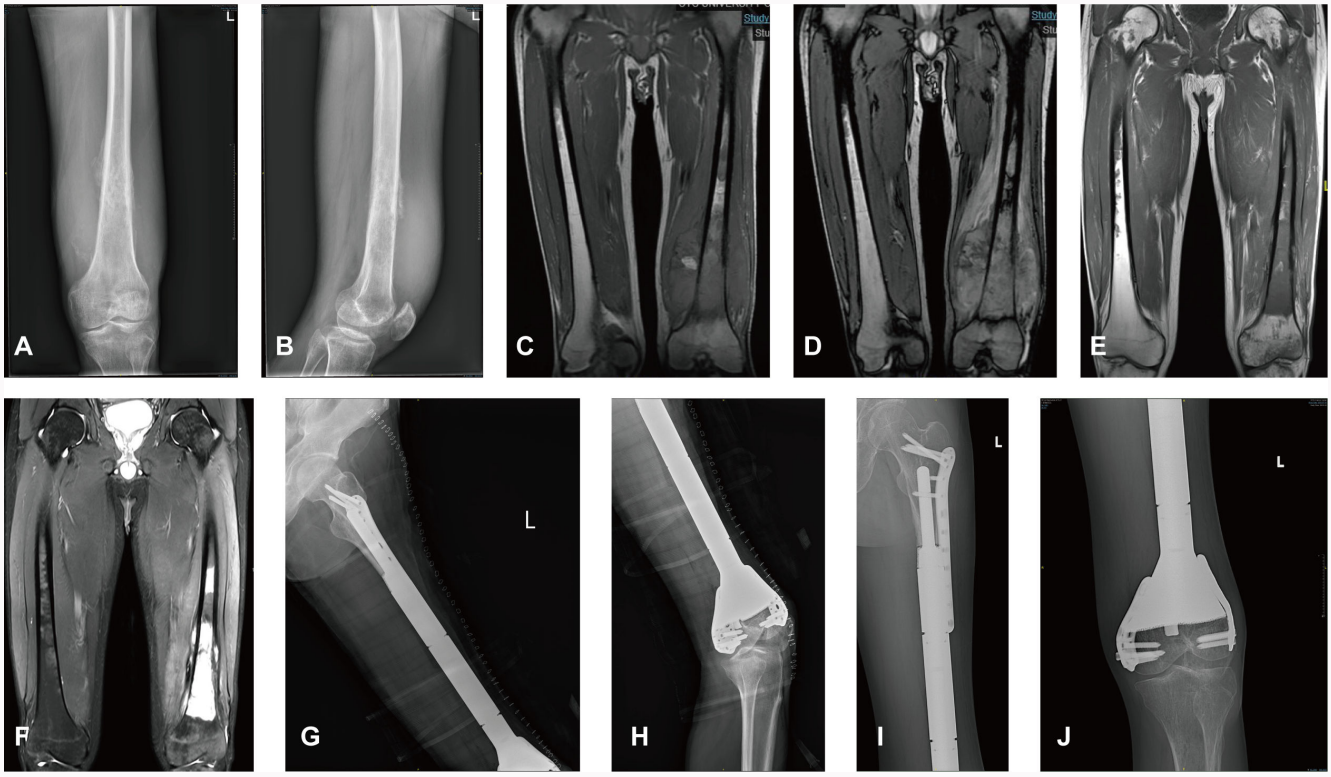

Fig. 2
A 31-year-old male patient complained of increasing left thigh pain during the last 12 months, and was found to have Ewing's sarcoma in the mid-shaft femur. a) and b), preoperative radiographs showing bone destruction of the distal femur. c) and d) T1-weighted and T2-weighted MRI before chemotherapy. e) and f) T1-weighted and T2-weighted MRI after six courses of chemotherapy revealed dramatic shrinkage of the tumour. g) and h) Postoperative radiographs. i) and j) Radiography showed an excellent position of the 3D-printed prosthesis and the Musculoskeletal Tumor Society score was 28 at the 30-month follow-up.

Treatment strategy

Individualized treatment regimens were tailored for each patient according to their personal characteristics. Prior to surgery, neoadjuvant chemotherapy was administered to all patients to shrink the tumour, and the extent of the lesions was carefully evaluated using CT and MRI. All prostheses were designed two to three weeks before operation by surgeons from our department based on 1 mm thin-layer CT imaging and manufactured by Lida Kang, China. The uncemented, press-fit prostheses were porous structure made of titanium alloy (Ti_6Al_4V) and consisted of three parts: a proximal 3D-printed stem with a titanium coating, a modular connection component in the middle part, and a distal 3D-printed component fixed by screws and plates. The diameter of the proximal stem was based on the width of the medullary cavity of the femoral shaft to maximize bicortical fixation, and the 3D-printed component can be combined with the modular component by the mortise structure and taper junction to match the length of the bone defect (Figure 1). Prior to implantation, the prostheses were ethylene oxide-sterilized. The goal of the surgery was complete lesion excision with a safe oncological margin > 20 mm. However, a minimum margin of 10 mm was acceptable when the tumour was adjacent to the epiphyseal region. During the operation, the sciatic nerves and femoral neurovascular bundles were dissected to expose the tumour fully, and the bone lesion, soft-tissue components, and biopsy channel were resected en bloc. A customized 3D-printed osteotomy guide plate was routinely used for the osteotomies. After intramedullary reaming, prosthesis installation was performed from the proximal to the distal femur, and lateral plate fixation was performed if the residual proximal femoral length was < 120 mm (Figure 2). Postoperatively, isometric quadriceps contractions were started on the second day after surgery, then partial and full weightbearing were allowed at one and six weeks post-surgery, respectively, to accelerate the recovery process.

Follow-up

Patients routinely underwent physical examinations, raradiography, reconstructive CT of the chest and thigh, and MRI at three, six, and nine months postoperatively, and every three months thereafter to monitor implant osseointegration, prosthetic complications, local control, and distant metastases. Positron emission tomography/CT was performed as a complement for some patients.

Statistical analysis

Continuous variables with normal distribution are presented as mean values (standard deviations (SDs)) and medians (interquartile range (IQR)) for those with non-normal distribution. Categorical variables are expressed as counts (percentages). The normality of the distribution was tested using the Kolmogorov-Smirnov test. All statistical analyses were performed using SPSS v. 26 for Mac (IBM, USA).

Table I. Patient demographics and operative details.

No	Sex/age, yrs	Histology	Osteotomy length, mm	Enneking stage	Operating time, mins	Blood loss, ml	Complication	F/U, mths	TESS	MSTS	Tumour control
1	M/51	UPS	140	IIB	112	200	No complication	44	90.83	27	No recurrence
2	M/32	MGCT	150	IIB	126	100	No complication	47	83.33	24	No recurrence
3	M/13	OS	190	IIB	123	200	No complication	46	91.67	28	No recurrence
4	F/59	ES	150	IIB	167	400	No complication	41	89.20	27	No recurrence
5	M/67	OS	140	IIB	95	200	Screw loosening	35	88.89	28	No recurrence
6	M/31	Ewing's sarcoma	270	IIB	250	600	No complication	30	94.17	28	No recurrence
7	M/11	OS	210	IIB	153	200	No complication	15	N/A	N/A	Recurrence and lung metastases
8	M/11	OS	158	IIB	118	100	No complication	27	94.79	29	No recurrence
9	F/15	OS	180	IIB	300	800	Wound infection	26	89.00	27	No recurrence
10	M/11	OS	165	IIB	115	20	No complication	25	90.63	28	No recurrence
11	M/17	OS	150	IIB	128	100	No complication	22	97.00	29	Lung metastases
12	F/61	DDC	260	IIB	246	400	No complication	23	88.46	26	Recurrence and bone metastases
13	M/10	OS	290	IIB	215	300	No complication	20	89.13	27	No recurrence
14	F/11	OS	240	IIB	230	400	No complication	20	96.88	29	No recurrence
15	M/17	OS	220	IIB	93	150	No complication	18	92.31	26	No recurrence
16	M/15	OS	265	IIB	287	400	No complication	18	92.00	28	No recurrence
17	M/74	OS	180	IIB	271	300	No complication	18	93.27	28	No recurrence

DDC, dedifferentiated chondrosarcoma; ES, epithelioid sarcoma; F/U, follow-up; MGCT, malignancy in giant cell tumour; MSTS, Musculoskeletal Tumor Society; OS, osteosarcoma; TESS, Toronto Extremity Salvage Score; UPS, undifferentiated pleomorphic sarcoma.

Results

Between January 2020 and June 2022, 17 consecutive patients with malignant bone tumours (Enneking stage IIB) located in the femoral diaphyseal region underwent JSLSS and reconstruction with 3D-printed modular prostheses at our orthopaedic department. A definitive diagnosis was made based on postoperative histopathology in all patients, and no patients were lost to follow-up. The median age of the patients was 17 years (IQR 11 to 55); 13 were male and four female. The most common primary tumour type was osteosarcoma (n = 12; 70.6%), followed by Ewing's sarcoma, dedifferentiated chondrosarcoma, undifferentiated pleomorphic sarcoma (Figure 3), malignancy in giant cell tumour of the bone, and epithelioid sarcoma in one patient (5.9%) each. None of the patients had distant metastases at the time of diagnosis.

The median operation time was 153 minutes (IQR 117 to 248), and the median estimated blood loss was 200 ml (IQR 125 to 400). All prostheses were positioned well, and the mean length of osteotomy was 197.5 mm (SD 12.3). The diameter and the length of proximal stem ranged from 12 to 20 mm and 50 to 130 mm, respectively.

The median follow-up period was 25 months (IQR 19 to 38). Ultimately, three patients developed recurrence; one (5.9%) had distant metastases, and two (11.8%) experienced local relapses with distant metastases, and the time to local failure was six and eight months, respectively. Case 7 underwent amputation because of local failure at six-month follow-up. However, the patient experienced systemic progression and died one month after the second surgery. For the remaining 16 patients, the median MSTS score and TESS score were 28 (IQR 27 to 28) and 91.25 (IQR 89.03 to 93.95) at the final follow-up visit, respectively. All patients could walk unassisted.

Two perioperative complications were observed. Case 9 had a superficial wound infection that did not respond to the initial antibiotic treatment and was eventually controlled by thorough debridement. Revision surgery was conducted in Case 5 because of early screw loosening after a fall at home three months after the first operation. Fortunately, the patient recovered well and had a good functional result after the revision surgery. No periprosthesis fracture, aseptic loosening, or implant breakage was observed during follow-up (Table I).

Discussion

Multidisciplinary therapy is essential for managing primary bone malignancies, and neoadjuvant chemotherapy combined with subsequent limb salvage surgery has become a standard treatment strategy. Recent technical advances in radiology, navigation, and surgical technology have enabled precise excision of tumours and significantly enhanced patient survival, making long-term functional preservation of the limbs the next urgent demand for survivors. JSLSS permits better limb function by preserving the adjacent native joints and ligaments. Zucchini et al[9] reported a retrospective study of 23 patients with tumour of distal femur, and found that the lower limb dysmetria in transmetaphyseal resection cases was better than transepiphyseal resection cases. In our cases, none of the surviving patients required any assistive walking device, and the median MSTS score at the final follow-up was 28 (IQR 27 to 28), better than that of patients who underwent distal

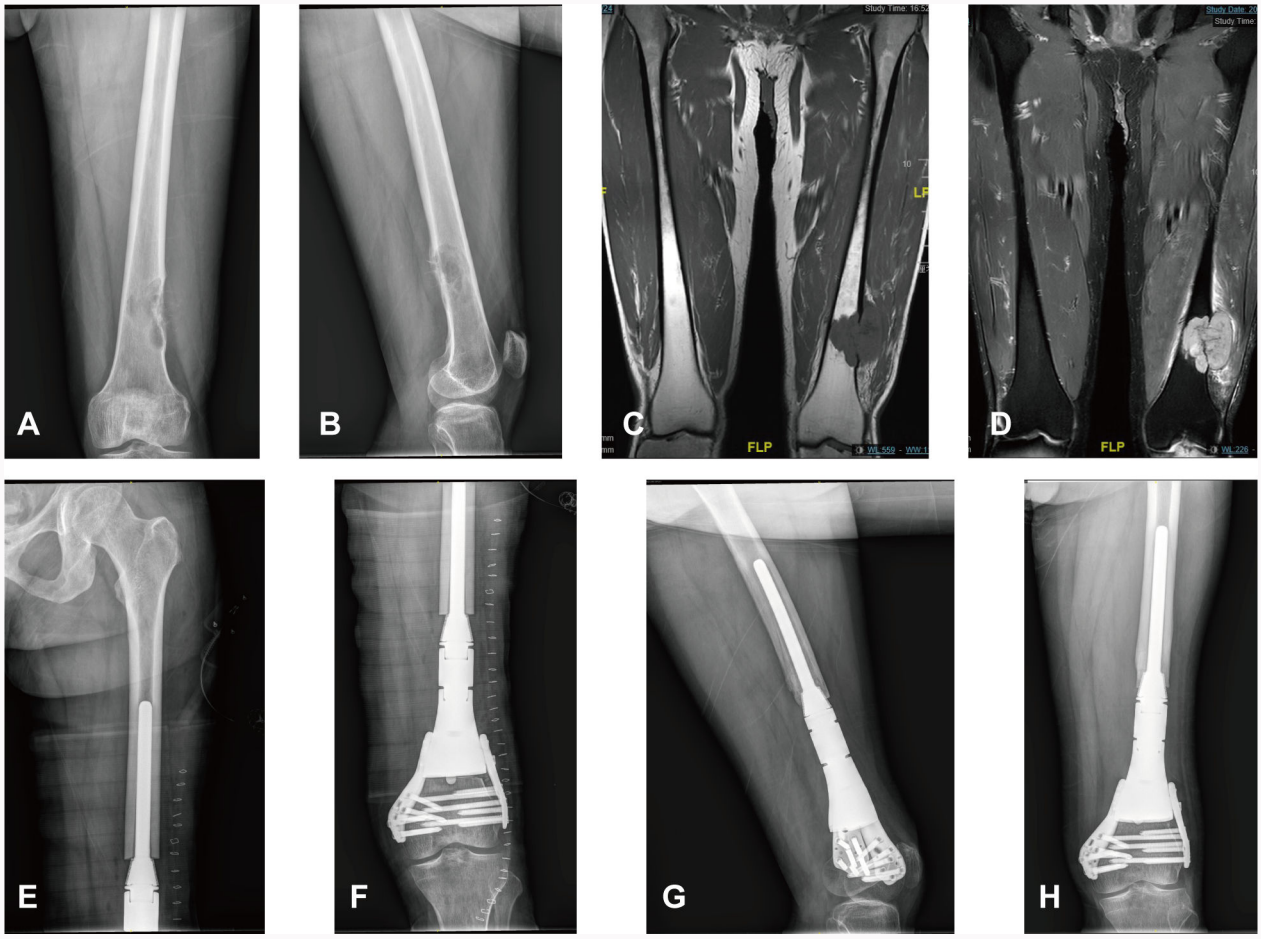

Fig. 3
A 51-year-old male with undifferentiated pleomorphic sarcoma experienced progressive left thigh pain for sixmonths. a) and b) preoperative radiograph; c) and d) T1-weighted and T2-weighted MRI before chemotherapy; e) and f) postoperative radiograph; and g) and h) radiography demonstrating an excellent position of the prosthesis. The Musculoskeletal Tumor Society score was 27 at 44-month follow-up.

femur arthroplasty in the literature.[16] However, the reconstruction of large irregular bone defects remains a great challenge for surgeons, especially when the tumour extends into the proximal femur and has an ultrashort proximal femur (UPF). To date, various techniques, including biological and mechanical reconstruction, have been used to repair these large intercalary bone defects. However, the optimal reconstruction strategy has not yet been determined.

Biological reconstructions, such as autografts and allografts, allow the preservation of the juxta-articular bone and joint and have fewer long-term mechanical problems.[7] Gupta et al[17] retrospectively reviewed 46 patients reconstructed with intercalary allografts; the overall survival of the allograft was 84.8% and the function outcomes was encouraging, with mean MSTS score of 93 and mean TESS score of 82.2 and 81.2, respectively. However, the shortcomings of biological reconstructions include the risk of disease transmission, delayed rehabilitation, and a relatively high risk of immune rejection, nonunions, infections, and fracture.[5,7,10,18,19] According to Ramkumar et al,[20] patients who underwent JSLSS and intercalary allograft had more major complications than those underwent proximal femoral resections with allograft-prosthetic compsite reconstructions. Compared with biological reconstruction, using metallic prostheses shortens the non-weightbearing period and have low incidence of early complications, which is associated with a shorter hospital stay and better quality of life.[10] Lempberg et al[21] successfully used segmental prostheses to restore tumour-destroyed diaphyseal bone in salvage procedures for the first time; all three patients were able to accept weightbearing in the early postoperative stage, and the curative effect was satisfactory. Nevertheless, it should be acknowledged that this technique also has some drawbacks, including the high risk of late instrumentation failure and the subsequent need for revision surgery.[11] According to Aldlyami et al,[5] the overall instrumentation failure rate of diaphyseal endoprostheses is 60% at ten years, which is higher than that of prostheses used at other sites. Similar results were observed by Errani et al,[10] who recently undertook a updated literature review and reported the aseptic loosening rates of modular prosthesis ranged 0% to 33%. Moreover, conventional reconstruction techniques require superb surgical skills for trimming and fitting the implant, thus prolonging the surgical procedure and increasing the risk of bleeding.[22]

The advent of 3D-printed modular prostheses with porous structures allows for precise bone-defect matching and better bone ingrowth, which might facilitate implant-bone osseointegration and decrease prosthesis-related complications.[23] In a series by Zhang et al,[22] 28 patients with bone tumours of the limbs were treated with limb salvage surgery,

and patients who were treated with 3D-printed prostheses had significantly shorter osseointegration times and lower complication rates than those who received conventional allografts. However, there are few studies on the outcomes of 3D-printed prostheses, and the long-term outcomes of this technique remain unclear.

In the present study, almost all patients had an uneventful postoperative recovery and could receive early rehabilitation exercises. In addition, the median surgical time and estimated blood loss were 153 minutes (IQR 117 to 248) and 200 ml (IQR 125 to 400), respectively, indicating the safety and feasibility of this technique. Notably, the majority of the prostheses in our study were positioned well with the assistance of a 3D-printed osteotomy guide plate, and only one of the 17 patients experienced screw loosening caused by traumatic injury. This is consistent with previous reports, in which a customized 3D-printed guide plate helped to achieve accurate tumour excision.[24,25] Zhang et al[22] used a patient-specific guide to achieve an accurate osteotomy and concluded that it could help decrease the surgical time and number of fluoroscopies.

There is little consensus on the definition of UPF. You et al[6] defined UPF as the length from the pyriform fossa to the osteotomy level of no more than 80 mm. Dieckmann et al[16] adopted a unique short stem to preserve the hip joint in patients with a UPF of 110 mm, and reported a satisfactory curative effect. From our point of view, the UPFs of children and adults are different, as bone growth and adaptive ability in paediatric patients vary substantially compared with that of adults. Thus, we suggest that measures of the distance between the tumour margin and the lower edge of the lesser trochanter can be used as indicators for JSLSS, and that patients with a distance of less than 10 mm may not be suitable candidates for this modified procedure. Moreover, we adopted lateral plate fixation if the residual proximal femoral length was < 120 mm to ensure prosthesis stability. With regard to the distal femur, the indication for knee joint-preserving tumour resection is a distance of at least 10 mm between the tumour margin and the distal femoral physis. Two patients in our study experienced local failure, which arose in the soft-tissue of the proximal limbs, suggesting that a resection margin of 1 cm from the tumour was adequate.

Studies have shown that the main surgical complications of JSLSS include infection, fractures, aseptic loosening, and delayed union or nonunion, which may significantly influence the surgical outcomes.[10,11,26,27] However, the excellent biological fixation and long-term longevity of 3D-printing prostheses can help reduce the rate of complications and improve patients' quality of life.[18,28] In this study, only two complications were discovered at the final follow-up, and no aseptic loosening or fractures were observed, illustrating the excellent reliability of 3D-printed prostheses.

The limitations of this preliminary study include its retrospective nature, inadequate sample size, and single-centre design. Additionally, the follow-up duration of this study was relatively short. Prosthetic mechanical complications, reported to be late and severe in previously published studies, require a longer observation period.

In conclusion, the 3D-printed modular prosthesis offers a reliable reconstruction option with a low risk of complications for diaphyseal bone defects after femoral diaphyseal tumour resection. It can help to improve the limb salvage rate, restore limb function, and achieve better short-term effectiveness. However, the long-term effects of this technique warrant further investigation.

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Author information

X. Zhu, MD, Surgeon
J. Hu, MD, Surgeon
J. Lin, MD, Surgeon
G. Song, MD, Surgeon
H. Xu, MD, Surgeon
J. Lu, MD, Surgeon
Q. Tang, MD, Surgeon
J. Wang, MD, Surgeon
Department of Musculoskeletal Oncology, Sun Yat-Sen University Cancer Center, Guangzhou, China; State Key Laboratory of Oncology in South China, Guangdong Provincial Clinical Research Center for Cancer, Sun Yat-sen University Cancer Center, Guangzhou, China.

Author contributions

X. Zhu: Conceptualization, Data curation, Writing – original draft.
J. Hu: Data curation, Writing – original draft.
J. Lin: Data curation, Resources.
G. Song: Investigation, Resources.
H. Xu: Data curation, Resources.
J. Lu: Resources.
Q. Tang: Resources.
J. Wang: Supervision, Writing – review & editing.

X. Zhu and J. Hu contributed equally to this work.

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The authors confirm that they have no disclosures to declare.

Data sharing

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Ethical review statement

This study was approved by the ethics committee of our hospital.

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