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Three-dimension-printed custom-made prosthetic reconstructions: from revision surgery to oncologic reconstructions

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Abstract

Background The use of custom-made 3D-printed prostheses for reconstruction of severe bone defects in selected cases is increasing. The aims of this study were to evaluate (1) the feasibility of surgical reconstruction with these prostheses in oncologic and non-oncologic settings and (2) the functional results, complications, and outcomes at short-term follow-up.

Methods We analyzed 13 prospectively collected patients treated between June 2016 and January 2018. Diagnoses were primary bone tumour (7 patients), metastasis (3 patients), and revision of total hip arthroplasty (3 patients). Pelvis was the most frequent site of reconstruction (7 cases). Functional results were assessed with MSTS score and complications according to Henderson et al. Statistical analysis was performed using Kaplan-Meier and log-rank test curves.

Results At a mean follow-up of 13.7 months (range, 6–26 months), all patients except one were alive. Oncologic outcomes show seven patients NED (no evidence of disease), one NED after treatment of metastasis, one patient died of disease, and another one was alive with disease. Overall survival was 100% and 80% at one and two years, respectively. Seven complications occurred in five patients (38.5%). Survival to all complications was 62% at two years of follow-up. Functional outcome was good or excellent in all cases with a mean score of 80.3%.

Conclusion 3D-printed custom-made prostheses represent a promising reconstructive technique in musculoskeletal oncology and challenging revision surgery. Preliminary results were satisfactory. Further studies are needed to evaluate prosthetic design, fixation methods, and stability of the implants at long-term.

Keywords Pelvic tumours . Computer-aided design . 3D-printed prosthesis . Reconstruction . Complications . Bone tumour . Pelvis

Introduction

In recent decades, thanks to the advances in chemotherapy, radiological and surgical techniques, limb-salvage surgery has been shown to be safe and effective for the management of primary and secondary bone tumors. Different reconstructive strategies may be used to replace bone defect after tumour removal, but each has its own specific indications and contraindications $[1-3]$ $[1-3]$ $[1-3]$ $[1-3]$. Modular endoprostheses are nowadays the most common method of reconstruction after resection of the long bones in the extremities for their

Study design: case series: level of evidence 4

 \boxtimes Pietro Ruggieri pietro.ruggieri@unipd.it availability, relative ease use, immediate fixation and longterm stability, early weight bearing, relatively rapid restoration of function, and acceptable cosmesis [[3](#page-8-0)–[5](#page-8-0)]. Modular prosthetic implants have been used also for pelvic reconstructions with acceptable results [[6,](#page-8-0) [7\]](#page-8-0). With the advent of computer-aided design techniques and the improvement of 3D printing technology, in the last years, there is the possibility to reconstruct bone defects with personalized custom-made prostheses [\[8](#page-8-0), [9](#page-8-0)]. These types of implants are specifically tailored for the defect and produced by electron beam melting (EBM) technology that allows the integration of the porous structure of the implant with the host bone $[10-12]$ $[10-12]$ $[10-12]$ $[10-12]$. The expectation at long-term follow-up is the reduction of mechanical complications, such as loosening and fracture/breakage compared to conventional prosthetic or allograft reconstructions [[4,](#page-8-0) [10\]](#page-8-0).

The aims of this study were to evaluate (1) the feasibility of surgical reconstruction with custom made 3D-printed

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prostheses in patients with oncologic and non-oncologic settings and (2) the functional results, complications, and outcomes at short-term follow-up.

Materials and methods

We analyzed patients treated with custom-made 3D-printed prosthesis, prospectively collected at the Authors' institution from June 2016 to January 2018. The research has been performed in accordance with the Declaration of Helsinki. All patients or their relatives gave written informed consent to be included in scientific studies at the admission to the hospital. As this analysis consists of anonymized clinical routine data, Research Ethics Committee Approval was not necessary in our Institution. For all patients, we reviewed data regarding patient comorbidities, cancer type, disease duration, staging, and prognosis. Moreover, the analysis includes pre-operative history and course, imaging evaluation, surgical data, use of adjuvant treatments, oncologic outcome, complications, and their applied treatment.

Thirteen patients were included in the study: there were 3 males (23%) and 10 females (77%) with a mean age of 55.3 years (range, 10–77 years) at surgery. The demographic and oncological data are summarized in Table 1. All patients underwent pre-operative plain radiography, computerized tomography (CT), and magnetic resonance imaging (MRI) of the affected bone segment. Moreover, a high-resolution CT scan (thin layer 1 mm) was performed on every patient before the surgical procedure, possibly after removal of all previous implants in case of revision surgery. The acquired images in DICOM format were transferred to the manufacturing company, and an accurate 3D virtual image and project was created, via software, for each patient. In order to increase the stability of the reconstruction, screw holes and other tools for fixation of the prosthesis were designed together with engineers. In two cases of pelvic reconstruction, polyaxial screws were used on the back for connection with lumbar pedicle instrumentation. With the EBM technology, the previously designed titanium prosthesis is printed by the sintering of titanium powder and then adequately prepared before surgical implantation. The custom-made 3D-printed prostheses are provided with cutting guides and textured surfaces to improve their integration with bone and soft tissue. It took approximately three to four weeks for the design and manufacture of each personalized 3D-printed prosthesis. Three different implants were used: Promade (Lima, San Daniele del Friuli, Udine, Italy), Mt. Ortho (Catania, Italy), and C-Fit 3D® (Implantcast Ltd., Buxtehude, Germany).

Clinical data and surgical procedures Despite multiple surgeons contributing to patients' management, the choice of operative strategy was based on multidisciplinary evaluation Table 1 Demographic and oncological data of patients reconstructed with custom-made 3D-printed prostheses $(n = 13)$

of our oncological team. The general indications for resection and reconstruction with custom-made 3D-printed prosthesis were (1) extensive bone loss and bone destruction that precluded the use of standard modular prostheses and (2) affecting site where massive allografts were the only alternative reconstructive method. Reasons for custom-made 3D-printed prosthetic implant were reported in Table [2](#page-2-0). In summary, in three patients, it was used as revision implant after failure of total hip replacement, and in ten patients with oncologic disease as primary implant after resection of bone tumour (7 cases) or as revision implant after failed previous replacement (2 cases) or local recurrence (1 case). Revision surgery in oncologic setting was performed in one patient using an intercalary custom prosthesis after breakage of femoral intramedullary nail due to myeloma diaphyseal localization, in another patient as revision of mobilized modular stemmed acetabular cup and in a patient with recurrent giant cell tumor (GCT) of the distal tibia after multiple intralesional treatments. Anatomical sites of reconstruction were pelvis in seven cases and scapula, ulnar diaphysis, distal radius, calcaneus, distal tibia, and femoral diaphysis in one case each. Stem fixation

Table 2 Patient characteristics and indications for custom-made

3D-printed prosthetic implant

was cemented in older patients with bone metastases and low bone stock (3 cases), while press-fit in younger patients and patients with primary bone tumours (10 cases). Histological diagnoses in ten patients with oncologic disease included chondrosarcoma in three (23%) patients, metastatic carcinoma in three (23%), osteosarcoma in two (15.3%), Ewing's sarcoma and giant cell tumour in one each. According to the surgical staging system for musculoskeletal tumors, one benign tumour was classified as stage 3 and malignant tumours were classified as stage IIb $(n = 6)$ and stage IIIb $(n = 3)$. Adjuvant treatments were administered according to the primary cancer. Chemotherapy was performed in six patients with osteosarcoma, Ewing's sarcoma, and metastatic lesion, whereas three of these received external beam radiotherapy also. The patient treated

for recurrent GCT had pre-operative treatment with denosumab.

Post-operative assessments All patients were followed by the rehabilitation center at our institution. Post-operative immobilization was obtained with pelvic-thigh brace in all cases of pelvic reconstruction: brace was positioned at 10° of abduction and fixed in extension for 1 month, then with flexion up to 90° for another month. Weight bearing was allowed after one week in case of cemented stem and after one month in case of press-fit stem. Immobilization for a month was obtained with brace at 15° of abduction after shoulder reconstruction, with Velpeau-brace after ulnar reconstruction, with Walker-brace after distal tibia reconstruction and with wrist-brace after distal radio reconstruction. Anti-thrombotic stockings and calf compression

devices were routinely used for prophylaxis against deep vein thrombosis after lower limb or pelvic reconstruction. Routine follow-up examinations were performed with ambulatory checks every three months during the first three years after surgery, then every four months in the fourth years, then every six months for one year, and then annually. Follow-up evaluations included physical examination, radiographs, and disease-specific chest imaging. No patient was lost to follow-up. Oncologic results were evaluated according to local recurrence, metastasis, or death, and patients were classified as follows: (1) no evidence of disease at the latest routine check (NED); (2) disease free after treatment of local recurrence or metastasis (NEDrl or NEDm); (3) alive with disease, due to presence of local recurrence or metastasis (AWD); and (4) dead of disease (DWD). Survival was defined as the time from surgery to last follow-up or death. Complications were classified according to Henderson et al. [[13\]](#page-8-0) in type I (soft tissue failure), type II (aseptic loosening), type III (breakage), type IV (infection), and type V (local recurrence). Moreover, complications were considered as intra-operative, early (within 6 months post-operatively), and late (more than 6 months post-operatively). Functional results were assessed for all surviving patients using the Musculoskeletal Tumor Society (MSTS) functional rating system.

Statistical analysis The categorical variables were expressed as percentages. Survival was analyzed using the Kaplan-Meier analysis. Comparison of the curves was done with the log-rank test. Differences were considered statistically significant when the p value was less than 0.05. The data were recorded in a Microsoft1 Excel1 2003 spreadsheet and analyzed using Med-Calc Software Version 11.1 (MedCalc Software, Mariakerke, Belgium).

Results

Operational outcomes En-bloc resection was achieved in all patients with wide surgical margins. One patient had an osteosarcoma with suspicious tumour localization in the fifth lumbar vertebra; therefore, resection was extended and cement was used to fill the space between custom-prosthesis and host bone at the time of surgery. Two patients with oncologic pelvic reconstruction were stabilized with spino-pelvic instrumentation, whereas in the other two cases, iliac and sacral screws were used. No patient died of intra/perioperative complications.

Oncologic outcomes At a mean follow-up of 13.7 months (range, 6–26 months), patients with oncologic disease were NED in seven cases, AWD in one case, NEDm in one case, and DWD in one case. One patient with distal radius osteosarcoma is without evidence of disease after surgical treatment of lung metastasis, one patient with stage IIb pelvic osteosarcoma died 15 months after surgery due to rapid tumour progression with bone and visceral metastases, while one patient with breast cancer metastasis is still alive with disease and she is under chemotherapy for other bone metastases. Overall survival was 100% and 80%, respectively, at 12 and 24 months (Fig. 1).

Fig. 2 Kaplan-Meier survival curves show a the overall survival to complications that was 62% at 1 and 2 years, respectively, and b the survival to major complications (loosening, breakage, infection) that was 85% at 6 months and 72% after 1 year of follow-up

Complications Complications occurred in 38.5% of cases (7 complications in 5/13 patients), at a mean time of 2.7 months (range, 0.3–12 months). Survival of the entire series to all complications was 62% at one year follow-up (Fig. 2a), whereas it was 72% considering major complications only (Fig. 2b). Type I complications occurred in four cases as post-operative (less than 1 month after surgery) wound dehiscence. Wound dehiscence was successfully treated with surgical wound debridement, antibiotic therapy per os, and VAC therapy in one patient (case no. 1 Table [2\)](#page-2-0) with custom prosthesis as revision of THA failure. The patient with reconstruction of the calcaneus (case no. 13 Table [2](#page-2-0)) was successfully treated with surgical debridement and musculocutaneous flap without implant removal. In the other cases (pelvic reconstruction, case nos. 5 and 6 Table [2](#page-2-0)), wound dehiscence was treated with surgical debridement and antibiotic therapy, but successively, patients developed deep infection (type IV) at a mean of four months (range, 1–12 months). One of these was early diagnosed and then successfully treated with surgical debridement and musculocutaneous flap without implant removal. The other one developed a late infection (12 months after surgery) and was treated with surgical debridement, plastic flap, and oral antibiotic drugs without prosthesis removal due to poor general condition: in fact, the patient had multiple bone and visceral metastases and died three months later. We observed a higher incidence of infections in patients treated with pelvic reconstructions than other sites, even if without a significant difference at univariate analysis ($p = 0.2667$). Type II and type V complications never occurred, while type III complication was reported in one case (case no. 11). Patient treated with intercalary femur reconstruction had a periprosthetic fracture due to fall 45 days after surgery and was revised with a less invasive stabilization system (LISS) plate and bone allograft.

Functional results After surgery, all patients experienced improvement in quality of life resulting from reduction or resolving of pain. The recovery of the affected limb function was assessed according to the MSTS score in all alive patients at the final follow-up. The mean MSTS score was 80.3%, with good (between 51 and 75%) or excellent (between 76 and 100%) in all patients. Analyzing separately the functional results, we observed a mean MSTS score of 64.5% (range, 57– 70%) in patients treated of complex revision surgery in nononcologic settings, 74% (range, 73–76%) in reconstructions after resection of pelvic bone tumours, and 88% (range, 80– 93%) in patients with reconstruction of sites other than pelvis, with a statistically significant difference $(p = 0.010)$ (Fig. 3).

Discussion

The introduction of 3D printing technology increased the armamentarium of the orthopaedic surgeon in approaching large bone defects in complex revision surgery and musculoskeletal oncology. This technology may realize customizable patientspecific implants that could be used as alternative to massive

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bone allografts or in other sites where modular prosthesis are not available [[10](#page-8-0), [14\]](#page-8-0). The advantages include (1) the possibility to produce implants with complex shapes with a porous structure; the porous scaffold allows the growth of host bone inside the implant to achieve a stable reconstruction; (2) the increased accuracy of skeletal reconstruction reducing the risk of miss-match between allografts/adapted prostheses to host bone; (3) immediate stability with production of titanium prostheses that has sufficient mechanical strength to bear the body weight or allow full function of the body segment; and (4) the full availability than the allograft or other systems in most institutions $[10, 14–17]$ $[10, 14–17]$ $[10, 14–17]$ $[10, 14–17]$ $[10, 14–17]$ $[10, 14–17]$ $[10, 14–17]$. We present the preliminary results of our series of 13 patients treated with custom-designed 3D-printed prostheses in different oncologic and nononcologic settings. These prostheses have been used for different types of demanding bone defects, showing satisfactory results in terms of surgical technique, operating time, safety, and functional outcomes. The complication rate is comparable to that of other complex reconstructions based on skeletal site.

Our study has some limitations. (1) There was heterogeneity of the patient population, and indications for all patients were either oncologic or revision; therefore, surgical exposures were not standardized and were dictated by the tumor location or pre-existing incisions. (2) Although this study is one of the largest series of custom-made 3D-printed prostheses, it has only 13 patients with adequate follow-up and heterogeneous surgical indications, thereby limiting the power of the series to show potentially statistically significant trends. On the other hand, this study provides interesting data and information for this new reconstructive technique. Moreover, considering the difficulty of analyzing large homogeneous series, a power analysis to determine how many patients in each group should be included to show a difference was not

performed. (3) Heterogeneity and small sample size should be considered in the analysis of possible confounding variables. (4) The relatively short follow-up period of this study does not account for late complications that may arise as we follow these patients for a longer time. However, all the patients were prospectively analyzed and collected, reducing the risk of erroneous data or lost to follow-up. Larger multicentric studies should be realized for better evaluation of surgical indications, with comparison of different experienced centres at long-term follow-up.

The treatment of extensive acetabular bone loss and pelvic discontinuity is challenging in some cases of complex revisions. None of the commonly used reconstructive techniques has been able to provide optimal results in case of Paprosky 3A and 3B bone defects [[18,](#page-8-0) [19](#page-9-0)]. In the recent years, several Authors have therefore begun to use custom-made 3D-printed prostheses in non-oncologic settings, with encouraging results [\[15,](#page-8-0) [20](#page-9-0)–[22](#page-9-0)]. Some Authors reported encouraging results with custom 3D-printed tri-flanged acetabular implants for the management of severe acetabular defects: Taunton et al. retrospectively analyzed 57 patients with pelvic discontinuity reporting a stable implant at a mean follow-up of 65 months, despite high incidence of complications [\[21\]](#page-9-0). A significant improvement in functional scores and radiographic outcomes has been reported in other series of patients treated with custom-made 3D-printed pelvic reconstructions, with a complication rate ranging from 12.5 to 33.3% [[23](#page-9-0)–[26](#page-9-0)]. In our series, we reported similar results in three female patients (nos. 1, 2, and 3) with a mean age of 75 years (range, 68– 79 years) treated for failed revised total hip arthroplasty. At a mean follow-up of 18 months (range, 8–24 months), only one complication (wound dehiscence) was observed and has been surgically treated without removal of the implant. At the last follow-up, all patients presented no sign of loosening at radiographs and the mean MSTS score was 64.5% (range, 57– 70%). Considering the good results obtained in revision surgery of the pelvis, the use of 3D simulation and printing techniques have been recently extended in other fields of orthopedics, such as treatment of complex pelvic fractures [\[27](#page-9-0), [28\]](#page-9-0) or surgical planning and correction of technically challenging bone deformities [\[29,](#page-9-0) [30\]](#page-9-0).

Concerning pelvic tumours, in the past, most of these cases were considered inoperable or the common method of managing was external hemipelvectomy [\[31](#page-9-0)]. Currently, with advances in radio/chemotherapy and surgical techniques, limb-salvage surgery has become an accepted treatment [\[22](#page-9-0)–[36\]](#page-9-0). Various biological and prosthetic methods have been used for pelvic reconstruction after tumor resection including arthrodesis, hip transposition, massive allograft/autograft, and different designed prosthetic implants [[33](#page-9-0), [34](#page-9-0), [36\]](#page-9-0). However, the optimal reconstruction method remains controversial, especially in periacetabular area. Biological reconstruction has the theoretical potential of a permanent consolidation with host bone, even if the high rate of deep infection (range 15– 55%) and mechanical failures (range 9–22%) significantly reduced their use in recent years [[34](#page-9-0), [37](#page-9-0)–[39\]](#page-9-0). Prosthetic reconstruction has the advantages of allowing early mobilization, immediate and long-term stability with satisfactory cosmetic, and functional results [\[9](#page-8-0), [35,](#page-9-0) [40](#page-9-0), [41\]](#page-9-0). The advent of 3D printing technology may combine the benefits of both techniques, and recently, there has been a great increase in the use in oncologic settings [\[8](#page-8-0), [9](#page-8-0), [14](#page-8-0), [41](#page-9-0)]. In 2002, Ozaki et al. [\[41](#page-9-0)] reported an experience with computer-aided custom-made Vitallium prostheses for pelvic reconstruction. In this early report, the Authors observed a high complication rate and poor functional results after hemipelvic resection and prosthetic reconstruction. Dai et al. [[9\]](#page-8-0) reported in 2007 their experience in using custom-made 3D-printed prostheses after pelvic resection. They analyzed ten patients treated for bone tumours involving the acetabular area at a mean age of 48 years. Despite the rate of complications remaining high compared to previous reports, functional results were good in more than 70% of the cases at a mean of 34-month follow-up [\[9\]](#page-8-0). Wang et al. [\[42\]](#page-9-0) recently reported their experience in 11 treated for malignant tumours (localized sarcoma or solitary metastasis) in the periacetabular region. They used a 3D-printed prosthesis that precisely matched the residual part of the iliac crest, sacroiliac joint, or sacrum (fixed with cancellous and locking screws) and the pubis, searching a complete restoration of the pelvic ring. Liang et al. [\[14\]](#page-8-0) reported the largest series of patients (35 cases) treated reconstructed with custom-made 3D-printed prostheses after pelvic resection for bone tumours. Types of pelvic resections were the following: type I in three cases, type $II + III$ in 12 cases, type I + II in five cases, type $I + II + III$ in two cases, type $I + II + IV$ in ten cases, and type $I + II + III + IV$ in 3 cases. They used three different prosthetic concepts. A 3D-printed iliac prosthesis of adequate size fixed with sacral, ischium, and pubic screws was used in type I resections to restore the continuity of the pelvic ring. A 3D-printed hemipelvic prosthesis of suitable size, augmented with bone cement and conventional total hip arthroplasty, was used for resections including acetabular area. The fixation was obtained with perfect fit to the contour of residual ilium, long sacral cancellous screws, and two or more cortical screws. A 3D-printed prosthesis with screw-rod connection has been used for larger reconstructions of the entire hemipelvis [[14\]](#page-8-0). In our experience, we adopt a slightly different protocol to decide the type of pelvic reconstruction after bone tumor resection, primarily based on the proximal resection level of the ilium (Fig. [4\)](#page-7-0). In pelvic resections involving the entire iliac bone or part of the sacrum, we prefer a reconstruction with a custom-made 3D-printed prosthesis with spinopelvic stabilization (Fig. [5a](#page-7-0)). The same choice when the residual part of the ilium is not adequate and sufficient to accommodate a modular stemmed acetabular cup (Fig. [5b](#page-7-0)). In type I–II resections with a good support of the iliac bone,

Fig. 4 Decision-making algorithm for the choice of reconstructive technique after pelvic resection for bone tumors based on our experience

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Fig. 5 Explicative cases of pelvic reconstruction based on our decisionmaking algorithm. a Twenty-six-year-old female, with stage III osteosarcoma of the iliac wing treated with type I pelvic resection and reconstruction with 3D-printed custom prosthesis and spinopelvic fixation (case no. 6 of the present series). b Fifty-three-year-old female, with Ewing's sarcoma of the pelvis treated with type I–II pelvic resection and reconstruction with 3D-printed custom prosthesis and spinopelvic fixation (case no. 7 of the present series). c Seventy-two-year-old male, with peripheral chondrosarcoma of the acetabular area treated with type II pelvic resection and reconstruction using modular prosthesis with stemmed acetabular cup. d Fifty-eight-year-old male, with grade 2 chondrosarcoma of the acetabulum treated with type II resection and ileo-femoral coarctation considering the limited shortening expected and good muscle preservation

we prefer a modular prosthesis with stemmed acetabular cup (Fig. [5](#page-7-0)c). A coarctation is used in specific cases such as young patients with limited muscle removal and limited shortening expected or old patients with poor general conditions (Fig. [5d](#page-7-0)).

Other field of application of custom-made 3D-printed prostheses includes the reconstruction after bone resection for tumour in particular skeletal segments in which there are no available standard modular prostheses, as an alternative to massive allograft. In literature, there are described small series and case reports reporting custom-made prosthetic reconstructions of the scapula, clavicula, radius, vertebral body, and calcaneus [16, [43](#page-9-0)–[45](#page-9-0)]. In most of the cases, immediate stability and good cosmetic appearance have been achieved with these anatomical reconstructions, even if the follow-up is usually too short in order to establish functional results and complication rate. In our series, we have reported six cases of custom-made 3Dprinted prosthetic reconstructions of unusual sites (scapula, intercalary ulna, distal radius, calcaneus, distal tibia, and intercalary femur). At a mean follow-up of 9.4 months (range 6– 17 months), two complications were observed: a periprosthetic fracture after accidental traumatic fall and a wound dehiscence which however did not require removal of the implant. Functional results were satisfactory in all cases, with an average MSTS score of 88% (range, 80–93%).

Conclusions

The use of 3D-printed titanium prostheses is growing in musculoskeletal oncology and revision surgery. This technology may be useful to obtain a complete restoration of the bone defect and acceptable functional results, even if the complication rate remains high in difficult sites such as the pelvis. We believe that custom-made 3D-printed prostheses represent today a promising reconstructive technique, maintaining however the correct indications for their use in musculoskeletal oncology and challenging revision surgery. Further studies are needed to validate the more appropriate design of prosthesis and its fixation to the host bone (especially in pelvic reconstructions), in terms of stability at long-term follow-up.

Compliance with ethical standards

Conflict of interest The authors declare that they have no conflict of interest.

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