Ten- to 15-Year Clinical and Radiographic Results for a Compression Molded Monoblock Elliptical Acetabular Component

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Abstract: The aim of this study was to report the long-term results from a previously published midterm follow-up of a titanium monoblock, elliptical acetabular component. A total of 258 primary total hip arthroplasties (212 patients) with a monoblock, acetabular component were followed up for a mean period of 11.1 years (10-15). Average yearly wear rate was 0.08 mm/y (0.0009-0.32). Acetabular radiolucencies were present in 6 hips (2.4%); all were nonprogressive and present in acetabular zone I. Acetabular osteolysis was present in 5 patients (5 hips, 1.9%); all cups were stable. Four acetabular components were revised, 3 because of recurrent instability. No acetabular components were revised for polyethylene wear or dissociation, acetabular osteolysis, loosening, or deep infection. This monoblock design demonstrates excellent long-term survival and low rate of osteolysis. **Keywords:** monoblock, acetabular cup, polyethylene wear, osteolysis, backside wear.

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Background

In modern primary total hip arthroplasty (THA), monoblock uncemented acetabular components have been used as an alternative to cemented polyethylene and uncemented modular acetabular implants, with or without screws for supplemental fixation, in an attempt to enhance initial fixation and reduce the rate of osteolysis [1-6]. Cemented all-polyethylene components may be technically difficult to implant and have a higher rate of loosening [7]. Concerns have been noted also with modular acetabular components. Poor locking mechanisms have been blamed for polyethylene liner dislodgement; backside wear; and, in addition, metallic debris [8-11]. Screw holes may provide a conduit for polyethylene particles and potentially lead to pelvic

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http://dx.doi.org/10.1016/j.arth.2012.05.013

osteolysis [12]. Screws also produce fretting interfaces, which may increase metallic debris.

The rationale behind the design of a monoblock component focuses on the following features. The monoblock design eliminates the modularity of the metal and polyethylene. The polyethylene is compression molded into the shell, thus reducing the backside micromotion and polyethylene wear and the metallic debris from locking rings. In addition, it allows for 100% uniform support, improving contact stresses on the polyethylene, ideally leading to less wear. The monoblock cup has a hemi-ellipsoid geometry shape; its equator diameter is 2 mm larger than its polar diameter. It is inserted using the press-fit technique, allowing for a solid press fit. This technique maximizes the initial stability and fixation, and minimizes the risk for bottoming out in the bony acetabulum before a press fit is obtained on the acetabular rim. The lack of screw holes maximizes also the surface area for ongrowth and, along with solid fixation, eliminates the conduits for migration of wear particle.

Coupled with these advantages, monoblock implants introduce the potential disadvantages of the inability to see if the cup is fully seated during implantation, to easily exchange a polyethylene liner, to augment with adjoin fixation (screws) to optimize the stabilization of the component, and to modify the orientation of an elevated liner at final implantation [4].

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Submitted July 27, 2011; accepted May 14, 2012.

The Conflict of Interest statement associated with this article can be found at http://dx.doi.org/10.1016/j.arth.2012.05.013.

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The senior author of this article (TPS) has used a monoblock acetabular component (Implex, Allendale, New Jersey) since 1995. This component is composed of Ti6V4Al alloy, and the beads are commercially pure titanium. The beads are between 200 and 300 mm in size; the coating consists of 3 layers of beads. The polyethylene is GUR 1020 (Perplas Medical Ltd, Lancashire, UK), packaged in a nitrogen atmosphere and gamma radiation sterilized to a nominal 30 kGy (30 Mrad). We previously described the midterm results of this acetabular component [13] that demonstrated excellent survivorship; no acetabular components were revised for polyethylene wear or dissociation, acetabular osteolysis, or loosening. Average yearly wear rate was 0.079 mm (range, 0-0.31).

The purpose of the present study was to provide a concise follow-up, at a minimum of 10 years, of this acetabular component with an emphasis on the polyethylene wear rates, rates of progressive periacetabular radiolucent lines, acetabular osteolysis, and acetabular loosening, and complications such as infection, dislocation, and heterotopic ossification.

Materials and Methods

A consecutive series of patients who presented to the senior author's offices between 1995 and 1999 for primary THA were considered eligible for the study. The following patients were excluded from the study population: patients with severe acetabular dysplasia; patients with severe bone loss on the acetabular side, requiring screws for acetabular fixation; or patients in whom the press fit was inadequate intraoperatively and the shell had to be converted to a shell with screws. Data on all patients were collected prospectively for a minimum of 10 years or until failure.

All operations were performed at a single institution (Hospital for Special Surgery) by the senior author



Fig. 1. Elliptical monoblock acetabular component (Implex) with cutout showing the reverse taper locking mechanism.

(TPS). All patients had a 28-mm-diameter femoral head. The Implex porous-coated elliptical acetabular component was used in all patients (Fig. 1). Polyethylene thickness was at least 7 mm in all cases. Overreaming by 1 mm to the entire hemisphere of the acetabulum was performed, allowing the implant to bottom out to the acetabular floor and achieve a tight peripheral rim fit that is 1 mm underreamed to the elliptical shell rim. Most patients (95%) had cemented femoral reconstructions with either the Cobrex (Implex) or the Reality (Kinamed, Warsaw, Indiana) femoral component.

Postoperatively, patients had an anteroposterior radiograph of the pelvis and lateral radiograph of the affected hip performed. Patients had anteroposterior and lateral radiographs performed at their most recent follow-up. All radiographs were digitized and compared by using the Martell hip analysis software as previously outlined in the midterm results study [13]. Radiographs were examined for evidence of osteolysis or component loosening. Complications such as dislocation, infection, acetabular progressive radiolucent lines, polyethylene dislodgment, bead shedding, and heterotopic ossification were recorded.

Results

A total of 212 patients with 258 hips were available with a mean radiographic follow-up of 11.1 years (range, 10-15 years). Patient demographics and wear rates are summarized in Table 1. There were no instances of polyethylene liner dissociation and no cases of bead shedding.

Clinical Results

Although all cups in this series were implanted in the safe zone, there were 4 episodes of dislocation. Three acetabular components were revised for instability. None of these 4 patients who dislocated had any risk factor for dislocation. Two dislocations were anterior and likely due to component malposition. One of these cases was revised to a constrained component, whereas the other one had repositioning of the acetabular component. One dislocation was posterior and occurred within

Table 1. Patient Demographics and Mean Annual Wear Ra	ate
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Mean age at surgery, y (range)	61.2 (29-87)
Male:female	79:133
Mean follow-up,	11.1 (10-15)
y (range)	
BMI (range)	26.2 (17.7-37.7)
Diagnosis	Osteoarthritis, 200; avascular necrosis, 19; rheumatoid arthritis, 10; other, 29
Mean annual wear rate, mm/y (range)	0.08 (0.0009-0.32)

the first 6 weeks, after hyperflexion and internal rotation; the patient underwent a closed reduction and had no further instability, not requiring further surgical treatment. The fourth one was revised approximately at 10 years after index surgery because of gait imbalance attributable to acquired neurological disorder. None of the 4 cases have had any further episodes of instability. No acetabular components were revised for polyethylene wear, acetabular osteolysis, or aseptic loosening. Three femoral components were revised because of aseptic loosening at 5, 6, and 8 years postimplantation, respectively. One patient underwent revision of both components because of periprosthetic femoral fracturedislocation. No hips developed deep infection requiring removal of components.

Radiographic Results

Four acetabular components were revised without completing the minimum 10-year follow-up. Thus, 254 hips were available for radiographic analysis. The annual linear wear averaged 0.08 mm/y (range, 0.0009-0.32 mm/y). Acetabular radiolucencies were present in 6 hips (2.4%). All radiolucencies were less than 1 mm in width, were nonprogressive, and were present in acetabular zone I, as described by DeLee and Charnley [14] (Fig. 2). No acetabular components had a complete radiolucent line. None of these radiolucencies was associated with the presence of osteolysis at the latest follow-up. Acetabular osteolysis was present in 5 patients (5 hips, 1.9%). The osteolytic lesions were present in the ischium in 5 hips and in the pubis in 3 hips (3 patients had 2 lesions: ischium and pubis). No retroacetabular lesions were observed (Fig. 3); all cups were stable without clinical consequences. The incidence of heterotopic ossification was assessed in the anteroposterior view at the latest follow-up and graded according to Brooker classification. Heterotopic ossification was



Fig. 2. Nonprogressive radiolucent line in acetabular zone I at 10-year follow-up.



Fig. 3. Anteroposterior radiograph showing one osteolytic lesion in the ischium, without affecting the cup stability. The patient was asymptomatic at latest follow-up.

observed in 20 hips (8%). Heterotopic bone was graded as class I in 11 (4.5%) hips, class II in 5 (2%) hips, class III in 3 (1%) hips, and class IV in 1 hip (0.5%). No reoperation due to heterotopic ossification was performed. No polar dome gaps exceeding 1.5 mm were seen on postoperative radiographs (Fig. 4).

Discussion

In this cohort of patients, the monoblock titanium acetabular component had an excellent overall longterm survivorship at a minimum of 10-year follow-up. Monoblock acetabular components have been criticized because of the surgeon's inability to modify the orientation of an elevated liner at final implantation, so as to fine-tune acetabular version and potentially



Fig. 4. Anteroposterior radiograph made at the final follow-up evaluation, 15 years postoperatively, showing no signs of acetabular osteolysis or loosening.

minimize instability. The rate of dislocation in this series was 1.5% including both early positional and late dislocations (mean follow-up, 11.1 years; range, 10-15). In all cases, a posterolateral approach was used with enhanced soft tissue repair; the dislocation rate reported is lower than in most reported series [15,16]. A second concern with monoblock acetabular components is the inability to determine if the shell is fully seated. Although there was a rate of polar dome gaps of 6% in the first series of patients [13], this did not lead

to any adverse clinical consequences, such as acetabular component migration or loosening. At the latest radiological follow-up, no polar dome gaps exceeding 1.5 mm were observed.

Monoblock shells do not have the ability to augment with adjoin fixation to stabilize the component and consequently may not seat properly or lack initial stability. Therefore, the surgeon may need to re-ream and convert the shell to one with screws, potentially wasting another component. During the study period, 2 cups had to be converted to shell with screws because of insufficient fixation intraoperatively; these 2 patients (2 cups) were not included in the final analysis.

By overreaming by 1 mm to the entire hemisphere of the acetabulum, the implant was allowed to bottom out to the acetabular floor and achieve a tight peripheral rim fit that is 1 mm underreamed to the elliptical shell rim. The tight peripheral rim, depending on acetabular anatomy and bone characteristics, could potentially lead to either acetabular fracture in osteoporotic bone or inferior seating of the component. Although monoblock elliptical components have been associated with higher intraoperative fracture rate compared with elliptical modular cups and hemispherical modular cups [17], there were no intraoperative acetabular fractures observed in this specific series. In addition, no components were observed to be inferiorly seated. Both were accomplished by carefully reaming until the medial wall without increasing the reamer size, by focusing on reaming the peripheral rim of the acetabulum with the last size reamer, and by not leaving the superior roof of the acetabulum flattened or underreamed, which could block the component from fully seating.

Sintered bead coatings allow for excellent osseointegration; however, there have been problems with bead shedding [18]. There was no early or late bead shedding in this series, which is consistent with the findings of our midterm series [13]. Locking mechanisms in modular designs have improved significantly. However, liner dissociation and backside wear may be a problem with some modern designs but not all [8-10]. The reverse taper lock of the monoblock cup allows for a very secure fit between the titanium shell and the polyethylene liner when fabricated. There were no instances of liner dissociation in our latest series; and the rate of acetabular osteolysis was very low (1.9%), implying that there was minimal backside wear.

Polyethylene wear can be measured with the highest accuracy by using the Martell hip analysis software [19]. The 2-dimensional total penetration of the head measurements using anteroposterior radiographs have been validated as a way to measure polyethylene wear in vivo [20-22]. Studies have demonstrated that 81% to 95% of the total wear can be estimated by

measuring penetration on the anteroposterior radiograph only, indicating that direction of the wear vector is almost coplanar with the frontal plane [20,21]. Wear rate and associated incidence of acetabular osteolysis comparisons with other uncemented acetabular components in the literature are outlined in Table 2. The present study showed an average annual linear polyethylene wear rate of 0.08 mm/y (range, 0.0009-0.32 mm/y), which is consistent with the findings of our previously published study (0.079, 0-0.31) [[13], and lower compared with rates reported in other studies in the literature (Table 2). This study did not separate wear over the initial run-in period from the overall wear rates. Assuming that wear rates are higher in the first year, allowing for this initial run-in phase, our overall wear rates may overestimate the true long-term wear rates. Nevertheless, the monoblock design used in this series has greater liner-shell conformity and less liner-shell micromotion than the modular components [8]; thus, it is expected to have a decreased bedding-in process [22]. These design factors could have favorably altered the stress distribution throughout the liner and could have thereby decreased wear.

Numerous studies have shown that annual polyethylene wear rates of more than 0.1 mm/y are associated with osteolysis, whereas wear rates of less than 0.1 mm/ y do not seem to be associated with osteolysis (Table 2). In our latest series, the prevalence of radiographic evidence of acetabular osteolysis was 1.9% and did not influence the stability of these components at an average follow-up of 11.1 years. This low rate of acetabular osteolysis corresponds with the average annual linear polyethylene wear rate of 0.08 mm/y reported in our study. The absence of retroacetabular osteolysis—medial and superior to the cup—can be justified by the lack of screw holes and central insertion holes in the monoblock component. Claus et al [30] studied the prevalence of periprosthetic osteolysis associated with modular acetabular cups with and without holes in patients who were followed for a minimum of 10 years. All 126 AML monoblock cups (DePuy, Warsaw, Indiana) without holes and 112 Arthropor modular cups (Joint Medical Products, Stamford, Connecticut) with holes articulated with 32-mm heads. The prevalence of acetabular and femoral osteolysis was similar in both groups (47%). However, retroacetabular lesions were predominantly associated with cups with holes; and periacetabular lesions were predominantly associated with cups without holes [30].

Our series and studies outlined in Table 2 are limited in that they used plain radiographs in their radiographic evaluation, and it is well acknowledged that plain radiographs underestimate the true prevalence of osteolysis [31-35]. It has been demonstrated in a cadaveric study [36] that radiographs underestimate the detection of osteolytic lesions by as much as 26.4%. In the current body of literature, computed tomographic (CT) studies have demonstrated the excellent survivorship of monoblock components in relation to the development of acetabular osteolysis after THA. Meneghini et al [37] reported CT results on 9 monoblock porous tantalum cups at a mean followup of 7.7 years and found no evidence of osteolysis. Similarly, Moen et al [38] found no evidence of osteolysis on CT scan on 51 monoblock porous tantalum cups at a mean follow-up of 10.3 years (range, 9.6-10.8). The results of these 2 studies are consistent with the findings of our series and underline the importance of the combination of the monoblock design of the cup and the porous tantalum in the implant. By eliminating potential conduits for the propagation of wear particles and enhancing bone ingrowth to help seal off the effective joint space, a

able 2. Annual Wear Rates and Incidence of Acetabular Osteolysis for Different Noncemented Acetabular Components

Investigator	THA Acetabular Component Type	Mean Follow-Up, y (Range)	Acetabular Annual Wear Rate, mm/y (Range or SD)	Incidence of Acetabular Osteolysis (%)
Present study	Monoblock Elliptical (Implex)	11.1 (10-15)	0.08 (0.0009-0.32)	1.9
Mayman et al [13]	Monoblock Elliptical (Implex)	7.2 (5-9)	0.079 (0-0.31)	0
Young et al [8]	Monoblock Porous-Coated (DePuy)	5.3 (3.8-6.8)	0.11 (±0.13)	0
Della Valle et al [23]	Modular Trilogy (Zimmer, Warsaw, Indiana)	5.3 (4-7)	0.09 (0-0.45)	1.7
Chen et al [9]	Modular Hemispheric Duraloc (DePuy)	6.8 (5-8.2)	$0.10 (\pm 0.14)$	2.2
Ito et al [24]	Modular Omnifit PSL (Howmedica Osteonics, Allendale, New Jersey)	8.6 (5.2-12.1)	0.18 (0.02-0.42)	5
Kim et al [25]	Modular Hemispheric Duraloc (DePuy)	9.8 (8-11)	0.12 (0.01-0.24)	9
Udomkiat et al [26]	Modular Anatomic Porous Replacement (APR, Sulzer Orthopaedics, Austin, Texas)	10.2 (7-11.9)	0.16 (±0.13)	3.6
Young et al [8]	Modular Hemispheric Duraloc (DePuy)	5.5 (3.8-8)	0.16 (±0.08)	5
Archibeck et al [27]	Modular Hemispheric Harris-Galante II (Zimmer)	10 (8-11)	0.16 (0-0.47)	16
Barrack et al [28]	Modular Hemispheric Long-term Stable Fixation (LSF, Implant Technology, Secaucus, New Jersey)	6 (5-8)	0.10 (0-0.5)	11
Crowther et al [29]	Modular Harris-Galante I (Zimmer)	11 (9-14)	0.15 (0.02-0.59)	23

monoblock porous tantalum acetabular cup can further diminish the incidence of osteolysis. Because of the excellent survivorship of the monoblock titanium component, at minimum 10-year follow-up, and the tantalum's unique mechanical properties and potential for bone ingrowth, the senior author (TPS) has used the monoblock porous tantalum acetabular cup since 2005 with excellent midterm results.

In conclusion, the monoblock titanium porous-coated acetabular component has a very low complication rate at a minimum 10-year follow-up. Furthermore, it is associated with the lowest conventional polyethylene wear rate reported in the current literature and a very low incidence of acetabular osteolysis. The inability to change the direction of the elevation in the liner and the inability to see when the component is fully seated did not lead to higher dislocation rates, component migration, or component loosening.

Acknowledgment

We would like to thank Nikolaos Chatzoudis, MD, for his assistance with data collection and database management.

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