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Initial experience, feasibility, and technical development with an electromagnetic navigation assistance in percutaneous pelvic bone cementoplasty: retrospective analysis

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Abstract

Objectives To assess the feasibility and technical outcomes of pelvic bone cementoplasty using an electromagnetic navigation system (EMNS) in standard practice.

Materials and methods Monocentric retrospective study of all consecutive patients treated with cementoplasty or reinforced cementoplasty of the pelvic bone with EMNS-assisted procedures. The endpoints were periprocedural adverse events, needle repositioning rates, procedure duration, and radiation exposure.

Results A detailed description of the technical steps is provided. Thirty-three patients (68 years ± 10) were treated between February 2016 and February 2020. Needle repositioning was required for 1/33 patients (3%). The main minor technical adverse event was soft tissue PMMA cement leaks. No major adverse event was noted. The median number of CT acquisitions throughout the procedures was 4 (range: 2 to 8). Radiation exposure and mean procedure duration are provided.

Conclusion Electromagnetic navigation system–assisted percutaneous interventions for the pelvic bone are feasible and lead to low rates of minor technical adverse events and needle repositioning. Procedure duration and radiation exposure were low.

Key Points

- Initial experience for 33 patients treated with an electromagnetic navigation assistance for pelvic cementoplasty shows feasibility and safety.
- The use of an electromagnetic navigation system does not expose to high procedure duration or radiation exposure.
- The system is efficient in assisting the radiologist for extra-axial planes in challenging approaches.

Keywords Cementoplasty · Osteoporosis · Fractures · Pelvic bones

Abbreviations

CBCT	Cone-beam CT	ED	Effective dose
CT	Computed tomography	EMNS	Electromagnetic navigation system
DAP	Dose-area product	FICS	Fixation by internal cemented screw
DLP	Dose-length product	MBD	Metastatic bone disease
		MRI	Magnetic resonance imaging

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PC	Percutaneous cementoplasty
PMMA	Poly-methyl-methacrylate
RC	Reinforced cementoplasty

Introduction

The pelvis is the second most common site of metastatic bone disease (MBD) after the spine [1] and is a frequent site for osteoporotic fractures. Both can lead to pain, functional impairment, and subsequent increased morbidity and mortality. Focal therapies include radiotherapy, surgery, and image-guided interventions. While radiation therapy is effective for treating bone-lesion-related pain in more than 60% of the cases [2], it does not enable bone consolidation nor prevents secondary fractures. Surgical solutions, such as open approaches, are extensive and can be especially challenging for weight-bearing regions such as the periacetabular area [3, 4]. Similarly, sacral insufficiency fractures are rarely accessible to surgical treatment and the patient's general condition may constitute a limiting factor for such interventions.

As an alternative, interventional radiologists are now treating patients suffering from pelvic bone fractures or impending secondary fractures with percutaneous cementoplasty-based techniques. These techniques include standard cementoplasty, fixation by internal cemented screw (FICS) [5] and reinforced cementoplasty (RC, percutaneous internal fixation using dedicated spindles combined with cementoplasty) [6]. They were developed for pain relief and bone stabilization, and are feasible under computed tomography (CT) or cone-beam CT (CBCT) guidance with comparable results [5, 7, 8]. CT-based guidance is more easily used for trajectories within an axial or near-axial plane, whereas CBCT permits three-dimensional trajectories up to extensive C-arms angulations. However, extreme craniocaudal angulations are not easily feasible using either technology.

Optimal consolidative treatment relies on a thorough understanding of the biomechanics of the pelvis; it requires tailored pre-treatment planification that should try to mimic the physiological pelvic stability [4]. These prerequisites pave the way for innovative technology that could permit working with projections that were previously considered difficult or impossible to reach. The conventional axial plane is inadequate for the curved shape of the sacral bone or the oblique distributions of the biomechanics constraints around the periacetabular area; inappropriate techniques could result in the use of multiple needles to fully cover the lesion, in increased risk of cement leakage or in inadequate screw or spindle fixation.

Difficult trajectories can theoretically be conceived with navigation assisting tools. The use of an electromagnetic navigation system (EMNS) has been documented for CT-guided percutaneous interventions [9–11]. However, no study on pelvic bone cementoplasty using EMNS has been

published so far, a setting where such system might broaden the scope of percutaneous approaches.

The aim of this retrospective monocentric study was to assess the feasibility of pelvic bone cementoplasty using EMNS and to assess technical outcomes in terms of cement leakage, procedure duration, and radiation exposure.

Materials and methods

Study population and procedures

All consecutive patients treated with between February 2016 and February 2020 in a single tertiary center were retrospectively included. The study received IRB approval (IRB approval # HJ_24_9_21). Written consent was waived by our IRB. Patients who underwent EMNS-assisted procedures were the study population and patients with conventional procedures were excluded. Clinical and peri-procedural imaging data were systematically retrieved. The flow chart is provided in Fig. 1.

Each procedure was performed following either the recommendation of a multidisciplinary board meeting for patients with bone metastases or a consultation with the operator for patients with bone insufficiency fractures. Interventions were performed by radiologists with an experience in pelvic cementoplasty ranging from 2 years to 20 years.

The interventions were performed using a hybrid angiosuite with a flat C-arm and a 16-row CT-scan (Somatom Emotion 16 rows, Siemens). Patients were treated either under general anesthesia or conscious sedation according to a technique previously described [12]. Briefly, standard cementoplasties were performed with 11-gauge bone needles (Thiebaud) and poly-methyl-methacrylate (PMMA) cement injected under fluoroscopic X-ray guidance.

Reinforced cementoplasty (RC) has been previously described in [6]: it was performed using a 9-gauge bone needle (Thiebaud). 2.5-mm diameter spindles (Thiebaud) with length ranging from 5 to 8 cm were pushed by means of the mandrel into the lesion through the bone needle and PMMA cement was injected under fluoroscopic X-ray guidance (Figs. 2 and 3).

The peri-operative imaging data were reviewed by a radiologist with 5 years of experience. The following information was extracted: underlying etiology, procedure site and type, radiation exposure, and procedure times (from the first CT acquisition to the immediate postoperative control CT). Minor technical adverse events were defined as unintentional per-procedural features without major clinical significance: cement leaks in soft tissue; asymptomatic cement leaks in coxo-femoral joints; spindles in contact with nerve; attempt of spindle removal; minor soft tissue hematoma. Major adverse events were defined as events that required additional therapy or prolonged hospital stay, including post-operative infections. Needle

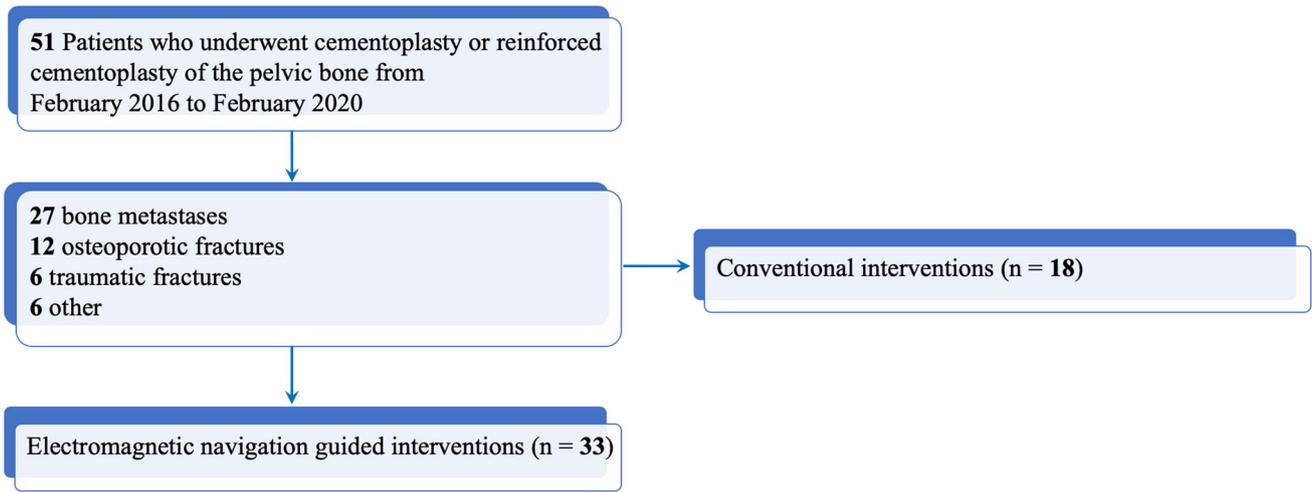


Fig. 1 Flow chart diagram

repositioning was defined by the change in direction of the needle past the cortical layer of the bone. Changes of trajectories outside the bone were not assessed.

Navigated CT-guided procedures

An EMNS (CT-Navigation, Imactis) was used to carry out computer-assisted procedures. The system is composed by three main components: an electromagnetic (EM) emitter, an EM receiver inserted into a needle holder (NH), and a

workstation. The emitter generates a magnetic field of known geometry which is detected by the sensing coils of the receptor. The position and orientation of the NH can be determined in real-time. The workstation's screen displays the expected needle trajectory (i.e., needle inserted along the NH axis and through the NH tip) in two 2D reconstructed CT views (pseudo axial, sagittal or coronal views). The operator can navigate in these images by translating and tilting the NH.

Once the patient is positioned, the emitter is taped near the puncture site. A CT-acquisition of the patient (with the emitter

Fig. 2 A 50-year-old patient presenting hyperalgetic sacral and femoral localizations of a multiple myeloma. She was referred to reinforced cementoplasty. Axial view of the initial CT acquisition (a) shows the target lesion (white arrow) and the initial positioning of the electromagnetic emitter (dotted white arrow). Sagittal view of the per-interventional CT acquisition (b) shows the ascending paramedian insertion of a 11-gauge bone needle. Axial view of the per-interventional CT acquisition (c) shows the positioning of 2.5-mm-large spindles (white arrow) through 9-gauge bone needles (dotted white arrows) positioned with a trans-sacroiliac approach. Axial view of the final CT acquisition (d) shows the cementoplasty results and the 2.5-mm-diameter spindle

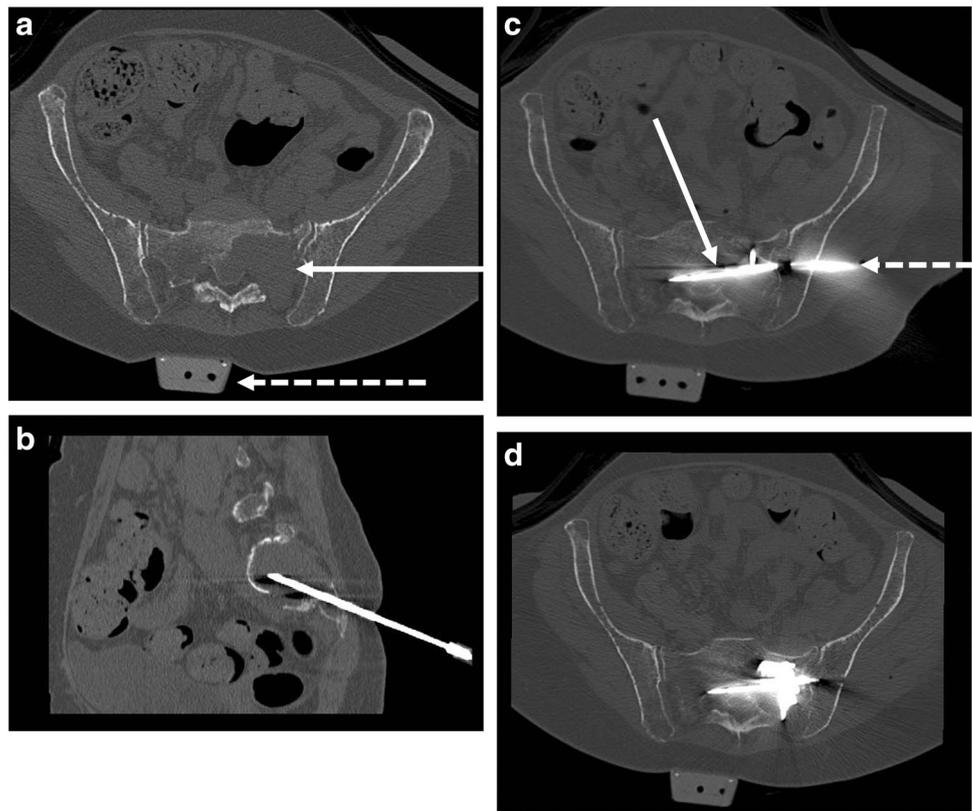
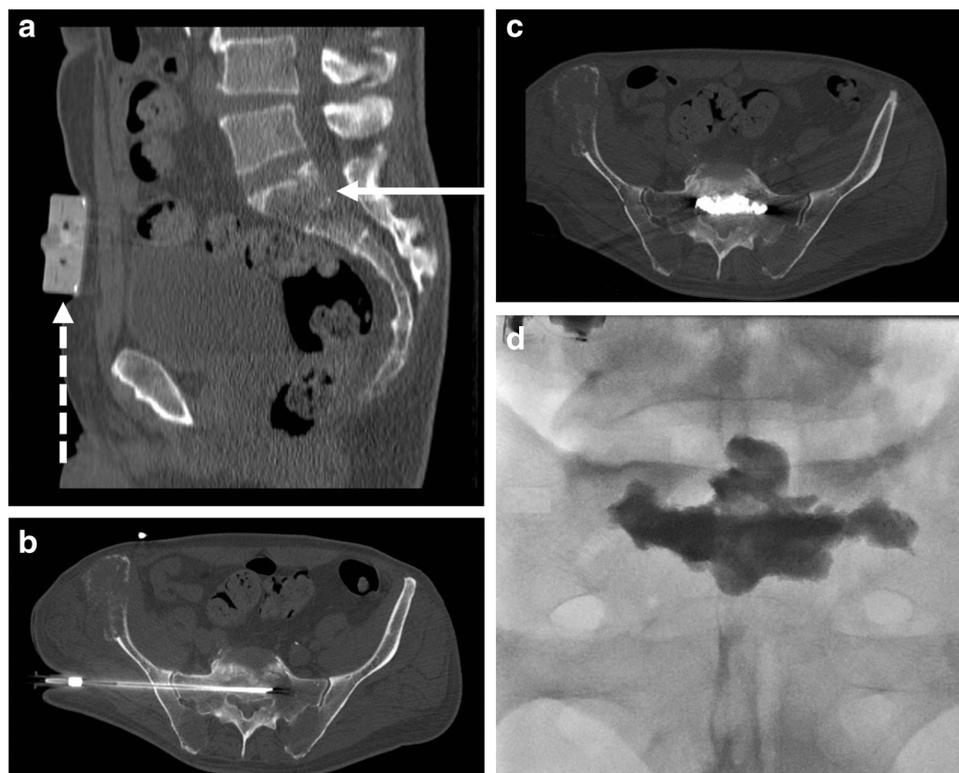


Fig. 3 A 65-year-old patient presenting a hyperalgetic and unstable S1 localization of an undifferentiated adenocarcinoma of unknown origin. He was referred to cementoplasty. Sagittal view of the initial CT acquisition (**a**) shows the target lesion (white arrow) and the initial positioning of the electromagnetic emitter (dotted white arrow). Axial view of the per-interventional CT acquisition (**b**) shows the insertion of a 11-gauge bone needle into the body of S1 with a trans sacroiliac lateral approach. Axial view of the final CT acquisition (**c**) and postero-anterior pelvic view (**d**) show the cemented S1 posterior body



in the field of view) is processed and the set of CT images is transferred to the workstation. The operator can define the desired entry point and trajectory using the needle holder. During pelvic bone cementoplasty, several needles were usually inserted. The operator would first define the expected trajectory directly on the workstation using multi-oblique reconstructions. The needle length (100, 125, or 150 mm) is manually entered into the system in order to produce live virtual images of both the needle trajectory and the advancement into the patient. Each trajectory can be saved into the workstation for future use throughout the intervention, and additional CT acquisitions can be performed if a discrepancy between the virtual image and the real patient position is detected. After switching to a sterile configuration (EM receptor put in a sterile cover and locked in a sterile NH, patient draped in a sterile field), the radiologist can insert the needle according to the previously defined trajectory. Additional CT controls can be acquired to monitor the progression of the needle. The other aspects of the procedure are analogous to the conventional CT-guided procedure. An example is given in Figs. 2, 3, and 4.

Outcomes

The assessment included the rate of minor technical adverse events and major adverse events. A descriptive analysis was also performed for needle repositioning rates, procedure duration, number of CT acquisitions, and radiation exposure

assessed by total effective dose (ED), dose-area product (DAP), and dose-length product (DLP).

Statistical analysis

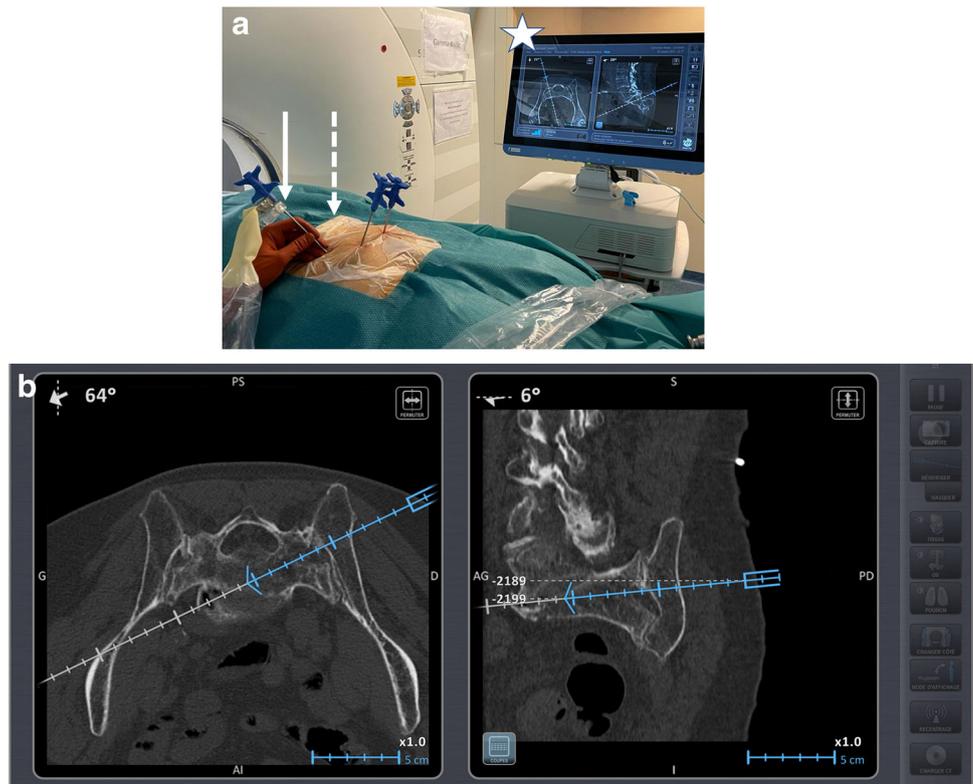
The statistical analysis was carried out using version 4.0.3 of R software. Categorical variables were analyzed with either Fisher or chi-square tests. If considered normally distributed (with a Shapiro-Wilk test), continuous variables were described using mean and standard deviation and were then compared using two-sided *t*-tests. Other variable types were characterized using median as well as first and third quartile and range. They were compared using a Mann-Whitney *U* test. The level of significance was set at 0.05.

Results

Patients

The baseline characteristics of the patient population are given in Table 1. A total of 51 patients were treated with cementoplasty or RC of pelvic bones between February 2016 and February 2020. Thirty-three patients (mean age: 68 years \pm 10; sex ratio M/F: 22/11) were treated using an electromagnetic navigation assistance and included in the study.

Fig. 4 A 85-year-old patient with a history of pelvic radiotherapy and complex pelvic bone fracture. Per-operative photograph (a) of the electromagnetic navigation system with the workstation (white star), the electromagnetic receiver inserted into a needle holder (white arrow), and the electromagnetic emitter (dotted white arrow). Electromagnetic navigation workstation screenshot (b) shows the intended approach along a dorsolateral descending trajectory into the S1 body with a lateral trans sacroiliac trajectory



Patient fractures resulted from the following etiologies: bone insufficiency, tumor metastasis, and trauma. Procedure

Table 1 Baseline characteristics of the patient population

Total population (N = 33)	ENMS navigation
Age (years)	68 ± 10
Sex (M/F)	22/11 (67%/33%)
Etiology	
Bone insufficiency	10/33 (30%)
Metastasis	14/33 (42%)
Traumatic	5/33 (15%)
Other	4/33 (12%)
Procedure site:	
Sacrum	19/33 (58%)
Pubis	3/33 (9%)
Acetabulum	6/33 (18%)
Iliac bone	1/33 (3%)
Femoral neck	1/33 (3%)
Multiple locations	3/33 (9%)
Procedure type:	
Sacroplasty	13/33 (39%)
Other pelvic cementoplasty	11/33 (33%)
Sacral reinforced sacroplasty	7/33 (21%)
Other pelvic reinforced cementoplasty	2/33 (6%)

Quantitative variables are expressed as means ± the standard deviation

sites were as follows: the sacrum, pubis, acetabulum, iliac bone, and femoral neck. The navigation system was used primarily for sacral interventions (in 58% of the cases). Three patients presented with fractures in several locations. Procedure types were as listed: sacroplasty, reinforced sacroplasty, other pelvic cementoplasty, and other pelvic reinforced cementoplasty. Sacroplasty was the main procedure type (in 39% of the cases).

Procedures were performed by radiologists with greater than 10 years of experience in 6% of the procedures.

Adverse events

Needles were successfully positioned and PMMA was injected in the targeted lesions or fractures for all the 33 patients. Needle repositioning was performed for 1/33 patients (3%). The needle was repositioned once for the patient.

Minor technical adverse events were analyzed retrospectively from the independent review of clinical and imaging data. They were present for 13/33 patients (39%). The main event was soft tissue PMMA cement leaks, found in 10/33 patients (30%). Three specific adverse events occurred: one cement leak in the coxo-femoral joint, one spindle in contact with a nerve, and one attempt of spindle removal. None of these complications required additional therapy or resulted in a deviation from the normal post-therapeutic course.

No post-procedural infections were noted. No major adverse event was noted.

Adverse events are summarized in Table 2.

Procedure times and radiation exposure

The mean procedure duration from the initial CT to the immediate post-interventional CT was 75 ± 18 min.

The median number of CT acquisitions throughout the procedures was 4 (range: 2 to 8).

The mean total effective dose (ED), dose area product (DAP), and dose-length product (DLP) were respectively 30 mSv (± 21), $3655 \mu\text{Gy}\cdot\text{m}^2$ (± 8775), and $1449 \text{mGy}\cdot\text{cm}$ (± 712).

Discussion

Our series represents an initial experience on the use of an electromagnetic navigation assistance for pelvic cementoplasty in standard practice. Most of the procedures were performed by radiologists with less than 10 years of experience in pelvic cementoplasty. The EMNS was successfully used for all intended interventions.

The results indicate that the EMNS is safe to use for pelvic bone cementoplasties and RCs, especially for less experienced radiologists, and does not compromise the benefits of such interventions in regard to duration or radiation exposure. Previously, a study on 37 patients found that computer-assisted navigation vertebroplasties were safe and reduced both radiation exposure and procedure duration [11]. The system was also assessed on challenging craniocaudal angulations for FICS in a 2019 study by Moulin et al [10] and in

prospective randomized trial conducted for multiple CT-guided interventions (drainage, biopsy, tumor ablation, infiltration, and sympathectomy) [9], with satisfactory results.

The focus of the present study was on pelvic procedures rather than vertebroplasties, and it could be argued that the former is a more challenging intervention given its more recent development [6, 8]. More precisely, the high rate of sacroplasty interventions in the studied population suggests that the system is efficient in assisting the radiologist for extra-axial planes in challenging approaches. This could be a competitive solution to previously suggested techniques for sacral interventions [13], and should be considered for assessment versus competing 3D navigation tools [14].

Several limitations within this study should be discussed. First is the absence of a control group that did not permit a comparison with conventional interventions. Second, no study on the level of difficulty of the planned intervention was performed. This could help estimate the added-value of the device. Third, the radiologists' learning curve was not properly assessed and could play a major role in procedure times and radiation exposure.

Conclusion

Our initial experience suggests that electromagnetic navigation system-assisted percutaneous interventions (cementoplasties and reinforced cementoplasties) of the pelvic bones are feasible and may reduce the rate of minor technical adverse events (especially cement leakages and needle repositioning). Further prospective randomized series on larger populations are warranted to confirm these promising preliminary results.

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Declarations

Guarantor The scientific guarantor of this publication is Pr Frederic Clarencon.

Conflict of interest The authors of this manuscript declare no relationships with any companies whose products or services may be related to the subject matter of the article.

Statistics and biometry No complex statistical methods were necessary for this paper.

Informed consent Written informed consent was not required for this study because of the type of study.

Ethical approval Institutional Review Board approval was obtained.

Table 2 Procedure duration, minor and major adverse events, and radiation exposure

Total population	ENMS navigation
Procedure duration (min)	75 (± 18)
Minor technical adverse event ($N = 26/51$)	13/33 (39%)
<i>Cement leaks in soft tissue</i>	10/33 (30%)
<i>Cement leaks in coxo-femoral joint</i>	1/33 (3%)
<i>Spindles in contact with nerve</i>	1/33 (3%)
<i>Attempt of spindle removal</i>	1/33 (3%)
Needle repositioning	1/33 (3%)
Radiation exposure:	
<i>Number of CT acquisitions</i>	4 [range: 2 to 8]
<i>Effective dose (ED) (mSv)</i>	30 (± 21)
<i>Dose area product (DAP) ($\mu\text{Gy}\cdot\text{m}^2$)</i>	$3655 \mu\text{Gy}\cdot\text{m}^2$ (± 8775)
<i>Dose-length product (DLP) (mGy.cm)</i>	1449 (± 712)

Quantitative variables are expressed as means \pm the standard deviation or as median [range]

Methodology

- retrospective
- observational
- performed at one institution

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