Fixation of Ultrahigh-molecular-weight Polyethylene Liners to Metal-backed Acetabular Cups

Victor G. Williams II, BS, Leo A. Whiteside, MD, Stephen E. White, MS, and Daniel S. McCarthy

Abstract: Locking mechanisms and metal-liner interface surfaces of six modular acetabular systems were evaluated to determine their effect on micromotion and backside wear of the polyethylene liner. Rotational and axial motion between the metal shell and polyethylene liner was measured in the Duraloc (DePuy, Warsaw, IN), Harris–Galante (Zimmer, Warsaw, IN), Impact (Biomet, Warsaw, IN), Lip Loc (Biomet), Precision Osteoloc (Howmedica, Rutherford, NJ), and Reflection (Smith & Nephew Orthopaedics, Memphis, TN) designs at the start of each test, and at 1 million, 5 million, and 10 million cycles. At 10 million cycles, the Lip Loc and Reflection cups had significantly lower rim micromotion than the Duraloc and Harris–Galante cups (F < .0010). The Impact, Precision Osteoloc, and Reflection cups had significantly lower rim subsidence than the Harris–Galante cup (F < .0025). The Harris–Galante cup had significantly greater rotational micromotion than the Lip Loc cup (F < .0074), and had significantly greater interface slippage than the Impact and Reflection cups (F < .0070). The Lip Loc produced significantly lower dome micromotion than the Harris–Galante (F < .0300). The Lip Loc and Reflection cups had significantly less backside wear than the Duraloc and Harris–Galante cups (P < .0001), the Impact cup (P < .0243), and the Precision Osteoloc (P < .0027) cup.

Key words: total hip arthroplasty, implant design, acetabulum, wear, polyethylene.

Modular acetabular components with a metal shell were developed in the 1970s to limit the deformation of all-polyethylene components that appeared to cause aseptic loosening of cemented devices [1]. Crowninshield et al. reported that the metal shell provided a more uniform stress distribution in the bone–cement [2]; however, a number of reports link polymeric and metal debris with osteolysis in total hip arthroplasty (THA) [1,3–6]. Wear of the polyethylene cup liner in the metal-backed acetabular cup has been shown to stimulate osteolysis [1,3–5], and, in some cases, to cause failure of the hip prosthesis. Recent reports suggest that outer wear on the surface of the polyethylene liner results from micromotion of the liner with the metal shell [7,8].

Most acetabular metal shells depend on their locking mechanism to limit motion between the liner and the metal shell [8]. This study evaluated fixation of the polyethylene liner in the metal shell of six total hip systems and analyzed the effect of the locking mechanism and inner surface finish of the metal shell on the generation of backside wear of the polyethylene liner. We hypothesized that acetabular systems with peripheral locking tabs and a polished metal surface would produce the least amount of wear at the interface between the polyethylene liner and the metal shell.
Materials and Methods

Rotational and axial motion between the metal shell and the polyethylene liner was measured in the Duraloc (DePuy, Warsaw, IN), Harris–Galante (Zimmer, Warsaw, IN), Impact (Biomet, Warsaw, IN), Lip Loc (Biomet), Precision Osteoloc (Howmedica, Rutherford, NJ), and Reflection (Smith & Nephew Orthopaedics, Memphis, TN). Each acetabular component has a unique locking mechanism that is self-engaging on loading. The Duraloc uses the sensor ring, a spring mechanism that locks the metal shell into a recessed groove in the polyethylene liner (Fig. 1). The Harris–Galante polyethylene liner is press-fit into five locking tabs that groove the polyethylene as it is inserted. The Impact component secures the polyethylene liner with a hemispherical metal ring and three locking tabs. The polyethylene is press-fit around the tabs, and the locking ring prevents the cup from backing out. The Lip Loc component secures the polyethylene with a recessed lip and three locking tabs. The polyethylene liner of the Precision Osteoloc has 12 peripheral tabs, an inferior recessed groove, and a circumferential ring with 12 miniature tabs. The 12 peripheral tabs rest on a circumferential rim in the metal shell, which is the upper ledge of a recessed ring that secures the 12 miniature tabs. The Reflection has tapered dovetail locking tabs that snap into the slots of the cup. A ridge sits on a circumferential ring that supports the tabs of the polyethylene. The inner surface of the Reflection cup is polished (Fig. 2).

Three components for each design were tested. Each acetabular component was mounted in a servohydraulic testing device (model 8501, Instron, Canton, MA) with a 25° tilt in the inferior–superior direction to simulate in vivo placement (Fig. 3). Axial and torsional loads were applied to the polyethylene liner through a 28-mm femoral head glued to the polyethylene liner. Compressive axial loads from 272 to 2720 N and internal–external torsional loads from ± 7.5 N-m were applied using a sinusoidal waveform at 10
Hz for 10 million cycles. This load was chosen to apply torsional load of approximately twice that occurring during normal activity [9] to evaluate the safety factor built into the locking mechanism. Three linearly variable differential transducers (LBB-375-PA-060, Schaevitz, Pennsauken, NJ) were used to detect motion between the polyethylene liner and the metal backing. One linearly variable differential transducer mounted parallel to the rim measured rotational micromotion and interface slippage at the rim, one mounted perpendicular to the rim measured rim micromotion and rim subsidence, and one mounted perpendicular to the dome of the metal shell measured dome micromotion and dome subsidence. Micromotion was defined as the recoverable motion between cycles. Subsidence was defined as the nonrecoverable sinking displacement of the polyethylene into the shell, and interface slippage was defined as the nonrecoverable rotational displacement between the polyethylene liner and the metal shell. Micromotion, subsidence, and interface slippage were measured and recorded at the start of each test and at 1 million, 5 million, and 10 million cycles. The data obtained at 10 million cycles were compared statistically. The square root of the motion was used to obtain a normal distribution of the data to satisfy model assumptions. Statistically significant differences in the square roots of scores among the groups was determined using the F statistic associated with analysis of variance. Scheffé post hoc tests (P < .05) were used to measure the level of significance between pairs. Goodness-of-fit of the analysis of variance model was checked by careful examination of the residuals.

One of the three components for each design was sputter-coated with gold-palladium before testing. These components were examined with a Wild Leitz photomacroscope at magnifications varying from 6.3× to 32× (model M420, Wild Leitz, Heerbrugg, Switzerland.) Wear on the backside of the polyethylene liner was measured at a magnification of 16× with a previously published scoring system that evaluated burnishing, scratching, abrasion, cold flow, pitting, and delamination [9]. The polyethylene liners were placed under a grid that divided the liner into eight equal sectors. Each sector was assigned a score (0–6) based on the severity of burnishing, scratching, abrasion, cold flow, pitting, and delamination (Table 1).

<table>
<thead>
<tr>
<th>Score</th>
<th>Type of Wear</th>
</tr>
</thead>
<tbody>
<tr>
<td>0</td>
<td>No evidence of wear</td>
</tr>
<tr>
<td>1</td>
<td>Burnishing covered &lt; 10% of a sector</td>
</tr>
<tr>
<td>2</td>
<td>Burnishing covered &lt; 25% of a sector</td>
</tr>
<tr>
<td>3</td>
<td>Burnishing covered 25–50% of a sector</td>
</tr>
<tr>
<td>4</td>
<td>Burnishing covered &gt; 50% of a sector</td>
</tr>
<tr>
<td>5</td>
<td>Cold flow, abrasion, scratching</td>
</tr>
<tr>
<td>6</td>
<td>Cold flow, abrasion, scratching</td>
</tr>
</tbody>
</table>

Rim micromotion between the polyethylene liner and metal shell decreased as the number of cycles increased for each cup (Table 2). A significant difference appeared among the designs when motion at the rim was analyzed for all six designs (F < .0010). At 10 million cycles, the Duraloc cup produced significantly greater rim micromotion than the Lip Loc cup with a square root mean difference of 5.3 μm (confidence limits [CL], 1.0–9.50 μm) and the Reflection cup with a square root mean difference of 5.0 μm (CL, 0.8–9.3 μm). The Harris–Galante cup produced significantly greater rim micromotion than the Lip Loc and Reflection cups. Micromotion values at 10 million cycles are listed in Table 2.

Rim subsidence increased as the number of cycles increased for each acetabular cup. A statistically significant difference occurred among the designs when motion at the rim was analyzed (F < .0025). At 10 million cycles, the Harris–Galante had significantly greater subsidence than the Impact, Precision Osteoloc, and Reflection cups. Subsidence values at 10 million cycles are listed in Table 2.

Rotational micromotion decreased as the cycles increased for every cup (Table 2). A significant difference occurred among the designs when the amount of rotational micromotion was analyzed (F < .0074). The Harris–Galante cup produced significantly greater micromotion throughout the test than did the Lip Loc cup. The rotational micromotion values at 10 million cycles are listed in Table 2.

Interface slippage did not change significantly as the number of cycles increased for each cup. Those
with low initial slippage tended to maintain good fixation throughout the test, and those with high early slippage continued to slip throughout the test (Table 2). A significant difference occurred among the designs when the amount of interface slippage was analyzed ($F < .0070$). At 10 million cycles, the Harris-Galante and Duraloc cups had the greatest interface slippage. After 10 million cycles, the Harris-Galante produced significantly greater interface slippage than did the Impact and Reflection cups.

Dome pistoning micromotion and subsidence decreased as the number of cycles increased in some implants and remained unchanged in others (Table 2). A significant difference occurred among the designs when motion at the dome was analyzed ($F < .0314$). The Harris-Galante produced significantly greater dome pistoning micromotion than did the Lip Loc cup. No significant differences occurred among the six designs for dome subsidence after 10 million cycles ($F < .2000$).

Macroscopic evaluation of the liners showed significant wear on both the Duraloc and Harris-Galante cups (Figs. 4, 5). The Duraloc and Harris–Galante polyethylene liners had evidence of cold flow, scratching, and abrasion of polyethylene in the dome region (Fig. 4). Metal debris was embedded in 40% of one of the Duraloc polyethylene liners and there was evidence of severe delamination (Fig. 5). The differences in backside wear among the four components with a rigid peripheral locking mechanism were minimal, and consisted of flattening of machine marks around the edges of the screw holes. No abrasion or cold flow was seen on any of the polyethylene components that had rigid peripheral locking mechanisms (Fig. 6).

The mean wear scores at 10 million cycles were $3.0 \pm 0.125$ for the Duraloc, $3.6 \pm 0.4$ for the Harris–Galante, $1.0 \pm 0.07$ for the Precision Osteoloc, $0.8 \pm 0.2$ for the Impact, $0.125 \pm 0.125$ for the Reflection, and $0.083 \pm 0.144$ for the Lip Loc. The Lip Loc, Reflection, Impact, and Precision Osteoloc cups produced significantly lower wear scores than did the Duraloc ($P < .0001$) and the Harris-Galante ($P < .0001$) cups. The Lip Loc produced significantly lower wear scores than did the Impact ($P < .0163$) and Precision Osteoloc ($P < .0019$) cups. The Reflection produced significantly lower wear scores than did the Impact ($P < .0243$) and Precision Osteoloc ($P < .0027$) cups (Fig. 7).
Fig. 4. Gold-palladium-coated specimen of the Harris-Galante polyethylene liner after 10 million cycles. Severe abrasion surrounds the screw holes and extends across most of the surface of the component. Gouged-out defects mark the position of the peripheral tabs.

Discussion

Osteolytic destruction of bone is a major complication of both cemented and cementless hip arthroplasty [10]. Particulate wear debris, primarily from ultrahigh-molecular-weight polyethylene, induces osteolysis via inflammatory mediators [1,3,4-7]. Recent reports suggest that backside wear of the polyethylene liner may be a significant source of polyethylene wear debris. Zhu et al. reported that micromotion between the liner and the shell is caused mostly by rotational forces [8]. To ensure that a reasonable safety margin was tested, a value for torsional load approximately twice physiologic load [11] was chosen for this study. The locking mechanism is the feature of the modular acetabular component that controls the motion between the polyethylene liner and the metal shell. The results of this study demonstrate that rigid peripheral capture of the polyethylene liner could effectively control micromotion and minimize wear.

The cups that did not employ a tight peripheral snap-fit mechanism to lock the polyethylene liner directly to the metal shell provided minimal rotational stability. The ring on the Duraloc shell initially secured the liner in place, but lacked a mechanism to limit rotational motion. This inability to resist rotational motion generated polyethylene debris at the locking springs. The flexible tab locking mechanism on the Harris–Galante cup did not adequately resist rotational forces and, therefore, allowed a large amount of rotational micromotion. Seating of the polyethylene liner in the metal shell produced large polyethylene slivers as the fingers grooved the polyethylene. Peripheral capture mechanisms that locked the polyethylene liner directly to the metal shell effectively limited rotational motion. The Impact, Precision Osteoloc, and Reflection implants have oversized tabs on the metal shell and slightly undersized slots in the polyethylene liners that facilitate tight fit at the tab interface.

Most studies that have examined liner conformity have reported gaps between the liner and the metal shell [7,12]. The ability of the polyethylene liners to conform with the shell depends on several mechanisms. Both Fehring et al. and Huk et al. found that some implants require load to create contact area between the liner and the shell, while others depend on cold flow to conform the liner to the shell [7,12]. Conformity of the polyethylene liner to the metal-backed shell can also determine the amount of motion that is seen at the interface of the two surfaces. Zhu et al. reported that poor conformity between the polyethylene liner and the metal shell can cause excessive micromotion at the

Fig. 5. Mating surfaces of a Duraloc acetabular component. Metal debris particles are embedded in most of the superior region of the polyethylene liner. The metal surfaces are also worn.

Fig. 6. Gold-palladium-coated specimen of the Lip Loc polyethylene component after 10 million cycles. No signs of abrasion are present. The machining marks are flattened around the periphery of the screw holes.
interface of surfaces [8]. During the 1-million-cycle test performed in this study, however, progressively increasing conformity did not improve fixation, although it did result in cold flow of the polyethylene into the screw holes.

Backside wear of a polyethylene liner seems to be directly related to motion between the shell and liner. The more axial and rotational motion that occurred between the liner and the shell, the more cold flow, abrasion, pitting, and scratching of the backside surface were apparent. Cups that had significant rim and rotational micromotion such as the Duraloc and Harris-Galante cups had the most backside wear and the highest wear scores in the group. The Impact, Precision Osteoloc, and Reflection cups had the least backside wear and micromotion.

Bobyn et al. reported that a smoother finish diminishes polyethylene debris from liner shell motion [13]. The Duraloc and Harris-Galante cups did not have a highly polished inner surface, and this probably contributed to the severe wear on the outer surface of the polyethylene liners seen in this study. The implant with a polished inner metal shell did not have significantly less wear than that of the other implants with rigid peripheral locking mechanisms, so it is likely that the most important feature to prevent backside wear is the locking mechanism and not the surface finish of the metal shell. As there was no difference in wear scores among implants that had effective locking of the polyethylene, it is not likely that minor polishing of the inner surface will produce significant wear reduction over that achieved by rigid capture of the liner.

Recent reports of severe wear of the outer surface of the polyethylene liner support the findings of this study [7,14]. It is clear that ineffective locking of the polyethylene liner in the metal shell can cause osteolysis and early failure of the implant [7,14]. Acetabular components with sound peripheral locking mechanisms between the metal and polyethylene, and snug fit of the liner in the shell, are likely to have superior clinical performance.

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References