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Thigh Pain Occurrence Rate in a Short, Tapered, Porous, Proximally-Coated Cementless Femoral Stem - Clinical and Radiological Results at 2-Year Follow-Up

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Abstract

Introduction: Short stems have been designed with the purpose of preserving bone tissue, decreasing the incidence of thigh pain and facilitating surgical techniques. The aim of our study was to assess whether a shortened tapered conventional stem was able to reduce the incidence of thigh pain.

Methods: Between March 2010 and December 2012, 200 patients were enrolled in the study. Visual analogue scale (VAS) that included mapping of the pain, Harris Hip Score (HHS), Short Form-12 (SF-12) and radiographic outcomes were evaluated prior to surgery as well as at 6, 12 and 24 months post-operatively.

Results: After 6 months, 6 patients (3%) had thigh pain. After 12 months, 3 patients (1.5%) complained about thigh pain. After 2 years, 2 patients (1%) had thigh pain. There was no correlation between pain and clinical, radiological, or demographic variables.

Conclusion: The shortened tapered conventional stem resulted in a lower incidence of thigh pain for up to 2-years following surgery, compared with conventional or other short stems.

Keywords: *hip osteoarthritis; osseointegration ; radiographic evaluation; short stem prosthesis; thigh pain; total hip arthroplasty*
Level of Evidence: *AAOS Therapeutic Level III*

Introduction

There has been increasing interest for minimally invasive total hip replacement (THR) [1,2] and most of the attention has been focused on reducing surgical exposure [3].

The main reason is related to expectations after joint replacements particularly with regard to restoring quality of life, involving high-activity recreational interests. Consequently patients may face revision procedures within their lifetime [4,5] therefore also preserving bone stock is par-

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ticularly important [6].

The incidence of thigh pain after cementless hip prosthesis has been reported in the literature as being present in 1.9% to 40.4% of cases [7], while the occurrence of thigh pain in patients with the original Tri-Lock design varies from 2% to 9% [8,9].

Short stems have been designed with the theoretical advantages of preserving bone tissue, decreasing stress shielding, reducing the incidence of thigh pain post-operatively, facilitating minimally invasive surgical techniques, increasing long-term survival of the stem, and enabling surgical revision procedures.

The Tri-Lock stem has been available since 2009 in the USA and since 2010 in Europe in its short-stemmed (Trilock BPS) variant [9-11].

The primary aim of our study was to assess whether the new stem was able to reduce the incidence of thigh pain reported to vary from 2% to 9% with the original design [8,9]. Additionally, the study was also designed to assess if pain, when present, was positively associated with different clinical, radiological and demographic variables.

Methods

Between March 2010 and December 2012, 200 consecutive patients were enrolled in the study. All implantations were performed by a single surgeon. All patients underwent Total Hip Arthroplasty (THA) using the cementless femoral Tri-lock BPS (DePuySynthes, Warsaw, IN), a Pinnacle acetabular cup (DePuySynthes), a polyethylene insert (Marathon 10° hooded insert, DePuySynthes) and a ceramic head Biolox Delta 32 mm ball head (Ceramtec, Plochingen, Germany).

Table 1. Demographics of Patients

Sex	
- Females	120 (60%)
- Males	80 (40%)
Age* (years)	68.7 (37.5-85)
BMI* (kg/m2)	26.7(16.4-38.1)
Femoral canal (Dorr type)	
- Type A	49 (24.9%)
- Type B	139 (69.5%)
- Type C	12 (6%)
Offset	
- Standard	29 (14.6%)
- High	171 (85.4%)

**Presented as mean (range)*

All patients underwent total hip replacement performed via postero-lateral approach.

Patients were assessed both clinically and radiographically prior to surgery and at 6, 12 and 24 months post-operatively. Postoperative evaluation included the assessment of pain using the VAS, which included mapping of the pain.

On the Visual Analogue Scale pain ranging from 1 to 3 cm was classified as mild, from 3 to 7 cm as moderate, and from 7 to 10 cm as severe. For assessing thigh pain, the definition of Barrack was used, i.e. only in the anterior portion of the thigh and distally to the inguinal area [12].

Patients were also evaluated preoperatively and at each follow-up by means of Harris Hip Score (HHS) [13] and the self-administered Short Form-12 (SF-12) [14].

Radiographic assessment was conducted according to a standard radiographic protocol. The antero-posterior view of the pelvis was taken in weight-bearing conditions and with the legs internally rotated by 15°. Radiographic analysis was conducted with the aid of IMPAX (Server application: CZPACS; IMPAX Version 6.4.0.3125 2011; AGFA Healthcare N.V., Septestraat 27, B-2640 Morstsel, Belgium).

Radiographic assessment included classification of the morphology of the femoral canal according to Dorr [15], frontal alignment of the prosthetic implant (Figure 1), along with subsidence of the stem over time [16], osteolysis, radiolucent lines (RLL), and heterotopic ossification according to Brooker [17]. The presence of cortical hypertrophy was also assessed.

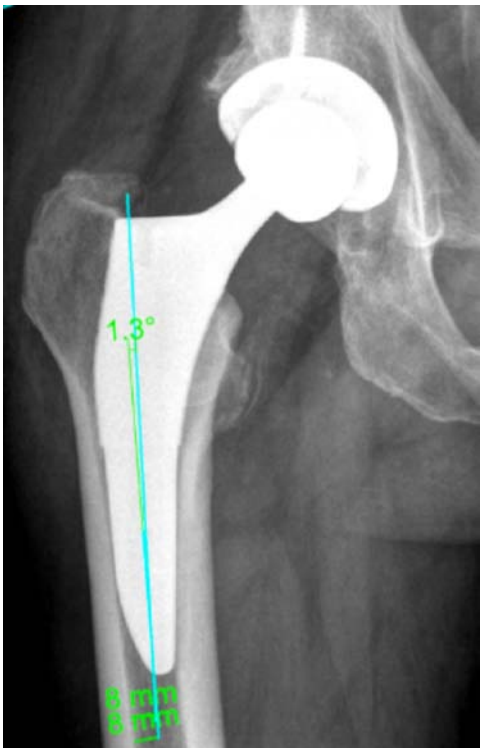

Figure 1. X-ray based determination of varus-valgus angles. The individual varus-valgus angle is calculated by 90° minus the depicted angle.

We considered a threshold value of 5° for varus/valgus malposition and a progressive subsidence of more than 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. Informed consent was obtained from all individual participants included in the study.

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 (IQR). Normally distributed continuous data are presented as means±standard deviation (SD). Categorical variables are presented as frequencies and percentages. Statistical analyses were performed using Stata/SE 12.1 (Stata Corp, College Station, TX, USA)

Results

The mean age of the study population at the time of index surgery was 68.7 ± 9.8 years (range, 37.5 – 85.1 years). There were 120 females (60%) and 80 males (40%). The mean BMI was 26.7 ± 3.7 kg/m2 (range, 16.4 – 38.1 kg/m2). 49 patients (24.5%) were classified as Dorr A, 139 patients (69.5%) as Dorr B, and 12 patients (6%) as Dorr C. 171 patients (85.4%) received a high offset stem, whereas 29 patients (14.6%) received a standard offset stem (Table I). Total HHS of the patients increased from a median of 44 (IQR, 35 - 52), preoperatively, to 98 (IQR, 96 - 100) after 6 months, 100 (97 - 100) after 12 months and 100 (98 – 100) after 24 months. The median Harris Hip Pain score was 10 (IQR, 0-20) at the preoperative assessment, and 44 (44 – 44) at each subsequent follow-up (Figure 2).

At 12 months, one patient failed to present at follow-up; at 24 months, two additional patients withdrew their consent for further participation in the study.

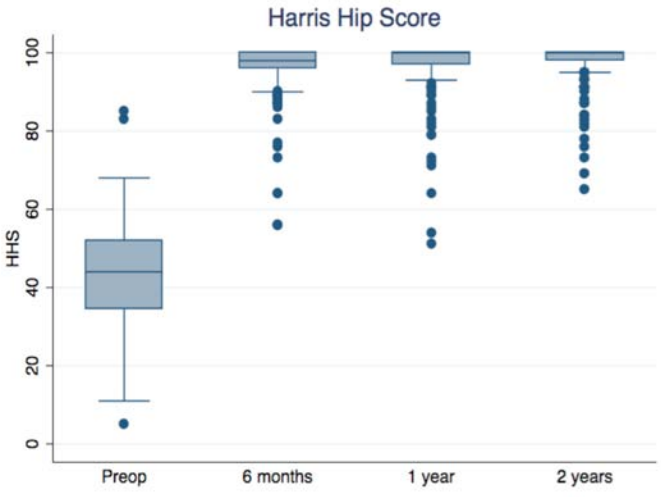

Figure 2. Harris Hip Score at each visit

At 6 month follow-up, 11 out of 200 patients (5.5%) complained of pain, 6 patients (3%) had thigh pain and 5 patients (2.5%) had trochanteric pain. After 12 months, 6 out of 199 patients (3%) experienced pain, 3 patients (1.5%) had thigh pain, and 3 patients (1.5%) had trochanteric pain. After 2 years, 5 out of 197 patients (2.5%) experienced pain, 2 patients (1%) with thigh pain and 3 patients (1.5%) with trochanteric pain. At 6 months, 2 patients experienced moderate pain, and at 12 and 24 months, 1 patient experienced moderate pain (Figure 3).

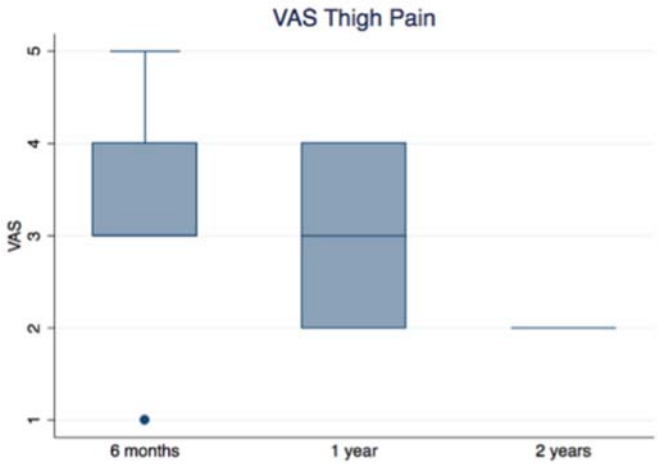

Figure 3. VAS score for thigh pain

Trochanteric pain was mild in 3 patients and moderate in 2 patients at 6 months. At both 12 as 24 months, trochanteric pain was mild in 1 case and moderate in 2 cases. We had no occurrence of inguinal pain in this cohort of patients.

The mean preoperative SF-12 Physical Health Composite Scale scores (PCS) was 27.4 ± 3.5; at 6, 12 and 24 months of follow-up, 53.5 ± 4.5, 53.9 ± 4.7, and 54.1 ±5.2, respectively. The mean preoperative SF-12 Mental Health Composite Scale scores (MCS) was 56.4 ± 5.7; at 6, 12 and 24 months of follow-up 59.7 ± 2.7, 59.6 ±3.4, and 59.6 ± 3.4, respectively. At the final radiological follow-up, subsidence of 3 mm or more was observed in 8 patients, with a mean (SD) subsidence value of 3.4 (SD, 0.5, range, 0-4) mm. In 87 patients, the stem was positioned at the slight varus (mean angle 1.5°) in 106 patients in slight valgus, (mean angle of 2.5°). In 4 patients in neutral alignment.

Implant positioning in the frontal plane could not be determined in 3 patients. No RLLs or osteolytic lesions were seen. Pedestal formation was observed in 18 out of 197 patients at the 2 year follow-up (9.1%). Concomitant pedestal formation did not occur in any of the patients with subsidence of at least 3 mm. In 1 patient (0.5%), at the 2-year follow-up, detachment of the greater trochanter oc-

curred. In a second patient (0.5%), partial avulsion of the apex of the greater trochanter took place. In both cases, treatment was conservative and successful. Two patients presented grade III heterotopic bone formation, but neither of these cases reported thigh or trochanteric pain.

In total, we observed 10 cases of cortical hypertrophy (5%), 3 cases at 12 months and 7 cases at 24 months. No correlation with pain was observed. We had no cases of periprosthetic fracture to report.

No patients underwent revision surgery during the 2 years of observation.

Discussion

The incidence of pain in the thigh with the original Tri-Lock design was reported as being between 2-9% [22] and 9.5% at 1 year and 8.7% at 2 years [23]. In 2008, the Tri-Lock femoral stem was modified so as to preserve the proximal femoral bone stock.

The aim of the study was to assess if the modified Tri-Lock BPS stem was able to reduce the incidence of thigh pain.

The literature evidence on these type of stems is limited. In the work of Khanuja et al. for Type-4 stem designs, which we refer to for Tri-Lock BPS, there are four reports altogether, involving 563 hips [8] reporting favourable clinical outcome results.

In a paper recently published [24], investigators reported favorable clinical and radiological results with Tri-Lock BPS at 5 years in a cohort of 119 out of 124 originally enrolled patients with a low (1.6%) incidence of thigh pain.

In our experience at 6 months, 2 patients (1%) experienced moderate pain, and at 12 and 24 months 1 of these 2 patients (0.5%) still reported moderate pain. Trochanteric pain was reported in 9 different patients (4.5%). At 12 and 24 months, trochanteric pain was mild in 1 case (0.5%) and moderate in 2 cases (1%).

In agreement with observations from other authors that in these Type-4 stems an extremely low incidence of periprosthetic fractures was reported (mean, 0.2%; range, 0% to 0.6%) [8], we also had no cases of periprosthetic fracture to report.

The total HHS, increased from a median preoperative value of 44 to 100 at 24 months.

The SF-12 in its two components mental (MCS) and physical (PCS) showed the following pattern: we reported a mean preoperative SF-12 MCS of 56.4 ± 5.7; and at 6, 12 and 24 months the SF-12 MCS were 59.7 ± 2.7, 59.6 ±3.4, and 59.6 ± 3.4, respectively.

Conversely, the PCS, which is centered on concrete activities shows a more dynamic and positive pattern between pre- and post-operative values, with mean preoperative SF-12 PCS of 27.4 ± 3.5; at 6, 12 and 24 months the SF-12 PCS values increased to 53.5 ± 4.5, 53.9 ± 4.7, and 54.1 ±5.2, respectively.

Strengths of this study are its completeness of pre-operative data and the low postoperative dropout rate, along with the meticulous reporting of thigh pain. Study limitations include the lack of a control group as well as the short follow-up period of the study. Due to the low incidence of postoperative pain, we were unable to highlight any factors that might be associated with postoperative pain.

Conclusion

Tri-lock BPS DePuy proved to be an easy-to-use device. Results obtained up to 2 years of follow-up show excellent radiographic osseointegration, no cases of septic loosening, and no images of progressive RLL or periprosthetic osteolysis. Furthermore, compared to the literature, there was a low percentage of thigh pain at 6, 12 and 24 months of follow-up.

These are the first clinical and radiological results on a relevant cohort of patients with Tri-lock BPS, which in this primary phase (2-year follow-up), concentrated primarily on incidence and prevalence of thigh pain. This observation deserves longer-term follow-up on clinical outcome, radiological appearance and implant survival.

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Disclosure

The authors declare that there is no conflict of interest regarding the publication of this paper. For full disclosures refer to last page of this journal.

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