The Dual-Mobility POLARCUP: First Results From a Multicenter Study

P. BAUCHU; O. BONNARD; A. CYPRÈS; A. FIQUET; P. GIRARDIN; D. NOYER [AU: PLEASE GIVE FIRST NAMES AND ACADEMIC DEGREES FOR EACH CONTRIBUTOR.]

abstract

Dislocation is a leading cause of revision after total hip arthroplasty (THA). To address this risk, dual-mobility technology was developed, which features a mobile polyethylene liner locked onto a femoral head and articulating in a metallic acetabular shell. This study reports clinical outcome data after implantation of the third-generation POLARCUP dual-mobility system. Primary THA procedures were performed in 150 patients. At 7.1 years, cumulative cup survival according to Kaplan-Meier was 97.4%. The mean Postel-Merle d'Aubigne score improved from 8.9 to 17.1 during the investigation. Two cups were revised at 5.4 and 6.4 years because of aseptic loosening. No dislocations were observed during follow-up. The current results confirm excellent early to midterm clinical outcomes for the POLARCUP Dual-Mobility System.

Total hip arthroplasty (THA) has been established as an extremely successful procedure for the treatment of advanced hip osteoarthritis. However, limitations in contemporary surgical technique and implant design continue to yield less than optimal clinical success. In particular, postoperative hip dislocation remains a leading cause of hip revision.[1,2] **[AU: Per journal style, please cite references in Reference section below to correspond with numbered references in text.]** This complication is reported to occur in upward of 3.9% of all primary THA patients,[1,3,4] with rates as high as 14.4% after revision THA.[1,5]

To address dislocation risk after THA, the dual-mobility concept was introduced by Bousquet and colleagues in 1976.[6] With dual mobility, a freely mobile polyethylene liner articulates within a metallic acetabular shell. Moreover, the design of the liner allows it to lock onto the femoral head, limiting dislocation. The femoral head rotates within the liner as with traditional designs, with the exception that during extended range of motion (ROM), the liner is able to rotate within the cup. This configuration allows for the reduced dislocation risk and improved ROM often limited to large femoral heads, while simultaneously supporting low friction and reduced implant wear.[6-11]

Long-term outcomes for early-generation dual-mobility cups have been promising. In a retrospective study reporting 10-year outcome data for 106 hips, Philippot et al[7] have reported a 94.6% survival rate. Similar results were obtained by Farizon[8] et al, who calculated a survival rate of 95.4% after 12 years in their cohort of 135 cases operated between 1980 and 1981. In a multicenter retrospective study reporting 17-year follow-up data for 438 hips, Philippot et al[12] reported a prosthesis survival rate of 89.2%, with a cup survival rate of 96.3%. In that study, there were 13 cases of aseptic loosening, 23 intraprosthetic dislocations, and 7 polyethylene revisions due to wear. Given the relative clinical success, the use of dual-mobility cups has been recommended for primary THA, particularly for patients at risk of postoperative hip instability.[7,8,12]

Despite excellent clinical results with early-generation dual-mobility hips, there are still design limitations. When the implant moves through full ROM, contact is made between the polyethylene liner and the neck of the femoral stem. This contact

Dr Bauchert is from Polyclinique des Minguettes, Vénissieux, France; Dr Bonnard is from Clinique du Tonkin, Villeurbanne, France; Dr Cyprès is from Clinique du Renaison, Roanne, France; Dr Fiquet is from Infirmerie Protestante, Cedex, France; Dr Girardin is from Hopital Beauregard, Montbrison, France; and Dr Noyer is from Cabinet Médical "le Caducée," Bourgoin-Jallieu, France.

Correspondence should be addressed to A. Fiquet, MD, Infirmerie Protestante, 1-3 chemin du Penthod, 69641 Caluire Cedex, France.

has the potential to erode the mobile liner, leading to revision.[6] To address this complication, the POLARCUP Dual-Mobility System was developed with a true third articulation, consisting of a mirror-polished femoral stem that makes contact with a chamfered liner adapted to the shape of the stem.[6]

Although this third-generation dual-mobility design is quite promising, clinical outcome data are necessary to evaluate its clinical performance. Therefore, the purpose of our investigation was to assess the safety and efficacy of the POLARCUP Dual-Mobility System, as determined by clinical, radiologic, and survivorship analyses. To our knowledge, this is one of the first complete reports of midterm clinical outcome data for this particular implant.

Materials and Methods

Beginning January 1, 2001, 150 consecutive primary THA procedures were performed by the investigators. The study is a multicenter retrospective analysis of this initial patient cohort. Functional performance of the hips was measured with the use of the Postel-Merle d'Aubigne score, and the radiographic outcome was assessed according to DeLee & Charnley on standard anteroposterior (AP) and lateral images. Ectopic ossifications were classified according to Brooker. Survival of the cups was studied using the method of Kaplan-Meier, with a 95% confidence interval and cup revision due to aseptic loosening as endpoints. **[AU: As meant?]**

The cohort included 61 males and, and mean patient age at the time of surgery was 69.0 ± 11.2 years (range, 40.3-90.5 years). Mean body mass index (BMI) of the patient sample was 27.2 ± 5.2 (range, 15.6-43.6). Of the patients, 131 had a diagnosis of primary osteoarthritis (87%), with 13 patients presenting with femoral head necrosis (8.7%) and 6 patients with secondary osteoarthritis (4%). Eighty-three (83) patients had a preoperative Charnley classification of A, whereas 56 were classified as B, and 11 classified as C. Preoperative Postel-Merle d'Aubigne score was 8.9 ± 2.3 (range, 3-15).

All patients were implanted with POLARCUP Dual-Mobility acetabular cups (Smith & Nephew Orthopaedics AG, Rotkreuz, Switzerland) (Figure 1) made of stainless steel **[AU: As meant?]** with a hydroxyapatite **[AU: As meant?]** coating. A posterior surgical approach was used in all cases. Of the cups, 140 were fixed without the use of screws, with 10 requiring the use of screws. One hundred seven hips were implanted with metal-on-polyethylene articulations, and 43 utilized a ceramic-on-polyethylene coupling. Size 28 femoral heads were implanted in 81 patients, and size 22 heads were implanted in the remaining 69 patients. The cups were combined with noncemented stems in 106 hips and with cemented stems in 44 hips. The Corail stem (Depuy Orthopaedics, Warsaw, Indiana) was used in 46 cases, with the Académie (Sanortho, Wilmington, North Carolina) used in 26, the Aura II (Biomet, Warsaw Indiana) in 24, the Symetric (Aston) **[AU: Please give location for Aston.]** in 22, the Viso (Serf) **[AU: Please give location for Serf.]** in 12 cases, and a Zweymuller stem in 8 cases. Twelve patients received various stems. After implantation of the POLARCUP, AP position was found to be between 40º and 50º for 125 patients, greater than 50º for 23 patients, and less than 40º for 2 patients. Intra- and perioperative complications included 6 cases of deep-vein thrombosis, 2 cases of edema, and 1 case each of embolism, neurologic problems, and phlebitis.

Results

At time of the investigation, 20 patients of the original cohort had died from causes unrelated to the intervention. Seven patients were lost to follow-up after surgery, and 2 cups had been revised, leaving 121 patients in the study. Mean follow-up for patients analyzed was 6.2 ± 0.8 years (range, 3.3 -7.1 years). The Postel-Merle d'Aubigne score improved during the investigation to 17.1 ± 1.2 (range, 12-18) at follow-up. In regard to radiographic results, there was no evidence of periprosthetic osteolysis or radiolucencies around the cup (Figure 2). Moreover, cup position remained unchanged for all patients during follow-up. One hundred (100) hips had class 0 Brooker classification, whereas 16 hips had class 1 and 5 hips had class 3.

Figure 1: POLARCUP Dual-Mobility Hip Prosthesis.

During follow-up, there were 4 observed complications, including 1 case each of infection, nerve paralysis, pelvic fracture, and femoral revision due to persistent thigh pain. Two cups were revised for aseptic loosening after 5.4 and 6.4 years, respectively, the first occurring after the patient had undergone chemotherapy for cancer.

With cup revision due to aseptic loosening as an endpoint, Kaplan-Meier survival rate at 7.1 years was 97.4% (95% CI: 89.4-99.4) (Figure 3).

Discussion

This investigation reports midterm clinical outcome data after THA using the POLARCUP Dual-Mobility Hip System. At a mean follow-up of 6.2 years postoperatively, the current third-generation dual-mobility design appears to be performing favorably.

As indicated previously, the primary design feature of dual-mobility cups is reduced risk of dislocation during full ROM. The results of our investigation support this feature because there were no observed dislocations during follow-up.

This finding supports data published previously for the POLARCUP. After the implantation of 450 prostheses for osteoarthritis, Fiquet and Noyer6 reported a final dislocation rate of 0.22%. These results are particularly favorable when compared with published dislocation rates for THA using conventional cups, which can be upward of 3.9%.1,5

In addition to reducing dislocation risk and improving ROM, dual-mobility has been reported to support low friction and reduced implant wear.6-11 It is well understood that the generation of polyethylene wear particles is positively correlated with periprosthetic osteolysis.13,14 Although there was no direct measurement of wear in our investigation, the presence of osteolysis would suggest premature wear as a primary factor. However, at follow-up, there was no evidence of osteolysis or implant loosening for any of the cups. As such, the generation of wear particles after implantation of the POLARCUP may be relatively low. Moreover, overall radiographic results were excellent for the current patient cohort. Although these data do suggest low wear, additional research is necessary to support this observation.

Figure 2: AP radiographs of a POLARCUP fixed with two screws through the flanges and two pegs in combination with an uncemented stem and a POLARCUP fixed without screws or pegs in combination with an uncemented POLARSTEM.

Both clinical function and implant survival rate in this study compare favorably with previous reports for dual-mobility systems. The mean Postel-Merle d'Aubigne score improved from 8.9 to 17.1, and similar improvements were reported by Philippot et al[7] (7.1 to 15.8 at final follow-up at 10 years). At a follow-up of 7.1 years, implant survival in this study was 97.4%. Retrospective studies published by Farizon et al [8] and a more recent series by Philippot et al [7] report survival of early-generation dual-mobility cups of 95.4% after 12 years and 94.6% at 10 years, respectively. Although Farizon did not report aseptic loosening, Philippot reports 2 cup revisions due to aseptic loosening in the initial 106 cases. These data suggest that outcomes for the third-generation POLARCUP implant compare

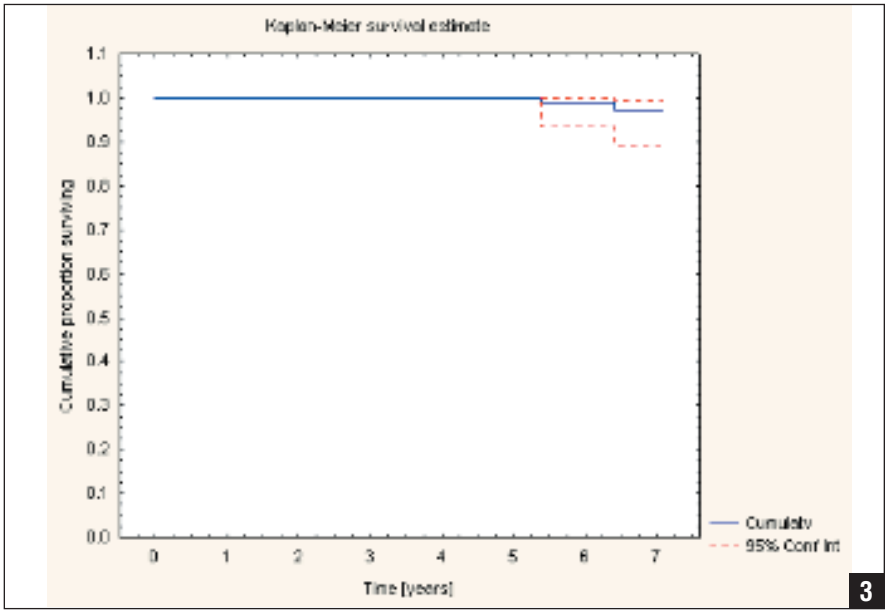

Figure 3: Kaplan-Meier survival analysis at 7.1 years with cup revision due to aseptic loosening as endpoint: 97.4% cumulative survival (95% C.I.: 89.4-99.4).

favorably with early-generation dual-mobility systems.

The results of this investigation suggest excellent early to midterm clinical outcomes for the POLARCUP Dual-Mobility System. After an assessment of midterm follow-up, the use of this device can be recommended as an excellent option for primary THA. Additional research will be performed to assess long-term clinical safety and efficacy of the POLARCUP.

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