Multicenter Clinical Observation Using the Cementless Version of the POLARSTEM®

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SUMMARY

Objective: Validation of the POLARSTEM® as state-of-the-art implant in terms of radiographic, clinical performance and long-time survivorship.

Study design: Prospective study

Study population: Total of 225 patients in 3 different sites

Intervention (if applicable): Implantation of a total hip prosthesis

Main study parameters/endpoints: Radiographic: radiolucent lines, osteolysis, hypo- or hypertrophy; implant loosening or migration; Clinical: Harris Hip Score and HOOS Score

Nature and extent of the burden and risks associated with participation, benefit and group relatedness: Patients will benefit without restriction from their total hip prosthesis. Patients enrolled in this study will receive the same operation and the same follow-up treatments as patients not enrolled. Therefore, no additional risks are expected.

1 STUDY OBJECTIVES

1.1 Background

Total hip arthroplasty (THA) has been an established treatment procedure for patients suffering osteoarthritis of the hip and other joint diseases. However, THA alters the distribution of mechanical forces around the hip joint leading to bone remodeling related to implant design and mechanical properties as implied by Wolff's law. According to this law, an implantation of a femoral prosthesis induces a reduction of the proximal compressive stresses and a reactive loss of the proximal femoral bone mass. Although stress shielding has been described as clinically irrelevant with some stem designs (i.e., double-tapered form) [1], others suggest that this phenomena can compromise the implant stability and thus the clinical outcome of a THA and may predispose to loosening, migration as well as complications of the implant during revision [2, 3]. Furthermore, proximal radiolucent lines may provide wear particles (e.g., polyethylene) the possibility to migrate along the bone-implant interface, enlarging the risk of osteolytic processes [4].

Hydroxyapatite (HA) coatings have been widely used in THA due to their osseoconductive properties [5, 6]. HA on proximal stems have been shown to improve osseointegration, thus facilitating load transmission in the metaphysal part of the femur and hence reduced stress shielding. An improved osseointegration may also function as a barrier to migration of wear debris to the bone-implant interface, eventually leading to reduced osteolysis and increased implant long-term survival.

1.2 The POLARSTEM®

The POLARSTEM® is a double-tapered stem with a large proximal part and a short and slim distal end and it is forged from a Ti-6Al-4V alloy. The neck of the POLARSTEM® is mirror-polished to reduce the risk of insert damage during impingement. The bone-contacting part of the stem is coated with a ground layer from porous titanium (150 µm) and covered with a HA-coating (80 µm) offering excellent primary stability and improved osseointegration. Furthermore, the POLARSTEM® exhibits proximal grooves perpendicular to the internal curve and to the average load direction to reduce the risk of implant subsidence. For increased rotational stability the stem also features distal grooves reversed to the rotational direction.

Fig. 1: *Cementless version of the POLARSTEM® made from a Ti-6Al-4V alloy exhibiting its characteristic grooves on the hydroxyapatit (HA)-coating (see text for details).*

1.3 Objectives

The goal of this multicenter clinical observation is to validate short-, mid-, and long-term outcome (efficacy and safety) of the POLARSTEM®.

Efficacy evaluations

- Evaluation of function, range of motion (ROM) and pain as assessed by Harris Hip Score, Hip disability and osteoarthritis outcome score (HOOS) [7, 8], an extension of the Western Ontario and McMaster Universities Osteoarthritis Index (WOMAC).
- Radiographic changes as defined by radiolucent lines, osteolysis, hypo- and hypertrophy, implant loosening or migration

Safety evaluations

- Intra- and perioperative device-related adverse events (AE) and complications up to discharge
- Postoperative AE up to 10 years

Long-term survivorship will be calculated according to Kaplan-Meier with stem revision due to any reason as endpoint.

2 STUDY DESIGN

This is a prospective long-term multicenter clinical observation study using the cementless version of the POLARSTEM®. Overall, a minimum of 225 patients will be enrolled in 3 sites. Each site will enroll the patients consecutively; the number of patients per site will be defined together with each investigator.

2.1 Patient selection

Patients enrolled in this multicenter clinical observation will have at least one of the indications listed below and meet all of the inclusion criteria. Patients meeting any of the exclusion criteria are not eligible for this study.

Indications

- Primary or secondary coxarthrosis
- Rheumatoid arthritis
- Developmental dysplasia of the hip (Crowe type I and II)
- Fracture or avascular necrosis of the femoral head

Inclusion criteria

- Patient has no general medical contraindication to surgery
- Informed consent to participate in the MCO signed by the patient
- Routine radiographic assessment is possible
- Patient is likely to comply with study follow-up requirements
- Primary total hip replacement (THR) to the affected side, unilateral or bilateral

Exclusion criteria

- Previously failed endoprosthesis and /or THR components in relevant hip
- History of infection in the affected joint; systemic infections
- Grossly insufficient femoral or acetabular bone stock in the involved hip
- Charcot joint disease or other severe neurosensory deficit
- Severe spinal disorders
- Age of patient at date of surgery > 75 years

- High comorbidity
- Cemented acetabular cup

2.2 Sample size consideration

Sample size estimations have been made on the assumption that for a valid statistical data analysis according to Kaplan-Meier, at least 100 implants surviving 10 years are necessary. Over a period of 10 years, a drop-out rate of 30% should be considered. Therefore, 150 initial implantations are needed in each group.

2.3 Study duration

It is expected to enroll all patients within 12 months. Each patient will be called for follow-up investigations after 3 months, 1 year, 3 years, 5 years, and 10 years.

2.4 Pseudonymisation of patient identifiable information

Patients' data are pseudonymized using a consecutive number according to their study enrolment.

3 STUDY METHOD

3.1 General

Patients' pre-operative status, surgical procedure as well as clinical and radiological outcome will be documented by means of Case Report Forms (CRFs) that are provided by the study sponsor. CRFs will be filled in the investigator or specially assigned hospital personnel who have been trained for the study. Completed CRFs are faxed from the site to the sponsor immediately upon completion. Case Report Forms are the basis for further data evaluation.

Pain, function, gait, range of motion (HHS) and radiographic status determinations are made pre-operatively and at each post-operative examination. Radiographic analysis will be done on standard AP and lateral view X-rays.

Pre-and postoperative HOOS questionnaires are filled in by the patients themselves. Patients must have the possibility to complete the forms on their own, without any external influence. This means patients should have the possibility to take the questionnaire home and return it to the hospital at a later date.

3.2 Postoperative rehabilitation

Postoperative rehabilitation is carried out according to each hospital's standard procedure.

3.3 Follow-up

The follow-up schedule is shown in table 1.

Table 1: *Time windows for investigations*

	Time-window	HHS/HOOS	Clinical	Radiographic
Preoperative	45–0 days	X	X	-
3 months	10–14 weeks	X	X	X
1 year	11–13 months	X	X	X
3 years	36-38 months	X	X	X
5 years	60–63 months	X	X	X
10 years	120–123 months	X	X	X

3.4 Complications/adverse events/lost-to follow-up

Complications and adverse events are noted at each follow-up interval. For completed observations due to death of the patient, explantation of the device or patient's address unknown the latest status will be recorded as an endpoint. Patients will be considered lost to follow-up after they have missed two visits and all attempts to locate and evaluate them have failed. Patients who refuse to attend follow-up or patients unable to attend follow-up will be assessed by telephone if possible. Minimal data concerning the implant status should be acquired by telephone.

3.5 Patient recruitment

Ethical approval is required according to the local regulations of the participating countries. Patients will be screened according to inclusion and exclusion criteria by the investigator. If inclusion criteria are met, patients will be informed about the observation accompanying the surgical procedure. Patients are enrolled in this observation only after they have given a written informed consent. The Patient enrolment has to be carried out within a period of 12 months.

4 DESCRIPTION OF THE DEVICES

4.1 Implants

In this study, the cementless POLARSTEM® will be used in combination with a well documented, cementless acetabular component from Smith & Nephew Orthopaedics AG.

4.2 Instruments

The participating surgeons will only use instruments supplied by Smith & Nephew Orthopaedics AG for the implantation of the POLARSTEM®. All instruments will be used conform to the instructions of the manufacturer.

5 ETHICAL AND LEGAL ASPECTS

5.1 Ethical aspects

This clinical trial will be performed in agreement with the "Declaration of Helsinki" (Version of 1994) and ISO 14155.

Participation in this study is voluntary and it is the patients' right to stop the participation at any time without any declaration of reasons.

Patients will be informed orally and in written form about the study, its risks and benefits and their signed informed consent will be recorded.

5.2 Legal aspects

Approval from ethics committee is required prior any patient recruitment.

Patients' name and other confidential information are subject to confidential medical communication and patients' data will be made fully anonymous for analysis purposes.

For monitoring purposes (through notified bodies or the study monitors), it might be necessary to identify the patients' name and to check original medical records to ensure proper study procedure. For this case the patient has given his signed informed consent.

6 PARTNERS

6.1 Study sponsor and monitor

Smith & Nephew Orthopaedics AG
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6.2 Investigators

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6.3 Publication policy

The results of all study sites will be pooled regularly into an overall-publication and submitted to a peer-reviewed anglophone journal. The publication schedule will be defined by the group of investigators. The authorship is defined as follows:

Johannigmann K; Graven F; Dabis E; Peterlein CD, Efe T, Schofer M, Zumstein M, Willburger RE

Any change to this authorship requires mutual written agreement from the INVESTIGATORS

7 SIGNATURE

I agree to conduct this clinical study in accordance with the design and specific provisions of this protocol.

Investigator Signature

_____

Date of Signature

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