Evidence Table

Clinical Area: Ceramic TRANSCEND® Articulation Hip System
Keywords: Total hip replacement, ceramic

Study Type: Randomized controlled trial
Study Aim: 1) To compare the use of alumina-on-alumina ceramics in hip replacement with the established alternative, cobalt-chrome-on-polyethylene bearings;  2) To compare the complications associated with alumina ceramic bearing couples with earlier ceramic designs.

Outcomes
• Primary: Did not specify primary outcome. Assessed pain and functioning; calculated Harris hip score (HHS).
• Secondary: Radiographic variables.

Design
• Number of subjects: n=514 hips (the number of patients was unclear; both 458 and 495 were reported).
• Description of study population: Multisite study conducted for FDA investigational device exemption. ABC system 1: 66% male; mean age=53 years; 81% main diagnosis osteoarthritis: ABC system 2: 64% male; mean age=53 years; 76% main diagnosis osteoarthritis: Control: 60% male; mean age=53 years; 76% main diagnosis osteoarthritis.
• Inclusion criteria: Not reported.
• Exclusion criteria: Not reported.
• Power: Not reported.
• Method of randomization: Not reported.
• Intervention: Patients were randomized to receive one of three cup designs. The first two systems used alumina-on-alumina bearings and the third system used cobalt-chrome-on-polyethylene: 1) Alumina head, ABC alumina insert (Stryker Howmedica Osteonics), microstructured ABC shell; 2) Alumina head, ABC alumina insert, Arc deposited HA ABC shell; 3) cobalt-chrome femoral head, polyethylene insert, microstructured shell. All systems used the same femoral stem (Omnifit, Howmedica Osteonics).
• Blinding: Patient and surgeon were blinded. Not clear if outcome assessment (pain, function) was blinded.
• Source of outcome data (e.g. patient self-report, doctor report, lab results): Clinical examination, radiographic data.
• Length of follow-up: Patients were seen at baseline, and 6-8 weeks, 6 months and 1 year post-operatively and annually thereafter.
• Completeness of follow-up: 2 alumina-on-alumina hips: 307 patients at 24 months, 227 at 36 months and 71 patients at 48 months (mean=35 months’ follow-up); Control: 147 patients at 24 months, 111 patients at 36 months, 26 patients at 48 months (mean=34 months’ follow-up).

Validity
• Is the study type appropriate for the questions being asked? Yes.
• Was the study population typical of patients with this disease? Unknown because eligibility criteria were not reported.
• Were the treatment/control groups comparable at baseline? Yes, on reported characteristics.
• Was the intervention compared to placebo and/or best accepted intervention? Compared to accepted alternative intervention.
• Was there compliance with the intervention? Yes.
• Were there equal intensity of observation of study and control subjects? Yes.
• Was the process of observation likely to effect the outcome? No.
• Intention to treat analysis? No.

Conclusions regarding validity of methods:
The authors did not report inclusion/exclusion criteria, statistical power or method of randomization. Threats to validity are possible including lack of sufficient power to detect clinically meaningful differences, inadequate randomization and a biased sample. In addition, there was no intention to treat analysis and no statistical analysis.

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Results
Clinical outcome data, 2-4 years' follow-up (mean=3 years)
Notes: Data presented by hip, not patient
No statistical comparisons were reported

<table>
<thead>
<tr>
<th></th>
<th>ABC system 1 (n=166)</th>
<th>ABC system 2 (n=172)</th>
<th>Control (n=151)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Pain none/slight (%)</td>
<td>91</td>
<td>92</td>
<td>93</td>
</tr>
<tr>
<td>Limp none/mild (%)</td>
<td>98</td>
<td>96</td>
<td>97</td>
</tr>
<tr>
<td>Mean Harris hip score</td>
<td>95.4</td>
<td>96.6</td>
<td>95.9</td>
</tr>
<tr>
<td>Harris, good/excell* (%)</td>
<td>94</td>
<td>94</td>
<td>96</td>
</tr>
<tr>
<td>% of patients satisfied</td>
<td>95</td>
<td>98</td>
<td>97</td>
</tr>
</tbody>
</table>

* Good=score 80-89, excellent=90-100.

Adverse effects, No. (%)

<table>
<thead>
<tr>
<th></th>
<th>ABC system 1</th>
<th>ABC system 2</th>
<th>Control</th>
</tr>
</thead>
<tbody>
<tr>
<td>Revision</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Acetabular</td>
<td>0</td>
<td>1 (0.6)</td>
<td>2 (1.2)</td>
</tr>
<tr>
<td>Femoral</td>
<td>1 (0.6)</td>
<td>0</td>
<td>2 (1.2)</td>
</tr>
<tr>
<td>Both</td>
<td>0</td>
<td>2 (1.1)</td>
<td>0</td>
</tr>
<tr>
<td>Ceramic fracture</td>
<td>0</td>
<td>0</td>
<td>NA</td>
</tr>
<tr>
<td>Post-op femoral fracture</td>
<td>4 (2.3)</td>
<td>2 (1.1)</td>
<td>2 (1.2)</td>
</tr>
<tr>
<td>Dislocation</td>
<td>4 (2.3)</td>
<td>6 (3.4)</td>
<td>7 (4.2)</td>
</tr>
<tr>
<td>Heterotopic bone</td>
<td>5 (2.9)</td>
<td>6 (3.4)</td>
<td>10 (6.1)</td>
</tr>
<tr>
<td>Intraoperative insert chip</td>
<td>5 (2.9)</td>
<td>4 (2.3)</td>
<td>NA</td>
</tr>
</tbody>
</table>

NA=not applicable

Authors’ Conclusions
“In the current study involving 349 ABC alumina ceramic implants, no component fracture was experienced. Nine peripheral chips occurred with the ABC system because of technical problems involving placement of the alumina ceramic insert within the titanium acetabular component. After recognizing this technical problem, a fourth study arm (Trident implant; Howmedica) has been underway for 3 years evaluating a metal-backed alumina insert that is placed within the acetabular shell…We believe the use of alumina-on-alumina ceramic bearings, when properly designed, is indicated for younger and more active patients.”

Reviewer’s Conclusions
The authors compared two hip replacement systems with alumina-on-alumina bearings and one system with cobalt-chrome-on-polyethylene bearings. The clinical outcomes in the three groups appear similar, but the authors did not present statistical comparisons. After a mean of 3 years of follow-up, there were no ceramic fractures; there was a 2-3% rate of intraoperative insert chips.