

Reconstruction after Pelvic Bone Massive Resection: Evolution and Actuality of 3D-Printing Technology

Rekonstrukce po masivní resekci pánevní kosti: vývoj a současnost technologie 3D tisku

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ABSTRACT

PURPOSE OF THE STUDY

Pelvic reconstructions after massive bone resections are among the most challenging practices in orthopedic surgery. Whether the bone gap results after a trauma, a tumor resection, or it is due to a prosthetic revision, it is mandatory to reconstruct pelvic bone continuity and rebuild the functional thread that connects spine and hip joint. Several different approaches have been described in literature through the decades to achieve those goals.

MATERIAL AND METHODS

To this date, 3D-printed implants represent one of the most promising surgical technologies in orthopedic oncology and complex reconstructive surgery. We present our experience with 3D-printed custom-made pelvic prostheses to fulfill bone gaps resulting from massive bone loss due to tumor resections. We retrospectively evaluated 17 cases treated with pelvic bone reconstruction using 3D-printed prostheses. Cases were evaluated in terms of both oncological and functional outcomes.

RESULTS

At the last follow-up, local complications were found in 6 cases (36%): in 4 (23.5%) of them the cause was a local recurrence of the disease, whereas only 2 (12.5%) had non-oncologic issues. The mean MSTS score in our population increased from 8.2 before surgery to 22.3 at the latest clinical control after surgery.

DISCUSSION

3D-printing technology, used to produce cutting jigs and prosthetic implants, can lead to good clinical and functional outcomes. These encouraging results are comparable with the ones obtained with other more frequently used reconstructive approaches and support custom-made implants as a promising reconstructive approach.

CONCLUSIONS

Our data confirm 3D-printing and custom-made implants as promising technologies that could shape the next future of orthopedic oncology and reconstructive surgery.

Key words: custom made prosthesis, pelvic reconstruction, orthopedic oncology, cutting jigs, 3D-printing.

INTRODUCTION

The reconstruction of the pelvic bone represents one of the most challenging procedures in orthopedic surgery. The resection of malignant tumors, severe bone comminution due to high energy traumas, revision surgeries, and arthroplasty failures can imply massive bone losses of the pelvis. Several reconstructive approaches have been used and described in literature over the decades (5, 7, 9). Although biological reconstruction with allografts has been largely used for the last decades, the most recent innovations in imaging technologies and additive manufacturing led to the in-

troduction of a new generation of prosthetic implants. The new 3D-printed custom-made prostheses, based on pre-operative acquisitions of patients' native bones, accurately reproduce the size and shape of the resected pelvic segment, thereby respecting patients' anatomy (2, 17, 24). Despite the recent publication of some research papers in recent years, there is still a paucity of large-scale studies on this topic (2).

In this study, we provide our experience with using 3D-printing technology to create pelvic prostheses and custom-made cutting jigs for intra-operative use, evaluating the clinical and functional outcomes of these innovative technologies.

MATERIAL AND METHODS

This study was performed according to the ethical standards of the 1964 Declaration of Helsinki and its later amendments. All patients gave their written consent to participate.

Our study consisted of a review of all the cases treated with massive resections of the pelvic bones using custom-made cutting jigs and the implant of 3D-printed custom-made titanium prostheses in our institution between November 2016 and January 2022. Both oncologic and non-oncologic cases were included in our study.

Patients were divided into two groups depending on whether they had a one-step surgery (Group 1) or a two-step procedure (Group 2). All cases underwent similar diagnostic and therapeutic processes as follows.

Pre-operative phase

For each case, we collected data regarding their age, gender, weight and Body Mass Index (BMI). The cause of bone resection, whether a tumor or a prosthetic failure, was recorded. X-rays, CT scans, and MRI images of each case were to investigate the localization of the osteolytic areas and - for oncologic cases - to assess the tumor size.

Imaging evidence was also used to evaluate the shape and dimension of patients' pelvis, which was necessary for the design and production of custom-made implants and cutting jigs. All the devices were 3D-printed with additive manufacturing. Cutting jigs were made of unbendable resistant plastic material, whereas definitive endopelvic implants comprised porous and trabecular titanium. Their design was arranged according to the necessities of each single case, considering the shape of the involved bones, the surrounding tissues, and the osteotomy level. Our surgical team and biomedical engineers agreed on the size of the prosthesis, its shape, and its anchor sites. Manufacturing companies were Adler Ortho® (Milan, Italy), Lima Corporate Pro Made (Udine, Italy), Link® Waldemar Link GmbH & Co. KG (Hamburg, Germany) and MT Ortho (Catania, Italy).

Each patient underwent an accurate anesthesiologic evaluation before surgery to decide the best anesthetic procedure and forecast possible clinical concerns.

Each patient's post-operative functional status was evaluated according to the MSTs score, whereas pain was assessed using the VAS scale.

Plan X-rays were used to assess the pre-operative hip pivot point and acetabular angle.

Surgical procedure

Surgery was performed in a single center by our orthopedic team, alongside other specialists such as general surgeons, urologists, or vascular surgeons, depending on the necessities of each case.

The surgical approach of choice was the Enneking utilitarian pelvic approach, adapted from case to case. Once the major local vascular and nervous structures had been isolated and protected, a careful skeletonization of the pelvic bone was carried out. Osteotomies were then performed using oscillating and/or knife saws, guided with custom-made 3D-printed cutting jigs that allowed to respect the osteotomy lines decided during the pre-operative planning (Fig. 1). Resections were categorized according to the Enneking-Dunham classification.

Once the resection was over, phantom implants were set in place to evaluate the correct match between the osteotomy lines and the shape of the prosthetic implants. If necessary, slight changes to the cut lines were made to fit the prosthesis better. In oncological patients, surgical margins were sent for histopathological evaluation to evaluate the quality of resection margins. In the case of positive margins, a re-cut was carried out.

For those treated with a single surgery (Group 1), definitive implants were immediately set into place and stabilized with stems or plates and screws of variable size, depending on the design of each prosthesis. The acetabular cup was placed and cemented in its accommodation inside the prosthetic implant for classical standards for its anteversion and inclination (safe zone).

Once the implant was reduced, the capsule and the other healthy soft tissues were reinserted into the native bone with trans-osseous sutures or taking advantage of anchor points in the implant's body.

For those that received a two-stage treatment (Group 2), the resection was followed by the implant of an antibiotic cement spacer armed with Kirschner wires. In a second surgical time, the antibiotic spacer was re-

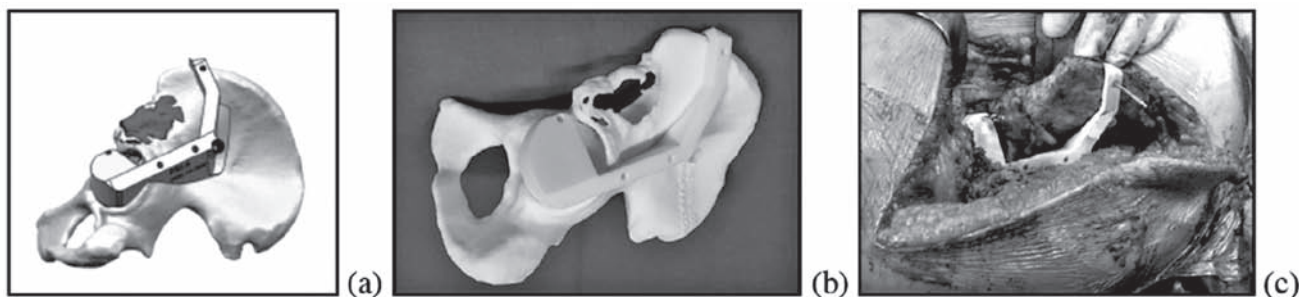


Fig. 1. Cutting jigs in orthopedic oncology in the pelvic region: pre-operative planning (a), trial on a 3D-printed model (b), intra-operative use (c).

moved and replaced by the definitive custom-made implant, designed on the imaging revelations obtained after the first intervention and modeled on the size and shape of the pelvic bone that had already been resected during the first intervention.

At the end of each surgical procedure, two subfascial drains were positioned, and the wound was closed. Once the wound was closed, closed incisional negative pressure wound therapy (ciNPWT) was set.

Antibiotic prophylaxis was performed using Vancomycin 1g and Tobramycin 100mg, administered intravenously every 12 hours from the night before surgery until the complete removal of surgical drains.

The duration of each surgical intervention was recorded.

Post-operative phase

After surgery, cases that required close monitoring underwent clinical observation in a sub-intensive care unit; they returned to the orthopedic ward once their clinical conditions were stabilized.

Antibiotic prophylaxis was performed with the modalities described in the above section.

Thromboembolic prophylaxis with heparin began 12 hours after surgery and lasted until a total weight load on the involved limb was allowed.

Transfusions were performed in case of severe anemia ($Hb < 7.9$ g/dl). The total number of blood units transfused for each patient was recorded.

Post-operative plan X-rays were used to evaluate the post-operative hip pivot point and acetabular angle, which were compared with pre-operative ones.

After surgery, each case wore an articulated hip brace for two months to prevent hip luxation or other self-induced damage to the soft tissues at the root of the lower limb. The hip's articular range of motion (ROM) was gradually increased through the post-operative intercourse to dovetail external mechanical support to the hip with patients' functional recovery. Partial loading was allowed since the second week after surgery. Complete load and crutches dismissal were not allowed within the second month after surgery.

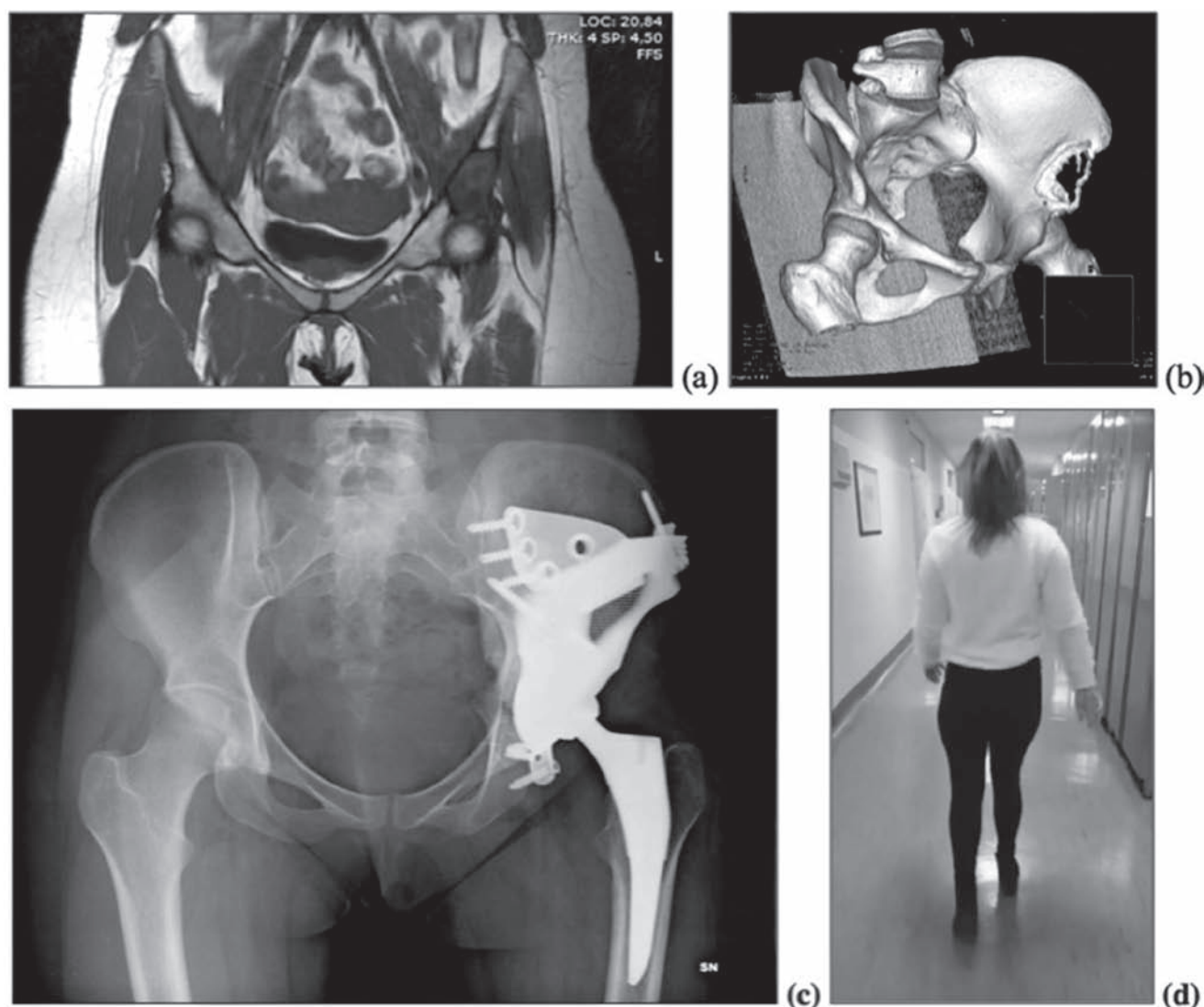


Fig. 2. One of our cases with her coronal T1 MRI images (a), tridimensional CT scan reconstruction (b), RX-rays and walk 24 months after surgery (c, d).

After their discharge from our hospital, cases underwent periodic outpatient visits with clinical and radiological evaluations. Visits were scheduled one month after surgery, then every three months for the following two years, and then twice per year for the following three years. Complications were classified according to the Henderson failure mode. Oncological monitoring was carried out for all oncologic patients whose final status was expressed with the acronyms DOD (dead of disease), DOC (dead of other causes), AWD (alive with disease), NED (no evidence of disease) or CDF (continuously disease free).

Statistics

Statistical analysis was performed using Stata SE 13 (StataCorp LLC, College Station, TX). Statistical significance was set at 0.05 for all endpoints.

RESULTS

Seventeen cases, twelve females and five males, were included in our study. Their mean age at surgery was 56 (21–76) years. Their average weight and BMI were 69 (48–115) kg and 25 (16–38) respectively. Nine of our 17 patients suffered from bone tumors: five primary bone sarcomas and four metastases. The remaining eight cases required pelvic resection and custom-made reconstruction to treat prosthetic loosening or pseudotumors attributable to metal-on-metal-induced metallosis.

The resection was limited to the periacetabular region alone in nine cases (Enneking-Dunham class II), whereas it was also extended to the iliac wing (Enneking-Dunham class I–II; Fig. 2) in four cases and to the anterior pelvis (Enneking-Dunham class II–III) in the remaining four cases.

The hip articulation was replaced and reconstructed in each case. In 10 cases, the custom-made pelvic implants included a standard total hip prosthesis. Among the other seven, five required a proximal femur megaprosthesis, and two had a total femur replacement.

In only one case, the hip rotation center (HRC) maintained its position on the cranio-caudal axis after surgery. The HRC was proximalized in eight cases and distalized in other 8 cases, although the difference between pre-operative and post-operative positions exceeded 2cm in only two patients.

Comparing the HRC on the medial-lateral axis before and after surgery, it had been medialized in 14 cases and lateralized in the remaining three cases. Medio-lateral migration was larger than 2 cm in only one case. Prosthetic hips were more horizontal than the native ones in 78.6% of our cases. Migrations of the HRC were not significantly associated with functional outcomes (Pearson correlation test; $p > 0.05$) or complication rates (two-tailed Student's T-test; $p > 0.05$). Age, weight, and BMI were also not significantly associated with clinical and functional outcomes or complication rates (Pearson correlation test and two-tailed Student's T-test; $p > 0.05$).

Cases were divided into two groups depending on the choice of a single surgical step (Group 1) or a two-step surgery (Group 2). Group 1 and Group 2 included 7 and 10 patients, respectively. The mean total surgical times was 7.0 hours for Group 1 and 10.2 hours for Group 2. The two groups did not differ regarding RBC units administered per patient throughout the treatment (8.6 and 8.0 for Group 1 and Group 2, respectively; two-tailed Student's T-test, $p > 0.05$). On the other hand, considering the "RBC units per intervention" ratio, it was significantly higher for those who underwent a single intervention (two-tailed Student's T-test, $p = 0.001$).

The mean post-operative follow-up was 26.8 (7–54) months. The oncological outcomes of the 9 cases treated for bone tumors were classified as 3 DOD, 3 CDF, 2 NED (original diagnosis of metastatic bone tumor), and 1 AWD who suffered from lung metastasis but did not experience local recurrence. All the 3 cases who died of disease during their follow-up developed a local neoplasm recurrence. One was treated with external hemipelvectomy, which failed to eradicate the disease; another underwent palliative treatment with radiant therapy, and the latter refused further treatments.

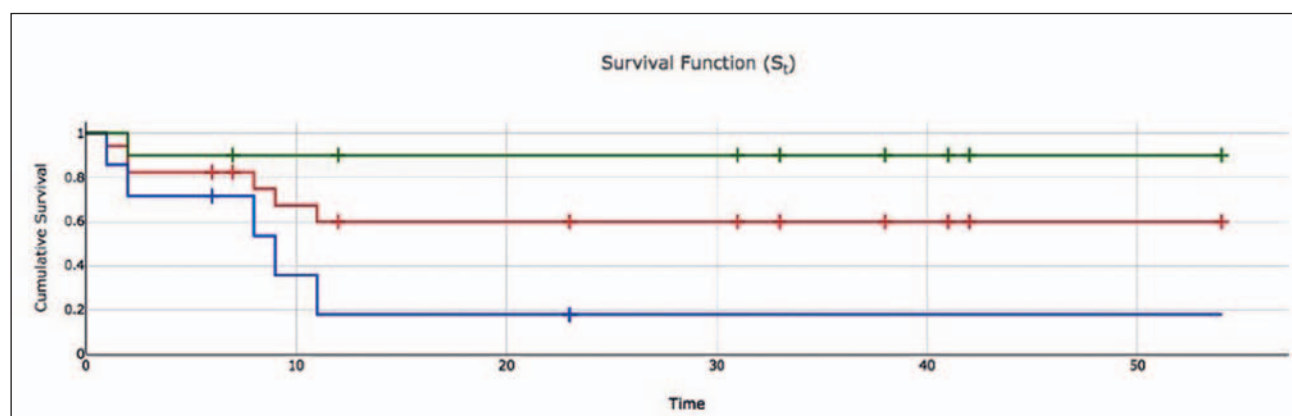


Fig. 3. Kaplan-Meier survival rate to complications through the follow-up. The red line represents the overall population, whereas the blue line represents those who had a single intervention and the green one is for those who were treated with a two-step approach.

Table 1. Resume of our cases' personal data, diagnosis, resection site and reconstruction characteristics

Case	Age	GEN.	BMI	Diagnosis	Surg. times	Resection (Enneking classif.)	Gluteus maximus resection	Reconstruction	RC migration (C-C / M-L axis) (mm)	Acet. angle change (A-P projection)
1	58	M	22	CS	1	II-III	No	Pelvis and hip	15 / 10	-12
2	72	F	21	Pseudotumor	2	II	Yes	Pelvis + proximal femur	10 / 18	-16
3	70	F	27	Aseptic loosen.	2	II	Yes	Pelvis + total femur	5 / 10	6
4	32	F	22	CS	1	II-III	Yes	Pelvis + proximal femur	7 / 25	-13
5	76	M	20	MTS (Sertoli C)	2	II-III	No	Pelvis and hip	9 / 13	-5
6	70	M	21	CS	2	I-II	Yes	Pelvis + proximal femur	60 / 16	-10
7	26	F	24	MTS (Kidney)	1	II	Yes	Pelvis and hip	5 / 5	2
8	38	M	23	CS	2	I-II	No	Pelvis and hip	9 / 11	0
9	46	F	25	MTS (Tyroid)	2	II	No	Pelvis and hip	15 / 3	-23
10	21	F	16	OS	1	II-III	No	Pelvis and hip	12 / 15	-20
11	55	F	21	OS	1	I-II	No	Pelvis and hip	58 / 5	-22
12	61	M	20	Aseptic loosen.	1	II	Yes	Pelvis + proximal femur	8 / 14	-18
13	74	F	24	Septic loosen.	2	II	Yes	Pelvis + total femur	13 / 7	-4
14	67	F	35	Pseudotumor	2	II	Yes	Pelvis + proximal femur	/	/
15	67	F	38	Pseudotumor	2	II	No	Pelvis and hip	/	/
16	58	F	22	Aseptic loosen.	2	I-II	No	Pelvis and hip	/	/
17	67	F	37	Aseptic loosen.	1	II	No	Pelvis and hip	5 / 5	-3

GEN. – gender, RC – hip rotational center, C-C – cranio-caudal axis, M-L – medial-to-lateral axis, A-P – antero-posterior projection

The mean pre-operative VAS score was 5.7 (3–9), whereas the post-operative one was reduced to 1.8 (0–9). The average pre-operative MSTs score was 8.2; at the latest follow-up, the value increased to 22.30. Student's T-tests proved that the difference between pre-operative and post-operative values was significant ($p=0.001$). The MSTs and VAS scores improved as the follow-up time increased, as testified by Pearson correlation tests ($p=0.040$ and $p=0.036$, respectively).

Six of our 17 cases (35%) developed at least one local complication according to the Henderson failure mode in their post-operative intercourse. Three of them were the aforementioned local recurrences. Two patients had a hip luxation, treated surgically with liner replacement and intra-operative implant reduction. Both patients presented a pre-operative factor risk for dislocation: one patient had a gluteus atrophy due to radiotherapy irradiation. The other already had a total femur implant with consistent biomechanical modification in lower limb. Despite the dislocation, the two patients had good functional outcomes according to the MSTs score at their latest follow-up (87.7% and 60%). Lastly, in one case, X-rays evidenced a break of the fixation device. In this case, no treatment was undertaken since the patient did not show any symptoms or functional limitations.

Cases belonging to Group 1 had a cumulative complication incidence of 73%, whereas the incidence in Group 2 was 9%. In our population, cases treated with a two-step procedure had a significantly lower risk of

developing post-operative complications compared to those who received a single-step approach, according to an exact Fisher test ($p=0.013$).

Half of all complications were diagnosed within the first six months from surgery, while the remaining 50% occurred later. The complication-free survival of our patients was graphically described with a Kaplan-Meier graph in Fig. 3.

Some of the data collected are summarized in Table 1 and Table 2.

DISCUSSION

During the last century, limb-sparing surgery revolutionized the surgical approach to pelvic resection. However, the best reconstruction technique is still debated. The recent advent of 3D-printing technology and the introduction of the new generation of custom-made implants is revolutionizing the reconstructive approach to large bone defects in orthopedic oncology, trauma, and revision surgery (1, 14, 19, 21). Literature reports that the use of 3D-printing technology reduces operation times and blood losses, ensuring bone preservation and neoplasm free margins (12, 18, 22, 25).

Furthermore, from a biomechanical point of view, modern custom-made implants can provide advantages in terms of primary and secondary stability, thereby improving osteointegration and maximizing patients' post-operative functional and clinical outcomes (14, 19, 20, 24, 27, 28).

Table 2. Summary of our cases' oncological status, complications and functional outcomes

Case	Oncological outcome	Complications (Henderson F.M.)	Reinterventions	VAS pre	VAS post	MSTS pre	MSTS post	Follow-up (months)
1	DOD	V	None	9	9	4	4	7
2	-	None	None	4	1	9	26	54
3	-	None	None	5	0	10	24	41
4	DOD	IB + V	External hemipelvectomy	6	3	8	24	27
5	NED (mts)	None	None	3	0	9	26	42
6	CDF	None	None	6	0	8	26	38
7	AWD (mts)	IA	PTA revision	6	0	9	26	43
8	CDF	None	None	5	0	7	23	33
9	NED (mts)	None	None	7	2	8	23	31
10	DOD	V	Local recurrence excision	6	3	9	24	8
11	CDF	III	None	7	3	9	22	26
12	-	None	None	5	2	8	24	23
13	-	IA	Dislocation (2)	6	3	7	18	12
14	-	None	None	5	1	9	19	12
15	-	None	None	6	3	7	20	7
16	-	None	None	5	0	9	26	7
17	-	None	None	6	0	9	24	6

In our case series, custom-made pelvic implants significantly reduced patients' VAS scores and improved their MSTS scores, underlining a benefit for treated patients regarding both functional outcomes and pain recovery ($p < 0.033$). Moreover, the MSTS and VAS improvement was directly proportional to the length of the follow-up ($p = 0.041$), suggesting the importance of complete rehabilitation after surgery. Excluding DOD and DOC patients who could not complete their functional recovery, our mean MSTS score reached up to 80%. This result is particularly encouraging, especially if compared to traditional reconstruction techniques such as allografts that lead to average values of approximately 60% in literature (3, 4, 6, 15). These outcomes result from the recent innovations in prosthetic designs and bioengineering. Porous titanium ensures better primary stability and high grip, bypassing stress forces developed at support flanges and plates. The porosity promotes osteo-conduction capacity and soft tissue adhesion, improving implant secondary stability. In parallel, the new *low-profile* designs of these prostheses make them even lighter and less bulky, with smooth areas in contact with vessels and nerves, which are thereby more respected and less exposed to iatrogenic damage (28).

Totally we obtained 36% of major complications rate, half of which were local recurrences. Considering only non-oncological patients, the rate of major complications was as low as 12,5%. Both results are aligned with recent literature data. Fujiwara et al. (10), in a recent work, described a major complications rate of 62% in 65 patients treated with custom-made implants between 1971 until 2015.

Our experience testified that a two-step surgical approach could effectively minimize the risk of complications in oncologic and non-oncologic patients ($p = 0.013$). In terms of control of the disease, an early resection decreases the risk of tumor dissemination locally and systemically. A two-step approach also allows surgeons to extend the resection to get wide margins. An extender resection would not undermine the fixation of the prosthesis, whose shape and size would not be pre-established but would be based on the native bone left. The ideas align with the fact that none of our oncologic patients treated with a two-step approach suffered from local complications, whereas 60% of our oncologic patients suffered from a local recurrence.

Our experience also suggested that the advantages of a two-step approach in preventing complications could extend beyond orthopedic oncology. Splitting the surgical procedure into two different operations allows a significant reduction in the duration of each single intervention. Although the cumulative time of resection and reconstruction surgeries was longer, on average, each of these two surgeries was more than two hours shorter than the mean duration of a one-step surgery. Splitting the procedure in two allowed a significant reduction of blood transfusions for each surgery (4.0 instead of 8.6), with theoretical benefits in terms of infection risks and systemic homeostasis (8, 13).

We successfully used negative pressure to minimize the risk of wound dehiscence or superficial infection, confirming previous evidence in literature (11). As regards deep infections, literature reports a percentage close to 25% for allografts and 32% for custom-made prostheses (1, 4, 6, 16, 20, 23); while no case of deep

infection was present in our series. From a theoretical point of view, surgery performed in two steps could reduce the rates of post-operative infections. Surgeons could apply antibiotic cement spacers to dissuade bacterial proliferation. However, in case of deep infections, they could also take samples for cultures and administer the most suitable drugs systemically and locally during the reconstructive intervention.

Separating the resection of the damaged bone from the subsequent reconstruction can also positively affect the latter's quality. Beyond the advantages of imaging (absence of scattering in revision surgery) and match accuracy between the implant and native bone, even the most experienced surgeon can benefit from performing the procedure fresh and rested, with the prosthesis implant as his or her only focus. Moreover, implanting a prosthesis on already retracted soft tissues, which had healed after precious resection, could lead to better intra-operative stability and prevent mobilizations. In terms of implant stability, none of our cases suffered from aseptic loosening, though similar complications have been described in literature (16, 22). Implant stability was obtained using thick anatomic areas such as the iliac neck, the sacroiliac (SI) joint, and the innominate line as anchorage points. Conversely, we avoided using the anterior ring as an anchorage site since some authors suggested that it could lead to rigidity and increased risk of post-operative mobilization (20).

In our series, the dislocation rate was 11.8%; a value in line with those reported in previous literature (16, 22). In our series, the modifications of the native center of rotation (COR) and the variation of cotyle inclination did not seem to influence our patients' dislocation risk nor the post-operative clinical and functional results.

We acknowledge that our study is not free of limitations. The retrospective nature of our study and the custom-made design of these implants did not allow a complete standardization of our analysis. Another limitation is represented by the short size of our cohort, which partially limited the statistical significance of some of the data associations we wanted to investigate at the beginning of our research. These issues could be partially overcome in the next future performing similar evaluations on a prospective basis and on wider populations.

Despite these limitations, our study testified that 3D-printing technology, used to produce cutting jigs and prosthetic implants, can lead to good clinical and functional outcomes. These encouraging results are comparable with the ones obtained with other more frequently used reconstructive approaches and support custom-made implants as a promising reconstructive approach.

CONCLUSIONS

3D-printed custom-made implants and cutting jigs can provide several advantages in orthopedics and orthopedic oncology, particularly for reconstructing com-

plex bone segments such as the pelvis. Although one-stage approaches may represent the approach of choice for some cases, two-stage approaches should be considered for selected cases with bone tumors or previous arthroplasty failures.

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