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Original Research

Migration Characteristics of a Proximally Coated Collarless Femoral Stem: A Prospective 2-Year Radiostereometric Analysis Study

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ABSTRACT

Background: Collared femoral stems have been considered to reduce the risk of early subsidence over collarless stems. However, with advances in material technology, new surface treatments have been introduced into cementless stem design to enhance primary fixation and long-term stability. This study aims to analyze the early migration behaviors of a proximally coated collarless femoral stem and cementless acetabular component and compare the outcomes with commercially available cementless stems and acetabular cups.

Methods: A total of 24 patients (25 hips) undergoing total hip arthroplasty were recruited and followed up for 2 years. All patients received a Masterloc femoral stem (Medacta International SA, Castel San Pietro, Switzerland) and an Mpact acetabular component (Medacta International SA, Castel San Pietro, Switzerland) with tantalum beads embedded during the operation. Radiographs for radiostereometric analysis were taken immediately postsurgery, 6-months, 1-year, and 2-years postoperatively.

Results: The median condition number for this study was 59. The median stem subsidence was −0.08 mm (−2.47 to 0.40) at 2 years. The median cup subsidence was −0.03 mm (−0.38 to 0.57) at 2 years. The migration of the Masterloc stem was less than that of other cementless collarless, as well as collared stems, as reported in literature.

Conclusions: This study has demonstrated the high stability and fixation provided with the use of a collarless cementless stem. The subsidence seen in both this cementless femoral stem and acetabular cup at 2 years postoperative was below the range reported in literature for cementless collarless and collared stems.

Introduction

The Australian Orthopaedic Association National Joint Replacement Registry has reported loosening as one of the top 4 reasons for revision in total hip arthroplasty in Australia [1]. Several studies have reported that early-stage micromotion between the implant and bone can be an indicator of the long-term fixation for cementless stems [2,3]. The proven relationship between micromotion and aseptic loosening has led to a growing interest in the measurement of implant micromotion. Radiostereometric analysis (RSA) has been used extensively as a valuable clinical tool to measure the migration of implants [4]. RSA provides accurate measurements to quantify the motion of an implant in reference to the bone in 3 dimensions [5].

Among cementless stems, collared femoral stem has been considered to minimize the risk of periprosthetic fractures and provide rotational stability [6,7]. The collar has been designed to provide immediate mechanical stability of the femoral stem when the patient begins weight-bearing, thereby acting to minimize the risk of early subsidence [6,8-11]. In comparison, collarless stems rely solely on press-fit fixation for initial fixation, followed by osseointegration of the implant for long-term stability. Various cementless, collarless implant designs have explored methods to improve both the initial and long-term fixation through treatment of the implant surface for bony ingrowth as well as designing for an anatomical fit that will assist in providing initial fixation.

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This study aims to evaluate the early migration behaviors of a proximal plasma-spray titanium-coated collarless stem coupled with a cementless hemispherical press-fit acetabular component and compare the stability of the implant with other cementless stem and acetabular cup designs.

Material and methods

Study design

This study was approved by the Sydney Local Health District. Twenty-four patients who were scheduled for a total hip arthroplasty were prospectively enrolled in this single surgeon, single center study. The mean age range for the entire cohort was 60.7 ± 8.8 years (42 to 75 years), with a male to female ratio of 54%. The study population consisted of patients with symptomatic primary osteoarthritis of the hip and was excluded in case of revision surgery, previous infection, or treatment of osteoporosis of the affected hip. All patients willingly gave informed consent and complied with the postoperative follow-up. The femur type was assessed using Dorr classification by 2 independent reviewers using the preoperative anterior-posterior x-ray [12]. The patient demographic and implant component details are tabulated in Table 1.

Surgical procedure

All patients received the Masterloc collarless femoral stem (Medacta International SA, Castel San Pietro, Switzerland). This stem is a cementless flat dual-tapered wedge stem. The stem features a shortened stem length and consists of a proximal coating of plasma-sprayed titanium using a proprietary technology to enhance biological fixation (Fig. 1). The plasma-sprayed titanium coating consisted of continuous interconnected pores with a total thickness of 700 μm. The pore diameter ranged between 100-350 μm with a pore distribution of 40%-70%.

The Mpact acetabular component (Medacta International SA, Castel San Pietro, Switzerland) was implanted as the acetabular component. The acetabular component is a cementless hemispherical press-fit acetabular shell, which also utilizes proprietary technology to enhance the fixation of the component.

Tantalum beads of 1.0-mm diameter were inserted into the proximal femur and the periacetabular bone with the use of an insertion device. The beads were inserted in a dispersed arrangement, with 6 to 9 tantalum markers placed in the proximal femur and 6 to 9 markers in each bone of the periacetabulum to obtain skeletal landmarks (Fig. 2). All surgical procedures were performed by a single experienced surgeon with a posterior approach.

Table 1
Patient demographics and implant component details for the study group.

Number of patients	
Female	11
Male	13
Total	24
Number of hip arthroplasties	25
Mean age (y)	60.7 (42-75)
BMI (kg/m^2)	29.6 (20.1-38.5)
Femur type	
A	44%
B	52%
C	4%
Mean stem sizes	6.96 (3-10)
Stem type	
Standard	7
Lateralized	18
Lateralized Plus	0

Range is given in brackets.

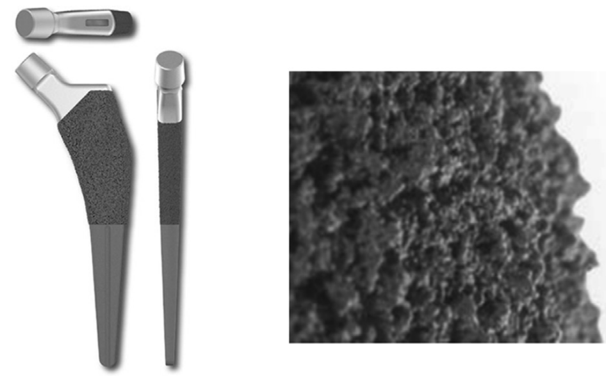

Figure 1. Masterloc femoral stem (left) and a close-up image of the plasma-sprayed Ti coated surface (right).

RSA analysis

All RSA imaging was performed at a single center, and the deidentified images were sent to Medical Device Research Australia (Sydney, Australia), where the analysis was performed using computer-aided design-based RSA. The RSA set-up consisted of 2 X-ray tubes positioned 1.2 m above a high-resolution X-ray cassette contained in a calibration box that defines the three-dimensional coordinate system at a 20° angle to the vertical. Both X-ray tubes exposed the films simultaneously. The micromotion analysis was performed using a model-based RSA image analysis software.

RSA X-rays were taken with patients in the supine position. The first computer-aided design-based RSA examination (within 5 days after surgery and prior to weight-bearing) served as the reference baseline. All subsequent evaluations of micromotion were related to the relative position of the implanted medical device with respect to the bone, as defined by the bone markers at the time of the evaluation. Micromotion of the implanted components was expressed as translation of the center of gravity of the components with respect to the bone markers along the 3 anatomic axes. The motion of the femoral stem and acetabular cup were described in relation to the marker beads placed in the proximal femur and acetabular bone during surgery, respectively. RSA measures include

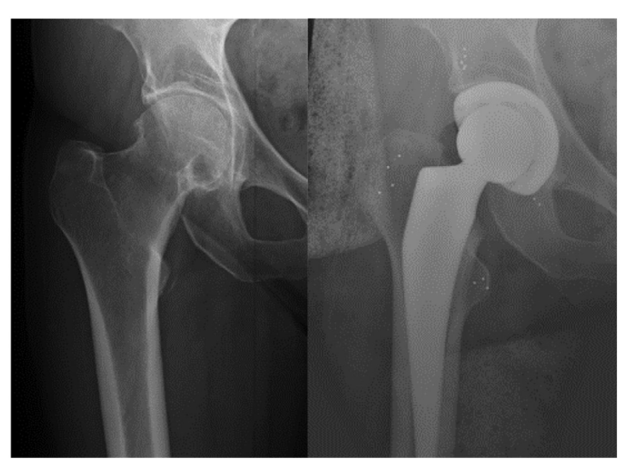

Figure 2. Anterior to posterior x-rays presurgery (left) and postsurgery (right) with the implant and tantalum beads.

an estimation of subsidence of the hip stem. Mean, median, minimum, and maximum values were calculated for all variables.

RSA follow-up

RSA examination was performed per the following schedule: immediate postsurgery, 6 months, 1 year, and 2 years. The median (range) of immediate postoperative follow-up was 14 days (0-43).

Results

The final number of hips included in the analysis at each timepoint was 25. The median condition number for this study was 59. Out of 25 hips, there was one dislocation that occurred at 9 months postsurgery. No patients had shown signs of loosening.

Table 2 presents the tabulated data for the cementless femoral stem migration. The data presented is the migration in the 3 planes: anteroposterior, subsidence distally in the femur, and lateral migration.

The median subsidence of the femoral stem was −0.08 mm (−2.47 to 0.40) at 2 years. Subsidence was initially seen at the first timepoint and stabilized afterward with a median subsidence of less than 0.1 mm seen at the 12- and 24-month timepoints. The anteroposterior subsidence in the femur at 2 years was 0.07 mm (−0.55 to 0.91). While the median lateral migration of the femoral stem was −0.22 mm (−3.12 to 0.31).

Table 3 presents the tabulated data for the cementless acetabular component migration. The data presented is the migration in the 3 planes: anteroposterior, subsidence proximally into the acetabulum, and lateral migration.

The median subsidence of the acetabular cup was −0.03 mm (−0.38 to 0.57) at 2 years. The median lateral migration of the acetabular cup at 2 years was −0.08 mm (−0.98 to 0.22). The median subsidence of the acetabular cup in the anteroposterior plane at 2-years was −0.17 mm (−2.64 to 0.50).

Discussion

The primary objective of this study was to evaluate the subsidence of a proximally coated, collarless femoral component and cementless hemispherical press-fit acetabular component and compare the migration behaviors with clinically proven cementless implants. This study showed no stems had failed because of fixation or showed evidence of loosening. The results demonstrated stabilization of the stem after initial subsidence, with a median stem migration of 0.08mm at 2 years postoperatively. Early subsidence is expected in cementless femoral stems, as the implants are designed to achieve primary stability through a press-fit into the bone. However, the secondary fixation is established over time through osseointegration to prevent aseptic mechanical loosening. Thus, RSA studies on cementless stems have found early subsidence in cementless stems that decreases over time [13-16].

Table 2
The mean, median, minimum, maximum, and error related to the rigid body fit of the RSA results at 6 months, 1-year, and 2-years postoperatively for the femoral stem.

Measurement	Postoperative timepoints	Translation (mm)			
		Anteroposterior	Subsidence (distal)	Lateral	Error
Median	6 months	0.02	−0.15	−0.32	0.17
	1 year	0.02	−0.10	−0.28	0.15
	2 years	0.07	−0.08	−0.22	0.23
Mean	6 months	−0.02	−0.25	−0.36	0.16
	1 year	0.06	−0.18	−0.39	0.25
	2 years	0.07	−0.27	−0.60	0.20
Minimum	6 months	−0.55	−1.82	−2.12	0.04
	1 year	−0.29	−2.34	−3.36	0.01
	2 years	−0.55	−2.47	−3.12	0.04
Maximum	6 months	0.34	0.16	0.36	0.36
	1 year	0.59	0.21	0.48	1.95
	2 years	0.91	0.40	0.31	0.35

Table 3
The mean, median, minimum, maximum, and error related to the rigid body fit of the RSA results at 6 months, 1-year, and 2-years postoperatively for the acetabular component.

Measurement	Postoperative timepoints	Translation (mm)			
		Anteroposterior	Subsidence (proximal)	Lateral	Error
Median	6 months	−0.15	0.07	−0.27	0.04
	1 year	−0.15	−0.01	−0.19	0.08
	2 years	−0.17	−0.03	−0.08	0.07
Mean	6 months	−0.19	0.05	−0.27	0.05
	1 year	−0.11	−0.01	−0.19	0.09
	2 years	−0.31	0.01	−0.19	0.10
Minimum	6 months	−0.78	−0.21	−0.74	0.01
	1 year	−0.99	−0.65	−1.58	0.01
	2 years	−2.64	−0.38	−0.98	0.00
Maximum	6 months	0.26	0.32	0.09	0.18
	1 year	1.48	0.61	0.80	0.29
	2 years	0.50	0.57	0.22	0.32

The distribution of the markers and reliability of RSA can be assessed using the condition number, where a high condition number can indicate poor marker distribution. Lower numbers in the range of 110 or less are considered very reliable and thus sufficient for determining prosthetic migration [5,17,18]. In this current study, the median condition number was 59, thereby indicating that the results from this study are highly reliable.

The Corail (DePuy Orthopaedics Inc., Warsaw, IN) is a well-established fully hydroxyapatite (HA) coated press-fit femoral stem with a high survivorship of 97% at 15 years [19]. Campbell et al [13] conducted a study to analyze the early migration behavior of the cementless collarless Corail femoral stem and provided a benchmark for new HA-coated press-fit femoral components. From a cohort of 18 with full datasets, Campbell et al identified a mean subsidence of 0.58 mm (−0.23-3.71 mm) at 24 months. While the stem in this study did not have any HA-coating, with only a proximally coated plasma-spray titanium treatment, the stem subsidence was similar to the Corail, with a mean subsidence of 0.27 mm.

Similarly, a randomized control RSA study conducted by Reiner et al [20] using a cementless grit-blasted titanium with proximal HA-coated dual-tapered femoral stem (SL-PLUS and SL-PLUS MIA stem, Smith & Nephew Orthopaedics AG, Baar, Switzerland) also demonstrated comparable results to the current study. A total of 29 patients were randomized into the 2 treatment groups. SL-PLUS MIA had a mean proximal/distal subsidence of −1.08 mm at 2 years in comparison to SL-PLUS with a subsidence of −0.40 mm (P = .030). When compared to the results from this study, the subsidence seen using the proximally coated plasma-sprayed stem was similar to the HA-coated femoral stem.

The Taperloc stem (Zimmer Biomet, Warsaw, IN, USA) is a stem design that is comparable to the stem in this study, being a cementless tapered femoral stem with a proximal titanium plasma-sprayed coating. Nebergall et al [16], found that from a cohort of 41 hips, the Taperloc stem had a median distal subsidence of 0.03 mm at 5 years postoperatively, with no significant differences over time observed after initial settling. More recently, Kok et al [21] conducted a randomized control trial with 3 experienced orthopaedic surgeons to determine the primary stability of the 4 Taperloc designs. Seventy-four stems were analyzed at the 2-year timepoint, which resulted in a mean subsidence ranging from −0.69 to −1.28 mm. In comparison to both studies, the results from this current study demonstrated comparable median and mean subsidence in comparison to the Taperloc cementless stems.

There are a number of studies that suggest collared stems have less subsidence than collarless stems [7-9,22,23]. Al-Najjim et al [7] found that in a study of 121 hips that had been grouped into receiving a corail collared and collarless stems, the collarless stems showed significant radiological subsidence in postoperative anterior-posterior radiograph compared to the collared stem. Similarly, in an EBRA-FCA (Einzel-Bild-Roentgen Analyze, Femoral Component Analysis) retrospective study conducted by Dammerer et al [22], the study found that the mean subsidence seen in the collared stem was significantly lower than that of collarless corail cementless implants. Dammerer et al concluded that at 18 months, the mean subsidence of the collared stems was significantly lower than that of the collarless stem cohort. In the present study, the collarless stem showed little subsidence. In comparison to both the collared and collarless corail stem cohorts from Dammerer et al's study, which had a mean subsidence of 1.6 mm and 2.2 mm, respectively, the collarless stem from this study showed less subsidence.

The minimal subsidence seen in the proximally coated collarless stem from this study could be a result of the proprietary porous coating on the implant. The stem follows the design concept of a flat tapered wedge design to obtain the initial stability. Although the stem used in this current study did not have HA-coating, the proximal surface of the stem had been treated with the proprietary porous coating treatment of titanium applied via plasma-spray. Both HA-coating and plasma-spray treatment are designed to facilitate the physiological loading of the bone by creating a large surface area for bony contact and ingrowth due to the coating topography. In an animal study by Walsh et al [24], where a HA-coated titanium alloy implant was compared to a plasma-sprayed titanium coating, evidence of new bone formation within the titanium plasma surfaces were seen in vivo, allowing for fixation at the microlevel to resist shear forces. Walsh et al concluded that although both HA-coated and titanium plasma-sprayed surfaces provided an osteoconductive surface for bone on-growth, the titanium plasma-sprayed samples provided a more robust cortical bone-implant interface that is required for long-term implant stability.

The subsidence of the cementless acetabular cup at 2 years has shown a median subsidence of 0.03 mm. The subsidence seen with the cementless acetabular component from the current study was less than that of literature, where an average range of 0.09 to 1.4 mm were seen in various directions [25-28]. Jorgensen et al [25] conducted an RSA study to compare the migration of porous components and a porous cup coated with HA. The study found that the HA-coated cup had more subsidence than the cup without at all timepoints, with a 2-year subsidence of 0.2 mm and 0.09 mm, respectively. When compared to the findings by Jorgensen et al, the cementless acetabular component in the present study resulted in less subsidence in comparison to both acetabular component types. There was one dislocation that occurred between the 6-month and 1-year timepoints in a type A femur where a smaller femoral stem had been implanted. The fixation seen at the 2 timepoints were of no concern.

A limitation of this study was that all stems were implanted using a posterior approach by a single experienced surgeon. Subsidence of the implant may vary with other surgical approaches and parameters.

Conclusions

This study has demonstrated the high stability and fixation provided with the use of cementless components. The proximally coated, collarless stem and cementless acetabular cup showed high secondary stability with no signs of implant loosening throughout the 2-year follow-up period. Based on the early fixation seen from the current study, excellent long-term survival of these cementless components can be predicted.

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Conflicts of interest

M. Dixon receives royalties from Medacta Australia Pty Ltd. L. Suzuki and S. Munir are paid employees of Medacta Australia Pty Ltd.

For full disclosure statements refer to https://doi.org/10.1016/j.artd.2023.101157.

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