Biomechanical Evaluation of a Newly Developed Monocortical Expansion Screw for Use in Anterior Internal Fixation of the Cervical Spine

In Vitro Comparison With Two Established Internal Fixation Systems

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Study Design. The primary biomechanical stability of anterior internal fixation of the cervical spine obtained with a new monocortical expansion screw in vitro was evaluated.

Objectives. The primary aim was to compare the anterior internal fixation of the spine obtained with the new monocortical expansion screw provides biomechanical stability comparable with that obtained with bicortical fixation.

Summary of Background Data. The anterior plate instrumentation used with bicortical screw fixation in the cervical spine provides a primary stability superior to that associated with monocortical screw fixation. However, bicortical screws have the potential to perforate the posterior cortex. Therefore, monocortical instrumentation systems were developed, but without the biomechanical stability associated with bicortical systems. A new expansion screw for monocortical fixation was developed to improve biomechanical stability of monocortical systems.

Methods. Three different internal fixation systems were compared in this study: 1) H-plate with AO 3.5-mm bicortical screws, 2) cervical spine locking plate with monocortical screws, and 3) H-plate with the new monocortical expansion screws. Eight fresh human cadaveric spine segments from C4 to C7 were tested in flexion-extension, axial rotation, and lateral bending using pure moments of ± 2.5 Nm without axial preload. Five conditions were investigated consecutively: 1) Intact spine; 2) uninstrumented spine with the segment C5–C6 destabilized; 3–5) instrumentation of the segment C5–C6 with the three implants mentioned above after removal of the disc and insertion of an interbody spacer.

Results. Between bicortical and monocortical expansion screw H-plate fixation, no significant differences were observed in all load cases concerning range of motion and neutral zone. The neutral zone and range of motion were significantly larger for the cervical spine locking plate than for bicortical and monocortical expansion screw fixation in all load cases, except neutral zone for axial rotation versus bicortical screw fixation. The instrumented cases only had a significantly lower range of motion and neutral zone than the intact cases in extension–flexion, whereas for lateral bending and axial rotation no significant differences could be observed. Because the experimental design precluded any cyclic testing, the data represent only the primary stability of the implants.

Conclusions. In anterior instrumentation of the cervical spine using a H-plate, the new monocortical expansion screw provides the same biomechanical stability as the bicortical 3.5-mm AO screw and a significantly better biomechanical stability than the cervical spine locking plate. Therefore, the expansion screw may be an alternative to the bicortical fixation and does not involve the risk of perforation of the posterior vertebral body cortex. [Key words: anterior instrumentation, biomechanical testing, cervical spine, expansion screw, in vitro] Spine 1999;24:207–212

Anterior plate instrumentation of the cervical spine is an established method for managing cervical spine instability.9,22 Instrumentation systems using special plates in combination with bicortical screws were introduced by Caspar2 and by Orosco.15 Because of the risk of bicortical screws perforating the posterior cortex, their use may cause neurologic injuries. To avoid these risks, monocortical instrumentation systems such as the cervical spine locking plate (CSLP) were developed.12,13

Although good clinical results were reported for the CSLP,23 in vitro studies suggest that bicortical screw fixation in the cervical spine provides a superior stability than that obtained with the CSLP with monocortical screw fixation.3 Because of the above-mentioned advantages of monocortical screws, one of the current authors (PK), together with Ulrich Medizintechnik (Ulm, Germany) and Endotec GmbH (Burscheid, Germany), developed a new expansion screw for monocortical fixation in an attempt to improve the biomechanical stability of monocortical systems.

The purpose of the current in vitro study was to evaluate the biomechanical stability of this newly developed expansion screw and to compare it's stability with that of a monocortical and a bicortical anterior fixation system for the cervical spine.

Materials and Methods

Eight human cadaveric cervical spine segments (C4–C7) with a mean age of 84.8 ± 11.2 years were tested. The specimens were wrapped in triple-sealed plastic bags and kept frozen at –20°C before preparation and testing. Before testing, the specimens were thawed at room temperature, and all musculature was removed while carefully preserving ligamentous and bony structures.
Bone quality was assessed by measuring the bone mineral density (BMD) of C6 with peripheral quantitative computed tomography (CT) (XCT 960A, Stratec, Pforzheim, Germany). The CT scan was calibrated using a hydroxyapatite phantom. An attenuation coefficient of 0.43 cm\(^{-1}\) was used for data analysis.

The cranial vertebra (C4) and the caudal vertebra (C7) were potted in polymethylmethacrylate (Technovit 3040, Heraeus Kulzer GmbH, Wehrheim, Germany). To achieve a better anchorage of the vertebrae in the plastic material, short screws were partially driven into the two embedded vertebrae. The specimens were mounted in a previously described spinal loading simulator.\(^29\) C7 was fixed rigidly in the testing device. C4 was fixed in a gimbal containing integrated stepper motors that could introduce pure moments separately around three axes. The other 5 of 6 degrees of freedom were free, enabling the specimen to move unconstrained. Monosegmental motion of C5-C6 was measured using a noncontacting ultrasound motion analysis system (Zebris 50/4, Isny, Germany). Alternating sequences of flexion-extension (\(\pm M_y\)), left/right axial rotation (\(\pm M_z\)), and right/left lateral bending (\(\pm M_x\)) moments of 2.5 Nm in each direction were applied at a constant rate of 2 degrees/second. Two precycles were applied to precondition the construct to minimize the viscoelastic effects, and data of the third cycle were recorded.

The range of motion (ROM) and the neutral zone (NZ) of C5-C6 were determined for each direction of loading. Range of motion was defined as the angular deformation at maximum load. The neutral zone was defined as the difference at zero load between the angular positions corresponding to the loading and unloading phases of the test cycle, which corresponds to the range in which only very small moments are needed to flex, rotate, and bend the specimen.

Three different internal fixation systems were tested according to the testing criteria for spinal implants. These criteria followed the recommendations for the standardization of in vitro stability testing of spinal implants created by the study group for preclinical testing formed by the German Society for Spinal Surgery 30 (Figure 1). The three fixation systems included the following:

H-BIC: Titanium H-plate fixed with four AO 3.5-mm bicortical screws (Ulrich Medizintechnik, Ulm, Germany; screws: Synthes GmbH, Freiburg, Germany)

CSLP: Titanium cervical spine locking plate fixed with four 4.0-mm hollow titanium monocortical screws (Synthes GmbH, Freiburg, Germany)

H-EXP: Titanium H-plate fixed with four 5.0-mm titanium monocortical expansion screws (Ulrich Medizintechnik, Ulm, Germany).

The expansion screw system (Figure 2) is made of titanium and consists of three implant parts and special instruments for implantation. The screw with a central hole is implanted with a special screwdriver in which the screw is fixed temporarily. After implantation, a conus, which provides the expansion of the screw, is screwed in the central hole of the expansion screw. The expansion force is approximately 350 N, if the insertion torque of the inner conus is 1.2 Nm. The major diameter of the expansion screw is 5.0 mm, and the root diameter of the thread is 3.5 mm; the lengths available are 14 mm, 16 mm, and 18 mm. The outside diameter of the screw can be expanded up to

\[r^2=0.11; y=14.3-0.04x\]

\[r^2=0.56; y=25.8-0.07x\]

\[r^2=0.38; y=14.3-0.04x\]

\[r^2=0.81; y=23.3-0.07x\]

\[r^2=0.56; y=25.8-0.07x\]

\[r^2=0.38; y=14.3-0.04x\]

Bone mineral density (g/cm\(^3\))

Figure 3. Regression analysis results between bone mineral density (BMD) of the specimens and the range of motion (ROM) of the instrumented C5-C6 cervical spine segments for flexion-extension with pure moments of \(\pm 2.5\) Nm applied. In axial rotation and lateral bending, significant negative correlations also were found for all implants.
Table 1. Range of Motion (ROM) and Neutral Zone (NZ) of the Segment C5–C6 for All Loading Conditions Tested With Pure Moments of ±2.5 Nm: Mean and Standard Deviation

<table>
<thead>
<tr>
<th></th>
<th>ROM (°)</th>
<th>NZ (°)</th>
</tr>
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<tbody>
<tr>
<td>C5–C6 intact</td>
<td>13.4 ± 3.1</td>
<td>10.3 ± 2.8</td>
</tr>
<tr>
<td>C5–C6 destabilized</td>
<td>20.5 ± 1.9</td>
<td>16.5 ± 2.3</td>
</tr>
<tr>
<td>H-plate with bicortical screws</td>
<td>4.1 ± 2.8</td>
<td>1.8 ± 1.4</td>
</tr>
<tr>
<td>Cervical spine locking plate</td>
<td>6.1 ± 3.5</td>
<td>3.2 ± 2.2</td>
</tr>
<tr>
<td>H-plate with expansion screws</td>
<td>3.3 ± 2.5</td>
<td>1.6 ± 1.3</td>
</tr>
</tbody>
</table>

Results

The mean BMD of C6 was 0.27 ± 0.04 g/cm³. Negative significant correlations between the BMD and the ROM and NZ after instrumentation with all of the three implants could be observed for all loading cases (Figure 3).

Table 2. Significance Levels Concerning Range of Motion (ROM) and Neutral Zone (NZ) of the Segment C5–C6 for All Loading Conditions Tested With Pure Moments of ±2.5 Nm: Mean and Standard Deviation

<table>
<thead>
<tr>
<th></th>
<th>Flexion–Extension</th>
<th>Axial Rotation</th>
<th>Lateral Bending</th>
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<tbody>
<tr>
<td></td>
<td>ROM (°)</td>
<td>NZ (°)</td>
<td>ROM (°)</td>
</tr>
<tr>
<td>C5–C6 destabilized</td>
<td>A</td>
<td>A</td>
<td>A</td>
</tr>
<tr>
<td>H-plate with bicortical screws</td>
<td>A, B, C</td>
<td>A, B, C</td>
<td>B, C</td>
</tr>
<tr>
<td>Cervical spine locking plate</td>
<td>A, B</td>
<td>B</td>
<td>NS</td>
</tr>
<tr>
<td>H-plate with expansion screws</td>
<td>A, B, C</td>
<td>A, B, C</td>
<td>B, C</td>
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Discussion

This study showed that H-plate fixation with the new monocortical expansion screw provides a comparable primary stability to H-plate fixation with bicortical AO 3.5-mm screws.
The clinical instability of the spine has been defined as the loss of ability of the spine to maintain under physiologic loads its pattern of displacement, so that there is no initial or additional neurologic deficit, no major deformity, and no incapacitating pain. The indications for cervical spine stabilization vary and include traumatic, degenerative, infectious, and neoplastic instability, as well as iatrogenic instability. The adequate stabilization technique depends on the type and nature of the instability. Posterior stabilization is indicated when there is significant disruption of the posterior ligamentous structures, including the posterior longitudinal ligament. Anterior stabilization combined with interbody fusion is mainly indicated for fractures with involvement of the anterior bony and ligamentous structures or when anterior decompression with or without vertebrectomy is required. A combined approach may be indicated for a combined anterior and posterior instability including the posterior longitudinal ligament, especially in severe cervical spine fracture, e.g., flexion teardrop fracture, vertical compression burst fracture with significant posterior ligamentous injury, or bilateral facet dislocation with associated compression of the ventral cord.

According to the indications for anterior stabilization, the authors of this study produced a type of ligamentous instability in vitro, which could be treated in vivo by anterior stabilization with interbody fusion.

As mentioned previously in this report, anterior plate fixation with bicortical screws provides more stability than either monocortical fixation or the angle-stable CSLP. Nevertheless, it should be noted that the CSLP and the bicortical systems have yielded good clinical results. Therefore, the authors of this study compared their new monocortical system with the CSLP and with H-plate fixation with bicortical screws.

This study's protocol was defined according to the testing criteria for spinal implants, which follow the recommendations for the standardization of in vitro stability testing of spinal implants created by the German Society for Spinal Surgery's study group for preclinical testing. The purpose of using this testing protocol was to allow comparisons of the authors' data with future results from various research groups. Previously, it has been very difficult to compare in vitro data of research groups according to the varying study protocols. For example, the applied moments for in vitro stability testing of cervical spine implants vary over a great range from $+0.3\ Nm$, $+0.45\ Nm$, $+1\ Nm$, $+1.8\ Nm$, $+2.5\ Nm$, $+3\ Nm$.

The results of the current study indicate that significant stabilizing effects, compared with the destabilized segment C5–C6, could be achieved by all implants only
in flexion-extension. In axial rotation, only the H-plate fixed with bicortical screws and the monocortical expansion screws reduced the ROM significantly. For lateral bending, none of the implants significantly stabilized the segment C5–C6 compared with the destabilized segment, although the data showed a tendency for all implants to stabilize to some degree in this loading condition. Taking into account the great variation among the specimens and the limited number of specimens, these differences were not statistically significant.

A significantly improved in vitro stability after instrumentation was found in all loading conditions using the H-plate fixed with bicortical screws and the monocortical expansion screws, compared with that found in specimens instrumented with the CSLP. These results corroborate the results reported by Clausen et al. They found a greater in vitro stability with the bicortical fixed Caspar plate than with the CSLP in anterior instrumentation of the cervical spine.

No significant differences between H-plate fixed with bicortical screws and the monocortical expansion screws were observed, so the authors recommend the expansion screw system for use in anterior internal fixation of the cervical spine. In the authors’ opinion, based on the in vitro data, the new expansion screw system is a good alternative to bicortical systems and the CSLP. The major advantage of this system over bicortical systems is the reduced iatrogenic risk of iatrogenic damage. Possible advantages over the CSLP may be the better initial stability and the possible angle between plate and screw of approximately 25°, which can make implantation easier in some cases.

The BMD of the specimens in this study was low compared with that of specimens in previous studies, but can be explained by the high mean age of the human specimen donors (84.8 years). The observed correlations between the BMD and the ROM of all loading cases indicate that in vitro stability after anterior instrumentation of the cervical spine is significantly dependent on the bone quality. These findings should be taken into account when considering the postoperative rehabilitation protocol.

Several limitations in the current study should be noted. The method of applying pure moments does not truly represent physiologic loads, because compressive and shear forces are neglected. However, in vitro motion patterns are well reproduced, and loading is consistent and thus known at every point in the specimen, which makes reproducible loading possible from one specimen to another or from one study to the next. The implants were tested in the same sequence with increasing screw diameter. Therefore, the second and third implant in the sequence may be slightly disadvantaged. The main goal of this study, however, was to compare the bicortical fixation with the new monocortical expansion screw, and, according to the testing sequence, the new implant is surely not advantaged. The CSLP was included in the study to compare it with the expansion screw system and not with the bicortical system, because previous studies have shown that the bicortical fixation provides a better stability than the CSLP.

The CSLP may be disadvantaged compared with the bicortical fixation but not compared with the expansion screw system as it was tested before the expansion screw system in each specimen. The BMD of the specimens in the current study was very low because of the mean age of the donors. The positive correlations between the BMD and the ROM showed that primary stability is strongly dependent on BMD. Therefore, in specimens with a higher BMD, all implants might have had more primary stability, and there might have been smaller or insignificant differences between the implants. Nevertheless, patients with a low BMD (and not patients with high BMD) often show problems with the stability of implants, especially with implant loosening; thus, the data on specimens with low BMD should be interesting for the clinical application of the implants. The study design in which all implants were tested with the same specimens precluded any cyclic testing, so that the data represent only the primary stability of the implants.

Based on the promising in vitro results of this study, a randomized clinical multicenter study is scheduled to begin in April 1999 to prove the clinical mid- and long-term outcomes of the new implant and its performance in comparison with that of the CSLP.

In light of the biomechanical stability achieved by all implants in axial rotation and lateral bending, especially in specimens with poor bone quality, the authors recommend a semirigid external fixation for 6–12 weeks after surgery, depending on the bone quality assessed intraoperatively.

Conclusions

In the anterior instrumentation of the cervical spine, using an H-plate fixed with monocortical expansion screws provides biomechanical stability comparable with that achieved using bicortical fixation with the 3.5-mm AO screw and significantly better biomechanical stability than that achieved using the CSLP. Therefore, the expansion screw may be an alternative to bicortical fixation instrumentation without the potential risks associated with the penetration of the posterior vertebral body cortex.

References


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Point of View

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This study examines the stability achieved by three separate anterior cervical plating systems in a cadaveric injury model. The work focuses on a newly designed unicortical plate system, which is compared with a bicortically secured AO plate and the cervical spine locking plate (CSLP). The plates are placed sequentially into the same vertebrae, which theoretically would introduce bias. The CSLP plate is particularly at a disadvantage because its screw diameter is only 0.5 mm greater than the diameter of the AO screw, which was tested first. This small difference may result in a decrease in screw purchase. The new screws, tested last, were a full centimeter larger than the CSLP screws, which makes placing them in pre-existing holes less of a concern. It would have been most informative if the authors had reported the insertion torques for each system. Such information would help to either confirm the existence of bias or allay concerns regarding this issue. It also would be informative to know the lengths of the new system screws that were used in the study. Although it probably does not matter in terms of this biomechanical study, I do not understand why the hollow CSLP screws, which are no longer marketed, were used instead of the new 4.3-mm solid screws, which carry a more aggressive thread pitch.

Despite the above-mentioned criticisms, the results are generally similar to what would be predicted from previous work in this area. Anterior cervical plate devices provide relatively good resistance to sagittal plane rotation and are only marginally effective at providing torsional and lateral bending stability.

The new system appears to be a fairly rigid device and, as such, it may be most useful for situations of gross instability. Recent concerns regarding rigidity in anterior cervical plates and the potential for stress shielding have led to the development of a number of devices that allow for dynamic loading of the grafts. These less-rigid systems may be preferable for the management of degenerative conditions in which gross instability is not an issue.