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Excellent midterm survival and functional outcomes of a fully hydroxyapatite-coated cementless stem: first results of a prospective multicenter study

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ABSTRACT

Background: The Polarstem (Smith & Nephew, Baar, Switzerland) is a tapered straight stem, an implant with an excellent survival rate. Although the most recent annual report of the National Joint Registry in the United Kingdom also reports excellent survivorship for the cementless Polarstem, no prospective studies have been published focusing on both its efficacy and clinical performance. Therefore, the present study was designed to prospectively evaluate its functional and radiographic outcomes at midterm.
Methods: This prospective observational study conducted at 3 independent orthopaedic hospitals was designed to collect data in patients undergoing cementless primary total hip arthroplasty (THA). A total of 225 total hip arthroplasties (75 at each site) were performed. The predominant diagnosis was primary osteoarthritis. Anteroposterior and lateral radiographs were obtained at each follow-up (3 months, and 1, 3, and 5 years). Survivorship and the Harris Hip Score (HHS) and Western Ontario and McMaster Universities Index (WOMAC) were calculated.
Results: Subjects experienced statistically significant improvements from baseline in mean HHS (48.5 to 88.0, $P < .01$) and WOMAC scores (58.6 to 9.3, $P < .01$) at all intervals through 5 years. The stem survivorship was 99.6% at 5 years with stem revision due to any reason. There were no observed cases of mechanical failure of the stem or signs of radiographic loosening.
Conclusions: A revision rate of the femoral stem for any reason of 0.4%, as well as good clinical results based on HHS and WOMAC scores, was noted at 5-year follow-up. Therefore, safety and efficacy of the cementless Polarstem at midterm follow-up is confirmed.

Introduction

The cementless Polarstem (Smith & Nephew, Baar, Switzerland) is manufactured from titanium alloy, coated with a ground layer of porous titanium, and then fully covered with a hydroxyapatite coating of an average thickness of 50 micrometers. The Polarstem uses a tapered straight stem design. Earlier devices using this design have exhibited an excellent survival rate [1] and preservation of proximal bone structure over the long term [2].

The Australian National Joint Replacement Registry 2012 annual report showed an unexpected high revision rate of the Polarstem, with a 3-year cumulative percentage of 3% [3]; however, the latest report from this registry notes revision rates of 0.8% and 3.2% at 5 years for the 2 acetabular cup combinations with which Polarstem has available data [4]. In contrast to these earlier findings, Lee and Evans (2014) [5] reported a 3-year revision rate of only 0.15% in a cohort of 646 stems with 100% follow-up. A recent update of patients from this cohort observed that the low risk of revision was maintained at midterm follow-up, standing at 1.47% at 7 years [6]. These reports agree with the 2018 annual report of the National Joint Registry of England, Wales, Northern Ireland, and the Isle of Man, which found a 5-year revision rate of just 0.97% [7].

Despite appearing in multiple national registries, there are currently no published prospective studies detailing clinical outcome and improvement compared to preoperative status with

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this cementless stem. The present study is the first to present not only survival rate but also clinical outcomes (compared to preoperative levels) in the course of 5 years of follow-up.

Material and methods

Study design

This prospective observational study was conducted at 3 independent orthopaedic hospitals and was designed to collect data in patients undergoing primary total hip arthroplasty (THA) for various reasons. The study was performed according to ISO 14155 guidelines and in accordance with the Declaration of Helsinki. All patients signed the informed consent form before surgery and the approval of the local ethics committee was obtained for all sites (Aarau 001/2009, Bochum 3449-09, Marburg 116/08).

Inclusion criteria were primary THA for the indications of primary or secondary coxarthrosis, rheumatoid arthritis, developmental dysplasia of the hip (Crowe type I and II), fracture, or avascular necrosis of the femoral head; patient able to comply with study follow-up requirements, including routine radiographic assessment; informed consent to participate signed by the patient, and no general medical contraindications to surgery. Patients with a history of infection in the affected joint or systemic infections, grossly insufficient femoral or acetabular bone stock, and an age under 18 or over 75 years were excluded. Surgery was performed by 6 senior orthopaedic surgeons between March 2009 and April 2010.

Sample size was determined based on the necessary implant numbers to conduct a valid statistical data analysis according to Kaplan-Meier. It was therefore necessary for at least 100 implants to survive at 10 years. Assuming a 30% dropout rate over that time period, at least 150 initial implants were required.

Prospective data were collected by medical personnel independent from the surgeon preoperatively, and again at postoperative follow-up visits conducted at 3 months, and 1, 3, and 5 years. Subjects who could not attend on-site follow-up were contacted by phone to inquire whether they were suffering hip pain or any other complaints indicating problems with the hip. They were also asked if the hip was revised or in situ.

Patients

Among 498 primary THAs performed at the 3 study centers during the study period, 225 (75 at each site) were performed with the study implant in a cohort of 218 patients (112 females and 113 males). The mean subject age, height, and weight at the time of surgery were 64.7 years (range 37-76), 170.6 cm (range 151-195), and 82.4 kg (range 50-136), respectively. The predominant diagnosis was primary osteoarthritis (82.7%). Most subjects (92.2%) had no surgical history on the ipsilateral hip.

One hundred forty-two subjects (63.1%) were implanted with standard and 83 (36.9%) with lateralized offset stems. On the acetabular side, a cementless hemispherical press-fit cup (EP-FIT [Smith & Nephew] in 142 subjects and FITMORE [Zimmer-Biomet, Warsaw, IN] in 8 subjects) was used in 150 of the hips and a threaded-type cup (HI, Smith & Nephew) in the remaining 75 hips. Inserts used included highly-cross-linked polyethylene in 143 cups (63.5%) and standard polyethylene in 35 cups (15.5%). A metal-on-metal articulation was used in 47 hips (21%). Of all inserts used, 22 (10%) had elevated rims. The femoral head size was 32 mm in 133 hips (59%) and 28 mm in 92 (41%) cases. Cup inclination was 40°-50° in 143 hips (64%), <40° in 39 (17%), and >50° in 43 (19%) cases. Stem position was neutral in 207 (92%) hips, varus <5° in 11 (5%), and valgus in 7 (3%) cases. None of the stems were implanted in a position >5° from neutral axis.

Surgical technique

The size of the implant components was planned preoperatively and verified intraoperatively. Antibiotic prophylaxis (single-dose cefuroxime or cefazolin) was used in all patients 15-60 minutes before surgery. A conventional transgluteal approach was applied in 177 hips (79%), anterolateral in 5 (2%), and anterior in 43 (19%).

The mean surgical time was 80.4 minutes (95% confidence interval [CI]: 76.8-84.0 minute). Leg length, soft-tissue tension, and stability were tested before implantation of the final components. Closed suction drains were used in all patients. The postoperative regimen differed between the study sites, but all patients did have early mobilization at day 1 postoperatively. Full weight-bearing using 2 crutches was allowed at 2 sites immediately, and partial weight-bearing was recommended for at least 4 weeks postoperatively at the remaining site.

Outcomes

Anteroposterior (a-p) and lateral radiographs in the supine position were obtained at each follow-up appointment. Radiographic evaluation was measured and defined according to the guidelines set forth by Johnston [8]. A component was considered loose when radiolucent lines (RLLs) were seen in all zones or progression of radiolucent line was observed compared to earlier films.

The Harris Hip Score (HHS) was calculated [9], which incorporated one modification by which the “distance walked” section of the score replaced the number of blocks with the actual distance. The HHS scoring assessment ranges from 0 to 100, with higher scores representing improvement. Scores of 90-100 and 80-89 points represent excellent and good results or functional status, respectively.

Patient self-assessment, using the standardized Western Ontario and McMaster Universities Index (WOMAC), part of the Hip disability and Osteoarthritis Outcome Score, was also calculated to evaluate changes in self-assessed subject condition [10]. The WOMAC scoring assessment ranges from 0 to 96, with higher scores representing greater disability.

Statistical analysis

Cumulative survival rates were calculated according to the Kaplan-Meier method. Selected endpoints were reoperation for any reason and component revision for aseptic loosening or mechanical failure. Nonparametric tests (Mann-Whitney) were used for comparing data. Analysis of variance (ANOVA) was used to analyze the differences among group means and their associated procedures.

Results

Patients

The number of subjects included in this analysis, at each follow-up time point, is indicated in Figure 1. Between the 3-month and 5-year follow-up, 14 subjects had died of causes unrelated to surgery or the hip implant. One stem was removed after 6 weeks due to infection.

Extra measures were taken to collect the survival information of the Polarstem for the subjects who missed the 5-year follow-up visit. Revision information was collected via telephone interview for all these 30 subjects. None had been revised or had complaints indicating component loosening or hip implant dependent disability or pain.

Clinical results

Mean HHS and each subscore showed improvement following THA at each time point. Overall, the mean HHS from baseline to the

5-year evaluation improved from 48.5 to 88.0 ($P < .01$), with a significant improvement at 3 months and thereafter when comparing to baseline (Table 1).

The mean total WOMAC score decreased from 58.6 at baseline to 9.3 ($P < .01$) at the 5-year interval. A significant improvement in mean total WOMAC score and for each of the subscores compared to baseline was observed at each follow-up (Table 2).

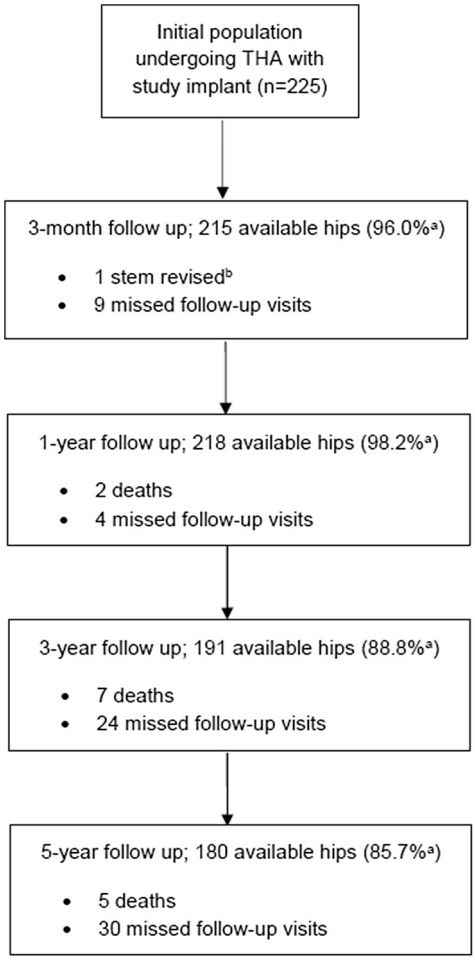
Safety evaluations

Out of 225 subjects, 222 (98.7%) did not experience an intraoperative complication. Three subjects had intraoperative events: one femoral fracture without dislocation and a stable stem (this is the patient with early septic complication mentioned again later), one trochanter fracture, and one increased bleeding tendency during and after surgery, but with primary wound healing. Two patients (0.9%) were reported with a temporary paralysis of the peroneal nerve. Twenty-six (11.6%) subjects experienced at least one early postoperative complication (29 complications in total), such as minor cardiovascular events, gastric or renal disorders, urinary tract infection, herpes zoster, patch allergy, heel decubitus, and metabolic imbalance of diabetes mellitus.

Thirteen additional complications were reported beyond the immediate perioperative period up to the 5-year interval. At the 3-month follow-up, 2 subjects (0.9%) had a single dislocation treated by closed reduction and one early infection with implant removal (0.5%). At the 1-year follow-up, one luxation (0.5%) with open reposition and 4 other local complications (1.8%) such as groin pain, bursitis trochanterica, and trochanteric pain without fracture (identified on plain radiographs) were reported. At the 3-year follow-up, one subject had a fracture (0.5%) and 2 other complications (1.1%). At the 5-year follow-up, 2 other complications were reported (1.1%) described as groin pain and lateral hip pain.

Revisions and survival analysis

One subject had a stem revision at 6 weeks due to a septic complication (group C Streptococcus) and therefore was excluded from further follow-up. Three cup revisions in 2 subjects were reported in total. One subject had a second cup revision 11 months after the first cup revision due to a fall. Both subjects continued with the study as the stem was not revised. There were no cases of mechanical failure of the stem or signs of subsidence (after 3-month follow-up) or radiographic loosening in any patient. There was a 99.6% stem survivorship (95% CI: 96.9%-99.9%) at 5 years with stem revision due to any reason as the endpoint.



[a] Calculated from actual visits divided by expected visits (theoretically due minus death and revisions)

[b] Only stem revisions listed. Subjects with cup revisions (n=2) continued the study

Figure 1. Flowchart of data at study follow-up visits.

Table 1
Summary of Harris Hip Scores, and individual subscales of pain, function, absence of deformity, and range of motion.

Outcome	Statistic	Preop	3 mo	1 y	3 y	5 y
Harris Hip Score (0-100)	N	224	215	216	191	166
	MEAN	48.5	82.9	89.4	89.1	88.0
	MIN	6	29	45	38	28
	MAX	82	100	100	100	100
	STD DEV	11.5	13.3	12.1	13.1	15.2
	P value[a]	Reference	.000	.000	.000	.000
Function Score (0-47)	N	225	216	217	191	171
	MEAN	28.1	36.6	41.0	40.8	39.5
	MIN	0	8	13	3	5
	MAX	44	47	47	47	47
	STD DEV	8.1	8.2	6.6	8.2	9.5
	P value[a]	Reference	.000	.000	.000	.000
Absence of deformity (0 or 4)	N	224	215	216	191	166
	MEAN	3.8	4.0	4.0	3.9	4.0
	MIN	0	0	0	0	0
	MAX	4	4	4	4	4
	STD DEV	0.9	0.4	0.4	0.5	0.3
	P value[a]	Reference	.003	.003	.016	.000
Range of motion (0-5)	N	225	215	217	191	166
	MEAN	3.0	3.9	4.5	4.7	4.7
	MIN	0	2	2	2	3
	MAX	5	5	5	5	5
	STD DEV	0.8	0.7	0.6	0.5	0.4
	P value[a]	Reference	.000	.000	.000	.000
Pain score (0-44)	N	225	216	217	195	183[b]
	MEAN	13.4	38.5	39.7	39.5	40.0
	MIN	0	10	10	10	10
	MAX	30	44	44	44	44
	STD DEV	5.6	7.4	7.7	7.3	7.8
	P value[a]	Reference	.000	.000	.000	.000

[a] *P*-values are calculated based on ANOVA.
[b] Three subjects provided HHS information at 5-y interval but other assessments were not performed.

Table 2
Summary of WOMAC, and individual subscales of pain, stiffness, function.

Outcome	Statistic	Preop	3 mo	1 y	3 y	5 y
WOMAC total score (0-96)	N	224	212	209	185	164
	MEAN	58.6	14.0	10.5	9.8	9.3
	MIN	8	0	0	0	0
	MAX	92	72	64	71	60
	STD DEV	13.9	14.3	12.2	13.5	12.3
	P value[a]	Reference	.000	.000	.000	.000
Pain (0-20)	N	225	215	217	196	182[b]
	MEAN	11.5	1.9	1.5	1.7	1.5
	MIN	2	0	0	0	0
	MAX	19	12	10	14	15
	STD DEV	3.1	2.5	2.2	2.6	2.7
	P value[a]	Reference	.000	.000	.000	.000
Stiffness (0-8)	N	225	215	217	196	183[c]
	MEAN	5.0	1.6	1.1	1.0	0.7
	MIN	0	0	0	0	0
	MAX	8	6	5	8	6
	STD DEV	1.5	1.5	1.2	1.5	1.2
	P value[a]	Reference	.000	.000	.000	.000
Function (0-68)	N	224	212	209	185	164
	MEAN	42.0	10.6	7.9	7.4	7.6
	MIN	5	0	0	0	0
	MAX	66	55	51	60	45
	STD DEV	10.5	11.2	9.5	10.6	10.0
	P value[a]	Reference	.000	.000	.000	.000

[a] *P*-values are calculated based on ANOVA.
[b] Two subjects provided information, but 5-y follow-up was not performed.
[c] Three subjects provided WOMAC information, but 5-y follow-up was not performed.

Discussion

The 2014 National Institute for Health and Care Excellence (NICE) technology appraisal guideline requires a rate of revision of 5% or less at 10 years for THA and hip resurfacing prostheses [11]. For hip prostheses with less than 10 years of follow-up, a revision rate of 0.5% or less per year of implantation is stated by the Orthopaedics Data Evaluation Panel [12] as acceptable. The 15th Annual Report of the National Joint Registry for England, Wales, Northern Ireland, and the Isle of Man [7] shows a 0.97% probability of revision at 5 years for the cementless Polarstem in combination with R3 cementless cup, which is below the rate for all other registered cementless hip combinations.

In our study, a 99.6% (95% CI: 96.9%-99.9%) survivorship rate of the cementless Polarstem was observed at 5 years with revision of the stem due to any reason as primary endpoint. Stem revision was reported in only one subject, due to septic complication 6 weeks after implantation. By contrast, the 2012 Annual Report from the Australian National Joint Registry [3] reported a high cumulative revision rate (3% after 3 years) for the cementless Polarstem, in which 7 revisions (38.9%) were due to infection. We can therefore endorse that our results are in line with the high cumulative 3-year survival rate of 99.7% reported by Lee and Evans [5] and 97.69% at 7 years by Assaf et al. [6], which drew from the same patient cohort.

Midterm follow-up at 5 years from our study suggests that this hydroxyapatite-coated cementless tapered femoral stem has also an excellent clinical outcome. The stepped geometry is similar to the other taper stem designs to minimize shear forces and maximize compression loading in the cancellous bone. The proximal diameter of the cementless Polarstem is approximately 20% wider than other tapered designs and its stem length is 10% shorter. These design features further enhance the proximal loading and reduce distal mechanical load bearing. Therefore, the proximal stress shielding should be further reduced and the bone stock preserved [2,13,14].

The cementless Polarstem has been found to perform with equal success across a wide range of pathological entities, patient profiles, and bone types [5]. Our study, which used different surgical approaches, also documented a low intraoperative complication rate, a safe surgery profile, and excellent functional outcomes.

The UK National Joint Registry (unpublished results) documents the result of Oxford Hip Score (OHS: a joint-specific outcome measure tool designed to assess disability in patients undergoing total hip replacement) and EQ-5D Index (a standardized instrument for the use as a measure of health outcome). In both, the patient-reported outcome was superior in the cementless Polarstem group compared to all cementless stems (OHS improved 98% vs 97%, EQ-5D Index improved 92% vs 89%) in that national joint registry. However, it should be noted that the patient-reported outcome measures are not described in detail.

Our prospective multicenter study is the first describing in detail the efficacy outcome analysis of 2 widely used patient-reported outcome measures of clinical performance (HHS, WOMAC). Subjects experienced statistically significant improvements from baseline in mean HHS and WOMAC scores at all intervals through 5 years.

There are limitations to the present study. The first is the inclusion of several bearing couples (eg, metal-on-polyethylene, metal-on-metal), which have the potential to significantly impact the primary endpoint of component survivorship. Ideally, the bearing couple would have been controlled across all groups. The second limitation is excluding potential subjects that were over the age of 75 years. This was done because the study is a 10-year follow-up and the investigators wanted to ensure that a large number of subjects would be living to assess at the final interval. Finally, 30 patients were unable to attend in-person follow-up visits and were instead contacted by phone. Although this allowed us to ascertain their revision status and complaints (eg, pain or disability), potentially relevant radiographic findings could not be obtained for these patients.

Conclusions

The survivorship at 5 years observed in this study for the cementless Polarstem is well in line with current suggestions for THA. The most recent annual report of the National Joint Registry in the United Kingdom shows a cumulative revision rate at 5 years for all cementless THAs of 2.85% (2.79%-2.91%) [7]. The Polarstem revision rate (unpublished results) was 0.7% (95% CI: 0.5%-1.1%), which is comparable to the revision rate observed in our study (0.4%). The literature provides similar results for the cementless Polarstem. Reports from Lee and Evans [5] and Assaf et al. [6] showed a cumulative survival rate of 99.7% at 3 year and 97.69% at 7 years, respectively, which is comparable to the rate observed in our study. Good to very good clinical results were also documented in the present study. Therefore, safety and efficacy of the cementless Polarstem can be confirmed by the findings of our 5-year results. Further documentation of these devices is necessary to determine if these favorable results are maintained in the long run.

Conflict of interest

The authors declare the following financial interests/personal relationships which may be considered as potential competing interests: Turgay Efe, MD, and Roland E. Willburger, MD, received research support from Smith & Nephew as principal investigators for the present prospective study. Turgay Efe, MD, and Karl-F Schüttler, MD, report appointments for the AGA research committee, with no conflict regarding the current submission. Matthias Heukamp, MD, Philippe Lindenlaub, MD, and Christian-D. Peterlein, MD, declare that they have no known competing financial interests or personal relationships that could have appeared to influence the work reported in this paper.

For full disclosure statements refer to https://doi.org/10.1016/j.artd.2020.01.009

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