Application of an expandable pedicle screw in the severe osteoporotic spine: A preliminary study

Abstract

Purpose. To investigate the clinical abstractned radiographic outcome of multi-axial expandable pedicle screws (MEPS) in patients with osteoporosis.

Methods. One hundred and twenty-five consecutive patients received MEPS from the UPASS spinal fixation system to obtain thorocolumbar or lumbosacral stabilization. All patients underwent bone mineral density (BMD) scans. The indications for use of the MEPS were spinal diseases with severe osteoporosis (degenerative diseases 46 cases, compression fractures 28 cases, lumbar tuberculosis 27 cases and revision spine surgery 24 cases). The pre-operative and three months post-operative functional evaluations were graded with JOA and VAS scoring system. One week, six months and 12 months after surgery, plain film and three-dimensional CT scans were obtained to evaluate the spinal fusion and fixation effectiveness of MEPS.

Results The mean follow-up period was 18 months (ranged from 6 to 33 months). All patients suffered from severely osteoporosis with a decrease of 25.3% in BMD. The pre-operative JOA and VAS scores were 11.3±3.0 and 6.7±1.8 mm, respectively. Three months after operation, the JOA and VAS scores were 25.2±2.0 and 2.3±1.7 mm. The recovery rate was 78.1±11.5% and the clinical results were satisfying. There were no instances of screw loosening or pullout of the MEPS and the screw-bone interface was excellent. The radiographic results showed that bone healing, both around the screws and inter-vertebral, was achieved.

Conclusion In osteoporosis spine surgery, excellent bone-screw interface and fixation strength can be achieved by using MEPS. MEPS are a novel approach to increase the pedicle screw fixation in osteoporotic and revision spine surgeries.
The transpedicular fixation technique is the most important and useful method in the posterior fixation of the spine. It can be inserted into virtually any level of the thoracic and lumbar spine and provides three-column stability. The fixation strength of the pedicle screws depends on the bone mineral density so efficacy of the pedicle screw in patients with low bone density is a concern.

Among the elderly patients, osteoporosis is the most common metabolic bone disorder. Osteoporotic patients requiring spinal instrumentation as treatment for instability or deformity are in high risk of internal fixation failure. Surgical remedies currently in practice include increasing the diameter and/or length of the pedicle screw [1] or, in cases of severe bone loss, filling in the void with such materials as polymethylmethacrylate (PMMA) or calcium phosphate cement (CPC) [2-4]. These strategies, however, have numerous drawbacks, including increased risks of pedicle fracture with resultant neural injury with larger screws, anterior body penetration with ensuing vascular or visceral injury with longer screws [5], or problems associated with a non-absorbable foreign body in the spinal canal [6-8].

A better solution for increasing pedicle screw fixation may be the use of an alternate screw design. Cook et al. [9] have developed expandable pedicle screws (Omega21 spinal fixation system, EBI, L.P., Parsippany, New Jersey) that could increase the bone fixation strength significantly, especially in the osteoporotic spine. Clinical results showed that the expandable screws are ideal in problematic situations of bone compromised by osteoporosis or pedicle screw revision, providing clinical results similar to those expected in normal bone and primary surgery [10]. The Omega21 spinal fixation system, however, has a uniaxial-designed that is limited by the spine curvature and requires more operation technique and clinical experience than conventional screws. Multi-axial heads have made the pedicle screw more versatile, particularly improving ease of connecting rod application; however, there are no published reports describing the use of multi-axial expandable pedicle screws (MEPS).

The purpose of this study was to investigate the clinical and radiographic outcomes of MEPS in patients with osteoporosis. The attainment of solid fusion was evaluated using dynamic radiographs, as well as three-dimensional CT, to evaluate its clinical stability and reliability. Complications related to the instrumentation were also evaluated.

Materials and Methods

Implant description

The newly designed MEPS (Shandong Weigao Orthopedic Device Co., Limited, Shandong, China) 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. MEPS has a curve head, a two-piece interlocking coupling element that mounts about the curvate head, and a rod-receiving cylindrical body with a tapered socket into which both the screw and the interlocking coupling element are securely nestled. 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 MEPS and opens 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.

Patients

This study was carried out with 125 consecutive patients presented with pain and neurologic complaints between June 2005 and December 2007, and diagnosed with degenerative spinal disorders, compression fractures, lumbar tuberculosis and revision spine surgery. All patients underwent a dual-energy X-ray absorptiometry scan (DXA, Lunar Corp, Madison, WI) and the values of bone mineral density (BMD) in the lumbar spine were determined. Osteoporosis was diagnosis if BMD was lower than that of the young adult mean (T-score) by 2.5 standard deviations (SD) or more. Inclusion criteria included osteoporosis or poor bone quality and revision of previous pedicle screw fixation. The preoperative pathology of patients included degenerative disease, vertebral fracture, lumbar tuberculosis and revision spine surgery (Table 1). Patients were observed for a minimum of six months after the operation. Mean duration of follow-up was 18±2.2 months (maxi-

![FIGURE 1. Left: The multi-axial expandable pedicle screw (MEPS) is comprised of a pedicle screw, rod, gauge screw and nut. Right: The MEPS is constructed by the following process A: Implantation of the pedicle screw; B: Insertion the gauge screw; C: Putting in the rod; D: Screwing in the nut and advancing the gauge screw; E: The fins are then expanded concentrically.](image-url)
mum, 33 months). Mean age was 53.4±12.4 years (range, 34-73 years). Seventy-three patients were female and 52 patients were male.

**Neurologic and Radiographic Evaluation**

Patients were encouraged to walk wearing a customized lumbo-sacral orthosis on the day after surgery and for one month postoperative. In this study, patients’ vigorous work and activity were restricted for up to three months after surgery. After that time, unrestricted activity was permitted, depending on the patients’ neurologic situation. Three months after operation, functional evaluations were again performed and patients were graded with the JOA and VAS scoring systems. Neurologic assessments on each patient were made using a rating system based on the JOA scale system. Postoperative back pain intensity was recorded on VAS (10-point scale). The recovery rate was calculated as (postoperative score - preoperative score)/(full marks - preoperative score)×100%

Radiographic assessment was performed using lateral and posteroanterior vertebral radiographs (standing position), dynamic radiographs in flexion and extension and three-dimensional CT images computed tomography (CT) before and after surgery. CT scans, including reconstruction images, were taken immediately after surgery, at six months, and then once a year after index surgery. Fusion was considered successful according to Sapkas’ [11] and Christiansen’s [12] radiologic methods. Sapkas’ method: 1. plain radiographs or CT showed clear trabecular bone bridging across the segment to be fused; 2. there was no sign of radiolucency around the pedicle screws; and, 3. the dynamic radiographs showed no movement between the fused segments. Failure of any one of these three requirements was classified as a pseudoarthrosis. Christiansen’s method: Grade 3: continuous intersegmental bony bridge; Grade 2: doubtful fusion intersegmental bony bridge; Grade 1: no intersegmental bony bridging fusion. As fusion (Grade 3) was considered continuous bridging at all levels of instrumentation, at least at one plain roentgenogram associated with no pathologic movement in the bending roentgenograms was required. Complications related to the hardware were also evaluated based on clinical and radiographic records.

**Results**

Nine hundred and ninety-eight MEPS were implanted in this study (T12:42, L1:30, L2:48, L3: 244, L4:228, L5:284, S1:122, total: 998). Fourteen patients were lost from the study after the first follow-up (six months after operation). Thus, the follow-up rate was 89%. The mean follow-up period was 18 months (ranged from 6 to 33 months). Prior to surgery, all patients suffered from osteoporosis with a decrease of 25.3% (17.1%~45.4%) in BMD. The pre-operative JOA and VAS scores were 11.3±3.0 and 6.7±1.8 respectively. Three months after operation, the JOA and VAS scores were 25.2±1.3 and 2.3±1.4. The recovery rate was 78.1±15.5%. Surgical details can be seen in Table 2. One hundred and sixteen of the 125 patients (92.8%) satisfied all three radiographic criteria for fusion. On the AP and oblique views of the spines, there was an increasing intertransverse bony bridging that was present as early as three months after surgery and was completed six to eight months after surgery. The CT scan showed solid fusion in the facet joints eight to 10 months after surgery. The average radiographic score regarding dorsolateral and intertransverse fusion according the Christiansen’s radiologic method was 2.6 (range, 2–3). In all fused patients, trabecular bone could clearly be seen radiographically between the fused segments, there was no screw loosening, and there was no motion on dynamic radiographs (Figs. 2–6). In nine patients, there was no radiographic evidence of fusion, and although there was no pathologic motion, they were considered failed fusions. Fusion rates in degenerative disease, compressive fracture, spinal tuberculosis and reoperation patients were 95.7%, 89.3%, 96.3% and 87.5%, respectively.

There were no instances of screw loosening or pullout in any patient. In all patients, no expandable screw breakage occurred. No pedicle screw instrumentation was removed after surgery.

| TABLE 1. Diagnosis, Pre- and Postoperative JOA and VAS Values Related to MEPS |
|--------------------------|----------|-------------|-------------|-------------|----------|
| Diagnosis                | BMD      | MEPS Case/Screw | JOA Preop | JOA Postop | VAS Preop | VAS Postop | Recovery Rate |
| Degenerative disease     | 75.7±5.5% | 46 (242)       | 11.0±3.0  | 24.8±1.9   | 7.1±1.4   | 2.4±1.7    | 76.4±11.0%   |
| Vertebral fracture       | 70.7±3.7% | 28 (154)       | 10.0±1.7  | 25.6±1.8   | 7.8±1.3   | 1.7±1.4    | 82.0±9.9%    |
| Spinal trabeculosis      | 74.5±3.6% | 27 (118)       | 13.4±3.1  | 26.2±1.3   | 5.3±1.8   | 1.7±1.2    | 80.8±10.9%   |
| Re-operation             | 77.5±5.1% | 24 (88)        | 11.3±3.0  | 24.4±2.4   | 6.2±1.7   | 3.2±1.9    | 73.6±12.9%   |
| Total                    | 74.7±5.2% | 125 (998)      | 11.3±3.0  | 25.2±2.0   | 6.7±1.8   | 2.3±1.7    | 78.1±11.5%   |
Spinal trabeculosis
Vertebra fracture
Degenerative disease

**TABLE 2. Surgical Details**

<table>
<thead>
<tr>
<th>Diagnosis</th>
<th>Age (years)</th>
<th>Duration (Min)</th>
<th>Bleeding (ml)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Degenerative disease</td>
<td>59.4±10.6</td>
<td>257.5±64.4</td>
<td>517.1±223.9</td>
</tr>
<tr>
<td>Vertebra fracture</td>
<td>69.8±6.6</td>
<td>193.3±21.6</td>
<td>550.0±288.1</td>
</tr>
<tr>
<td>Spinal trabeculosis</td>
<td>34.6±9.9</td>
<td>250.0±163.8</td>
<td>487.5±364.3</td>
</tr>
<tr>
<td>Re-operation</td>
<td>44.0±7.5</td>
<td>285.0±26.5</td>
<td>1000.0±336.7</td>
</tr>
</tbody>
</table>

Discussion

The development of transpediclar internal fixation devices to provide stability, reduce deformity, and enhance fusion rates has greatly influenced spinal surgery. Pedicle screw instrumentation has become increasingly popular over the last decade. It has three main advantages over conventional screws: the ability to provide 3-column fixation, facilitate the instrumentation of short segments, and maintain anatomic or desired sagittal alignment [13]. These advantages depend on the abilities of pedicle screws to retain the bone purchase until the fusion mass is stable. The loosening and back out of pedicle screws, resulting from failure of screw fixation, remains a significant clinical problem, particularly in patients with poor bone quality, leading to an overall instrumentation failure rate of 0.6% to 11% [14-17]. Similarly, the removal and replacement of a pedicle screw in revision surgery substantially decreases the mechanical fixation strength of the screw [18-20]. Furthermore, the turning back of the screws becomes necessary when surgeons cannot successfully insert screws into the proper position during the first attempt, which reduces the holding strength [21].

The optimum augmentation methods of pedicle screw fixation strength have been widely debated. Renner [4] and Rohmiller [22] demonstrated, using a cadaver model, that calcium phosphate cement can improve the axial pullout strength of revised and augmented pedicle screws when injected along the entire length of the screw. In addition, Korovessis et al. [23] reported on the results of minimal invasive short posterior instrumentation plus balloon kyphoplasty with calcium phosphate for burst and severe compression lumbar fractures, and found that they can increase the fusion rate and improve the instrumentation stability; however, these methods may lead to cement leakage and result in disastrous consequence.

To avoid these complications, Cook et al. [9-10] developed a uni-axial expandable pedicle screw (Omega21 spinal fixation system). Biomechanical tests have shown that expandable pedicle screws can increase pullout strength by 30% in comparison with conventional pedicle screws, including an approximately 50% increase in pullout strength in osteoporotic bone. The clinical results indicate that the screws may be particularly useful in situations of expected compromised fixation strength, such as reoperation and osteoporosis. The structure of Omega21 screws is uni-axial, which may add extra difficulties for surgeons to connect rods with screws in L5S1 spondylolisthesis particularly in degenerative scoliosis, and because of the restricted space between L5 and S1, it is more difficult to fix the cross-link by using uni-axial pedicle screws. The fundamental improvement in pullout strength obtained by cross link has been documented [24]. Chen et al. [25] demonstrated that the addition of the cross link can form a more rigid rectangular frame, thus increasing implant stiffness and stability. Dick et al. [26] showed that cross-link devices significantly increased torsional rigidity. Benzel [27] also demonstrated that cross links can resist lateral displacement and quadrilateral shift of paired rods, and enhance screw pullout strength by linking bilateral implants; so a mainstream multi-axial head design can not only improve the ease of connecting rod application but reduce the time of operation.

Another significant advantage of the multi-axial head design was that the multi-axial head coupling to the screw is the first to fail and may be a protective feature of the pedicle screw, preventing pedicle screw breakage [28]. This is more important for the hollow-structured pedicle screws, which has fatigue strength lower than that of solid-structured screws. In Cook’s study, breakage rate of the Omega21 screw was 2.8% (4/145), which comprised 10 of the 389 expandable screws used (2.6%). Screw breakage rate in sacral anchoring in L5-S1 fusions was 5% (3/57). In the present study, no screw breakage occurred. The difference in screw structure might partly explain why no screw breakage occurred. On the other hand, patients in this study were wearing a customized lumbosacral orthosis for one month after surgery and did not resume their work and activity until three months after surgery. This may also play an important role in preventing screw breakage.

Although MEPS could improve the spinal surgeon’s ability to repair the osteoporotic spine, it has some limitations. One limitation is screw removal. During the primary operation, MEPS can be extracted by removing the central pin, which collapses the anterior portion of the screw. The MEPS can then be backed out normally. During the revision operation, because
FIGURES 2-6. A 71-year-old woman with secondary osteoporosis and degenerative stenosis complained of severe back pain and neurogenic claudication. Pre-operative radiographs (Figure 3 and 4) and MR image (Figure 5) show a severe multi-level stenosis and degenerative spondylolisthesis. Post-operative radiographs (Figure 6) (12 months post-op) show successful spinal fusion is achieved without screw loosening.
bone tissues have already grown into the fins and MEPS can not return to its original shape: the pedicles would be widened unavoidably. Nevertheless, because the diameter of the expanding screw tip increases by only 2.0 mm, risk of nerve roots and dura injury is relatively low. In this study, six expandable pedicle screws (1.8%) were removed because of pseudarthrosis. No nerve roots or dura injury occurred during revision surgery. PMMA augmentation was used to fill screw tracts when replaced pedicle screws. Similarly, Cook [10] also reported that the expandable pedicle screw instrumentation was removed in six patients (4%) after eight months or longer post-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 [29-31].

Conclusions

In summary, the use of the multi-axial expandable pedicle screw can improve fixation strength in bone of poor quality. The multi-axial expandable screws are ideal in problematic situations of bone compromised by osteoporosis or pedicle screw revision surgery. The hollow-structured design did not increase the screw breakage rate. The addition of an expandable pedicle screw design adds a valuable tool to the growing armamentarium of spinal instrumentation.

References

23. Korovesis P, Hadjiipavlou A, Repantis T. Minimal invasive short posterior instrumentation plus balloon kyphoplasty with cal-


