Large-Head Metal-on-Metal Total Hip Arthroplasty Using the Durom Acetabular Component at Minimum 1-Year Interval

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Abstract: Large-head metal-on-metal total hip arthroplasty represents novel technology, and outcome data are lacking. We prospectively compared the performance of a nonmodular metal-on-metal acetabular component (Durom; Zimmer, Warsaw, IN) with a modular titanium component (Trilogy, Zimmer). All Durom components placed at our institution with minimum 1-year follow up (n = 63) were compared with an age- and sex-matched Trilogy control group (n = 100). *Failure* defined as revision or persistent moderate/severe groin pain was significantly higher for the Durom (11.1%) compared with the Trilogy group (0%) (P = .002). Although all acetabular components in both groups appeared radiographically stable, no significant bone ingrowth was noted at the time of Durom revisions. We could not identify any patient/surgical-related factors predictive of failure. Further study is needed to determine the scientific basis for these observations. **Keywords:** metal-on-metal total hip arthroplasty, Durom, Trilogy, acetabular revision.

Total hip arthroplasty (THA) using a conventional cementless acetabular component with optional screw fixation and a metal-on-polyethylene articulation has demonstrated excellent results, with very low revision rates for acetabular loosening in primary THA at 10 years [1-5]. However, polyethylene wear, dislocation, and limb length discrepancy remain clinical challenges with these designs using conventional polyethylene and standard femoral head sizes (22- to 32-mm diameter) [6-9]. Alternative bearing designs have been introduced to reduce wear through improved tribology and reduce the risks of dislocation and limb length discrepancy by allowing the use of larger femoral heads (>32-mm diameter) [8,9].

Large-head metal-on-metal (MOM) designs with nonmodular acetabular components theoretically increase range of motion, reduce wear, and reduce dislocation rates; however, the clinical results with these components have been limited [10-15]. Design concerns with these components remain, including whether the lack of optional screw fixation may result in increased rates of early acetabular loosening [16]. Although encouraging early reports have been noted with some nonmodular, large-head MOM acetabular designs [10,14,17], most studies are limited to hip resurfacing applications, lack long-term data, and reflect the experience of the designing surgeons. Recent reports in the lay press and the voluntary withdrawal of certain nonmodular, large-head MOM designs from the market (Durom; Zimmer, Warsaw, IN) have served to emphasize the need for further study regarding outcomes with these devices. It is currently unclear whether failure rates with these nonmodular, large-head MOM designs will be design specific and whether patient selection factors play a significant role in the risk of early acetabular loosening.

The purpose of our study is to compare the clinical and radiographic outcomes of a nonmodular, large-head MOM acetabular component (Durom) with a modern, modular titanium acetabular component (Trilogy, Zimmer) using conventional head sizes and metal-on-highly cross-linked polyethylene articulations (Longevity, Zimmer) at minimum 1-year follow-up interval. Our hypothesis was that a nonmodular, large-head MOM acetabular component would have a higher early failure

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rate when compared with a modular titanium acetabular component.

Materials and Methods

The Durom is a nonmodular acetabular component and uses a high-carbon, forged chromium-cobalt bearing surface with a titanium plasma spray surface for bone ingrowth. The implant is a 165° truncated hemisphere with an elliptical shape providing a 2-mm press fit circumferentially. The Durom cup also has rim fins that are designed to engage the peripheral bone and extend an additional 1 mm from the edge of the component (Fig. 1). Initial stability is achieved by the press fit at the rim and the purchase of the peripheral rim fins in the acetabular bone.

The Trilogy is a modular acetabular component and uses a titanium fiber-metal mesh surface for bone ingrowth. The implant is a full 180° hemisphere and allows for supplemental screw fixation (Fig. 2). Excellent results with very low rates of early loosening have been noted with this implant using a metal-on-polyethylene bearing surface [4,5,18].

Institutional review board approval was granted for our study. A prospective total joint database is maintained at our institution. The Harris Hip Scores were self reported by patients by way of a questionnaire during the preoperative and postoperative clinic visits. These questionnaires were collected by the nursing staff and subsequently entered into our database by a research assistant. This database was used to compare Harris Hip Scores and radiographic outcomes of the Durom and Trilogy acetabular components at minimum 1-year follow-up interval. All Durom components implanted at our institution with minimum 1-year follow-up were included. A department statistician used the average age and proportion of women in the Durom group to create a control group using a Trilogy component. All procedures were performed by the 3 senior authors.

Preoperative and 1-year postoperative Harris Hip Scores were retrieved from our prospective arthroplasty database and compared. *Failure* of the acetabular component was defined as acetabular revision, planned acetabular revision, or persistent moderate/severe groin pain as determined by the Harris Hip Score. Radiographs were reviewed by the attending surgeon at the time of the one year follow-up to determine if acetabular component migration or radiolucent lines were evident in either group.

The rates of acetabular component failure were compared using Fisher exact test. The mean Harris Hip Scores were compared using the Student *t* test. A level of significance was set at $P = .05$ for all statistical tests. All

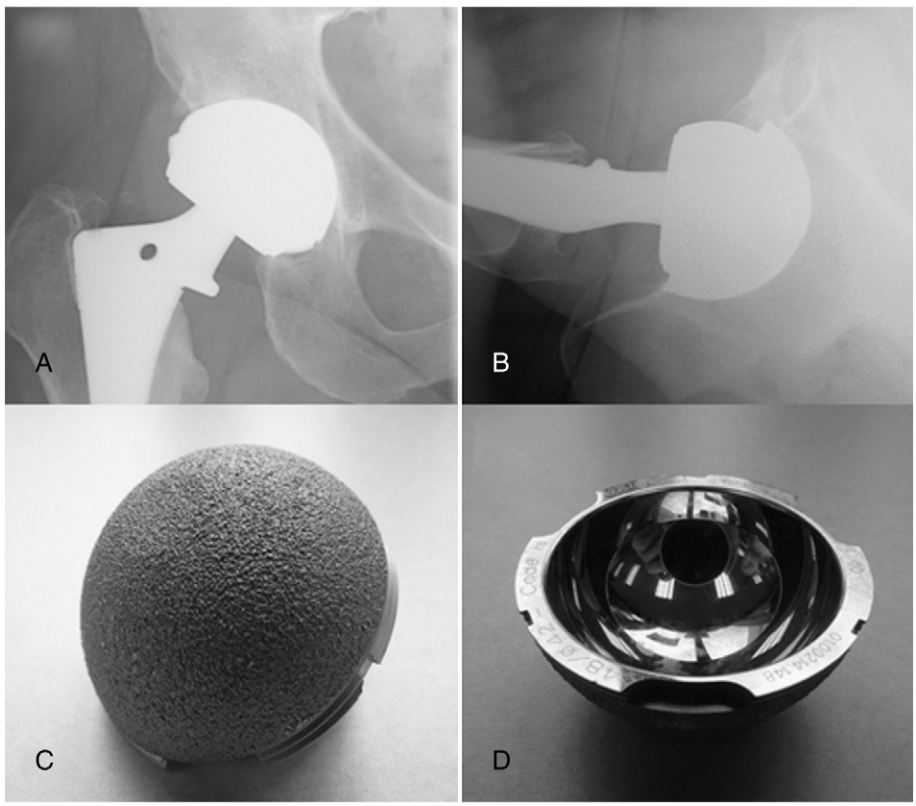

Fig. 1. The Durom acetabular component. (A, B) Anteroposterior and lateral radiographs of a 58-year-old woman 24 months following primary THA with the Durom acetabular component. This patient had severe persistent groin pain. No continuous radiolucent lines were present. (C, D) Photographs of the explanted Durom acetabular component from the patient above demonstrating no bone ingrowth. The implant is a 165° truncated hemisphere with an elliptical shape and peripheral rim fins.

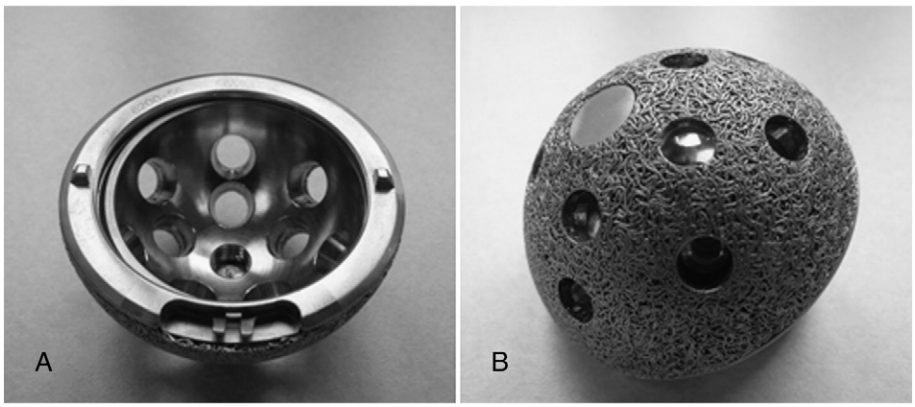

Fig. 2. The Trilogy acetabular component. (A, B) Photographs of the Trilogy acetabular component. The implant is a full 180° hemisphere, has a titanium fiber-metal mesh bone ingrowth surface, and allows for supplemental screw fixation.

statistics were computed using the R statistical computing software (version 2.8.1, R Foundation for Statistical Computing). Power analysis was performed to demonstrate that the sample sizes were adequate. Using the proportion of failures seen for Trilogy and Durom in our study, a power analysis indicated that approximately 21 Durom components would have been needed for a minimal power of 0.80 to support a difference in the rates of failure.

Results

Sixty-three of the 196 Durom components implanted at our institution had completed their 1-year follow-up. There were 100 components in the Trilogy control group. In the Durom group, the average age at the time of surgery was 59 years and 23% were female. In the Trilogy group, the average age was 59 years and 49% were female. No significant differences were noted comparing the age or sex for the Trilogy and Durom groups ($P > .05$). The preoperative Harris Hip Scores were significantly higher in the Durom compared with the Trilogy group (52.84 vs 45.9, respectively; $P = .001$) (Table 1). At the 1-year postoperative interval, similar Harris Hip Scores were achieved in the Trilogy and Durom groups (91.7 vs 89.7, respectively; $P = .364$). However, a subset of the Durom group performed poorly. The rates of failure noted in the Durom group were significantly higher compared with the Trilogy group (7/63 [11.1%] vs 0/100 [0%]. respectively; $P = .002$) (Table 1). In the failed Durom group, all patients underwent revision THA for persistent severe groin pain. The preoperative Harris Hip Scores for the failed Durom group were similar to the Trilogy controls (58.7 vs 45.9, respectively; $P > .05$) and the nonfailed Durom group (52.8 vs 45.9, respectively; $P > .05$). The 1-year postoperative Harris Hip Scores were significantly lower for the failed Durom group compared with the Trilogy group (54 vs 91.7, respectively; $P = .02$) and compared with the nonfailed Durom group (54 vs 91.6, respectively; $P = .02$) (Fig. 3). The group of nonfailed Durom patients (56/63, 88.9%) was functioning well with Harris Hip Scores comparable with the Trilogy controls at 1 year postoperatively (91.6 vs 91.7, respectively; $P > .05$).

Radiographic assessment failed to reveal any significant migration or osteolysis in either the Trilogy or Durom groups. The interface between the implant and the acetabular bone failed to reveal any progressive radiolucent lines in either the Durom or Trilogy groups. Findings at revision surgery have been consistent. No Durom cup has been found to be infected. During revision, all Durom cups were tested; and none were grossly loose. However, in all cases, the cups were easily removed as soon as the peripheral rim fins were disengaged. Despite the lack of radiographic evidence for loosening, there was no significant bone ingrowth noted at the time of explantation for any of the Durom

Table 1. Harris Hip Scores and Failure Rates

	Trilogy (n = 100)	Durom (n = 63)	*P* Value
Preoperative HHS	45.9	52.8	.001
Postoperative HHS	91.7	89.7	.364
Failure rates (%)	0	11.1	.002

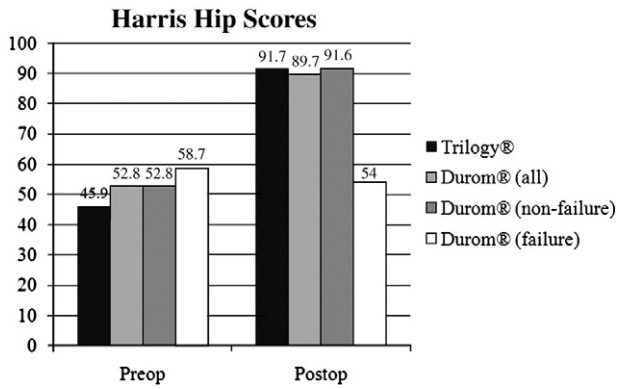

Fig. 3. Average preoperative and 1-year postoperative Harris Hip Scores in the Trilogy and Durom groups.

components (Fig. 1). All Durom components that underwent revision were replaced using a modular titanium acetabular component fixed with screws and a highly cross-linked polyethylene articulation.

Discussion

Clinical results in primary THA using modular cementless acetabular components and conventional femoral head sizes have demonstrated durable fixation at 10 to 15 years with very low rates of early loosing [1-4]. However, polyethylene wear, limb length discrepancy, dislocation, and polyethylene liner fracture remain clinical limitations with these designs. Large-head MOM THA using nonmodular acetabular components have been introduced to reduce wear, eliminate the risk of liner fracture, optimize the head-neck ratio, reduce dislocation risks, and eliminate the need for dislocation precautions after surgery.

Despite these potential clinical advantages, concerns remain including whether the lack of supplemental screw fixation with these nonmodular large-head MOM acetabular components could reduce early fixation compared with traditional modular acetabular components [16]. The longest-term follow-up data with these large-head, nonmodular MOM acetabular designs are approximately 8 to 10 years and are available with only one design with data provided by the designing surgeons (Birmingham Hip Resurfacing, Smith and Nephew - Midland Medical Technology, Birmingham, UK) [10,19,20]. It is unclear whether these promising Birmingham Hip Resurfacing results will be confirmed by independent investigators at similar follow-up intervals and whether similar failure rates will be noted for other nonmodular large-head MOM acetabular component designs. Little or no long-term data are available with the majority of nonmodular large-head MOM acetabular devices currently in use in either hip resurfacing or THA applications [12,14,17].

The Durom acetabular component is an elliptically shaped, truncated hemisphere (165°) with peripheral circumferential fins (Fig. 1). Initial stability is achieved via press fit as well as engagement of the peripheral fins. The articular surface is forged chromium-cobalt with a titanium plasma sprayed bone ingrowth surface. It should be noted that the version used in the United States has a slightly thicker titanium plasma coating than the European version due to specific Food and Drug Administration requirements. The US and European versions of the Durom components were otherwise identical. All components used in this study were the US version. Early encouraging clinical data regarding the use of the European version of the Durom component have been noted in resurfacing applications [12,13]. No data are currently available regarding outcomes using the US version in primary THA or hip resurfacing applications.

Our study represents one of the first reviews of the clinical and radiographic outcomes using the US version of the Durom acetabular component. It should be noted that the majority of the patients with a Durom component (88.9%) had an uneventful postoperative course, noted the typical complete or near-complete hip pain relief, achieved a high degree of hip function, and demonstrated high Harris Hip Scores that were similar to the Trilogy group at 1 year postoperatively (91.6 vs 91.7, respectively; $P > .05$). Unfortunately, a subset of the Durom group did not perform well. We found that the rate of failure was significantly higher with the Durom components (11.1%) compared with Trilogy control group (0%) at minimum 1-year follow-up interval ($P = .002$). The cause of these failures is not clear.

The clinical presentation has been fairly consistent. Most patients complain of persistent groin pain that is worse with activity. Many patients describe startup pain that occasionally improves as they walk greater distances. Preoperative evaluation has included complete blood count with differential, erythrocyte sedimentation rate, and C-reactive protein. In every case, these serologic values have been normal. Radiographic assessment has included plain films, bone scans, and magnetic resonance imaging. In most cases, the radiographic assessment has not been helpful. No cases of frank loosening have been noted, and no cases of migration evident on plain radiographs have been seen. No cases demonstrated continuous radiolucent lines, although some cases of stable, 1- to 2-mm peripheral radiolucent lines have been seen isolated usually to the superior-lateral portion of the acetabular component-bone interface. The presence or absence of radiolucent lines has not been predictive of failure. Bone scans have not demonstrated any increased uptake around either the acetabular or femoral components. The magnetic resonance imaging studies have generally not been helpful. Most studies have demonstrating a small amount of periarticular fluid, although one case of a pseudotumor has been noted. In summary, the radiographic and serologic preoperative assessments have failed to reveal a cause of failure. Clinicians are often left in the difficult position of managing patients with persistent groin pain with no clear cause and with components that appear radiographically well fixed. Further study is needed to determine why standard radiographic tests have not demonstrated component loosening in this nonmodular monoblock cup design.

Findings at surgery have also been fairly consistent: all femoral components have been well fixed, and the acetabular components have not been grossly loose. The peripheral fins have engaged the acetabular bone, and they could not simply be extracted. In all cases, the rim fins were cut free of the peripheral bone; and as soon as this was achieved, the cups were removed easily. No significant bone ingrowth had occurred in any of these Durom revision cases (Fig. 1). In most cases, no inflammatory membrane has been found; and the acetabular bone behind the failed Durom component

appeared healthy. Pathology and microbiology tests have been sent in all cases. No cases of infection have been noted. The pathology test failed to demonstrate significant inflammation other than the one case of pseudotumor that demonstrated a typical T-cell reaction [21]. In all cases, the failed Durom components have been revised to a traditional, modular titanium acetabular component fixed with screws and used a highly cross-linked polyethylene articulation.

The cause of failure for these implants remains unclear. Although no significant macromotion could be identified at the time of revision in these cases, relatively little micromotion (>40 μm) would be required to impair or prevent bone ingrowth. We therefore cannot establish whether lack of initial stability contributed to these early failures. We also cannot determine if differences in the US and European versions of the titanium plasma spray surface might contribute to differences in relative early failure rates [12,13]. With the numbers available in our study, we could not determine if patient selection factors, surgical technique, or specific Durom implant design features contributed to the observed increased early failure rates. Further study in this area is needed to determine the cause of failure and the optimal preoperative evaluation strategy for these challenging cases. Longer follow-up in a larger cohort of patients is also needed to determine success rates for revision of these failed large-head MOM devices.

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