Clinical Performance of a Durasul Highly Cross-Linked Polyethylene Acetabular Liner for Total Hip Arthroplasty at Five Years

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**Supplementary material**

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Clinical Performance of a Durasul Highly Cross-Linked Polyethylene Acetabular Liner for Total Hip Arthroplasty at Five Years

By Lawrence D. Dorr, MD, Zhinian Wan, MD, Cambize Shahrdar, MD, Leighellen Sirianni, OPA-C, Myriam Boutary, BS, and Andrew Yun, MD

Background: Highly cross-linked polyethylene is currently the most common articulation surface used for total hip arthroplasty. The hypothesis of the present study was that the Durasul highly cross-linked polyethylene acetabular liner would have less wear at five years than would a conventional polyethylene liner used in association with the same total hip replacement system.

Methods: Forty-three consecutive patients (fifty hips) underwent total hip replacement with an uncemented titanium porous-coated metal cup and a Durasul liner that was mated with a 28-mm cobalt-chromium femoral head. Thirty-one patients (thirty-seven hips) were followed for at least five years. Thirty-five other patients (thirty-seven hips) underwent total hip arthroplasty with the same system but with a conventional polyethylene liner, and these patients also were followed for five years. Clinical assessment was performed with use of the Harris hip score and a patient self-assessment examination. Radiographic analysis included measurements of acetabular component position, fixation, and osteolysis. Femoral head penetration of the Durasul liners was compared with that of the conventional liners.

Results: The clinical results as determined on the basis of Harris hip scores and patient self-assessment examinations did not differ between the Durasul group and the control group. The mean bedding-in penetration was 0.054 ± 0.07 mm for the Durasul group and 0.059 ± 0.154 mm for the control group. The subsequent penetration, with elimination of the bedding-in wear, resulted in a linear wear rate of 0.029 ± 0.02 mm per year for the Durasul group, compared with 0.065 ± 0.03 mm per year for the control group (p < 0.005). The annual penetration at one and five years was 0.074 mm and 0.011 mm, respectively, for the Durasul group, compared with 0.151 mm and 0.04 mm, respectively, for the control group.

Conclusions: While the qualitative wear pattern of the highly cross-linked polyethylene liner was the same as that of the conventional polyethylene liner, the annual linear wear rate was 45% of that seen with the conventional polyethylene liner. Therefore, we believe that these early data support the continued use of this highly cross-linked polyethylene liner for total hip arthroplasty.

Level of Evidence: Therapeutic Level III. See Instructions to Authors for a complete description of levels of evidence.
ventional polyethylene liner used with the same total hip arthroplasty system. The patterns of wear associated with this polyethylene were also compared, both qualitatively and quantitatively, with the established patterns associated with conventional polyethylene.

**Materials and Methods**

The United States Food and Drug Administration approved the use of the Durasul highly cross-linked polyethylene liner (Zimmer, Warsaw, Indiana) in February 1999, and forty-three consecutive patients (fifty hips) underwent total hip replacement with use of this insert between March and May 1999. Data were collected prospectively at the time of scheduled patient visits for clinical and radiographic follow-up. The collection of data for publication was approved by our institutional review board, and patients gave informed consent to participate in the study. Twelve patients (thirteen hips) were eliminated from the study: four patients (four hips) died for reasons that were unrelated to the hip surgery, four patients (four hips) were lost after less than one year of follow-up, and four patients (five hips) had revision of the cup in the first two years because of the recall of the InterOp acetabular shell (Sulzer, Austin, Texas). Thus, the study group comprised thirty-one patients with thirty-seven hips (including fourteen men [seventeen hips] and seventeen women [twenty hips]). Demographic data for these patients are presented in Table I. The diagnosis was osteoarthritis for twenty-nine hips, osteonecrosis for six, and developmental dysplasia for two. Activity was categorized as unlimited activity, active community ambulation (the ability to walk six to eight blocks), limited community ambulation (the ability to walk two to three blocks), household ambulation (the ability to walk in the home and yard), or wheelchair-bound.

Thirty-five patients (thirty-seven hips) who had been managed with the same cup and stem, but with a conventional polyethylene liner, constituted the control group. These patients were drawn from a pool of seventy-nine patients (one left hip and at the eight o’clock position in right hips. The Durasul liner was machined from ram-extruded bars of GUR1050 polyethylene. The polyethylene was preheated to 125°C in air and then was treated with electron-beam irradiation (9.5 Mrad). The preforms were then melted and annealed over two hours to quench remaining free radicals. After machining, the components were sterilized in ethylene oxide for packaging. The conventional polyethylene liners (Sulene; Zimmer) were manufactured from 1020 resin (stearate-free) and were packaged in an oxygenless environment. The acetabular metal shell in all hips was the InterOp cup, which was a 3.5-mm-thick, walled, titanium-alloy shell with a sintered titanium cancellous structured porous coating.

The clinical outcomes for all patients were followed prospectively. The Harris hip score was recorded preoperatively, at six months and one year postoperatively, and at the time of the most recent follow-up. Specific scores for pain and limp were determined with use of this scoring system. A patient self-assessment examination (Orthographics, Salt Lake City, Utah) was used to determine the activity level of each patient.

### Table I: Demographic Data

<table>
<thead>
<tr>
<th>Polyethylene</th>
<th>Age (yr)</th>
<th>Weight (kg)</th>
<th>Male:Female Ratio (no. of hips)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Durasul (n = 37)</td>
<td>60.2 ± 16.2</td>
<td>82.5 ± 17.7</td>
<td>17:20</td>
</tr>
<tr>
<td>Conventional (n = 37)</td>
<td>65.1 ± 10.8</td>
<td>78.5 ± 12.7</td>
<td>17:20</td>
</tr>
<tr>
<td>P value</td>
<td>0.136</td>
<td>0.277</td>
<td>0.816</td>
</tr>
</tbody>
</table>

### Table II: Annual Number of Hip Radiographs

<table>
<thead>
<tr>
<th>Year</th>
<th>Durasul (no. of hips)</th>
<th>Conventional (no. of hips)</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>28</td>
<td>22</td>
</tr>
<tr>
<td>2</td>
<td>22</td>
<td>20</td>
</tr>
<tr>
<td>3</td>
<td>29</td>
<td>27</td>
</tr>
<tr>
<td>4</td>
<td>14</td>
<td>24</td>
</tr>
<tr>
<td>5</td>
<td>23</td>
<td>17</td>
</tr>
</tbody>
</table>
and to grade the result of the operation (excellent, good, fair, or poor).

A supine anteroposterior hip and pelvic radiograph and a Lauenstein lateral radiograph were made postoperatively at six weeks, three months, one year, and at each annual follow-up visit that the patient attended. All radiographs were made by the same two technicians throughout the study period. Acetabular abduction and version were measured with previously described methods. Two-dimensional femoral head penetration was manually measured with use of the method described by two of us (L.D.D. and Z.W.), which has been found to have an intraobserver error of 0.1 mm for two measurements (unpublished data). This method was validated as being more accurate for the evaluation of clinical radiographs than computerized methods are, at least for total wear of <1 mm, by both Barrack et al. and Ebramzadeh et al.

We attempted to measure penetration on the radiographs of hips with Durasul liners after five years of follow-up with use of the Martell computer method. One-hundred and twelve follow-up radiographs from thirty-six hips were measured with the computer method, with eighteen of these hips having five years of follow-up. The radiographs of five hips could not be measured at five years because they had been mailed from out of town and were not adequate for computer measurements. Unfortunately, these thirty-six hips had such a small amount of wear that, on the basis of computer measurements, forty-nine (43.8%) of the 112 radiographs demonstrated a negative vector of wear (with the vector of wear pointing away from the cup surface) and sixty-three (56.3%) demonstrated a positive vector of wear. Likewise, among the eighteen hips with five years of follow-up, eight (44%) had negative wear and ten (56%) had positive wear. Negative wear is a measurement error associated with the computer technique that is caused by the distortion of the circular femoral head and blurring of the edges of the femoral head and the acetabular cup that occurs on clinical radiographs. Therefore, the true centers of the femoral head and acetabular shell are not correctly located and a measurement error occurs. The error is greater in association with smaller amounts of wear. The number of negative measurements in

![Table III Annual Linear Wear Rate According to the Method of Sychterz et al.](image)

<table>
<thead>
<tr>
<th>Year</th>
<th>Durasul (mm/yr)</th>
<th>Conventional (mm/yr)</th>
<th>P Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>0.02 ± 0.01</td>
<td>0.091 ± 0.08</td>
<td>&lt;0.005</td>
</tr>
<tr>
<td>2</td>
<td>0.05 ± 0.042</td>
<td>0.083 ± 0.045</td>
<td>0.001</td>
</tr>
<tr>
<td>3</td>
<td>0.035 ± 0.029</td>
<td>0.059 ± 0.034</td>
<td>0.004</td>
</tr>
<tr>
<td>4</td>
<td>0.031 ± 0.021</td>
<td>0.062 ± 0.032</td>
<td>0.003</td>
</tr>
<tr>
<td>5</td>
<td>0.025 ± 0.01</td>
<td>0.053 ± 0.023</td>
<td>0.002</td>
</tr>
<tr>
<td>Mean</td>
<td>0.029 ± 0.02</td>
<td>0.065 ± 0.026</td>
<td>0.005</td>
</tr>
</tbody>
</table>

*The values are given as the mean and the standard deviation.
TABLE IV Mean Total Penetration

<table>
<thead>
<tr>
<th>Year</th>
<th>Mean Total Penetration* (mm)</th>
<th>Durasul</th>
<th>Conventional</th>
<th>P Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Bedding-in period</td>
<td>0.054 ± 0.07 (0-0.29)</td>
<td>0.059 ± 0.154 (0.02-0.41)</td>
<td>0.51</td>
<td></td>
</tr>
<tr>
<td>1†</td>
<td>0.074 ± 0.07 (0.027)</td>
<td>0.151 ± 0.167 (0.01-0.67)</td>
<td>&lt;0.005</td>
<td></td>
</tr>
<tr>
<td>2</td>
<td>0.150 ± 0.09 (0.351)</td>
<td>0.191 ± 0.098 (0.04-0.40)</td>
<td>0.465</td>
<td></td>
</tr>
<tr>
<td>3</td>
<td>0.161 ± 0.125 (0.01-0.625)</td>
<td>0.23 ± 0.153 (0.02-0.73)</td>
<td>0.016</td>
<td></td>
</tr>
<tr>
<td>4</td>
<td>0.181 ± 0.082 (0.04-0.635)</td>
<td>0.28 ± 0.166 (0.05-0.87)</td>
<td>0.003</td>
<td></td>
</tr>
<tr>
<td>5</td>
<td>0.192 ± 0.085 (0.06-0.473)</td>
<td>0.32 ± 0.187 (0.02-0.91)</td>
<td>&lt;0.005</td>
<td></td>
</tr>
</tbody>
</table>

*The values are given as the mean and the standard deviation, with the range in parentheses. †Year 1 total penetration includes bedding-in penetration.

these hips detracts from the evaluation of the true wear.

The initial bedding-in penetration of the femoral head was measured on the six-week to three-month radiographs. Sychterz et al.12 calculated subsequent penetration of the femoral head by subtracting the bedding-in penetration from the total penetration. The annual linear wear rates for the Durasul liners and the comparative data for conventional polyethylene liners are reported with use of the method described by Sychterz et al.12.

Total penetration included the bedding-in value. The total penetration can be expressed for each individual year, and we have newly defined this measurement as “annual penetration.” This pattern of penetration defines the time of running-in creep13-15 and the steady state of annual penetration by each year. It differs from the annual linear wear rate because the annual linear wear rate reflects the mean of several years whereas “annual penetration” describes the amount of penetration for an individual year. The annual penetration was expressed as a mean value for all of the patients in the study who returned to the clinic in that year, and therefore the standard deviation could not be calculated. The standard deviation could have been calculated if each patient returned each year so that the penetration on the radiographs of individual patients could be tracked.

Radiographs were evaluated with regard to fixation and osteolysis on pelvic and iliac oblique views of the acetabulum according to established methods6,16-18. All measurements were made by a single research physician (Z.W.). Statistical analysis was performed for all data with use of SPSS software (SPSS, Chicago, Illinois). Univariate regression analysis was used to evaluate the relationship, if any, between penetration and the variables of age, gender, weight, diagnosis, the duration of follow-up, and acetabular inclination and anteversion. The 95% confidence level was used to determine
significant differences. The amount of penetration, the annual rate of penetration, and the cup position are expressed as the mean and the standard deviation.

Results
Clinical Assessment
At the time of the final follow-up, the Harris hip score was 94 ± 8 points (range, 70 to 100 points) for the thirty-seven hips with a Durasul liner compared with 96 ± 7 points (range, 70 to 100 points) for those with a conventional polyethylene liner. At the time of the final follow-up, the self-assessment examination revealed thirty-three excellent, two very good, one good, and one fair result in the Durasul group compared with twenty-nine excellent and eight very good results in the control group. In the Durasul group, activity was categorized as unlimited ambulation for twenty-six hips, active community ambulation for four, limited community ambulation for three, and household ambulation for four. In the control group, activity was categorized as unlimited ambulation for twenty-nine hips, active community ambulation for six, limited community ambulation for one, and household ambulation for one.

Radiographic Assessment
All sockets were fixed without cement and without screws. The mean inclination angle was 38° ± 5.3° (range, 28° to 50°) for cups with Durasul liners and 39° ± 6.3° (range, 28° to 59°) for cups with conventional polyethylene liners (p = 0.39). The mean anteverision was 19° ± 6.7° (range, 7.5° to 29°) for cups with Durasul liners and 18° ± 4.7° (range, 9° to 27°) for cups with conventional polyethylene liners (p = 0.71). There was no evidence of osteolysis, progressive radiolucent lines, or component migration in any of the hips.

The annual linear wear rates as determined with the method of Sychtzer et al., which eliminates the bedding-in value, are provided in Table III. For each year, the linear wear rate for the conventional polyethylene liners was higher than that for the Durasul liners. The five-year annual linear wear rate was 0.029 ± 0.02 mm per year for Durasul liners and 0.065 ± 0.026 mm per year for conventional polyethylene liners (p < 0.005).

The cumulative five-year penetration of Durasul and conventional polyethylene liners is shown in Table IV and Figure 1. The conventional polyethylene liners had a linear curve after Year 1, whereas the Durasul liners had a linear curve after Year 2.

The annual penetration is a simplified method of expressing the penetration that occurs each year. The annual penetration of Durasul and conventional polyethylene liners in Years 1 through 5 is shown in Table V and Figure 2. The steady state was reached after Year 1 for conventional polyethylene liners and after Year 2 for Durasul liners. The annual penetration for conventional polyethylene liners had a steady rate of 0.04 mm per year from Year 2 through Year 5. The annual penetration with a Durasul liner varied from 25% to 40% of that for a conventional polyethylene liner after the steady state is reached.

At five years, no hip with either a Durasul or a conventional liner was an outlier for the osteolysis threshold of 0.10 mm per year13,19, with all liners having a wear rate at or below this level. With the numbers available, univariate regression analysis did not demonstrate that age, gender, weight, activity, cup abduction, or cup anteversion had any influence on penetration.

Discussion
Duraspul liners have the same quantitative pattern as conventional polyethylene liners do with regard to the bedding-in and running-in periods to a steady state of wear20-24. In the present study, the steady state was reached after two years in hips with Durasul liners and after one year in hips with conventional polyethylene liners. This finding suggests that Durasul highly cross-linked polyethylene adapts more slowly to penetration of the metal femoral head. This slower rate of adaption did not appear to have any adverse consequences. Di-gas et al.20 used radiostereometric examination to study the penetration of 28-mm metal femoral heads into Durasul all-polyethylene cemented cups. At two years postoperatively, the mean total penetration was 0.13 mm in that study, compared with 0.15 mm in the present study. In Year 3, the mean penetration was 0.01 mm in that study, compared with 0.011 mm in the present study. Thus, the running-in period was two years in both studies.

Although qualitatively the same, the quantitative wear patterns of Durasul and conventional polyethylene liners were different. The hypothesis of the present study was confirmed: Durasul liners had less wear at five years than conventional polyethylene liners did. The annual linear wear rate with conventional polyethylene liners continued to decrease to Year 5, largely because all of the running-in creep penetration (0.151 mm) occurred in Year 1. Durasul liners had the same total amount of running-in penetration (0.150 mm), but this occurred over two years, which allowed the linear wear rate to be steady at Years 4 and 5. The mean annual linear wear rate of Durasul liners (0.029 mm per year) was 45% of that of the conventional polyethylene liners (0.065 mm per year). Our wear data for Durasul liners show an approximately 80% reduction in linear wear when compared with the wear rates for conventional polyethylene liners as reported in studies by Sychtzer et al.12 (0.17 mm per year), Dowd et al.15 (0.18 mm per year), and Pedersen et al.13 (0.14 mm per year).

The annual penetration concept is used to establish a

<table>
<thead>
<tr>
<th>Year</th>
<th>Durasul</th>
<th>Conventional</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>0.074</td>
<td>0.151</td>
</tr>
<tr>
<td>2</td>
<td>0.076</td>
<td>0.04</td>
</tr>
<tr>
<td>3</td>
<td>0.011</td>
<td>0.039</td>
</tr>
<tr>
<td>4</td>
<td>0.02</td>
<td>0.05</td>
</tr>
<tr>
<td>5</td>
<td>0.011</td>
<td>0.04</td>
</tr>
</tbody>
</table>
steady state of wear by measuring the yearly penetration without the influence of running-in creep. Therefore, this method is different from the traditional linear wear rate, which eliminates bedding-in penetration but includes the running-in creep. Eliminating running-in creep provides a clearer picture of the amount of actual wear, whereas the traditional method combines wear and creep. With this method, conventional polyethylene liners reached a steady state of 0.04 mm per year beginning with Year 2 (Table V). Durasul liners reached a steady state of wear after the running-in period of two years and then had an annual penetration of 0.01 mm to 0.02 mm (between 25% and 40% of the values for conventional polyethylene) between three and five years. The annual penetration remained steady for both Durasul and conventional polyethylene in Years 3, 4, and 5.

The limitations of the present study are that it was not randomized, it included only thirty-seven hips, and only twenty-three hips were available for study at five years. However, our data showed the same qualitative and quantitative patterns as did the data in the randomized study by Digas et al., and the total number of hips in the present study is similar to that in other studies on cross-linked polyethylene.

These data should be considered as early results. Time is needed to observe whether the rate of wear will remain steady and below the osteolysis threshold of 0.10 mm per year. While the long-term effects of the altered mechanical properties of highly cross-linked polyethylene remain unknown, the data to date are promising in that the early penetration and wear performance is 55% less than that associated with conventional polyethylene and the wear rates are well below the osteolysis threshold and seem to have reached a steady state after the second year. Because of these findings, we are recommending the further use of this type of liner to our patients.

References


