

# Effectiveness and reliability of cannulated fenestrated screws augmented with polymethylmethacrylate cement in the surgical treatment of osteoporotic vertebral fractures

## ABSTRACT

**Background:** Implants' stability, especially in osteoporosis patients, is a challenging matter. Nowadays, the adoption of cannulated fenestrated screws augmented with polymethylmethacrylate cement (PMMA CSF) is described by some authors. This single-center, retrospective observational study aims to evaluate the long-term effectiveness, reliability, and mechanical performances of this type of screws in osteoporotic fractures.

**Materials and Methods:** All the patients surgically treated from January 2009 to December 2019 with PMMA CSF were evaluated and submitted to the inclusion and exclusion criteria. Clinical and radiological evaluations were performed at pre- and post-surgery time and at the follow-up (FU). Loss of correction in the sagittal plane (bisegmental Cobb angle), kyphosis angle of the fracture (fractured vertebral angle), loosening of pedicle screws (screw's apex vertebral body's anterior cortex mean gap called SAAC gap and screw's apex vertebral body's superior endplate mean gap called SASE gap), visual analog scale, and Oswestry disability index scores were evaluated.

**Results:** One hundred and sixty-three patients (58 males and 105 females) aged over 65 years affected by vertebral osteoporotic fractures were included in the study. At FU, we do not found significant differences in radiological items in respect to the postoperative period. Only one case of loosening and 18 cases of cement leaking (without neurological impairments) were found. Clinical scores improvement was significant in the interval between preoperative and FU.

**Conclusions:** PMMA CSF seems to can guarantee good efficacy and effectiveness in the surgical treatment of vertebral fractures in osteoporosis.

**Keywords:** Bone cement, elderly, osteoporosis, spine, surgical treatment

## INTRODUCTION

Osteoporosis is nowadays a public health problem; its prevalence in Europe stated approximately 6% of men and 21% of women aged between 50 and 84 years.<sup>[1]</sup>

The lack of bone density may predispose to mechanical complications such as progression of kyphosis, loosening, pullout, and migration of the screws.<sup>[2]</sup> Different options are available today for increasing the bone grip of the screws, but cannulated fenestrated screws augmented with polymethylmethacrylate cement (PMMA CSF) are the most used.<sup>[3-5]</sup>

This monocentric retrospective study aims to evaluate the efficacy, effectiveness, and reliability of posterior stabilization

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**Submitted:** 03-Nov-20  
**Published:** 04-Mar-21

**Accepted:** 04-Nov-20

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**How to cite this article:** Coniglio A, Rava A, Fusini F, Colò G, Massè A, Girardo M. Effectiveness and reliability of cannulated fenestrated screws augmented with polymethylmethacrylate cement in the surgical treatment of osteoporotic vertebral fractures. J Craniovert Jun Spine 2021;12:33-7.

Access this article online	
<b>Website:</b> www.jcvjs.com	<b>Quick Response Code</b> 
<b>DOI:</b> 10.4103/jcvjs.JCVJS_188_20	

with the adoption of PMMA CSF for thoracolumbar vertebral fractures in aged patients affected by osteoporosis.

## MATERIALS AND METHODS

All patients who underwent posterior surgical stabilization (between January 2009 and December 2019) with PMMA CSF and with follow-up (FU) of at least 6 months were included in the study.

We included vertebral fractures according to the AO Spine Classification:<sup>[6]</sup> Type A and B, single level, and without neurological impairment.

Cases with pathologic fractures, ankylosing spondylitis, spondylodiscitis-related fractures, and concomitant cervical fractures were not included.<sup>[7-9]</sup> Before surgical treatment, all patients have been submitted to radiological examinations: standard X-rays, computed tomography (TC), and magnetic resonance imaging. The operative treatment was performed using pedicle cannulated screws with an inner core of 1.75 mm augmented with 2 or 3 cc of PMMA cement [Figure 1].

Posterior instrumentation was conducted with a standard open surgical approach. No neurosurgical navigator was used. Additional anterior stabilization was never performed. Accurate clinical examination was performed during all the hospitalization period and during all outpatient visits. X-ray examinations were performed on 1<sup>st</sup> day after surgery (T1) and at 1, 3, and 6 months after surgery. Later, annually, X-ray examinations were conducted. The last X-ray examination was set as FU.

Radiological data were evaluated for the loss of correction in the sagittal plane (bisegmental Cobb angle), kyphosis angle

of the fracture (fractured vertebral angle), and loosening of pedicle screws (screw's apex vertebral body's anterior cortex mean gap called SAAC gap and screw's apex vertebral body's superior endplate mean gap called SASE gap). Radiological measurements were conducted blindly by two independent operators with the same radiological program (Synapse–Fujifilm). The mean value of the two calibrations was taken as valuable. Evaluation of cement leakage was also conducted and classified with Yeom<sup>[10]</sup> classification. Statistical Student's *t*-test was conducted analyzing mechanical complications (screw's loosening, bisegmental Cobb angle, and fractured vertebra angle). Clinical items were evaluated reviewing all clinical data about visual analog scale (VAS) and low back disability questionnaire Oswestry.<sup>[11]</sup> Level of significance was set at  $P < 0.05$ . Clinical results were evaluated as a secondary endpoint.

## RESULTS

### General results

A total of 163 patients (58 males and 105 females) aged over 65 years (mean age 71.3 years; standard deviation [SD]  $\pm 5.87$ ) affected by vertebral osteoporotic fractures were included in the study. General data of these 163 patients are reported in Table 1.

The mean FU was 56.98 months (SD  $\pm 32.22$ ).

All patients were affected by osteoporosis (T score  $< -2.5$  in DEXA examination).

We collected 19 Type A2, 83 Type A3, 55 Type A4, 3 Type B1, and 3 Type B2 vertebral fractures. Level of fracture was T10 in 20 cases, T11 in 35 cases, T12 in 41 cases, L1 in 48 cases, and L2 in 19 cases [Table 1].



**Figure 1: Clinical case. A 74-year-old woman. T12 body fracture surgically treated. (a and b) Frontal and lateral view (X-ray) at trauma time. (c and d) Frontal and lateral view (X-ray) after surgery**

A total of 1109 PMMA CSFs were implanted for a mean of 6.8 screws per patient.

### Radiological results

The mean SASE at T1 and FU was, respectively, 10.5 mm (SD ± 4.22) and 10.8 mm (SD ± 5.01),  $P > 0.05$ . The mean SAAC at T1 and FU was, respectively, 6.9 mm (SD ± 4.67) and 7.17 mm (SD ± 4.89),  $P > 0.05$  [Figure 2].

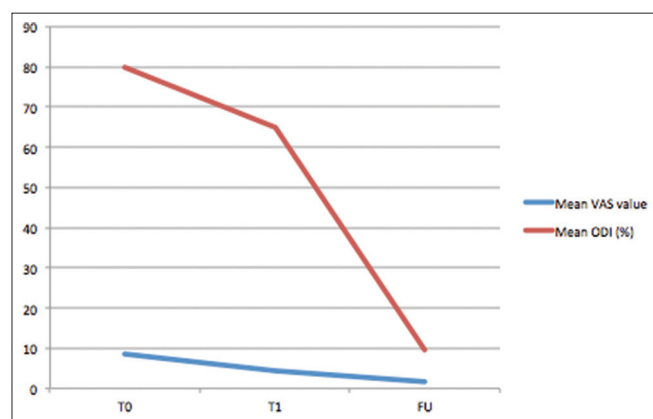
No appreciable loss of correction in the sagittal plane at bisegmental Cobb angle was found in this group, while the mean loss of kyphosis angle of the fractured vertebra was  $2^\circ \pm 1^\circ$ . Eighteen cases of cement leaking were found: 5 Type C, 3 Type B, and 10 Type S. Fortunately, no neurological sequelae occurred after the procedure.

### Clinical results

VAS and Oswestry disability index (ODI) questionnaire were submitted to all patients at T0, T1, and FU [Figure 3]. The results revealed an improvement in a VAS mean value from 8.7 (range 7–10) to 1.7 (range 0–4) in the interval T0–FU. Similar improvements were recorded in ODI that decreases from 80% to 9.5% (range 7%–12%) in the time-lapse T0–FU. All these variables had  $P < 0.05$  at the Student’s *t*-test.

**Table 1: General information of the population studied**

Data	Value
Mean age (years)	71.3 (65-82)
Gender (male: female)	58:105
Spinal segment fracture (n)	
T10	20
T11	35
T12	41
L1	48
L2	19



**Figure 2: Visual analog scale score and Oswestry Disability Index scores in T0, T1, and follow-up**

### Complications

A total of 17 cases of clinical complications were reported in our study: 1 case of screw loosening that required surgical revision, 1 case of death due to embolism, 4 cases of wound dehiscence regressed with VAC application, 2 cases of superficial infections treated with oral antibiotic therapy, 5 cases of neurological impairments (3 cases of neurological bladder associated with claudication and 2 cases of paresthesia), while fractures in the adjacent levels were reported in four cases.

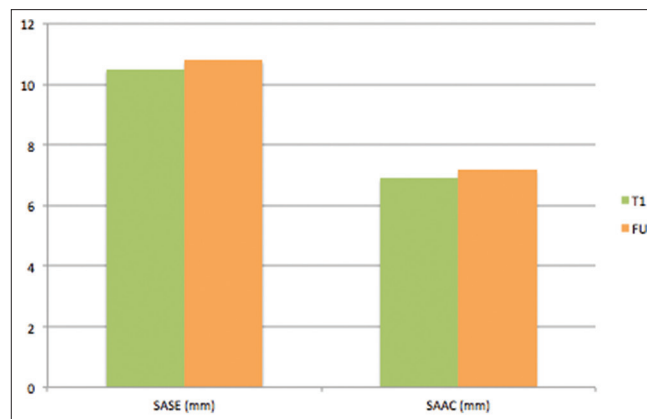
### DISCUSSION

It is well known that osteoporosis severely affects the bone mass, decreasing its mechanical properties reducing the capability of screws of having a good grip at the screw–bone interface. The factors needed for good results are skilled spine surgeons, suitable pedicle screws, and correct insertion technique.

In the literature, we can find many authors who report different devices and techniques for obtaining a reliable strength of the screws to pullout.

Bigger screws’ diameter was advocated in the 90s<sup>[12,13]</sup> but is well known that increase the screws’ diameter is not always possible. Later, vertebral body became the new target for having more strength with the adoption of expandable screws;<sup>[14]</sup> however, unfortunately, the vertebral body is rich in cancellous bone and poor of the cortex and cannot guarantee optimal grip at screw–bone interface.

The evolution of engineering passes successively through the hydroxyapatite-coated screws to augment the screws with PMMA cement.<sup>[15]</sup>



**Figure 3: SASE (screw’s apex vertebral body’s superior endplate mean gap) and SAAC (screw’s apex vertebral body’s anterior cortex mean gap) values in T1 and follow-up**

The latest is nowadays the principal strategy for osteoporotic bone management; numerous studies demonstrate that augmentation can increase the screws' pull out strength in osteoporotic and normal vertebrae in several spine pathologies.<sup>[5,16-20]</sup>

Initially, the cement was used to fill the drilled hole in which the screw was inserted during the final step. Initially, the cement was used to fill the drilled hole in which the screw was inserted during the final step. Nowadays PMMA CFS let to inject the cement after screw insertion, thus improving pullout forces respect the ancient technique.<sup>[21]</sup>

The systematically adoption of acrylic cement versus other cement has a lot of advantages to our knowledge because of its immediate availability, it is cheap, and it is easy and fast preparation technique. In fact, PMMA cement permits immediate screw fixation to the cancellous bone that is not permitted by calcium sulfate, calcium phosphate, and other materials adopted in routine orthopedic surgery. Despite these many qualities and advantages related to the adoption of PMMA, surgeons must be aware of the risks of leakages derived by a not correct insertion technique. These complications may drive to catastrophic events that may severely affect the patients' prognosis. As we reported in our results, we had to face, despite the experience of our spine team, 18 cases of leakage that corresponds to 11% of the total cases treated. Fortunately, no neurological sequelae occurred. We suggest that an accurate palpation of the pedicle and of the vertebral body's anterior cortex is important, before and after the screw insertion. We also suggest the injection of an amount of maximum 3 cc for lumbar vertebrae and 2 cc for thoracic ones despite exact cement quantity to inject in vertebral body is not known in the literature.

Thanks to the good results, we reported that, in this study, associated with other reported in literature, we can suggest surgeons to consider the surgical approach with PMMA CSF to osteoporosis fracture as a safe and reliable treatment. Despite these results is suggestable, for very frail patients, to consider conservative approaches,<sup>[22]</sup> and every surgeon that decides to approach this kind of surgery must be aware of the many possible complications; it is strongly recommended to avoid the occasional surgery.

#### Financial support and sponsorship

Nil.

#### Conflicts of interest

There are no conflicts of interest.

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