

A comparative study on screw loosening in osteoporotic lumbar spine fusion between expandable and conventional pedicle screws

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Abstract

Introduction The aim of this study is to compare the rate of screw loosening and clinical outcomes of expandable pedicle screws (EPS) with those of conventional pedicle

screws (CPS) in patients treated for spinal stenosis (SS) combined with osteoporosis.

Methods One hundred and fifty-seven consecutive patients with SS received either EPS fixation ($n = 80$) or CPS fixation ($n = 77$) to obtain lumbosacral stabilization. Patients were observed for a minimum of 24 months. Outcome measures included screw loosening, fusion rate, Japanese Orthopaedic Association (JOA) scores and Oswestry disability index (ODI) scoring system, and complications.

Results In the EPS group, 20 screws became loose (4.1%) in 6 patients (7.5%), and two screws (0.4%) had broken. In the CPS group, 48 screws became loose (12.9%) in 15 patients (19.5%), but no screws were broken. The fusion rate in the EPS group (92.5%) was significantly higher than that of the CPS group (80.5%). The rate of screw loosening in the EPS group (4.1%) was significantly lower than that of the CPS group (12.9%). Six EPS (1.8%) screws were removed. In the EPS group, two screws had broken but without neural complications. Twelve months after surgeries, JOA and ODI scores in the EPS group were significantly improved. There were four cases of dural tears, which healed after corresponding treatment.

Conclusions EPS can decrease the risk of screw loosening and achieve better fixation strength and clinical results in osteoporotic lumbar spine fusion.

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Introduction

Pedicle screw instrumentation has become increasingly popular over the last decade. Transpedicle fixation

technique has three main advantages over other internal spinal fixation constructs: the ability to provide three-column fixation, facilitate the instrumentation of short segments, and maintain anatomic or desired sagittal alignment [1]. However, in elderly patients, the loosening and back-out of pedicle screws resulting from failure of screw fixation remains a significant clinical problem, with an overall instrumentation failure rate of 0.6 to 11% [2–5].

Many experimental studies have proved that the stiffness and strength of pedicle screw fixation can be significantly increased when the pedicle screw is augmented with various bone cements [6–10]. Nevertheless, there has been a longstanding concern about the exothermic properties of bone cement and the risk of neural injury in the event of extravasation. Pedicle screws augmented with bone cement are also very difficult to remove thus greatly complicating revision surgery [11]. To solve these problems, several novel expandable pedicle screws have been designed in pursuit of a pedicle screw that can maintain fixation in weak or osteoporotic bone. These new devices include Omega21 Spinal Fixation System (EBI, L.P. Parsippany, NJ, USA), BeadEx implant (Expandis Ltd, Hof HaCarmel, Israel), as well as Thunder Expandable Screw System (Sofamor-Weigao Orthopedic Device Co., Limited, Shandong Province, China). Biomechanical and clinical studies have shown that expandable screws provided significantly higher pullout strength and lower rates of instrument failures [12–16]. However, prospective clinical control studies on expandable pedicle screws are rare.

The aim of this study is to compare the clinical outcomes and fusion rates of expandable pedicle screws (EPS) (Sofamor-Weigao Orthopedic Device Co., Limited, Shandong Province, China) with those of conventional pedicle screws (CPS) in severely osteoporotic patients requiring spine surgery due to the spinal stenosis.

Materials and methods

Implant description

The multi-axial EPS (Sofamor-Weigao Orthopedic Device Co., Limited, Shandong Province, China) was barrel-shaped, with an outer diameter of 6.5 mm (and 7.0 mm), a 2.5 mm bore, and a 3 mm pitch. A smaller gauge can be inserted into the interior of EPS to open the fins concentrically as it is advanced. This system increases the diameter of the expanding screw tip by approximately 2.0 mm (Fig. 1). The diameter of the posterior portion of the screw remains constant in order to prevent the fracture of the pedicle during the expansion of the screw. CD Horizon M8 system (Sofamor-Danek, Memphis, TN) was used in CPS group.



Fig. 1 The multi-axial expandable pedicle screw (EPS) was barrel-shaped, with an outer diameter of 6.5 mm (and 7.0 mm), a 2.5 mm bore and a 3 mm pitch. A smaller gauge can be inserted into the interior of EPS to open the fins concentrically as it is advanced. This system increases the diameter of the expanding screw tip by approximately 2.0 mm

Patients' enrollment

The clinical study proposal was approved by the medical ethical committee of the authors' institution. From January 2004 to January 2009, 157 consecutive patients with a mean age of 62.1 (range, 52–74 years) were enrolled in this study. There were 96 female and 61 male patients. All patients were randomized into two groups (EPS group: 80; CPS group: 77) according to the table of random numbers. Before enrollment, all patients gave their written consent for study participation. The inclusion criteria were: (1) patients having a history of neurogenic claudication or radicular leg symptoms for at least 12 weeks with confirmatory cross-sectional images showing lumbar spinal stenosis at one or more levels, and (2) BMD 2.5 standard deviations (SD) or more below the young adult mean (*T*-score at or below -2.5). The exclusion criteria were: (1) underwent surgery before, and (2) diagnosis included spondylolisthesis, spondylolysis, kyphosis, cancer, or pseudarthrosis. All patients underwent standard lumbar spine decompression surgery, with or without intervertebral fusion. All pedicle screws were implanted under C-arm guide to ensure the correct position. Auto grafts from resected spinous processes and lamina are generally used for intervertebral cage and dorsolateral spinal fusion. Patients were observed for a minimum of 24 months. Mean duration of follow-up was 43 months (range 24–60 months).

In this study, patients were encouraged to walk wearing a customized lumbosacral orthosis on the following day after surgery for 1 month. Patients' vigorous work and activity were restricted up to 3 months after surgery. After that process, unrestricted activity was permitted along with patients' neurologic situation. At 3, 12, and 24 months after the surgery, functional evaluations were graded again with the Japanese Orthopaedic Association (JOA) and Oswestry disability index (ODI) scoring system [17].

Dynamic radiographs in flexion and extension were used to evaluate fusion at 3, 12, and 24 months after surgery. Thin-cut 1 mm CT scans were taken at 3 and 12 months. Two independent, blinded radiologists interpreted all radiographs and CT scans. A third independent, blinded radiologist was used to adjudicate conflicting fusion findings. Spinal fusion was considered successful as follows [18, 19]: (1) clear trabecular bone bridging across the segment to be fused; (2) translation of 3 mm or less and angulation of $<5^\circ$ on flexion–extension radiographs; (3) continuous bone growth connecting the vertebral bodies. Screw loosening was considered when there was radiolucency around the pedicle screws and/or screws were displaced. Complications related to the hardware were also evaluated based on clinical and radiographic records. Patients who developed pseudarthrosis with dysfunctional syndromes and/or recurrence of back symptoms will undergo re-surgery.

Statistical analysis

The data were analyzed using SPSS for Windows ver. 11.0 (SPSS Inc., Chicago, IL). Descriptive statistics were calculated and expressed as mean \pm standard deviation. A comparison of data was performed using LSD-*t* test, χ^2 test, and Fisher's exact test. In all cases, the significance level was set at $P < 0.05$.

Results

The follow-up rate at 24 months for the entire study cohort was 90.4% (142/157). There was no statistically significant difference between the EPS group (88.8%) and the CPS group (92.2%) returning at 24 months ($P = 0.64$). There was no statistically significant difference between the treatment groups in age, BMD, baseline JOA and ODI (Table 1).

Four hundred and eighty-eight expandable pedicle screws (Figs. 2, 3, 4, 5) and 464 conventional pedicle screws were implanted. In the EPS group, 20 screws became loose (4.1%, 20/488) in six patients (7.5%, 6/80) and two screws had broken (0.4%, 2/488). In the CPS group, 48 screws became loose (12.9%, 48/464) in 15 patients (19.5%, 15/77) but no screws were broken. According to the three radiographic criteria, the fusion rate

Table 1 Clinical characteristics

	EPS group	CPS group	<i>P</i> value
No. males/females	26/54	20/57	0.4698
Age	62.3 \pm 3.5	61.9 \pm 2.8	0.4314
BMD (g/cm ²)	0.784 \pm 0.25	0.821 \pm 0.18	0.2905
BMD (<i>T</i> -scores)	−2.84SD	−2.75SD	/
No. implanted screw	488	464	/
Pre-op ODI	37.7 \pm 2.2	38.4 \pm 3.5	0.134
Post-op ODI (3 months)	11.7 \pm 1.7	12.1 \pm 1.1	0.0833
Post-op ODI (12 months)	11.4 \pm 1.4	14.6 \pm 1.5	0.000
Pre-op JOA	14.9 \pm 1.3	15.3 \pm 1.5	0.0758
Post-op JOA (3 months)	23.6 \pm 1.9	22.9 \pm 2.6	0.055
Post-op JOA (12 months)	22.5 \pm 1.5	19.8 \pm 1.4	0.000
Recovery rate (3 months)	68.8%	55.5%	/
Recovery rate (12 months)	53.9%	32.8%	/
No. screw loosening	20	48	0.000
No. screw breakage	2	0	0.34

The recovery rate = (postoperative score – preoperative score)/(full marks – preoperative score) \times 100%

EPS expandable pedicle screw, CPS conventional pedicle screw

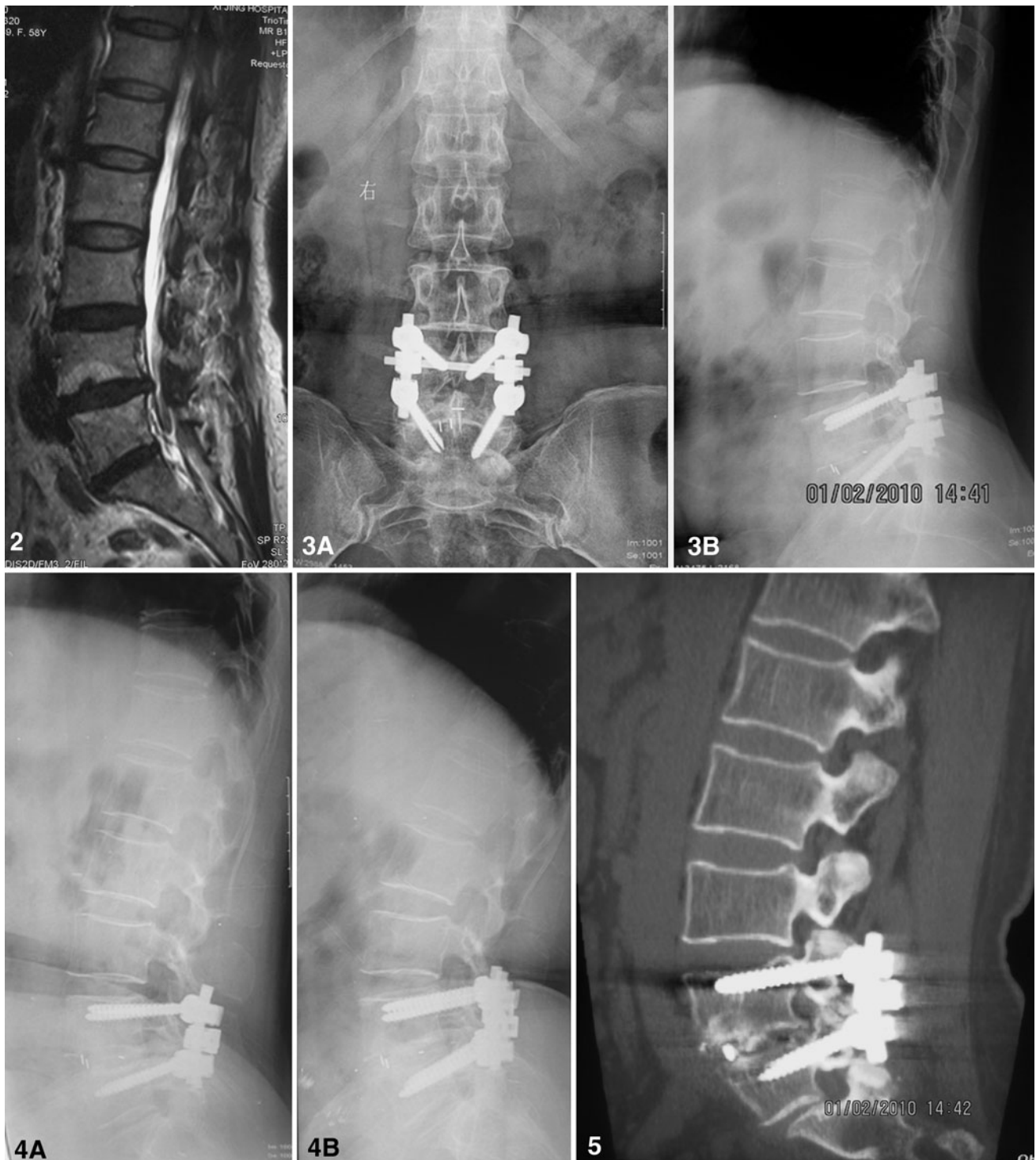
BMD bone mineral density, ODI Oswestry disability index, JOA Japanese Orthopaedic Association

in the EPS group (92.5%, 74/80) was significantly higher than that of the CPS group (80.5%, 62/77) ($P = 0.048$). The rate of screw loosening in the EPS group (4.1%) was significantly lower as compared with the CPS group (12.9%) ($P < 0.01$). Of the 21 nonunion patients, 5 patients (EPS, $n = 1$; CPS, $n = 4$) required revision for pseudarthrosis. Six expandable pedicle screws (1.8%) were removed. However, no statistically significant differences were found in the revision rate between the two groups ($P = 0.34$). In the EPS group, two screws had broken but without neural complications.

The results of the functional evaluations are shown in Table 1. In both the groups, post-surgery JOA and ODI scores had significantly improved ($P < 0.05$). However, no significant differences were found in the post-surgery JOA and ODI scores between the two groups 3 months after surgeries ($P > 0.05$). Twelve months after surgeries, JOA and ODI scores in the EPS group had significantly improved as compared with the CPS group ($P < 0.05$). There were four cases of dural tears, which healed after corresponding treatment. There were no other complications such as nerve root injury and infection.

Discussion

Transpedicular fixation technique is the most important and useful method in the posterior fixation of the spine. The



Figs. 2–5 A 64-year-old woman with postmenopausal osteoporosis and degenerative stenosis complained of severe back pain and neurogenic claudication. BMD of lumbar vertebra decreased by 2.7 SD. Pre-surgery MR image. Fig. 2 shows a severe stenosis at L4/5.

Twenty-four months after surgery, anterior-posterior. Fig. 3 a, b and dynamic radiographs. Fig. 4 a, b and 3-D CT scan. Fig. 5 showed successful spinal fusion was achieved and there was no screw loosening or breakage

fixation strength of pedicle screws depends on the geometric characteristics of the screw and the mechanical properties of the trabecular bone on the bone-screw

interface [20]. However, among the elderly patients, osteoporosis is the most common metabolic bone disorder and leads to the screw loosening. To solve this problem, novel

approaches and instruments have been designed to increase purchase and reduce implant subsidence and the incidence of revision surgery as a result of construct failure in this patient population.

One device is the Omega21 Spinal Fixation System (EBI, L.P. Parsippany, NJ, USA), which is an expandable pedicle screw that expands after it is positioned in the pedicle. The clinical results indicated that Omega21 might be particularly useful in situations of expected compromised fixation strength, such as re-surgery and osteoporosis [12, 13]. BeadEx (Expandis, Ltd, Hof HaCarmel, Israel) implant is another kind of expandable pedicle screw. It is composed of a cannulated pedicle screw (7 mm outer diameter) with numerous small titanium rolls (3 mm diameter, 4 mm length) that are passed through the pedicle screw and layered on top of each other to expand within the vertebral body. Biomechanical study showed that BeadEx provided better stability [21]. Since the cortex is the most rigid part in the vertebral body, emphasis on cortex-anchorage may present an optimal fixation of screws. To improve the fixation of the instrumentation for an osteoporotic spine, a new screw with the cortex-anchorage was designed by Chen. The biomechanical results indicated that the mean pullout force increased 47% as compared with the conventional screws. Although proven effective in increasing fixation strength, these novel implants have a common shortcoming. These screws are uniaxial, wherein surgeons might find it more difficult to connect rods with screws in L5–S1 spondylolisthesis, particularly, in degenerative scoliosis. Thus, a mainstream multiaxial head design not only improves ease of connecting rod application but also reduces the duration of surgery. Thunder expandable screw system is another multiaxial expandable instrument. Another significant advantage of the multiaxial design is preventing pedicle screw breakage [22]. This is more important in the hollow-structured pedicle screws whose fatigue strength is lower than that of the solid-structured screws. In Cook's study, breakage rate of Omega21 screw was 2.8% (4/145), which totaled 10 of the 389 expandable screws used (2.6%). Screw breakage rate in sacral anchoring in L5–S1 fusions was 5% (3/57). However, in the present study, total breakage rate was 0.4% (2/488). The difference in screw structure might partly explain the lower screw breakage rate. On the other hand, patients in this study were wearing a customized lumbosacral orthosis for 1 month and resumed their work and activity 3 months after surgery. This may also play an important role in preventing screw breakage.

In the EPS group, failed fusions occurred in six patients and the fusion rate was 92.5% (74/80). Indicated by lucency about the screw, the rate of loosening in the EPS group (7.5%, 48/464) was significantly lower than that of the CPS group (19.5%, 15/77). Most of the screw loosening

occurred in the caudal or cephalad instrumented vertebral level. The mechanism of failure was that additional stresses focused on the caudal or cephalad screws due to multilevel fusion. To decrease the risk of instrument failure, De Wald et al. [23] reviewed a series of patients over the age of 65 with a minimum of five-level fusions. They suggested that multiple fixation sites are needed both at the cephalad and caudal aspects of a spinal construct in a patient with poor bone quality. Some authors also suggested using bilateral iliac screws to increase S1 pullout resistance and decrease S1 screw failures [24, 25]. Although many methods have been used to enhance screw fixation strength, yet a spinal disorder, which is too osteoporotic for surgical intervention remains largely unknown.

Although the EPS could improve the spine surgeon's ability to instrument the osteoporotic spine, it has some limitations. One limitation is the screw removal. During the primary surgery, EPS can be extracted by removing the central pin, which collapses the anterior portion of the screw. The EPS is then backed out normally. However, during the revision surgery, because bone tissues have already grown into the fins and EPS could not return to normal shape, the pedicles would be damaged unavoidably. Nevertheless, because the diameter of the expanding screw tip increases by approximately 2.0 mm, risk of nerve root and dural injury is lower relatively. In this study, six expandable pedicle screws (1.2%) were removed because of pseudarthrosis. No nerve root or dural injury occurred during revision surgery. PMMA augmentation was used to fill screw tracts when pedicle screws were replaced. Similarly, Cook et al. [12] also reported that the expandable pedicle screw instrumentation was removed in six patients (4%) after 8 months or longer after surgery because of local discomfort. The instrumentation was removed without any postoperative problem. Thus, special methods such as PMMA augmentation should be applied in revision surgeries [26–28].

Conclusions

In osteoporosis spine surgery, expandable pedicle screws can decrease the risk of screw loosening and achieve better fixation strength. The hollow-structured design does not increase the risk of screw breakage significantly. The expandable pedicle screw design adds a valuable tool to the growing armamentarium of spinal instrumentation.

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