Disappointing Short-Term Results With the DePuy ASR XL Metal-on-Metal Total Hip Arthroplasty

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Abstract: Outcomes of ultralarge-diameter femoral heads used in metal-on-metal (MOM) total hip arthroplasty (THA) are relatively unknown. This study reports on early failures of the ASR XL (Depuy, Warsaw, Ind) and assesses whether a correlation with cup positioning exists. A retrospective review of 70 consecutive MOM THAs with ultralarge-diameter femoral head and monoblock acetabular component was conducted. Minimum follow-up was 24 months. Of 70 THAs, 12 (17.1%) required revision within 3 years for pain (7), loosening (3), and squeaking (2). Three additional THAs noted squeaking, 2 noted grinding, and 3 additional hips had persistent pain. In total, 20 (28.6%) of 70 demonstrated implant dysfunction. Acetabular components for all symptomatic hips were in acceptable range of cup abduction and anteversion. The failures noted with this design do not correlate to cup placement. The high rate of implant dysfunction at early follow-up suggests serious concerns with the concept of MOM THA with an ultralarge-diameter femoral head paired with a monoblock acetabular cup. **Keywords:** metal-on-metal, large-diameter total hip arthroplasty.

Although total hip arthroplasty (THA) has proven to be a predictable operation with good long-term results, changing patient activity levels, demands, and expectations are driving the need for even more durable and longer-lasting implants. The optimal bearing couple remains open to debate. Although long-term data demonstrating low rates of revision and osteolysis have become available for metal-on-conventional uncross-linked polyethylene bearing surfaces [1-3], the changing demographic of the hip arthroplasty patient continues to drive the pursuit of improvements in bearing surfaces to extend implant longevity. New bearing combinations such as metal or ceramic-on-highly-cross-linked-polyethylene, ceramic-on-ceramic, and metal-on-metal implants are anticipated to have the potential to outperform the traditional metal-on-conventional uncross-linked polyethylene implants, although long-term data are lacking at this time. Short-term results have suggested promising longevity with metal on highly cross-linked polyethylene couples [4]. Although significant advances in wear reduction with cross-linked polyethylene have been made, advocates of hard-on-hard bearing surfaces continue to argue that these implants can yield a superior wear profile, prevent osteolysis, and further improve implant longevity [5,6]. Furthermore, hard-on-hard bearing combinations allow implantation of larger-diameter femoral heads, increasing the head-to-neck ratio and the jump height and theoretically improving range of motion while decreasing dislocation risk [7].

The Depuy ASR XL (Depuy, Warsaw, Ind) metal-on-metal prosthesis pairs an ultralarge-diameter metal modular cobalt-chromium femoral head with a monoblock cobalt-chromium acetabular shell. The ASR acetabular component is a nonhemispheric thin-walled cup with a hydroxyappetite coating. The device received US Food and Drug Administration approval in 2003. The device was heavily marketed in the United States stressing improved range of motion, low potential dislocation rate, and favorable wear profile. The implant was released on the US market and advertised using early survivorship data from European markets (Depuy

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Surgeon Information Product Manual). Depuy voluntarily stopped US sales of the device in March 2010 after an increasing number of product complaints and issued a formal global product recall in August 2010.

Concerns with the early performance of this design led our institution to stop using this device after less than 2 years. Presented is a retrospective review of our early clinical experience with 70 consecutive Depuy ASR XL THA procedures performed by a single senior academic orthopedic surgeon. We have assessed this implant design's performance with respect to (1) reduction of dislocation risk, (2) reduction in osteolysis, and (3) rate of early clinical failure. We also reviewed cup positioning to determine if implant dysfunction could be correlated to technical error.

Materials and Methods

The study population is a retrospective cohort of 70 consecutive primary THAs (62 patients) performed with the DePuy ASR XL implant in the practice of a single attending orthopedic surgeon at a tertiary care medical center between July 2006 and August 2008. All surgeries were performed by the senior author who was performing between 350 and 400 hip and knee arthroplasty procedures per year during the time of the study. All acetabular components were monoblock cobalt-chrome DePuy ASR acetabular components (DePuy Inc), and they were each mated to the modular ultralarge-diameter cobalt-chrome DePuy ASR XL femoral heads. All cups were 50 mm or larger (range, 50-62mm), and all femoral heads were 45 mm or larger (range, 45-55 mm). Sixty-four tapered titanium DePuy Summit femoral stems were used. Six modular titanium DePuy SROM stems were implanted for patients with abnormal femoral anatomy at the discretion of the attending surgeon. The ASR XL implant was used for all patients undergoing primary THA for primary or secondary osteoarthritis unless a contraindication existed. The operating surgeon felt that the following conditions represented a relative contraindication to use of this metal-on-metal design: (1) diagnosis of a systemic inflammatory disease, (2) acetabular reconstruction expected to require auxiliary acetabular fixation with screws, (3) known metal allergy, (4) renal insufficiency, and (5) women of childbearing age.

Mean patient age was 67.8 years (range, 25-91 years), and mean weight was 183.1 lb (range, 108-295 lb). Preoperative diagnoses are shown (Table 1). Patients had varying preoperative activity levels and were assessed with a preoperative Harris hip score. All procedures were performed through a posterior approach with repair of the short external rotators. One millimeter under press-fit reaming technique was used, and target cup position was 40° of cup abduction and 20° to 30° of cup anteversion. An intraoperative cross-table anteroposterior pelvis radiograph was obtained in all cases to assess cup position and cup seating.

Table 1. Patient Demographics

	Men (39 Hips, 35 Patients)	Women (31 Hips, 27 Patients)
Age (y)	55.8 ± 12.2	63.7 ± 12.5
Weight (kg)	90.7 ± 19.9	72.7 ± 17.4
Body mass index (kg/m^2)	28.2 ± 5.1	27.0 ± 6.1
Diagnosis (hips)	33 OA (29), 4 ON (4), 2 Fx (2)	26 OA (23), 2 ON (1), 3 Fx (3)

OA indicates osteoarthritis; ON, osteonecrosis; Fx, fracture.

All 70 implants were followed up to a minimum of 2 years after implantation (2.0-5.0 years). All patients were followed up with clinical and radiographic examination at 1 month, 3 months, and 1 year postoperatively, with yearly follow-up thereafter. Clinical data points collected at each visit included Harris hip score, incidence of groin pain, grinding, squeaking, dislocation, and revision. Cup abduction was measured on a supine anteroposterior low pelvis radiograph by the method of Callaghan et al [8]. Cup anteversion was measured on a Johnson lateral by the modified technique of Ackland et al [9]. Fixation and osteolysis were assessed in each of the zones described by DeLee and Charnley [10]. All radiographic measurements and assessments were made independent of the operating surgeon.

All revision procedures were performed through a posterior approach. Cups were removed with Zimmer Explant blades (Zimmer, Warsaw, Ind). Zimmer Revision Trabecular Metal acetabular components were used in all revision surgeries, and acetabular components were upsized 6 to 8 mm because of softening of surrounding acetabular bone. Screw augmentation was performed in all revisions, as was an iliopsoas tendon release.

Descriptive statistics were performed using the STATA Software (Version 10; StataCorp LP, College Station, Tex). Data were compared by using a 2-tailed Student t test, and statistical significance was set at $P < .05$.

Results

There were 12 early failures (17.1%) of the ASR XL metal-on-metal THAs requiring revision surgery within 3 years of the index procedure. All 12 of these hips were functioning well at 1 year of follow-up. The first failure occurred because of frank loosening and acetabular component spinout at 15 months (Fig. 1). The next 5 revisions were performed because of persistent pain with no radiographic evidence of loosening. All 5 of these hips were pain free at the 12-month follow-up visit. The seventh revision was performed for pain and loosening noted on x-ray. Five additional revisions are pending at the time of this submission for intractable pain, squeaking, and/or suspected failure of ingrowth. In addition to those revised and those scheduled for

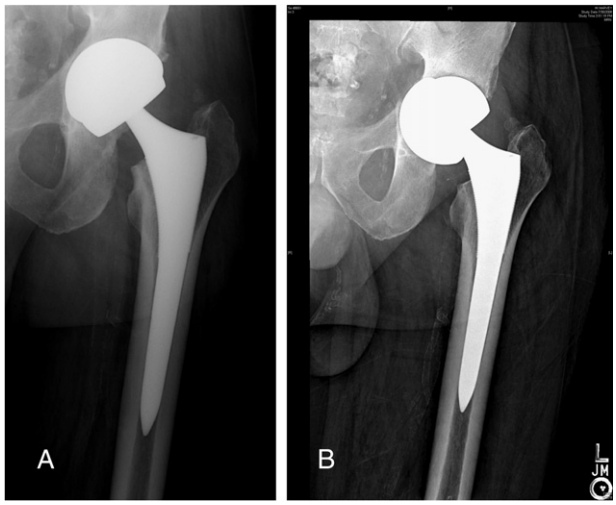

Fig. 1. (A) Immediate postoperative anteroposterior radiograph of hip that would eventually fail because of loosening. (B) Radiograph of the same implant at 15 months postoperative showing acetabular spinout.

revision, 3 additional patients (4%) noted symptomatic "squeaking," and 2 (3%) noted a "grinding" sensation in the groin. Three additional patients (4%) reported ongoing, intermittent pain but not to the extent to which they would consider revision surgery. There were zero cases of dislocation and zero cases of osteolysis. In total, 20 (29%) of 70 cases demonstrated some level of implant dysfunction.

The mean preoperative Harris hip score for this cohort was 50.8 (range, 21.0-89.5), and the postoperative mean Harris hip score was 92.2 (range, 54.6-99.7). Overall mean postoperative abduction angle was 37° (range, 20.1°-47.8°), and the mean anteversion angle was 33° (range, 10.5°-52.3°). The hip revised for spinout had initial postoperative radiographic measurements of 42° abduction and 31° anteversion. The hip revised for loosening and pain measured 31° and 30°. The hips revised for pain alone measured 30° and 21°, 41° and 18 °, 36° and 34°, 34° and 38°, and 35° and 28°, respectively. The hips scheduled for revision for pain measure 42° and 41° and 41° and 43°. The hips scheduled for revision for squeaking measure 44° and 36° and 41° and 32°. The hip scheduled for revision for loosening measures 47° and 19°. Measurements of the squeaking, grinding, and painful hips are shown (Table 2, Fig. 2). There was no statistically significant difference in cup position, either abduction or anteversion, between the symptomatic hips and the asymptomatic hips.

There were no cases of femoral fracture (intraoperative or postoperative). There were no cases of infection. There was no radiograph evidence of osteolysis. There were no cases of dislocation.

In the revision procedures performed, no cases demonstrated formation of a pseudotumor. Mild formation of grey-appearing tissue similar to that found in

Table 2. Component Positioning

	Mean Abduction Angle	Mean Anteversion Angle
All patients (N = 70)	37°	33°
Patients requiring revision (n = 12)	39° (P = .34)	31° (P = .57)
Patients with persistent pain (n = 3)	33° (P = .07)	30° (P = .71)
Patients with "grinding" (n = 2)	39° (P = .48)	37° (P = .33)
Patients with "Squeaking" (n = 3)	41° (P = .18)	30° (P = .51)

P values are in 2-tailed t test comparison with the all patient mean.

revisions for polyethylene-associated osteolysis was seen. Mild metal staining was noted in the soft tissues. Aside from the 2 cases of gross loosening of the acetabular component, cups appeared mechanically stable; however, an osteolytic membrane was encountered around the outer rim in all cases. Less than 25% ingrowth was noted on the explanted cups. Significant stress shielding of the retroacetabular bone was encountered. Cystic changes were noted in nearly all of the cases. By 6 weeks postrevision, all patients noted marked improvement in preoperative pain. By 3 months postrevision, all patients were asymptomatic.

Discussion

Since the original description of Dr Philip Wile [11] of a metal-on-metal THA in 1938, there have been many evolutions in both the design and manufacture of this hard-on-hard bearing concept. The early stainless steel prostheses were subject to a high rate of failure because

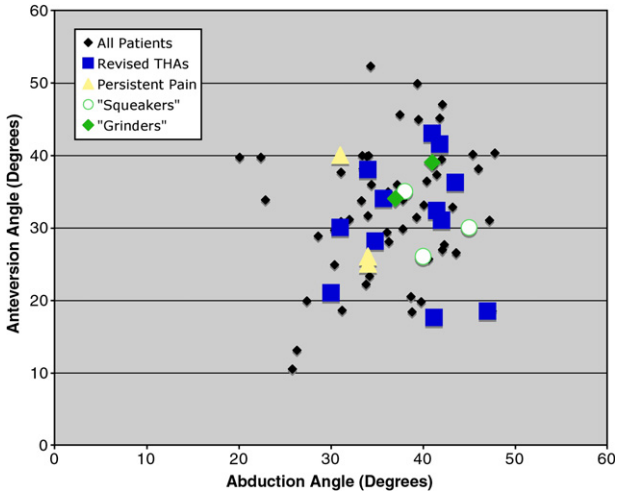

Fig. 2. Scatterplot showing cup positioning for all implants. The abduction angle is noted on x-axis, and anteversion angle, on the y-axis. Implants with dysfunction are noted by symbols demarcated in the figure. Note that the implants requiring revision, the persistently painful implants, the "squeaking" implants, and the "grinding" implants all seem to be within acceptable range in cup abduction and anteversion.

of a poor understanding of component tribology. Contemporary metal-on-metal prostheses now use a cobalt-chrome–on–cobalt-chrome combination. The bearing couple is available in a version with a modular titanium acetabular shell into which a cobalt-chrome liner can be inserted or as a monoblock cobalt-chrome acetabular cup that allows the use of an ultralarge femoral head (5-7 mm smaller than outer diamerter of shell). These hard-on-hard bearing designs that allow the use of larger head diameters all have the theoretical advantages of both lower dislocation rate [12,13] and increased longevity given low rate of bearing surface wear [14]. In contrast to metal-on-polyethylene bearings, metal-on-metal hip replacements have shown minimal bearing surface sliding during in vivo ambulation attributed to an in vitro suction phenomenon that keeps the metal-on-metal bearing surfaces linked by a fluid film layer [15,16].

Although metal-on-metal bearings have an appealing upside, persistent concerns surrounding the widespread use of metal-on-metal couples exist. Metal-on-metal bearing combinations release cobalt and chromium ions that can be detected in a patient's blood serum. The long-term effect of this exposure is unknown. Studies on metal-on-metal designs have raised concerns regarding increased serum metal ions [17], metallosis [18], groin pain [19], and pseudotumor formation [20]. Reports on a competing design of a monoblock acetabular component paired with ultralarge-diameter metal-on-metal head have already noted an unacceptably high rate of early aseptic failure [18,21].

Despite the theoretical advantages of increased head size and low bearing surface wear, our single-surgeon cohort of THA performed with the Depuy ASR XL had a 17.1% incidence of early revision, an 11.4% rate of ongoing grinding, squeaking or groin pain, and an overall 28.6% rate of implant dysfunction. This higher-than-expected early rate of failure and lower-than-expected overall patient satisfaction resulted in abandoning the use of this implant design 2 years before its subsequent recall.

The results presented in this study raise serious concerns not only about this particular design but also about the concept of ultralarge-diameter metal-on-metal THAs that use a monoblock acetabular component. Previous studies have shown an increased rate of revision in the Zimmer Durom Metasul prosthesis that was thought to be design specific [21]. Recently released data from the Australian Joint Registry 2009 Annual Report on the DePuy ASR have shown a higher-than-expected incidence of revision in the hip resurfacing version of this implant, which correlates well with the findings noted in our study [22]. The surgeon notification provided by Depuy in conjunction with the August 2010 recall of the device noted a 13% revision rate for the ASR XL metal-on-metal THA [23]. We believe that the failures seen in this series are less of a result of a specific feature of the ASR XL and more indicative of a conceptual flaw that uses monoblock cobalt-chromium acetabular shells with ultralarge-diameter femoral heads.

Our study demonstrated a higher-than-expected rate of failure and lower-than-expected overall patient satisfaction for ultralarge-diameter monoblock metal-on-metal THA components. Component position does not appear to be the cause of these adverse outcomes because there was no difference in position in the symptomatic and asymptomatic components. Other studies have demonstrated failure of fixation [21] and high cup abduction angle to be etiologies of failure in metal-on-metal devices [24]. Although the power of this study is inadequate to make a definitive statement regarding etiology, there does not appear to be a correlation between abduction angle and failure. There was also no correlation between sex and implant dysfunction.

The Depuy recall notification suggested that smaller acetabular components (<50 mm in diameter and implants in female patients) demonstrated the highest failure rate. As the ASR subhemispheric cup ranges in coverage based on size (144° in the smallest cups and 165° in the largest), the implication is that the smaller coverage arcs may lead to higher failure rates. This theory is supported by recent work by Griffin et al [25], which describes the "effective cup angle," or coverage arc, from 6 different metal-on-metal implants on the market. They demonstrate that the "effective cup angle" of a 44-mm ASR of 151.8° is smaller than that of the BHR (Smith and Nephew, Memphis, Tenn), Durom (Zimmer), Cormet (Stryker, Kalamazoo, Mich), Conserve (Wright Medical, Arlington, Tenn), and Magnum implants (Biomet, Warsaw, Ind; mean, 160.5°) and markedly less than the traditional 180° arc of a conventional acetabular component [25]. Griffin et al [25] conclude that because cups with smaller coverage arcs are more susceptible to edge loading, cup placement is paramount because these cups have less tolerance for suboptimal positioning. Although we acknowledge this phenomenon of edge loading at less extreme positions (especially vertical cup placement) in cups with smaller functional arcs, our study did not demonstrate a correlation between cup position and failure. In addition, because the series presented here had no shells smaller than 50 mm, which correspond to a 156° or greater coverage arc, we believe that the limited tolerance for cup position is potentially less of an issue in this cohort. The high failure rate in this series despite a cohort with only larger cups (and therefore larger coverage arcs) and no cups with positioned outside the targeted range suggests that there are additional factors involved in the poor results noted with this implant.

Other possible modes of failure include inadequate cup fixation because of decreased ingrowth into a CoCr monoblock acetabular cup. At revision, the failed acetabular components demonstrated the absence of stable bony ingrowth. It is possible that the increased stiffness of the component may affect achieving stable bony ingrowth. Based on our 2 late failures of fixation, this is difficult to assess. To our knowledge has been no proposed mechanism for squeaking in large-diameter metal-on-metal THA components. There is concern that during insertion of a press-fit monoblock acetabular that the component may deform during insertion altering the clearance of the bearing and possibly causing bearing seizure and squeaking. This phenomenon has been described in Pinnacle cups placed with a press fit technique as greater than 90% of the cups demonstrated measurable deformation [26]. Although the Pinnacle cup is titanium and thus more susceptible to deformation, the ASR is also at risk because it is a thin, monoblock cup. In addition, the nonhemispheric ASR may be especially susceptible to deformation when impacted into an acetabulum that has been reamed with hemispheric reamers.

A possible etiology for the observed pain and grinding is soft tissue impingement. As the ultralarge-diameter femoral head implanted may exceed the diameter of the native femoral head, a sharp transition at the anterior edge of the oversized prosthetic femoral head provides a potential site for iliopsoas/capsular irritation and impingement. In this cohort, the revision procedure undertaken for persistent groin pain involved downsizing the femoral head, converting to a modular titanium and polyethylene component, and performing an iliopsoas release. This has resulted in resolution of symptoms. Although the most common cause of iliopsoas irritation is a retroverted and/or uncovered acetabular component [27,28], that is not the case with these patients requiring revision. The patients reporting grinding have typically noted that it occurs with high flexion, abduction and internal rotation, which supports the iliopsoas as the source of symptoms [29]. This is undoubtedly an area in which further research is needed.

Weaknesses of the study include small size, nonrandomization and limited follow-up. Two-year follow-up is not a long enough period to observe the purported advantages of lower rates of bearing wear in the metal-on-metal group, although the high rate of early implant dysfunction renders this a moot point. In addition, bad surgical technique, inappropriate surgical indications, and ineffective postoperative care can all lead to poor outcomes in a single-surgeon series.

Nonetheless, there are also significant strengths in performing a single-surgeon series: there is consistency of surgical technique, relative surgeon experience with the implant, standardized indications, and standardized postoperative regimen. In addition, the senior surgeon in this series has had extensive experience placing uncemented acetabular components without auxiliary screw fixation before using the Depuy ASR prosthesis. The surgeon also has experience with hip resurfacing with another prosthetic design and has noted none of the issues noted with the Depuy ASR in his series of surface arthroplasties. Finally, this single-surgeon cohort of patients was followed up longitudinally for a minimum of 2 years postoperatively with a validated outcome metric.

Specifically, patients with Depuy ASR XL implants need to be followed up more closely than patients with other implants. The failure rate is unusually high, and the index of suspicion with which we evaluate these implants needs to correspond to that. In addition, the alarming failure rate of this implant challenges the arthroplasty community to develop a clear algorithm for evaluating underperforming metal-on-metal implants. In broader terms, longer-term, prospective randomized studies are indicated to assess the various bearing couples available. These poor early results with a relatively new implant design again highlight the need for a national joint registry because an implant such as this with a poorer-than-expected survivorship could have been more quickly identified and removed from the market. The process of how new products are brought to market and widely released needs to be reevaluated. What was a well intended design improvement aimed to reduce dislocations and improve longevity has instead yielded a product that will increase the revision burden for THAs far in excess of the implant designs it sought to replace.

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