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Clinical Performance, Patient Reported Outcome, and Radiological Results of a Short, Tapered, Porous, Proximally Coated Cementless Femoral Stem: Results up to Seven Years of Follow-Up

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ABSTRACT

Background: The primary aim of our study was to assess clinical performance, patient reported outcome and radiological results of cementless primary total hip arthroplasty using Tri-Lock Bone Preservation Stem.

Methods: Between March 2010 and June 2012, 163 consecutive patients, were enrolled in the study. Patients were assessed clinically and radiographically prior to surgery as well as at 6, 12, 24 months and then at 5, 6, and 7 years postoperatively.

Results: Using the Dorr classification, 39 patients (23.9%) were classified as Dorr A, 116 patients (71.2%) as Dorr B, and 8 patients (4.9%) as Dorr C. A total of 139 patients (85.3%) received a high offset, whereas 24 patients (14.7%) received a standard offset stem. Total Harris Hip Score of the patients increased from a mean of 27.29 (±4.6) preoperatively, upto 97.28 (±9.0) after 5 years. Mean preoperative Short Form-12 (SF-12) Physical Health Composite Scale score was 27.31 (±3.8). After 5 year was 55.3 (34-57). The mean preoperative SF-12 Mental Health Composite Scale score was 57.02 (±5.9). After 5 year was 59.3 (28.7-60.8). Only one patient underwent revision surgery for dislocation and revision of the head.

Conclusion: Tri-lock Bone Preservation Stem DePuy proved to be an easy-to-use device. Results obtained up to 7 years of FU show excellent clinical performance, as well as radiographic osseointegration, with no cases of aseptic loosening and no images of progressive radiolucent lines or periprosthetic osteolysis.

We have assisted in the recent years within the orthopedic community to an increasing interest and spread in use of short stems [1].

Short femoral stems, also called metaphyseal stems, are available in a wide range of stems that differ in design, surgical technique, and outcomes and have been designed with the supposed, theoretical advantage of preserving bone tissue, decreasing stress shielding, reducing the incidence of thigh pain postoperatively, facilitating minimally invasive surgical techniques, increasing long-term survival of the stem, and simplifying surgical revision procedures. This latter aspect is of particular relevance in relation to the increased use of joint replacements in young and active patients who frequently have very high expectations, particularly with regard to restoring their quality of life, which frequently involves high-activity recreational interests. Consequently, this group of patients in their lifetime may face a number of revision procedures [2,3], where preserving the bone stock is particularly important [4].

Additionally, improvements in surgical techniques and materials have expanded the use of cementless stems to a larger number of patients, regardless of their age. In this clinical series, we have performed cementless primary total hip arthroplasty (THA) Tri-Lock Bone Preservation Stem (BPS).

Khanuja et al [5] published a classification of short stems, which we have adopted, that classifies the Tri-Lock BPS as Type 4, that is, a shortened tapered conventional stem. Type 4 stems were not conceived to be neck-preserving. The tapered-wedge design and

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the proximal porous coating allows the proximal fixation of the implant; these implants are similar to the conventional porous-coated tapered design, but present a shorter length and/or a reduced distal part of the stem.

The Tri-Lock stem has been available since 2009 in the United States and since 2010 in Europe in its short-stemmed (Tri-Lock BPS) variant [6–8]. The stem has been then reduced in size and shape compared to the original stem variant. The Tri-Lock femoral stem has been in use for about 30 years as a cementless stem in THAs, and is characterized by having excellent clinical results. The Tri-Lock system is based on noncemented stems, with a straight, collarless, chrome-cobalt Muller design, which was popular in the 1980s and 1990s [9–11].

Compared to the conventional Tri-Lock, Tri-Lock BPS has an increased surface roughness, thanks to GRIPTION technology [12].

The aim of our study is to assess clinical performance, patient reported outcome, and radiological results of cementless primary THA using Tri-Lock BPS.

Materials and Methods

Between March 2010 and June 2012, 163 consecutive patients were enrolled in the study. All patients underwent THA using the cementless femoral Tri-Lock BPS (DePuy Synthes, Warsaw, IN), a PINNACLE acetabular cup (DePuy Synthes), a polyethylene insert (Marathon 10° hooded insert; DePuy Synthes), and a ceramic head BIOLOX Delta 32-mm ball head (CeramTec, Plochingen, Germany).

Because this study refers to a “real world” situation both inclusion and exclusion criteria were in line with those reported in the Information For Use leaflet released by the manufacturer. As a consequence, all primary cases treated in this period received the implant except for the following:

- Active local or systemic infection
- Loss of musculature, neuromuscular compromise, or vascular deficiency in the affected limb rendering the procedure unjustified
- Poor bone quality such as osteoporosis where, in the surgeon's opinion, there could be considerable migration of the prosthesis or a significant chance of fracture of the femoral shaft and/or the lack of adequate bone to support the implant
- Charcot's or Paget's disease.

All implantations were performed by a single surgeon. All procedures were performed taking particular care of the broaching technique in order to minimize possible sit up of the definitive stem in respect to the last utilized trial rasp due to GRIPTION porous coating on the implant. This possibility needs to be indeed considered in subjects with good bone quality. In these latter cases, the trial rasp should perfectly fit in the desired sitting level as described in the surgical technique.

All patients underwent total hip replacement performed via posterolateral approach after having signed written informed consent to the intervention.

Patients were assessed both clinically and radiographically prior to surgery as well as at 6, 12, 24 months and then at 5, 6, and 7 years postoperatively. At 12 months, 1 patient failed to present at follow-up (FU); furthermore, 1 patient was lost to FU at 5 years and 2 at 6 years for a total of 4 patients lost to FU at the 7-year time point out of 163 of the study cohort.

Therefore, the final number of patients available for clinical and radiological FU was 20 at 7 years, 83 at 6 years, and 56 at 5 years for a total of 159.

Additionally, during the study period, 3 patients died after 2 years and 2 after 5 years from intervention hitting the 24 months and 5 years of clinical and radiological FU timelines (the stem was still in situ and without any kind of complication).

Postoperative evaluation included the assessment of pain using the visual analogue scale (VAS) (mapping of the pain) as well as the Harris Hip Score (HHS) [13]. VAS was indicated by the patient on a 10-cm straight line, which visually represented the magnitude of pain that a patient experienced. One end indicated the absence of pain, the other end indicated the worst imaginable pain. Pain ranging from 1 to 3 cm was classified as mild, 4 to 7 cm as moderate, and 8 to 10 cm as severe. Patients reported the outcome preoperatively and at each FU by means of the self-administered general health questionnaire Short Form-12 (SF-12) [14].

Radiographic assessment was conducted according to a standard radiographic protocol. The anteroposterior view of the pelvis was taken in weight-bearing conditions and with the legs internally rotated by 15°.

Radiographic analysis was conducted retrospectively by 2 co-authors experienced in these types of radiological assessments, with the aid of IMPAX (Server application: CZPACS; IMPAX Version 6.4.0.3125 2011; AGFA Healthcare N.V., Mortsel, Belgium) which allowed calculation of image magnification as well as a precise determination of subsidence, varus/valgus position of the implant, and the occurrence of radiolucent lines (RLL).

Preoperatively, radiographic assessment included classification of the morphology of the femoral canal according to Dorr [15]. Postoperatively, radiographic assessment included frontal alignment of the prosthetic implant, subsidence of the stem over time [10], osteolysis, RLL, and heterotopic ossification according to Brooker et al [16]. The presence of cortical hypertrophy was also assessed. RLL was defined as regularly shaped zones between the implant and the surrounding bone, typically parallel to the implant [17]. Subsidence was determined by measuring the distance between the apex of the prosthesis and the greater trochanter [7]; subsidence was considered to be present if the difference between the baseline and final FU measurement exceeded 3 mm.

In order to calculate the varus-valgus angle, an indirect method was applied. A line was drawn along the major axis of the prosthetic implant representing the prosthetic axis (reproduction of correct prosthetic axis was obtained from drawings and specifications provided by the manufacturer), and compared with a line passing through 2 different points obtained by calculating the exact half of the distance between the surfaces of the endo-cortex of 2 different points distal to the apex of the implant, the latter line representing the anatomical femoral axis. The angle measured between these 2 axes represented the difference in either the varus or the valgus between the position of the implant in the femoral canal and the natural femoral axis of the patient (Fig. 1).

We considered a threshold value of 5° for varus/valgus malposition and a progressive subsidence superior to 3 mm as a negative indicator of future stability of the implant [18–21].

Ethics Committee approval was obtained for collection and retrospective analysis of the data regarding this cohort of patients.

For continuous data, Shapiro-Wilk tests were used to test for major violations of the normality assumption. As normal distribution could not be assumed for clinical outcome data, data are presented as median and interquartile range. Normally distributed continuous data are presented as means ± standard deviation (SD). Categorical variables are presented as frequencies and percentages. Statistical analyses were performed using IBM SPSS Statistics version 20.0 (IBM, Armonk, NY). Survival analysis was performed using Kaplan-Meier method with 95% confidence interval. Implant survival was determined taking stem revision or impending revision for any reason as endpoint. Time course between procedure and revision was the measurement of implant survival. Correlations