

CERAMIC-CERAMIC BEARINGS IN TOTAL HIP ARTHROPLASTY: PRELIMINARY CLINICAL RESULTS

STEPHEN B. MURPHY, MD AND WAEL K. BARSOUM, MD

NEW ENGLAND BONE AND JOINT INSTITUTE, NEW ENGLAND BAPTIST HOSPITAL, BETH ISRAEL-DEACONESS MEDICAL CENTER, HARVARD MEDICAL SCHOOL

INTRODUCTION

Total hip arthroplasty (THA) is a cost effective surgical procedure for relief of pain and restoration of function of the diseased hip. Successful THA has contributed to enhanced mobility and comfortable independent living for people who would otherwise be substantially disabled. Currently, the majority of devices include a bearing that consists of a metallic modular head articulating against ultra-high molecular weight polyethylene (UHMWPE). A consequence of the metal-on-polyethylene articulation is surface wear, liberating polyethylene and metal wear debris. Today, osteolysis as a result wear debris is the major cause of long-term failure of primary THA.

The increasing volume of THA performed in younger patients, in conjunction with a greater patient longevity, has raised expectations of implant survivorship beyond that expected of traditional bearings. Twenty-five years ago, DeLee and Charnley published their initial results attempting to quantify the rate of penetration of the femoral head into a cemented, all-polyethylene acetabular component.¹ Since this report, much has been written on the result of wear and osteolysis, in which metal-on-polyethylene articulation is considered "the weak link" in primary THA.²⁻⁸ Therefore, enhancing the metal-on-polyethylene articulation has been aggressively pursued by surgeons and industry.

Alternatively, ceramic-on-ceramic bearings offer the opportunity to eliminate the metal-on-polyethylene bearing and polyethylene wear debris entirely. Lyman-Smith is often credited with the earliest published report (1963) of the use and the body's tolerance of implanted ceramic materials. This was a porous ceramic (alumina - Al_2O_3) imbedded with epoxy resins.^{9,10} However, ceramic material for implantation were reported thirty years earlier in the German patent literature.¹¹

The advantages of ceramic components for the articulation in primary THA include their relatively inert properties in body fluids, negligible amounts of toxic degradation products,

and their resistance to wear. Concerns regarding ceramics frequently involve their brittle nature and mechanical properties in high load applications. The purpose of this article is to summarize current issues relating to the manufacturing and use of ceramic-on-ceramic articulations for THA, including the author's clinical experience.

PROPERTIES OF CERAMICS

Unlike metals (solid solutions of elements), or polymers (long chain molecules of carbon and hydrogen), ceramics are solid compounds of metal and non-metals. The formation of a ceramic compound between a base metal (aluminum) and oxygen produces a stable oxide compound in its highest state of oxidation, in which further spontaneous reaction is not possible. Therefore, ceramics, such as aluminum oxide (alumina - Al_2O_3) are inert of biological, chemical and electrochemical reaction within the body. The subsequent strong atomic bonds result in an inert, stiff and hard compound.¹²

All articulations in THA generate wear debris, including the ceramic-on-ceramic articulation. However, the amount of cytokines in aseptically loose ceramic-on-ceramic THA components is significantly less than that found in the presence of UHMWPE debris.¹³ Therefore, based on the particle size, volume and bioinert properties, the incidence of wear debris induced osteolysis in THA with ceramic-on-ceramic articulations may be less than that seen with standard metal-on-polyethylene articulations.

CERAMIC MANUFACTURING

Alumina oxide ceramics is manufactured from purified natural minerals. Pure oxide is milled to a mesh of 0.1 - 10 μ m. Dies that are manufactured to the component shape are used in which the oxide powder is compressed using 70 Mpa pressure (~10,000 psi). The compressed product is transferred to an oven and baked at low temperature to its point of fusion (~1,700 degrees Fahrenheit), and is slowly cooled to room temperature. On the MOHS hardness scale, current alumina products for THA are classed 9. The hardest material rated just above alumina, class 10, is diamond.⁹ Current ceramic components have a reported overall incidence of fracture five times less than early generation ceramic components (early - 1:2,000 current - 1:10,000). This is a result of manufacturing processes that include a smaller grain size (1.8 μ versus 4.5 μ), increased density (3.98 g/cc versus 3.50 g/cc), and a higher alumina purity (99.9% versus 99.5%). These variables have led to optimized component material properties.

MATERIALS AND METHODS

Between June 1997 and February 2001, 75 THA's (75 hips

Stephen B. Murphy, MD is a Clinical Instructor in Orthopaedic Surgery at Harvard Medical School.

Wael K. Barsoum, MD is a Total Joint Arthroplasty Fellow at the New England Baptist Hospital, Boston, MA.

Address correspondence to:

Stephen B. Murphy, MD
New England Baptist Hospital
Department of Orthopaedic Surgery
125 Parker Hill Avenue
Boston, MA 02120



Figure 1. Ceramic-ceramic total hip arthroplasty

in 69 patients). The acetabular component used in all cases was a press-fit, porous-coated titanium shell (Transcend™ Cup–Wright Medical Technology, Memphis, TN). An alumina ceramic acetabular bearing was inserted into the metal shell and locked with an 18° taper. The alumina acetabular bearing articulates with a modular alumina femoral head component (Figure 1). All acetabulae were under-reamed by 1 mm to ensure stability upon impaction. Screws to augment acetabular fixation were generally not used. All patients were followed prospectively as part of an FDA/IDE approved study. The patients were evaluated clinically and radiographically pre-operatively, and post-operatively at 3, 6 and 12 months and annually thereafter. Outcome evaluation included Harris hips scores and SF-12 questionnaires.

There were 28 (37%) left hips, 33 (44%) right hips and 14 (19%) bilateral hips. 40 (53%) were male and 35 (47%) were female. Mean patient age at surgery was 48 years (SD = 13, range 18-75 years). Pre-operative diagnoses included osteoarthritis 45 (60%), developmental dysplastic hip 21 (28%), avascular necrosis 6 (8%), traumatic arthritis 2 (3%), Legg-Calve-Perthes disease 1 (1%). Mean ± SD follow-up time for all cases was 11 ± 12 months.

RESULTS

To date, all components are well fixed. There have been no cases of ceramic head or liner fracture post-operatively and no signs of grossly visible wear. The acetabular components were fixed without screws in all but two hips (one patient). The acetabular

component abduction angle averaged 43 degrees (SD = 4 degrees, range 30-53 degrees). Intraoperatively, one femur cracked during component insertion and was treated by cerclage wires. One ceramic liner chipped when inserted eccentrically and was replaced at the time. Postoperatively, one hip underwent irrigation and debridement 3 weeks postoperatively for increased pain and low-grade temperature and was culture negative. One liner was mal-seated and replaced on post-op day 3. There were no dislocations or infections.

DISCUSSION

Early results have demonstrated no major problems associated with ceramic-ceramic bearings in THA, such as bearing fracture or catastrophic wear. All preliminary series of ceramic-ceramic bearings have shown an incidence of liner chipping or mal-seating, especially early on. In fact, ceramic liners are generally easier to insert than polyethylene liners but need to be properly seated by hand before impaction. Since, unlike polyethylene, bearing thickness does not affect wear, ceramic-ceramic bearings are especially useful for dysplastic hips (Figure 2). These patients are typically young, with small socket components, where thin polyethylene typically leads to a high rate of polyethylene wear.

In an FDA approved, multi-center, clinical trial of 333 THA's with the same component (of which the author has participated and results are combined), Garino reported short-term results.¹⁴ As with the current study, the preliminary results had no post-operative cases of ceramic bearing fracture or visible wear. There were 2 additional intraoperative liner “chip” fractures due to eccentric insertion treated by intraoperative exchange of the liner.

Similarly, Bizot, et al, reported a 93% survivorship rate in 234 THA's with a non-cemented, metal-backed, ceramic-on-

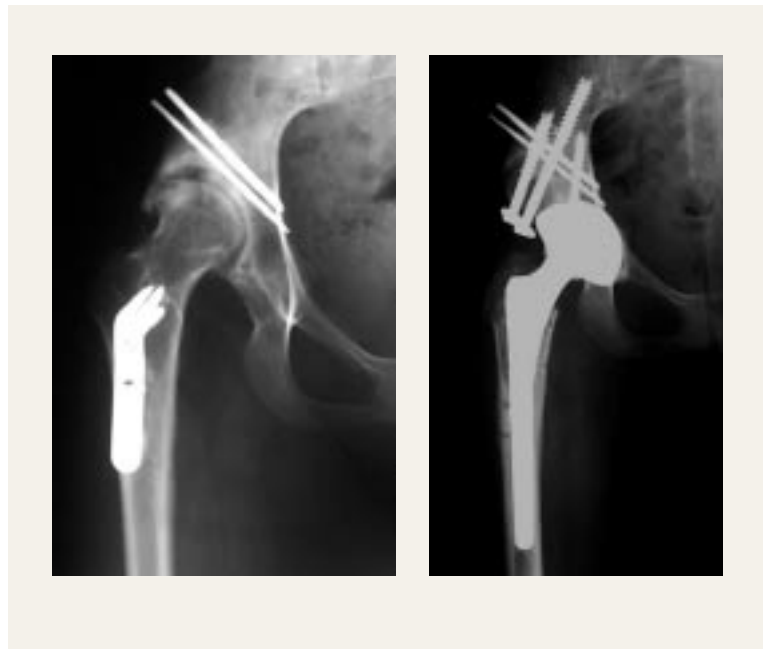


Figure 2. Ceramic-ceramic bearings may be especially advantageous in dysplastic hips with small sockets where polyethylene wear due to thin plastic liners remains a serious problem.

ceramic acetabular component, when revision was the end-point.¹⁵ Of these cases, only one was ceramic related (fractured femoral head). There were three hips in which the acetabular component had a complete, non-progressive radiolucent line less than 1 mm thick. In each case, neither component migration nor osteolysis adjacent to the acetabular component was detected radiographically. These intermediate reports of this component show results equal to that of conventional THA with metal-on-polyethylene articulation.

CONCLUSION

Early results of the use of ceramic-ceramic bearings for THA show promise for eliminating polyethylene debris and reducing wear debris. Since polyethylene appears to induce a stronger histological reaction than inert ceramic wear particles, there is potential for less osteolysis even given an equivalent concentration of wear particles. Ceramic bearings may prove especially useful in younger patients and small, dysplastic hips.

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