Abstract

Because of several failures by dissociation of a redesigned bipolar prosthesis, a new, dynamic test was developed. This dynamic cam-out test represents a closer simulation of one possible clinical mechanism of bipolar disassociation. The results of dynamic testing are affected by the bipolar design, particularly the locking mechanism that was the problem with the redesigned prosthesis.

Disassociation of the inner head from the outer head bearing of bipolar prostheses is rare but necessitates revision. Among the causes of this disassociation is the use of an incorrectly sized inner head, excessive wear of the polyethylene bearing causing its fragmentation, or wear of the locking mechanism by impingement with the neck of the stem. Most testing of bipolar prostheses for disassociation has been similar to that used with constrained cups which involves pullout and lever-out of the inner head from the outer bearing. Recently, a redesigned bipolar prosthesis, designed for increased range of motion, which performed well in these tests, demonstrated several early clinical failures by disassociation. Therefore a new dynamic test for bipolar disassociation was developed.

Materials and Methods

All testing was performed on a multi-axis, servo-hydraulic testing machine (MTS Mini Bionix 858, MTS Corp., Minneapolis, MN). The test machine was configured with an additional inline axial/torsional actuator. The test set-up is shown in Figure 1.

A hip stem with a 22 mm +8 mm offset head was potted in bone cement in a mounting fixture and attached to the loading fixture. The femoral component was potted such that there was a 110 mm distance between the center of the femoral head and the center of the rotation axis when the long axis of the femoral component was perpendicular to the axial actuator. The bipolar component was rigidly attached to the axial/torsional actuator of the test frame with the use of three set screws. The femoral head was then manually seated...
in the bipolar component. The components were manually aligned so that the neck of the femoral component was near impingement with the bipolar component.

The bipolar component was rotated at a rate of 3 revolutions per minute (rpm). An axial compressive load was applied to the construct at a rate of 90 N/min. Loading was continued until separation/disassociation of the femoral head from the bipolar component occurred. Axial load and angle of revolution were recorded. Testing for static cam-out was performed in a similar manner but with the bipolar component fixed and not allowed to rotate.

Results

A comparison of static and dynamic cam-out tests for System I and redesigned bipolar designs is given in Table 1.

Discussion

Dynamic testing showed that the redesigned bipolar system showed a significantly (p < 0.001) lower dynamic cam-out strength than the System I bipolar design. In contrast, there was no difference in the static cam-out strengths. The redesigned bipolar design was based upon the System I design with the polyethylene entrance of the inner bearing widened and redesigned to improve inner bearing range of motion (System 1: 64°; redesigned bipolar: 81°). This alteration allowed the neck of the stem as it rotated to impinge on the locking ring at its split causing the ring to open and displace within its slot, which permitted head disassociation (Fig. 2).

Because rotation of the inner head and outer shell and flexion of the stem would be expected in an activity such as crossing the legs during sitting, the dynamic cam-out test duplicates a motion know to cause dislocation and possibly disassociation.

Conclusion

Although the dynamic cam-out test is more severe than the static test, it represents a closer simulation of one possible mechanism of bipolar disassociation. The results of dynamic testing are affected by the bipolar design, particularly the locking mechanism.

References


Table 1 Comparison of Static and Dynamic Cam-Out Strengths (Average of 5 Tests)

<table>
<thead>
<tr>
<th>Bipolar System</th>
<th>Static Cam-Out (N-m)</th>
<th>Dynamic Cam-Out (N)</th>
</tr>
</thead>
<tbody>
<tr>
<td>System I</td>
<td>27 ± 3</td>
<td>203 ± 31</td>
</tr>
<tr>
<td>Redesigned bipolar</td>
<td>24 ± 2</td>
<td>52 ± 1</td>
</tr>
</tbody>
</table>

Figure 2 Mechanism of head disassociation in the redesigned prosthesis. Cross section of bipolar head shows impingement of the neck of the prosthesis stem on the retaining ring.