Comparison of the Fixation Strengths of Screws between the Traditional Trajectory and the Single and Double Endplate Penetrating Screw Trajectories Using Osteoporotic Vertebral Body Models Based on the Finite Element Method

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Study Design: This is a finite element (FE) study.

Purpose: To compare the fixation strength of traditional trajectory (TT) and single and double endplate penetrating screw trajectories (SEPST/DEPST) to the osteoporotic vertebral body model based on the FE method.

Overview of Literature: SEPST/DEPST have been developed to enhance the fixation strength in patients with diffuse idiopathic hyperostosis (DISH). This technique was also applied to patients with osteoporosis. However, determining the superiority of SEPST/DEPST is difficult because of the heterogeneous patient backgrounds.

Methods: Twenty vertebrae (T12 and L1) from 10 patients with osteoporosis (two males and eight females; mean age, 74.7 years) were obtained to create the 10 FE models. First, a single screw was placed with TT and SEPST/DEPST, and the fixation strength was compared by axial pullout strength (POS) and multidirectional loading tests. Second, two screws were placed on the bilateral pedicles with TT and SEPST/DEPST, and the fixation force of the vertebrae in the constructs in flexion, extension, lateral flexion, and axial rotation was examined.

Results: SEPST and DEPST had 140% and 171% higher POS values than TT, respectively, and the DEPST result was statistically significant (p=0.007). The multidirectional fixation strength was significantly higher in DEPST and SEPST than in TT in the cranial, caudal, and medial directions (p<0.05) but not in the lateral direction (p=0.05). The vertebral fracture strength at the lower instrumented vertebra of the DEPST tended to be higher than that of TT. The vertebral motion angles in SEPST and DEPST were significantly smaller in lateral bending (p=0.02) and tended to be smaller in flexion and extension than in TT (p=0.13).

Conclusions: This study may provide useful information for spine surgeons in deciding whether to choose the SEPS or DEPS technique for augmenting fixation in osteoporotic vertebral fracture surgery.

Keywords: Diffuse idiopathic hyperostosis; Osteoporotic vertebral fractures; Single endplate penetrating screw trajectory; Double endplate penetrating screw trajectory; Finite element
Introduction

In spinal disorders associated with diffuse idiopathic hyperostosis (DISH), the vertebral body is susceptible to three-column injury and subsequent neurological deficits because of a long lever arm resulting from vertebral body fusion. Therefore, long-range fixation with three vertebrae above and below the affected vertebra is recommended for DISH-associated spinal disorders, with either the conventional open or percutaneous pedicle screw (PPS) technique [1,2].

We have developed a novel PPS insertion technique, i.e., a single or double endplate penetrating screw (SEPS/DEPS) technique in DISH-associated spinal disorders and have reported on its usefulness [3]. In this technique, to achieve a strong fixation, the PPS is inserted from the outer caudal side of the pedicle toward the inner cranial side and penetrates the lower endplate of the upper vertebra. Previously, the insertion torque was compared between the DEPS and conventional techniques in patients with DISH, which showed a 134% higher insertion torque in the DEPS technique than in the conventional technique [3]. Moreover, compared with the conventional technique, the DEPS technique showed significantly less implant failure [3,4]. Currently, several fixation techniques that involve penetrating the endplate have been reported [4], including those using navigation systems [5].

Owing to the aging society, the number of patients with osteoporotic vertebral fractures (OVFs) is dramatically increasing, as is the number of surgical procedures required for OVFs. However, many controversies remain, concerning which surgeries for OVFs are most effective, such as the choice of surgical technique including the approach, fixation range, and selection of implants and fixation augmentation techniques. Several studies have reported that the rates of PS loosening can reach up to 60% in patients with osteoporosis, and various techniques to reinforce fixation have been reported; however, the results are still unsatisfactory [6,7]. Recently, the cement-injected fenestrated screw (FS) was reported to provide strong fixation even in fragile bones. In a cadaver study, Charles et al. [8] reported that the FS had approximately 2 times higher POS than a conventional screw. However, in Japan, its use is currently limited to multilevel spinal fixation, and complications such as cement leakage have been reported in nearly half of the patients [9,10]. Therefore, in addition to DISH-related spinal disorders, we are currently applying SEPS and DEPS techniques to augment fixation in patients with OVFs in whom sufficient fixation is unlikely to be achieved with conventional techniques. However, definitively determining superiority in terms of clinical outcomes using the DEPS technique over that of conventional techniques in patients with OVF is difficult because of the heterogeneous patient backgrounds. The most accurate comparison of the in vivo fixation strength of the DEPS and conventional techniques would be to compare the insertion torques of these methods using the same pedicle from the same patient, which is not feasible in vivo or even with a cadaver. Therefore, we planned to verify the superiority of this technique using the finite element (FE) method [11-15]. Accordingly, this study aimed to compare the fixation strength of SEPS and DEPS trajectories (SEPST/DEPST) and traditional trajectory (TT) using the same osteoporotic vertebral body models based on the FE method.

Materials and Methods

Computed tomography (CT) DICOM data of 20 vertebrae (T12 and L1) from 10 patients with osteoporosis with a young adult mean bone mineral density (BMD) of the hip of <70% (two men and eight women; mean age, 74.7±4.6 years; range, 70–87 years) were obtained to create 10 FE models. The BMD of the femoral neck was measured by dual-energy X-ray absorptiometry preoperatively (Table 1).

This study was conducted with the approval of the Ethics Committee of the University Hospital, Kyoto Prefectural University of Medicine, Kyoto, Japan.

Table 1. The demographic data of the patients

<table>
<thead>
<tr>
<th>Case</th>
<th>Age (yr)</th>
<th>Gender (M/F)</th>
<th>BMD (g/cm²)</th>
<th>YAM (%)</th>
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</tr>
<tr>
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<td>F</td>
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<tr>
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<td>F</td>
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<td>ASD</td>
</tr>
<tr>
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</tr>
<tr>
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<td>M</td>
<td>0.60</td>
<td>64.7</td>
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</tr>
<tr>
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<td>F</td>
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<td>OVF</td>
</tr>
<tr>
<td>7</td>
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</tr>
<tr>
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<td>70.0</td>
<td>M</td>
<td>0.64</td>
<td>67.0</td>
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<tr>
<td>9</td>
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<td>68.0</td>
<td>LSS</td>
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<tr>
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<td>F</td>
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<td>OVF</td>
</tr>
<tr>
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<td>74.7</td>
<td>0.58</td>
<td>62.4</td>
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</tbody>
</table>

M, male; F, female; BMD, bone mineral density; YAM, young adult mean; ASD, adult spinal deformity; OVF, osteoporotic vertebral fracture; LSS, lumbar spinal stenosis.
Comparison of Fixation Strength of TT/SEPST/DEPST with FEM

Asian Spine Journal

R03-188). Written informed consents were obtained from all participants in this study. All statistical analyses were performed with EZR (https://www.r-project.org/) [16], which is a modified version of R commander designed to add statistical functions. All data were statistically analyzed using the Mann-Whitney U test for between-group comparisons, and the one-way analysis of variance was used for comparisons among three groups. The significance level for all the tests was defined as $p<0.05$.

1. FE model creation

Mechanical Finder ver. 11.0 (extended edition; Research Center of Computational Mechanics Inc., Tokyo, Japan) was used for the FE analysis. In each patient, CT data of the T12 and L1 vertebrae were imported to a workstation to create three-dimensional FE models. CT was performed using Revolution EVO (GE Healthcare, Milwaukee, WI, USA), with the following imaging parameters: 64-row detector; 120 kV; Smart mA, 80–400 mA; noise index, 20; slice thickness, 0.625 mm; and pixel width, 0.35 mm. As in the previous study, a mesh was made using first-order tetrahedral elements. The global size of the element was <1 mm, and smaller elements were generated to satisfy the 0.075-mm tolerance to sufficiently create the surface geometry of the screw threads [11]. The analysis models contained approximately 450,000–650,000 solid elements, 80,000–140,000 nodes, and 50,000–60,000 shell elements. To simulate the inhomogeneity of the bone material distribution, the bone density of each element was first defined corresponding to the Hounsfield unit value of CT, and Young’s modulus was obtained from the bone density. For relative evaluation, Young’s modulus and the yield stress of each element were adopted from the study by Keyak et al. [17] and previous studies of the spine. Poisson’s ratio of each element was set to 0.4, and the lower Young’s modulus of the shell element was set to 10 GPa. The intervertebral disk between T12 and L1 was not created, and the posterior facet joint was modeled as fused. The PS data used were stereolithography data from Saccura Spinal System (TEIJIN, Okayama, Japan), a titanium alloy model with a full cancellous thread. Ti6Al4V was the titanium alloy used, with Young’s modulus of 108,853.8 MPa, yield stress of 824.7 MPa, critical stress of 899.3 MPa, and Poisson’s ratio of 0.28 (Table 2) [15]. The contact conditions were defined on the interfaces of the PS to the bone. The coefficient of friction of the contact surface was zero based on a previous study [11].

2. Model for the comparison of single-screw fixation strength

First, the fixation strength of a single screw was verified. A PS with a diameter of 6.5 mm and a length of 50 mm was placed at the appropriate position in only the left pedicle of the FE model using TT and DEPST, and a PS with a diameter of 6.5 mm and a length of 40 mm was placed using SEPST. TT was employed according to the technique by Weinstein et al. [18], along the anatomical axis of the pedicle in the horizontal plane and parallel to the superior endplate of the vertebral body in the sagittal plane. In the horizontal plane, the SEPST or DEPST was inserted along the anatomical axis of the pedicle in the same way as in TT. In the sagittal plane, the SEPST only penetrated the upper endplate of the inserted vertebra, whereas the DEPST directly penetrated the lower endplate of the superior adjacent vertebra as previously reported (Fig. 1) [3].

1) Comparison of POS

With the upper endplate of the T12 vertebra and lower endplate of the L1 vertebra fully restrained, the load–displacement curves were calculated for the axial pullout of the PS head, and the POS values of the three insertion techniques were compared (Fig. 2A). The values at which the load–displacement curve changed steeply under a

| Table 2. Material properties, where $\rho_{\text{HA}}$ means HA-equivalent density (g/cm$^3$) |
|---------------------------------|-----------------|-----------------|-----------------|-----------------|
| Young’s modulus (MPa)          | Yield stress (MPa) | Critical stress (MPa) | Poisson’s ratio |
| Bone                           | 0.001 ($\rho_{\text{HA}}=0$) | 137$\rho_{\text{HA}}^{1/3}$ ($\rho_{\text{HA}}<0.27$) | Yieldstress>0.8 | 0.4 |
|                               | 3398$\rho_{\text{HA}}^{1/3}$ ($\rho_{\text{HA}}=0.27$) | 114$\rho_{\text{HA}}^{1/3}$ ($\rho_{\text{HA}}<0.6$) |
|                               | 5307$\rho_{\text{HA}}^{1/3}$ ($\rho_{\text{HA}}=0.6$) | 1020$\rho_{\text{HA}}^{1/3}$ ($\rho_{\text{HA}}>0.6$) |
| Screw (Ti6AI4V)                | 108,853.8        | 824.7           | 899.3           | 0.28            |

HA, hydroxyapatite.
continuous pullout load at 0.001 mm per 1 step were defined as the POS of that insertion technique.

2) Comparison of the fixation strength for four-directional loading
With the upper endplate of the T12 vertebra and lower endplate of the L1 vertebra fully restrained, the fixation strength of the screws was examined by applying loads of up to 200 N in the cranial, caudal, medial, and lateral directions perpendicular to the anteroposterior vertebral axis (Fig. 2B). The screw fixation strength was calculated using the inclination of the load–displacement curve between the initial loading and inflection point.

Fig. 1. (A–D) Finite element models of T12 and L1 vertebrae with a single screw. This figure shows the illustrative case using the patient 6. TT, traditional trajectory; SEPST/DEPST, single and double endplate penetrating screw trajectory.

Fig. 2. Finite element model of traditional trajectory and chart of load–displacement curve. (A) Pull-out strength verification. (B) Fixation strength verification in four directions. This figure shows the illustrative case using the patient 6. (A) Red part: upper endplate of T12 vertebra and lower endplate of L1 vertebra are completely restrained. Red line: axis of pedicle screw insertion. Pink part and arrow: Load site and direction of pull-out. (B) Red circle and red arrows: load site and four directions of loading (cranial, caudal, medial, and lateral).
3. Model for comparison of the fixation strength to the lower instrumented vertebra

In previous studies of posterior spinal fixation using DEPST, implant failure was observed more often at the lower instrumented vertebra (LIV) than at the upper instrumented vertebra [3,4]. Therefore, to assess the fixation strength of the screws at the caudal end of the spinal fusion, the following model was created to mimic the load at the LIV during motion. With the upper endplate of the T12 vertebra and bilateral PS head fully restrained, PSs with a diameter of 6.5 mm and a length of 50 mm were bilaterally placed at L1 in the FE model using the same TT and DEPST as above, whereas a 40-mm long PS was used with SEPST. A disk-shaped object with an embedded crossbar (titanium alloy) adhered to the L1 lower endplate.

1) Comparison of the vertebral fracture strength

By moving the crossbar, flexion or extension, or lateral bending or axial rotation loading, was applied to the L1 lower endplate at 5 N/step up to 200 steps (Fig. 3). A vertebral fracture was defined as the point at which the load–displacement curve changed from the initial elastic region to the plastic region, which was when the inclination became 20 times higher than the initial inclination and when the fracture of the shell was fully confirmed in the FE models. Under these conditions, the strengths at which vertebral fractures would occur were compared between TT and DEPST.

2) Comparison of the vertebral motion angle

The fixation strengths of TT, SEPS, and DEPST were compared using the vertebral motion angle when the 7.5 Nm moment was applied to the center of the L1 lower endplate of the caudal vertebra, which was the same strength as in previous reports that compared the fixation strength of screws [19-21].

Results

1. Comparison of the single-screw fixation strength

1) Comparison of the POS

The POS values were 431.7±197.4 N for TT, 605.4±197.1 N for SEPST, and 738.3±205.8 N for DEPST, showing a significant difference (p=0.008). DEPST and SEPST demonstrated 171% and 140% higher POS than TT, respectively, with DEPST having a significantly higher POS than TT (p=0.007) (Fig. 4A).

2) Comparison of the fixation strength for four-directional loading

The four-directional fixation strengths in TT, SEPST, and DEPST were measured and were cranial (TT/SEPST/DEPST; 1,479.8±619 N/mm, 2,513.8±902.2 N/mm, and 3,384±2,000 N/mm; p=0.006), caudal (1,220±577.4 N/mm, 2,712.9±1,610.7 N/mm, and 3,191.2±1,811.7 N/mm; p=0.005), lateral (1,215.9±549.8 N/mm, 1,664.9±644.4 N/mm, and 2,350.8±1,337.4 N/mm; p=0.05), and medial (1,004.2±377.7 N/mm, 1,960.7±1,066.7 N/mm, and 2,798.1±1,923.3 N/mm; p=0.002). DEPST and SEPST had
2. Comparison of the fixation strength to the LIV

1) Comparison of the vertebral fracture strength
The vertebral fracture strengths at the LIV in TT and DEPST were 14.1±7.5 Nm and 15.8±6.8 Nm (p=0.25) in flexion, 15.1±6.6 Nm and 15.7±6.3 Nm (p=0.69) in extension, 19.7±4.8 Nm and 23.9±7.2 Nm (p=0.14) in lateral bending, and 25.6±10.5 Nm and 27.2±9.1 Nm (p=0.72) in axial rotation. The vertebral fracture strength of DEPST tended to be higher than that of TT, although no significant difference was found (Fig. 5A).

2) Comparison of the vertebral motion angle
The mean vertebral motion angles at a 7.5-Nm load applied to the tip of the crossbar were significantly smaller in DEPST and SEPST than in TT in lateral bending (TT/SEPST/DEPST; 0.77°±0.9°, 0.25°±0.1°, and 0.22°±0.2°; p=0.02) and tended to be smaller in flexion (TT/SEPST/DEPST; 1.62°±2.8°, 0.76°±0.7°, and 0.46°±0.2°; p=0.13) and extension (1.40°±2.1°, 0.97°±1.3°, and 0.45°±0.2°; p=0.13). However, no significant difference was found in the axial rotation (0.18°±0.06°, 0.17°±0.06°, and 0.15°±0.06°; p=0.65) (Fig. 5B).

Discussion
The number of patients with OVF in countries with aging populations and the number of patients requiring
OVF surgery have been increasing [22]. Similar to DISH, postoperative implant failure cases are common because of bone weakness in OVFs. To prevent postoperative complications, rigid fixation in fragile bones must be achieved. Recently, FS has been developed, which is reported to provide strong fixation in OVF surgery. According to Charles et al. [8], FS had approximately 2 times greater POS than a screw alone in a biomechanical validation using a cadaver. Ehresman et al. [23] reported that PS loosening was observed in only 0.2% of patients with thoracolumbar instrumentation surgery using FS. However, cement leaks were observed in 55.6% of the patients, and if the screw is not positioned correctly, cement may leak through the malpositioned hole. Therefore, great care must be taken considering cement viscosity and accuracy of PS insertion.

To enhance anchorage in a fragile vertebra using a strategy different from that above, SEPS and DEPS techniques for OVF surgery were used in patients aged >75 years with severe osteoporosis (BMD of ≤−3.3 standard deviation). The SEPS and DEPS can be simply inserted by changing the probing direction intraoperatively if there are concerns about screw stability or position in the TT, which is an advantage over FS. In patients with severely deformed vertebrae such as vertebral flattening or wedging within the planned fixation area, we intentionally penetrate the endplate similar to SEPST because of the difficulty in placing screws in the appropriate position within the vertebra. Finally, SEPS and DEPS techniques were applied at the level to be fused posteriorly with bone grafting where disk mobility does not need to be considered. As disk injury and the risk of implant breakage due to penetrating through the mobile disk are potential disadvantages of using the SEPS and DEPS techniques in patients with OVFs, these techniques were applied to patients with OVFs only when obtaining stability is more important than avoiding these disadvantages.

According to Minamide et al. [24], transdiscal L5–S1 fixation produced a 1.6–1.8 times stronger construct than traditional PS fixation in a cadaveric model of simulated L5–S1 spondylolisthesis. Rodriguez-Martinez et al. [25] reported that transvertebral screw fixation showed a good fixation strength similar to traditional PS fixation. In our previous study, the DEPS technique demonstrated a 134% higher insertion torque than the conventional technique [3]. However, as this did not result from the same pedicle of the same vertebra, accurate comparisons of the fixation strengths of different trajectories are difficult. Therefore, we planned to compare and verify the fixation strength in the same models using the FE method [11-15]. In a cadaveric study, Charles et al. [8] reported that the FS had approximately 2 times higher POS values than TT. Our results showed that DEPST had a 1.7 times and SEPST had a 1.4 times higher POS than TT in the FE method. As our study used the FE method, which was different from the study by Charles et al. [8], direct comparison of absolute values was inappropriate. However, as a relative POS comparison to TT, DEPST would provide a similar POS to the FS. In the comparison of the strengths of the PSs in four directions, DEPST and SEPST had significantly higher fixation strengths than TT in three directions. However, in the study of the fixation strength to the LIV, no difference in strength leading to vertebral fractures was found between TT and DEPST. However, DEPST significantly suppressed the vertebral motion angles, except for axial rotation. DEPST lacked superiority in axial rotation because the axis of rotation is located near the point where the screw penetrates the endplate and therefore may be less affected than the other directions of motion.

This study has several limitations. First, this model was made with only two vertebrae, not multiple vertebrae as in actual surgery, and only screws were used. Therefore, the evaluation of a construct model including rods and screws with multiple vertebrae should be performed. Second, although this study included patients who were potentially suited for the DEPS technique, the degree of the deformation of the vertebral bodies, loss of the intervertebral disk spaces, or bony fusion between vertebral bodies varied greatly among models; therefore, clarifying which patients would be most suitable for the SEPS and DEPS techniques based on their vertebral conditions may be beneficial. Third, as in previous studies, the present study conducted FE analysis using the only data by Keyak et al. [17], and no experimental validation was taken. Thus, the fixation strength cannot be evaluated in absolute values, and only relative comparisons can be made. Consequently, further biomechanical evaluations using cadavers in future studies are needed. Finally, FE studies could not evaluate cyclic loading, which is believed to be one of the causes of screw loosening [26].

Conclusions

To our knowledge, this is the first report of SEPST and
DEPST to clarify the fixation strength for an osteoporotic model using the FE method. Compared with TT, SEPST and DEPST showed superior fixation strengths of individual screws and sufficient strength against flexion, extension, and lateral bending loads in the construct model. These results may provide useful information for spine surgeons when deciding between SEPS and DEPS technique for augmenting fixation in OVF surgery.

Conflict of Interest

No potential conflict of interest relevant to this article was reported.

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References


