Biomechanical Test of the Stability of a Cervical Interfacet Self-Locking Cage

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Research Article

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Abstract

Purpose To compare the biomechanical properties of a novel 3D-printed cervical interfacet self-locking cage (CISC) using medical titanium alloy (Ti-6Al-4V) material with the lateral mass screw–rod system.

Methods CT scans were performed on seven preserved human cervical spine specimens (C2–T1) to exclude deformities, infections, tumors, fractures and other lesions, and titanium CISCs were 3D-printed based on the CT scan data. A moment of 1.5 Nm was applied to the specimen using a biomechanics machine. The range of motion (ROM) in bending, extension, lateral bending and rotation directions of each specimen in the different groups was measured, including an intact group (group A), a C5–C6 posterior ligamentous complex (PLC) resection group (group B), a C5–C6 lateral mass screw–rod system fixation group (group C), and a C5–C6 novel CISC fixation group (group D).

Results Groups C and D had smaller ROM than groups A and B in flexion–extension, lateral bending and rotation directions, and the difference was statistically significant ($P < 0.05$). Group D had significantly greater ROM than group C in the forward flexion and posterior extension directions ($P < 0.05$).

Conclusions Injury to the posterior ligament complex of the lower cervical spine can cause flexion and extension, lateral bending, and instability in the direction of axial rotation. CISC fixation is equivalent to the fixation effect of the lateral mass screw-rod system, and can be used as a simple fixation or supplementary fixation for the posterior cervical spine.

Introduction

Posterior cervical facet joint fixation and fusion technology includes the traditional lateral mass transarticular facet screw (TFS) fixation technique and cervical interfacet posterior cage implantation technology. Related studies have shown that cervical single-space TFS fixation has approximate biomechanical stability to posterior lateral mass screw–rod fixation, being weaker than the lateral mass screw–rod fixation system only in the flexion and extension direction $[1]$. The cervical interfacet joint spacer or cage can distract the joint spaces, effectively increase intervertebral foramina, relieve posterior spinal ligamenta flava folding and indirectly enlarge the volume of vertebral canals to achieve the pressure-relieving effect $[2]$. This technology has achieved satisfactory clinical effects in the treatment of adjacent segment degeneration after cervical ACDF and postoperative pseudarthrosis formation $[3]$. Especially, it has advantages under circumstances such as when anterior cervical reoperation is difficult, e.g., local fibrous scar formation at high parts of the C$_{2-3}$ and C$_{3-4}$ segments. Moreover, this technology is conducive to the treatment of elderly patients suffering from respiratory symptoms and dysphagia $[4]$.

We designed a cervical interfacet self-locking cage (CISC) based on the advantages of both technologies. The graft is divided into two parts: the main body of Spacer and the fixed guide plate. The fixed guide plate is connected with Spacer and attach to dorsal side of the lateral mass. When the Spacer was
inserted into the cervical facet joint space, the screw was placed directly according to the fixation guide. See Fig. 1 for the CISC.

Materials And Methods

Study design

A total of seven formalin-fixed specimens of human cervical spine (C2–T1) provided by the Department of Anatomy, Xuzhou Medical University, were selected. All groups were operated by experienced doctors with senior professional titles. All steps in the experiment comply with Helsinki Declaration and are approved by the Ethics Committee of Affiliated Hospital of Xuzhou Medical University.

General information

Of the included specimens, four were from male patients and three from females, aged 35–65 years (mean 47.9 ± 4.2 years). The specimens were numbered in numerical order from 1 to 7, and all specimens were scanned by computed tomography (CT; Siemens AG, Erlangen, Germany) to exclude malformations, tumors, fractures and other lesions before testing. The CISC was 3D-printed correspondingly based on reconstruction results to maximize the fusion area and improve stability. Specimens were sealed in a double plastic bag, stored at -20°C and thawed naturally at room temperature prior to testing. All biomechanical tests on all seven specimens were completed within 1 week.

Preparation of Test Specimens and Operative Method

The muscle tissue around each specimen was removed, and the ligaments and joint capsule were preserved as much as possible to keep the articular structure intact. All specimens were taken out and thawed at room temperature for 8 hours before testing, and the C2 and T1 parts were embedded in dental plaster powder. After being tested in their intact state, the posterior ligamentous complex (PLC) of segment C5–C6 of each specimen was severed to prepare the PLC injury model \(^5\). The CISC for the C5–C6 segment was made from medical Ti-6Al-4V alloy and manufactured using 3D printing technology (Junchen 3D Printing Technology (Shanghai) Co., Ltd., Shanghai, China). After insertion, the spacer was stabilized and fixed using joint screw technology (i.e., the Klekamp method) via a fixation channel. In the Klekamp method, the medial 1mm of the central point of the lateral mass was used as the entry point, and the entry angle was 40 ° in the sagittal plane and 20 ° in the coronal plane. The C5–C6 segment was fixed via the posterior approach using the lateral mass screw–rod fixation method, i.e. the Magerl method \(^6\), and the insertion point of the lateral mass screw was 1 mm below the median point of the lateral mass of the C5–C6 segment and was first drilled with a 2.5 mm diameter bit angled 25° upwards parallel to the facet joint, with a screw channel depth of 12 mm. After the bone of the four walls of the screw channel was probed and found to be intact, a 3.5 mm × 12 mm screw was slowly inserted along the screw channel until the thread was fully inserted into the screw channel, and then fixed with a titanium rod of 3.5 mm diameter, without transverse connection. The above two kinds of nail exercises are performed by the same experienced physician. The lateral mass screw fixation was made of Ti-6Al-4V
alloy and was supplied by Shandong WEGO Group Co., Ltd. See Fig. 2 for X-rays of the cervical spine fixed by the two methods.

**Biomechanical Testing**

Each numbered specimen was subjected to four stress tests in different states, comprising the following four groups: a cervical spine specimen intact group (group A), a C5–C6 PLC resection group (group B), a C5–C6 lateral mass screw–rod fixation group (group C), and a C5–C6 posterior CISC fixation group (group D). The range of motion (ROM) of each specimen was tested in the flexion–extension, lateral bending and rotation directions. Biomechanical testing of all specimens was performed in a non-destructive manner on a Universal Material Mechanics Testing Machine (Instron E10000, Instron Corporation Norwood, MA, USA). See Fig. 3a for the machine. Each embedded specimen was fixed onto one side of the loading joint, not coaxial with the mechanical sensor, and the specimen was connected with the loading joint through the force arm of the special fixture, through which the compressive load was transferred to the test specimen. During the test, the product of the compressive load loaded by the loading joint and the moment arm was applied as the moment acting on the specimen to simulate the forward flexion, backward extension, left and right flexion motions of the human cervical spine with a moment of 1.5 Nm, a force arm length of 105 mm, and a loading rate of 3 mm/min. In addition, during the test, the mobility of the specimen was recorded using a digital level measuring device to measure the movement angle, while the load–displacement curve was recorded using Bluehill 2.0 software, and the intervertebral mobility of the adjacent segments above and below the injured spine was calculated based on the data recorded by both measuring devices. See Fig. 3b for the Bluehill 2.0 software. Each group of specimens was tested in four states (intact cervical specimen state, target segment PLC injury state, and two fixation states) and repeated measures were adopted according to the test design, i.e., each specimen was first tested in the intact state, after which the C5–C6 PLC was severed and tested for injury status, followed by tests in the states of cervical lateral mass screw–rod system fixation and CISC fixation. To exclude the effects of the test sequence, the sequence of the posterior lateral mass screw–rod system fixation group and the CISC fixation group were randomized. Moreover, for the test of the same state, the test sequence of different movement directions was also randomized, with the compressive load applied three times in each direction and the mean value was taken after processing. The same specimen was tested within 24 hours, during which saline was intermittently sprayed (every 30 minutes) to maintain the humidity of the specimen and to ensure that all tests were performed at a constant temperature of 25°C.

**Observation Indicators**

The ROM of specimens C2–T1 in forward flexion, back extension, left and right lateral flexion, and left and right axial rotation directions were observed. See Fig. 4 of specimens undergoing biomechanical testing.

**Statistical method**
SPSS 24.0 was used for statistical processing, and data are expressed as the mean ± standard deviation (x ± s). Analysis of variance (ANOVA) was applied for comparisons between groups and the SNK (Student–Newman–Keuls) q test method was used for paired comparisons, with a test level of \( \alpha = 0.05 \); \( P < 0.05 \) indicated that the difference was statistically significant.

**Results**

The ROM of each numbered specimen was measured in the flexion–extension, lateral bending, and rotation directions in the intact group (Group A), the C5–C6 PLC resection group (Group B), the C5–C6 lateral mass screw-rod fixation group (Group C), and the C5–C6 CISC fixation group (Group D) in each of the four states. The measurement data and analysis results of each group of specimens are shown in Table 1. There were no instances of screw loosening or internal fixation failure during the test.

**Table 1: Overall mobility of cervical spine specimen (°, x̄±s)**

<table>
<thead>
<tr>
<th></th>
<th>Group A</th>
<th>Group B</th>
<th>Group C</th>
<th>Group D</th>
</tr>
</thead>
<tbody>
<tr>
<td>Forward bending</td>
<td>2.93±0.92</td>
<td>5.51±0.7</td>
<td>0.95±0.28</td>
<td>1.03±0.33</td>
</tr>
<tr>
<td>Backward extension</td>
<td>2.59±1.10</td>
<td>5.50±1.8</td>
<td>0.83±0.37</td>
<td>0.99±0.37</td>
</tr>
<tr>
<td>Left lateral bending</td>
<td>2.80±0.55</td>
<td>5.32±0.6</td>
<td>1.09±0.57</td>
<td>0.82±0.26</td>
</tr>
<tr>
<td>Right lateral bending</td>
<td>2.25±0.56</td>
<td>5.40±1.0</td>
<td>1.11±0.32</td>
<td>0.84±0.14</td>
</tr>
<tr>
<td>Left rotation</td>
<td>4.19±0.62</td>
<td>7.66±0.8</td>
<td>2.03±0.41</td>
<td>1.85±0.43</td>
</tr>
<tr>
<td>Right rotation</td>
<td>4.52±0.49</td>
<td>7.71±1.5</td>
<td>2.55±0.59</td>
<td>2.04±0.37</td>
</tr>
</tbody>
</table>

Note:  indicates that \( P < 0.05 \) compared with group A.  indicates that \( P < 0.05 \) compared with groups A and B.  indicates that \( P < 0.05 \) compared with group C.

**Lateral Mass Screw–rod System Fixation**

Group C showed an increase in stability in all directions compared with group B: the ROM in the anterior flexion direction decreased from 5.51 ± 0.74° to 0.95 ± 0.28° (\( P < 0.05 \)), the ROM in the posterior extension direction decreased from 5.50 ± 1.82° to 0.83 ± 0.37° (\( P < 0.05 \)), the ROM in the left lateral bending direction decreased from 5.32 ± 0.60° to 1.09 ± 0.57° (\( P < 0.05 \)), the ROM in the right lateral bending direction decreased from 5.40 ± 1.04° to 1.11 ± 0.324° (\( P < 0.05 \)), the ROM in the left rotation direction decreased from 7.66 ± 0.83° to 2.03 ± 0.41° (\( P < 0.05 \)) and the ROM in the right rotation direction decreased from 7.71 ± 1.56° to 2.55 ± 0.59° (\( P < 0.05 \)).

**Cervical Interfacet Self-locking Cage Fixation**
Group D also showed increased cervical stability in all directions compared to group B: the ROM in the forward flexion direction decreased from 5.51 ± 0.74° to 1.03 ± 0.33° ($P < 0.05$), the ROM in the posterior extension direction decreased from 5.50 ± 1.82° to 0.99 ± 0.37° ($P < 0.05$), the ROM in the left lateral bending direction decreased from 5.32 ± 0.60° to 0.82 ± 0.26° ($P < 0.05$), the ROM in the right lateral bending direction decreased from 5.40 ± 1.04° to 0.84 ± 0.14° ($P < 0.05$), the ROM in the left rotation direction decreased from 7.66 ± 0.83° to 1.85 ± 0.43° ($P < 0.05$) and the ROM in the right rotation direction decreased from 7.71 ± 1.56° to 2.04 ± 0.37° ($P < 0.05$).

**Comparisons Between Cervical Interfacet Self-locking Cage Fixation and Lateral Mass Screw–rod System Fixation**

Group D had a greater ROM than Group C in both the forward flexion and posterior extension directions: the ROM in the forward flexion direction of group C and group D was 0.95 ± 0.28° and 1.03 ± 0.33°, respectively ($P < 0.05$), while the ROM in the backward extension direction of group C and group D was 0.83 ± 0.37° and 0.99 ± 0.37° ($P < 0.05$) respectively. Group D had a smaller ROM (0.82 ± 0.26°) in the direction of left lateral bending than group C (1.09 ± 0.57°) and the difference was statistically significant ($P < 0.05$). In addition, group D had a smaller ROM than group C in the right lateral bending and left and right axial rotation directions: the ROM in the right lateral bending direction of group C and group D was 0.84 ± 0.14° and 1.11 ± 0.32° respectively ($P > 0.05$), the ROM in the left rotation direction of group D and group C was 1.85 ± 0.43° and 2.03 ± 0.41°, respectively ($P > 0.05$) and the ROM in the right rotation direction of group D and group C was 2.04 ± 0.37° and 2.55 ± 0.59° ($P > 0.05$) respectively.

According to the test results, the ROM in flexion–extension, lateral bending and axial rotation of group B was significantly greater than that of group A ($P < 0.05$), indicating that injury to the PLC of the lower cervical spine could lead to instability in all directions of movement. The ROM of group C and group D was smaller than that of groups A and B in the flexion–extension, lateral bending, and rotation directions, and the difference was statistically significant ($P < 0.05$), indicating that the reconstruction by both fixation methods provided stability in the anterior–posterior flexion–extension, left–right lateral bending, and left–right axial rotation directions after cervical instability due to injury to the PLC. The ROM of group D was greater than that of group C in anterior flexion and posterior extension directions, and the difference was statistically significant ($P < 0.05$). The ROM of group D was smaller than that of group C in the direction of right bending and left and right axial rotation, but the difference was not statistically significant ($P > 0.05$). These results suggested that the novel CISC was equivalent to the lateral mass screw–rod fixation system, and could be used as a simple or complementary fixation for the posterior cervical approach. In particular, the CISC was superior to the lateral mass screw–rod system in terms of stability in the left and right lateral bending and axial rotation directions, but inferior in its capability of limiting anterior–posterior flexion and extension.

**Discussion**
Among cervical spine surgeries, anterior cervical surgery has undisputed advantages due to its minimal surgical trauma, and although the resulting complications can be serious, the probability of occurrence is very small\cite{7}. One of the major disadvantages of posterior cervical approach surgery is post-operative neck pain caused by intraoperative muscle damage and soft tissue ruptures. Compared to the conventional posterior approach, posterior percutaneous placement of an interfacet distractor or cage does not require removal of bone tissue, thereby avoiding the risk of postoperative iatrogenic instability of cervical vertebrae, nor does it require direct manipulation of the nerve roots, thus, avoiding the risk of nerve root injury and also facilitating fusion. A prospective multicenter study suggested that the use of a cervical interfacet cage shortened the postoperative hospital stay compared to posterior cervical lateral mass screw–rod fixation\cite{8}. Even for the severely degenerated cervical spine, the cervical interfacet distractor or cage is a promising solution\cite{9}. In addition, with regard to whether the postoperative stability of the cervical spine can be ensured, it is necessary to evaluate the postoperative effect of facet fusion and whether the expansion of the cervical facet joint can indirectly enlarge the intervertebral foramen and thus promote indirect decompression. Goel and Shah\cite{10} demonstrated in a study of the therapeutic effects of cervical interfacet cages on neurogenic and spinal cervical spondylosis, that 70% of patients achieved excellent results at a minimum follow-up period of 6 months as early as 2011. Similarly, in a two-year follow-up study of patients who had failed non-surgical treatment for single-segment neurogenic cervical spondylosis, Siemionow and his research team\cite{11} found no significant changes in overall and segmental cervical lordosis after bilateral placement of the DTRAX facet cages, and imaging analysis showed a 98.1% postoperative facet joint fusion rate, which is equivalent to the fusion rate of anterior cervical discectomy and fusion (ACDF) reported previously\cite{12}. Tan\cite{13} and his team found an average increase of 18.4% in the area of the anterior intervertebral foramen after placement of the facet cage, indicating that posterior cervical interfacet distraction and fusion can achieve indirect decompression of the nerve root without direct decompression of the involved nerve root. Through a specimen study to determine the biomechanical properties of the cervical interfacet cage, Leasure and Buckley\cite{14} demonstrated that the placement of the cage improved the stability of the associated vertebral bodies during all movements, except anterior and posterior flexion and extension movements, which is the same as the results of the present study. They also documented postoperative enlargement of the foramen in 86% of the specimens, and the rate of effective enlargement was not affected by postural changes such as flexion, extension and axial rotation. Voronov et al.\cite{15,16} suggested in a related study that the stability of the relevant cervical segments after placement of the cervical interfacet cage was similar to that of the lateral mass screw–rod system or ACDF. Moreover, the combination of a lateral mass screw–rod or an interbody cage in a specimen fixed with a cervical interfacet cage may provide greater postoperative stability of the cervical spine.

Maulucci et al.\cite{17} investigated the effects of a cervical interfacet cage on the intervertebral dynamics of cadaveric cervical spine specimens. This study demonstrated that the significant increase in stability of the relevant segment by the use of a cervical interfacet cage alone was not shown to be statistically significant, except when combined with posterior fixation, which also resulted in a significant decrease in
mobility. In order to improve the postoperative stability of interfacet spacers alone, the novel CISC reported in this study combines a lateral mass transfacet screw with a cervical interfacet spacer, with the two connected by a fixation guide plate. Since it is fixed with lateral mass transfacet screw at a posterior facet joint of the cervical spine, away from the center of the vertebral body, it has better stability against lateral bending. Because the lateral mass transfacet screws are perpendicular to the articular surface and penetrate through four layers of cortical bone, the screw resistance to extraction is significantly greater than that of the lateral mass screw–rod technology. In particular, compared to the lateral mass screw–rod technology, the lateral mass transfacet screw technique reduces the number of screws used and placed. However, in the lateral mass screw–rod system the screws are placed parallel to the articular surface to penetrate the double-layer cortex for fixation, so it is inferior to the lateral mass transfacet screw technique in terms of stability in the rotation direction.

According to our test results, it is clear that the CISC is less stable than the lateral mass screw–rod system in the flexion–extension direction, but more stable than the lateral mass screw–rod system in the lateral bending and rotation directions, which may be related to the fact that the cervical lateral mass transfacet screws have a higher resistance to extraction and greater stability than the lateral mass screws. Seong Yi and other scholars demonstrated that transarticular facet screws and lateral mass screws–rods system had similar biomechanical stability in single-level insertions. Lee and his research team demonstrated, with the use of C4 and C5 vertebral models, that the posterior cervical lateral mass fixation was less stable in flexion and extension than the lateral mass fixation system in flexion and extension. In 2014, Traynelis et al. compared the stability of ACDF with that of posterior lateral mass transfacet screws and the results suggested that posterior cervical lateral mass transfacet screw fixation combined with ACDF resulted in better stability. The results of the above studies are consistent with those of the present study. In this study, a novel CISC was developed by combining the cervical interfacet fusion cage with lateral mass transfacet screw fixation. It can also be applied to ACDF supplemental fixation and improve cervical stability.

The biomechanical results of the novel CISC in cervical spine specimens showed that the ROM in the anterior–posterior flexion–extension, left–right lateral bending, and axial rotation directions was greater in the severed C5–C6 segment than that in the intact state, indicating that the PLC may play a role in maintaining the stability of the corresponding segments. Compared to those in the intact and injured states, the ROM of the segment fixed with both the CISC and the lateral mass screw rod system was significantly reduced in all directions. In terms of the anterior–posterior flexion–extension direction, the stability of the CISC group was weaker than the posterior lateral mass screw–rod fixation group. The author assumes that the CISC only fixes the posterior facet joint of the cervical spine, which is far from the instantaneous rotational center during flexion and extension, while the lateral mass screw–rod system is similar to the posterior tension band structure when the cervical spine flexes, and the rigidity of the rod can also play a better supporting role when the cervical spine is extended. Therefore, for PLC injuries, the CISC is slightly less capable of maintaining stability in the flexion–extension direction than
the lateral mass screw–rod system. However, that stability of the posterior CISC was slightly more stable than that provided by the lateral mass screw–rod system in the left lateral bending test, and the difference was statistically significant. In the right lateral bending and axial rotation directions, the ROM of corresponding segments after CISC placement tended to decrease compared with posterior lateral mass screw–rod fixation, but the difference was not statistically significant.

Under the present experimental conditions. 1. The novel CISC designed by combining the characteristics of both TFS and cervical interfacet spacers (CIS) technologies can instantly stabilize the relative motion between the vertebrae, with the characteristics of "opening", "self-locking" and "easy operation". 2. With a fixation effect equivalent to that of the lateral mass screw–rod system, this novel CISC can be used as a simple or complementary fixation for the posterior cervical spine.

**Declaration**

1. **Ethical Approval and consent to participate**

   All steps in the experiment comply with Helsinki Declaration and are approved by the Ethics Committee of Affiliated Hospital of Xuzhou Medical University under "Ethical Approval and consent to participate.

2. **Consent to Publication**

   All authors agree to submit and publish the article.

3. **Data Availability statement**

   The datasets used and/or analyzed during the current study are available from the corresponding author on reasonable request. We do not have ethical permission to upload the dataset into a repository. Please note that all study data has been anonymised for confidentiality purposes.

4. **Conflict of interest**

   The authors declare that they have no conflict of interest.

5. **Funding**

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6. **Acknowledgment**

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7. **Author contribution**

   Maji Sun and Zhongwei Li have contributed equally to this work. All authors contributed to the study conception and design. Material preparation, data collection and analysis were performed by Maji Sun,
Zhongwei Li and Qiuans Wang. The first draft of the manuscript was written by Maji Sun and all authors commented on previous versions of the manuscript.

References


Figures
Figure 1

Design drawing of the new-type posterior CISC and photographic images of the 3D-printed material object

Note: a. 3D schematic diagram showing a CT data reconstruction of a corpse specimen and a CISC, b. Photographic image of the produced CISC.
Figure 2

X-ray files of cervical vertebrae fixed with a novel cervical interfacet self-locking cage and cervical lateral mass screw rod.

Note: A1, A2: anterior and lateral X-ray films of cervical vertebrae fixed with cervical lateral mass screw-rod. B1, B2: anterior and lateral X-ray films of the joint space fixed with titanium alloy CISC.
Figure 3

Biomechanical laboratory instruments and software

Note: a: universal material mechanics testing machine, b: Experimental computer and software

Figure 4

Biomechanical testing of cervical interfacet self-locking cage and cervical lateral mass screw–rod fixation

Note: a. intact group, b. injured group, c lateral mass screw-rod fixation group, and d. titanium alloy CISC fixation group.