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CLINICAL PRACTICE

First application of 3D design custom-made uncemented prosthetic stem for distal femoral cemented megaprosthesis revision

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Abstract

Objectives: 3D design, which is widely used in orthopedics, can be applied for precise distal femoral megaprosthetic revision. This research aimed to present and evaluate the design, perioperative management, and mid-term clinical outcomes of a 3D design custom-made uncemented prosthetic stem.

Methods: Between January 2014 and January 2016, seven patients received 3D design custom-made uncemented prosthetic stem revision at our institution. Clinical records and radiographs were evaluated retrospectively.

Results: There were no hardware-related complications during the follow-up (average 24.3 months; range 24–48 months). The average Musculoskeletal Tumor Society (MSTS) score at the last follow-up after revision (27.7 points, range 25–28 points) was significantly higher than that before (16.0 points, range 13–18 points). In addition, the range of motion (ROM) of the affected knee, and the scores of pain, function, emotional acceptance, support, walking and gait all improved significantly. The antecurvature radian of the revision stem averaged at 3.6°. Of the seven patients, three received femoral stem revision and four received revision of the femoral stem and the femoral component; three of them used longer prostheses than the others. There were no significant differences in function between these two groups at the last follow-up after revision.

Conclusion: The 3D design custom-made prosthesis is a typical precision medicine technology in oncologic orthopedics. Characterized by its individually and precisely designed uncemented stem, it offers an alternative option for distal femoral cemented prosthesis revision. Besides the 3D design itself, the perioperative management, especially the techniques for stem implantation, and long-term follow-up are also crucial.

Key words: distal femur; bone tumor; 3D design; prosthetic stem; revision; precision medicine

†These authors contributed equally to this work.

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Introduction

Compared with allograft reconstruction, pasteurized autograft reconstruction, bone elongation, arthrodesis, rotationplasty and amputations, stemmed distal femoral megaprosthesis is the most commonly used reconstruction strategy for distal femur tumor, with advantages of preserving the entire limb, facilitating stable limb function, and leading to an early return to social activities.[1–10]

Advancements in medical treatment and surgical techniques mean that the survival rate of lower limb megaprostheses is much higher than ever before, reported as 75.9–83.1% after 5 years and 47.2–79.3% after 10 years.[11–14] Therefore, long-term megaprosthetic failure is inevitable, especially for most of the young and active patients.[15] As time goes by, the demand for megaprosthetic revision in most of these patients will eventually increase.[15,16] One of the most common reasons for megaprosthetic failure is aseptic loosening of the stem.[3,16–20]

Revision of megaprosthesis stem poses a challenge for oncologic orthopedists in terms of how to improve the success rate of the revision under insufficient quantity and quality of the affected bone. Several revisions for distal femoral megaprosthetic stem have been reported through cemented stemmed implant reconstruction, allograft-prosthetic composite (APC) reconstruction, or total femur replacement.[17,21–23] However, disadvantages such as relatively higher failure rate, allograft-related complications, and innocent joint sacrifice, have restricted their clinical application. Uncemented stemmed implant reconstruction is seldom used for megaprosthesis revision.[19,23,24] Importantly, preoperative design is not precise enough. Since 2003, the Compress Compliant Pre-Stress implant (Biomet, Warsaw, IN, USA) has grown in popularity for megoprosthesis revision; however, this is non-custom-made, strictly limited to good quantity or quality of bone, and at risk of breakage at the traction bar.[25]

To preserve the remaining femoral bone stock and accomplish a more individual, precise, and durable stem revision, a three-dimensional (3D) design custom-made uncemented prosthetic stem is proposed as a better choice. To our best knowledge, there is no related study regarding 3D designed prosthetic stem for the revision of distal femoral megaprosthesis. Therefore, the goals of this study are to present and evaluate the design, perioperative management, and mid-term clinical outcomes of this 3D design custom-made uncemented prosthetic stem for revision of distal femoral megaprosthesis.

Patients and methods

Patients

Between January 2014 and January 2016, seven patients with failed distal femoral megaprosthesis reconstruction received 3D design custom-made uncemented prosthetic stem revision at our institution. Their previous diagnoses were four osteosarcomas (Ennecking IIb), two giant cell tumors of bone (Campanacci 3), and one chondrosarcoma (Ennecking IIb). Five patients were male and two female, with an average age at admission of 30.3 years (range 21–49 years). The types of primary megaprostheses included two modular hinge knee tumor prostheses and five modular rotating hinge knee tumor prostheses. All the prostheses were manufactured by Chunli Co, Ltd, Tongzhou, Beijing, China. The chief complaint of these patients was pain in the affected thigh and knee, especially when walking. The average survival time of the failed distal femoral megaprostheses was 4.9 years (range 3–8 years). Aseptic loosening was the reason for all the failures. The offset angle between the antecurvature radian of femur and the stem averaged at 9.1° (range 8–12°). At this admission, there was no recurrence or metastasis. During the stem design and fabrication, all the patients received anti-osteoporosis treatment, but no more chemotherapy or radiotherapy (Table 1).

X-ray and three-dimensional computed tomography (3D-CT) were performed on all patients, and these were evaluated before surgery according to the Musculoskeletal Tumor Society (MSTS) scoring system (Figure 1 and 2).[26,27] The range of motion (ROM) of the affected knee was recorded.

This study was approved and monitored by the Ethical Committee of West China Hospital, Sichuan University in China. All patients balanced the risks and benefits of the 3D design custom-made uncemented prosthetic stem before signing the informed consent.

Prosthesis design and fabrication

The components for revision of the prosthesis were decided on the basis of preoperative clinical evaluation, radiographic assessment, and the type of the primary megaprosthesis. If the primary prosthesis was not modular, or the clinical and radiographic assessments showed severe wearing of the joint liner, the femoral prosthetic stem and the femoral component required replacement. Otherwise, only the femoral prosthetic stem required replacement.

All prosthetic stems were individually designed by our clinical team and fabricated by Chunli Co, Ltd, Tongzhou, Beijing, China. The bone quality and quantity of the femur, and individual and precise matching between the prosthesis and the anatomic features of host femur were the major considerations for our design. The criterion for good bone quantity was more than 2.5 mm of cortical thickness. Building 3D computer models of the femur and the primary megaprosthesis for these patients was the first step, by importing data from the 3D-CT scan into Mimics V17.0 Software (Materialise Corp. Belgium). Then on the basis of the Mimics images, we measured the revision stem for its antecurvature radian, length, and the diameter of the medullary cavity at 1 cm intervals. Additionally, four anti-rotation longitudinal fins were created, equally distributed on the surface of the stem base. After precision forging, all prosthetic stems were coated with titanium or titanium and hydroxyapatite (Figure 3A-B and 4A-B).

Table 1. Patients' basic characteristics and the primary prosthesis information.

Patients	Age (years)	Gender	Side	Diagnosis (stage)	Initial prosthesis	Lifespan of initial prosthesis (years)	Reasons for failure	Offset angle between the antecurvature radian of femur and the stem (°)
1	21	Male	Left	OS (Ennecking IIb)	Modular hinge knee tumor prosthesis	3	Aseptic loosening	8
2	35	Male	Right	GCT (Campanacci 3)	Modular hinge knee tumor prosthesis	4	Aseptic loosening	9
3	27	Male	Left	OS (Ennecking IIb)	Modular rotating hinge knee tumor prosthesis	5	Aseptic loosening	8
4	26	Female	Left	CS (Ennecking IIb)	Modular rotating hinge knee tumor prosthesis	6	Aseptic loosening	12
5	49	Male	Right	OS (Ennecking IIb)	Modular rotating hinge knee tumor prosthesis	8	Aseptic loosening	10
6	22	Female	Right	GCT (Campanacci 3)	Modular rotating hinge knee tumor prosthesis	5	Aseptic loosening	8
7	32	Male	Right	OS (Ennecking IIb)	Modular rotating hinge knee tumor prosthesis	3	Aseptic loosening	9
Mean	30.3					4.9	Aseptic loosening	9.1

OS: osteosarcoma, GCT: giant cell tumor of bone, CS: chondrosarcoma.

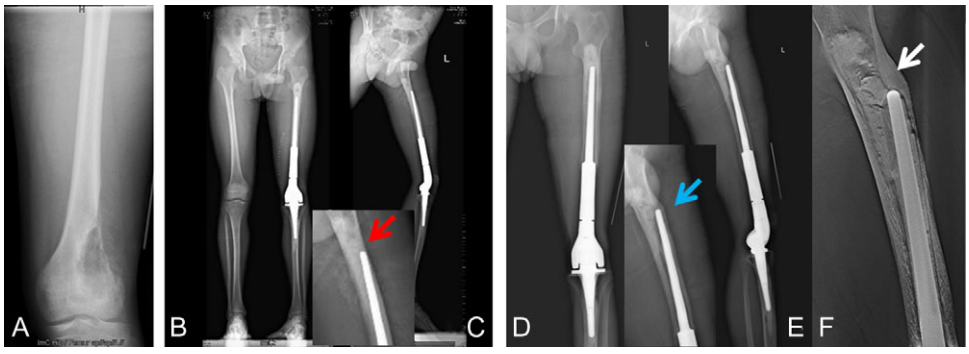

Figure 1. The preoperative, postoperative and 3 years follow-up radiographs of Patient 1 during the previous surgery. (**A**) the anteroposterior preoperative radiograph; (**B**, **C**) the immediate postoperative anteroposterior and lateral radiographs, the red arrow shows the tip of the stem had to deviate to the anterior part of femur; (**D**,**E**) the anteroposterior and lateral radiographs at 3 years follow-up , the blue arrow shows the aseptic loosening of stem and the bone hyperplasia; (**F**) the T-SMART image at 3 years follow-up, the white arrow shows that the breakage of cement and the aseptic loosening of the stem.

Surgical technique

All the surgeries were performed by the senior surgeon (Chongqi Tu). Exposure was through the previous approach under general anesthesia. After removing the failed prosthesis and partial cement, the scar, granulation tissue, and wear debris around the prosthesis was cleaned away. As much as possible of the residual cement in the medullary canal was removed with

standard cement removal techniques and instruments (e.g. a high-speed burr or cement removal tool).

Before stem implantation, flexible reamers were used for canal preparation. During reaming, the canal was in accordance with the normal anatomic shape of the femur; the "gradient reaming method" was followed to ensure that the diameters of reaming were precisely matched to the diameters of the stem at any level. Autologous cancellous bone grafting around the canal is recommended. During stem implantation, the press-fit technique was applied.

Postoperative management

During the first 4–6 weeks postoperatively, toe-touch weightbearing was allowed, but rotation of the affected lower extremity was forbidden. Afterwards, 50% weightbearing can be gradually achieved in 6 weeks. If stability was ascertained clinical and radiographically, full weightbearing was allowed. Clinical stability was defined as no pain during physical examination with internal and external hip rotation with the knee fixed at 90° of flexion.[25] Radiographic stability was confirmed by implant osteointegration on the T-SMART (tomosynthesis-shimadzu metal artefact reduction technology) images. All the patients received anti-osteoporosis treatment until confirmation of stem stability.

Follow-up

All patients were followed up clinically and radiologically every month during the first 6 months, every 3 months during the first 2 years, and then once in 1 year. At each follow-up visit, patients were evaluated for metastasis, local recurrence, complications, mobility, ROM of the affected knee, and pain. Radiographic assessment was used for observing implant osteointegration. Functional evaluation was performed using the MSTS scoring system.

Statistical analysis

The normality of the continuous data was checked using a one-sample Kolmogorov-Smirnov test. Normally distributed parameters were assessed by paired-samples t-test or independent-samples t-test, and nonnormally

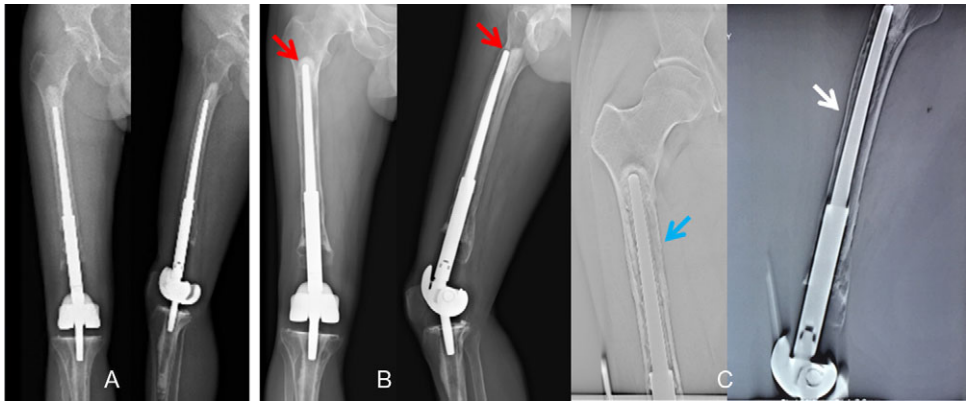

Figure 2. The preoperative radiographs of Patient 5 before revision surgery. (**A**) The postoperative anteroposterior and lateral radiograph immediately after the primary megaprosthesis reconstruction; (**B**) the preoperative anteroposterior and lateral radiograph before revision surgery, the red arrows show that the stem is not only aseptic loosening but also shift upwards for a long distance, and the anterior cortex of bone is very thin; (**C**) the T-SMART image before revision surgery, the blue arrow shows that there is bright line between the cement and the stem, the white arrow shows that the bone quality and quantity of anterior femoral bone is very thin for standard stem.

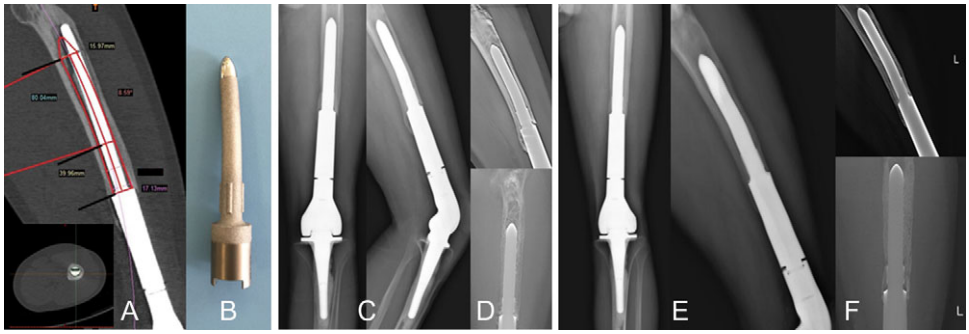

Figure 3. The prosthesis design and the postoperative radiographs of Patient 1 during the revision surgery. (**A**) the 3D precise design of the prosthesis based on the Mimics 3D images; (**B**) the prosthesis with titanium coating; (**C**) the postoperative anteroposterior and lateral radiographs images immediately after the revision surgery; (**D**) the T-SMART images immediately after the revision surgery; (**E**) the anteroposterior and lateral radiographs at 1 year follow-up; (**F**) the T-SMART images at 1 year follow-up.

distributed parameters were assessed by the Mann-Whitney U test. A P value of 0.05 or less was considered to be statistically significant.

Results

The average duration of follow-up was 24.3 months (range 24–48 months) (Table 2). There was no metastasis or local recurrence, and there were no hardware-related complications, such as aseptic loosening, structural failure, or infection (Figure 3C–F, 4C–D, 5 and 6).

The average MSTS score at the last follow-up after revision (27.7 points, range 27–29 points) was significantly higher than that before revision (16.0 points, range 13–18 points) ($P = 0.000$) (Table 3). Compared with the score before revision, the scores for pain ($P = 0.000$), function ($P = 0.000$), emotional acceptance ($P = 0.000$), support ($P = 0.000$), walking ($P = 0.000$) and gait ($P = 0.018$) were all significantly higher (Table 3). The flexion of the affected knee before revision was significantly lower than that at the last follow-up after revision ($P = 0.003$); however, there was no significant difference between the affected knee extension before revision and that at the last follow-up after revision ($P = 0.356$) (Table 3).

Through 3D design, the antecurvature radian of the revision stem averaged at 3.6° (Table 2).

The average revision stem length was 134.3 mm (range 110–180 mm). There were four prostheses with standard long stem (100 mm) shorter than the primary prosthetic stem, and three prostheses with long stem (150–180 mm) longer than the primary prosthetic stem (Table 2). Comparing the data between the long stem revision patients and the short stem revision patients at the last follow-up after revision, there were no significant differences in pain, function ($P = 0.513$), emotional acceptance, support, walking, gait ($P = 0.576$), MSTS ($P = 0.576$), flexion ($P = 0.507$), and extension ($P = 0.203$) (Table 3).

Three patients received femoral stem component revision but preserved the other parts of the primary prosthesis, and the other four patients received revision of the femoral stem as well as the femoral component but preserved the tibial parts of the primary prosthesis (Table 2). Comparing the data between the patients who received femoral stem revision and the patients who received revision of the femoral stem as well as the femoral component at the last follow-up after revision, there were no significant differences in pain, function ($P = 0.203$), emotional acceptance, support, walking, gait ($P = 0.286$), MSTS ($P = 0.117$), flexion ($P = 0.795$), and extension ($P = 0.203$) (Table 3).

Discussion

Megaprosthetic reconstruction is the preferred limb salvage method after tumor resection in the distal femur.

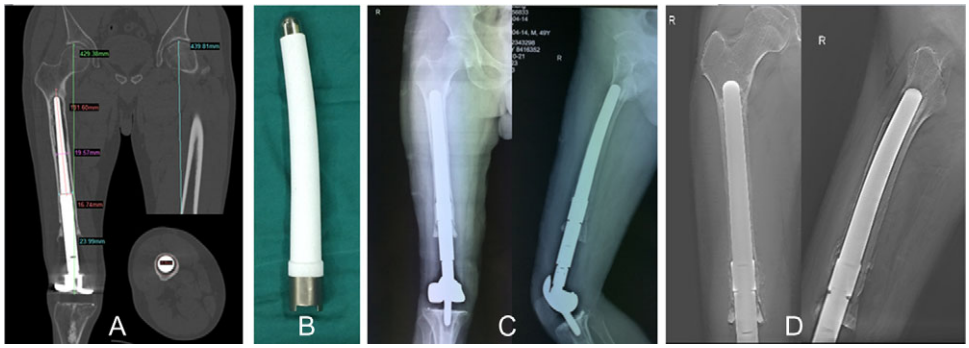

Figure 4. The prosthesis design and the radiographs of Patient 5 after the revision surgery. (**A**) The 3D precise design of the prosthesis based on the Mimics 3D images; (**B**) the prosthesis with titanium and hydroxyapatite coating; (**C**) the immediately postoperative anteroposterior and lateral radiographs; (**D**) the T-SMART images immediately after the revision surgery.

Table 2. Revision prosthesis information and follow-up.

Patients	Revision prosthesis	Revision stem length (mm)	Antecurvature radian of the revision stem (°)	Follow-up/m
1	Femoral stem	110	4	42
2	Femoral stem	150	3	48
3	Femoral stem and the femoral component	110	4	36
4	Femoral stem and the femoral component	110	5	36
5	Femoral stem and the femoral component	180	3	30
6	Femoral stem and the femoral component	110	3	24
7	Femoral stem	170	3	24
Mean		134.3	3.6	34.3

OS: osteosarcoma, GCT: giant cell tumor of bone, CS: chondrosarcoma.

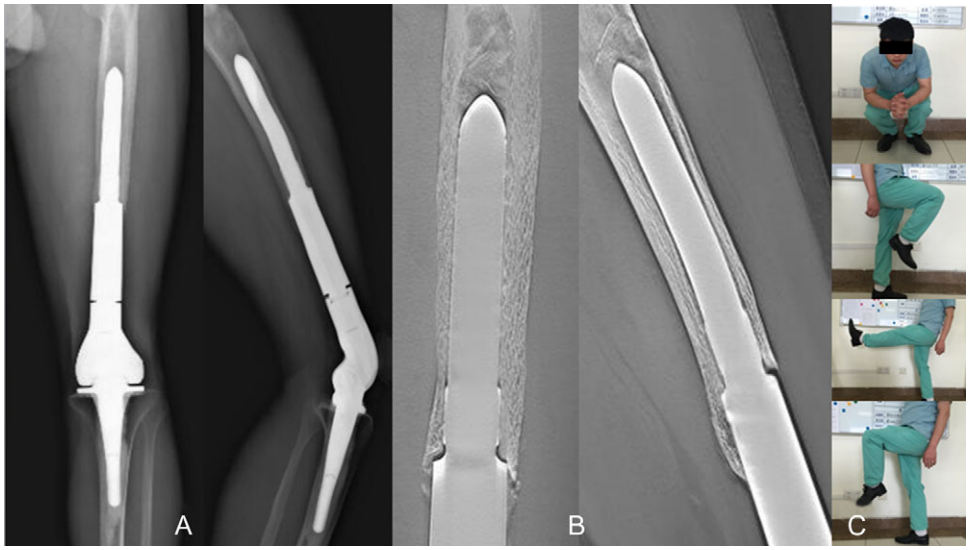

Figure 5. The radiographs and function of Patient 1 at 3.5 years follow-up after the revision surgery. (**A**) anteroposterior and lateral radiographs; (**B**) the T-SMART images show the implant osteointegration; function photos show the patient has a good knee range of motion.

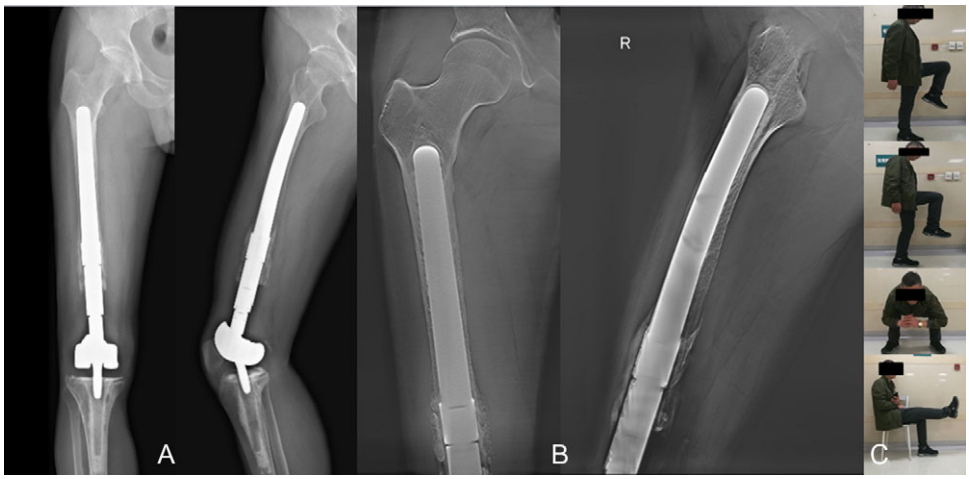

Figure 6. The radiographs and function of Patient 5 at 2.5 years follow-up after the revision surgery. (**A**) The anteroposterior and lateral radiographs; (**B**) the T-SMART images show the implant osteointegration; (**C**) the function photos show the patient has a good knee range of motion.

Improvements in megaprosthetic designs and cementing techniques make preferable cement fixation of prosthetic stem because of the immediate stability;[28,29] however, aseptic loosening remains a major complication, especially in young active patients.[30] In recent years, the rate of aseptic loosening in distal femur was less than 40% at median follow-up ranging from 4 to 12.2 years.[28,29,31–33] Additionally, it is highly problematic during revision. Hence, cemented megaprosthesis should be carried out carefully.

Cement fixation of the megaprosthetic stem can be influenced by many factors, such as the porosity, thickness, and integrity of cement, cement pressurization technology, the offset extent of the stem from the mechanical axis of the lower limb, the stem design, and so on.[34–36] In our series, all the primary prosthetic stems were straight, not matching to the anatomic antecurvature of the femur. Therefore, the tip of the stem had to deviate to the anterior part of femur, resulting in weakening of the anterior cortex of femur. Meanwhile, aseptic loosening of the tumor prosthesis is inevitable.

At present, although cemented megaprosthetic stem is used for revision, the rate of second revision for cemented megaprosthesis revision is around 35%.[22,23] Moreover, bone defect of the femoral cortex caused by stem waggle and cement removal can influence fixation of the cemented stem. Therefore, use of an uncemented stem has gradually become accepted as the optimal method for revision.

Successful application of a custom-made uncemented prosthetic stem mainly depends on the precise design of the stem, including anatomic characteristics and surface

Table 3. MSTS score before operation and at last follow-up.

Patients	Before operation								At last follow-up							
	Pain	Function	Emotional acceptance	Support	Walking	Gait	MSTS score	ROM (F-E, °)	Pain	Function	Emotional acceptance	Support	Walking	Gait	MSTS score	ROM (F-E, °)
1	3	2	2	4	3	3	17	80–0	5	4	5	5	5	5	29	100–0
2	3	2	2	4	3	4	18	75–0	5	4	5	5	5	4	28	90–0
3	2	1	2	3	3	2	13	80–10	5	3	5	5	5	4	27	80–0
4	2	1	2	4	3	3	15	80–10	5	4	5	5	5	4	28	90–10
5	2	2	2	3	3	3	15	80–0	5	3	5	5	5	4	27	90–0
6	3	2	2	3	3	3	16	85–10	5	4	5	5	5	4	28	100–10
7	3	2	2	4	3	4	18	75–0	5	4	5	5	5	4	28	85–0
Mean	2.6	1.7	2.0	3.6	3.0	3.1	16.0	79.3–4.3	5.0	3.7	5.0	5.0	5.0	4.1	27.9	90.7–2.9

ROM: range of motion, F-E: flexion-extension.

features of the stem. Firstly, the stem should precisely match the anatomic morphology of the host femur. Our 3D reconstructive images helped in design of the antecurvature radian, length, and multi-level diameter of the stem. Previous study has demonstrated that the long-term stability of a shorter stem is more reliable.[37] Hence, here a short stem was used if the bone quality and quantity was good, otherwise a longer stem (1 cm longer than primary one) was chosen. The diameter of the stem is controlled not only by the anatomy of the femur, but also by the demand of the stem primary stability. The design should guarantee more than 3 cm tight contact distance or less than 150 μm relative micromotion between the stem and the bone bed.[13,38] If the prosthesis with standard long stem is used, the anti-rotation longitudinal fins of the stem should be designed for strengthening the anti-rotation role of the stem's antecurvature shape. Secondly, implant osteointegration can be achieved by bone ongrowth through changing the surface features of the stem. To combine the advantages of titanium and hydroxyapatite, titanium was coated between the stem and the hydroxyapatite layer. In our clinical work, surgery was successful in all patients, and satisfactory follow-up results were obtained, to further verify our viewpoints on the precise design. The revision components were decided according to the preoperative clinical evaluation, radiographic assessment, and the type of the primary megaprosthesis. There were no significant differences in the function and MSTS score at the last follow-up between different revision components or different lengths of prosthetic stem, indicating that our prosthetic stem design and operative plan are both successful.

Perioperatively, anti-osteoporosis treatment was given to increase the opportunity of implant osteointegration. During surgery, cement removal and press-fit implantation of stem without sacrificing normal bone are technically difficult. Theoretically, all the cement should be removed, but at least, removal of the cement along the length of revision stem should be achieved. In addition, reaming along the primary stem canal will cause an abnormal force line of the prosthesis, and eventually prosthesis failure. To avoid implantation of the revision prosthetic stem in the wrong direction, a flexible reamer should be used and a force from the anterior to the posterior part of the femur should be loaded on the reamer. For the best press-fit, the "gradient reaming method" and autogenous cancellous bone grafting were used. In addition, during the stem implantation, if the anterior bone cortex is too weak, a protective wire cerclage can be temporarily or permanently used. According to our results, the initial stability of the revision prosthetic stem after surgery is acceptable, and the bone ongrowth of the stem can be observed through T-SMART images during follow-up.

Rehabilitation is particularly important for these patients with uncemented fixation. Exercise should be properly scheduled based on the bone quality and quantity, and the primary stability of the stem. The primary

stability of the prosthesis depends on the implant osteointegration.[40] Previous study indicated that osteointegration of the primary uncemented implant can be observed 2 weeks postoperatively. Hence, any weightbearing exercise should be delayed owing to the relatively poor condition of bone quality and quantity in our series. Meanwhile, during the first 4–6 weeks postoperatively, rotation of the affected lower extremity is forbidden. Afterwards, partial weightbearing can be gradually increased to normal level.

We recognize the following limitations of our study. This is a retrospective analysis of patients who had revision of failed distal femoral megaprostheses. There was no control group for comparison. The major limitation is the small number of patients, but they are homogeneous with respect to anatomic location and prosthetic type. Furthermore, long-term follow-up is necessary to verify the exact outcomes of this individually and precisely designed prosthesis.

Conclusions

The 3D design custom-made uncemented prosthesis, with individual and precisely designed stem, is an application of precision medicine in oncologic orthopedics. This prosthesis not only can protect the already damaged bone from further damage, but also can precisely reconstruct the limb function of the patients with failed distal femoral cemented prosthesis. Besides the individual and precise design, perioperative management is also crucial, especially preoperative and intraoperative assessment of bone quality and quantity, operative techniques (especially the technique for stem implantation), and a postoperative rehabilitation program. As we have demonstrated only mid-term follow-up results, the exact long-term outcomes of this prosthesis are yet to be observed. Moreover, further research on 3D design, 3D printing techniques, materials science and biomechanics will help us to better repair the bone defect with megaprosthesis.

Acknowledgements

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Conflict of interest statement

None declared.

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