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Surgical Treatment of Osteoporotic Thoracolumbar Compressive Fractures with Open Vertebral Cement Augmentation of Expandable Pedicle Screw Fixation: A Biomechanical Study and a 2-Year Follow-up of 20 Patients

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Background. **The incidence of screw loosening increases significantly in elderly patients with severe osteoporosis. Open vertebral cement augmentation of expandable pedicle screw fixation may improve fixation strength in the osteoporotic vertebrae.**

Materials and Methods. **Twenty cadaveric vertebrae (L1-L5) were harvested from six osteoporotic lumbar spines. Axial pullout tests were performed to compare the maximum pullout strength (Fmax) of four methods: 1. Conventional pedicle screws (CPS), 2. Expandable pedicle screws (EPS), 3. Cement augmentation of CPS (cemented-CPS), 4. Cement augmentation of EPS (cemented-EPS). Thirty-six consecutive patients with single-vertebral osteoporotic compressive fractures received posterior decompression and spinal fusion with cemented-CPS (16 cases) or cemented-EPS (20 cases). Plain film and/or CT scan were conducted to evaluate the spinal fusion and fixation effectiveness.**

Results. **The Fmax and energy absorption of cemented-EPS were significantly greater than three control groups. The mean BMD in the severe osteoporosis group was significantly lower than that in the osteoporosis group ($t = 2.04$, $P = 0.036$). In the osteoporosis group, cemented-EPS improved the Fmax by 43% and 21% over CPS and cemented-CPS group. In the severe osteoporosis group, cemented-EPS increased the Fmax by 59%, 22%, and 26% over CPS, EPS, and cemented-CPS, respectively. The clinical results showed that all patients suffered from severe osteoporosis. Six months after operation, the JOA and VAS scores in cemented-EPS group improved from 11.4 ± 2.6 and 7.0 ± 1.4 mm to 24.9 ± 1.6 and 2.1 ± 1.3 mm, respectively. No screw loosening occurred in the cemented-EPS group and spinal fusion was achieved. In the cemented-CPS group, four screws loosened (4.2%) according to the radiolucency. Six months after operation, the JOA and VAS scores improved from 13.1 ± 1.9 and 7.6 ± 1.5 mm to 22.8 ± 2.2 and 2.5 ± 1.6 mm, respectively. No cement leaked into the spinal canal in both groups.**

Conclusions. **Cemented-EPS could increase fixation strength biomechanically. It could reduce the risks of screw loosening in patients with severe osteoporosis, requiring instrumented arthrodesis.**

Key Words: **Pedicle screws; Osteoporosis; Fixation strength; Polymethylmethacrylate; Spinal fracture; Clinical study.**

Osteoporotic thoracolumbar compressive fracture is a common disease in aged population. For spine surgeons, it is unavoidable to encounter patients with osteoporotic spinal fractures who need spinal decompression and instrumentation due to neurologic deficit. The pedicle screw fixation strength is decreased significantly in osteoporotic spine [1–3]. Thus, the incidence of internal fixation failure increases significantly in these elderly patients with severe osteoporosis.

To enhance fixation strength, various methods have been developed, including expandable pedicle screws, pedicle screws augmented with various absorbable or nonabsorbable cements [4]. Clinical results show that the expandable pedicle screw and cement augmentation are ideal in problematic situations of bone compromised by osteoporosis or pedicle screw revision, providing clinical results similar to that expected in normal bone

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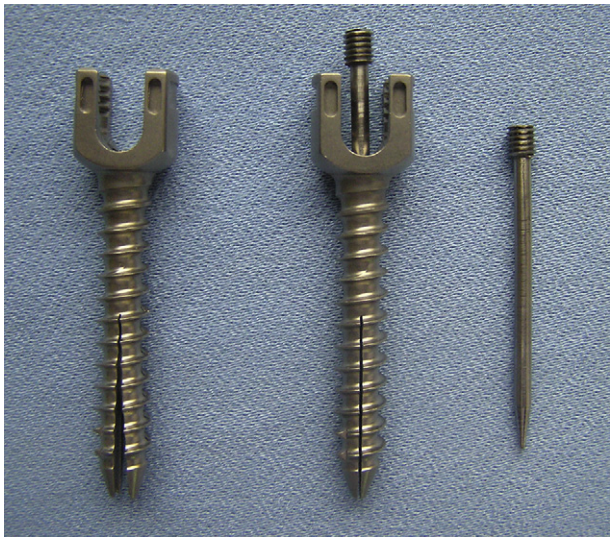

FIG. 1. The expandable pedicle screw is constructed by a pedicle screw and gauge screw. (Color version of figure is available online.)

and primary surgery [5, 6]. However, in some special conditions (severe osteoporosis complicated with vertebral compressive fracture), even the expandable pedicle screw or cement augmentation cannot supply sufficient fixation strength until fusion is achieved.

The purpose of this study was to evaluate the fixation strength of vertebral cement augmentation of expandable pedicle screw and to demonstrate its feasibility and safety in surgical treatment of patients with osteoporotic thoracolumbar compressive fractures.

MATERIAL AND METHODS

Implant Description

The newly designed multi-axial expandable pedicle screw (EPS) (Weigao Orthopedic Device Co. Ltd., Shandong, China) is barrel-shaped, with an outer diameter of 6.5 mm, a 2.5-mm bore, and a 3-mm pitch. The anterior half of the screw is split lengthwise by a groove to form two anterior fins. A smaller gauge can be inserted into the interior of EPS and opens the fins concentrically as they are 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 in the pedicle during the expansion of the screw. CD Horizon M8 system (Sofamor-Danek, Memphis, TN) was used in CPS group as conventional pedicle screws.

Biomechanical Tests

Specimens

All procedures were performed to conform to the ethics guidelines established by the Fourth Military Medical University. Twenty cadaveric vertebrae (L1-L5) were harvested from six osteoporotic lumbar spines aged from 71 to 87 y through the University, Division of Anatomy. The vertebrae were cleaned of all soft tissues. To maintain the integrity of the vertebral body, half of each adjacent intervertebral disc was left attached at the superior and inferior ends. Bone mineral densities (BMD) of vertebrae were determined using dual-energy X-ray absorptiometry (Lunar Corporation, Madison, WI) and reported in g/cm^2. The inclusion criteria were: (1) all donors' age > 70; (2) BMD: 2.0 standard deviations (SD) or more below the young adult mean (T-score at or below –2.0); (3) died of cardiocerebrovascular diseases; (4) confirmatory X-ray showing no lumbar compressive fractures and bone tumor. Exclusion criteria: (1) received prior lumbar operation; (2) died of trauma; (3) chronic vertebral compression fracture. The specimens were double-bagged and frozen at –20°C within 1 h after sample collection. On the day of testing, each vertebra was thawed at room temperature.

Grouping

According to the value of BMD assessed by DXA, 20 vertebral bodies were divided into two groups ($n = 10$): (1) osteoporosis group with BMD ranged from 0.6 to 0.9 g/cm^2; (2) severe osteoporosis group with BMD lower than 0.6 g/cm^2. In each group, 20 pedicles were randomized into four subgroups: conventional pedicle screw (CPS group); expandable pedicle screw (EPS group); cement augmented conventional pedicle screw (cemented-CPS group); cement augmented expandable pedicle screw (cemented-EPS group). By this method, there was no difference in BMD between different subgroups.

Screw Placement Technique

All screw insertions were performed by an orthopedic surgeon following the proper clinical procedure (Fig.2). The pedicle screws were inserted into the lumbar pedicles using instruments specifically designed for EPS and CPS. Extra care was taken to avoid the penetration of the anterior cortex. For the cement augmentation groups, all the pedicles were drilled manually using a 5.0-mm drill. The pilot

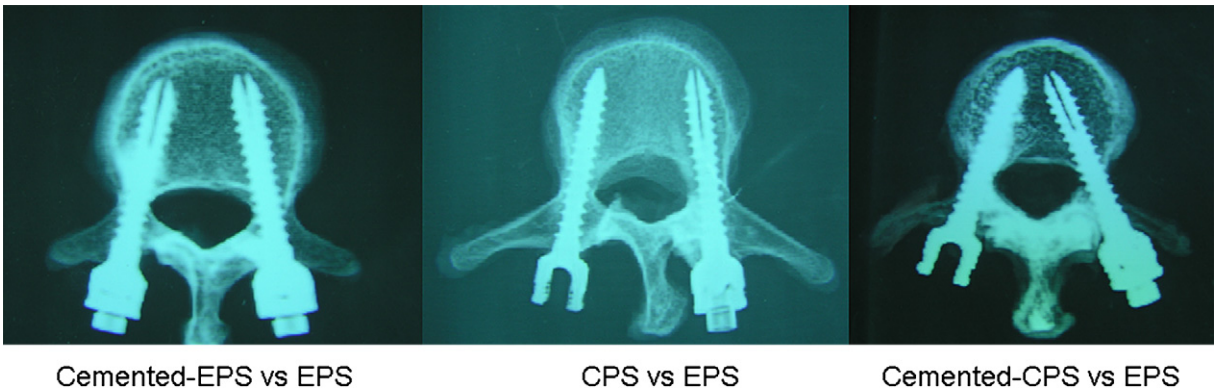

FIG. 2. Axial radiographs of the different pedicle screws inserted with cement augmentation: PMMA was injected to augment the screw along its entire length. (Color version of figure is available online.)