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Original article

# Resection margins obtained with patient-specific instruments for resecting primary pelvic bone sarcomas: A case-control study

Robin Evrard[a,b,c], Thomas Schubert[a,b,c], Laurent Paul[d], Pierre-Louis Docquier[a,b,c,â?^]

[a] Neuro Musculo-Skeletal Laboratory (NMSK), secteur des sciences de la santÃ©, institut de recherche expÃ©rimentale et clinique, universitÃ© catholique de Louvain, avenue Mounier 53, 1200 Brussels, Belgium
[b] Service dâ€™orthopÃ©die et de traumatologie de lâ€™appareil locomoteur, cliniques universitaires Saint-Luc, avenue Hippocrate 10, 1200 Brussels, Belgium
[c] CancÃ©rologie et hÃ©matologie, institut Roi-Albert-II, cliniques universitaires Saint-Luc, avenue Hippocrate 10, 1200 Brussels, Belgium
[d] 3D-Side, 5, rue AndrÃ©-Dumont, Mont-Saint-Guibert, Belgium

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ABSTRACT

*Background:* Limb salvage surgery for pelvic bone sarcoma carries a very high risk of local recurrence. Patient-specific instruments (PSIs) have shown promise for obtaining tumour-free resection margins. However, no data are available on medium-term outcomes including local recurrence rates after PSI-guided resection. The objectives of this case-control study were to determine whether PSI-guided resection: 1) was associated with a lower local recurrence rate, 2) allowed a shorter operative time, 3) was associated with better-quality allograft reconstruction.
*Hypothesis:* PSI-guided resection decreases the local recurrence rate by improving the resection margins in patients with primary pelvic bone sarcomas.
*Patients and methods:* PSI-guided resection was performed in 9 consecutive patients (cases) with primary pelvic sarcomas (chondrosarcoma, $n = 3$; Ewing's sarcoma, $n = 3$; osteosarcoma, $n = 1$; fibrosarcoma, $n = 1$; and radiation-induced sarcoma, $n = 1$). Age ranged from 11 to 63 years. Outcomes were compared to those in a historical control group of 19 patients with primary bone sarcomas who underwent resection surgery in the same hospital without PSI guidance. The case and control groups were similar regarding age, sex distribution, and follow-up duration. The local recurrence rate and operative time were compared between the two groups. Resection margins were classified as R0, R1, or R2. The quality of allograft reconstruction, which was performed in 7 of the 9 cases, was assessed.
*Results:* After a mean follow-up of 52 months (range, 30âŁ“90 months), none of the cases had experienced local bone or soft-tissue recurrences, compared to 7 of the 19 controls ($p = 0.03$), in whom mean follow-up was 62 months (range, 24âŁ“134 months). Bone resection margins were R0 in 8 cases; in the remaining patient, R1 resection was performed deliberately to preserve an S1 root. All 9 cases had R0 soft-tissue resection margins. In the control group, bone resection margins were R0 in 13 patients, R1 in 5 patients, and R2 in 1 patient ($p = 0.47$). Mean operative time was similar in the cases (612 minutes [range, 435âŁ“854 minutes]) and controls (633 minutes [range, 420âŁ“990 minutes]) ($p = 0.87$). In the 7 patients who underwent pelvic allograft reconstruction, allograft contact in the defect and osteosynthesis stability were deemed satisfactory by the surgeon.
*Discussion:* The lower local recurrence rate in the cases demonstrates that the improved resection accuracy provided by PSIs directly influences the risk of local recurrence. In addition, the R0 bone margins in 8 cases establishes that PSIs are effective in improving resection accuracy.
*Level of evidence:* III, case-control study.



## 1. Introduction

When resecting sarcomas located at challenging sites such as the pelvis and sacrum, the resection margins may be suboptimal (intralesional or marginal) [1,2]. Pelvic sarcomas are associated with high local recurrence rates of 28% to 35% in previous reports [3] and 29% (7/24) at our institution [3]. To overcome challenges

â?^Corresponding author.
*E-mail address:* pierre-louis.docquier@uclouvain.be (P.-L. Docquier).

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**Table 1**
Main features of the 9 patients and tumours managed using patient-specific instruments (cases).

| Patients | | *N* = 9 |
|---|---|---|
| Sex | Males/Females | 5/4 |
| Age, years | Mean (range) | 39 (11–63) |
| Tumour histology | Chondrosarcoma | 3 |
| | Ewing's sarcoma | 3 |
| | Osteosarcoma | 1 |
| | Fibrosarcoma | 1 |
| | Radiation-induced sarcoma | 1 |
| Tumours | | |
| Tumour location (Enneking–Dunham zones) [15] | I | 1 |
| | I-II-III | 1 |
| | I-II-IV | 1 |
| | I-II-III-IV | 1 |
| | I-IV | 2 |
| | II-III | 3 |
| Largest tumour dimension, cm | Mean (range) | 11.3 (4.5–17) |
| Metastases at surgery | Lung metastases | 0 |
| Treatments | | |
| Neoadjuvant treatments | Combination chemotherapy | 5 |
| | Radiotherapy | 1 |
| Adjuvant treatments | Combination chemotherapy | 5 |
| | Radiotherapy | 3 |

in obtaining tumour-free resection margins, methods intended to improve resection accuracy have been developed, including computed tomography (CT)-guided navigation with an O-arm [4], optical navigation [5], and patient-specific instruments (PSIs) [6,7]. Intraoperative navigation and PSIs have been proven to improve accuracy compared to free hand tumour resection [8,9]. The contribution of these methods is particularly important when the tumour involves the pelvis, where some of the bone cuts must be made without the benefit of visual guidance, as the extension of the tumour within the bone is not visible.

PSI was recently reported as a new surgical technique of potential usefulness for bone tumour resection [7,10]. Most studies focused on the degree of resection accuracy achieved by using PSIs [11,12], although short-term resection-margin data have been provided also [6]. A few studies also described the combined use of PSI-guided resection and of individually-tailored reconstruction using implants [13] or allografts [14]. No studies, however, have evaluated the potential impact of PSI use on the local recurrence rate after bone sarcoma resection.

The objective of this case-control study was to determine whether PSI-guided resection was associated:

- with a lower local recurrence rate;
- a shorter operative time;
- better-quality allograft reconstruction.

The working hypothesis was that PSI-guided resection decreased the local recurrence rate by improving the resection margins.

## 2. Material and methods

### 2.1. Patients

Between March 2011 and February 2016, 9 consecutive patients underwent PSI-guided resection of bone sarcomas of the pelvis and/or sacrum at our institution. Table 1 reports their main features.

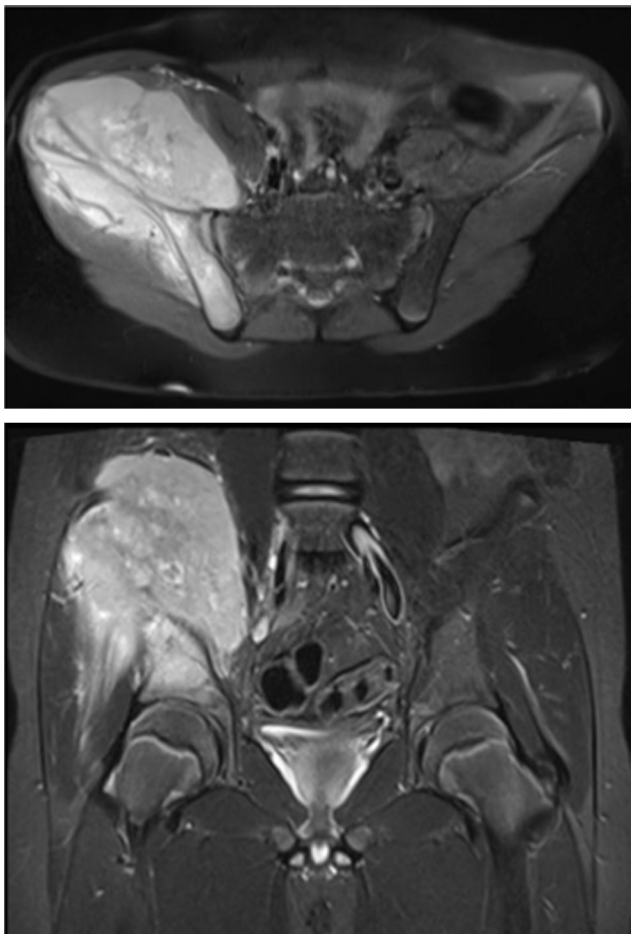

**Fig. 1.** Ewing's sarcoma involving Enneking–Dunham zones I, II, and IV [15] of the right innominate bone in a 14-year-old boy. Magnetic resonance imaging, axial and coronal views.

Our institutional review board approved a retrospective study in these patients (2015/26JAN/025, Belgian registration number B403201523492). The diagnosis was chondrosarcoma in 3 patients, Ewing's sarcoma in 3 patients, osteosarcoma in 1 patient, fibrosarcoma in 1 patient, and radiation-induced sarcoma in 1 patient. Mean longest tumour dimension was 11.3cm (range, 4.5–17cm). The Enneking–Dunham zones [15] involved were I in 1 patient; I, II, and III in 1 patient; I, II, and IV in 1 patient; I, II, III, and IV in 1 patient; I and IV in 2 patients; and II and III in 3 patients. The patient with osteosarcoma had neurofibromatosis type 1 and had undergone marginal resection of a malignant peripheral nerve sheath tumour 1 year earlier.

### 2.2. Methods

#### 2.2.1. Preoperative planning of tumour resection

The same procedure was used in all 9 patients. The CT and magnetic resonance imaging (MRI) scans performed to establish the diagnosis were uploaded in DICOM format from our institution's PACS and sent to the PSI manufacturer (3D-side, Louvain-la-Neuve, Belgium). The surgeon worked with a radiologist specialised in bone imaging to delineate the tumour contours on all the MRI views where the tumour was visible. This task was performed using ITK-SNAP software V2.0 (http://www.itksnap.org/) [16] and tumour segmentation software specifically designed by 3D-Side (Interact V1.0). The sequence providing the best contrast between tumour tissue and healthy tissue was selected. The two types of software rely on a similar polygon tool to delineate the tumour contours on

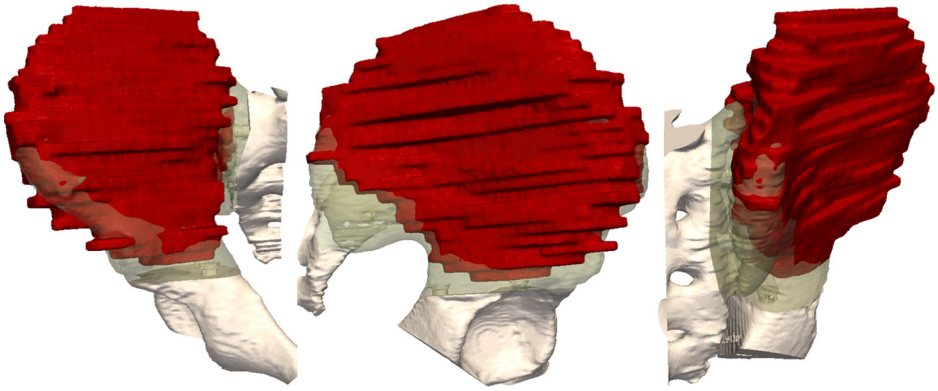

**Fig. 2.** Same patient as in Fig. 1: reconstruction of the tumour at its location in the patient's bone. Anterior, lateral, and posterior views of the pelvis. The tumour is in red and the planned resection zone allowing for a 10-mm tumour-free margin is in light green.

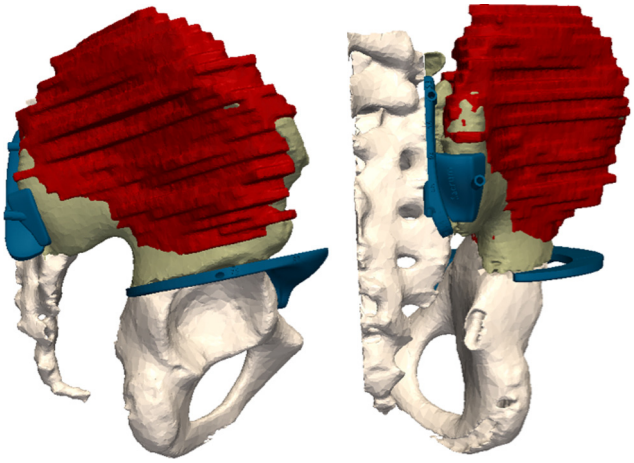

**Fig. 3.** Same patient as in Fig. 1: resection planes. Two patient-specific instruments (in blue) were produced, one for the sagittal cut through the sacral wing and the other for the horizontal cut just above the acetabulum.

each of the views showing the tumour. This segmentation procedure lasted a few minutes to 30 minutes depending on the number of views in the sequence. Once tumour segmentation was complete, all the 2D images were used to create a 3D volumetric image of the tumour (Figs. 1 and 2). By merging the MRI and CT images, the tumour volume was transferred from the MRI scan to the CT scan to produce a 3D reconstruction of the tumour at its location in the bone (Fig. 2). The resection planes (i.e., the surgical saw trajectory) were defined by including a 10-mm default safety margin (Fig. 3). However, for 1 patient the safety margin was set at 0 at a site where the resection plane was in contact with an S1 nerve root, in order to spare the root (planned R1 resection).

*2.2.2. Patient-specific instruments (PSIs)*

For each patient, a PSI was designed and manufactured by 3D printing (using selective laser sintering). The powdered material was biocompatible sterilisable polyamide. The surface of each PSI was shaped to allow a single position when the PSI was placed in contact with the bone. The PSI was equipped with stainless steel cylinders specifically designed to hold 2-mm K-wires to secure the PSI to the bone. A flat surface on the PSI served to guide the saw blade along the planned resection plane (Fig. 3). The cost of designing and manufacturing each tumour-resection PSI then shipping it to our institution was 3000€.

*2.2.3. Preoperative planning of allograft contouring*

Allograft reconstruction was performed in 8 patients. The remaining patient had a tumour confined to Enneking–Dunham zone I and therefore did not require reconstruction. A fibula was used in 1 patient to restore pelvic ring continuity. In the remaining 7 patients, an iliac bone allograft was used, combined in 4 patients with total hip arthroplasty. For these 7 patients, a specific procedure was applied to select the allograft then shape it to match the bony defect. The iliac bone allografts available at our institution's bone bank were imaged using CT. The CT images of each allograft were merged with the CT images of the patient, and the best match was selected based on patient-specific anatomical criteria such as cortical continuity and joint congruence. The resection planes planned on the patient's images were transferred to the selected allograft. Finally, a PSI for contouring the allograft was designed and manufactured. This PSI was designed to fit on the graft site to avoid bone loss related to the thickness of the saw blade (Fig. 4). Thus, the surgeon was free to choose any type of saw blade. Allograft reconstruction was simulated virtually (Fig. 5). The cost of selecting the best allograft and of designing and manufacturing the PSI was 2000€.

*2.2.4. Assisted surgery*

The PSIs were received 3 to 4 weeks after the tumour segmentation data were sent to the manufacturer. In urgent cases, for instance for chondrosarcoma, which does not require neoadjuvant chemotherapy, a fast response on the part of the surgical team and manufacturer allowed the PSI to be made available within 2 weeks. The PSIs were delivered a few days before the surgical procedure and were sterilised in a standard autoclave. Use of the PSI proved feasible in all 9 patients.

The soft tissues were dissected as usual, without guidance. The slender PSI profile (4–10mm) did not require any additional soft tissue dissection. The bone models supplied with the PSIs were sterilised and used by the surgeon as orientation tools that helped to reach the resection site during soft-tissue dissection. This method, which resembled optical navigation on a physical body, provided continuous guidance of the dissection. The PSI was placed on the bone in a position considered sufficiently stable and similar to that planned on the bone models. K-wires were then inserted into the holders to temporarily secure the PSI to the bone, thereby preventing movements of the PSI during use of the saw. An oscillating saw was then applied to perform the PSI-guided bone cuts. The same procedure was followed to contour the allograft, which was thus matched to the bony defect. Internal fixation was performed using standard techniques (e.g., plate or screw) appropriate for the location of the tumour (Fig. 6).

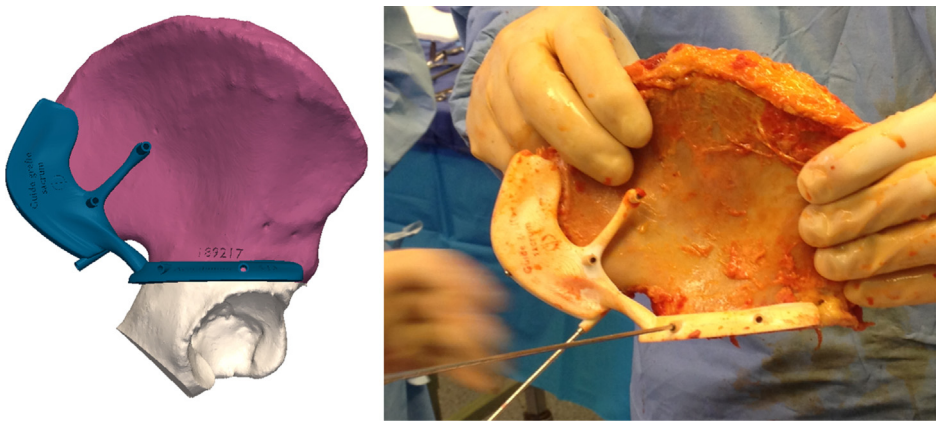

**Fig. 4.** Same patient as in Fig. 1: patient-specific instrument designed to contour the allograft. Virtual simulation of the cutting guide positioned on the allograft (left) and intraoperative view of the contoured allograft (right).

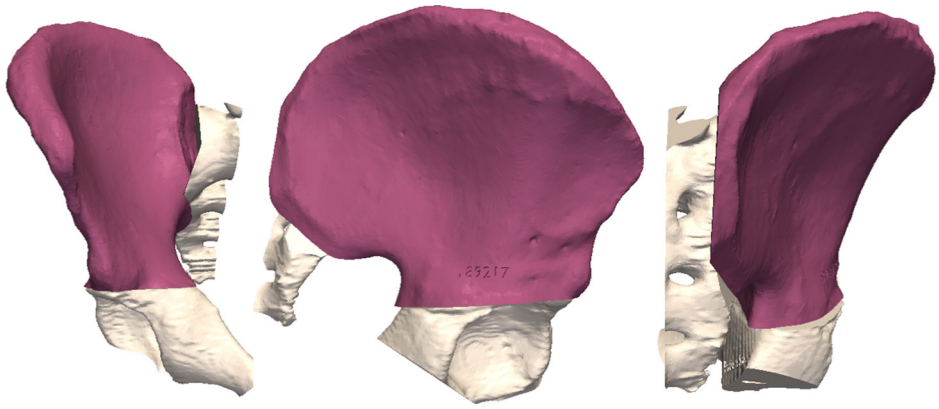

**Fig. 5.** Same patient as in Fig. 1: simulation of the reconstruction, anterior, lateral, and posterior views. The allograft (in purple) is inserted into the bony defect created by the resection of the tumour.

### 2.3. Assessment methods

#### 2.3.1. Assessments in the cases

The tumour resection specimens were sent to the laboratory for histopathological studies. A system derived from the UICC R0, R1, R2 classification was used to categorise the resection margins [17]. R0 resection was defined as a margin of healthy tissue of at least 1mm all around the tumour. R1 (marginal) resection was defined as up to 1mm of healthy tissue around the tumour. R2 resection was defined as resection within the tumour, with no margin of healthy tissue. The bony margins and soft-tissue margins were classified separately.

The local recurrence rate was assessed at last follow-up; mean follow-up was 2.5 years. Finally, the operative time was measured.

#### 2.3.2. Historical controls

The data obtained in the 9 cases were compared to those in a historical control group of 19 patients who had had primary pelvic sarcoma resection without navigation in our department. The outcomes in this group were reported in 2007 [3]. In all, 24 pelvic malignancies were resected, but only 19 of these were primary tumours. The case and control groups were similar for follow-up duration, age, and sex distribution (Table 2). The local recurrence rate, operative time, and survival at last follow-up were compared between the two groups.

### 2.4. Statistical methods

Patient age, operative time, and postoperative follow-up duration were compared between the cases and controls by applying the Mann–Whitney test. The $Chi^2$ test was chosen to compare sex distribution, resection margins, local recurrence rates, and survival rates. All statistical tests were done using SPSS v.20 software (IBM, Armonk, NY, USA).

## 3. Results

### 3.1. Local recurrence rate in the cases and controls

Of the 9 cases, 6 were alive and disease-free after a mean follow-up of 52 months (range, 30–90 months). The other 3 patients died after metastatic dissemination to the lungs, remote bone sites, or both, respectively; postoperative survival in these 3 patients was 50 months, 9 months, and 23 months, respectively.

None of the 9 cases experienced local tumour recurrences in the bone or soft tissues. In the historical control group, 7 of the 19 patients experienced local recurrence; times to recurrence were less than 1 year in 3 patients, 1 to 2 years in 2 patients, 31 months in 1 patient, and 62 months in 1 patient. The local recurrence rate was significantly lower in the cases than in the controls ($p = 0.035$). Of the 19 controls, 6 were alive and disease-free at last follow-up. Survival was non-significantly better in the cases than in the controls ($p = 0.08$) (Table 2).

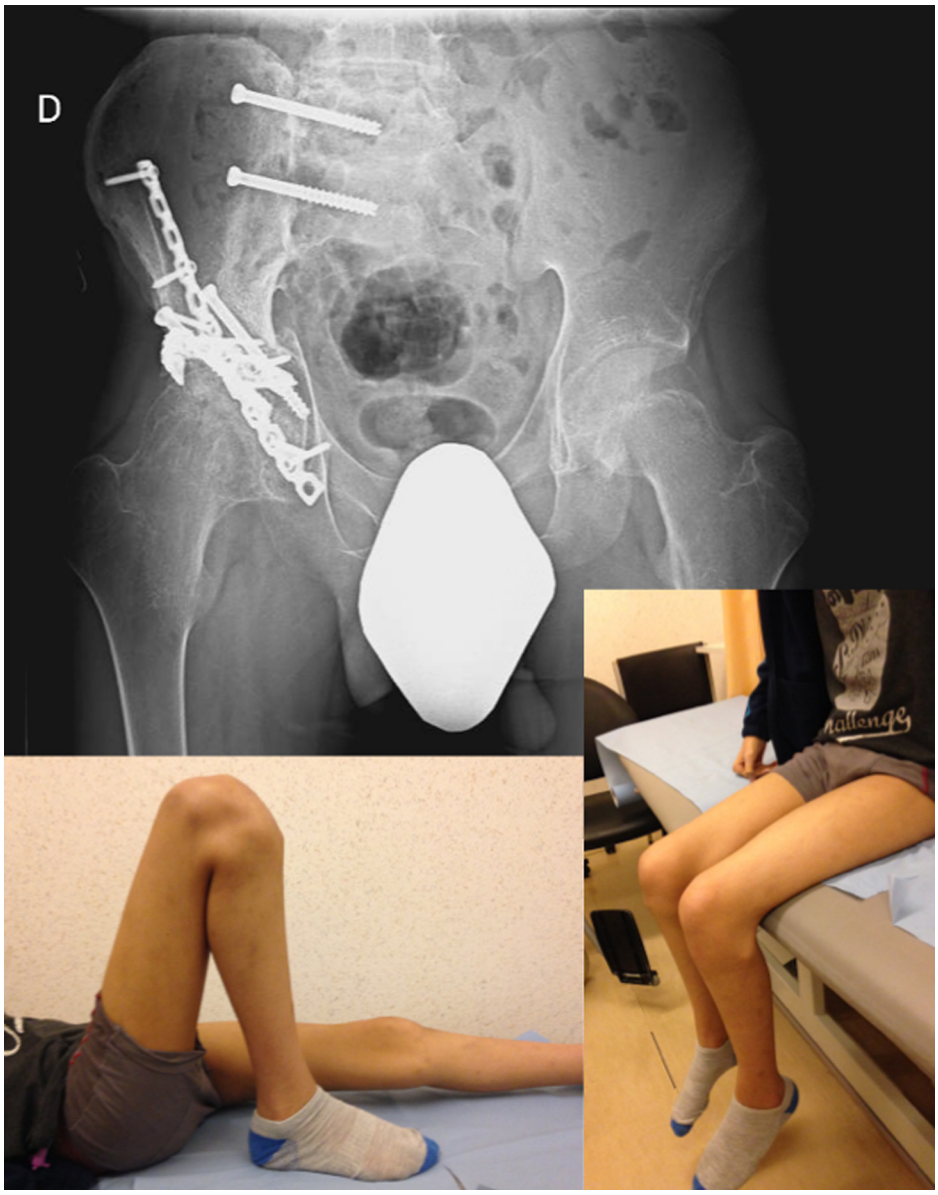


**Fig. 6.** Same patient as in Fig. 1: reconstruction. Radiograph taken 2 years and 8 months after surgery and functional outcome 3 years after surgery.

**Table 2**
Comparison of the 9 patients managed with patient-specific instruments (cases) and of the 19 historical controls.

| | 9 cases | 19 historical controls | *p*-value |
|---|---|---|---|
| Age, years, mean (range) | 39 (11–63) | 29 (8–76) | 0.362 |
| Males/Females | 5/4 | 13/6 | 0.507 |
| Resection margins [17] | *N* = 9 | *N* = 19 | |
| *Bone* | | | |
| R0 | 8 | 13 | 0.479 |
| R1 | 1 (planned R1) | 5 | |
| R2 | 0 | 1 | |
| *Soft tissues* | | | |
| R0 | 9 | | |
| R1 | 0 | | |
| R2 | 0 | | |
| Follow-up, months, mean (range) | 52 (30–90) | 62 (24–134) | 0.873 |
| Local recurrences | 0/9 | 7/19 | 0.035 |
| *Survival* | | | |
| Alive and disease-free | 6/9 | 6/19 | 0.08 |
| Died from the malignancy | 3/9 | 13/19 | 0.08 |
| Operative time, minutes, mean (range) | 612 (435–854) | 633 (420–990) | 0.877 |

### 3.2. Resection margins in the cases and controls

Bone resection margins were R0 in 8 cases and R1 in 1 case. The R1 resection was planned in order to spare an S1 nerve root. Soft-tissue resection margins were R0 in all 9 cases. Of the 19 controls, 5 had R1 margins and 1 had R2 margins; of these 6 patients, 3 developed local recurrences, after 9, 9, and 3 months, respectively; 2 died with metastatic disease; and only 1 was alive at last follow-up (Table 2).

### 3.3. Operative time in the cases and controls

Mean operative time was measured from the skin incision to the end of wound closure. In the cases, mean operative time was 612 minutes (range, 435–854 minutes) (Table 2), which was not significantly different from the value in the historical controls (633 minutes; range, 420–990 minutes; $p = 0.877$).

### 3.4. Allograft cutting in the cases

In the 7 patients who underwent pelvic allograft reconstruction, allograft contact within the bony defect and allograft stability after internal fixation were deemed satisfactory by the surgeon.

### 3.5. Postoperative complications

Postoperative complications occurred in 2 of the 9 cases and consisted of infections ($n = 2$) and radiation-induced avascular necrosis of the femoral head ($n = 1$).

## 4. Discussion

The use of PSIs has been described in detail for various procedures including arthroplasties, osteotomies, and tumour resection. This work supplies new data on the medium-term (at least 2.5 years) local recurrence rate in 9 consecutive patients who underwent PSI-guided resection of primary pelvic sarcomas. When no guiding system is used, these tumours are associated with high local recurrence rates of 28% to 35% [3,7,12]. Similarly, of our 19 historical controls, 7 (39%) experienced local recurrences (Table 2). None of the patients managed with PSI-guided resection subsequently had local tumour recurrences within the bone. In addition, although the use of a PSI has no direct impact on the soft-tissue resection, no local soft-tissue recurrences were observed. These data demonstrate that use of a PSI significantly decreases the medium-term local recurrence rate. To our knowledge, this is the first study to provide information on the medium-term local recurrence rate after PSI-guided sarcoma resection. Local recurrences usually occur within 3 years after surgery and become extremely uncommon after 5 years [18,19]. The local recurrences seen in our historical controls were diagnosed 21 months postoperatively on average, with a range of 9 to 62 months. A direct correlation exists between the survival rate and the local recurrence rate. In a retrospective study of 59 patients with pelvic chondrosarcoma, Deloin et al. [18] found that suboptimal margins were associated with a higher risk of local recurrence. Sabourin et al. [2] showed that local recurrence carried a very grim prognosis. Nevertheless, local recurrence is a multifactorial event that is dependent not only on the accuracy of the resection, but also on the histological type, grade, size, and location of the tumour and on the response to chemotherapy.

The accuracy of the various surgical resection techniques is a matter of debate. In work by Li et al. [20], the amount of error during free hand resection of tumours in long bones (femur, tibia, fibula, humerus, radius, ulna) was less than 10mm in 69.8% of cases, 10 to 20mm in 26.6% of cases, and more than 20mm in 3.6% of cases. During an experimental study [21], when the goal was to obtain a 10-mm margin around the tumour, free hand resection was within the tumour in 8% of cases. The first methods devised specifically to improve surgical accuracy during pelvic sarcoma resection were CT-based optical navigation systems [8,9,22], which were used successfully in several patients [5]. Soon afterwards, the first PSIs were evaluated then used for tumour resection. Over time, PSIs proved somewhat more accurate than optical navigation systems. PSIs were first evaluated on experimental laboratory models [9]. The results have prompted us to make PSI-guided resection the reference standard technique in our institution. PSIs were subsequently tested on cadaver specimens. In a study comparing a CT-based navigation system to PSIs for resecting peri-acetabular tumours, Wong et al. [11] found that accuracy was similar but that the operative time was shorter with a PSI. A cadaver study by Bosma et al. [12] compared navigation to PSI for resection at the distal femur and proximal tibia and found that the PSI method not only shortened the operative time, but also significantly improved accuracy. A few clinical studies have described experience with the accuracy of PSI-guided tumour resection. Of 4 patients reported by Jentzsch et al. [7], 3 had tumour-free resection margins; the margins were not measurable in the remaining patient because the tumour was removed by curettage. Similarly, of 11 patients studied by Gouin et al. [6], 10 had tumour-free bone margins and 1 had R2 margins due to tumour morselisation. The authors' opinion was that PSIs improved osteotomy accuracy, therefore providing good bone resection margins [6]. Resection accuracy in our study was consistent with these previous reports, indicating that PSIs provide a high degree of resection accuracy that translates into good margins.

The operative time was not shorter in the cases managed using PSIs compared to the historical controls managed with no guidance system. In experimental studies, PSI use was associated with shorter operative times compared to free hand resection and to CT-based optical navigation-assisted resection. Wong et al. [11] found a shorter operative time with PSIs in a cadaver study. This discrepancy may be ascribable to our definition of the operative time as the time from incision to closure as opposed to the time needed to perform the bone cuts.

Using a PSI to guide the allograft cuts improves allograft fit and should therefore benefit the quality of the reconstruction. PSI guidance may well be the only method capable of producing a perfect match between the cuts in the recipient bone and the cuts in the allograft. The close host bone-allograft fit thus obtained would be expected to expedite bone healing while also increasing the healing rate, although proof of such effects cannot be provided by the present study. Alternatives exist for reconstruction, an example being use of the autologous ipsilateral proximal femur as described by Puget, which however requires total hip arthroplasty [23].

The limitations of this study include the retrospective design. However, the very low incidence of primary pelvic bone sarcomas would be a major obstacle to a randomised controlled trial. Also, and importantly, given the evidence that guiding systems improve the surgical success rate, a randomised trial might be ethically unacceptable. The comparison of our patients to a group of historical controls diminished the impact of any bias related to the retrospective design. A second limitation is the heterogeneity in histological tumour types. Given the low incidence of primary pelvic sarcomas, collecting a sufficient number of patients with a single tumour type would be difficult. We consequently elected to confine the study to primary pelvic malignancies, excluding metastases. Finally, costs were not accurately assessed. If not covered by health insurance systems, the cost of PSIs may constitute a limiting factor unless funding can be provided by the hospital or research

organisations. Nevertheless, our findings suggest that the lower local recurrence rate after PSI-guided surgery may translate into cost savings for health insurance systems, since the cost of managing a local recurrence ranges from a few thousand to 50,000€. Thus, the savings achieved by avoiding a single local recurrence would cover the cost of PSIs for several patients. A cost model study would be expected to demonstrate cost savings of sufficient magnitude to convince healthcare authorities that PSI costs should be covered for patients requiring primary bone malignancy resection.

## 5. Conclusion

This retrospective study demonstrated that using PSIs for primary pelvic bone sarcoma resection ensures that good resection margins are achieved, thus considerably decreasing the risk of local bone recurrence. However, the use of PSIs has no effect on soft-tissue margins.

## Disclosure of interest

Laurent Paul is a co-founder and co-CEO of 3D-Side, which manufactured the patient-specific instruments used for the study.

The other authors declare that they have no competing interest.

## Funding

The non-profit organisation *Fondation contre le Cancer* provided the funding needed to obtain the patient-specific instruments for all 9 cases included in the study.

## Contributions

Robin Evrard retrospectively reviewed the files of all the study participants, contributed to collect the study data, and contributed to draft the manuscript.

Pierre-Louis Docquier contributed to conceive and design the study, performed the surgical procedures in some of the patients, and contributed to draft the manuscript.

Thomas Schubert performed the surgical procedures in some of the patients, and contributed to draft the manuscript.

Laurent Paul contributed to conceive and design the study, designed and manufactured all the patient-specific instruments, and contributed to draft the manuscript.

## Appendix A. Supplementary data

Supplementary data associated with this article can be found, in the online version, at doi:10.1016/j.otsr.2018.12.016.

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