IN VITRO MECHANICAL EVALUATION OF SPINAL FIXATION ROD CONNECTORS

EVALUACIÓN MECÁNICA IN VITRO DE CONECTORES DE VARILLAS DE FIJACIÓN DE LA COLUMNA

ABSTRACT

Objective: Evaluate and compare the mechanical resistance and the fatigue behavior associated with the use of three different modalities of vertebral fixation system rod connectors through in vitro pre-clinical mechanical tests developed specifically for this application (linear, lateral with square connector and lateral with oblique connector). Methods: Cobalt chromium rods 5.5 mm in diameter were used and coupled with three types of connectors: a) side rod with oblique connector, b) side rod with square connector, and c) rod and linear connectors. Quasi-static mechanical four-point bending and fatigue tests were performed. The variables measured were (I) the bending moment at the yield limit, (II) the displacement at the yield limit, (III) the rigidity of the system in flexion and (IV) the number of cycles until system failure. Results: The linear system presented the greatest force and the greatest moment at the yield limit, as well as the greatest stiffness equivalent to bending. All specimens with square and oblique connectors endured 2.5 million cycles in the minimum and maximum conditions of applied moment. The specimens with linear connector endured 2.5 million cycles with fractions of 40.14% of the bending moment at the yield limit, but failed with levels of 60.17% and 80.27%. Conclusions: Systems with linear connectors showed greater mechanical resistance when compared to systems with square and oblique connectors. All systems supported cyclic loads that mimic in vivo demands. Level of evidence V; In vitro research.

Keywords: Spinal Fusion; Essay; Experimental Implants; Arthrodesis.

RESUMO

Objetivo: Avaliar e comparar a resistência mecânica e o comportamento em fadiga associado ao uso de três modalidades distintas de conectores de hastes do sistema de fixação vertebral por meio de ensaios mecânicos pré-clínicos in vitro desenvolvidos especificamente para essa aplicação (linear, lateral com conector quadrado e lateral com conector obliquo). Métodos: Foram usadas hastes de Cromo-cobalto de 5,5 mm de diâmetro acopladas a três modalidades de conectores: a) haste lateral com conector obliquo, b) haste lateral com conector quadrado e c) haste e conector lineares. Foram realizados ensaios mecânicos quase-estáticos e de fadiga sob flexão em quatro pontos. As variáveis medidas foram (I) o momento fletor no limite de escoamento, (II) o deslocamento no limite de escoamento e (III) a rigidez do sistema em flexão e (IV) número de ciclos até a falha do sistema. Resultados: O sistema linear apresentou maior força e o maior momento no limite de escoamento, bem como maior rigidez equivalente à flexão. Todos os corpos de prova com conector quadrado e obliquo suportaram 2,5 milhões de ciclos nas condições mínimas e máximas de momento aplicado. Os corpos de prova com conector linear suportaram 2,5 milhões de ciclos com frações de 40,14% do momento fletor no limite de escoamento, porém falharam com níveis de 60,17% e 80,27%. Conclusões: Os sistemas com conectores lineares apresentaram maior resistência mecânica quando comparados aos sistemas com conectores quadrados e obliquos. Todos os corpos suportaram carregamentos cíclicos que imitam as solicitações in vivo. Nível de evidência V; Pesquisa in vitro.

Descritores: Fusão Vertebral; Ensaio; Implantes Experimentais; Arthrodesese.

RESUMEN

Objetivo: Evaluar y comparar la resistencia mecánica y el comportamiento de fatiga asociado al uso de tres modalidades distintas de conectores de varillas del sistema de fijación vertebral a través de ensayos mecánicos preclínicos in vitro desarrollados específicamente para esta aplicación (lineal, lateral con conector cuadrado y lateral con conector oblicuo). Métodos: Se utilizaron varillas de cromo-cobalto de 5.5 mm de diámetro acopladas a tres tipos de conectores: a) varilla lateral con conector oblicuo, b) varilla lateral con conector cuadrado y c) varilla y conector lineales. Se realizaron ensayos mecánicos y de fatiga cuasi-estáticos y ensayos por flexión de cuatro puntos. Las variables medidas fueron (I) el momento fletor en el límite elástico, (II) el desplazamiento en el límite elástico y (III) la rigidez del sistema en flexión y (IV) el número de ciclos hasta la falla del sistema. Resultados: El sistema lineal presentó la mayor fuerza y el mayor momento en el límite elástico, así como la mayor rigidez equivalente a la flexión. Todas las probetas con conectores cuadrados y oblicuos soportaron...
INTRODUCTION

Rigid, larger-diameter rods have been widely used in vertebral fixation systems for posterior spinal stabilization in recent decades. These rods have been used as connection components in vertebral fixation systems, usually coupled to the hooks or screws, which are the bone anchoring elements of these systems. This vertebral fixation modality has been widely used in the treatment of degenerative, tumor, and traumatic diseases and deformities of the spine.\(^1\)

In revision surgeries, the extension of the vertebral fixation can be performed by surgical exposure of the initially operated vertebral segment, removal of the rod, and its replacement with a longer rod. Another technical option is the use of an additional rod connected to the rod of the primary vertebral fixation system. Connecting the rods allows the procedure to be performed with less morbidity, avoiding surgical exposure of the previously fixed vertebral segment.\(^2,3\) The connection is also used for multi-rod constructs, in which additional rods are used to increase biomechanical stability.\(^4\)

The connection of the vertebral fixation system rods can be accomplished with linear or lateral connectors, which must be designed so the biomechanical stability of the vertebral fixation system is maintained. The alignment of the fixation system screws determines the choice of the rod connector modality. Linear connectors have been used when screws are aligned, and lateral connectors when the screws are misaligned and linear connection of the rods is not possible.\(^5,6\)

With the goal of mitigating the risk of adverse events during the use of these systems, technical standard ASTM F2193-18a (Standard Specification and Test Methods for Components Used in the Surgical Fixation of the Spinal Skeletal System), defines a clinically relevant in vitro testing method for verifying the safety of straight rod vertebral fixation system designs. However, there is no testing method described in the world literature that considers the effect of connector use on rod fatigue life in vertebral fixation systems. The objective of the present original experimental study is to evaluate and compare the structural characteristics and fatigue resistance associated with the use of three different modalities of vertebral fixation system rod connectors (linear, lateral with square connector, and lateral with oblique connector). The authors’ hypothesis is that different connector models result in different fatigue performance of connected rod systems.

METHODS

Approval of this study by an institutional review board was not required since the research was not conducted in human or live animals. Sixty-six (66) longitudinal CoCr rods (ASTM F1573) measuring 5.5 mm in diameter and 100 mm in length (Safe System, Víncula, Brazil) and 33 titanium connectors (ASTM F136) were used to form three (3) experimental groups defined by the rod connector modality used, i.e., oblique, square or linear (Figure 1). Each specimen was made up of two rods joined by the respective connector. The oblique connector joins the rods obliquely by means of two locking counter screws. The square connector joins the rods laterally by means of four locking counter screws. The locking counter screws were tightened with a torque wrench and standardized at 12000 N.mm.

For each group, a total of eleven (11) specimens were used. Five (5) specimens were used in quasi-static four-point bending tests to determine the relevant structural characteristics for ensuring system functionality, while six (6) specimens from each group were subjected to fatigue tests. The experimental study was conducted at the Biomechanical Engineering Laboratory at the Universidade Federal de Santa Catarina (LEBm/HU-UFSC).

The authors' hypothesis is that different connector models result in different fatigue performance of connected rod systems.

Mechanical four-point bending test

The parameters used in the tests are described in technical standard ASTM F2193-18a (Standard Specification and Test Methods for Components Used in the Surgical Fixation of the Spinal Skeletal System) for bending testing of straight rods used in spinal fixation systems. The novel change proposed here involved positioning the connection region of the rods at the location of the maximum bending moment (Figure 2) during the loading application phase in the quasi-static four-point bending test.

The device was adjusted so that the distance between two support points (L) was equal to 129 mm and the distance between the two load application points, as well as the distance between the load application point and the closest support, was equal to 43 mm. The support and load application rollers used are made of SAE 1040 steel and are 9.5 mm in diameter with a V-shaped notch at the midpoint of their length to better accommodate the specimen. After a pre-load of 10 N was applied to the specimen, the test was conducted under displacement control at a speed of 10 mm/min, and the Force (N) x Displacement (mm) curve was obtained for each of the specimens tested. The variables measured were (I) force at the yield point (N), (II) bending moment at the yield point (N.mm), (III) displacement at the yield point (mm), (IV) maximum force (N), (V) bending moment at the resistance limit, (VI) displacement at the resistance limit, the bending stiffness of the system. The 0.2% offset method and linear regression of the initial force x displacement curve were used to determine the yield point. The tests were performed using a universal testing machine (DL3000, EMIC, Brazil).

To perform the cyclic fatigue test, loadings of 50.00%, 75.00% and 90.00% of the mean bending moment in the yield were applied to the system with oblique connector, of 75.00%, 85.00% and 95.00% to the square connector group, and of 40.14%, 60.17%...
and 80.27% to the group with the linear connector, calculated from the results of the quasi-static test for each group. A frequency of 5 Hz for 2.5 x 10⁸ cycles was used to test the systems with square and oblique connectors. For the systems with a linear connector, however, a frequency of 6 Hz was applied. Two specimens were used for each loading configuration in each group. The tests were conducted using a servo-hydraulic fatigue testing machine (BME, Brasília, Brazil).

Statistical analysis

For the statistical analysis of the results of the variables measured in the quasi-static four-point bending test, Bartlett’s tests were performed to evaluate the homogeneity of variance and one-way analysis of variance (ANOVA) with Tukey’s test were performed for paired comparisons. In the situation where the condition of homogeneity of variance was not satisfied, the ANOVA test with Welch correction was applied. The level of significance applied was equal to 0.05.

RESULTS

The results obtained in the quasi-static test are described in Table 1 and Figure 3. The linear connector systems presented the greatest force and the greatest moment at the yield limit than the other connection philosophies. The square and oblique connector systems showed no difference in maximum force, and both presented greater maximum force than the linear connector systems. The square connector system presented the greatest moment at the resistance limit, followed by the systems with linear and oblique connectors, respectively. Stiffness was greater in the square connector system, followed by the oblique and linear systems. As regards equivalent bending stiffness, however, the system with the greatest magnitude used the linear connector, followed by the square and oblique connector systems.

All the oblique and square connector system specimens withstand all the moments applied during 2.5 million cycles (Table 2). The linear connector system specimens withstand the bending moment of 6101.00 N.mm (40.14% of the bending moment at the yield limit) during 2.5 million cycles and failed before reaching 2.5 million cycles when subjected to bending moments of 9010.00 N.mm and 12020.00 N.mm (60.14% and 80.27% of the bending moment at the yield limit), respectively.

DISCUSSION

The literature has shown that the risk of rod breakage following surgery to restore the natural curve of the spine increases considerably when connectors are used.6 Connector failure accounts for 12.2% of all spine correction surgery failures and on average occurs after 2 years of implantation.2 However, it has been shown that the loads experienced by rods subject to daily physiological conditions are not sufficient to warrant the failure rate observed.10 Rod fractures can occur due to bending fatigue and the concentration of stress at specific points of the rod. The presence of connectors in rod systems generates stress concentrators in the associated rods.

In the present study, a method was developed to evaluate the effect of different connectors on the fatigue performance of long constructions. In the quasi-static tests, the linear connector system showed the greatest force and greatest moment at the yield limit by a significant margin when compared to the systems with square and oblique connectors. Comparing the last two systems, both force and moment at the yield limit were greater using the square connector system. The square connector also presented the greatest moment at the resistance limit and the greatest stiffness as compared to the other systems. The linear

Table 1. Mean (standard deviation) values resulting from the quasi-static mechanical test.

<table>
<thead>
<tr>
<th></th>
<th>Oblique connector</th>
<th>Square connector</th>
<th>Linear connector</th>
</tr>
</thead>
<tbody>
<tr>
<td>Force at the yield limit (N)</td>
<td>439.25 (11.11)</td>
<td>465.93 (15.96)</td>
<td>544.20 (14.89)</td>
</tr>
<tr>
<td>Moment at the yield limit (N.mm)</td>
<td>9447.23 (238.84)</td>
<td>10250.55 (351.14)</td>
<td>14974.00 (409.80)</td>
</tr>
<tr>
<td>Maximum force (N)</td>
<td>1384.14 (11.28)</td>
<td>1385.24 (6.00)</td>
<td>1092.20 (8.55)</td>
</tr>
<tr>
<td>Moment at the resistance limit (N.mm)</td>
<td>29759.01 (242.46)</td>
<td>30475.28 (132.04)</td>
<td>30036.00 (239.75)</td>
</tr>
<tr>
<td>Stiffness (N/mm²)</td>
<td>8.40 (0.18)</td>
<td>10.73 (0.12)</td>
<td>11.86 (0.51)</td>
</tr>
</tbody>
</table>

Figure 2. Example of the positioning of the specimens for conducting the mechanical tests.

Figure 3. Quasi-static test results. * - P < 0.05, # - P < 0.01.
IN VITRO MECHANICAL EVALUATION OF SPINAL FIXATION ROD CONNECTORS

Table 2. Fatigue test results.

<table>
<thead>
<tr>
<th>Oblique connector</th>
<th>Moment applied (N.mm)</th>
<th>Specimen</th>
<th>Life cycles</th>
</tr>
</thead>
<tbody>
<tr>
<td>Fraction of the moment at yield</td>
<td>50.00%</td>
<td>4723.62</td>
<td>Sp 1, Sp 2</td>
</tr>
<tr>
<td></td>
<td>75.00%</td>
<td>7085.42</td>
<td>Sp 1, Sp 2</td>
</tr>
<tr>
<td></td>
<td>90.00%</td>
<td>8502.51</td>
<td>Sp 1, Sp 2</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Square connector</th>
<th>Moment applied (N.mm)</th>
<th>Specimen</th>
<th>Life cycles</th>
</tr>
</thead>
<tbody>
<tr>
<td>Fraction of the moment at yield</td>
<td>75.00%</td>
<td>7687.91</td>
<td>Sp 1, Sp 2</td>
</tr>
<tr>
<td></td>
<td>85.00%</td>
<td>8712.97</td>
<td>Sp 1, Sp 2</td>
</tr>
<tr>
<td></td>
<td>95.00%</td>
<td>9738.02</td>
<td>Sp 1, Sp 2</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Linear connector</th>
<th>Moment applied (N.mm)</th>
<th>Specimen</th>
<th>Life cycles</th>
</tr>
</thead>
<tbody>
<tr>
<td>Fraction of the moment at yield</td>
<td>40.24%</td>
<td>6010.00</td>
<td>Sp 1, Sp 2</td>
</tr>
<tr>
<td></td>
<td>60.17%</td>
<td>9010.00</td>
<td>Sp 1</td>
</tr>
<tr>
<td></td>
<td>60.17%</td>
<td>9010.00</td>
<td>Sp 2</td>
</tr>
<tr>
<td></td>
<td>80.27%</td>
<td>12020.00</td>
<td>Sp 1</td>
</tr>
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<td></td>
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<td>12020.00</td>
<td>Sp 2</td>
</tr>
</tbody>
</table>

The present study has some limitations. First, the mechanical tests were not conducted in a saline bath at a temperature of 37°C, creating conditions different from in vivo conditions. The use of a pH-controlled liquid bath would add corrosion effects to the analysis, more closely approximating reality. However, for the purpose of comparing the designs of different connectors, the same comparative basis was used (open air test/room temperature), validating the results obtained. In addition, only the bending of the systems was analyzed. Rods are subject to the effects of torsion, which can also impact system fatigue resistance. However, bending is the main loading mode supported by these medical devices.

The study hypothesis, that different connector models imply different fatigue performance in connected rod systems, was confirmed.
CONCLUSION
Rod systems connected by linear connectors support greater bending moments before they suffer permanent deformation than square and oblique connector systems, even though they are less rigid. All the systems have fatigue resistance deemed acceptable for their intended use according to the bending moment applied during a gait cycle.
All authors declare no potential conflict of interest related to this article.

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REFERENCES