Design and biomechanical study of a modified pedicle screw

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【Abstract】Objective: In pedicle screw fixation, the heads of monoaxial screws need to be directed in the same straight line to accommodate the rod placement by backing out during operation, which decreases the insertional torque and internal fixation strength. While polyaxial screws facilitate the assembly of the connecting rod, but its ball-in-cup locking mechanism reduces the static compressive bending yield strength as compared with monoaxial screws. Our study aimed to assess the mechanical performance of a modified pedicle screw.

Methods: In this study, the tail of the screw body of the modified pedicle screw was designed to be a cylinder-shaped structure that well matched the inner wall of the screw head and the screw head only rotated around the cylinder. Monoaxial screws, modified screws and polyaxial screws were respectively assembled into 3 groups of vertebrectomy models simulated by ultra high molecular weight polyethylene (UHMWPE) blocks. This model was developed according to a standard for destructive mechanical testing published by the American Society for Testing Materials (ASTM F1717–04). Each screw design had 6 subgroups, including 3 for static tension, load compression and torsion tests, and the rest for dynamic compression tests. In dynamic tests, the cyclic loads were 25%, 50%, and 75% of the compressive bending ultimate loads respectively. Yield load, yield ultimate load, yield stiffness, torsional stiffness, cycles to failure and modes of failure for the 3 types of screws were recorded. The results of modified screws were compared with those of monoaxial and polyaxial screws.

Results: In static tests, results of bending stiffness, yield load, yield torque and torsional stiffness indicated no significant differences between the modified and monoaxial screws (P>0.05), but both differed significantly from those of polyaxial screws (P<0.05). In dynamic compression tests, both modified and monoaxial screws showed failures that occurred at the insertion point of screw body into the UHMWPE block, while the polyaxial screw group showed screw body swung up and down the screw head because of loosening of the ball-in-cup mechanism.

Conclusions: The modified screw is well-designed and biomechanically improved. And it can provide sufficient stability for segment fixation as monoaxial screws.

Key words: Bone screws; Biomechanics; Spine; Internal fixators

Transpedicular screw fixation, which provides excellent initial stability for damaged segments by fixating the three-column spine, has been extensively applied in managing spinal disorders such as degenerative diseases, fractures, tumors, scoliosis, deformities, etc.1,2 And the surgical procedures of posterior approach are already well established in spinal surgery. However, the placement of pedicle screws requires precise alignment of the screw heads to allow for incorporation of interlocking rods. Unfortunately, during pedicle screw placement, surgeons usually determine whether the screw heads have achieved precise alignment by experience, and sufficient holding strength by feeling the necessary torque applied to tighten screws. When difficulties are encountered in assembling the connecting rod, the directions of the screw heads need to be adjusted precisely in the same straight line by backing out or changing screws intraoperatively. Shepard et al3 suggested that the intraoperative adjustment of pedicle screws in the original site may decrease the insertional torque and compromise the internal fixation strength. Some scholars sug-
gested that the insertional torque can predict a mechanical stability and they found a linear correlation between the insertional torque and the pull out strength.\textsuperscript{4-7}

A variety of strategies can be done to decrease complications caused by adjusting or backing out screws intraoperatively, including use of a larger or longer or both larger and longer screw, augmentation of the failed hole with bone cement, or placement of the screw in a new site.\textsuperscript{8} Obviously, this will inevitably prolong the operation time and increase the surgical risk. The design of the polyaxial screw allows the screw head to deviate away the perpendicular line to the longitudinal rod, which makes assembly of the connecting rod in the curved spine more convenient. However, compared with monaxial screws, polyaxial screws only have the effect of compression and traction on the posterior vertebral column and thus can hardly achieve an effective reduction of the anterior column of the fractured vertebral body. Furthermore, the design of ball-in-cup locking mechanism of the rod-screw link reduces the static compressive bending yield strength and fatigue resistance.\textsuperscript{9}

We designed a new kind of pedicle screw (modified screw) that possesses the effect of compression and traction on the anterior and middle column of the vertebral body as monaxial screws. Meanwhile, it facilitates assembly of the connecting rod by only adjusting the directions of the screw heads in the same straight line. According to our knowledge, no reports have described a similar pedicle screw design or carried out a similar biomechanical research. The purpose of this study was to assess the biomechanical characteristics of the modified pedicle screw and to provide a basis for its future application in clinic.

**METHODS**

**Design of the modified pedicle screw**

The modified pedicle screw consisted of 3 parts: screw body, head and nut. The tail of the screw body was designed to be a cylinder-shaped structure that well matched the inner wall of the screw head in order to make the screw head only rotate round the cylinder (Figure 1), not swing multiaxially as the polyaxial screw head. Parameters for other structures, such as the inner hexagon of the screw body tail, thread and hollow structure of the screw body and diameter (1.8 mm) were the same as those of polyaxial screws. The screw body could be implanted into the pedicle by a wrench through the hexagon of the screw body tail.

**Synthetic models**

The test models for corpectomy were established with ultra high molecular weight polyethylene (UHMWPE) blocks based on a similar model which was developed according to the testing standard for vertebral fixation (F1717-04) of the American Society for Testing Materials (ASTM). The UHMWPE blocks were instrumented with spinal implants strictly followed the manufacturers’ recommendations. A tightening torque of 10 Nm was applied to combine screws and rods with set screws. The posterior part of each block was obliquely cut to maintain a consistent insertion condition for each pedicle screw that is perpendicular to the facet. The horizontal distance between the two insertion points was 40 mm, and the longitudinal distance between the two pedicle-screw axes was 76.0 mm. The inserted pedicle screws formed a 45.0 mm-long lever arm, extending from the centerline of the posterior longitudinal rod to the actuator axis of the testing machine. Then the construct and a jig were mounted in the mechanical testing machine (Minibionix 858; Eden Prairie, MN, USA). Transverse connectors were not used in all the implant constructs (Figure 2). All implants were unused before testing and not retested.

All the test screws were provided by the Naton Medical Group of International Orthopaedic Research Center (Beijing, China). Because they were designed for the same fixation system, the structure of internal screw and nut, diameter (6.0 mm), length (45 mm) and thread designs were the same. Moreover, diameter, thread and figure designs of the screw body inserted into UHMWPE blocks were of the same parameters.

The spinal implant constructs were divided into 3 groups, instrumented with monaxial screws in Group 1, modified screws in Group 2 and polyaxial screws in Group 3. Each type of screw had 6 subgroups (5 assemblies for each), half for static tests and the rest for dynamic compression tests. The static test included compression, tension and torsion test and the dynamic compression test had 3 cyclic load levels (25%, 50%, and 75% of the compressive bending ultimate loads respectively). All the mechanical tests were performed on mechanical testing machine.
The static mechanical tests were performed in the air at room temperature. The test apparatus was loaded at a rate of 25.0 mm/min for axial compression test and 60°/min for torsion test. Values for load-displacement curve, compression bending yield load (N), compression bending stiffness (N/mm), compression bending ultimate load (N) and torsional stiffness (Nm/degree) were recorded. The mode of failure of each construct was observed after testing.

Dynamic compression tests were carried out with the assemblies submerged in saline solution at 37°C. In the fatigue test, a sinusoidal displacement to the spinal construct was applied (R≥10). The fatigue frequency was 5.0 Hz, and displacement 3.0 mm. Throughout the test, the displacement was monitored. The initial fatigue load was 25% of the compressive bending ultimate strength as determined in the static compression bending test and the others were 50% and 75% of the ultimate failure load, respectively. We especially observed the mode of failure and deformation of components and evaluated all the changes of their surfaces.

Statistic analysis
The general form of each null hypothesis was that the load, stiffness, or cycles to failure of the specimen were the same for any 2 groups or levels compared. Analysis of variance (LSD-t, ANOVA) was used to investigate the significance of the separate and interactive effects of loads, stiffness, and cycles to failure at 25%, 50%, and 75% load levels respectively. Data were processed with the SPSS 15.0 computer software (IL, Chicago, USA). P<0.05 was considered statistically significant.

RESULTS
The measured mechanical properties of 3 kinds of screws in static compression test are shown in Table 1, and typical static compression load-displacement curves in Figure 3. The results of ANOVA showed no significant differences between modified screws and monoaxial screws (P>0.05) in terms of compression bending stiffness, compression bending yield load and compression bending ultimate load, but a significant difference between modified screws and polyaxial screws (P<0.05) in static mechanical properties. Modified and monoaxial screw assemblies demonstrated plastic deformation of the longitudinal rods (Figure 4A). In addition, curved deformity occurred to 2 monoaxial screws at the insertion point when the compressive bending ultimate load was exceeded (Figure 4B). In polyaxial screw assemblies, angular deformity occurred to the longitudinal axes of the screw body and the screw head because of rotational slip of the multiaxial link.

The measured torque stiffness was 7.3 Nm/degree, 6.8 Nm/degree and 5.4 Nm/degree for monoaxial, modified and polyaxial screws, respectively. ANOVA demonstrated that the stiffness of modified screws was similar to that of monoaxial screws (P>0.05), but stronger than that of polyaxial screws (P<0.05).

The condition of tension bending properties was very similar to that of compression properties in magnitude and did not differentiate further between screw designs. The amount of cycles to failure at each load level for the 3 different kinds of screws is shown in Table 2. All screw designs achieved 5 million cycles at the 25% load level. Significant differences in the number of cycles to failure between screw designs were found at 50% and 75% load levels (Table 2). Fatigue tests showed that the failure of modified and monoaxial screw bodies occurred at the insertion point into UHMWPE blocks (Figure 5). While the failed mode of polyaxial screw group was that screw body swung up and down the screw head because of loosening of the ball-in-cup mechanism.

<table>
<thead>
<tr>
<th>Groups</th>
<th>Bending stiffness (N/mm)</th>
<th>Bending yield load (N)</th>
<th>Bending ultimate load (N)</th>
<th>Torsional stiffness  (Nm/degree)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Monoaxial screws</td>
<td>65.2±5.9</td>
<td>612.8±24.4</td>
<td>963.8±29.9</td>
<td>7.3±0.9</td>
</tr>
<tr>
<td>Modified screws</td>
<td>58.2±7.8</td>
<td>575.8±31.0</td>
<td>919.4±27.7</td>
<td>6.8±0.5</td>
</tr>
<tr>
<td>Polyaxial screws</td>
<td>24.8±1.9 *</td>
<td>231.4±23.6 *</td>
<td>320.4±19.2 *</td>
<td>5.4±0.8 *</td>
</tr>
</tbody>
</table>

*P<0.05, compared with the modified group.
DISCUSSION

According to the testing standard (ASTM F1717–04) for vertebral fixation, we adopted UHMWPE to simulate standardized vertebral bodies to test the biomechanical properties of a modified monoaxial screw. UHMWPE blocks were instrumented with spinal implants and the rod was the only connection between blocks. This represented the worst condition for implants when the middle vertebral body was removed. The
UHMWPE block-simulated vertebral segments ensured the same condition for pedicle screw fixation and eliminated the influence of variability of bones and morphologies often associated with cadaveric tissues, for example, variability in bone mineral density due to age, size of vertebrae, history, etc. Thus, the test in our experiment is more precise and reproducible than that in cadaver models. However, the test results cannot predict the actual situation of the in vivo application of the modified screws.

Transverse connectors were not used in this study because we aimed to assess the rationality of the design of the modified screw without interference of transverse connectors. Previous studies demonstrated that transverse connectors do not influence the results of compression bending mechanical tests but significantly improve the torsional stiffness according to their sites, numbers and shapes. The way to insert the modified screws is significantly different from that for monoaxial screws. Modified screws are implanted using a wrench through the inner hexagonal hole in the screw body tail. When the last thread of the screw body has been inserted into the pedicle and achieved full torque, the screw head still can rotate axially around the cylinder at the end of the screw body. By this means, partial backing out of the screw thread can be avoided when installation of the connecting rod is difficult and alignment of the screw heads need to be adjusted. The pullout strength test is not performed in this study for the pullout strength of screws is not only related to the adjusted direction of the screw head, but also to the structural design, screw diameter, bone mineral density, angle of screw insertion, hole for repeated insertion, etc.

The main role of the screw-rod system is to bear compressive bending loads and maintain stability of the spine balance in the sagittal plane in vivo. Therefore, a desirable mechanical behavior of pedicle screw designs is closely related to the compression bending. Several studies showed that the pedicle screw system can bear 38%-55% of the axial compressive bending loads. Once the spinal axial compression load exceeds the compression stiffness of the internal devices, permanent deformation of the system may occur and result in kyphotic deformity of the segments. If the ultimate load of the fixated spinal device is exceeded, disastrous complications will develop. The mechanical performances of the screw-rod system are similar between compressive bending loads and tensile bending loads, so we did not make a detailed mechanical analysis of the tensile bending loads in this paper.

The biomechanical properties of monoaxial pedicle screws had been widely reported in the literature. Although there are different implant methods due to various designs of the screw-rod system, all pedicle screws can provide sufficient mechanical stabilities for the fixated spinal segments and obtain satisfactory clinical effects. Polyaxial screws facilitate the installation of the connecting rod, and their biomechanical properties have been reported in several studies. Stanford et al suggested that the rod-screw link design of the polyaxial screw reduces its static compressive bending yield strength as compared with the fixed screw designs. The ball-in-cup locking mechanism of the rod-screw link appear vulnerable to fatigue failure. Shepard et al suggested that polyaxial screws do not significantly decrease the stiffness of the construct. On the contrary, it is feasible because the polyaxial constructs create a more secure holding environment by permitting better contact and holding strength between the screw head and the rod. When there is a combined effect of bending loads and shear force to the rods, higher resistance to rotational slippage would occur between the rod and the screw head.

We first report the biomechanical properties of the modified pedicle screw. The static test results indicate that modified screws are similar to monoaxial screws (P>0.05), but significantly superior to polyaxial screws (P<0.05) in terms of compressive bending stiffness, compressive bending yield load, compressive bending ultimate load and torsional stiffness. This may be explained by the specific design of the cylindrical surface between the screw head and the end of the screw body for modified screws. This design makes the screw head only rotate around the cylinder and avoids multiaxial slippage. When the screw-rod system is locked completely, the fixation mode of modified screws and monoaxial screws are the same. Bending deformities occurred at the connecting-rod or screw body when the screw-rod system achieved the maximum load. For polyaxial screw group, angular deformity normally occurred between the longitudinal axes of the screw body and the screw head due to slipping of the ball-in-cup.
mechanism, but no obvious bending deformities occurred at the connecting rod in static axial compression tests. This demonstrates that the ball-in-cup mechanism do decrease the compressive bending stiffness of polyaxial screws. We deem that the modified screw has a similar structural stiffness as the monoaxial screw and can provide the same rigid mechanical stability for segment fixation. While polyaxial screws have a smaller compressive strength and torsional stiffness, but a better resistance to failure, compared with modified or monoaxial screws.

The fatigue test found that all the 3 kinds of screws were able to complete 5 million cycles of fatigue test under 25% of the compressive bending ultimate loads. However, the amount of loads at 25%, 50%, and 75% load levels in modified monoaxial screw group were significantly larger than in polyaxial screw group (P<0.05). At a cyclic load of about 210 N, the cyclic times of polyaxial screws (23 000 cycles) were much fewer than those of modified or monoaxial screws (P<0.001). The cyclic times of modified screws were close to those of monoaxial screws under a cyclic load at 25%, 50% and 75% levels (P>0.05). Moreover, the fatigue failures occurred both in modified and monoaxial screws at the insertion point, the beginning of thread of the screw body. The above data indicate that modified screws are similar to monoaxial screws in dynamic biomechanical properties. In the polyaxial screw group, rotational slippage of the ball-in-cup mechanism occurred, and then the screw body swung up and down the UHMWPE blocks. The smooth surface of the multiaxial locking mechanism is prone to slippage under cyclic loads, and finally results in loosening of the ball-in-cup mechanism, which seems a protective design from fatigue failure for polyaxial screws.

The limitations of present study are that though UHMWPE blocks simulate the worst situation of vertebral fractures, installation of the screw-rods system can achieve the best match. The experimental results comparatively analyze the biomechanical properties of the 3 kinds of screws installed in the best condition of match, which is difficult to meet during clinical surgical procedures. So our results cannot be applied to predict the biomechanical performances of these screw-rod systems in vivo.

In conclusion, the design of this modified monoaxial pedicle screw, when implanted in the way of polyaxial screws, facilitates assembly of the connecting rod by only adjusting the direction of the screw head. Meantime, the modified screws could provide sufficient mechanical stability for the fixated segments as monoaxial screws. The biomechanical stability of the modified or monoaxial pedicle screws is more rigid than that of the polyaxial screws, while the polyaxial screws have a better resistance to failure.

REFERENCES


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