Early migration characteristics of a hydroxyapatite-coated femoral stem: an RSA study

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Abstract Measurement of early stem subsidence can be used to predict the likelihood of long-term femoral component loosening and clinical failure. Data that examines the early migration pattern of clinically proven stems will provide clinicians with useful baseline data with which to compare new stem designs. This study was performed to evaluate the early migration pattern of a hydroxyapatite-coated press-fit femoral component that has been in use for over ten years. We enrolled 30 patients who underwent THA for osteoarthritis. The median age was 70 years (range, 55–80 years). Patients were clinically assessed using the Harris hip score. Radiostereometric analysis was used to evaluate stem migration at three to four days, six months, one year and two years. We observed a mean subsidence of 0.73 mm at six months, 0.62 mm at one year and 0.58 mm at two years

and a mean retroversion of 1.82° at six months, 1.90° at one year and 1.59° at two years. This data suggests that subsidence is confined to the first six months after which there was no further subsidence. The results from this study can be compared with those from novel cementless stem designs to help predict the long-term outcome one may expect from new cementless stem designs.

Introduction

Primary total hip arthroplasty (THA) is a common procedure, having been performed in over 135,000 patients in Australia between 1999 and 2007 [1] and in over 200,000 patients in the United States in 2003 alone [2]. Of the components used in Australia, four out of the five most frequently used femoral stems are cementless [1]. Cementless femoral stems ideally achieve direct integration between the stem surface and endosteal bone with the aim of decreasing the incidence of aseptic loosening [3, 4]. Nonetheless, the incidence of revision for cementless stems is similar to cemented components [1, 5].

Revision of loose prostheses can be surgically demanding, costly and associated with considerable patient morbidity [6]. Therefore, in an effort to improve function and survival of prostheses, new materials and designs are continually emerging and require validation. However, the complex behaviour of prostheses in clinical patients has limited the value of in vitro testing [7]. Instead, surgeons place greater reliance on long-term, longitudinal studies [4, 8], which are limited in their ability to identify poorly performing components early in their clinical use. Short-term clinical studies that are able to accurately predict the long-term clinical success of novel components would represent a substantial benefit for hip arthroplasty implant development.

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Early migration of prostheses predicts later loosening and implant failure [9, 10]. However, small amounts of early micromotion are difficult to detect on conventional radiographs. Radiostereometric analysis (RSA) is an accurate method of measuring implant micromotion [11]. It is accurate to $\pm 47 \mu\text{m}$, with a precision of $30 \mu\text{m}$ when monitoring femoral stem distal migration [12]. The RSA technique has been used to evaluate mid to long-term outcome, compare cementless and cemented stems, or, more commonly, assess the wear of the acetabular component of hip prostheses [13–15]. However, there are comparatively few studies evaluating early migration characteristics of cementless stems using this technique.

One hydroxyapatite-coated press-fit femoral component reportedly has high survivorship (97% at 15 years [16]) since its introduction in 1986 and is currently the most frequently used cementless femoral stem in Australia [1, 16]. Studies evaluating the long-term outcome of this stem have attributed its clinical success to a combination of its tapered design resulting in reduced proximal stress shielding and its fully coated surface promoting osseointegration and long-term durability [8, 17]. However, despite the excellent clinical results, there are no studies that examine the early migration characteristics that are fundamental to the long-term performance of this commonly used prosthesis.

This study aims to characterise the migration behaviour of a hydroxyapatite-coated press-fit femoral component and create a benchmark to which new prostheses may be compared using the same technique.

Materials and methods

We prospectively recruited 30 patients with osteoarthritis from the orthopaedic waiting list allocated for primary THA. We excluded patients who lived outside the Adelaide metropolitan area, those older than 80 years of age, and those with abnormal anatomy of the hip, inflammatory arthritis, or severe osteoporosis. One patient died, one relocated, and we excluded one patient owing to an intraoperative fracture during reaming of the canal. This left 27 patients (27 hips); nine were men and 18 women. The median age was 70 years (range, 55–80 years). The median height was 161 cm (range, 157–196 cm). The median weight was 78 kg (range, 51–105 kg). The study began in 2004 on receipt of ethical approval from the Repatriation General Hospital Research and Ethics Committee. All patients provided informed consent for the insertion of tantalum markers during surgery and subsequent RSA radiographs.

Twenty-eight of the 30 patients were operated upon by two surgeons (DC, GM). Each patient received a Corail hydroxyapatite coated, standard offset, collarless, press-fit

femoral stem (Corail; DePuy Orthopaedics Inc, Warsaw, IN).

We attached tantalum markers (1.0 mm diameter; RSA Biomedical, Umea, Sweden) at the time of manufacture to the shoulder and distal tip of the stem to allow RSA measurements of the stem in vivo (Fig. 1). Seven to nine tantalum markers (0.8 mm diameter; RSA Biomedical, Umea, Sweden) were inserted intraoperatively into the cancellous bone in the lateral and medial aspects of the proximal femur (Fig. 1). Each patient had RSA radiographs taken at three to four days, six months, one year and two years postoperatively. The radiographic exposures were taken using 100 kV and 4–6 mAS. We analysed each resultant pair of RSA radiographs using UmRSA software (version 6.0; RSA Biomedical, Umea, Sweden). Segment analysis was used to compare the translations and rotations of the two stem markers and centre of the femoral head relative to markers in the bone.

All patients were allowed to weightbear as tolerated postoperatively.

Functionality was measured by a research physiotherapist (VW) using the Harris hip score [18] preoperatively and at one and two years after surgery.

Eighteen of the 27 hips (67%) had complete RSA follow-up with radiographs taken at three to four days, six months, one year and two years. Two patients had no immediate postoperative RSA radiographs and one patient had radiographs of inadequate quality; hence, results from 24 patients were reported. Also, three patients had no six-month radiographs (one of these patients also had inade-

Fig. 1 A postoperative radiograph showing the markers inserted into the femur (a) and attached to the stem (b)

quate two year radiographs) and three additional patients had inadequate RSA examinations with either the femoral head or distal marker of the stem not being included in the radiographs. The usable results from these six patients were included in the study.

Results

After two years, the mean subsidence (distal migration) of the stem within the femoral canal was 0.58 mm (range, −0.23 to 3.71 mm) (Table 1; Fig. 2). At six months, nine patients (38%) had subsidence of more than 0.5 mm. None of these patients had more than 0.3 mm subsidence between six months and two years (Fig. 3). The mean retroversion rotation of the stem was 1.59° (range, −1.23° to 7.2°) (Table 1; Fig. 4). Seven stems (29%) rotated more than 2° into retroversion (Fig. 5). Of these, only one hip continued to rotate relative to the femoral bone after six months. This hip rotated a further 1.85° into retroversion.

Results of the Harris hip score demonstrated that all patients had considerable postoperative improvement in function. Preoperatively, patients had a mean total score of 35.41±10.05 (mean ± SD). At one year postoperatively the mean total score was 87.00±14.24, and at two years postoperatively the mean total score was 88.13±12.36. We observed an improvement in the mean Harris hip scores from preoperative to one year postoperative, but the mean remained unchanged between the first and second postoperative years.

Discussion

The aim of this study was to accurately characterise the migration pattern of a clinically proven cementless stem

over a two-year period using published RSA techniques [10, 19].

One limitation of this study was the number of patients in which RSA examinations were incomplete or in which the radiographs were of insufficient quality. Second, although the intended length of follow-up was short, a longer RSA study would be useful to confirm the ability of early RSA evaluation to predict the long-term behaviour of cementless stems.

Our data demonstrate that distal stem migration was confined to the first six postoperative months. Subsidence subsequently stabilised, with no further measurable subsidence between six months and two years (Fig. 2). This pattern of early migration has been reported previously with other cementless stems; however, there is limited information in the literature regarding a definitive cause for this early migration [20–22]. Impaction of the stem during the early postoperative phase may account for this finding of migration limited to the first six months. While our study did not evaluate the pattern of subsidence within the first six postoperative months, a previous study of migration in a cementless stem showed the majority of stem subsidence occurs within the first two months with no major stem migration occurring within the first week of implantation [22].

Subsidence caused by postoperative impaction may be exaggerated by early, unrestricted weightbearing. A study of the influence of postoperative weightbearing on distal stem migration after THA demonstrated that although the degree of loading did not correlate with stem micromotion at two years, immediate unrestricted postoperative loading did increase early subsidence [23]. Furthermore, Ström et al. [23] reported that early migration of the cementless CLS stem (Centerpulse, Bern, Switzerland) was consistently followed by stabilisation of the implant, further supporting the notion that the early subsidence measured for the Corail

Table 1 The mean, range and standard deviation of radiostereometric analysis (RSA) results for each axis of movement of the stem relative to femoral bone at six months, one year and two years postoperatively.

The number of hips included for analysis at each time point were 20, 24 and 21, respectively

Measurement	Postoperative time	Rotations (degrees)			Translations (mm)		
		Anterior tilt (+ve) Posterior tilt (−ve)	Retroversion (+ve) Anteversion (−ve)	Valgus (+ve) Varus (−ve)	Medial (+ve) Lateral (−ve)	Proximal (+ve) Distal (−ve)	Anterior (+ve) Posterior (−ve)
Mean	6 months	−0.30	1.82	−0.14	0.12	−0.73	−0.41
	1 year	−0.32	1.90	−0.13	0.15	−0.62	−0.49
	2 years	−0.30	1.59	−0.07	0.17	−0.58	−0.31
Range	6 months	−1.32 to 0.57	−1.54 to 8.02	−1.67 to 1.15	−0.37 to 0.93	−3.46 to 0.26	−2.18 to 0.44
	1 year	−1.14 to 0.32	−1.63 to 9.80	−1.45 to 1.04	−0.41 to 0.90	−3.66 to 0.35	−3.01 to 0.34
	2 years	−1.02 to 0.41	−1.23 to 7.20	−1.03 to 1.40	−0.45 to 0.92	−3.71 to 0.23	−2.26 to 0.69
SD	6 months	0.55	2.88	0.53	0.34	0.96	0.74
	1 year	0.42	2.86	0.43	0.30	0.93	0.83
	2 years	0.44	2.51	0.44	0.34	0.92	0.68

Fig. 2 Mean stem subsidence (mm) after 6, 12 and 24 months. The ranges show the standard error of the mean

stem is a result of “impaction” rather than “true” subsidence related to implant instability. In addition to the similarities in the pattern of migration between the uncoated CLS stem and the hydroxyapatite-coated Corail stem, the magnitudes of subsidence were also comparable [23].

Kärrholm et al. [10] suggest acceptable early migration (subsidence) for cementless stems is less than 1–1.5 mm within the first two years when measured by RSA. Although the measurements of stem subsidence in this study fall well below this threshold, the authors report subsidence of 0.5–1.0 mm within the first one to two years is cause for concern as a result of the increased risk of clinical failure seen with early migration [10]. A striking feature of our study is the variability in the magnitude of subsidence between patients measured at six months. Over one third of the patients whose data were included in the results experienced subsidence of over 0.5 mm within the first six months. Although these patients lie within the limit

of this accepted range (0.5–1.0 mm), the proven clinical success of this stem suggests one should be cautious in predicting the long-term performance of a stem purely on the numeric basis of its initial subsidence. A possible explanation for the variability in subsidence seen between patients is a difference in the quality of the initial stem fixation. Patients with a stem that is comparatively less impacted at the time of surgery may be expected to have more initial migration than those patients with a firmly impacted stem. Also, differences in the quality of the bone surrounding the prosthesis may account for some of the variability in subsidence.

Krismer et al. [20] highlighted the importance of the pattern of early migration during evaluation of the ten-year migration patterns of both cemented and cementless stems using the Einzel-Bild-Roentgen-Analyse (EBRA) method. The findings of this study showed a large proportion of the stems demonstrated early subsidence followed by subse-

Fig. 3 Graph showing stem subsidence (mm) for individual patients after 6, 12 and 24 months

Fig. 4 Mean stem rotation (degrees) after 6, 12 and 24 months. The ranges show the standard error of the mean

quent stability and good long-term survivorship. The authors concluded initial subsidence does not always lead to early revision [20]. A similar study by Kroell et al. [24] also evaluated the migration patterns of cemented and cementless stems. In contrast to the study by Krismer et al. [20], all the stems evaluated were ultimately revised. The results demonstrated that the majority of cementless stems requiring revision had a pattern of continual subsidence, with a smaller portion undergoing late onset migration. Interestingly, none of the stems which ultimately failed demonstrated a pattern of early subsidence followed by stability. Despite the large variation in early subsidence seen in our study, all of the stems subsequently stabilised. This feature of the Corail stem may be related to its design and hydroxyapatite coating and may help to explain its historically good performance clinically. It also highlights

the importance of observing the stem subsidence pattern in conjunction with numeric evaluation.

The positioning of markers by the manufacturer on the proximal shoulder and distal tip of the stem enabled stem rotation and tilt to be measured in this study. As with the measurements of subsidence, maximum rotation in this study occurred within the first six months (Fig. 4). Evaluation of the stem rotation showed a mean rotation into retroversion of 1.90° at one year. The amount of rotation measured is consistent with reports in the literature from other cementless stems. In their study of early migration of the CLS stem, Ström et al. [22] found that stems rotated into retroversion on average 1.79° in patients with unrestricted weight bearing after one year. Almost one third of the patients implanted with the Corail stem experienced more than 2° of stem rotation into retroversion.

Fig. 5 Graph showing stem rotation (degrees) for individual patients after 6, 12 and 24 months

Although this is a large proportion of patients, only one of these patients experienced continued rotation after six months. Again this highlights the ability of the Corail stem to stabilise despite large variability in early rotational stability. The Corail stem demonstrated only a small amount of posterior tilt and varus rotation, which also occurred within the first six months of the study.

Although there is some information regarding the clinical outcome of cementless stems, there is a paucity of information that accurately describes the migration characteristics of a clinically successful cementless femoral stem. From the results of this study, surgeons may expect to find a variable degree of early migration when using the Corail stem; however, in all of the cases presented here this was followed by subsequent stability. The amount of overall migration for the Corail stem is within the limits suggested as acceptable in the literature within the first two years, with negligible subsidence occurring in the final 18 months of the study. We believe that these findings are valuable in creating a standard set of values for the magnitude and pattern of stem migration that is likely to result in a prosthesis that has consistently good clinical outcomes. These data may serve as a benchmark for others to compare novel cementless stem designs.

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Conflict of interest Although the author(s) has/have not received and will not receive benefits for personal or professional use from a commercial party related directly or indirectly to the subject of this manuscript, benefits have been or will be received but are directed solely to a research fund, foundation, educational institution, or other non-profit organisation with which one or more of the author(s) is/are associated.

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