

Low Frequency of Early Complications With Dual-mobility Acetabular Cups in Cementless Primary THA

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Abstract

Background Dislocation complicates 1% to 5% of primary total hip arthroplasties (THAs). As a result, some surgeons consider dual-mobility articulations, which are usually used in the revision setting to decrease the likelihood of dislocation, as an option for primary THA. However, few studies have evaluated their use in this setting.

Questions/purposes (1) What is the cup survivorship when the dual-mobility articulation is used in the setting of primary THA? (2) What are the clinical outcomes with this

approach? (3) What are the radiographic outcomes? (4) What are the complications of dual-mobility articulations in primary THA?

Methods Between 2011 and 2013, the five participating surgeons performed 495 cementless primary THAs. During that time, one of the five surgeons used dual-mobility articulations for all THAs, and the other four used it whenever the acetabular cup size was 52 mm or greater to enable a 28-mm head. Of the 495 patients, 453 (92%) were performed using this device. Smaller patients were treated with a standard THA. Of the 453 patients, a total of 43

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Each author certifies that his or her institution approved or waived approval for the human protocol for this investigation and that all investigations were conducted in conformity with ethical principles of research.

This work was performed at the Rubin Institute for Advanced Orthopedics, Center for Joint Preservation and Replacement, Sinai Hospital of Baltimore, Baltimore, MD, USA; Bonutti Clinic, Effingham, IL, USA; Mount Sinai Beth Israel, New York, NY, USA; University of Louisville Adult Reconstruction Program, Louisville, KY, USA; and OrthoIndy, Greenwood, IN, USA.

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patients (10%) were lost to followup before the 2-year minimum. The resulting 410 patients who were included in the analysis (164 men, 246 women) had a mean age of 64 years (SD, 12 years). The mean followup was 3 years (SD, 0.7 years). We performed Kaplan-Meier analyses to assess survivorship to aseptic failure and all-cause acetabular component survivorship. Clinical outcomes were evaluated using the Harris hip score (HHS); radiographs were assessed for cup migration, progressive radiolucencies, and positional changes of the components; and any surgery-related complications were recorded.

Results The survivorship to aseptic failure and all-cause acetabular component survivorship was 99.8% (failures, $n = 1$) (95% confidence interval [CI], 4.517–4.547) and 99.3% (failures, aseptic, $n = 1$; septic, $n = 2$) (95% CI, 4.494–4.543); one hip had trunnion notching caused by impingement of a malpositioned cup, which was treated with revision of the cup and stem; and two patients had periprosthetic infections that were treated with two-stage revisions. There were no dislocations. Patients had a mean HHS of 94 (SD, 6) at final followup. On radiographic evaluation, no progressive radiolucencies or positional changes of the components were identified. Surgical complications included one traumatic avulsion of the abductors, one traumatic avulsion of the greater trochanter, which was repaired without revision of any of the components, and one loose femoral stem, which required revision of the femoral component only.

Conclusions Dual-mobility cups in primary THA yield seemingly comparable survivorship and complications to conventional THA bearings at short-term followup. Because serious complications have occasionally been reported with the use of these bearings, larger, longer term, comparative—and ideally, randomized—trials will be needed to establish the superiority of one approach over the other. Until or unless such studies show the superiority of dual-mobility designs for primary THA, we recommend that in the setting of uncomplicated primary THA, dual-mobility articulations be used only in centers that track their results carefully or in research protocols.

Level of Evidence Level IV, therapeutic study.

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Introduction

Dislocation after THA remains a prominent concern, because its frequency is reported to range from 1% to 5% [4, 25]. With the increasing utilization rates of THAs [28], there is also an expected subsequent rise in the number of dislocations. Numerous factors may contribute to the frequency of this complication, including component design, patient characteristics, and surgical technique [27]; it still results in many major revision procedures.

To improve stability, implant modifications have included the use of constrained acetabular liners and large-diameter femoral heads. However, although constrained liners may aid in soft tissue tensioning and be cost-effective, they have been associated with a high risk of failure [12]. In addition, although large-diameter femoral heads, particularly those greater than 32 mm, are associated with greater impingement-free ROM [9] and a lower dislocation risk [4, 7], these designs are not as effective in decreasing instability as once hoped nor can they be used in all patients as a result of size limitations. Furthermore, both constrained liners and large-diameter femoral heads have been linked to complications such as accelerated polyethylene wear rates and altered bone-prosthesis osseointegration [22, 30]. Because of these, dual-mobility articulations have emerged as a potential solution for THA instability. These articulations work by containing a three-component and three-joint system: a socket, a free (not fixed) polyethylene liner, and a head. Dual-mobility articulations are commonly used in the revision setting [17]; however, there is a relative paucity of studies evaluating their use in primary THA [3, 5, 6, 8, 10, 11, 13, 15, 16, 20, 24, 26]. The present study similarly evaluates a dual-mobility articulation; however, it is different in design from most of the aforementioned studies. Although there are advantages to this design, it is not without its disadvantages such as polyethylene wear and intraprosthetic dislocation (IPD) (unique to these articulations). Intraprosthetic dislocation may lead to others such as femoral head wear, metallosis, and impingement, which may cause implant failure and necessitate revision surgery [1, 2, 14, 16, 18, 19, 21, 23].

Therefore, we asked: (1) What is the cup survivorship when the dual-mobility articulation is used in the setting of primary THA? (2) What are the clinical outcomes with this approach? (3) What are the radiographic outcomes? (4) What are the complications of dual-mobility articulations in primary THA?

Patients and Methods

We retrospectively evaluated longitudinally maintained databases from five institutions, which contained all

patients undergoing primary THA who had dual-mobility articulations between January 2011 and December 2013.

During this study period, the five participating surgeons performed 495 cementless primary THAs. Patients who (1) underwent primary cementless THA; (2) had dual-mobility articulations; and (3) had a minimum followup of 2 years were included in this study. Of the 495 patients, 453 (92%) were performed using the dual mobility. One of the five surgeons used dual-mobility articulations for all THAs, and the other four used it whenever the acetabular cup size was 52 mm or greater to enable a 28-mm head. Of the 453 patients on whom this device was used on, 43 patients (10%) were lost to followup before the 2-year minimum. Four hundred ten patients were included in the analysis (164 men, 246 women) who had a mean age of 64 years (SD, 12 years) and a mean body mass index of 31 kg/m² (SD, 7 kg/m²) (Table 1). The mean followup was 3 years (SD, 0.7 years). Patient data were collected preoperatively and at yearly followup points thereafter. Demographic, clinical, radiographic, and patient-reported outcomes were obtained from medical records, pre- and postoperative evaluations, and office charts.

All of the primary THAs were performed by five fellowship-trained, adult reconstructive surgeons (MAM, SFH, ALM, FRK, PMB). In addition to undergoing a cementless primary THA with dual-mobility articulations (Modular Dual Mobility; Stryker, Mahwah, NJ, USA), all patients received uncemented tapered-wedge femoral components with circumferential plasma spray coating and hydroxyapatite (Accolade TMZF or Accolade II; Stryker).

The dual-mobility articulations used in this study consisted of three components: a socket, a free (not fixed) polyethylene liner, and a metal head. The acetabular shell consists of titanium alloy with a porous, plasma-sprayed coat of titanium and hydroxyapatite on the outer surface, and a bearing surface of cobalt-chrome with screw holes for additional fixation, if deemed necessary by the surgeon. The polyethylene liner in the articulation consisted of highly crosslinked, ultrahigh-molecular-weight polyethylene.

Table 1. Baseline characteristics of the primary modular dual-mobility cohort

Demographic characteristic	Number (%)
Total	410
Sex	
Men	164 (40)
Women	246 (60)
Body mass index (kg/m ²) (SD)	31 (7)
Age (years) (SD)	64 (12)
Harris hip score (range)	51 (15)

All procedures were performed through the anterolateral approach. For all patients, the surgeons aimed to achieve proper hip biomechanical properties by maintaining the center of rotation of the hip. Intraoperatively, after placing the components, stability was confirmed by ensuring that no dislocation occurred during assessment of functional ROM (30° of hip abduction and adduction, 40° of internal and external rotation, and greater than 110° of flexion). All surgeons aimed to place the cups with a less than 45° acetabular opening angle; however, angular measurements were not recorded.

Variables collected included age, gender, body mass index, laterality of surgery, followup dates, revision surgeries, radiographic assessments, complications, and Harris hip scores (HHS). These data were gathered from medical records, pre- and postoperative evaluations, and office charts.

Statistical Analysis

Using the Kaplan-Meier analysis, survivorship to aseptic failure and all-cause survivorship of the cup were calculated to assess acetabular component longevity. Clinically, functional outcomes were assessed using the HHS system. These scores were recorded preoperatively and yearly thereafter. At latest followup, the mean HHS was determined.

For radiographic analysis, standard AP radiographs of the hip and Lauenstein lateral radiographs were obtained ad hoc and evaluated postoperatively and at 1- and 2-year visits by the operating surgeons to assess for cup migration, progressive radiolucencies, or positional changes in the cup or stem. In addition, we assessed the femoral component for circumferential radiolucencies on the femoral side in addition to subsidence and angular change. Assessments of the radiographs were performed by five of the authors (PMB, SFH, ALM, FRK, MAM). Component loosening was defined as the presence of subsidence of (> 2 mm) or an angular shift (> 3°) [29]. Progressive radiolucency was defined by location, size, and temporal progression. If nonprogressive radiolucency was found in the postoperative radiograph, it was not considered a complication. If a radiolucency progressed by > 1 mm in any of the zones around the acetabulum or femur, it was considered osteolysis.

Any complications related to the procedure were assessed and recorded, and they were categorized as either surgical or medical complications. In addition, we performed descriptive statistics to assess frequencies of complications.

All data were collected and entered into an Excel spreadsheet (Microsoft Corporation, Redmond, WA, USA).

Statistical analysis was performed using SPSS (IBM Corporation, Armonk, NY, USA). A cutoff *p* value of < 0.05 was set to determine statistical significance.

Results

The survivorship to aseptic failure (*n* = 1) (Fig. 1) and all-cause (aseptic, *n* = 1; septic, *n* = 2) (Fig. 2) Kaplan-Meier acetabular component survivorship were 99.8% (95% confidence interval [CI], 4.517–4.547) and 99.3% (95% CI, 4.494–4.543). There was one aseptic and two septic revisions. One hip had trunnion notching caused by impingement of a malpositioned cup, which resulted in revision of the cup and stem. Two patients developed a late infection, which were both treated with two-stage revision procedures.

With regard to clinical outcomes, the mean HHS at final followup was 94 points (SD, 6). Two patients reported HHS of ≤ 70. One patient did not have complications; however, the other patient was found to have a loose femoral stem, which is described subsequently.

On radiographic evaluation at 6-week and latest followup (3 years; SD, 0.7 years), no implants had a change in position in comparison to films taken within 6 weeks of surgery. There was no evidence of progressive radiolucencies.

Seven patients experienced complications. Surgical complications included one traumatic avulsion of the greater trochanter, which was repaired using a Dall-Miles cable system (Stryker). This did not result in revision of any of the components and the patient had a HHS of 96 at 24-month followup. One patient had a loose femoral stem, which was revised with a modular stem. This patient had a

HHS of 64 at 36-month followup. One patient had traumatic avulsion of the abductor muscles, which was treated with surgical repair. This patient had a HHS of 100 at 3-year followup. No patients in the series had a dislocation. Three patients developed deep vein thromboses and one patient had pulmonary embolism. All were treated pharmacologically and had no subsequent events.

Discussion

Dual-mobility articulations may help decrease instability after THA [3, 5, 6, 8, 10, 11, 13, 15, 16, 20, 24, 26]. This is likely the result of the increased effective size of the femoral head as well as the expanded impingement-free ROM. There is a relative paucity of studies evaluating their use in primary THA [3, 5, 6, 8, 10, 11, 13, 15, 16, 20, 24, 26]. In the present study, we similarly evaluated a dual-mobility articulation; however, it is different in design from most of the aforementioned studies. Although there are advantages to dual-mobility implants, they are not without disadvantages such as polyethylene wear, loosening, and the unique complication of IPD [1, 2, 14, 16, 18, 19, 21, 23]. We therefore asked: (1) What is the cup survivorship when the dual-mobility articulation is used in the setting of primary THA? (2) What are the clinical outcomes with this approach? (3) What are the radiographic outcomes? (4) What are the complications of dual-mobility articulations in primary THA?

There are several limitations to this study. Even with 410 patients, the study was not large enough to comment on the true frequency of an uncommon event like dislocation. Although increasing the cohort size would be ideal, we feel that this article can serve as a starting point for

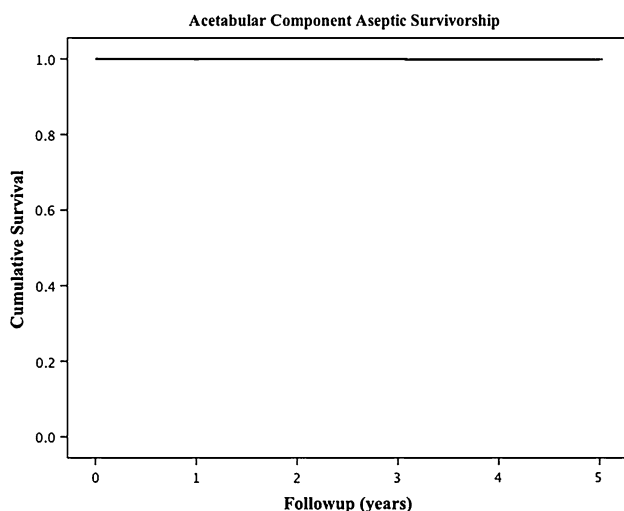


Fig. 1 The acetabular component aseptic survivorship is demonstrated using a Kaplan-Meier curve.

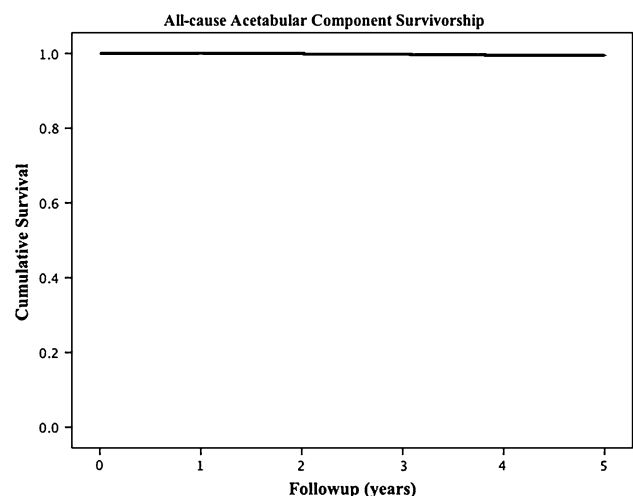


Fig. 2 The acetabular component all-cause survivorship is demonstrated using a Kaplan-Meier curve.

Table 2. Studies assessing dual mobility articulations in primary THA

Author, year (arranged chronologically)	Sample size	Minimum followup (years)	Cup	Dislocation (%)	Fixation technique	Polyethylene type
Farizon et al., 1998 [13]	135	10	Novae-1 cup (Orthodynamics Ltd, Gloucestershire, UK)	0.7	Cementless	N/A
Guyen et al., 2007 [15]	167	2	Saturne cup (Amplitude, Neyron, France)	0	Cementless	HMWPE
Bauchu et al., 2008 [3]	150	6 (mean)	Third-generation POLARCUP (Smith & Nephew Orthopaedics AG, Rotkreuz, Switzerland)	0	N/A	N/A
Hamadouche et al., 2012 [16]	168	5	Tregor unconstrained tripolar cup (Aston Medical, Saint Etienne, France)	2	Cementless	UHMWPE
Bouchet et al., 2011 [5]	105	1	Novae (Orthodynamics Ltd); Stafit (Zimmer GmbH, Winterthur, Switzerland); Avantage (Biomet, Valence, France); Gyros cups (DePuy, Warsaw, IN, USA)	0	Cementless	Not specified
Boyer et al., 2012 [6]	240	19	Novae tripodal (SERF) (Orthodynamics Ltd)	0	Cementless	UHMWPE
Prudhon et al., 2013 [26]	105	8 (median)	Quattro® (Groupe Lépine, Genay, France)	0.9	Cemented	UHMWPE
Epinette et al., 2014 [11]	437	2	Restoration ADM acetabular system (Stryker Orthopaedics, Mahwah, NJ, USA)	0	Cemented	HXLPE
Caton et al., 2014 [8]	105	10	Quattro® (Groupe Lépine, Genay, France)	0.9	Cemented	Standard
Epinette, 2015 [10]	143	2	Restoration ADM acetabular system (Stryker Orthopaedics)	0	Cementless	HXLPE
Mohammed et al., 2015 [20]	20	0.5	Serf Novae® Dual Mobility Acetabular cup (Orthodynamics Ltd)	0	Both	Not specified
Chughtai et al.*	410	2	Modular Dual Mobility (Stryker Orthopaedics)	0	Cementless	UHMWPE

* The present study; UHMWPE = ultrahigh-molecular-weight polyethylene; HXLPE = highly crosslinked polyethylene; N/A = not available.

other studies to see the short- to midterm results of this device. Additionally, it is important to note that 10% of patients were lost to followup; therefore, there may have been complications such as dislocation that were not captured. Patients with smaller acetabula were excluded by four of the five surgeons, which should be considered when interpreting the results. Furthermore, outcomes were assessed using only one questionnaire (HHS). However, the HHS contains subjective and objective parameters, thereby providing reasonable assessment of the patient. Moreover, this study had only a short followup period; therefore, it is important to emphasize the survivorship, minimal complications, and lack of IPD in this study may be a function of time and could potentially be unmasked by a longer followup study. Additionally, problems such as osteolysis or loosening may arise in the future, but could not be detected with a short-term study. Thus, our followup demonstrates that the short-term results with this device are no worse than what is on the market already. Although this study is similar to other studies in its evaluation of the dual-mobility articulations, it extends the current literature by evaluating a design that is different from that of most other studies (Table 2).

Several other studies have also illustrated good aseptic survivorship and lower dislocation proportion with the use of dual-mobility articulations in primary THAs (Table 2). In an analysis of 384 dual-mobility hips, Philippot et al. [24] observed a 4% dislocation proportion and cup survivorship of 97% at a minimum followup of 12 years. Similarly, Farizon et al. [13] conducted a study examining 135 cementless dual-mobility hips and found a 0.7% dislocation proportion at a minimum followup of 10 years with 95% implant survivorship at 12 years. In addition, Epinette [10] analyzed 143 cemented dual-mobility primary THAs, which showed 100% survivorship at minimum of 2 years postoperatively with no reported dislocations. Additionally, Hamadouche et al. [16] reviewed 168 cementless dual-mobility hips and found that 2% experienced dislocation at a minimum followup of 5 years with a survivorship proportion of 94% at 7 years. In an analysis of 150 dual-mobility hips, Bauchu et al. [3] reported that no patients experienced dislocation at a mean followup of 6 years. At 7 years, the proportion of cup survivorship was 97%. Similarly, Boyer et al. [6] analyzed 240 cementless dual-mobility hips and found no dislocations with 80% cup survivorship at a minimum followup of 18 years.

Furthermore, Guyen et al. [15] performed a study on 167 dual-mobility hips and reported no dislocations at a minimum followup of 2 years with a 5-year cup survivorship proportion of 96%. Moreover, Epinette et al. [11] analyzed 437 primary cemented THAs and noted a 100% cup survivorship for patients younger than 70 years of age and 99.7% for patients older than 70 years of age at minimum 2-year followup.

Similar to our study, Boyer et al. [6] reported a final followup mean HHS of 92 (SD, 1.9) in their retrospective study of 240 hips with a minimum followup of 18 years. Bauchu et al. [3] also reported an improvement in the mean Postel-Merle d'Aubigne score (from 9 to 17) in their study of 150 dual-mobility hips. Guyen et al. [15] reported improvement in HHS from preoperatively (mean, 40; range, 11–100) to 83 (range, 25–100) at the latest followup. Similarly, in the Epinette et al. [11] study, they reported mean HHS of 98 and 82 for the < 70 years of age and ≥ 70 years of age cohorts at final followup, respectively. In the Hamadouche et al. [16] study, the mean Merle d'Aubigné functional hip score increased from 11 (range, 6–16) preoperatively to 17 (range, 9–18) at latest followup.

Several studies have reported on radiographic findings of dual-mobility hips. Boyer et al. [6] radiographically analyzed 89 dual-mobility hips in their minimum 18-year followup study. They found two osteolytic lesions in De Lee and Charnley Zone I (3%) and six in Zone III (10%). However, implant loosening was not found. Additionally, a broken screw was found in one of the hips with Zone I osteolysis. Guyen et al. [15] reported migration of one (0.6%) noncemented acetabular component in addition to three fully hydroxyapatite-coated femoral components. As expected, because of short followup (range, 2–5 years), no tilting, migration, or IPD was recorded in the Epinette et al. [11] study. Similarly, in a study of 20 primary THAs in patients who received dual-mobility cups by Mohammed et al. [20], there was no evidence of loosening. In the Prudhon et al. [26] study, radiographic evaluation at the final followup did not reveal any cup migration or loosening. Of the 119 acetabular components in the Hamadouche et al. [16] study, there were no cases of cup migration. The Boyer et al. [6] study reported that 20 dual-mobility hips were revised because of cup aseptic loosening (8%), two hips were revised for septic loosening (0.8%), and 10 hips were revised for retentive failure (4%). Additionally, five hips were revised because of excessive liner wear (2%). Similarly, Bauchu et al. [3] reported revising two of their cups (1%) secondary to aseptic loosening. In the Epinette et al. [11] study, there was only a single patient with cup loosening; however, as mentioned before, it could be the result of the short followup in this study. Similarly, in the Prudhon et al. [26] study, the two (2%) acetabular component revision operations were

required related to loosening. The first case was because of aseptic loosening secondary to a Vancouver Type B fracture. The other case was secondary to septic loosening.

In terms of complications, Guyen et al. [15] reported five (3%) intraoperative fractures and one (0.6%) postoperative periprosthetic fracture of the femur. In the Farizon et al. [13] study, four implants (3%) were revised for mechanical failure after aseptic displacement of the cup. In the Hamadouche et al. [16] study, there four cases (2%) of IPD; orthopaedic surgeons should be aware of this complication associated with dual-mobility hips. During revision procedures, Langlois et al. [18] have described a case of a dual-mobility articulation with a dislodged femoral head with loss of sphericity secondary to IPD. Similarly, Banzhof et al. [2] also experienced a dislodged femoral head in a revised THA after attempting to reduce a dislocation with this device. Mohammed et al. [19] have reported severe metallosis after IPD in their case of a primary THA performed with a dual-mobility cup. Several other case reports have also demonstrated the potential complications of these designs [1, 2, 14, 16, 18, 19, 21, 23]. Further studies detail this important complication of dual-mobility articulations. In the present study, we experienced a single case of impingement, which is a complication that has been reported in other studies [16, 18].

Although not a variable in the present study, polyethylene wear was noted in several of the aforementioned studies. In the Hamadouche et al. [16] study, they used ultrahigh-molecular-weight polyethylene and found their revised inserts to have macroscopic signs of wear. Epinette [10] used highly crosslinked polyethylene and found a mean wear proportion of 0.03 mm per year in their cementless dual-mobility study. This may be the result of the frictional forces experienced at both interfaces of the polyethylene insert in dual-mobility articulations.

In this series, we found survivorship and complications similar to conventional THA bearings at short-term followup. Because serious complications have occasionally been reported with the use of these bearings [1, 2, 14, 16, 18, 19, 21, 23], larger, longer term, comparative—and ideally, randomized—trials will be needed to establish the superiority of one approach over the other. National registries may also help to inform this choice, and we look forward with interest to reports of the world's registries on this topic. Until or unless such studies show the superiority of dual-mobility designs for primary THA, we recommend that in the setting of uncomplicated primary THA, dual-mobility articulations be used only in centers that track their results carefully or in research protocols [3, 5, 6, 8, 10, 11, 13, 15, 16, 20, 24, 26]. Future research should be prospective, comparative, include larger sample sizes, and have longer term followup to evaluate the true outcomes of modular dual-mobility articulations.

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