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Reinforced cementoplasty for pelvic tumour lesions and pelvic traumatic fractures: preliminary experience

Amira Al Raaisi¹ · Kévin Premat¹ · Evelyne Cormier¹ · Eimad Shotar¹ · Mehdi Drir² · Véronique Morel³ · Jean-Philippe Spano^{4,5} · Hugues Pascal-Mousselard^{4,6} · Laetitia Morardet⁵ · Frédéric Clarençon^{1,4} · Jacques Chiras⁷

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Abstract

Objectives Pelvic bone pathological lesions and traumatic fractures are a considerable source of pain and disability. In this study, we sought to evaluate the effectiveness of reinforced cementoplasty (RC) in painful and unstable lesions involving the pelvic bone in terms of pain relief and functional recovery.

Methods All patients with neoplastic lesion or pelvic fracture for whom a pelvic bone RC was carried out between November 2013 and October 2017 were included in our study. All patients who failed the medical management, patients unsuitable for surgery, and patients with unstable osteolytic lesions were eligible to RC. Clinical outcome was evaluated with a 1-month and 6-month post-procedure follow-up. The primary endpoint was local pain relief measured by the visual analogue scale (VAS).

Results Twenty-two patients (18 females, 4 males; mean age of 65.4 ± 13.3 years [range 38–80]) presenting with painful and unstable pelvic lesions were treated by RC during the study period. Among the 22 patients, 8 patients presented with unstable pelvic fractures (3 patients with iliac crest fracture, 3 with sacral fractures, and the remaining 2 with peri-acetabular fractures). No procedure-related complications were recorded. All patients had significant pain relief and functional improvement at 1 month. One patient (4.5%) had suffered a secondary fracture due to local tumour progression.

Conclusions Reinforced cementoplasty is an original minimally invasive technique that may help in providing pain relief and effective bone stability for neoplastic and traumatic lesions involving the pelvic bone.

Key Points

- Reinforced cementoplasty is feasible in both traumatic fractures and tumoural bone lesions of the pelvis.
- Reinforced cementoplasty for pelvic bone lesions provides pain relief and functional recovery.
- Recurrence of pelvic bone fracture was observed in 4.5% of the cases in our series.

Keywords Neoplasms · Pelvic bones · Sacrum · Cementoplasty

✉ Frédéric Clarençon
fredclare5@gmail.com

¹ Department of Neuroradiology, Pitié-Salpêtrière Hospital, APHP, Sorbonne University, 47, Bd de l'Hôpital, 75013 Paris, France

² Department of Anesthesiology, Pitié-Salpêtrière Hospital, APHP, Sorbonne University, Paris, France

³ Department of Hematology, Pitié-Salpêtrière Hospital, APHP, Sorbonne University, Paris, France

⁴ Paris VI University, Sorbonne University, Paris, France

⁵ Department of Oncology, Pitié-Salpêtrière Hospital, APHP, Sorbonne University, Paris, France

⁶ Department of Orthopedic Surgery, Pitié-Salpêtrière Hospital, APHP, Sorbonne University, Paris, France

⁷ Clinique Bizet, Paris, France

Abbreviations

AP	Anteroposterior
CTCAE	Common Terminology Criteria for Adverse Events
ECOG	Eastern Cooperative Oncology Group
	Performance Status Scale
IRB	Institutional review board
IV	Intravenous
PMMA	Polymethyl methacrylate
RC	Reinforced cementoplasty
VAS	Visual analogue scale

Introduction

Pelvic lesions, either tumoural or traumatic, may be extremely painful, disabling, and impair the quality of life [1, 2]. Bone

metastases are frequent findings in patients with advanced cancer; bone is the third location of metastases in terms of frequency [1]. Pathological fractures may occur within either lytic or blastic foci. Approximately 90% of fractures which require surgical intervention occur in the femur, humerus, or peri-acetabular bony region [3]. Reinforced cementoplasty (RC) is a minimally invasive technique that combines the use of dedicated pins inserted percutaneously into the bony lesion via a bone needle, followed by the injection of bone cement. This technique has recently demonstrated its effectiveness in the management of osseous metastasis of the proximal femur [4].

In this study, we aimed to evaluate the effectiveness of RC for the management of painful pelvic pathologic lesions and pelvic fractures with intractable pain. We specifically sought to assess pain relief at 1- and 6-month follow-up, as well as functional recovery and quality of life at 6 months using the Eastern Cooperative Oncology Group (ECOG) Performance Status Scale.

Materials and methods

Study design

This is a monocentric retrospective study. The study was conducted according to the STROBE guidelines [5].

Patient selection

Inclusion criteria were as follows: adult patients (i.e. ≥ 18 years of age) with a painful pathological lesion or a fracture involving the pelvic bone. Exclusion criteria included inappropriateness for the RC procedure due to one of the following reasons: poor general condition, patient's refusal, untreatable coagulation disorder, known allergy to PMMA, current local or systemic signs of infection, and severe cardiopulmonary comorbidities.

Iliac bone involvement was present in nine cases, including 3 iliac wing fractures. Nine patients had sacral lesions including three cases with post-radiotherapy fractures and 6 malignant lesions due to multiple myeloma and metastatic breast cancer. Four lesions involved the acetabulum, two of which were traumatic fractures and the other two were metastatic lesions.

RC was performed as a first-line treatment in 19 (86.4%) of the 22 cases, whereas in the remaining 3 (13.6%) patients, the procedure was performed as a second-line therapy due to insufficient pain relief following percutaneous cementoplasty alone (Fig. 1). Data was retrospectively collected in the medical and computed patients' medical charts. The database was created using an Excel worksheet. All patients' names were anonymized.

Study endpoints

The primary endpoint of the study was the evaluation of the clinical effectiveness in terms of pain relief of RC for pelvic bone lesions. Secondary endpoints were the safety of RC and functional recovery provided by this technique.

Clinical and radiological assessments

All patients had preoperative pain evaluation using a visual analogue scale (VAS), full clinical examination, including the ECOG scale recording.

Patients underwent a non-enhanced computed tomography (CT) scan and magnetic resonance imaging (MRI) prior to the procedure to assess the nature of their lesions (osteolytic, osteoblastic, or mixed), the exact age determination of the bony fractures, and the extension toward the surrounding tissues.

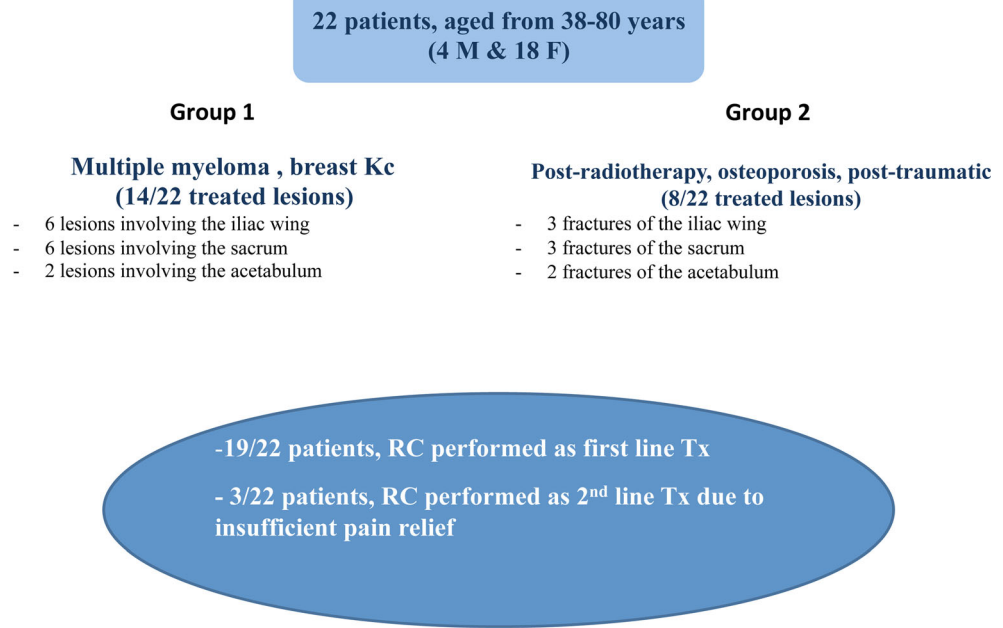
RC procedures

Patients were selected for the procedure by a multidisciplinary team, which included at least an oncologist, a rheumatologist, an orthopaedic surgeon, a radiotherapist, and an interventional radiologist.

All procedures were performed under sterile conditions with strict adherence to aseptic measures. To minimize the risk of infection, prophylactic 1 g intravenous (IV) cefazolin (or other broad-spectrum antibiotics) was administered at the beginning of the procedure in all cases. The procedure was performed under general anaesthesia with a multimodal fluoroscopic and CT guidance in a hybrid angiosuite (Miyabi Emotion 16, Siemens Healthineers) combining a C-arm flat panel and a 16-row CT scan (Somatom Emotion 16 rows, Siemens C).

Patients were treated in prone or supine position, depending on the location of their lesion. For example, sacral and posterior iliac lesions were treated in the prone position; iliac wing and peri-acetabular lesions were treated in the supine position. Lidocaine was used for local anaesthesia of the periosteum in order to reduce the postoperative pain. Eight-gauge (4 mm) bevelled bone needles were inserted under CT and/or fluoroscopic guidance in the target lesion. None of the approaches required any surgical incision; all procedures were performed in a percutaneous fashion. All patients underwent a tissue sample biopsy before RC. Sample biopsy was obtained via the bone needle used for the RC, using a 13G biopsy needle (Thiebaud) under fluoroscopic or CT guidance. Then, the pins were inserted through the bone needle and deployed in order to be anchored distally and proximally in normal bone tissue. The pins used had a 2.5-mm diameter; their lengths varied depending on the size and the location of the lesions to be treated (from 5 to 8 cm). Finally, polymethyl

Fig. 1 Patients' demographics. M, male; F, female; RC, reinforced cementoplasty; Kc, cancer; Tx, treatment



methacrylate (PMMA) bone cement (Biomet V Cement; Biomet) was injected around the pins via the bone needle(s).

All patients had a control non-enhanced CT scan immediately after the procedure to check the position of the pins and to detect any cement leakage or local postoperative haematoma in the soft tissues.

Clinical outcome

Periprocedural complications were systematically assessed. Complications were assessed using the Common Terminology Criteria for Adverse Events v5.0 (CTCAE): 5-point grading scale from the National Cancer Institute (grade 1: asymptomatic or mild symptoms; grade 2: moderate, minimal, local, or non-invasive intervention indicated; grade 3: severe or medically significant but not immediately life threatening; hospitalization or prolongation of hospitalization indicated; grade 4: life-threatening consequences, urgent intervention indicated; grade 5: death).

Clinical outcome was evaluated by the operator who performed the RC at 1- and 6-month post-procedure follow-up. VAS was graded at clinical follow-up. Functional outcome was assessed using the ECOG grading scale before RC procedures, at 1- and 6 months post-RC: (0) Fully active, able to carry on all pre-disease performance without restriction; (1) Restricted in physically strenuous activity but ambulatory and able to carry out work of a light or sedentary nature (e.g. light housework, office work); (2) Ambulatory and capable of all self-care but unable to carry out any work activities. Up and about more than 50% of waking hours; (3) Capable of only limited self-care, confined to bed or chair more than 50% of

waking hours; (4) Completely disabled. Cannot carry on any self-care. Totally confined to bed or chair; (5) Dead.

The occurrence of secondary fractures and post-procedure functional recovery were also assessed during the follow-up period.

Follow-up CT and/or MRI were performed depending on the patients' symptoms. At follow-up, additional imaging (CT and/or MRI) was undertaken if the patient did not experience pain relief or if the patient had a pain recurrence.

Since biomechanical differences exist between bone insufficiency caused by lytic lesions and osteoporosis, patients were divided into 2 groups: "group 1: tumour lesions" and "group 2: traumatic/osteoporotic lesions".

Statistical analysis

Comparison between pre-treatment VAS, 1 month VAS, and 6 month VAS was performed using a Student *T*-test or a Wilcoxon test, depending on the data's distribution, with the Stata software (Stata/IC 13.1 for Mac; StataCorp LP); *p* values less than 0.05 were considered statistically significant.

Ethical statement

The study protocol was approved by our local institutional review board (IRB) (IRB approval #: HH 1 4 21a) All patients had a pre-treatment consultation and gave oral consent for the intervention. Patient informed consent was waived by our local IRB for retrospective analyses of patients' records and imaging data.

Results

Patients' demographics

Patients' demographics are summarized in Fig. 1. From November 2013 to October 2017, 22 RC procedures were performed in our institution for 22 consecutive patients (18 females [81%], 4 males [18%]; mean age of 65.4 years, range 38–80), for either painful pelvic tumour lesions (group 1, $n = 14$; 63.6%) or painful and/or unstable fractures (group 2, $n = 8$; 26.4%) refractory to medical therapy (Tables 1, 2, 3, and 4).

In group 1, 3 patients (21.4%) had a history of breast cancer (Fig. 2), 5 patients (35.7%) had multiple myeloma, 3 patients (21.4%) with lung cancer, one patient (7%) with prostatic cancer, one patient (7%) with thyroid cancer, and one patient (7%) with renal carcinoma.

In group 2, 2 patients (25%) had a metastatic breast cancer, 2 patients (25%) had post-traumatic osteoporotic fractures (Fig. 3), 3 patients (37.5%) had a post-radiotherapy fracture in a multiple myeloma, and one patient (12.5%) presented with a metastatic prostatic cancer.

Regarding the location of the bone lesions, for group 1, 6 patients (42.8%) had iliac bone lesions, 6 patients (42.8%) with sacrum lesions, and 2 patients (14.2%) with peri-acetabular lesions. For Group 2, 3 patients (37.5%) had iliac bone fracture, 3 patients (37.5%) a sacrum fracture, and 2 patients (25%) a peri-acetabular fracture.

RC was performed as a first-line treatment in 19 of the cases, whereas in the remaining 3 patients, who presented initially with smaller lesions that were treated by percutaneous cementoplasty, the progression of their primary condition

made the percutaneous cementoplasty insufficient due to pain recurrence and/or risk fracture. The RC was thus performed as a second-line therapy (Fig. 1).

Pain relief

One-month pain evaluation was available for all patients. Pain improvement was observed at 1-month follow-up in all patients. Sixteen out of twenty-two patients (72.7%) had significant pain improvement (major improvement with a remaining VAS $\leq 5/10$), while the 6 remaining patients only had minor improvements (VAS $\geq 6/10$). No worsening of VAS at 1-month follow-up was recorded. At 6 months, 6 patients (27%) were pain free, 7 patients (31.8%) had further improved, 5 patients (22.7%) were unchanged, 2 patients (9%) were lost to follow-up, and 2 patients (9%) died because of disease progression.

In group 1, mean VAS decreased from 7.8 ± 1.8 at pre-treatment evaluation to 3.3 ± 2.6 at 1 month ($p < 0.05$) and remained stable at 6 months (3.3 ± 2.6 vs 2.4 ± 2.5 ; $p = 0.06$).

In group 2, mean VAS decreased from 9 ± 1.1 at pre-treatment evaluation to 4.9 ± 2.1 at 1 month ($p < 0.05$) and continued to decrease until 6 months (4.9 ± 2.1 to 1.8 ± 2.4 ; $p < 0.05$).

Safety/procedure-related complications

No major procedure-related complication was recorded, such as pulmonary embolism due to cement leakage or infection. Two patients presented with minor local haematomas that did not require surgical treatment or blood transfusion (grade 2 complications in the CTCAE grading

Table 1 Group 1 (patients with tumour lesions)

Patient no.	Gender	Age (y)	Site of lesion	Past medical history/underlying disease
1	F	55	Acetabulum	Breast cancer
2	F	79	Iliac wing	Lung cancer
3	F	63	Iliac wing	Multiple myeloma
4	F	48	Sacrum	Thyroid cancer
5	F	69	Sacrum	Multiple myeloma
6	M	50	Sacrum	Renal cancer
7	F	45	Iliac wing	Breast cancer
8	F	77	Sacrum	Lung cancer
9	F	60	Iliac wing	Multiple myeloma
10	M	80	Sacrum	Prostate cancer
11	F	49	Acetabulum	Breast cancer
12	F	74	Iliac wing	Multiple myeloma
13	F	67	Sacrum	Lung cancer
14	F	71	Iliac wing	Multiple myeloma

F indicates female, M male, y years

Table 2 Group 2 (patients presenting with fractures)

Patient no.	Gender	Age (y)	Site of fracture	Past medical history/underlying disease
1	F	37	Sacrum	Breast cancer
2	F	74	Acetabulum	Post-traumatic
3	F	80	Sacrum	Multiple myeloma, Post-radiotherapy
4	M	79	Iliac wing	Multiple myeloma
5	F	69	Sacrum	Breast cancer
6	M	56	Iliac wing	Prostate cancer
7	F	80	Acetabulum	Multiple myeloma, Post-radiotherapy
8	F	76	Iliac wing	Post-traumatic

F indicates female, *M* male, *y* years

scale). Five patients had worsening pain at day 1 postoperatively, with higher score on the VAS, which subsequently improved gradually.

Functional outcome

Functional outcome and quality of life were assessed using the ECOG Performance Status Scale. At 1-month post-RC, 11 patients (50%) had improved their ECOG score from initial score (from ECOG 3 before RC to ECOG 1) and were fully autonomous at 6 months follow-up. Seven patients (31.8%) with ECOG 2 before RC remained stable at 1 month and improved to ECOG 1 at 6-month follow-up. Two patients (9%) were lost to the follow-up. Finally, 2 patients (9%) had worsening of their clinical status because of tumour

progression, with initial ECOG scoring of 4 before RC and died before 1-month clinical follow-up (Table 5).

Bone stabilization

No additional surgical fixation was required except for one case (4.5%) during the follow-up period. Indeed, one secondary fracture was detected during the follow-up period, due to primary disease progression (patient#7 in group 2) depicted on imaging (CT scan and MRI); surgical fixation was required in this case.

Discussion

This retrospective study of 22 patients suggests that RC for metastatic and traumatic lesions of the pelvic bone is a safe and effective procedure, with no major complications. Pain relief (either partial or complete) was obtained in all the cases in this series. One patient (4.5%) presented with secondary

Table 3 Preoperative visual analogue scale (VAS), VAS at 1 month, and at 6 months post-procedure for the patients with tumour lesions

Patient no.	VAS pre-procedure	VAS at 1 month	VAS at 6 months
1	8/10	2/10	2/10
2	10/10	NA	NA
3	6/10	5/10	5/10
4	9/10	6/10	0/10
5	5/10	2/10	1/10
6	7/10	1/10	0/10
7	9/10	4/10	2/10
8	10/10	NA	NA
9	6/10	0/10	6/10
10	8/10	5/10	5/10
11	10/10	7/10	2/10
12	7/10	1/10	1/10
13	5/10	0/10	0/10
14	9/10	2/10	1/10

VAS indicates visual analogue scale, NA not available

Table 4 VAS pre-op, VAS at 1 month, and VAS at 6 months post-procedure for the patients with fractures

Patient no.	VAS pre-procedure	VAS at 1 month	VAS at 6 months
1	9/10	5/10	2/10
2	10/10	6/10	0/10
3	9/10	NA	NA
4	8/10	3/10	3/10
5	10/10	8/10	6/10
6	7/10	2/10	0/10
7	10/10	7/10	NA
8	9/10	3/10	0/10

VAS indicates visual analogue scale, NA not available

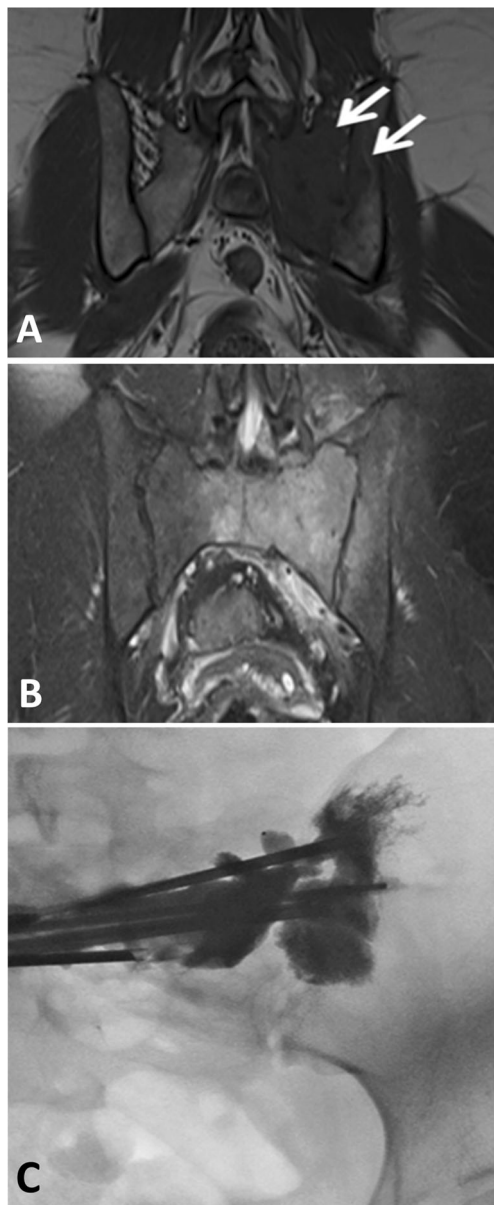


Fig. 2 A 38-year-old female with end-stage breast cancer presenting with voluminous osteolytic lesion invading the sacrum and the left sacral wing. Preoperative magnetic resonance imaging (MRI): **A** and **B**. Coronal MRI acquisitions showing hypo-intense signal related to bony metastases involving the sacrum and left sacral wing on T1-weighted image (WI) (**A**, arrows), with a hyperintense signal on T2-WI (**B**) and faint contrast enhancement after gadolinium injection (not presented). **C** Postoperative anteroposterior (AP) fluoroscopic view after RC procedure, showing a complete filling of the lesion with the cement, surrounding the pins. No secondary fracture occurred during the follow-up period

fracture due to disease progression and required surgical stabilization.

Pathological fractures of the pelvic bone may have significant consequences in this fragile population [6]. Avoiding these complications is one of the major objectives of the management of metastatic bone disease. When a pathologic fracture occurs, it significantly hinders the prognosis, and it is

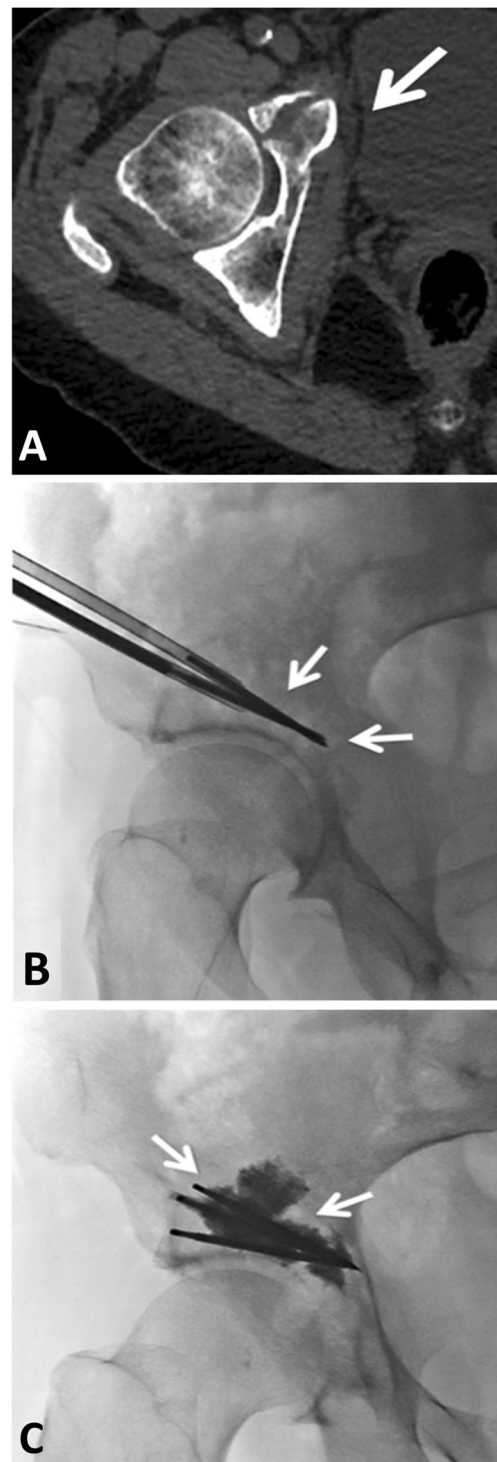


Fig. 3 A 74-year-old female presenting with post-traumatic right acetabulum fracture after a fall at ski. **A** Unenhanced CT scan, axial slice showing a non-displaced right acetabular fracture (arrow). **B** Intraoperative anteroposterior (AP) fluoroscopic view showing the pins' positioning through the fracture (arrows). **C** Control X-ray after cement injection in AP projection showing satisfactory distribution of the cement around the pins. No secondary fracture occurred during the follow-up period in this patient

Table 5 Baseline Eastern Cooperative Oncology Group (ECOG) Performance Status Scale, ECOG at 1 month, and ECOG at 6 months post-procedure

Patient	Baseline ECOG	ECOG at 1 month	ECOG at 6 months
1	3	1	0
2	3	1	0
3	3	2	---
4	3	1	0
5	2	2	1
6	3	1	0
7	2	2	-----
8	3	1	0
9	2	2	1
10	2	2	1
11	2	2	1
12	3	1	0
13	3	1	0
14	3	1	0
15	2	2	1
16	4	3	---
17	4	4	---
18	2	2	1
19	2	2	1
20	3	1	0
21	3	1	0
22	3	1	0

usually associated with debilitating pain that could be relieved through bone stabilization. Open surgery entails high risks due to poor condition of the underlying bone and an increased risk of perioperative complications (infections, haematomas, and bedsores complications) [7–9]. It also requires interrupting other anti-cancerous therapies to allow proper wound healing, which can promote the overall progression of the disease. Therefore, percutaneous techniques such as cementoplasty and RC could be of great use in these cases. Previous studies have suggested that cementoplasty and percutaneous osteosynthesis were safe and efficient techniques that could provide both pain relief and satisfactory bone stability in pathologic fractures [4, 10–12].

Ideally, treating teams would prefer preventing such fractures. As such, lytic lesions of the pelvic bone, especially in weight-bearing location, may also be good indications for percutaneous treatment [12–15]. Nevertheless, the main factors to consider when deciding between treatment options of bone metastases are the level of pain and disability. Indeed, severe dysfunction or pain requires a treatment that can predictably lead to a quick resumption of the pain. Minimally invasive interventions may arguably be the options of choice in these cases.

Lately, these techniques have been expanded to bone insufficiency as well as high-energy traumatic fractures of the pelvic bone, also with promising results [16, 17]. Although open surgery remains the technique of choice, which provides the best structural stability, it is associated with significant morbidity, heavy blood loss, and prolonged hospital stays, making it unsuitable for fragile patients [7, 8, 18]. Thus, nowadays indications are mostly reserved for high kinetic traumatic conditions responsible for unstable and/or displaced fractures of the pelvic ring [19].

When undergoing interventional procedures of the pelvic bone, one must be aware of the biomechanical properties of this complex osseous structure. It is of great importance to identify situations where cementoplasty alone can be sufficient from situations where additional osteosynthesis must be associated to provide the best needed stability [20]. Biomechanical studies of the pelvic bone have shown that the sacral promontory and the peri-acetabular region are the most constrained portions of the pelvis. They are critical for the overall stability and are mainly submitted to compressive stresses. For other localizations, the risk of mechanical failure can be considered as much lower [21]. Thus, PMMA cement appears as an interesting tool due to its excellent resistance to compression forces [22]. Additionally, its heat of polymerization and the direct toxic effect of monomers could be a mechanism of adjacent cellular toxicity. A temperature between 42 and 47 °C is sufficient to destroy gonadal, embryonic, blood cartilaginous, and neoplastic cells. Chamley et al had demonstrated that an acrylic cement mass of the size of a golf ball could reach the temperature of 90 °C [23]. However, as it lacks in shear forces' resistance, it sometimes needs to be reinforced by combining it to a spindling or an osteosynthesis. Although these two techniques have never been compared, RC could be beneficial for large lesions with cortical involvement or for displaced pathologic fractures. In this study, we also noted a marked efficacy of RC in pathologic fractures (either impending or completed) of the pelvis but also in insufficiency fractures. This technique, allowing for bone stabilization, may also be a promising tool for traumatic or osteoporotic fractures. Lesions involving the sacroiliac joint-sciatic buttress-acetabular axis may also be suitable for RC since they are not only exposed to compression, but also to shearing and, to a lesser extent, torsion forces. Those results seemed quite comparable to other series focusing on percutaneous osteosynthesis [11, 12, 14, 24]. The main advantage of RC over percutaneous osteosynthesis is its ability to implant several pins through one transcortical access, thus limiting the risk of haematomas and tumour seeding. The major drawbacks include the difficulty to remove a pin once it has been implanted; thus, the initial ballistic is critical and ideally should be assisted by navigating systems [25]. Secondly, the pins trapped in a PMMA cast are likely to hamper a rescue surgery if needed.

The goals of all interventional therapies are primarily pain control and osseous stabilization. However, local control of the disease can rarely be achieved alone. In this series, we noted that one patient suffered from a delayed secondary fracture, due to local progression, which is a common occurrence, even after standard surgery [26]. Therefore, ablation techniques [27] and/or radiation therapy are nowadays commonly employed to limit the local progression [6].

No severe complication was recorded in our series. However, several complications may potentially occur after RC or percutaneous osteosynthesis, like local infection, soft tissue haematoma, or spin malposition.

Limitations

The main limitation of this study is its retrospective and monocentre fashion of data collection. We managed to include only 22 patients treated with this strategy within 5 years, with a significant number of patients lost to the follow-up at 6 months. Additionally, the lesions treated in our series were heterogeneous, including tumour lesions from various origin, haematological malignancies, and traumatic fractures. Finally, this series lacks a comparison with the instrumented orthopaedic surgery, which remains the criterion standard for bone stabilization. However, this study adds to the body of the literature regarding the benefit of minimally invasive techniques and is the first to emphasize this original percutaneous technique.

Conclusions

Reinforced cementoplasty is an original minimally invasive technique that seems to help in providing pain relief by allowing effective bone stability for completed or impending pathologic fractures of the pelvic bone. It may also be implemented into the range of treatment options of bone insufficiency fractures as well as painful metastatic bone lesions.

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Pr F. Clarençon reports conflict of interest with Medtronic, Guerbet, Balt Extrusion, Penumbra (cor lab; non-related to the study), Codman Neurovascular, and MicroVention (core lab; non-related to the study).

Statistics and biometry One of the authors has significant statistical expertise.

Informed consent Written informed consent was waived by the institutional review board.

Ethical approval Institutional review board approval was obtained.

Methodology

- Retrospective
- Observational
- Performed at one institution

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