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Research Article

# Excellent Longterm Survival and Good to Excellent Functional Outcomes of a Fully Hydroxyapatit-Coated Cementless Stem: Results of a Prospectiv Study

**Roland E. Willburger*, Jan Krapp, Tobias Schulte, Stella Oberberg**

Department of Orthopaedic Surgery, Ruhr University Bochum, Katholisches Klinikum Bochum, Germany

***Corresponding author:** Roland E. Willburger, Department of Orthopaedic Surgery, Ruhr University Bochum, Katholisches Klinikum Bochum, Germany

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**Abstract**

**Purpose:** Although the reports of the National Joint Registries in the United Kingdom and Germany report excellent survivorship for the cementless Polarstem, no prospective longterm studies have been published focusing on both its efficacy and clinical performance. Therefore, the present study was designed to prospectively evaluate the functional and radiographic outcomes over 10 years.

**Methods:** Seventy five patients were included prospectively. Anteroposterior and lateral radiographs were obtained at each follow-up (3 months, and 1, 3, 5 and 10 years). Survivorship, the Harris Hip Score (HHS) and Hip disability and Osteoartritis Outcome Score (HOOS) were calculated.

**Results:** Subjects experienced statistically significant improvements from baseline in mean HHS and HOOS scores at all intervals. The stem survivorship was 100% at 10 years with stem revision due to any reason. There were no observed cases of mechanical failure of the stem or signs of radiographic loosening.

**Conclusion:** A revision rate of the femoral stem for any reason of 0%, as well as good to excellent clinical results based on HHS and HOOS scores, were noted at 10-year follow-up. Therefore, safety and efficacy of the cementless Polarstem at longterm follow-up is confirmed.

**Keywords:** Outcome; Polarstem; Proms; Total Hip Arthroplasty

**Abbrevations:** THA: Total Hip Arthroplasty; HI: Hofer Imhoff; RLL: Radiolucent Lines; HHS: Harris Hip Score; HOOS: Hip Disability And Osteoarthritis Outcome Score; PROMS: Patient Related Outcome Measures; FU: Follow Up.

## Background

The Polarstem (Smith & Nephew, Baar, Switzerland) is a tapered straight stem, coated with a ground layer of porous titanium, and then fully covered with a hydroxyapatite coating. Earlier devices using this design have exhibited an excellent survival rate [1] and preservation of proximal bone structure [2]. In 2012 the Australian National Joint Replacement Registry showed an unexpected high revision rate of the Polarstem, with cumulative 3% after 3 years [3]. In contrast to that, Lee and Evans (2014) reported a 3-year revision rate of only 0.15% in a cohort of 646 stems with 100% follow-up [4]. Meanwhile, the German Endoprosthesis Registry (EPRD) 2023 has calculated a probability of failure of the cementless Polarstem of 3.4 (with 3589 implantations) after 5 years and 3.9 (with 136 implantations) after 8 years [5]. These values are comparable to those of the cementless Corail stem, after 5 years 4.0 (with 9534 implantations) and after 8 years 5.2 (with 673 implantations). The

cementless Corail stem without collar has been documented most frequently in the EPRD register [5]. So far, no long term results of a prospective investigation of the cementless Polarstem have been published with regard to clinical results and PROMs. We already reported on the 5-year follow-up examinations in 2020 [6]. The present study is the first to present not only survival rate but also clinical outcome (compared to preoperative levels) in the course of 10 years.

## Methods

### Study Design

This prospective observational study was conducted 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 Decleration of Helsinki. All patients signed the informed consent form before surgery and the approval of the local ethics committee was obtained (3449-09). Inclusion criteria were primary THA for the indications of primary or secondary osteoarthritis, rheumatoid arthritis, developmental dysplasia of the hip (Crowe type I and II), vascular 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 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 2 senior orthopaedic surgeons between April 2009 and Januar 2010. 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, 5, and 10 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 and Implants

75 consecutive THAs (48 women, 27 men) were performed with the study implant. The mean subject age, and Body Mass Index (BMI) at the time of surgery was 66 years (range 37- 75), and 28 (range 19-41) respectively. The predominant diagnosis was primary osteoarthritis (n=61, 81%), followed by dysplasia (n=6, 8%), vascular necrosis (n=6, 8%) rheumatoid arthritis (n=1), and secondary osteoarthritis (n=1). Most subjects (n=72, 96%) had no surgical history on the ipsilateral hip, two had undergone repositioning osteotomy and one had undergone hip arthroscopy. 46 subjects (61%) were treated with a standard stem and 29 (39%) with an offset stem. On the acetabular side, in all subjects a threaded-type cup (HI, Smith & Nephew) was used. Inserts included highly-cross-linked polyethylene in 46 cups (61%) and standard polyethylene in 29 cups (39%). Off all inserts used, 2 (2.7%) had elevated rims. The femoral head size was 32 mm in 47 hips (63%) and 28 mm in 28 cases (37%). Ceramic femoral heads were implanted in 64 patients (85%) and metal femoral heads in 11 patients (15%). None of the stems was 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 cefazolin) was used in all patients before surgery. A transgluteal approach was applied in all hips. The mean surgical time was 76 minutes (rang 43-125 minutes). Closed suction drains were used in all patients. All patients had early mobilization at the first day postoperatively. Full weight-bearing using 2 crutches was recommended for at least 4 weeks postoperatively.

### Outcomes

Anteroposterior and lateral radiographs in the supine postion were obtained preoperatively and at each follow-up. Radiographic evaluation was measured and defined according to the guidelines set by Johnston [7]. 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 [8], 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. The Hip disability and Osteoarthritis Outcome Score (HOOS) was calculated to evaluate changes in self-assessed subject condition [9]. Interpretation of HOOS scores is dependent on several factors, including the patient‘s age, comorbidities, and expectations. However, in general, a higher score indicates better hip function and quality of life. A score of 100 represents the best possible outcome, indicating no hip symptoms or limitations.

### Statistical Analysis

After converting the verbal rating scales into numerical scales, HHS and HOOS point values were determined using standardized formulas. In order to be able to compare the examined collective with literature data, mean values were calculated for the respective categories as well as the total score. Patient satisfaction was reported as a percentage of the collective studied. Selected endpoints were reoperation for any reason and component revision for aseptic loosening or mechanical failure.

## Results

### Patients

The number of subjects included in this analysis, at each follow-up, is indicated in Table 1. Extra measures were taken to collect the survival information of the implants (Polarstem and HI cup) for the subjects who missed the follow-up visit. Information was collected via telephone interview. None had been revised or had complaints indicating component loosening or hip implant dependent disability or pain.

| | Before surgery | 3 months FU | 1 year FU | 3 years FU | 5 years FU | 10 years FU |
|---|---|---|---|---|---|---|
| Complete survey and FU | 75 | 73 | 74 | 68 | 62 | 41 |
| Phone call only | | 1 | 0 | 1 | 2 | 15 |
| Died | | 0 | 0 | 3 | 5 | 7 |
| Poor general condition | | 0 | 0 | 1 | 4 | 3 |
| Lack of cooperation | | 0 | 0 | 1 | 1 | 4 |
| Not available | | 1 | 1 | 1 | 1 | 5 |

**Table 1:** Number of patients (hips) included and reasons for missing Follow-Up (FU).

### Clinical Results

Mean HHS and each subsore showed improvement following THA at each time point up to and including the 1-year follow-up examination with slight deterioration after 3 and 10 years. This could be seen as age-related (Table 2). Based on HHS the outcome at 10 years FU was excellent in 62%, good in 16%, satisfactory in 15%, and poor in 7%. The mean total HOOS increased from baseline to all follow-ups (Table 2).

| | Before surgery | 3 months FU | 1 year FU | 3 years FU | 5 years FU | 10 years FU |
|---|---|---|---|---|---|---|
| HHS (maximum 100 points) | 50 | 85 | 91 | 89 | 89 | 87 |
| HOOS (maximum 100 points) | 38 | 94 | 91 | 93 | 92 | 94 |

**Table 2:** Mean values of the Harris Hip Score (HHS) and Hip disability and Osteoarthritis Outcome Score (HOOS) over the course of the study.

The question about satisfaction with the implanted hip prosthesis was answered after 10 years that no one was dissatisfied and 89.5% were very satisfied (Table 3).

| | 3 months FU | 1 year FU | 3 years FU | 5 years FU | 10 years FU |
|---|---|---|---|---|---|
| Very satisfied | 88.9 % | 83.8 % | 70.6 % | 74.6 % | 89.5 % |
| Mostly satisfied | 8.3 % | 16.2 % | 23.5 % | 20.6 % | 7% |
| Partially satisfied | 2.8 % | 0 | 5.9 % | 3.2 % | 3.5 % |
| Dissatisfied | 0 | 0 | 0 | 0 | 0 |

**Table 3:** Satisfaction with the operated hip joint

### Safety Evaluations

All 75 subjects did not experience an intraoperative complication. Postoperatively three patients experienced early complications outside the operated area. These were heel decubitus, a urinary tract infection and herpes zoster.

### Revisions and Survival Analysis

No subject had a stem revision. There was no case of mechanical failure of the Polarstem or signs of subsidence or radiographic loosening. Therefore stem survivorship was 100% at ten years. One patient reported discomfort in the groin at the 10-year follow-up examination. The x-ray examination showed a dislocation of the screw cup and thus certain loosening of this cup. This was changed in a revision surgery.

### Discussion

The 2014 National Institute for Health and Care Excellence (NICE) technology appraisal guideline requires a revision rate of 5% or less at 10 years for THA [10]. With less than 10 years follow-up, a revision rate of 0.5% or less per year of implantation is stated as acceptable by the Orthopaedics Data Evaluation Panel [11]. The 15th Annual Report of the National Joint Registry for England, Wales, Northern Ireland, and the Isle of Man [12] showed a 0.97% probability of revision at 5 years for the cementless Polarstem in combination with R3 cementless cup (Smith& Nephew), which was below the rate for all other registered cementless hip combinations. In our study, a 100% survivorship rate of the cementless Polarstem was observed at 10 years with revision of the stem due to any reason as primary endpoint. 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 [4] and 97.69% at 7 years by Assaf et al. [13].

Longterm follow-up at 10 years from our study suggests that the Polarstem has also an excellent clinical outcome. Our prospective study is the first describing in detail the efficacy outcome analysis of 2 widely used patient-reported outcome measures of clinical performance (HHS and HOOS). The slightly worse results after 10 years compared to the 5-year results are not due to the implant but, in our opinion, to the advanced age of the test subjects.

There are some limitations in our study. The first is the inclusion of different bearing couples (for example: metal-on-polyethylene, ceramic-on-polyethylen), which have the potential to significantly impact the primary endpoint of component survivorship. The second limitation is excluding subjects over the age of 75 years. This was done to ensure that a large number of subjects would be living to assess the interval of ten years. Finally, 34 patients were unable to attend the final in-person follow-up visits. 7 of them had died for reasons unrelated to the hips. The remaining were contacted by phone. Although this allowed us to ascertain their revision status and complaints (eg, pain or disability), potentially relvant radiographic findings could not be obtained for these patients. In conclusion the survivorship at 10 years observed in this study for the cementless Polarstem is well in line with current suggestions for THA. The literature provides similar results. Good to very good clinical results were documented in this study. Therefore, safety and efficacy of the cementless Polarstem can be confirmed by our data. Further documentation of the Polarstem is desireable to determine if these favorable results maintain in the longer run.

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