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TECHNICAL NOTE NON-VASCULAR INTERVENTIONS

Percutaneous Transpedicular Fixation by PEEK Polymer Implants Combined with Cementoplasty for Vertebral Compression Fractures: A Pilot Study

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Abstract

Purpose To evaluate the feasibility and safety of percutaneous transpedicular fixation by PEEK polymer implants and cementoplasty for vertebral compression fracture (VCF).

Materials and Methods From February 2019 to December 2019, 6 consecutive patients (3 men and 3 women; mean age 55 ± 8 years; range 40–64 years) who had percutaneous transpedicular fixation with cementoplasty for the treatment of VCF (5 tumor lesions, 1 traumatic) were included. The procedure duration, length of hospital stay, and complications were reported. Visual analog scale (VAS) and the Oswestry disability index (ODI) for pain and disability were assessed before and 2 months after the procedure.

Results The mean procedure duration was 74 ± 47 min (range 20–140 min). The median length of hospital stay was 3 days (range 2–63) after the procedure. Only minor adverse events were reported (4 asymptomatic cement leakages) but no severe complications. No cases of procedural site fracture during follow-up were noted (median 198 days; range 78–238 days). The mean VAS score decreased from 6.2 ± 1.8 mm (median 6 mm; range 4–9 mm) before the procedure to 1.7 ± 2.1 mm (median 1; range 0–5 mm) after the procedure. The ODI decreased from 36 ± 14% (range 18–54%) before the procedure to 23 ± 10% (range 11–30%) at 2-months follow-up.

Conclusions Percutaneous transpedicular fixation of VCF by PEEK implants with cementoplasty appears feasible and safe.

Keywords Vertebroplasty · Transpedicular fixation · Spine · Cancer · Osteoporosis

Introduction

Percutaneous vertebroplasty or kyphoplasty are considered as effective options to consolidate vertebral compression fractures (VCF), allowing pain relief [1–6]. To further improve the results and standardize the procedures, several spine implants have been developed helping to reduce the risks of cement leakage and to restore vertebral body height [7–9]. Among them, V-STRUT© (Hyprevention, Pessac, France) is an implantable device designed for treatment or prophylactic fixation of VCF in the thoracic and lumbar spine (from T9 to L5 levels) [10]. It is made of radiotransparent poly-ether-ether-ketone (PEEK) polymer, with a cannulated and perforated design. Two devices per vertebra are implanted through a transpedicular approach. The primary endpoint of this pilot study was therefore to evaluate the feasibility of percutaneous transpedicular fixation by V-STRUT© with cementoplasty for VCF and to report the short-term outcomes.

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Material and Methods

In this Institutional Review Board-approved prospective pilot study, informed consent was obtained from all patients. From February to December 2019, patients presenting with VCF were selected for treatment. Table 1 summarized the inclusion and exclusion criteria and Table 2 summarize patient's characteristics. Procedures were performed under Cone Beam Computed Tomography imaging guidance (Innova, GE Healthcare, Buc, France), under general anesthesia, with the patient placed in prone position. Two 11 Gauge trocars were inserted into each pedicle to converge into the vertebral body using the same technique used in vertebroplasty (Fig. 1). After positioning the trocar, two 1.6-mm-diameter Kirschner guidewires were introduced in the trocars (Fig. 2). A soft tissue dilation was then performed after the trocar removal allowing to insert a protection tube. Manual drilling of the implant's site was performed using 4.5, 5.5 and 6.5-mm-diameter drills through the protection tube. Device implantation was subsequently performed. Finally, PMMA (F20®, Teknimed, France) was carefully injected using a cannula inserted through the implants to ensure adequate filling. Immediately after the procedure, standard radiographs were obtained to assess implants position and cement leakage, if any. The patients were monitored for 6 h following the procedure in the intensive care unit. Complications were reported according to the Society of Interventional Radiology quality improvement guidelines for percutaneous vertebroplasty [11]. The severity of pain was assessed using visual analog scale (VAS) before and after the procedure, and at 2 months. All patients included were asked to complete Oswestry disability index (ODI) [12] before and 2 months after the procedure.

Results

A total of 6 patients (3 men and 3 women; mean age, 55 ± 8 years (range 40–64 years)) were included. All patients had symptomatic Magerl 1A VCF. VCF was due to a metastasis in 5 patients, and trauma in 1. The baseline characteristics and results for each patient are summarized in Table 1. The procedure was technically feasible in all patients, and the mean duration of the procedure was 74 ± 47 min (range 20–140 min). The devices were 5.5 or 6.5-mm diameter and ranged from 40–60-mm long. The mean volume of PMMA injected was 4.5 ± 2.3 mL (range = 2–8 mL). The patients were permitted to stand on the second day after the procedure, and the average length of hospital stay was 3 ± 1.4 days (median: 2 days; range 2–5 days), after exclusion of a patient with a 63-days hospitalization non-related to the studied device. Three patients were discharged from hospital the day after the procedure. No severe adverse event related to the procedure was observed during the follow-up. Only grade A minor complications (non-symptomatic cement leakages) were observed in 4 patients (4/6; 66.7%). There were no procedural or peri-procedural site fractures during follow-up (median: 198 days; range 78–238 days). Pain decreased from 6.2 ± 1.8 mm (median: 6 mm; range 4–9 mm) before treatment to 1.7 ± 2.1 mm (median: 1 mm; range

Table 1 Inclusion and exclusion criteria

Inclusion criteria	Exclusion criteria
Adult male and female patients	Unstable fractures
Painful VCF (VAS > 4 mm)	Neoplasms with posterior involvement
Type A.1, A.2 and A.3 VCF according to Magerl classification	Non mobile fractures
VCF due to osteoporosis or tumors	Spinal canal stenosis
VCF located in the thoracic and/or lumbar spine from T9 to L5	Neurologic symptoms related to the VCF
Patients status American Society Anesthesiologists (ASA) score < 4	Patient clearly improving on conservative treatment
For osteoporotic patient, fail in conservative treatment (8 days of antalgic medication Level III), and recent fracture (less than 6 weeks)	

VCF: vertebral compression fracture; VAS: visual analog scale

Table 2 Characteristics of patients

Patient	Sex	Age	Nature of lesion	Treated level	Lengths of hospital stay	VAS (mm)		ODI (%)		Cement volume (mL)	Follow-up duration (days)	Outcome
						Pre-treatment	Post-treatment (at discharge)	Pre-treatment	Post-treatment (at 2 months)			
1	F	59	Blastic tumor	L2	5	7	0	46	28	5	193	Total pain relief. From severe to moderate disability
2	M	58	Lytic tumor	L4	63	5	0	36	NK	2	99	Total pain relief. Death of the patient due to cancer progression
3	F	53	Lytic tumor	L4	2	7	3	20	11	4	238	Partial pain relief. Decrease in ODI score (minimal disability)
4	M	64	Lytic tumor	L3	4	9	2	42	30	2	235	Partial pain relief. From severe to moderate disability
5	M	57	Lytic tumor	L3	2	5	5	18	NK	8	78	Total pain relief. Death of the patient due to cancer progression
6	F	40	Traumatic	L1	2	4	0	54	NK	6	204	Total pain relief

ODI: Oswestry disability index; NK: Not known; VAS: visual analog scale

0–5 mm) after treatment, at discharge. The ODI decreased from 36 ± 14% (range 18–54%) before the procedure to 23 ± 10% (range 11–30%) at 2 months follow-up. Two patients deceased during follow-up due to cancer progression.

Discussion

The procedure of implantation of V-STRUT© was found to be feasible and safe. The device provided immediate pain relief and function improvement in all patients, as stand-alone vertebroplasty. The purpose of the device was to facilitate mechanical consolidation of VCF transferring the axial compression force to the posterior column in addition to the injection of PMMA [10]. Its cannulated design and its posterior pedicle anchorage are thought to bring support to the superior vertebral endplate and allow the vertebrae to resist to the axial compression, thus theoretically avoiding recurrence of fracture at the same site or below. The device is also combined with a relatively low volume of PMMA cement, aiming to avoid a stiff mass into the vertebral body, limiting the risk of adjacent fractures (15). However, fracture reduction is not performed by the device itself. The high rate of cement leakages (4/6 patients; 66.7%), similar to what is observed after vertebroplasty, may be explained by the lytic pattern of metastases. These cement leakages were asymptomatic in all cases. The small sample size and the short follow-up did not allow evaluating the occurrence of adjacent fractures. There is no comparison with other therapeutic options such as cementoplasty or kyphoplasty alone, as well as the lack of any treatment.

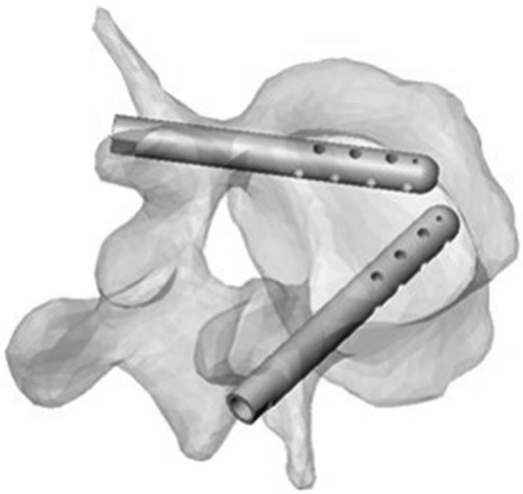

Fig. 1 Numerical view of the device in a vertebra: 2 transpedicular implants are shown

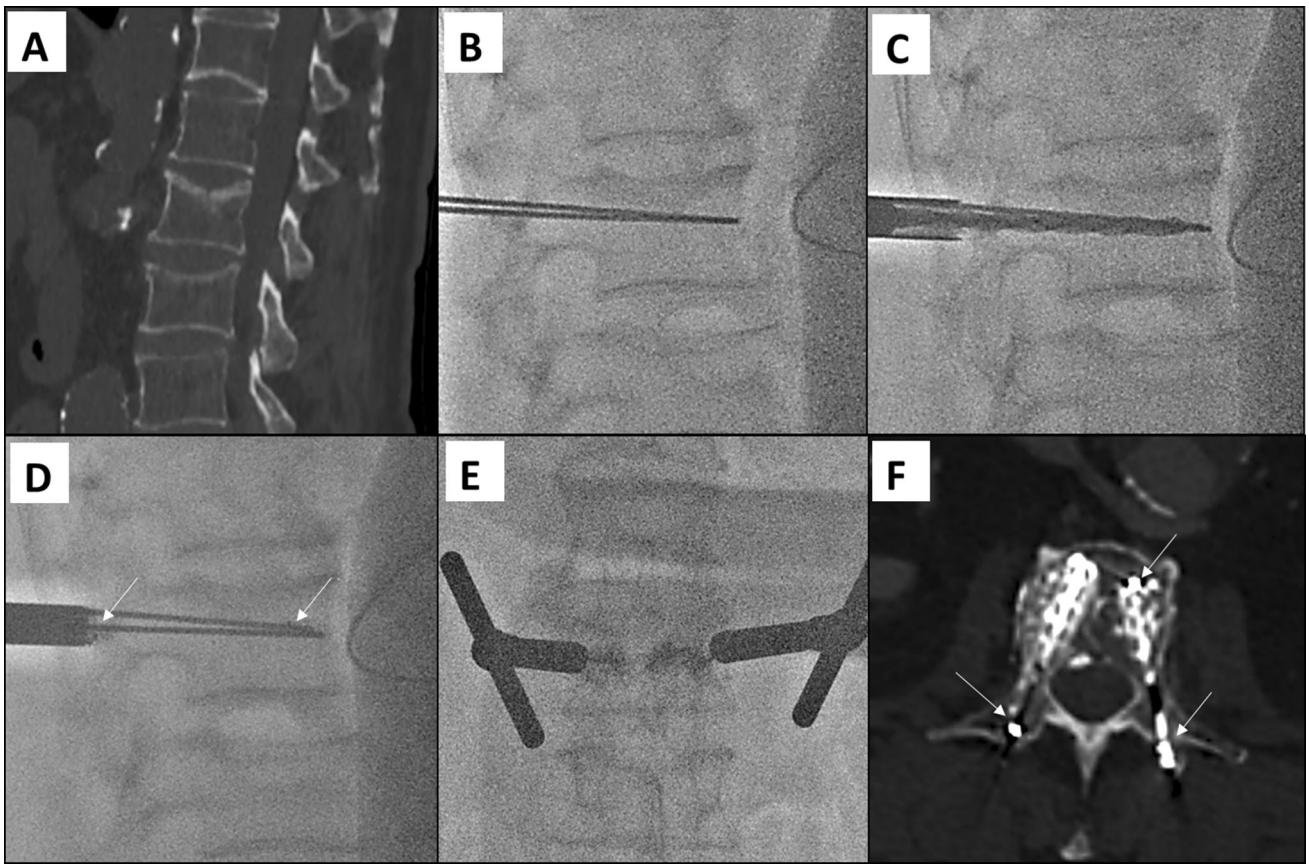

Fig. 2 Sixty-five-year-old man with a history of lung cancer and sudden onset of severe back pain. **A** Sagittal computed tomography of the lumbar spine shows a Magerl 1A vertebral compression fracture. **B** Lateral radiograph indicates the placement in the pedicle of two 2.4-mm guidewires under fluoroscopic guidance. **C** Lateral radiograph shows the protection tube placement using a soft tissue dilator and the 5.5-mm drill being placed coaxially through a protection tube. **D** Lateral radiograph shows the 5.5 mm implants (arrows shows implant markers). **E** Frontal radiograph after cementoplasty. **F** Axial computed tomography performed 10 months after the procedure demonstrates adequate position of the PEEK implants (arrows shows implant markers)

Percutaneous transpedicular fixation of VCF by PEEK implants with cementoplasty appears feasible and safe. Further larger and comparative evaluation is mandatory before drawing definitive treatment decision.

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Compliance with Ethical Standards

Conflict of interest F.H. Cornelis and F. Deschamps are members of the scientific board of Hyprevention (Pessac, France).

Ethical Approval All procedures performed in studies involving human participants were in accordance with the ethical standards of the institutional and national research committee and with the 1964 Helsinki declaration and its later amendments or comparable ethical standards.

Informed Consent Informed consent was obtained from all individual participants included in the study.

Consent for Publication Consent for publication was obtained for every individual person's data included in the study.

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