ORIGINAL STUDY

Clinical Results of Augmented Solid Pedicle Screws in Fixation of Osteoporotic Spine

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Abstract

Background data: **Spinal instrumentation in patients with osteoporosis is considered challenging. Using screw augmentation with bone cement is one of the methods used to overcome the structural weakness of vertebral bodies to minimize the risk of screws loosening and pullout.**

Purpose: **This study aims to evaluate the clinical results of using bone cement-augmented solid nonfenestrated screws in osteoporotic patients presented with either fractures or degenerative spinal diseases.**

Study design: **This is a retrospective clinical case study.**

Patients and methods: **We retrospectively reviewed all patients who had been operated on during the last five years for posterior spinal fixation and proven preoperatively to have osteoporotic spine. All patients had been operated on for spinal fixation using solid nonfenestrated transpedicular screws, which were augmented with bone cement. All patients had been evaluated clinically and radiologically before and after the surgery.**

Results: **We reported 37 patients (25 females and 12 males) with a main age of 59.19 ± 5.42 years. In total, 20 patients had degenerative spinal diseases and 17 patients had traumatic compression fractures. All participants had osteoporotic spine with a mean T score of −2.8 ± 0.24. Then, 220 screws were inserted into 110 vertebrae. The mean preoperative VAS of back pain was 9.06 ± 0.9 and after 6 months, it dropped to 2.24 ± 0.8. There were three cases (8.1%) of asymptomatic intravenous cement leaks and two cases (5.4%) of asymptomatic intraspinal leaks. There were no reported technique-related mortalities, screw loosening, or screw pullout during 15.24 ± 8.07 months of follow-up.**

Conclusion: **Solid nonfenestrated augmented pedicle screws are considered a safe and effective method for spinal fixation in patients with either degenerative or traumatic osteoporotic spinal pathologies.**

Keywords: Osteoporotic spine, Bone cement, Trauma, Degenerative spine, Solid screws, Fenestrated screws

Introduction

One of the most popular spinal procedures is the transpedicular screw fixation for different spinal pathologies, including fractures and degenerative diseases. Secondary to the increase in life-span, spine surgeons are faced frequently and commonly with patients having osteoporotic spine [1–3].

In osteoporotic patients, the risk of screws loosening and subsequent pullout is higher than that in normal spine. This has been proved to occur secondary to diminished bone density, which is supposed to provide an anchoring effect that holds the screw in place [4–9].

To overcome this structural defect, screws augmentation using bone cement has been widely used over the years, with proven clinical efficacy

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regarding improved functional outcomes and reduced revision rates. This augmentation increases the axial pullout strength, the transverse bending stiffness, and the resistance to toggle [3,10−14]. Cement leaks, either to the spinal canal or to the circulation, are considered the main possible complications of its use. To minimize this risk, many authors suggested to use high-viscosity cement [15−17]. The used augmented screws could be either the fenestrated or the traditional solid nonfenestrated screws [18,19]. The main disadvantage of the fenestrated screws is the higher cost, which is considered an economic burden in developing countries.

This study aims to evaluate the clinical results of the use of bone cement-augmented solid nonfenestrated screws in osteoporotic patients presented with either fractures or degenerative diseases.

Patients and methods

We retrospectively reviewed our hospital records for those patients who had been operated on during the last five years for posterior spinal fixation and preoperatively proven to have osteoporotic spine. The indication for spinal fixation was either compression fracture or degenerative spinal diseases. The plan in all patients was to augment the screw trajectory with bone cement before screw insertion. All the screws were solid nonfenestrated type and were inserted using the traditional posterior transpedicular trajectory. The institutional ethical committee approval has been obtained for the study with the code 36264PR334/9/23. Before the surgical procedure, informed consent was obtained from all patients.

Preoperative evaluation

Preoperative history taking and thorough neurological assessment were conducted on all patients. The main presenting symptom was back pain. We used the Visual Analogue Scale (VAS) to assess the preoperative pain level of back pain. The preoperative radiological investigations included plain X-rays, computed tomography (CT), magnetic resonance imaging (MRI), and dual X-ray absorptiometry (DEXA) scans. The usual preoperative laboratory workup was obtained from each patient to assess their readiness for surgery. The spinal levels to be included in the surgery were determined according to the presenting pathology and the radiological findings.

Inclusion criteria were patients who had osteoporotic spine with a T score ≤ -2.5 in the DEXA scan and were planned for transpedicular fixation surgeries. The indications for spinal fixation were compression fracture with a retropulsed fragment occupying more than 30% of the spinal canal that required decompression and fixation or patients with degenerative spinal stenosis (without or with mild instability) who complained of either back or radicular pain after the failure of conservative measures. Exclusion criteria were patients who had spinal tumors or infections, previous surgical intervention, coagulation disorders, cases that require anterior reconstructive surgery, marked spinal deformity, significant spinal instability (spondylolisthesis grade 2 or more), and patients with incomplete data or missed the follow-up visits.

Surgical technique

The initial steps were the same for degenerative or fracture cases. All procedures were done in the prone position under general anesthesia. A single dose of intravenous prophylactic antibiotic was given 1 h before the operation. An incision was made in the skin midline over the target levels. Then, the monopolar cautery probe was used to incise the dorsolumbar fascia, dissect the muscles from the spinous process laterally, and expose the facet joints and entry points of the target vertebrae on both sides.

Under fluoroscopic guidance in lateral view, the vertebral body was tapped using a tap that was 5 mm smaller than the permanent screw. A Jamshidi needle was then inserted through the tape trajectory till it reached the middle 1/3 of the vertebral body. The bone cement (Mendec® spine kit, Tecres S.p.A, Italy) was prepared and mixed to a doughy consistency to minimize the risk of cement leak. Under fluoroscopic guidance in lateral view, a volume of 2−3 mL (according to the screw size) was injected through the needle to fill the desired screw trajectory and adjacent part of the vertebral body. Then, the needle was removed, and the permanent solid transpedicular screw was immediately inserted in the same trajectory. The same procedure was then repeated for each screw. The whole procedure was conducted under fluoroscopic guidance for accurate localization of the screws' trajectory and to detect any possible cement leakage immediately. The rods were applied after confirming the bone cement hardening, which took about 10 min.

Laminectomy was performed for all patients. The aim was to decompress the spinal canal in fracture patients with a retropulsed fragment that occluded more than 30% of the spinal canal and in degenerative cases to relieve the radicular pain. The bone

derived from the spinous process and laminae was applied to the decorticated transverse process to maximize bone fusion. Discectomy was conducted for patients with degenerative stenosis who had soft disc bulges. The wound was then closed in layers.

After recovery from anesthesia, the patient was examined clinically for any neurological deficits and then discharged to the patients' ward. Analgesics were prescribed for all patients in the form of intravenous 1 gm paracetamol every 8 h for 48 h. After 1–2 days of hospital stay, patients were discharged home in a brace, and analgesics were advised on demand.

Postoperative evaluation

Plain X-ray radiographs were obtained for all patients on the 1st postoperative day. After discharge from the hospital, all patients were followed at the outpatient clinic. Follow-up visits were scheduled after 1 month, then at 3-month intervals. During the serial postoperative follow-up visits, patients were evaluated clinically for postoperative pain using VAS. Plain X-ray radiographs were obtained each visit to assess spinal fusion. In some cases, CT was also obtained. Spinal fusion was confirmed clinically (reduction of back pain) and radiologically (bone trabeculae formation across the fusion area, absence of hallow sign around screws, and absence of pseudoarthrosis). Any clinical or radiological manifestations of hardware failure, such as screws loosening or pullout, were documented.

All patients were referred also to the rheumatology department for further medical management of osteoporosis. All patients received subcutaneous injections of denosumab (60 mg) every 6 months plus daily oral calcium (1000 mg) and vitamin D (400 IU).

Results

This study included 37 patients (25 females and 12 males, with a female: male ratio of 2.08:1). The main age of the participants was 59.19 ± 5.42 (range 47–69) years. All patients were scheduled for spinal fixation: 20 patients for degenerative spinal diseases and 17 patients for compression fractures. All patients were proven to have spinal osteoporosis with a mean T score of −2.8 ± 0.24 (range of −2.5 to −3.5) (Table 1).

The total number of the involved vertebral bodies was 110, with a total screws number of 220. According to the number of involved vertebral levels in each case, two levels were involved in 10/37 cases (27%), three levels in 19/37 cases (51%), four levels in 7/37 cases (19%), and five levels in 1/37 cases (2.7%) (Table 2). In fracture cases, every case suffered from a single vertebral body fracture, except for one case that had two fractured vertebral bodies. The mean operative time was 130.81 ± 17.38 min (range, 100–170 min), and the mean operative blood loss was 222.97 ± 53.74 mL (range, 130–350 mL). No case required a blood transfusion.

The main presenting symptom in all cases was back pain with a mean preoperative of VAS 9.06 ± 0.9 (range, 7–10). It dropped after 1 month to 2.24 ± 0.8 (range, 1–4) and after 6 months to 1.81 ± 0.78 (range, 1–3). In degenerative cases, the mean VAS for the preoperative radicular pain was 8.2 ± 1.06 (range, 6–10); after 1 month, it dropped to 1.65 ± 0.75 (range, 1–3); and after 6 months, it reached 1.2 ± 0.41 (range, 1–2). Regarding the neurological status, neither pre- nor postoperative neurological deficits were documented in our group of patients (Table 3).

Table 1. Demographic data, clinical presentations, and radiological findings.

Parameters	Results	
Total number of patients	37	
Age (years)	59.19 ± 5.42 (47–69)	
Male: female	12:25 (1:2.1)	
Clinical presentation		
Back pain (n = 37, 100%)	9.06 ± 0.9 (7–10)	
Radicular pain (degenerative) (n = 20, 54%)	8.2 ± 1.06 (6–10)	
Radiological findings		
T score (Mean)	−2.8 ± 0.24 (−2.5 to −3.5)	
Fractured level (n = 17)	D12	1
	L1	3
	L2	4
	L3	1
	L4	7
	L5	2
Degenerative cases (n = 20)	Stenosis	15
	Spondylolisthesis	5
Comorbidity		
DM	6 (16%)	
HTN	10 (27%)	
Smoking	5 (14%)	

Table 2. Operative data.

Parameters	Results	
Operative time/minutes	130.81 ± 17.38 (100–170)	
Operative blood loss/mL	222.97 ± 53.74 (130–350)	
Total number of involved vertebrae	110	
Total number of screws	220	
Number of involved levels per case	2 levels	10/37 (27%)
	3 levels	19/37 (51%)
	4 levels	7/37 (19%)
	5 levels	1/37 (2.7%)
Hospital stay	2.24 ± 0.83 (1–4)	

Table 3. Clinical outcome and reported complications.

Parameters	Results	
Follow-up/months	15.24 ± 8.07 (6–36)	
Clinical outcome		
Back pain (n = 37, 100%)	Preoperatively	9.06 ± 0.9 (7–10)
	1 month postoperatively	2.24 ± 0.8 (1–4)
	6 months postoperatively	1.81 ± 0.78 (1–3)
Radicular pain (degenerative) (n = 20, 54%)	Preoperatively	8.2 ± 1.06 (6–10)
	1 month postoperatively	1.65 ± 0.75 (1–3)
	6 months (1–2)	
Complications		
Asymptomatic intraspinal cement leak	2/37 (5.4%)	
Asymptomatic paraspinal cement leak	3/37 (8.1%)	
Failed fusion	0 (0%)	
Hardware failure	0 (0%)	
Mortality	0 (0%)	

The mean follow-up duration was 15.24 ± 8.07 months (range, 6–36 months). During the period of follow-up, and according to our fusion criteria, no cases of failed fusion could be detected. Also, no cases of screw loosening or pullout were noticed (Figs. 2 and 3) (Table 3).

The procedure-related documented morbidity was an asymptomatic paraspinal cement leak in three cases (8.1%) (Fig. 1). Also, asymptomatic intraspinal leakage was observed in two cases (5.4%) (Fig. 2). No cases of pulmonary emboli were documented. No mortalities were documented.

Discussion

As a result of increased aging populations, spine surgeons nowadays treat more patients with osteoporotic spine. The most common spinal pathologies associated with osteoporosis are compression fractures and degenerative spinal diseases. Osteoporosis is related to structural weakness of vertebral bodies, which makes instrumentation of the spine more challenging. They are associated with higher risks of screws loosening and pullout, with a rate ranging from 0.6 to 11% [8,20–24].

In our study, we reported a marked reduction in the back pain VAS, where it dropped from 9.06 ± 0.9 preoperatively to 1.81 ± 0.78 after 6 months. In their study, Wang et al. [1] also observed a marked reduction in back pain VAS from 9 preoperatively to 1.8 at their last follow-up. Moreover, we noted no cases of screws loosening or pullout during our follow-up (mean 15.24 ± 8.07 months). Wang et al. [1] detected no cases of screws loosening or pullout over a mean follow-up duration of 12 months, whereas Mo et al. [2] reported screws loosening in only 2 out of 172 screws after 24 months of follow-up.

Screw augmentation has been used for a long time as an option to ensure adequate screw purchase within the vertebral body. Different clinical trials showed a significant reduction in the rate of screws loosening and pullout in augmented vs. non-augmented screws [2,19,25–28]. Many materials were used for augmentation, such as polymethyl methacrylate (PMMA), calcium sulfate, and hydroxyapatite. Among them, PMMA has been popularly used as being more available and cost-effective. It has also been proven to have stronger augmentation power than calcium sulfate [29–31]. In our study, we used the PMMA for its proven efficacy, in addition to its easier preparation and application.

The main fear while using bone cement is the risk of it leaking into either the spinal canal or the blood circulation. To minimize this risk, the PMMA was mixed to a doughy consistency, and the proper volume was injected under fluoroscopic guidance.

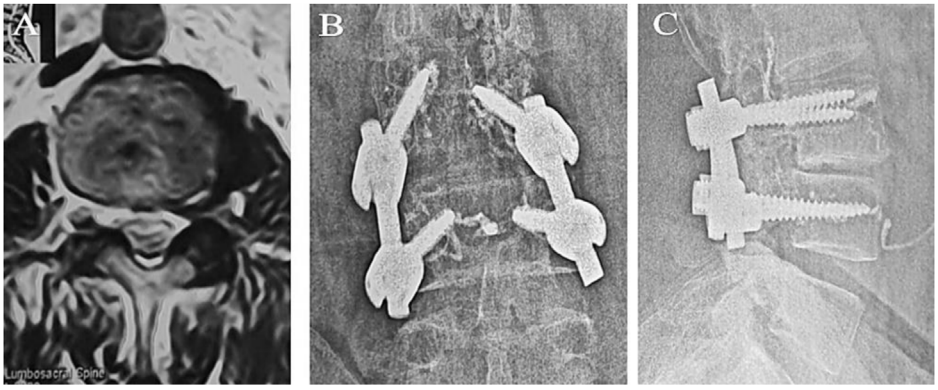

Fig. 1. A 48-year-old female patient with degenerative spondylolisthesis with left L3-L4 foraminal stenosis and facet osteoarthropathy: (A) preoperative axial T2 MRI; (B) postoperative anteroposterior; (C) lateral plain radiographs showing minimal vascular and intraspinal (opposite L2-L3 disc space) cement leak that was asymptomatic.

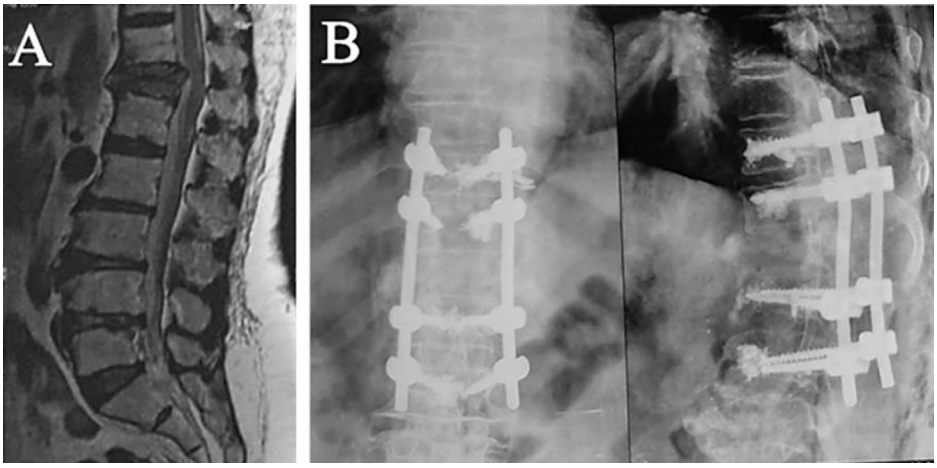

*Fig. 2. A 63-year-old female patient with an osteoporotic D12 compression fracture: **(A)** preoperative sagittal T2 MRI showing marked reduction of D12 vertebral body height; **(B)** 6-month postoperative plain radiographs in anteroposterior and lateral views showing shadows of bone cement within the vertebral bodies around the screws, with a small amount of paraspinal leak opposite DV 10.*

We injected 2–3 mL of PMMA for each screw according to its size. We reported asymptomatic paraspinal cement leak in three cases (8.1%) and asymptomatic intraspinal leakage in two cases (5.4%). In their study, Leichtle et al. [18] reported 17% of paraspinal or ventral cement leakage with no instances of intraspinal leakage. They attributed that to the use of high-viscosity cement with the appropriate volume, which was 1 mL for the thoracic vertebra and 3 mL for the lumbar vertebra [18].

Previous studies proposed and confirmed that proper cement volume ranges from 0.5 to 3 mL, whereas larger amounts may have no beneficial effect on stability and are associated with a higher risk of leak [14,18,32–34]. Less viscous cement was associated with a greater risk of leak and lower fixation strength as it would distribute widely into the vertebral body [20,27,35,36]. Another technical consideration that may help in reducing cement leakage is the use of the tap, which is just 5 mm smaller than the permanent screw in diameter and length. The tip of the injecting needle is then introduced to the middle of the vertebral body. The space that was created by the tap permits the injection of doughy viscous cement at low pressure [1].

Regarding the type of screws, controversy is still found between solid and fenestrated screws. Some authors reported a significantly higher failure rate for solid screws than that of fenestrated screws, considering that their studies were performed on

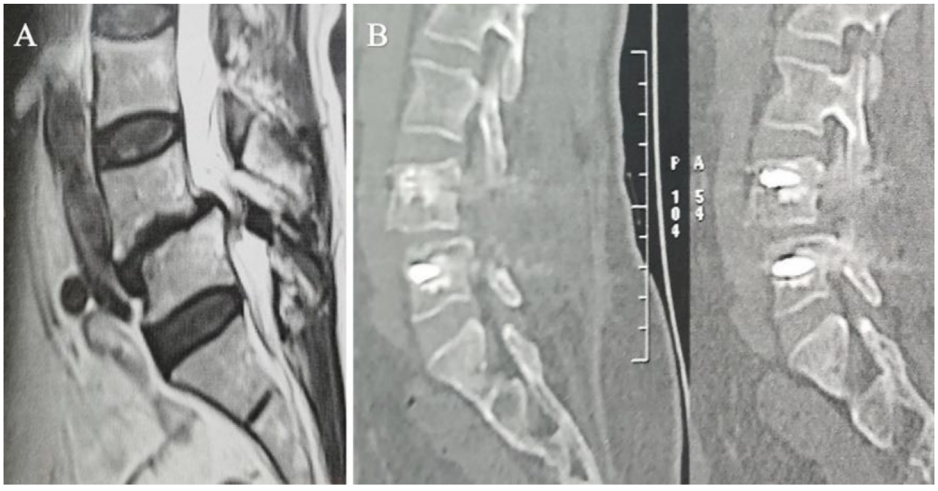

*Fig. 3. A 52-year-old female patient with isthmic L4-L5 spondylolisthesis: **(A)** preoperative sagittal T2 MRI showing L4-L5 spondylolisthesis with subsequent canal stenosis; **(B)** 12-month postoperative sagittal CT cuts showing shadows of bone cement within the vertebral bodies around the screws.*

osteoporotic-like artificial bone [11,37]. Other authors who studied human osteoporotic cadavers found that pullout was higher in fenestrated screws than that in solid ones [7]. Further studies revealed no significant difference between both types of screws [18,34]. Some authors suggested that the difference in results of fenestrated screws in various studies might be related to the design of the screw and the number of holes, in which failure rates were higher in screws with a smaller number of holes [18].

Leichtle et al. [18] compared both types of screws in the same vertebral body on human cadavers. Regarding the pullout strength, they concluded that there was no significant difference between the traditional solid screws and the more expensive and sophisticated fenestrated screws. We considered the solid screws a safe and effective substitute to the more expensive fenestrated ones.

The limitations of our study are the retrospective nature, the lack of a control group, the relatively small number of cases, and the short duration of follow-up. Further prospective clinical trials on a larger number of patients with longer follow-up periods are still warranted to ensure the efficacy of augmented solid pedicle screws in patients with osteoporotic spine.

Conclusion

Solid nonfenestrated augmented pedicle screws are considered a safe and effective method for spinal fixation in patients with either degenerative or traumatic osteoporotic spinal pathologies. Proper volume and preparation of bone cement may minimize the risks of cement leaks.

Ethics information

The article does not contain information about medical device(s)/drug(s).

Author declaration of funding statement

No funds were received in support of this work.

Conflicts of interest

The authors report no conflicts of interest.

Abbreviations

CT	Computed tomography
DEXA	Dual X-ray absorptiometry
MRI	Magnetic resonance imaging
PMMA	Polymethyl methacrylate
VAS	Visual analog scale

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