Segmental ploymethylmethacrylate-augmented fenestrated pedicle screw fixation in patients with osteoporotic unstable thoracolumbar fractures: a clinical evaluation

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Objective
Osteoporosis has been implicated as a cause of hardware failure and, more specifically, pedicle screw loosening and pull-out. A clinical evaluation of results of augmented fenestrated pedicle screws was performed to determine the safety, performance, and effectiveness of this technique in the osteoporotic spine with an unstable thoracolumbar fracture.

Patients and methods
Over the past 2.5 years, the clinical and radiographic results of 11 consecutive patients with poor bone stock with osteoporotic spinal fractures were reviewed. These patients underwent instrumented spinal fixation using fenestrated pedicular screws with cement augmentation. Implant stability was evaluated by initial postoperative plain radiography and three months, thereafter. After the first 12 months, radiographic controls were taken every 6 months. Complications were evaluated in all cases.

Results
All patient were followed clinically and radiologically for a mean of 11.3 ms (range: 6–30 ms). None of the patients experienced serious intraoperative complications (hypotension, cement embolization, myocardial infarction, or cement leakage) nor postoperative complications (late postoperative implant failure, or kyphosis), with early safe postoperative mobilization.

Conclusion
Pedicular fixation using fenestrated pedicular screws with cement augmentation for treatment of osteoporotic spinal fractures reduces the likelihood of pedicular screw loosening with subsequent reduction of late postoperative sagittal instability with early safe mobilization.

Keywords:
osteoporosis, pedicle screw augmentation, polymethylmethacrylate, spinal fracture

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Introduction

Pathologic vertebral compression fractures are a leading cause of disability and morbidity in patients with osteoporosis, multiple myeloma, and bone metastasis [1,2]. The consequences of these fractures include pain and often progressive vertebral collapse with resultant spinal kyphosis and survival [3]. In recent years, researchers have highlighted the reduced quality of life, functional limitations, and impaired pulmonary function associated with spinal kyphotic deformity from osteoporotic vertebral compression fractures [4,5]. By shifting the patient's center of gravity forward, kyphotic deformity not only increases the risk of additional fractures but may also lead to poor balance.

Spinal surgery is reserved for patient who has a fracture that is causing gross deformity or neurologic impairment. Careful perioperative management through a team approach can help decrease complications [6]. The ability of the surgeon to obtain adequate purchase in bone is the main problem affecting any type of spinal fixation in osteoporotic bone. Polymethylmethacrylate-enhanced pedicle screw fixation has been shown to improve the pull-out strength of these pedicle screws but care must be taken during bone cement placement to avoid extrusion into the canal or neuroforamen, leading to subsequent nerve or cord injury. Up to twofold increase in pull-out strength can be attained with bone cement[7].

Surgical treatment of patients with bone softening and spinal instability can be complicated. Although there are those who advocate minimally invasive percutaneous procedures, such as vertebroplasty [8,9], this would be contraindicated in patients with mechanical and/or

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neurological instability. In these patients, the ideal treatment would include surgical decompression of the neural elements followed by rigid spinal fixation. However, instrumentation of the osteoporotic spine may be fraught with complications [10]. As such a number of different techniques have been proposed to increase the pedicle screw pull-out strength including the use of bicortical purchase [8,9], pedicle undertapping, offset laminar hooks, and pedicle screw-bone interface augmentation including the use of expandable screws [10].

The purpose of this study was to determine the effect of using cemented fenestrated pedicle screw fixation in the treatment of osteoporotic fractures.

Patients and methods

Clinical series

Over the past two and half years, the clinical and radiographic results for 11 consecutive patients with instrumented spinal fixation using cemented perforated pedicular screws were reviewed. This study was approved by ethical committee of Mansoura University. All patients signed an informative consent form. All patients had primary osteoporosis apart from one who had secondary osteoporosis with chronic renal failure.

These patients underwent open transpedicular fixation using perforated Click'X pedicle screw (dePuy Synthes Jhonson & Jhonson, California, USA)(augmentable polyaxial pedicle screws with bone cement) in three patients (Fig. 1) and CD Horizon fenestrated polyaxial screws (MEDTRONIC, France) in eight patients (Fig. 2). The decision to augment was based on the combination of the preoperative radiographic finding of osteoporosis and Dexa scan, confirmed by the intraoperative tactile feel resistance of the vertebral body to the pedicle probe.

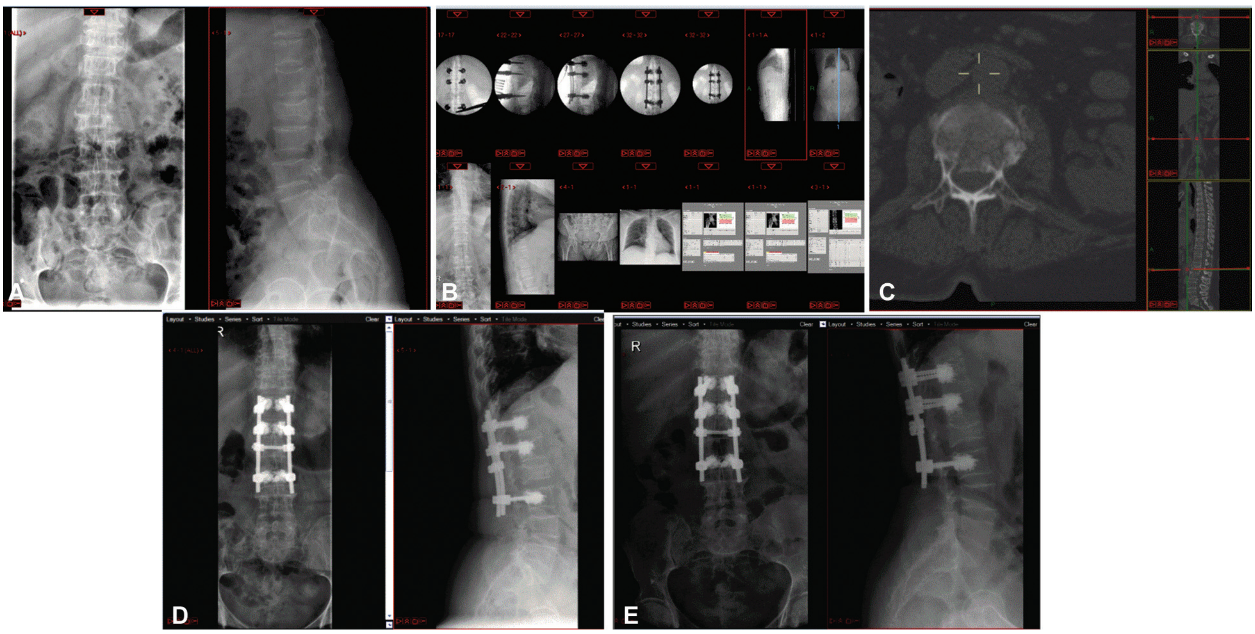
Figure 1

Click'X pedicle screw 5.2, 6.2, 7 mm perforated with Dual Core, TAN, length 35–55 mm, sterile.

Figure 2

CD HORIZON LEGACY Cannulated Multi-Axial Screw with the addition of six fenestrations near the tip.

Figure 3



(a) Preoperative radiography AP, LAT. (b) Preoperative computed tomography. (c) Preoperative, intraoperative radiography, and Dexa. (d) Early postoperative radiography AP, LAT. (e) Late postoperative radiography AP, LAT (16 ms). AP, anterioposterior; LAT, lateral.

Technique

The operative technique performed in these series of 11 patients (Fig. 3) is briefly described under fluoroscopic guidance with the level of surgery identified and localized. After exposure, the fenestrated pedicular screws were inserted according to the lateral entry technique of Weinstein. The levels to be instrumented are prepared with the appropriate selected screw lengths to be inserted. The screws with the maximum possible diameter and length to achieve maximum stability were used. The perforated polyaxial screws must enter in ~80% of the vertebral body. Using too short screw length, the injected bone cement will be too close to the pedicle , on the other hand, inserting too long screw might increase the risk of anterior cortical wall penetration with the risk of cement leakage. After screw insertion, 2 mm pointed kirschner wire is passed along the whole screw length reaching the screw tip to dislodge any bone debris within the screw shaft before cement injection to clear blocked injection pathway. Polymethylmethacrylate bone cement was mixed according to the manufacturer's recommendation. After mixing the liquid and powder, 0.5 ml cement, which was in the dough phase and looked like toothpaste or had spaghetti consistency, using a control syringe was injected, initially, per screw until the cement extruded from the perforation. We have to ensure that no cement leakage occurred outside the intended area. We had to hold cement injection immediately in the event of leakage. Following the same order of screws, augmentation is completed when each screw has been augmented with a total volume of ~2–2.5 ml.

The cement extrusion needs to be monitored under continuous fluoroscopic control. A growing cloud, not spider pattern should form around the screw fenestrated part. We have to wait until the cement has cured before continuing with the instrumentation (about 15 min after cement injection), and controlled by in-vitro cement hardening to avoid screw-cement loosening. After complete cement curing, the two contoured rods are connected to the screws and tightened with an additional cross connector applied in between to afford additional axial (rotational) stability.

Results

Our study included 11 patients (4 males and 7 females). Their age range from 52 to 70 years with a mean age of 61.9 years. The trauma was not significant in the majority of patients (sliding in the bathroom, falling down during walking or from stairs). However, in two patients there was a history of MCA. According to American spinal injury association (ASIA) [11] classification, 10 patients had no neurological deficit (type E) but 1 case (type A) with complete paraplegia with chronic renal failure.

The traumatized vertebra was classified according to Denis [12]: six cases with burst fracture, three cases with compression fracture (one case with T12 compression fracture with old compression fracture T11), one case with double-level fracture (L1 compression and L2 burst), and one case with T9, 10 collapse with vertebral body destruction secondary to renal osteodystrophy.

Table 1 Clinical data for patients undergoing fenestrated cemented pedicle screw augmentation

Patient no.	Sex	Age	Dexa	Level	Associated injury	Associated illness	Fixation	Sagittal angle (postoperative)	Sagittal angle (late follow-up)	Fu/ms
1	♀	61	−6.5	L1, 2	–	L5-S1 spondylolisthesis	6 cemented	2	4	30
2	♀	68	−4.8	L1	–	Old cerebral infarction	4 cemented	4	6	16
3	♂	52	−3.4	T9, 10	–	CRF	4 cemented	20	20	6
4	♀	57	−6.5	L1	–	–	6 cemented+2 coated with hydroxyapatite	3	3	20
5	♂	70	−4.8	T12	–	SPH	4 cemented	10	10	6
6	♂	60	−4.2	L3	Jefferson +metacarbar fractures	–	4	20	20	9
7	♀	60	−4.8	L1	Humeral shaft fracture	Old cerebral infarction	4	9	9	6
8	♂	70	−5.3	T12	Trochanteric fracture	Senile brain atrophy +old compression fracture T11	6	16	9.9	6
9	♀	60	−4	L2	–	–	6	4	4	16
10	♀	66	−3.8	T12	–	CVA, common carotid atherosclerosis	6	16	18	6
11	♀	64	−3.3	L1	–	–	4	7	9	6

The clinical results are summarized in Table 1. No difficulties were encountered in screw insertion or cement augmentation following the manufacturer's technique with well-positioned lateral fluoroscopy with strict adherence to the rules of pedicular screw insertion to avoid a pedicular breach. The patients were followed clinically and radiologically for an average of 11.5 ms with a range of 6–30 ms.

The Jikei scale [13,14] was used to radiographically grade the degree of osteoporosis as follows: grade 0, a normal pattern of transverse and vertical trabecula; grade 1, a decrease in transverse with the prominent appearance of vertical trabeculae and end plate; grade 2, a further decrease of vertical and transverse trabeculae; and grade 3, near disappearance of the transverse trabecular pattern and unclear vertical trabecula appearing as ground glass. All our patient were grade 2 according to Jekie scale.

The patient was also evaluated according to Dexa scan with an average −4.7 (range: −3.3 to 6.5). The amount of cement injection/pedicle was 1.5 ml for thoracic vertebra proximal to T12, 2 ml from T12L2, 2.5 ml down to L4.

There were no reported complications related to cement injection as intraoperative hypoxia, hypotension, pulmonary embolization, myocardial infarction, or death. No reported cases of cement extravasation (anteriorly through external venous plexus, ascending lumbar veins, or hemiazygos vein) or intraspinal leak.

Patients with no neurological deficit showed improved walking ability than before surgery with early postoperative mobilization out of bed, full weight bearing with initial zimmer support with resultant reduced bedridden complications.

No reported cases of implant failure in the form of loosening, backing out, and cement loosening. The average postoperative sagittal plane angulation according to Cobbs was an average 10 with a range from 2 to 20°. The average late sagittal angulation was 10.3 with a range between 3 and 20°. The overall loss is 0.3° only.

No cases of adjacent segment collapse. One case of superficial wound infection with staph epidermidis, which was treated with intravenous gentamicin.

Discussion

A number of serious potentials may occur with vertebral bone cement injection, so the use of polymethylmethacrylate in pedicle screw augmentation and in ballon kyphoplasty and vertebroplasty must be performed with great caution. The risk of Ploy methyl meth acrylate (PMMA) extravasation ranged between 27 and 74% in various series, with resultant neurological deficits, such as radiculopathy and cord compression occurring in 3.7 and 0.5%, respectively [15–18].

Our study is consistent with other studies that have shown that PMMA cement augmentation of pedicle screws increase fixation strength in a severely osteoporotic bone [19,20]. Many studies have shown that PMMA use can increase the fixation strength of pedicle screws by 2–3 folds in osteoporotic vertebrae. However, when pedicle screws are placed into an osteoporotic spine, an increased risk of screw.

Loosening, pull-out, and fixation failure exists; and osteoporosis has been considered a contraindication for pedicle screw fixation. Various technical strategies are applied for improving pedicle screw grip and fixation strength in osteoporotic bone including expandible pedicle screw, rod configuration, and screw with different screw designs [21,22].

The use of screws with a larger diameter than those previously implanted proved to be effective in revision surgery: they had to be at least 2 mm larger to ensure reliable purchase [23]. Nevertheless, it is not always possible to use a bigger screw for anatomical reasons. Moreover, their use increases the risk of fracture of the pedicle [24,25].

The use of longer screws, anchoring into the anterior cortex of the vertebral body has also been proposed. Upon using this type of fixation, Zindrick *et al.* [26] found that the force required to loosen the screws increased by 30%. In contrast, the risk of vascular or visceral injury cannot be ignored.

Expansion screws have been also used. The anterior two-thirds of this type of screw expands in diameter once the screw has passed through the pedicle. Experimental result in the osteoporotic spine has shown that such screws are more resistant to pull-out. In 2001, Cooke *et al.* [24], published their case review of 145 patients in whom expansion screws had been used in the presence of osteoporosis for implant revision and sacral anchorage. Their clinical results were comparable to those obtained by means of a conventional technique in unselected patients.

Coating pedicle screws with hydroxyapatite can also improve stability. In ovariectomized sheep, coated screws displayed significantly greater resistance to extractive torque stress [27]. In addition, in an experienced canine model, Hasegawa *et al.* [23], found that hydroxyapatite-coated screws offered 1.6-fold greater resistance to pull-out stresses than uncoated titanium screws. Nevertheless, bone/screw interface integration is not expected to happen immediately, so primary stability does not differ much from that of primary screws and consequently, cement augmentation with pedicular screws provides immediate postoperative stability against screw loosening and backing out.

In orthopedic surgery, the use of PMMA to fill and stabilize implants has been a standard procedure for decades. More recently, however, due to the popularity of kyphoplasty and vertebroplasty, the use of PMMA in spine surgery has become common. Indeed, PMMA can also be used to reinforce pedicular fixation in cases of impaired bone quality. Several experimental and clinical studies have proven that PMMA augmentation is capable of improving resistance to pull-out in osteoporotic and normal vertebrae [21,28–30]. In poor quality bone, a gap is frequently created between the threaded portion of the screw and the trabecular spongy bone: cement strengthens the bone-metal interface at such points. PMMA screw augmentation may increase both the primary stability and the fatigue resistance of the implants [28,29], making them better able to withstand the axial stresses responsible for pull-out [30,31].

In 2005, Yazu *et al.* [32], published an experimental study conducted on osteoporotic vertebrae from cadavers comparing the performance of fenestrated screws with that of traditional screws. Cement injection can be modulated more accurately using fenestrated screws reducing the risk of leakage into the canal and/or foramina.

One study reported that cyclic fatigue loading results in a 20% decrease in pull-out load in healthy, nonosteoporotic vertebrae, whereas the decrease is 33% in those with osteoporosis [33].

In the study carried out by Ying *et al.* [34], for fixation strength of PMMA–augmented pedicle screws in a synthetic bone model of osteoporotic vertebrae. In the groups with cement augmentation, the pull-out strength of the screw-in group was significantly decreased compared with that of the screws *in situ*, whereas the difference between the screw-out group and *in situ* was much smaller. The finding was comparable with the changes seen on the radiographs, which showed that screwing resulted in remarkable destruction to the bone–cement interface, which is the main source of screw stability. In contrast, in the screw-out group, no obvious damage existed to the bone–cement interface. This finding also suggests that removing a cement–augmented cannulated pedicle screw in severe osteoporotic bone is possible and may not cause significant destruction to the bone. This was not confirmed in our study because we do not have cases of implant failure nor loosening or deep infection that necessitates screw removal.

Cho *et al.* [35], also examined backing out pedicle screws augmented with PMMA in a cadaveric study and reported no pedicle or lamina fractures but the study did not examine the bone–cement screw interface.

In the study conducted by Amendola *et al.* [36], in 21 cases with bone softening using fenestrated pedicle screw augmented with bone cement leakage occurred in one patient, causing transitory nerve root palsy, which was attributed to injecting an excessive amount of cement (>3 ml) in the early part of the study. In the other case of leakage in the study, there was an interruption in the screw insertion. However, in our study, there were no cases reported on cement leakage and this was attributed to proper patient selection including intact pedicle and middle column cortical integrity with good preoperative computed tomography evaluation and strict adherence to insertion technique with the fenestrated part of screws located in the anterior part of the vertebral body. Amendola *et al.* [36], also in their study adviced that no more than 2 ml of PMMA should be injected under strict, continuous fluoroscopic monitoring, ceasing injection if leakage occurs, which go parallel with our study regarding injection amount in the lower thoracic region. However, in the lumbar spine, we injected 2.5 ml with no complications as leakage and this was attributed to the strict adherence to the company recommendation regarding the cement injection time, that is, never to inject bone cement before a doughy stage or attainment of spaghetti consistency.

The results in our study are consistent with many studies that have shown that PMMA cement augmentation of pedicle screws increase fixation strength in a severely osteoporotic bone. Burval *et al.* [29], increase the fixation strength in a severely osteoporotic bone and these results are in agreement with our study as we have no cases of implant loosening or lost sagittal plane angulation, which signifies strong screw-cement interface.

Conclusion

The use of fenestrated pedicle screws with cement augmentation in osteoporotic spine offers a relatively safe technique with rigid fixation with early safe postoperative patient mobilization with avoidance of early and late implant failure.

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Nil.

Conflicts of interest

There are no conflicts of interest.

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