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Midterm results with the fully hydroxyapatite-coated POLARSTEM® Femoral Stem

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Summary

The purpose of this study was to assess midterm outcomes of the fully hydroxyapatite-coated POLARSTEM Femoral Stem, used in combination with the single type dual-mobility POLARCUP®. Clinical and radiographic outcomes were assessed for 174 hips at an average follow-up of 5.6 years. In addition, a Kaplan-Meier survival analysis was performed with revision for any reason or aseptic loosening as the endpoints.

Results

- Postel-Merle d'Aubigné functional scores increased from a mean of 10.1 to 16.8
- 146 patients reported "very good" surgical results; 56.3% of patients had a Devane activity score of ≥ 3
- All hips were stable with little-or-no periarticular ossification observed
- Cumulative stem survival probability was 99.5%, with no revisions due to aseptic loosening. These results meet safety benchmark standards [1]

Conclusion

The POLARSTEM Femoral Stem showed excellent clinical and radiographic outcomes at a mean follow-up of 5.6 years. Follow-up of this patient group is ongoing to determine whether this performance is maintained at 10 years and beyond.

Introduction

The POLARSTEM Femoral Stem (Smith & Nephew Orthopaedics AG, Baar, Switzerland) has been in clinical use since 2002, and is available in both cemented and cementless versions (Figure 1). The cementless version is fully coated with titanium/hydroxyapatite (HA; 80 um), and may be used with dual-mobility or standard acetabular cups.

This stem has previously been examined at short-term in 600 patients, in combination with a dual-mobility cup using minimally invasive surgery [2]. In this study, dislocation occurred in a total of four hips (0.7%), with two revisions (0.3%) performed as a consequence of femoral fractures. While noteworthy, additional evidence is necessary to further confirm the safety and efficacy of this device at longer follow-up.

The current retrospective study examined a consecutive cohort of primary, cementless total hip arthroplasty (THA) patients in order to assess the midterm clinical, radiological, and survivorship outcomes of the POLARSTEM Femoral Stem.

Materials and Methods

Patients

Two hundred and twenty-seven patients from two study centers were implanted with the cementless POLARSTEM® Femoral Stem between January 2002 and December 2003. The femoral head size used was 22 mm in 74 cases and 28 mm in the remaining 153 cases. All stems were combined with an uncemented dual-mobility acetabular cup (POLARCUP®; Smith & Nephew Orthopaedics AG, Baar, Switzerland), 38 of which were supplemented with screws. One hundred and seventy-two (75.7%) hips were implanted with metal-on-polyethylene articulations, while 54 (23.7%) used a ceramic-on-polyethylene articulation. Information regarding articulation was not available for one patient (0.4%). A postero-lateral surgical approach was used in all cases.

Study outcomes

Baseline demographic data was gathered and the pre-surgery diagnosis was recorded from the hospital files. American Society of Anesthesiologists (ASA) physical status classification was used to assess the fitness of the patients before surgery, along with preoperative modified Charnley classification of comorbidity in relation to walking capacity [3].

Patients were evaluated at 1, 5, and 7 years, and were invited back to the hospital for a clinical and radiographic examination between 2007 and 2009. An informed consent for the use of the data was obtained from the patients at this point. Functional performance of the hips was measured using the Postel-Merle d'Aubigné (PMA) score [4], and each patient's activity level was graded using the Devane scale [5]. Patients also self-rated their surgical results at final follow-up as 'very good,' 'good,' 'normal,' 'bad,' or 'very bad.'

Radiographic outcome was assessed on standard anteroposterior x-rays. Determination of osteolysis was performed using the DeLee & Charnley zones [6]. Furthermore, periarticular ossification was classified using the Brooker grading system [7]. Kaplan-Meier survivorship analysis was performed to determine the cumulative survival rates of the femoral stem, as well as the complete THA. Endpoints were revision due to any reason and revision due to aseptic loosening.

Figure 1: The fully HA-coated POLARSTEM Femoral Stem
(Smith & Nephew Orthopaedics AG, Baar, Switzerland)

Results

Baseline demographic data are presented in Table I. Key study outcomes are as follows:

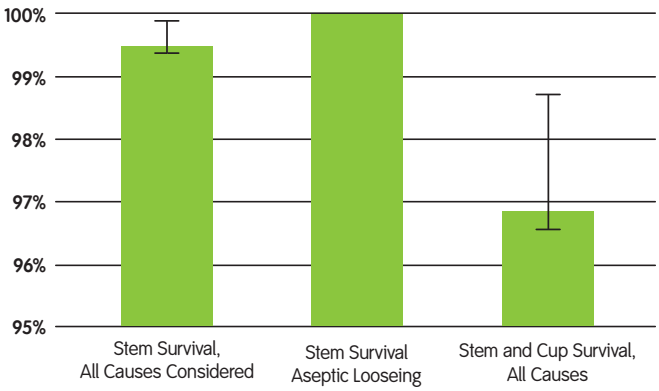
- Mean follow-up 5.6 ± 0.6 years (range, 4.1–7.2 years)
- Total mean PMA scores increased from 10.1 ± 2.3 to 16.8 ± 1.6
- Mean PMA scores for pain, mobility, and distance increased from 0.7 ± 0.7, 4.8 ± 1.2, and 4.6 ± 1.5 to 5.7 ± 0.5, 5.7 ± 0.5, and 5.4 ± 1.0 respectively
- Percentage of Devane activity scores ≥ 3 increased from 31.2% to 56.3%
- Patient-rated surgical results: very good (146), good (27), normal (1), bad or very bad (0)
- Radiographic results: 137 hips had no periarticular ossification; 29 hips had a score of 1, seven hips a score of 2, and one hip a score of 3. Minor osteolysis detected around one acetabular cup in Charnley zones I to III
- Recurrent dislocation reported for one hip (0.4%) in a patient with postoperative cognitive dysfunction
- Six revisions due to infection and acute sepsis (3), aseptic loosening of the cup (2), and fracture (1). Survival results are illustrated in Figure 2

Table 1: Pre-surgery demographic data

Characteristic	Mean ± SD (range)
Age at surgery (years)	70.3 ± 10.3 (36.7–91.2)
Total n/Female n (%)	227/115 (50.6)
Weight (kg)	74.5 ± 14.9 (40–120)
Height (cm)	165.1 ± 8.6 (143–185)
BMI (kg/m2)	27.2 ± 4.5 (17.2–40.6)
Diagnosis, n (%)	
Primary coxarthrosis	204 (89.8)
Rheumatoid arthritis	2 (0.8)
Epiphysiolysis	1 (0.4)
Necrosis (all)	11 (4.8)
Dysplasia	8 (3.5)
ASA physical status, n (%)	
1	38 (16.7)
2	151 (66.5)
3/4	38 (16.7)
Charnley classification, n (%)	
A	116 (51.1)
B	84 (37.0)
BB	27 (11.9)
C	0 (0)

Abbreviations: ASA= American Society of Anesthesiologists; BMI= body mass index; SD= standard deviation

Figure 2: Kaplan-Meier survival results



Discussion and Conclusion

This retrospective analysis demonstrates encouraging midterm performance for the POLARSTEM® Femoral Stem, with survival well within safety guidance standards [1]. Moreover, these outcomes compare favorably with those for similar HA-coated cementless straight stems, namely the well-documented Corail™ (DePuy, Leeds, UK) and Aura™ stems (Biomet, Valence, France). In three studies involving a total of 6,659 patients followed-up for between 4.5 and 11.5 years, the cementless Corail stem was found to have revision rates ranging from 0.18% to 2.0% [8-10]. Survival at 7, 10, and 15 years for the Corail stem was 98.9%, 98.0%, and 97.0%, respectively [9]. Recently, a follow-up study confirmed these earlier results, reporting a survival probability of 96.8% after 20 years and 96.3% after 24 years [11]. In a study of 107 hips in 63 patients over 10 years, the HA-coated cementless Aura stem underwent five revisions: one for acetabular loosening, two for traumatic ceramic head fracture, one for polyethylene replacement, and one for stem replacement due to bone fracture. The overall survival rate at 10 years was 95.6%, using revision of either component as an endpoint [12]. In terms of clinical function, the improvement in PMA scores noted in the current investigation are comparable to results reported for the Corail [8] and Aura [12] stems.

As expected, the observed dislocation rate for the POLARSTEM in combination with a POLARCUP® dual-mobility cup was low (0.4%). Only one case of recurrent dislocation during the early postoperative soft tissue healing phase was observed. A previous investigation of the same implant system revealed an early dislocation rate of 0.2% [13], and a study of the same dual-mobility cup at midterm reported no cases of dislocation [14]. The findings from the current analysis confirm the high success rate of this system in preventing early dislocation.

The primary limitation of the current study is that a mean follow-up time of 5.6 years is insufficient for providing reasonable insights into the long-term performance of this device. Specifically, complications such as increased aseptic loosening or dislocation could occur during this time [15, 16]. However, given that only one other analysis offering outcomes with the POLARSTEM has been published to date [2], it was decided that the presentation of midterm results would satisfy an unmet need by providing valuable findings to surgeons working with this femoral stem.

In conclusion, the findings of this study indicate that the POLARSTEM Femoral Stem offers excellent midterm clinical outcomes, with increased functional performance and patient satisfaction, as well as highly favorable radiographic results. Moreover, this analysis confirmed that excellent stability can be obtained when this stem is used in combination with a dual-mobility cup. Long-term results for the current cohort will be published and communicated to the orthopaedic community as soon as possible.

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References

1. National Institute for Clinical Excellence (NICE): Guidance for the Selection of Prostheses for Total Hip Replacement. 2000
2. Fiquet A, Noyer D. "Polarsystem" dual mobility hip prosthesis and "minimally invasive surgery" (MIS). Interact Surg 1(1-4): 51, 2006
3. Roder C, Staub LP, Eichler P, Widmer M, Dietrich D, Eggli S, Muller U. Avoiding misclassification bias with the traditional Charnley classification: rationale for a fourth Charnley class BB. J Orthop Res 24(9): 1803, 2006
4. Merle D'Aubigne R. [Numerical classification of the function of the hip. 1970]. Rev Chir Orthop Reparatrice Appar Mot 76(6): 371, 1990
5. Devane PA, Horne JG, Martin K, Coldham G, Krause B. Three-dimensional polyethylene wear of a press-fit titanium prosthesis. Factors influencing generation of polyethylene debris. J Arthroplasty 12(3): 256, 1997
6. DeLee JG, Charnley J. Radiological demarcation of cemented sockets in total hip replacement. Clin Orthop Relat Res (121): 20, 1976
7. Brooker AF, Bowerman JW, Robinson RA, Riley LH, Jr. Ectopic ossification following total hip replacement. Incidence and a method of classification. J Bone Joint Surg Am 55(8): 1629, 1973
8. Froimson MI, Garino J, Machenaud A, Vidalain JP. Minimum 10-year results of a tapered, titanium, hydroxyapatite-coated hip stem: an independent review. J Arthroplasty 22(1): 1, 2007
9. Hallan G, Lie SA, Furnes O, Engesaeter LB, Vollset SE, Havelin LI. Medium- and long-term performance of 11,516 uncemented primary femoral stems from the Norwegian arthroplasty register. J Bone Joint Surg Br 89(12): 1574, 2007
10. Havelin LI, Espehaug B, Vollset SE, Engesaeter LB. Early aseptic loosening of uncemented femoral components in primary total hip replacement. A review based on the Norwegian Arthroplasty Register. J Bone Joint Surg Br 77(1): 11, 1995
11. Vidalain JP. Twenty-year results of the cementless Corail stem. Int Orthop 35(2): 189, 2011
12. Fayard JP, Chalencon F, Passot JP, Dupre Latour L, Edorh G. Ten-year results of ALIZE acetabular cup with hydroxyapatite coating and AURA hydroxyapatite-coated stem in total hip arthroplasty. J Arthroplasty 21(7): 1021, 2006
13. Bourne RB, Mehin R. The dislocating hip: what to do, what to do. J Arthroplasty 19(4 Suppl 1): 111, 2004
14. Bauchu P, Bonnard O, Cypres A, Fiquet A, Girardin P, Noyer D. The dual-mobility POLARCUP: first results from a multicenter study. Orthopedics 31(12 Suppl 2), 2008
15. Lautridou C, Lebel B, Burdin G, Vielpeau C. [Survival of the cementless Bousquet dual mobility cup: Minimum 15-year follow-up of 437 total hip arthroplasties]. Rev Chir Orthop Reparatrice Appar Mot 94(8): 731, 2008
16. Lecuire F, Benareau I, Rubini J, Basso M. [Intra-prosthetic dislocation of the Bousquet dual mobility socket]. Rev Chir Orthop Reparatrice Appar Mot 90(3): 249, 2004

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