Bipolar Head Design
Inner Bearing Range of Motion and Disassociation

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Abstract
To address the clinical problems of joint stiffness, acetabular pain, and component wear, recent bipolar heads have been designed to achieve increased inner bearing range of motion. We tested four designs to determine if this compromises component integrity. Inner bearing ranges of motion were determined and the components then mechanically tested to determine inner bearing pull-out disassociation strengths as well as static and dynamic impingement forces for disassociation. Inner bearing ranges of motion with a 22 mm head were between 65° to 84° for the four prostheses. Pull-out forces for disassociation ranged between 700 N to 1475 N; static impingement forces were 20 Nm to 49 Nm and dynamic impingement forces were 5 Nm to 24 Nm. There was no relation between bipolar head inner bearing range of motion and the potential for component disassociation; however, one design modification produced a lowered disassociation strength. Design modifications must be evaluated by a variety of test methods to adequately determine their effects on bipolar head integrity.

Bipolar prostheses were originally designed to give an increased range of motion (ROM) and a decreased risk of dislocation compared to unipolar prostheses. In contrast to unipolar prostheses, bipolar designs incorporate two bearing surfaces. The outer metal bearing head articulates with the cartilage of the acetabulum. This head contains an insert of a constrained metal on polyethylene inner bearing component so that a portion of the total ROM occurs at this internal bearing in order to minimize acetabular wear and medial translation (protrusio). Motion occurs at the inner bearing until the stem impinges on the polyethylene and then motion at the outer shell occurs. The inner head is locked into the polyethylene insert. Locking systems are based on elastic deformation of polyethylene, commonly using an internal split ring or multiple tabs. These can be preassembled by the manufacturer or assembled, and in some cases disassembled, by the surgeon. In general the preassembled bipolar prostheses are the strongest but the latter offer greater flexibility for intraoperative sizing and possible revision. In some designs the insert can be locked into the outer shell by the surgeon.

Theoretically, bipolar prostheses should have the same or greater ROM as endoprostheses, although clinical results have demonstrated loss of outer bearing motion in some patients.1-2 Reasons for the loss of outer bearing ROM include: surgeon over-sizing of the outer head, acetabular geometry, acetabular condition (quality and thickness of cartilage), use of acetabular reaming, underlying disease (fracture, rheumatoid arthritis, or osteoarthritis) and osteophyte formation. Another possible factor is deformation of the acetabulum with load thereby entrapping the outer head.

Other clinical problems observed with bipolar hip prostheses include inner bearing wear and bearing disassociation.3-11 Other than the obvious reasons of incomplete component assembly or the use of improper inner head sizes (mixing components of several companies), impingement on or wear of the locking mechanism are thought to be the causes of disassembly. Most previous testing of component disassembly has followed FDA guidelines for constrained prostheses and involves pull-out and lever-out testing.12,13

These findings and unequivocal outcome studies equating bipolars with lower cost endoprostheses have led to the decreased use of bipolar prostheses in the United States.14,15 Newer bipolar designs have attempted to address some of
the problems observed with prior designs by the use of improved polyethylenes, better locking mechanisms, and increased inner bearing ROM.

The following experiments were performed to determine if there is a trade-off between inner bearing ROM and disassociation strengths for newer bipolar designs.

Materials and Methods

The following bipolar heads were obtained: UHR, Redesigned bipolar for the Asian market (UHRA), Centrax (all from Stryker Orthopedics, Mahwah, NJ), and Multipolar (Zimmer, Warsaw, IN). All had an outer diameter of 44-45 mm and accommodated an insert for 22 mm prosthesis heads. These had a variety of locking mechanisms ranging from a simple split ring (Fig. 1) to a complex multi-piece split rings and tabs (Fig. 2). All could be disassembled with an appropriate unlocking tool. Also obtained were corresponding femoral stems with a variety of 22 mm (skirted and unskirted) and 26 mm modular heads.

The inner surfaces of the polyethylene inserts and the outer surfaces of the neck region of the stems and heads were digitized with a Coordinate Measuring Machine (Mitutoyo FJ805, Kawasaki, Japan) that held the part on a mechanically translated “x-y” table and measured “z” with a coordinate accuracy of 0.005 mm. The digital data files (x, y, and z coordinates) were entered into a Pro/Engineering 2001 CAD software program (Parametric Technologies Corp., Needham, MA). This enabled detailed cross-sectional models of the surfaces of each bipolar head and associated proximal stem and inner head to be created with a resolution of 0.025 mm and manipulated by the computer. The stem with attached head was moved in an arc along one diameter of the bipolar head until it impinged on the inner bearing and the angle the stem transversed was determined. The outer shell was rotated 90° and the angle of stem transverse along an orthogonal diameter was determined. These two angles were averaged to give the range of motion of the inner bearing.

For the disassociation tests, three types of tests were run: static pull-out (axial distraction) and static cam-out, and a dynamic cam-out (Fig. 3).

All testing was performed on a multi-axis, servo-hydraulic testing machine (MTS Mini Bionix 858, MTS Corp., Minneapolis, MN). The MTS was configured with an additional torsional actuator for dynamic cam-out tests. For all tests, the outer, metal bipolar shell was fixed with epoxy in a holder. For axial distraction (pull-out), the bipolar component was held horizontally and the inner head vertically distracted at a rate of 10 cm/min until the head separated from the inner bearing. For the static cam-out tests, the outer shell was fixed with epoxy in a holder.
similarly fixed and the stem loaded at a fixed point (10 cm from the head center) at a rate of 90 N/min until the head disengaged. For the dynamic cam-out, the outer shell was fixed to the torsional actuator and rotated at three revolutions per minute; load was applied in a similar manner to the static cam-out test until disassociation occurred. For all tests, failure was defined as an abrupt change in the load-displacement curves.

A minimum of five tests were run for each prosthesis and testing modality.

Results

Inner bearing ROM with 22 mm inner heads ranged from 65° to 84° for the four prostheses (Table 1). Use of a skirted head decreased the ROM 20-35%; the 26 mm heads showed a slight increase in ROM compared to the 22 mm heads. Although ROM depends on the inner geometry of the polyethylene insert, it also depends on stem geometry. The Stryker stems were circular in cross-section and 10 mm in diameter where they contacted the insert; the Zimmer stem is rectangular in cross-section with dimensions of 8.7 mm and 11 mm where it contacted the insert.

As seen in Table 2, pull-out forces ranged between 700 to 1475 N, static cam-out torques from 20 to 49 Nm, and dynamic cam-out torques from 5 to 24 Nm. Dynamic cam-out tests of a Centrax bipolar with a 26 mm inner head showed over twice the strength of a 22 mm head.

Discussion

The obvious method to increase ROM of the inner bipolar bearing is to shorten the height or widen the diameter of the opening of the polyethylene rim. This reduces the space available for the locking mechanism and can result in the neck impinging on the more exposed locking mechanism which can increase polyethylene stresses or wear in this critical area. Although an increased inner head size increases inner bearing ROM and disassociation strength, it decreases polyethylene thickness in the insert that could lead to increased polyethylene wear due to increased surface stresses.

The UHRA bipolar design was modified from the UHR design by having the polyethylene entrance of the inner opening widened and the angle of the polyethylene rim decreased to improve inner bearing range of motion. This change 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. This finding shows that dynamic testing for disassociation can be of benefit in assessing design changes.

These tests are only short term and do not deal with wear that could occur and compromise bearing integrity. We did not test the mechanical strength of the skirted heads that have a different profile and expected different contact with the inner bearing surface than the stems. Although components were reused for mechanical testing, this did not appear to effect results.

Conclusion

Although several recent bipolar designs have attempted to increase inner bearing ROM, normal activities of daily living can be accomplished with a far lower ROM. Furthermore, the total ROM of the bipolar head is not affected by the amount of inner bearing motion. Design modification to increase inner bearing ROM must be evaluated by a variety of static and dynamic test methods to adequately determine its effect on the resistance of bipolar heads to disassociate. Designs that increase inner bearing motion at the expense of component stability are ill-advised.

References


Table 1 Inner Bearing Ranges of Motion in Degrees for the Four Bipolar Inner Bearings

<table>
<thead>
<tr>
<th>Bipolar System</th>
<th>22 mm Head</th>
<th>22 mm Skirted</th>
<th>26 mm Head</th>
</tr>
</thead>
<tbody>
<tr>
<td>UHR</td>
<td>65</td>
<td>40</td>
<td>68</td>
</tr>
<tr>
<td>UHRA</td>
<td>82</td>
<td>52</td>
<td>84</td>
</tr>
<tr>
<td>Centrax</td>
<td>84</td>
<td>70</td>
<td>85</td>
</tr>
<tr>
<td>Multipolar</td>
<td>70</td>
<td>55</td>
<td>NT</td>
</tr>
</tbody>
</table>

Table 2 Comparison of Pull-Out, Static, and Dynamic Cam-Out Strengths for 22 mm Inner Heads (SD)

<table>
<thead>
<tr>
<th>Bipolar System</th>
<th>Pull-Out N</th>
<th>Static Cam-Out Nm</th>
<th>Dynamic Cam-Out Nm</th>
</tr>
</thead>
<tbody>
<tr>
<td>UHR</td>
<td>900 (80)</td>
<td>27 (3)</td>
<td>20 (3)</td>
</tr>
<tr>
<td>UHRA</td>
<td>1100 (110)</td>
<td>24 (2)</td>
<td>5 (1)</td>
</tr>
<tr>
<td>Centrax</td>
<td>700 (125)</td>
<td>20 (3)</td>
<td>11 (3)</td>
</tr>
<tr>
<td>Multipolar</td>
<td>1475 (50)</td>
<td>49 (2)</td>
<td>24 (2)</td>
</tr>
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