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Design and performance of spinal fixation pedicle screw system

Necip Camuşcu¹ and Teyfik Demir²

Abstract
Pedicle screw-rod bilateral constructions are extensively used in spinal fixation. In this study, the common cause for failure of bilateral constructions has been determined to be the high stress concentration at the rod-setscrew interface. In order to overcome this problem, a design modification has been made by using a supplementary part (shoe) between rod and setscrew. Performance comparison of the conventional design and modified design has been done by conducting static tests. Design modification has resulted in 11%, 27%, 42% and 31% improvements in axial gripping capacity, torsional gripping capacity, flexion/extension resistance and subassembly compression strength, respectively. The most outstanding achievement has been obtained in the fatigue life, which was extended by almost three times.

Keywords
Pedicle screw, spinal fixation, fatigue life and implant

Introduction
Pedicle screws are extensively used in spinal fixation. Scoliosis, tumor containing bones or vertebral fractures are widely fixed by pedicle screw-rod systems.¹ ² Rigidity of the fixed part of the vertebrae is very important for the fusion process.³ Different types of vertebrectomy models were evaluated by scientists to determine the rigidity of fixation technique.⁴ Human cadaver and animal tests were performed in order to understand the static stiffness of pedicle screw-rod constructs.⁵ ⁸ Fatigue performance of vertebrectomy models were also studied by researchers to clarify the long term performance of constructions. Design parameters were evaluated to examine the fatigue and static strength of bilateral constructions.⁹ ¹⁵ Screw neck breakage and rod failure are stated to be the most common failures.¹⁶ Rholman et al.¹⁶ studied the screw breakage risk reducing techniques. Placing bone grafts may reduce the breakage as a result.¹⁶

Surface modifications were made to improve the fatigue life and strength of systems.¹⁷ Numerous modifications were tried by investigators to increase the pull-out strength of screws, such as core geometry, screw tooth profile and flat overlap area.¹² ¹₄ Chen et al.¹⁸ studied posterior spinal implants by means of material, connecting plate and pedicle screw design to show the most dominant factors on fatigue performance systems.

In 2004, Stanford et al.¹⁹ studied static and dynamic test performance of a multi-axial pedicle screw design. The study showed that, ball-in-cup multi-axial locking mechanisms were vulnerable to fatigue failure.

Screw breakage on the caudal side is a common failure type for spinal fixation.²⁰ Cyclic loading makes screw-rod systems highly sensitive to notch effects. Homogenizing the stress distribution on each element of construction became more important. Lindes et al.²¹ investigated the fatigue strength of a contoured rod-pedicle screw system on a vertebrectomy model. Similarly, Nguyen et al.²² also studied contoured cobalt chrome posterior spinal fusion rods. Both concluded that contouring decreases the fatigue life owing to notch effects.

On the other hand, there are only a few studies investigating the effect of the screw-head-rod interface area

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on fatigue and static performance of bilateral constructs.\textsuperscript{23–24}

In the present study, five commercial products were investigated under cyclic loading in accordance with ASTM F1717-10. The contact area between screw head and rod has been found as the most critical parameter affecting the performance of pedicle screw fixation systems. Small contact in the area between the rod and the screw-head setscrew results in stress concentration on the rod, which causes crack initiation and failure. Therefore, in order to overcome this problem, a brand new screw-head setscrew having a larger contact area has been designed for the best performed screw system among the five commercial products. A performance comparison was carried out between the previous design and new design in accordance with ASTM F1717-10 and F1798-08.

Design

The photographs of failed specimens of commercial products tested in our clinical biomechanics laboratory are given in Figure 1. It can be seen that in all specimens failure occurred at the contact zone between the rod and setscrew. When the contact zone of failed specimens is examined, it is obvious that the contact area between cylindrical surface of the rod and flat surface of the setscrew is very thin. There is, in fact, a line contact between them that causes very high stress concentration on the rod. It has been concluded that the contact area must be increased in order to reduce the stress concentration on the rod. This is the main concept of the new design. It is clear that increasing the contact area by making geometrical modifications on the setscrew is not possible. The setscrew moves towards the rod by rotating it about its longitudinal axis. Therefore, making geometrical modifications on the bottom surface of the setscrew, for instance opening a cylindrical groove that can mate with the cylindrical surface of the rod, does not help. This is because there will be a synchronization problem between set screw pitch and mating contact area. For this reason, the necessity for a secondary part between the setscrew and the rod has aroused. The secondary part, called a ‘shoe’, has been designed, which has a cylindrical surface exactly mating with the cylindrical surface of the rod. Additionally, it has a stem that is placed in the hole opened at the bottom surface of the setscrew. A schematic illustration of the pedicle screw–rod system with the shoe is given in Figure 2. The stem and the hole in which it is placed are concentric and the shoe can rotate relative to the setscrew, i.e. the rotational

Figure 1. Specimens of four different commercial products failed in fatigue tests. (a) Alpinendo Medical Devices Ltd, (b) Onspine Medical Ltd, (c) and (d) Norm Medical Devices Ltd.
motion of the shoe is not constrained by the rotational motion of the setscrew. In this way, during assembling, when the setscrew is tightened enough, it will start to compress the shoe on the rod. Schematic view of previous and new designs is illustrated in Figure 3. The new design gives the advantage of a much larger contact area. The increased contact area is expected to increase the axial/torsional gripping capacity, flexion/extension moment of the rod–screw system and fatigue strength.

**Experimental procedure**

Five different tests were performed using old and new designs. Axial and torsional gripping capacity tests and flexion/extension tests conducted in accordance with ASTM F1798-08. Five subassemblies containing a 110 mm rod, a 6.5 \( \times \) 45 screw and a relevant set screw were prepared for each test type. Axial gripping capacity tests were performed by fixing the rod to the fixture and pushing the screw head towards the rod’s main axis. While pushing the screw head displacement versus load, values are recorded. Test set-ups for axial gripping capacity tests can be seen in Figure 4. Similar to axial gripping capacity tests, torsional gripping tests are performed by fixing the rod and rotating the screw head clockwise about the main axis of the rod. While rotating the screw head, torque versus angle of twist values are recorded. Test set-ups for torsional gripping capacity tests can be seen in Figure 5. In flexion/extension moment tests, the rod is again fixed to the fixture as illustrated in Figure 6 and a stick is moved downwards through the screw. The screw is forced to plastically deform from the screw–screw-head interface. Load versus displacement values are recorded during the test. Screws are fixed to the rods in the middle and tightened to 10 Nm by a calibrated torque meter for all the tests in accordance with ASTM F1798-08. Crosshead speed was 2 mm/min and 10 data points are recorded per second in all tests. The Instron uni-axial testing frame and 55MT torsion test system were used in static tests. Dynamic tests were completed by a calibrated dynamic test frame developed in our laboratory.

Bilateral vertebrectomy models were prepared according to ASTM F1717-10 for subassembly compression and fatigue tests. A subassembly contains two rods, four multi-axial pedicle screws, relevant setscrews and two ultra-high molecular weight poly ethylene (UHMWPE) blocks simulating a vertebral bone as shown in Figure 7. All setscrews were tightened to 10 Nm with a calibrated torque meter. Static compression tests are made with a cross head speed of 2 mm/min. Load versus displacement values are recorded. Load ratio (R) is 10 for the fatigue tests, load frequency is 10 Hz and 5 specimens were used for each design type. The run out cycle is determined by the standard \( 5 \times 10^6 \) cycles.
Figure 4. Axial gripping capacity test set-up.

Figure 5. Torsional gripping capacity test set-up.

Figure 6. Flexion/extension moment test set-up.
Results and discussion

The results of the subassembly axial gripping capacity, torsional gripping capacity and flexion/extension moment tests are given in Tables 1, 2 and 3, respectively. Results clearly show that the static strength of the new design is superior to that of the conventional design. An improvement of 11\% in axial gripping capacity has been obtained. Similarly 27\% improvement has been obtained in torsional gripping capacity.

The enhancement in the axial and torsional gripping capacity is considered to be a direct result of the increased contact area between the rod and the shoe that is attached to the setscrew. An increased contact area means higher frictional forces between the mating parts. In the same manner, a 42\% improvement has been realized in the flexion/extension moment (see Table 4). This is believed to be owing to the more uniformly distributed contact pressure provided by the new design.

Table 1. Subassembly axial gripping capacity test results.

<table>
<thead>
<tr>
<th></th>
<th>Mean yield load (N)</th>
<th>Standard deviation</th>
<th>Mean yield displacement (mm)</th>
<th>Standard deviation</th>
</tr>
</thead>
<tbody>
<tr>
<td>Previous design</td>
<td>2210</td>
<td>20</td>
<td>0.5</td>
<td>0.08</td>
</tr>
<tr>
<td>New design</td>
<td>2457</td>
<td>16</td>
<td>0.4</td>
<td>0.03</td>
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*Number of specimens: 5.
shoe. The spherical end of the screw is placed in the housing of the screw head. There is another part between the spherical end of the screw and the screw head called the screw-head bed, which is in direct contact with the screw end. The screw-head bed provides a curved housing for the rod. The rod is placed between the shoe and the screw-head bed. In the conventional design, since there is no shoe, the flat bottom surface of the setscrew is in direct contact with the rod. In this case, compression forces coming from the setscrew are less uniformly transmitted to the screw-head bed, spherical end of the screw and housing of the screw head, respectively. However, this problem has been overcome by using a shoe between the rod and setscrew resulting in a considerable improvement in the flexion/extension moment. This improvement has significant advantages on the subassembly of bilateral construction. As a result, subassembly compression strength has been improved by 31%.

Among all tests carried out in this study, the most outstanding achievement has been obtained in fatigue tests. Fatigue tests are carried out at various percentages of yield loads (up to 80%) determined by the subassembly compression tests as stated in the ASTM F1717-10 standard. As can be seen in Table 5 and Figure 8, the new design has withstood a higher number of cycles at the same percentage levels of yield load than the conventional design. Fatigue-life improvement is approximately three fold for the failed specimens. Under 85% of yield load, the conventional design failed at approximately $2 \times 10^6$ cycles, while the new design lasted up to $5 \times 10^6$ cycles at which the

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**Table 2.** Subassembly torsional gripping capacity test results.

<table>
<thead>
<tr>
<th></th>
<th>Mean yield torque (N.m)</th>
<th>Standard deviation</th>
<th>Mean yield angle of twist (deg)</th>
<th>Standard deviation</th>
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<tr>
<td>Previous design</td>
<td>5.6</td>
<td>0.5</td>
<td>18</td>
<td>0.05</td>
</tr>
<tr>
<td>New design</td>
<td>7.1</td>
<td>0.2</td>
<td>14</td>
<td>0.05</td>
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</table>

*Number of specimens: 5.

**Table 3.** Subassembly flexion/extension moment test results.

<table>
<thead>
<tr>
<th></th>
<th>Mean yield moment (Nm)</th>
<th>Standard deviation</th>
<th>Mean yield displacement (mm)</th>
<th>Standard deviation</th>
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<tbody>
<tr>
<td>Previous design</td>
<td>4.5</td>
<td>0.225</td>
<td>1.3</td>
<td>0.1</td>
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<tr>
<td>New design</td>
<td>6.4</td>
<td>0.275</td>
<td>0.8</td>
<td>0.05</td>
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*Number of specimens: 5.

**Table 4.** Subassembly compression test results.

<table>
<thead>
<tr>
<th></th>
<th>Mean yield load (N)</th>
<th>Standard deviation</th>
<th>Mean yield displacement (mm)</th>
<th>Standard deviation</th>
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</thead>
<tbody>
<tr>
<td>Previous design</td>
<td>184</td>
<td>14</td>
<td>5.4</td>
<td>0.1</td>
</tr>
<tr>
<td>New design</td>
<td>241</td>
<td>12</td>
<td>5.1</td>
<td>0.05</td>
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*Number of specimens: 5.

**Table 5.** Fatigue test results.

<table>
<thead>
<tr>
<th>Specimen No</th>
<th>Yield load (%)</th>
<th>Previous design</th>
<th>New design</th>
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<tr>
<td></td>
<td>Load (N)</td>
<td>Number of cycles</td>
<td>Remark</td>
</tr>
<tr>
<td>1</td>
<td>100</td>
<td>184</td>
<td>1</td>
</tr>
<tr>
<td>2</td>
<td>95</td>
<td>175</td>
<td>418,245</td>
</tr>
<tr>
<td>3</td>
<td>90</td>
<td>166</td>
<td>859,411</td>
</tr>
<tr>
<td>4</td>
<td>90</td>
<td>166</td>
<td>837,874</td>
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<tr>
<td>6</td>
<td>85</td>
<td>156</td>
<td>1,916,284</td>
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<tr>
<td>7</td>
<td>85</td>
<td>156</td>
<td>2,014,417</td>
</tr>
<tr>
<td>8</td>
<td>80</td>
<td>147</td>
<td>5,000,000</td>
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The experiment was ceased. Remembering that the subassembly compression yield load of the new design is about 30% higher than that of the conventional design, the new design has a longer fatigue life at higher cyclic loads compared to the conventional design (see Figure 8). As mentioned in the section on ‘Design’, rod failure in the conventional design always occurred at the contact area between the rod and setscrew owing to high stress concentration on the load–setscrew interface. A photograph of the failed rod in bilateral construction of the new design is given in Figure 9. It can be clearly seen that the rod failure did not occur at the rod and setscrew contact region, but in the middle of the rod. This proves that increasing the contact area between the rod and the setscrew effectively reduces the stress concentration that is the main reason for the failure of the conventional design. As a result, fatigue life and

**Figure 8.** Fatigue life curves for bilateral constructions (a) yield load percent versus number of cycles and (b) load versus number of cycles (●: previous design and ◆: new design).

**Figure 9.** Failed sample of new design.
mechanical strength of the subassembly can be increased by using a newly designed shoe between the rod and setscrew as anticipated in the beginning.

Conclusion

In this study, pedicle screw subassemblies used in spinal fixation bilateral constructions have been modified to improve the mechanical strength and fatigue behaviour. The new design differs from the conventional design in that a new part called the 'shoe' has been used between the rod and setscrew resulting in a higher contact area. Advantages of the new design can be summarized as follows.

1. Axial and torsional gripping capacities have been enhanced by 11% and 27%, respectively.
2. Flexion/extension resistance of the subassembly has been improved 42%.
3. A higher subassembly compression strength of 31% has been achieved.
4. Much better fatigue resistance, with a higher number of cycles at higher loads, has been obtained.

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References

18. Chen PQ, Lin SJ, Wu SS and So H. Mechanical perfor-

