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Original article

Surgical treatment of osteoporotic degenerative spinal deformity with expandable pedicle screw fixation: 2-year follow-up clinical study

J. Fu^a, Z.M. Yao^{b,1}, Z. Wang^a, G. Cui^a, M. Ni^a, X. Li^a, J.Y. Chen^{a,*}

^a Department of Orthopaedics, Chinese People's Liberation Army General Hospital (301 Hospital), 28, Fuxing Road, 100853 Beijing, PR China
^b Department of Orthopaedics, Beijing Children's Hospital, Capital Medical University, National Center for Children's Health, Beijing, PR China

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ABSTRACT

Background: Osteoporotic bone offers poor purchase for the instrumentation in patients with degenerative spinal deformity (DSD), which could lead to several complications. Recently, augmentation methods to improve pedicle screw fixation have been proposed. This retrospective study was to investigate the clinical and radiographic outcomes of expandable pedicle screws (EPS) in patients with osteoporotic DSD. *Hypothesis:* Expandable pedicle screws (EPS) provide excellent instrument fixation in patients with osteoporotic DSD, improving radiographic and clinical outcomes.

Materials and methods: A total of 27 (6 males and 21 females) DSD patients who underwent orthopedics operation with EPS were retrospectively studied. Full-length standing spinal radiographs were obtained in all patients pre- and postoperatively and again at the two-year follow-up. The functional evaluations before operation and at two-year follow-up were graded with Scoliosis Research Society outcomes instrument-22 (SRS-22) and Oswestry Disability Index (ODI) scoring system.

Results: All patients obtained good corrective outcomes on spinal deformity. The preoperative ODI score was 36.7% and reduced to 11.9% at two-year follow-up (p = 0.0000). Before operation, the SRS-22 function, pain, appearance and mental scores were 2.7 ± 0.4 , 3 ± 0.6 , 2.7 ± 0.5 and 2.9 ± 0.6 , respectively. The scores at two-year follow-up were significantly improved to 3.8 ± 0.7 , 4.2 ± 0.6 , 4.3 ± 0.6 and 4.4 ± 0.7 , respectively (p = 0.0000). The SRS-22 satisfaction score was 4.6 ± 0.4 at two-year follow-up. No instances of screw breakage, loosening or pullout in any patient at follow-up.

Discussion: EPS provides excellent instrument fixation in patients with osteoporotic DSD, improving radiographic and clinical outcomes at two years' follow-up.

Type of study: Retrospective case series study. *Level of evidence:* IV.

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1. Introduction

The prevalence of degenerative spinal deformity (DSD) is increasing, to some extent, this is due to the domestic increase in the average life span. DSD is a form of adult-onset curve due to the degeneration of spinal motion segments, including any combination of the axial, coronal, and sagittal deformities [1]. Especially, asymmetrical disc dehydration, degeneration, and collapse in combination with facet degeneration and ligamentous laxity [2,3]. Together, these changes may result in instability of the spinal column with axial rotation, spondylolisthesis, lateral listhesis, scoliosis, and kyphosis, leading to lower back pain and different

* Corresponding author.

E-mail address: jiyingchen_301@163.com (J.Y. Chen).

¹ Co-first author.

https://doi.org/10.1016/j.otsr.2017.11.010 1877-0568/© 2017 Elsevier Masson SAS. All rights reserved. degrees of neurogenic problems such as muscle weakness, radiating pain, or numbness in the lower limbs.

A various studies have reported that a sufficient number of DSD patients had different degrees of osteoporosis, which was one of the main pathogenesis factors [4–6]. And the osteoporotic bone offers poor purchase for the instrumentation, often leads to implant failure, and is associated with a higher rate of pseudarthrosis. Cook et al. [7] and Lei and Wu [8] have developed expandable pedicle screws (EPS) that promise to increase bone fixation strength significantly.

As far as we know, there was no research about an application of EPS in osteoporotic DSD patients. The purpose of this retrospective study was to evaluate the clinical and radiographic outcomes of osteoporotic DSD patients treated with EPS. We hypothesized that Expandable pedicle screws (EPS) provide excellent instrument fixation in patients with osteoporotic DSD, improving radiographic and clinical outcomes.

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2. Methods

After approved by our Institutional Review Board and written informed consent was obtained from all participants, this retrospective study was carried out with patients presented with pain and neurologic complaints from January 2013 to January 2015, and diagnosed with osteoporotic DSD. The inclusion criteria were the following: (1) diagnosis of osteoporosis (Osteoporosis was diagnosed according to the World Health Organization's diagnostic criteria for osteoporosis, in which a patient's *t*-score of lumbar spine is less than or equal to -2.5 [9]); (2) mechanical low back pain resulting from coronal or sagittal spinal deformities, with or without lumbar spinal stenosis (radicular leg pain, neurogenic intermittent claudication, neurogenic low back pain); (3) no associated idiopathic, congenital, developmental, or neuromuscular spinal abnormalities; and (4) no history of spinal surgery.

A total of 27 (6 males and 21 females) osteoporotic DSD patients meeting with aforementioned criteria were included in this study. The mean age of the patients was 63.6 ± 6.2 years (range, 54 to 78 years). They were followed up for two years through periodic clinical and radiologic examinations. The patients and/or their families were informed that data from the case would be submitted for publication, and gave their consent.

3. Surgical technique

All patients in current study underwent posterior long segmental instrumentation fixation and those accompanied with lumbar spinal stenosis were simultaneously performed posterior decompression and intervertebral fusion in the impaired segment. All instrumentation used in this paper were the lumbar titanium alloy multi-axial EPS (Shandong Weigao Orthopedic Device Co., Limited, Shandong, China) [10], which is barrel-shaped, with an outer diameter of 6.5 mm (and 7.0 mm), a 2.5 mm bore and a 3 mm pitch. Proximal instrumented vertebra (PIV) was selected above the upper end vertebrae (UEV) or at least the neutral vertebra (NE) level. Selection of the lowest instrumented vertebra (LIV) was determined by the radiographic characteristics: in case that L5/S1 intervertebral space was intact and was not accompanied with spinal instability or spondyloschisis, LIV was located at L5. On condition that L5/S1 intervertebral space was required to manage, LIV was located at S1. When the longitudinal bone trabecula on X-ray was sparse or unapparent, it needed iliac screw fixation. While combining with sagittal imbalance across the thoracolumbar spine (T11-L1), PIV should be shifted to T10 for avoiding postoperatively adjacent segment degeneration. Intraoperative pedicle screws were placed bilaterally and confirmed safely and accurately by intraoperative fluoroscopy. The correction of DSD patients was a moderate degree, recovery to normal lumbar lordosis and coronary Cobb angle was not recommended.

3.1. Radiographic and clinical evaluation

All patients had full-length standing spinal radiographs pre- and postoperatively and again at the two-year follow-up. The corrective outcomes were assessed by the following parameters: (1) Cobb angle of lumbar curve: measured by the Cobb method; (2) sagittal vertical axis (SVA): horizontal distance between vertical line of C7 and the posterosuperior corner of S1; (3) thoracic kyphosis (TK): the angle between the superior endplate of T5 and the inferior endplate of T12; (4) lumbar lordosis (LL): the angle between the superior endplate of L1 and the sacral endplate; (5) pelvic incidence (PI): the angle between the perpendicular of the sacral plate and the line joining the middle of the sacral plate and the hip axis; (6) pelvic tilt (PT): the angle between the vertical line and the line joining the middle of the sacral plate and the hip axis; (7) sacral slope (SS): the angle between the sacral endplate and the horizontal plane.

One week after operation, all patients were encouraged to attempt ambulation wearing a customized lumbosacral orthosis, which should be worn for 3 months. The patients' clinical outcomes and their functional index were assessed using the Scoliosis Research Society outcomes instrument-22 (SRS-22) and the Oswestry Disability Index (ODI) scoring system preoperatively and at the two-year follow-up. The data were analyzed using the selfcontrol method. Complications related to instrumentation were also evaluated based on clinical and radiographic records, including screw loosening, pullout, or breakage, and PJK.

3.2. Statistical analysis

This was performed using SPSS 19.0 for Windows (SPSS Inc., Chicago, Illinois). Descriptive data are presented as mean \pm standard deviation with ranges. Corrective measurements, SRS-22 and ODI scores of pre-operation, post-operation and two-year follow-up were compared using the paired *t*-test or Wilcoxon's signed-rank test. A *p*-value of < 0.05 was considered as statistically significant.

4. Results

4.1. Surgical information

All patients completed the two-year follow up. The mean fusion levels were 7.1 ± 1.6 (4–9), and a total of 384 EPS were surgically implanted in patients during this study. There were 5 times of screw pullout (8 screws: 5 screws at the concave side of apical vertebrae and 3 screws at subthoracic vertebrae) during corrective process, all of them were replaced by pedicle screws with polymethyl methacrylate (PMMA). However, there were no instances of screw breakage, loosening or pullout in any patient at follow-up. No pedicle screw instrumentation was removed after surgery.

4.2. Radiographic and neurologic evaluation

Radiographic measurements taken preoperatively, postoperatively and at the two-year follow-up are shown in Table 1. Good corrective effects on spinal deformity were observed in all patients (Fig. 1). There were no proximal junctional kyphosis (PJK) and adding-on phenomenon in these patients.

The health related quality of life changes in pre-operation and two-year follow-up was summarized in Table 2. The preoperative ODI score was 36.7% (18% to 60%) and reduced to 11.9% (0% to 27%) at two-year follow-up (p=0.0000). Before operation, the SRS-22 function, pain, appearance and mental scores were 2.7 ± 0.4 (2–3.4), 3±0.6 (1.2–4.2), 2.7±0.5 (2–4) and 2.9±0.6 (2.2–4), respectively. The scores at two-year follow-up were significantly improved to 3.8±0.7 (2.8–5), 4.2±0.6 (3–5), 4.3±0.6 (3–5) and 4.4±0.7 (3–5), respectively (p=0.0000). The SRS-22 satisfaction score was 4.6±0.4 (4–5) at two-year follow-up.

5. Discussion

It is well documented that the strength of each fixation point is lowered in patients with osteoporosis, with pullout strength, cutout torque, and maximum insertional torque being directly proportional to bone mineral density [11–13]. Thus, patients with osteoporosis who underwent spine surgery suffered vertebral fractures after instrumentation, pseudarthrosis, and failure of hardware [14]. Recent developments in pedicle screw design have also improved fixation in osteoporotic bone [15]. However, there was

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