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Patient-specific guides for consistently achieving R0 bone margins after resection of primary malignant bone tumors of the pelvis

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Abstract

Aims Primary malignant bone tumor of the pelvis is an uncommon lesion, the resection of which via freehand osteotomy is subject to inaccuracy due to its three-dimensional anatomy. Patient-Specific Guides (PSG), also called Patient-Specific Instruments (PSI) are essential to ensure surgical planning and resection adequacy. Our aim was to assess their use and effectiveness.

Methods A monocentric retrospective study was conducted on 42 adult patients who underwent PSG-based resection of a primary malignant bone tumor of the pelvis. The primary outcome was the proportion of R0 bone margins. The secondary outcomes were the proportion of overall R0 margins, considering soft-tissue resection, the cumulative incidence of local recurrence, and the time of production for the guides. A comparison to a previous series at our institution was performed regarding histological margins.

Results Using PSGs, 100% R0 safe bone margin was achieved, and 88% overall R0 margin due to soft-tissue resection being contaminated, while the comparison to the previous series showed only 80% of R0 safe bone margin. The cumulative incidences of local recurrence were 10% (95% CI: 4–20%) at one year, 15% (95% CI: 6–27%) at two years, and 19% (95% CI: 8–33%) at five years. The median overall duration of the fabrication process of the guide was 35 days (Q1–Q3: 26–47) from the first contact to the surgery date.

Conclusions Patient-Specific Guides can provide a reproducible safe bony margin.

Keywords Primary malignant bone tumor, Pelvis, 3D printing, Patient-specific instrument

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Introduction

Primary malignant bone tumor is a rare pathology accounting for about 0.2% of all diagnosed cancers [1] and involves the pelvis in <10% of cases. Chondrosarcoma is the most common at this site, followed by Ewing's sarcoma and osteosarcoma [2]. Patients with bone sarcoma should be referred to experienced surgeons at tertiary referral centers [3, 4].

Post-resection tumor-free margins are associated with a lower local recurrence rate [5]. However, the complexity of the three-dimensional (3D) anatomy of the bony pelvis, the large size of primary bone tumors at this site, and the presence of closely related organs such as vessels, bladder, and rectum make it difficult to obtain negative, wide-margin resections [6, 7]. To achieve negative margins on pathological examination, it is recommended that an additional safe margin be sought between the planned osteotomy and the tumor (identified on the images) in the bone. The need for this extra safe margin is due to two uncertainties: the extent of the bone tumor and the osteotomy blade's position. There is, indeed, a well-known inaccuracy in freehand pelvic tumoral osteotomies despite surgeons' experience [8]. To address this matter, 3D planning and surgery may be performed using navigation devices [9–12]. Another solution to ensure surgical planning adequacy is using patient-specific guides (PSG) to steer a sawblade [13–19], with better in vitro and cadaveric results [20, 21].

We hypothesize that PSGs allow surgeons to achieve negative bone margins while resecting malignant pelvic tumors during osteotomies. This study reports a retrospective series of 42 consecutive adult patients who underwent surgical resection using PSGs to obtain negative margins for primary malignant bone tumors of the pelvis. The primary outcome was the proportion of negative bone margins. Secondary outcomes were the fabrication duration for the guides, overall safe margin, including soft tissue unguided margins, and the cumulative incidence of recurrence.

Table 1 Patient characteristics. Continuous data are presented with median and first to third quartile values (Q1-Q3); count data are presented with proportion and percentage

Characteristic	All patients (n=42)
Age, median (Q1-Q3)	39 (28–62)
Sex	
male	22 (52.4)
female	20 (47.6)
Histology	
Chondrosarcoma	21 (50%)
Ewing sarcoma	9 (21%)
Osteosarcoma	6 (14%)
Other	6 (14%)
Affected Enneking's zones	
1	7 (17%)
1+2	9 (21%)
1+2+3	9 (21%)
2	3 (7%)
2+3	3 (7%)
4+1	8 (19%)
4+1+2	1 (2%)
4+1+2+3	2 (5%)
Follow-up (months)	30 (15–40)

Materials and methods

Design of the study, selection criteria

This was a retrospective study conducted from June 2013 to October 2020. Patients were included if they presented with a primary malignant bone tumor of the pelvis and underwent surgical resection to obtain negative margins. Treatment modalities were decided at multidisciplinary tumor meetings. Patients were identified from the hospital database of bone tumor surgeries for which 3D cutting guides were manufactured. All patients gave informed consent for using data; as a retrospective study, only data from the medical reports were used. The study N° CER-2022-135 was approved by the local ethics committee ("Comité d'Ethique de la Recherche (CER) Paris Nord" (Institutional Review Board -IRB 00006477- of HUPNVS, Paris 7 University, AP-HP)) and conducted in accordance with the declaration of Helsinki.

Sixty-seven patients were eligible, and 25 were excluded: three patients with bone metastases; 16 with tumors of other bone (sacrum, 11; humerus, one; calcaneum, one; radius, one; tibia, two); three surgeries were canceled owing to tumor progression; two for benign tumor; one patient for whom a guide was not used. Surgeries were performed by five experienced oncosurgeons.

Patients (table 1)

Forty-two patients, 22 women (52%) and 20 men (48%), with a median age of 39 (Q1–Q3: 28–62), were included. The most common neoplastic lesions were chondrosarcoma (n=21, 50%). The tumor most frequently involved Enneking's zones 1+2 (n=9, 21%), zones 1+2+3 (n=9, 21%), and zones 4+1 (n=8, 19%).

Patient-Specific Guides

PSGs are designed by merging CT images for visualization of bony structures and MRI images on which the surgeon will have delineated the tumor. A 3D model is then created and cutting trajectories are positioned around the tumor, including a surgeon-defined margin of healthy tissues. Patient-matched base plate are designed with flat surfaces that indicate the cutting trajectories and physically support the saw blade during the osteotomies. The PSG is equipped with cylindrical guides for 2-mm-diameter Kirschner wires to be pinned on the bony structure and prevent any movement during the osteotomies as well as indicating the depth of the osteotomy (Fig. 1). Finally, the guides are manufactured by rapid prototyping using selective laser sintering in a biocompatible material and sent for sterilization before use in the operating room.

Surgery (table 2)

Surgeries were performed according to the surgical principles for treating bony tumors [22, 23]. When possible, a minimum 1 cm margin in the bone was aimed in unguided osteotomies, and a close to the tumor resection margin was targeted in the soft tissues. For guided osteotomies, the bone margin was determined by the surgeon in charge of the case; consequently, the median, minimum bone margin aimed for was 7 mm (Q1–Q3: 5–10). All patients were operated on under general anesthesia. One (n=28, 67%) or two (n=14, 33%) incisions were used. Two patients underwent hindquarter amputation. For them as well as for patients who underwent conservative surgery, no reconstruction was performed in 24 (57%); a prosthetic reconstruction was conducted in 13 patients (31%); and a biologic reconstruction was performed in 5 (n=12%). The median duration of the surgery was 04:30 h (Q1–Q3: 04:00–05:30).

Data measurements and statistical analysis

Because guides are meaningful as they allow the surgeon to circumscribe the tumor, we used the following classification to describe our use of PSG, a variation of Enneking's classification with a focus on the key elements: the acetabulum and the sacrum, as well as the extension to the contralateral pubic rami (Fig. 2).

Osteotomies preserving bone continuity were described separately (CPG for bone Continuity Preserving Guides). Then we individually described the proximal osteotomy (POG) and distal osteotomy (DOG) guides. Zones were defined as 'S' for sacrum with 'a' when lateral to the S1 foramen, 'b' when passing through the S1 foramen, and 'c' for those medial to the S1 foramen; 'I' for

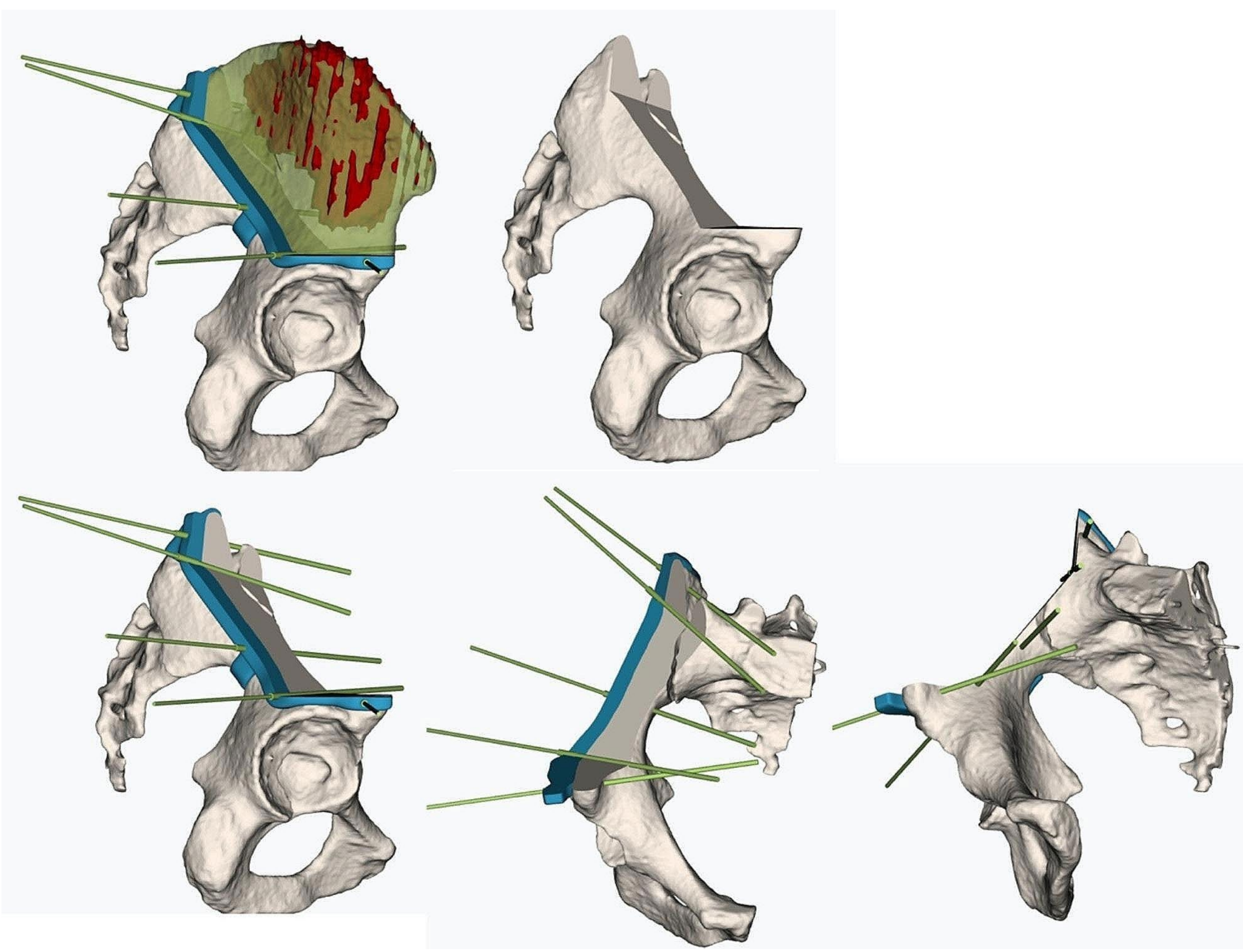

Fig. 1 Clinician interface display of a right iliac wing resection preserving bone continuity (1 + 4 resection). Up left: full view with tumor delineation by MRI and CT image merging, with planned resection in green as well as PSG and K-wires. Up right: hemipelvis after planned resection. Below: visualization of different rotations of cutting planes and the position of K-wires used for the intersection of the planes and guide fixation

Table 2 Surgery characteristics. Continuous data are presented with median and first to third quartile values (Q1-Q3); count data are presented with proportion and percentage

Characteristic	All patients (*n* = 42)
minimum bone margin aimed (mm), median (Q1-Q3)	7 (5-10)
Number of incisions	
1	28 (67%)
2	14 (33%)
Amputation	
yes	2 (5%)
no	40 (95%)
Reconstruction type	
none	24 (57%)
biologic	5 (12%)
prosthetic	13 (31%)
Duration of surgery (hours), median (Q1-Q3)	4:30 (4:00–5:30)
Bleeding (mL), median (Q1-Q3)	1200 (800–1900)
Number of PRBC (pp), median (Q1-Q3)	6 (4-8)

pp: per patient

PRBC: packed red blood cells

ilium; 'A' for acetabulum with 'a' for osteotomies passing through the upper half of the acetabulum and 'b' for those passing through the lower half; lastly, 'P' for pubic osteotomies with 'r' for pubic ramii, 's' for pubic symphysis, and 'sc' for pubic symphysis contralateral. Bone tumors affecting only the sacrum (zone 4) were not included in the present study; no guides were used for tumors of the ischium only (zone 3). For each guide type (CPG, POG, and DOG), we reported the number of guides, planes, and bones involved in the osteotomy. Proximal and distal guides were cross-tabulated (Table 3), and we also reported unguided osteotomies.

Clinical data, imaging, and details of treatment and follow-up were collected from hospital records by one resident (XdC) under the supervision of a senior surgeon (DB). All surgery, pathology, and follow-up consultation reports were analyzed. The primary outcome was the proportion of negative (R0) bone margins. Secondary outcomes included the duration of bone model fabrication (four different times; see below), the overall proportion of R0 margins (bone and soft tissue), and the cumulative incidence of local recurrence.

The following times were computed: overall duration of the process: from the date of first contact between the surgeon and the 3-D side manufacturer to the date of surgery; duration of guide fabrication: from the start date of guide modeling to the date of delivery; duration of model conception: from the start date of guide modeling start to the date of model validation; duration of model fabrication: from the start date of model printing to the end date of model printing; duration between fabrication and surgery (transportation-sterilization-waiting before surgery).

The surgical margins were classified as follows: R2 if there was macroscopic involvement at the inked margins; R1 if there was microscopic involvement at, or within 1 mm, of the inked margins; R0 if there was at least 1 mm of healthy tissue between the inked margin and the tumor. Margins were recorded at the osteotomy planes (bone margins) and soft tissue (soft-tissue margins). Two pathologists specialized in bone tumors and unaware of the present study performed all histology examinations at our center in clinical routine.

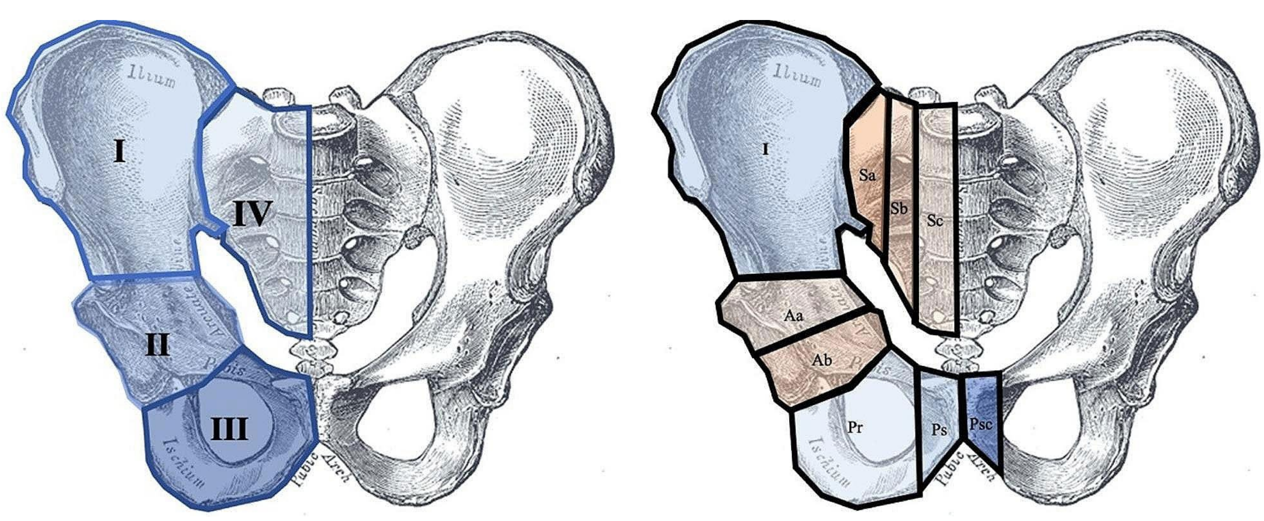

Fig. 2 Resection zones according to Enneking (left) and those used in this study (right). Adapted from Gray. Anatomy of the Human Body. 1918. Sa: sacrum, lateral to the S1 foramen; Sb: sacrum, passing through the S1 foramen; Sc: sacrum, medial to the S1 foramen; I for ilium; Aa: acetabulum, through the upper half of the acetabulum; Ab: acetabulum, passing through the lower half; Pr: pubic rami; Ps: pubic symphysis; Psc: pubic symphysis contralateral

Table 3 Cross-tabulation of proximal and distal osteotomies of the 30 patients with discontinuous bone resection

	PO	Sacrum			Ilium	total
DO		Sa	Sb	Sc	I	
Ilium	I	5	1	1		7
Acetabulum	Aa	2	1			3
	Ab	3^2			1^1	4^3
Pubis	Pr	6^6		1^1	2^2	9^9
	Ps	1^1				1^1
	Psc	2^2	1^1	1^1	2^2	6^6
total		19	3	3	5	30

PO: proximal osteotomy; DO: distal osteotomy; I: ilium; Aa: acetabulum, upper half; Ab: acetabulum, lower half; Pr: pubic rami; Ps: pubic symphysis; Psc: contralateral pubic rami.

Numbers in superscript indicate the number of patients who had unguided osteotomies: for instance, 3^2 indicates that among the three patients, two had unguided osteotomies, and one had guided osteotomies.

Table 4 Guide characteristics. This table displays the number of guides used per patient (pp) and the corresponding number of guided osteotomy planes allowed

Characteristic	All patients (*n* = 42)
Number of guides (pp)	
1	28 (67%)
2	13 (31%)
3	1 (2%)
Number of guided osteotomy planes (pp)	
1	5 (12%)
2	19 (45%)
3	8 (19%)
4	5 (12%)
5	4 (10%)
6	0 (0%)
7	1 (2%)

Cumulative incidences, as defined by Prentice et al. [24], of events were estimated from the date of resection of the tumor to either the event (local recurrence) or the competing event (death) or the last news when neither the event nor death was experienced (censored observation). Point estimates with 95% exact confidence intervals [25] are reported. Continuous data are presented as the median with first and third quartile values (Q1–Q3); categorical data are presented as counts and proportions.

Finally, a comparison was added to a previous unpublished series at our institution, on 121 pelvic resections for bone tumors in the previous 20 years without PSGs. Age, sex, histotypes and affected Enneking's zones were recorded, as well as bony margins, soft-tissue margins and overall margins.

Results

Overall, 57 guides were used in 42 patients: twenty-eight received a single guide, thirteen had two guides, and one had three guides (Table 4). The median number of guided planes per patient was 2 (Q1–Q3: 2–3). The median number of unguided osteotomies per patient was 1 (Q1–Q3: 0–1): 15 patients underwent one, 8 underwent two, and one underwent three unguided osteotomies.

Twelve patients had CPG (Fig. 1): 10 had a single guide, and two received two guides. The tumors were classified as Enneking's zone '4+1' in three cases, '4+1+2' in one case, '1' in four cases, '2' in one case, and '2+3' in three cases. The median number of guided osteotomies per patient was 3 (Q1–Q3: 2.75–4.25). Five patients required unguided osteotomies to complete the resection.

Thirty patients received guides used for discontinuous bone resection (Table 3). Among them, 18 patients received a single guide (Fig. 3), 11 had two, and one had three guides. The tumors were classified as Enneking's zone '4+1' in five cases, '4+1+2+3' in two cases, '1' in three cases, '1+2' in nine cases, '1+2+3' in nine cases, and '2' in two cases. The median number of guided osteotomies per patient was 2 (Q1–Q3: 2–3). Additionally, 19 patients underwent unguided osteotomies to complete the resection: ten patients underwent one, eight patients underwent two, and one patient underwent three.

POGs were used for sacral osteotomies in 25 patients, mostly type Sa (*n* = 19), and for iliac osteotomies in 5 patients. Proximal osteotomies were always guided. Distal osteotomies were performed through the iliac bone in 7 patients (all guided), through the acetabulum in 7 patients (3 unguided), and through the pubis in 16 patients (all unguided).

All patients had R0 bone margins (100%; 95% CI: 92–100%). Thirty-seven (88%; 95% CI: 74–96%) patients had R0 soft-tissue margins, and five had R1 soft-tissue margins. Overall, 37 (88%; 95% CI: 74 –96%) patients had R0 margins, including soft-tissue margin. The comparison of margins with our previous series is detailed in Table 5.

The following durations were recorded: the median overall duration of the process was 35 days (Q1–Q3: 26–47); the median duration of fabrication of the guide was 12 days (Q1–Q3: 8–17); the median duration of model conception was six days (Q1–Q3: 3–7); the median duration of model fabrication was five days

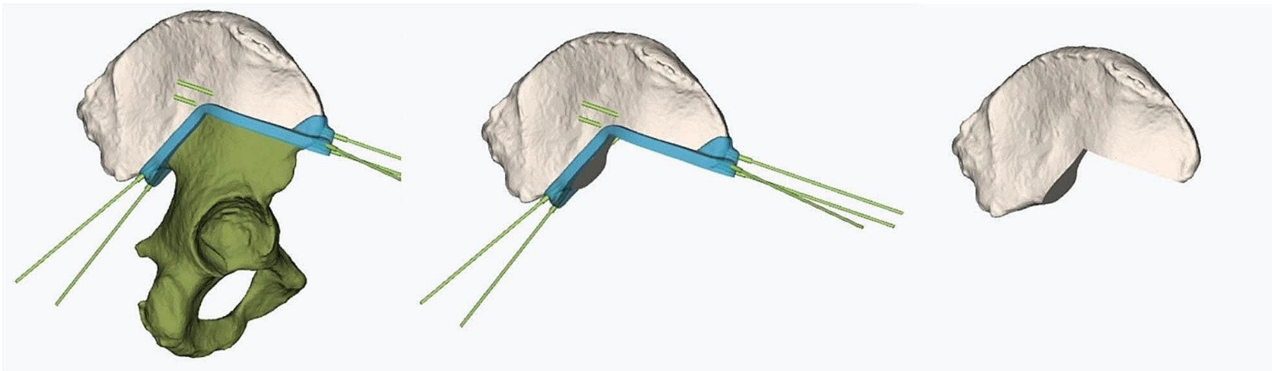

Fig. 3 Example of a right hemipelvic resection through the iliac wing and pubic symphysis: only the iliac resection is guided (POG) with two cutting planes and 4 K-wires

Table 5 Comparison to a comparable previous unpublished series on pelvic resections without PSGs: 100% R0 bony margins with PSGs vs. only 80% without PSGs. Continuous data are presented with median and first to third quartile values (Q1-Q3); count data are presented with proportion and percentage

Characteristic	All patients (*n* = 163)	Without PSG (*n* = 121)	With PSG (*n* = 42)	*P* Value
Age, median (Q1-Q3)	41 (27–53)	39 (27–52)	39 (28–62)	0.75
Sex				0.28
male	90 (55%)	70 (58%)	20 (48%)	
female	73 (45%)	51 (42%)	22 (52%)	
Histology				0.12
Chondrosarcoma	99 (61%)	78 (65%)	21 (50%)	
Ewing sarcoma	24 (15%)	15 (12%)	9 (21%)	
Osteosarcoma	24 (15%)	19 (16%)	6 (14%)	
Other	16 (10%)	9 (7%)	6 (14%)	
Affected Enneking's zones				0.0006
1	31 (19%)	24 (20%)	7 (17%)	
1 + 2	21 (13%)	12 (10%)	9 (21%)	
1 + 2 + 3	24 (15%)	15 (12%)	9 (21%)	
2	16 (10%)	13 (11%)	3 (7%)	
2 + 3	30 (18%)	27 (22%)	3 (7%)	
3	19 (12%)	19 (16%)	0 (0%)	
4 + 1	19 (12%)	11 (9%)	8 (19%)	
4 + 1 + 2	1 (2%)	0 (0%)	1 (2%)	
4 + 1 + 2 + 3	2 (1%)	0 (0%)	2 (5%)	
Bony margins				0.004
R0	139 (85%)	97 (80%)	42 (100%)	
R1	14 (9%)	14 (12%)	0 (0%)	
R2	10 (6%)	10 (8%)	0 (0%)	
Soft-tissue margins				0.13
R0	127 (78%)	90 (75%)	37 (88%)	
R1	14 (9%)	22 (18%)	5 (12%)	
R2	8 (5%)	8 (7%)	0 (0%)	
Overall margins				0.060
R0	121 (75%)	84 (70%)	37 (88%)	
R1	29 (18%)	24 (20%)	5 (12%)	
R2	11 (7%)	11 (9%)	0 (0%)	

(Q1–Q3: 1–8). The median duration between fabrication and surgery was 10 days (Q1–Q3): 10–12), with a minimum of 3 days (transportation and sterilization).

The cumulative incidences of local recurrence were 10% (95% CI: 4–20%) at one year, 15% (95% CI: 6–27%) at two years, and 19% (95% CI: 8–33%) at five years.Fig. (4)

Discussion

Patients with primary malignant bone tumors should be referred to tertiary referral centers, especially where pelvis involvement is suspected, since the 3D anatomy of the pelvis makes freehand osteotomies imprecise regardless of experience [8]. Several studies have concluded that employing PSGs for resecting bone tumors involving the pelvis increases accuracy [7, 15] and lowers recurrence rates [14], although with small sample sizes. This study was conducted on 42 patients, using 57 guides, making it the largest series yet published; equivalent studies are limited to up to 12 patients [14, 15, 17, 18] or include other tumors [26]. Our study has significant limitations, including a lack of a control group since all resections at the time of the study were conducted utilizing PSGs at our institution. However, no surgeons at our center would currently perform a complex pelvic resection without PSG; therefore, a randomized controlled trial is unfeasible. Lastly, all PSGs were manufactured by one company (3D-side), and these results may prove different with other companies.

Our study demonstrated a 100% safe R0 bone margin and 88% safe overall margin in the 42 patients. In multiple studies with 12–53 patients [27–31], the reported rates of positive margins after freehand pelvic resections ranged from 9 to 66%. At our institution, a similar previous study on 48 patients had 3% marginal and 19% contaminated freehand exeresis [27], while the comparison to a previous unpublished series on similar resections without PSGs showed only 80% of R0 bony margins and 8% of R2 bony margins. This 100% safe bone margin we achieved is mostly due to the fact a PSG ensures adequacy between planned and effective resection. Some factors may have influenced our

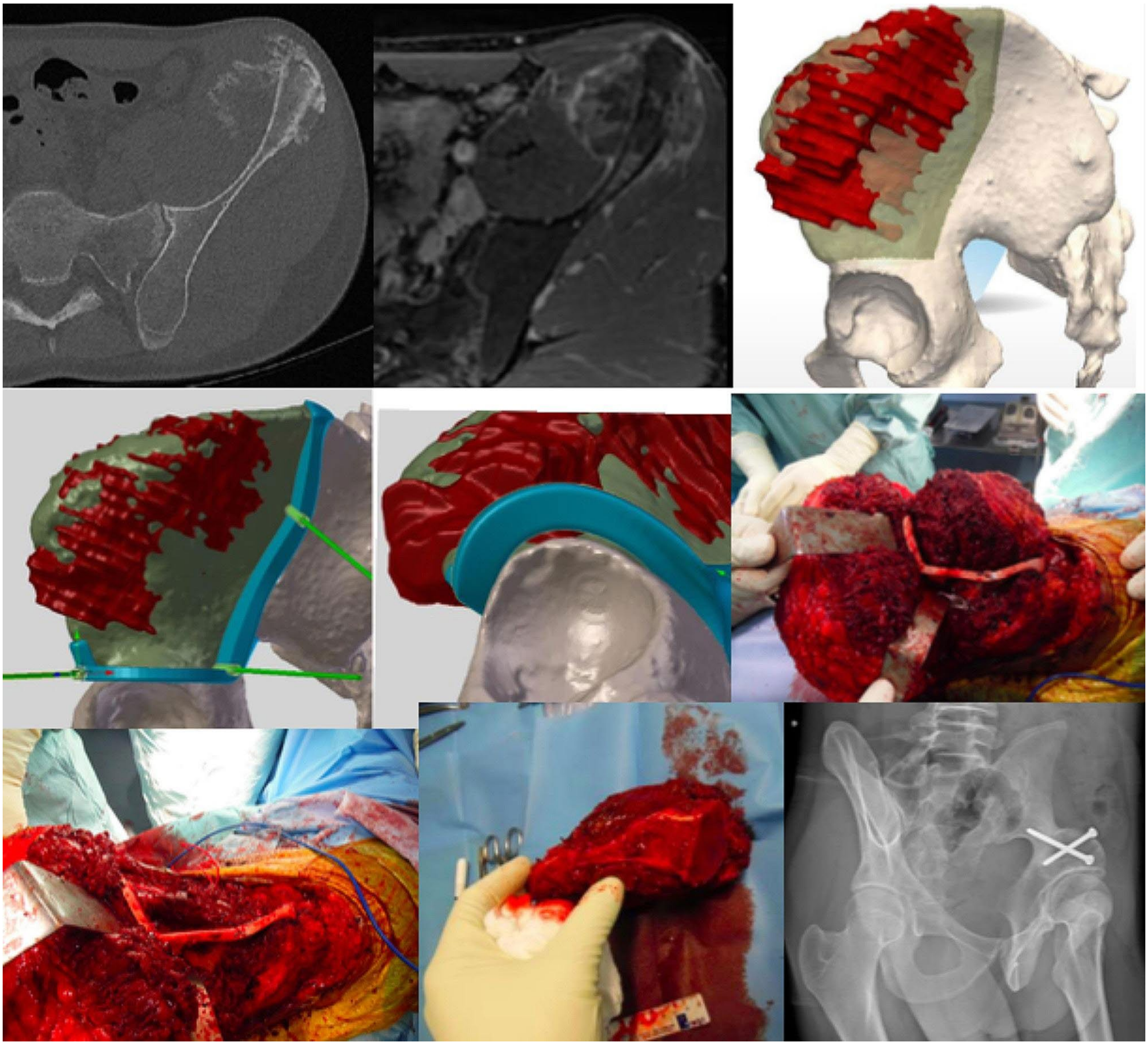

Fig. 4 Osteosarcoma of the left iliac wing in a 22-year-old male: planification using CT and MRI-scan, intraoperative views showing the PSG and post operative radiographic result. The acetabulum and pelvic ring continuity were preserved, and the histological examination showed R0 overall resection

results, such as patient selection or mostly imaging quality. Progress in MRI and CT scan technology has increased the resolution and delimitation of tumors, thus increasing the accuracy of surgical planning. Change in preoperative oncological treatments over time may also have influenced our results. Difficulty to delineate tumors on MRI due to peritumoral edema or infiltrative pattern remains a reason for positive soft-tissue margins.

We experienced a 15% local recurrence rate at two years and 19% at five years. In contrast, other PSG users experienced 10–33% [14, 15] local recurrence in studies comprising 9 to 11 patients at 1 to 4 years, with death being a competing event to recurrence. Although on a single histotype therefore not statistically comparable, a previous unguided series at our institution resulted in a 30% local recurrence rate at a mean follow-up of 3 years [27], in accordance with other reports [28]. For limb-salvage surgery, whether it be guided or not, a review article by Ahlawat et al. [32] calculated the overall local recurrence rate at 18% in 801 patients studied in 22 investigations. It remains uncertain whether differences in local recurrence are due to improvements in oncological treatment or surgical treatment (better imaging delineation and PSG resection). This study, along with previous series, has shown better results in achieving R0 bony margins. However, while PSGs allow for cutting closer to the tumor, this increased precision might also lead to a higher risk of soft-tissue contamination. Consequently, local recurrence rates may not necessarily improve despite

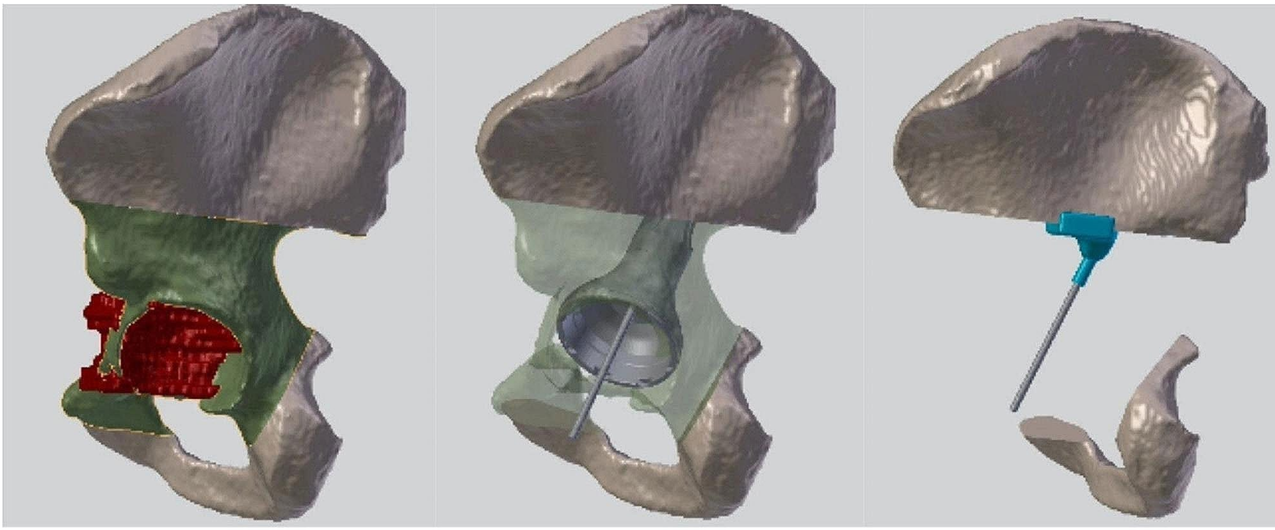

Fig. 5 Reconstruction using LUMIC® endoprosthesis: an additional guide is designed for positioning a K-Wire on which the prosthesis is placed

achieving closer resection margins. In a recent series, Dong et al. emphasize the possibility of contamination of the soft tissue near the section cut, despite an adequate section, due to the oscillating movements of the saw [33]. Considering He et al.'s systematic review [5] on over 1500 patients that concluded a higher recurrence rate of sarcomas involving the pelvis than peripheral sites, PSGs might lead to suboptimal resection despite adequate resection.

Another tool available for tumor resection is navigation. One of the downsides of using PSGs is the delay in allowing tumor growth. Our median overall duration of the process was 35 days, primarily due to the back-and-forth discussion between surgeons and engineers, but mostly because of delays in the surgeons' responses. Evrard et al. required, with the same company, an average of three weeks between tumor delineation and resection, even though guide conception could take only 7 to 10 days [34]. On the contrary, no delay is required with navigation, but cutting remains less constrained than when using PSG. Another difficulty is the space requirement of the guides at the pelvis, as for the example of the iliac wing: although simple in the approach above the crest, soft tissue allowed for less space from either side. Gouin et al. [15] proved the application on the pelvis to be fast—less than 5 min—without sacrificing a good to excellent application. Cooperation between engineers and surgeons is the key to better conception: one cannot use guides during the entire osteotomy procedure, or in all osteotomies, thus decreasing the volume of the guides to an absolute minimum. Their use should be restricted to the more difficult osteotomies, such as periacetabular or zone IV tumors, rather than zone I or III tumors, where wider resections are possible without comprising reconstruction. PSG resection finally gives the ability to guide zone II reconstruction devices such as LUMIC® endoprosthesis (Fig. 5), as well as biological reconstruction using allograft and autograft with excellent consolidation rates [33].

Conclusion

Patient-specific guides can provide a safe bony margin while performing closer resection for primary malignant bone tumors of the pelvis but at the expense of soft tissue margin.

Supplementary Information

The online version contains supplementary material available at https://doi.org/10.1186/s12957-024-03478-3.

Supplementary Material 1

Author contributions

X.C.R and D.B. wrote the main manuscript text. V.D, V. C-N, P. A. and D.B. contributed to data analysis. All authors reviewed the manuscript.

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Data availability

The dataset is available upon request from the corresponding author.

Declarations

Ethics declaration

The study was approved as N° CER-2022-135 by the local ethics committee: "Comité d'Ethique de la Recherche (CER) Paris Nord", Institutional Review Board -IRB 00006477- of HUPNVS, Paris 7 University, AP-HP).

Competing interests

The authors declare no competing interests.

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