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ORIGINAL ARTICLE

Biomimetic 3D-printed custom-made prosthesis for anterior column reconstruction in the thoracolumbar spine: a tailored option following en bloc resection for spinal tumors

Preliminary results on a case-series of 13 patients

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Abstract

Purpose Various techniques for anterior column reconstruction have been described after en bloc resection of spinal tumors. Limited evidence exists regarding one being superior to another. The purpose of this study is to evaluate 3D-printed vertebral bodies for spinal reconstruction after en bloc resection in the thoracolumbar spine.

Methods Prospective observational study on custom-made 3D-printed titanium reconstruction of vertebral bodies after en bloc resection for spinal tumor was conducted between November 2015 and June 2017. 3D-printed vertebral bodies were monitored for mechanical complications such as (1) migration, (2) subsidence into the adjacent vertebral bodies, and/or (3) breakage. Complications and related details were recorded.

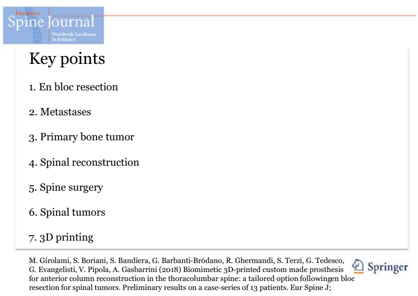
Results Thirteen patients (7 females and 6 males) were enrolled, and reconstruction of the anterior column was performed using custom-made 3D-printed titanium prosthesis after en bloc resection for spinal tumor (8 primary bone tumors and 5 solitary metastases). Subsidence into the adjacent vertebral bodies occurred in all patients at both proximal and distal bone–implant interfaces; however, it was clinically irrelevant (asymptomatic, and no consequences on posterior instrumentation), in 11 out of 12 patients (92%). In 1 patient (#4), severity of the subsidence led to revision of the construct. At an average 10-month follow-up (range 2–16), 1 implant was removed due to local recurrence of the disease and 1 was revisioned due to progressive distal junctional kyphosis.

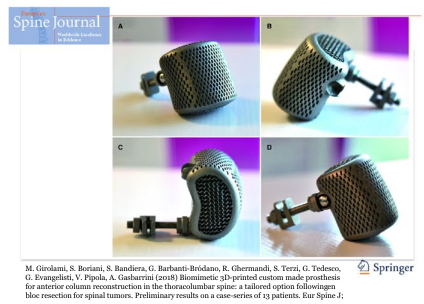
Conclusion Preliminary results from this series suggest that 3D printing can be effectively used to produce custom-made prosthesis for anterior column reconstruction.

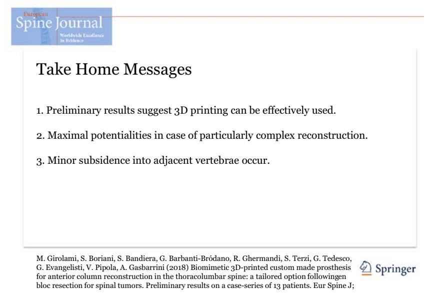
Electronic supplementary material The online version of this article (https://doi.org/10.1007/s00586-018-5708-8) contains supplementary material, which is available to authorized users.

Extended author information available on the last page of the article

Graphical abstract These slides can be retrieved under Electronic Supplementary Material.







Keywords En bloc resection · Metastases · Primary bone tumor · Spinal reconstruction · Spine surgery · Spinal tumors · 3D printing

Introduction

Reconstruction of segmental defects after en bloc resection is a challenging topic, still debated, in spine surgery literature. Various techniques for anterior column reconstruction have been described using of bone grafts [1, 2], mesh cages [3], carbon fiber stackable cages [4] (CFSC), or expandable cages [5]. Limited evidence exists regarding one being superior to another [6].

Main reason for this lack of strong evidence is the exceeding rarity of primary tumors of the spine, comprising only 10% or less of all bone tumors [7]. Spinal metastases instead are much more common: bone is the third most common site of metastases (following lung and liver), and the spine is the most common site of for bone metastases [8]. However, indication for en bloc resection in spinal metastases patients is as much as rare, being limited to highly selected patients [9].

The three-dimensional (3D) printing is a new technology, which might provide an additional option for spinal surgeons. The authors are aware of only two reports of the results of 3D printed vertebral bodies after "spondylectomy" for tumor in the mobile spine, both of them in the upper cervical region (C2) [10, 11].

The aim of this paper is to present the preliminary results on the use of 3D-printed vertebral bodies after en bloc resection in the thoracolumbar spine.

Methods

Patient population

This is a prospective observational study approved by the local Institutional Review Board (No. 0022368) according to the Declaration of Helsinki. A series of 13 non-consecutive patients were enrolled between November 2015 and June 2017 at a single public tertiary referral research institution (Table 1).

Inclusion criteria were: histologically confirmed diagnosis of primary spinal tumor or solitary bone metastasis in the thoracolumbar spine and en bloc resection of the tumor. Exclusion criterion was piecemeal excision of the tumor (debulking).

A validated algorithm was used to guide management of spinal metastases and select patients for whom en bloc resection is indicated [12–14].

Detailed information was provided to each patient, and written consent was obtained.

En bloc resection

En bloc resection is a complex surgical procedure, which aims at removing the whole tumor as single piece (Fig. 1). It is indicated in benign aggressive [15, 16] (Enneking stage 3, i.e., giant cell tumors, osteoblastoma), and malignant primary bone tumors [17–19] (i.e., chordoma, chondrosarcoma, osteosarcoma, Ewing sarcoma), and in highly selected cases of spinal metastases [9] (i.e., solitary metastasis from clear cell renal carcinoma).

With respect to margins [20, 21], as reported by the pathologist' examination of the surgical specimen, en bloc resections can be marginal, when dissection is carried out along the capsule or through the reactive peritumoral pseudocapsule, or wide, when a thick layer of peripheral healthy tissue, or an anatomic barrier not yet infiltrated by the tumor (i.e., pleura of fascia) fully covers the tumor. If the tumor is violated, by planned (in order to save important neurovascular structures) or unplanned transgression, then resection is en bloc intralesional. According to the

Table 1 Patient demographics

Patient	Age (years)	Sex	Diagnosis	Enneking	WBB	Intact case	Neo-adjuvant treatments	Resection		Adjuvant treatments	Onco-logical status	Follow-up (months)
								Type of resec-tion	Margin*			
1	65	F	Osteogenic sarcoma, T12	IIB	12–8/A-D	No (open biopsy)	CHT	2B	Wide	CHT	DOD	18
2	61	F	Chordoma, L2	IB	2–8/A-D	No (RT)	None	5	Marginal	None	CDF	16
3	32	F	Chordoma, L1	IB	4–8/B-D	Yes	None	2B	Wide	None	CDF	15
4	54	M	Adenocarcinoma met, L4	–	2–8/A-D	No (debulking)	None	3B	Wide	None	NED	14
5	30	F	Giant cell tumor, T12	Stage 3	5–9/A-D	Yes	None	2B	Wide	None	CDF	12
6	60	M	Renal cell carcinoma met, T12	–	5–10/A-D	No (vertebroplasty)	None	2B	Wide	None	CDF	12
7	40	M	Renal cell carcinoma met, T10	–	4–8/B-D	Yes	None	2B	Wide	None	CDF	11
8	18	F	Giant cell tumor, L2	Stage 3	5–10/B-D	Yes	Denosumab	3B	Intralesional	Denosumab	CDF	9
9	73	M	Chordoma, L2	IB	5–9/A-D	Yes	None	3B	Wide	None	CDF	8
10	29	F	Hepitelioid hemangioma, T5	Stage 3	4–9/A-D	Yes	None	2B	Wide	None	CDF	6
11	38	M	Adenocarcinoma met, L1	–	1–12/A-D	Yes	None	3B	Intralesional	None	CDF	6
12	44	M	Renal cell carcinoma met, T11-T12	–	2–8/A-D	Yes	None	2B	Wide	None	CDF	5
13	72	F	Chordoma, L1	IB	11–6/A-D	Yes	None	2B	Wide	None	CDF	2

RT radiation therapy, *CHT* chemotherapy, *DOD* died of the disease, *CDF* continues disease free, *NED* no evidence of disease

*As reported by the pathologist on surgical specimen examination

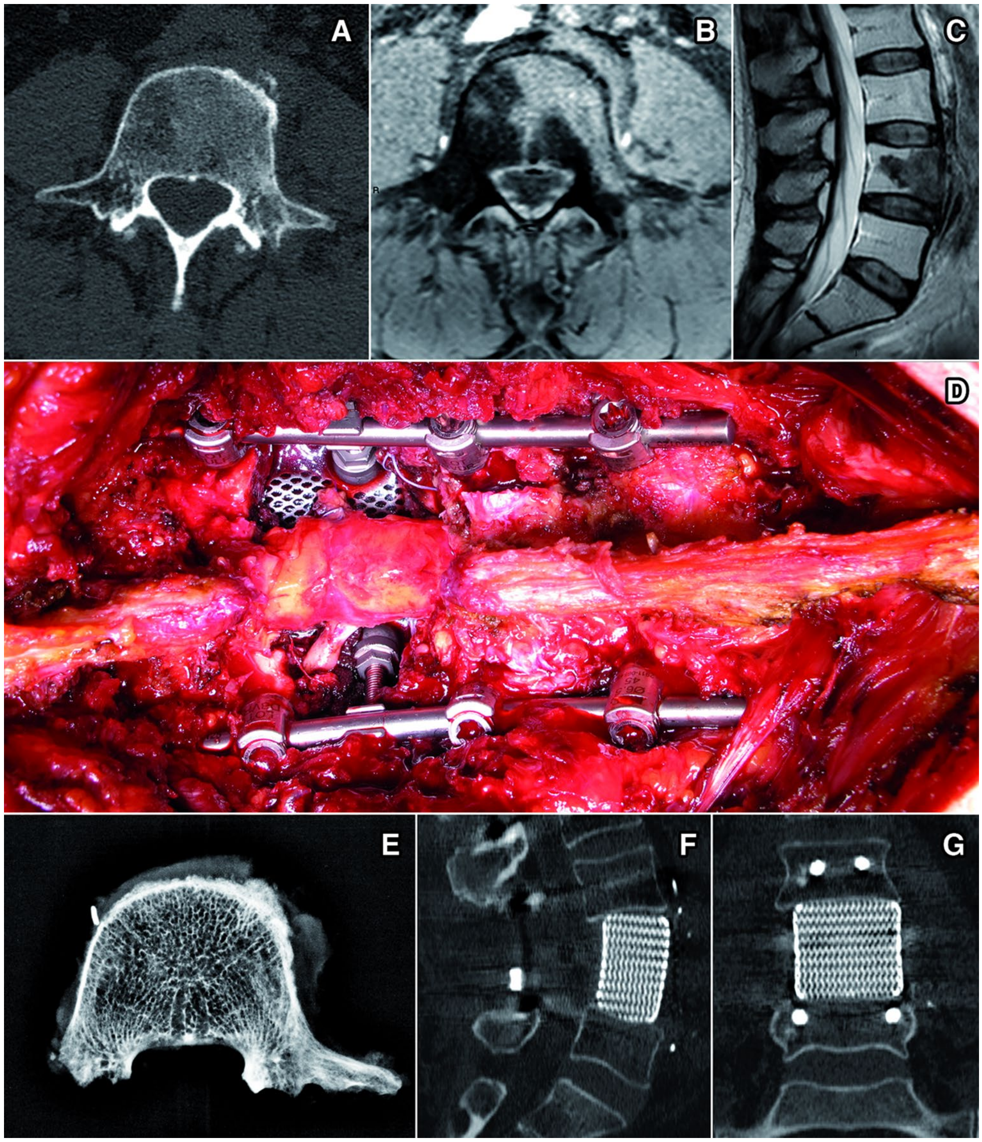


Fig. 1 Case 4. 55-year-old male non-intact patient affected by L4 solitary metastasis. Histological diagnosis reported adenocarcinoma metastasis. Physical examination did not reveal any deficit. Tumor extension according to WBB staging was 2–8/A–D (**a**), without epidural disease on sagittal MRI (**b**, **c**). Surgery was performed as single-stage double-approach procedure (type 3B, **d**). Resection was performed at the level of disk spaces L3–L4 and L4–L5 (**e**). Coronal (**f**) and sagittal (**g**) CT-scans showing reconstruction of the anterior column using BiomimeTiC prosthesis. Pathologic examination on surgical specimen reported wide margins

Weinstein-Boriani-Biagini (WBB) surgical staging system [22], 6 types of en bloc resections in the spine have been described [23].

All surgical procedures were performed by fully trained spinal surgeons with specific expertise in oncology surgery and dedicated staff.

Reconstruction

Multiple techniques have been described for anterior column reconstruction using bone grafts, mesh cages, carbon fiber stackable cages, and expandable cages. In the reported series, the reconstruction of the anterior column was performed using a personalized non-FDA (Food and Drug Administration) approved prosthesis made by Ti6Al4 V [24] and produced with three-dimensional (3D) printing technology (Arcam AB, Mölndal, Sweden) at a public research center.

The resection is planned according to the principles of musculoskeletal oncology above-mentioned, and the design of the prosthesis starts on preoperative computed tomography (CT) considering shape and length of the bone loss produced. Based on these data, a computer-aided design (CAD) model of the prosthesis is generated. Finally, the approved model is fabricated by successive layering of melted titanium alloy powder (electron beam melting) [25]. Each prosthesis is composed by an innermost three-dimensional lattice structure, mimicking cancellous bone, covered by a fine shell, mimicking cortical bone, according to the original framework of human vertebrae [26].

The prosthesis is connected to the posterior pedicle screw-rod instrumentation by a screw-rod connector system adjustable in length and orientation and housed in the same space of each removed pedicle (Fig. 2).

Radiographic analysis

Preoperative imaging studies for oncologic disease include upright preoperative radiographs, positron emission tomography (PET), CT, and magnetic resonance imaging (MRI).

Owing to oncologic follow-up purpose, both radiographs and CT or MRI were scheduled at 3, 6, 9 12 and 18 months providing means for accurate monitoring of the implants.

Prosthesis was monitored for mechanical complications such as (1) migration, (2) subsidence into the adjacent vertebral bodies, and/or (3) breakage. The extent of mobilization, or subsidence, if any, was determined on CT.

In 4 cases, there was a segmental kyphosis at the level of the tumor due to progressive deformity (#5, #8, and #10), or pathological fracture (#1). Kyphosis was measured from the upper and the lower endplates of the adjacent vertebrae, which were spanned by the prosthesis after resection of the fractured tumor (i.e., following a L1 resection, prosthesis was inserted between T12 and L2; thus, Cobb angle is measured between the superior endplate of T12 and the inferior endplate of L2). In 3 cases, the apex of the deformity was located at the thoracolumbar junction (T10-L2, Fig. 3), while the other was in the mid-thoracic spine (T5); thus, this latter was considered separately (Table 2).

All measurements were measured by a single independent observer (spine surgeon) who was not involved in the surgery or case of these patients.

Complications and related details were recorded. Severity was evaluated according to the McDonnell classification [27]. Correlation of recorded events to the presented reconstructive technique was thoroughly discussed.

Data were recorded, and descriptive statistical analysis was performed using Microsoft Excel 2016 (Microsoft, Richmond, WA) spreadsheet.

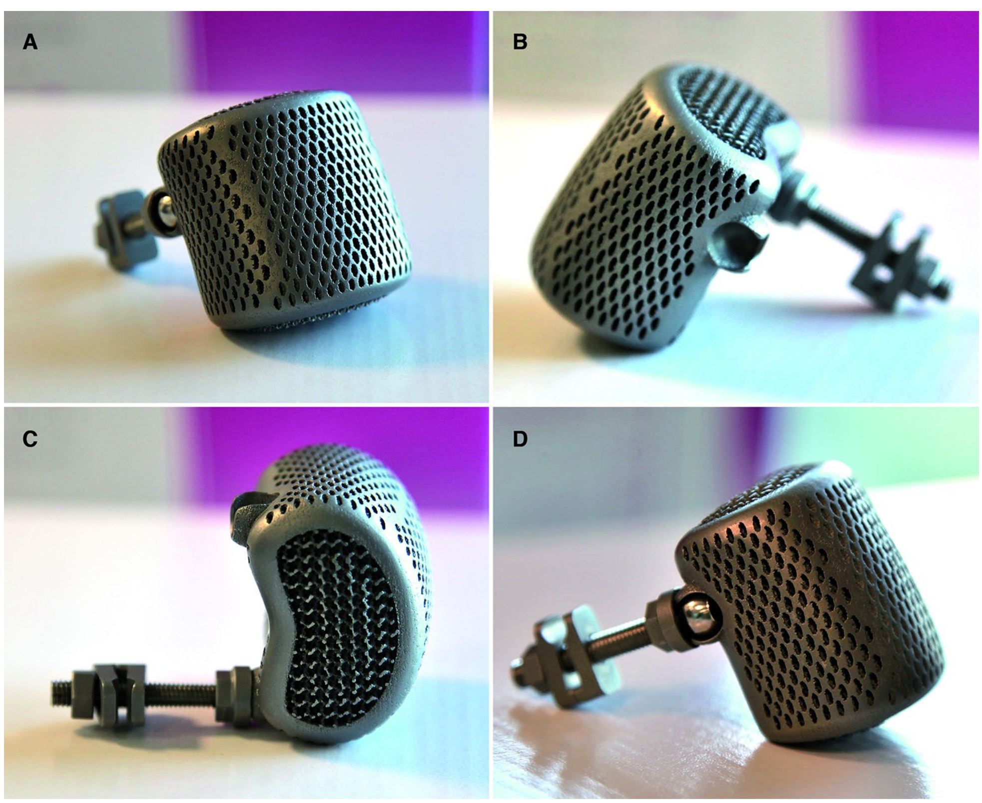


Fig. 2 BiomimeTiC titanium cage. Each prosthesis is composed by an innermost three-dimensional lattice structure, mimicking cancellous bone, covered by a fine shell, mimicking cortical bone. Oblique (**a**), lateral (**b**, **d**) and superior views (**c**)

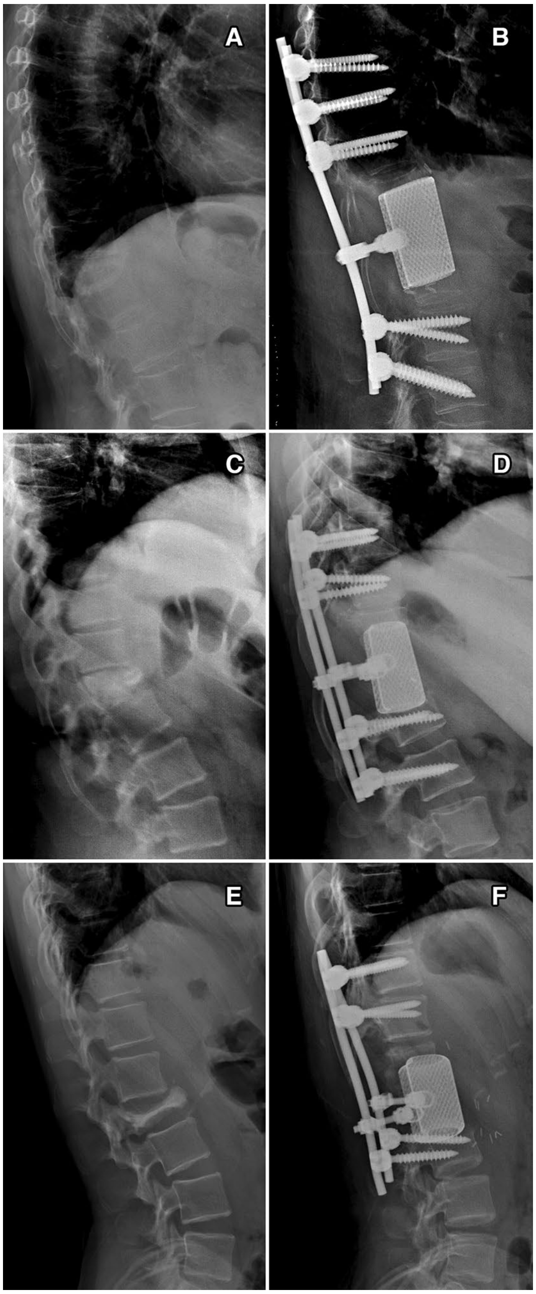


Fig. 3 Thoracolumbar junction kyphosis. In 3 cases, segmental kyphosis, due to progressive deformity, or pathological fracture, was reduced, restoring the original shape of the spine. Case #1 (A preoperative, B postoperative), case #5 (C preoperative, D postoperative) and case #8 (E preoperative, F postoperative)

Results

Average age of the patients (7 females and 6 males) was 47 years (range 18–73). Diagnosis was primary bone tumor in 8 patients (3 benign stage 3, and 5 malignant tumors) and metastasis in the remaining 5 patients.

Table 2 Segmental kyphosis

Patient	Kyphosis				Follow-up (months)
	Preoperative	Postoperative	Last follow-up	Correction (%)	
1	− 29°	+ 1°	+ 3°	97	14[†]
5	− 34°	− 12°	− 12°	65	12
8	− 30°	+ 1°	0°	97	9
10	− 32°	− 22°	− 21°	31	6

[†]Removed implant

In 6 cases, location of the lesion was in the thoracic spine and in the remaining 7 cases was in the lumbar spine. Nevertheless, the thoracolumbar junction (T10-L2) was affected in 11 cases (85%).

All of the patients were neurologically intact at presentation.

Oncologic outcome goes beyond the scope of the presented paper and hence is briefly summarized in Table 1.

Surgical technique

Resection

In 10 cases, a single vertebral body was resected (single-level group), while in the remaining 3, the resection involved 2 vertebral bodies (double-level group).

Among the single-level group, in 3 cases the resection was conducted in the disks, while in the other 7 cases the resection was conducted in the adjacent vertebral bodies with thread-wire saws and a dedicated device for spinal cord protection [28].

Among the double-level group, in 1 case the resection was conducted in the disks and in 1 case through the vertebral bodies at both proximal and distal ends. In the other remaining case, the resection was conducted in the vertebral body proximally and through the disk distally.

Surgery was performed with a single-posterior approach (type 2B resection, Fig. 4a) in 8 of the 9 cases at or above L1, while in the remaining cases (1 at L1 and 4 below L1) an additional anterior approach was necessary to release retroperitoneal structures from the tumor (type 3B resection, Fig. 4b) or to remove the mass preserving nerve roots (type 5 resection, Fig. 4c). In none of the cases, an anterior approach was performed as an additional surgical stage for reconstructive purpose.

In 2 cases (#8 and #11), oncologic principles have been intentionally transgressed after thorough discussion with the patient taking into account the nature of the disease, the predictable functional sacrifice needed otherwise and the purpose of the surgery.

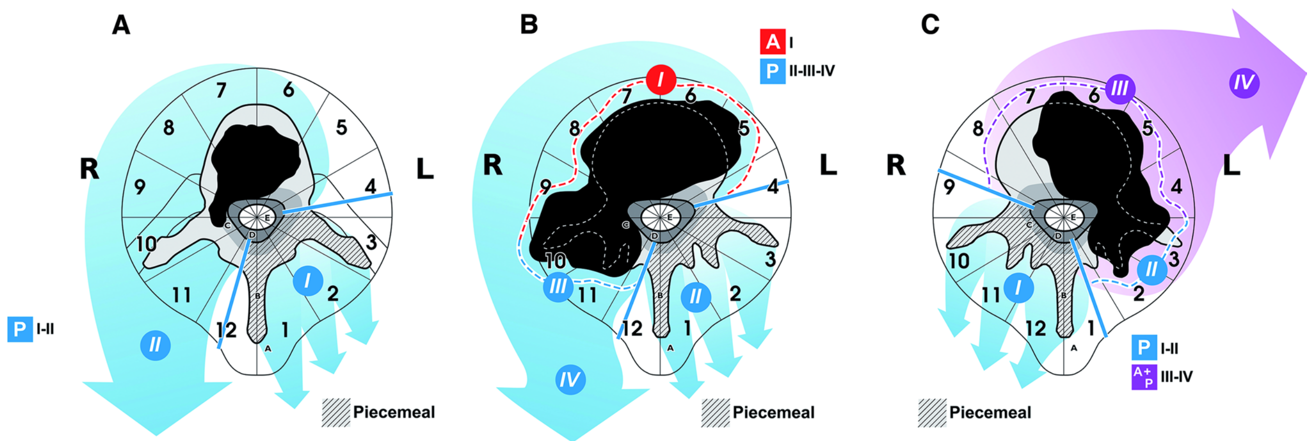


Fig. 4 Surgical techniques for en bloc resection. Type 2B (**a**), single-stage posterior approach for vertebral body resection (Roy Camille/Tomita technique). Criteria to achieve appropriate margins include sectors 9 or 4 free from tumor. Type 3B (**b**), double approach: anterior first, posterior second for resection of tumors growing anteriorly (layer A). Anterior approach must be performed as the first step to provide a wide/marginal margin under visual control. Type 5 (**c**), double approach: posterior first, combined (A + P in lateral position) second for resection of eccentrically growing tumors crossing the midline. Posterior approach must be performed to release the dura from the tumor, prior to its removal in the lateral position

Reconstruction

The length of the resected specimen varied from 32.7 to 76.5 mm with a mean (± standard deviation, SD) value of 53.4 (± 11.3) mm (Table 3).

Among the single-level group (10 cases), the mean (± SD) length of the resected specimen was 51.3 ± 9.8 mm. Within this group, in those cases where the resection was conducted in the disk spaces the mean (± SD) length of the resected specimen was 39.0 ± 5.4 mm, while when resection was performed in the adjacent vertebral bodies the mean (± SD), length was 55.4 ± 5.9 mm.

In the 3 cases of multilevel resections (2 vertebral bodies), the mean (± SD) length of the resected specimen was 60.6 ± 13.0 mm.

In all the cases, the preoperative plan of the resections was successfully accomplished; thus, no mismatch occurred between the printed implant and the actual void produced by the resection. The prosthesis fitted the gap providing a strong feeling of immediate stability, and none

Table 3 Final follow-up

Patient	Resection			Reconstruction				Implant status	Subsidence (mm)		Follow-up (months)
	Level	cranial	caudal	Levels spanned	Length of the implant (mm)	Instrumented levels					
						Above	Below		Proximal	Distal	
1	T12	VB	VB	T11–L1	56.25	+3	+2	SubS	3	4	14†
2	L2-L3	VB	D	L1–L4	76.46	+3	+2	SubS	4	0	16
3	L1	VB	VB	T12–L2	62.74	+3	+2	Subs	6	7	15
4	L4	D	D	L3–L5	45.93	+2	+1	SubS	0	22	14
5	T12	VB	VB	T11–L1	54.37	+2	+2(+)	SubS	4	5	12
6	T12	VB	VB	T11–L1	50.53	+3(+)	+2(+)	SubS	3	2	12
7	T10	D	D	T9–T11	32.66	+3	+2	SubS	4	3	11
8	L2	VB	VB	L1–L3	47.15	+2	+1(+)	SubS	2	3	9
9	L2	VB	VB	L1–L3	61.32	+3	+2	SubS	4	4	8
10	T4-T5	VB	VB	T3–T6	44.63	+2(+)	+3	SubS	3	2	6
11	L1	D	D	T12–L2	38.54	+2	+2	–	0	0	6
12	T11-T12	D	D	T10–L1	60.68	+3	+3	–	0	0	5
13	L1	VB	VB	T12–L2	63.20	+2	+2	–	–	–	2

(+) First screw at the same level of the osteotomy site; *VB* vertebral body; *D* disk; †removed implant; *SubS* subsidence of the cases required intraoperative change in the reconstruction technique.

The duration of the reconstruction varied from 18 to 68 min with a mean (± standard deviation, SD) value of 45 (± 13) min.

Instrumentation

Posterior screw-rods instrumentation was used to stabilize the spine in all cases (Table 3). Among the single-level group (10 cases), 2 to 3 levels (1:1) above and 1 to 2 levels (1:4) below the resection site were required. In 3 of these (#5, #6, and #8), the distal vertebral body osteotomy was performed above the level of the pedicles allowing for the placement of a couple of pedicle screws at that same level (Fig. 3d), thereby achieving the goal of sparing a distal motion segment maintaining 4 strong points of fixation. Analogously, in 1 case (#6) the proximal osteotomy performed below the level of the pedicle allowed for placement of pedicle screws at that level, providing 2 additional points of fixation in the thoracic spine.

Among the double-level group, 2 to 3 levels above (1:2) and below (1:2) the resection site were required.

Radiographic results

Statistical analysis on results was performed excluding the last implant in order to exclude a source of bias that could overrate outcomes.

Subsidence into the adjacent vertebral bodies occurred in all patients at both proximal and distal bone–implant interfaces; however, it was clinically irrelevant (asymptomatic and no consequences on posterior instrumentation), in 11 out of 12 patients (92%). In 1 patient (#4), severity of the subsidence led to revision of the construct; thus, it was classified as major mechanical complication (Fig. 5).

Mean (± SD) subsidence was 2.8 ± 1.8 mm at the proximal side and 4.3 ± 5.7 mm at the distal side of the implant. Excluding the case that was revisioned (#4), the mean subsidence at the distal side was 2.8 ± 2.1 mm.

In single-level resections, average subsidence was 2.5 ± 1.7 mm (average ± SD) at the proximal end and 2.5 ± 1.5 mm at the distal end in patients with follow-up between 6 months and 1 year (average 8 months).

In this same group, average subsidence was 3.2 ± 1.9 mm (average ± SD) at the proximal end and 8.0 ± 7.2 mm at the distal end in patients with at least 1-year follow-up (average 14 months). Excluding the case that was revisioned (#4), the mean subsidence at the distal side was 4.5 ± 1.8 mm.

Mean (± SD) preoperative thoracolumbar kyphosis was − 1 ± 2°, while mean (± SD) postoperative kyphosis was − 3 ± 6°. Near-complete reduction (97%) was possible in 2 cases, while only partially (65%) in the other case (Fig. 3).

In the case (#10) where the apex of the deformity was in the mid-thoracic spine, 10° of correction were obtained (from 32° preoperatively to 22° postoperatively) restoring the harmonious kyphotic alignment of the thoracic spine without radiographic, nor clinical, signs of compensatory mechanism recruitment to withstand upright posture.

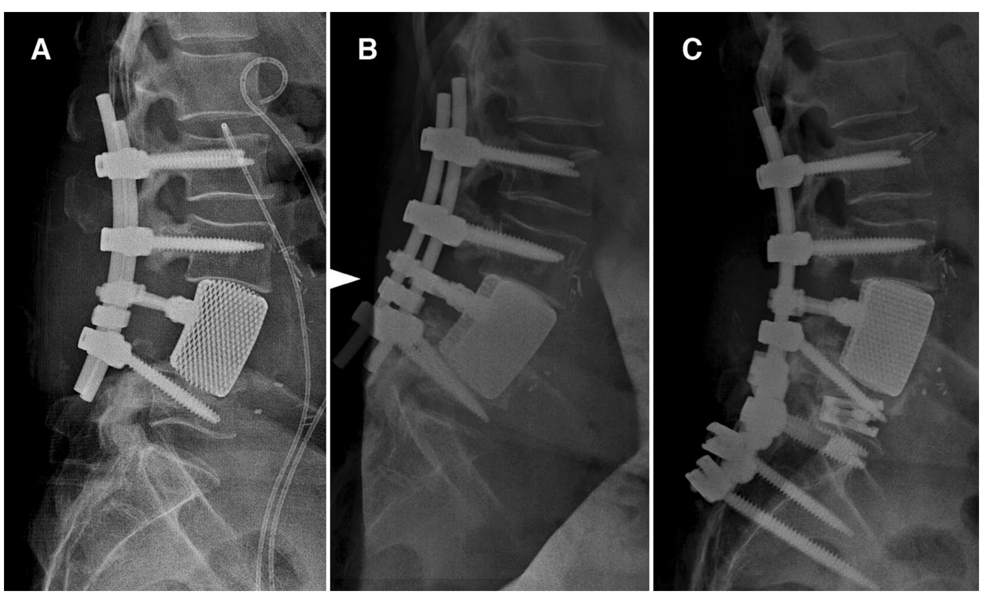


Fig. 5 Case 4. At 3-month follow-up subsidence was evident (**a**), which progressed at 6-month follow-up with global sagittal imbalance (**b**). The revision was conducted extending instrumentation down to ileum and providing additional support to the anterior column with L5-S1 expandable TLIF (**c**). Patient does not show evidence of the disease at 14-month follow-up

None of the prostheses broke, nor any migration occurred.

In one case (#1), the prosthesis was removed due to local recurrence of the disease at the distal end of the device and histological studies were conducted on the bone–metal interface, which revealed new bone formation inside the implant (unpublished results).

Discussion

The primary outcome measure was the ability of 3D-printed titanium biomimetic prosthesis to provide immediate and reliable anterior column support, restoring sagittal alignment if segmental deformity is present.

En bloc resection is the surgical removal of the whole tumor in a single piece, fully encased together with a layer of healthy tissue. The goal of the surgery is to obtain a tumor-free margin. Accepted indications are benign aggressive (Enneking stage 3) and malignant primary bone tumors in order to achieve the highest chance of local control of the disease. In fact, margin of the resection has been proven to be a major factor affecting long-term survival along with the biopsy technique. The role of the margin in the final outcome is such that in case of close proximity of relevant anatomic structures (i.e., nerve roots, spinal cord, major vessels), these should be included in the resected specimen.

On the contrary, in spinal metastases patients en bloc resection should only be performed in highly selected cases (i.e., solitary metastasis from clear cell renal carcinoma). In fact, the primary outcome is generally to improve or preserve function avoiding unnecessary morbidity. Thus, given the heterogeneity of this group of patients, decision-making process plays a key-role in the treatment.

Once successful resection of the tumor has been accomplished, surgeons face the two major issues that make spinal reconstruction challenging: bone loss and extreme degree of instability. There are several options available for reconstruction after en bloc resection, each of which has peculiar features so that pros and cons must be balanced. Bone grafts are cheap and have excellent potential for osteointegration; however, connection to the posterior instrumentation might be challenging and protection with anterior plating is advisable to avoid segmental kyphosis during the creeping substitution phase. Moreover, donor site morbidity and limited amount of bone that can be harvested are drawbacks that restrict the use of autografts, while the unavoidable (even if negligible) risk of disease transmission limits allograft. For the latter, bone bank is required.

Another common reconstruction technique is that of using mesh cages packed with cancellous bone graft. This combination allows for immediate weight-bearing and potential for osteointegration. Polymethyl-methacrylate (PMMA) is another option that has been reported for its good resistance to compression and low costs. Despite being this option reported as suitable only for short life expectancy patients, because of its debatable potential for osteointegration, some reports on long-term outcomes with this technique seem to disprove this [29]. The use of modular carbon fiber stackable cages represents a commonly used option, specially in oncology cases, due to the low atomic number of the carbon, so that scattering in the postoperative imaging is minimized allowing for optimal radiation therapy protocols. Moreover, carbon fiber permits excellent fusion proven to long-term follow-up. The main drawback that might eventually limit its use is the high cost of the implants. In the last decade, expandable cage has emerged with promising expectations. Although good results have been reported, the main issue in favor is represented by the possibility to position these implants from minimally invasive approaches and to expand them in situ to the final size. However, limitations are represented by the limited amount of bone graft that can be packed around the cage for anterior fusion. Finally, the extent of the resection (i.e., number of levels, nerve roots sacrifice), so as other patient-specific issues (i.e., balance of the spine, bone quality, concurrent degenerative spinal disease, general conditions that may impair bone formation capacity) needs to be taken in high consideration when evaluating the complexity of the reconstruction, over than just the pros/cons balance of any chosen technique.

Nevertheless, goals of reconstruction are: (1) restoration the load-bearing capacity of the anterior column, (2) fill the bone loss, (3) correction of any deformity eventually caused by the disease. Ability of the prosthesis to integrate with the host bone (osteointegration) is a key factor for long-term success of the reconstruction.

3D printing provides an additional option for complex reconstructions: it enables production of a prosthesis starting on the anatomy of each patient (i.e., shape, width, and length of the endplates), and taking into account the expected extent of the resection. These great potentialities may be maximally expressed in case of particularly complex reconstructions such as the lumbosacral junction or the upper cervical spine.

Opportunity to visualize of a virtual model prior to realization allows further refinement, and improvement until the final version can be produced. The innermost lattice structure of porous metal is designed to act as an osteoconductive scaffold for bone ingrowth, elastic enough to allow for micromovements (strains) that come back to the initial position after load release, and represent a stimulus for bone formation, while still providing a stable anterior mechanical support to the spine.

Additive manufacturing allows a non-stochastic production of the fine details that promote bone ingrowth such as the regularity of the lattice structure, size, and shape of fenestration and porosity of the metal. Finally, only $< 10\%$ of the actual volume of the prosthesis occupied by titanium, leaving a high potential for bone ingrowth.

Moreover, the immediate availability of the implant of the proper size that exactly reflects the dimension and shape of the resected specimen makes reconstruction quicker. This latter observation, although purely anecdotal, led the authors to consider the duration of the reconstructive phase as an additional parameter for further studies, comparing various techniques.

Authors believe that resection technique may have a role in promoting bone formation. Indeed, osteotomy through the vertebral body has been reported being performed using chisels, thread-wire saw, or both. In the presented series, all the osteotomies were performed using a thread-wire saw (coupled with a dedicated device for spinal cord protection) which allowed quick resections, without exposing chest or abdominal organs, nor to the cord at risk of predictable injuries, with the additional advantage of obtaining a smooth surface for reconstruction. This maximizes the contact area between host bone and prosthesis, decreases stress concentration, and is expected to have a role in the bone formation process.

Bone ingrowth is difficult to grade even with CT due to the dimension of the fenestration; thus, reliable in vivo bone ingrowth evaluation is difficult. In the presented series, an implanted prosthesis was removed due to local recurrence of the disease allowing histological study on bone–metal interface that revealed new bone growing into the prosthesis despite adverse concomitant factors (ongoing oncologic disease, chemotherapy).

A drawback of the use of custom-made prosthesis is the unavoidable commitment toward the preoperative planning, which must be meticulously respected in order not to have mismatch between the resected specimen and the prosthesis.

Authors suggest an alternative reconstruction option to be always available, in case of intraoperative change in surgical plan. This is particularly true when custom-made products are used, since these implants need such a thorough respect of the preoperative plan, that if an unpredictable situation may ever complicate the reconstruction, more versatile options need to be available. However, this attitude is suggested even when regular off-the-shelf products are used.

When reconstruction is planned for oncologic disease, timing of production must be taken into account since biology of the tumor progresses in the meanwhile of realization of the prosthesis. In the reported experience, it was kept within 2 weeks. In the presented series, an intentionally produced "reverse-mismatch" (prosthesis slightly bigger than the actual bone gap due to the segmental deformity) was used to aid reduction in the segmental kyphosis in 4 cases, restoring shape and original length of the spine.

In one case, subsidence has been a major complication requiring revision surgery. Reviewing retrospectively the course of the case, the authors commented on it observing that the choice of a short distal instrumentation (in order to spare motion at the lumbosacral junction) could have produced an uneven distribution of load-bearing forces between anterior and posterior columns, exposing the construct to a higher risk of distal junction kyphosis, rather than being it a real failure of the prosthesis itself. Further comments emphasized the important anchoring function of the pedicles that effectively prevented ventral migration of the prosthesis.

The authors acknowledge several limitations to the current study: first, the small sample size that limits the power of our analysis. Second, the group of patient is inhomogeneous in terms of expected ability to form new bone (age, nature of the lesion, previous radiation or chemotherapy, comorbidities), and overall bone quality.

The results from this series, the first reporting of anterior column reconstruction using 3D-printed custom-made prosthesis in the thoracolumbar spine and the largest overall in vivo experience with 3D-printed vertebral bodies, are just preliminary but suggest that this technique can be used effectively after en bloc resection. Although theses results are encouraging, further studies will be needed to reveal long-term outcomes and to compare this new technique to the others previously used.

Conclusions

Minor subsidence into the adjacent vertebral bodies occurred in almost all patients. Drawbacks of the use of custom-made prosthesis must be considered: meticulous respect of the preoperatively planned osteotomy levels and timing of production congruent to tumor biology. Preliminary results from this series suggest that 3D printing can be effectively used to produce custom-made prosthesis for anterior column reconstruction.

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Compliance with ethical standards

Conflict of interest None.

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