A titanium plasma-sprayed cup with and without hydroxyapatite-coating: a randomised radiostereometric study of stability and osseointegration

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ABSTRACT: We present a prospective, two-centre radiostereometric analysis (RSA) regarding the stability of a flattened pole titanium press-fit cup (EP-FIT PLUS), and whether additional hydroxyapatite coating leads to faster bone ingrowth into the porous coating. Forty-two postmenopausal female patients (44 hips) undergoing total hip arthroplasty for primary osteoarthritis, selected to avoid hormonal factors influencing bone metabolism, were randomised to receive this cup with a titanium-plasma-sprayed surface with or without an additional hydroxyapatite coating. RSA was used to measure cup translation and rotation along three cardinal axes with respect to the host bone at the following time points: immediately postoperatively, at 6 weeks, and at 3, 6, 12, and 24 months. The most pronounced translation was proximal (0.11 mm) and posterior tilt (-0.27°). No difference in translation and rotation could be detected between the two groups. With the exception of one cup with an isolated radiolucent line <2 mm in zone 1, all cups showed complete osseointegration on conventional radiographs. The flattened pole cup provided excellent early stability and no advantage could be detected with additional hydroxyapatite coating.

KEY WORDS: Total hip arthroplasty, Acetabular cup, Hydroxyapatite coating, Titanium-plasma-sprayed, Radiostereometric analysis

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INTRODUCTION

Registry data indicate that cementless total hip arthroplasty (THA) may have higher rates of revision than cemented THA, regardless of patient age (1). This discrepancy appears to be mainly related to the poorer performance of cementless cups (1), and has led to efforts to optimise fixation strategies and improve acetabular cup designs. The majority of press-fit components have hemispherical designs, but dual- or triple-radius designs offer potential improvements in physiological load transfer and bone contact that should theoretically result in enhanced stability (2, 3). These cups have an increased oversize and flattening at the pole, which has been recommended for achieving maximum peripheral contact (4). While data from several radiostereometric analyses (RSA) have reported
good early stability for hemispherical cups (5-7), such findings are unavailable to date for cups with flattened poles and triple-radius designs. The stability of cementless components is also influenced by the type of surface coating employed. Many cementless cups utilise porous titanium coatings, and sometimes an additional hydroxyapatite (HA) layer is applied to stimulate bone ingrowth. Several authors have described a closer bone-implant contact in HA-coated cups, evidenced by a lower frequency of radiolucent lines two years after implantation (5-7). RSA studies of HA-coated acetabular cups have reported less proximal migration and less rotation around the transverse (medial-lateral) axis of the components (5, 8, 9). Earlier studies have shown that there is a settling phase of the acetabular cup during the first postoperative months (6, 7). The addition of an osteoconductive HA layer might lead to faster bone ingrowth into the porous coating and earlier achievement of secondary stability compared with cups using only a titanium plasma-sprayed surface. The present study aimed to determine the amount of early migration of a flattened pole press-fit cup with a triple-radius configuration by means of RSA, and to compare the amount and patterns of early migration between cups with titanium plasma-sprayed surface with and without additional HA coating.

MATERIALS AND METHODS

Patient cohort

After appropriate ethical committee approval, 42 postmenopausal women (44 hips) undergoing THA for primary osteoarthritis were enrolled in this prospective, two-centre study. We limited the cohort to postmenopausal women, as males and females have differences in bone mass and bone mineral density (10) and menopause is associated with hormonal changes that also could affect bone metabolism, which collectively could bias the results. Additional inclusion criteria included clinical/radiographic evidence of hip osteoarthritis, age 60-75 years, and body mass index (BMI) <30 kg/m². Exclusion criteria included post-traumatic osteoarthritis, previous surgery or infection around the hip joint, hip dysplasia exceeding Crowe type 1, BMI >30 kg/m², and patients with diagnosed osteoporosis or regularly taking medication known to affect bone metabolism (e.g. cortisone). All participants provided written informed consent.

Implant characteristics

The EP-FIT PLUS cup is composed of pure titanium. Its outer surface has a triple-radius configuration on cross-section, creating peripheral, transitional, and polar zones (Fig. 1). Initial implant-bone contact is achieved at both the equator and the transition zone of the cup, whereas a small gap remains at the polar zone. It has a slight oversize of 2% at the periphery of the shell and of 3% at the peripherally located dentated ridges for an improved press-fit and to account for extra bone removed during hemispherical reaming (approximately 0.5 mm). The outer surface of the shell is coated with a double layer titanium plasma-sprayed porous surface (mean roughness, 200 µm). For the HA-coated version, a highly crystalline HA coating is plasma-sprayed on the porous titanium, with a thickness of 50 µm. Both components used in this analysis were identical in terms of their dimensions and the thickness of their coatings. All cups had a standard polyethylene liner, and articulated with a 28 mm ceramic ball head (BIOLOX
Surgical technique

Patients were operated upon between March 2005 and December 2006 by two senior surgeons. To reduce bias due to differences in surgical procedure, each centre recruited half of each group. One centre used a lateral transgluteal approach with patients in the supine position, while the other used a posterior approach with patients in the lateral decubitus position. The postoperative treatment regime was standardised for both centres with six weeks of partial (50%) weight bearing and full weight bearing thereafter.

Radiostereometric analysis

Model-based RSA as described by Kaptein and colleagues was used after a prior feasibility study confirmed its accuracy (11, 12). For the current study, six to nine 1 mm Tantalum markers, used as reference points for RSA analysis, were distributed in a scattered fashion into the acetabular bone after hemispherical reaming of the acetabulum and prior to implantation of the cup (13). A non-oversized cup without additional screw fixation was used in each case. Computer-aided models of the cup obtained from the manufacturer helped determine the position and orientation of the cup via automated contour matching (11). Because the cup has an axis of symmetry perpendicular to the base circle of the cup, rotation around this axis cannot be determined by this method (13). Baseline RSA images were taken within 7 days postoperatively, after mobilisation of the patients and used as a zero migration reference for the follow-up RSA images taken at 6 weeks, and 3, 6, 12, and 24 months. All RSA images were taken using a uniplanar setup with the patient in a supine position and with 15° internal rotation of the feet. The RSA calibration cage (Medis specials B.V., Leiden, The Netherlands) was placed under the examination table. Radiographs were loaded into RSA-CMS software version 4.0 (Medis B.V., Leiden, The Netherlands) for quality control and calibration. Cup position and orientation, relative to the markers in the acetabulum bone, was assessed using model-based RSA software version 1.34 (Medis specials B.V., Leiden, The Netherlands) (11). Cup migration was calculated as the relative change in position and orientation of the cup with respect to the bone markers over time (Fig. 2).

At the 6-month time point, RSA precision was assessed with 38 double examinations (Tab. I). Migration exceeding the upper limit of the 95% confidence interval (CI) of the difference between replicate examinations was considered significant and not caused by measurement error.

Clinical and radiographic evaluation

Harris Hip Scores were assessed preoperatively and at 2 years. Patients completed the Western Ontario and...
McMaster Universities (WOMAC) Osteoarthritis Index at the last follow-up. Conventional radiographic evaluation was done on anteroposterior images of the pelvis and lateral images of the hip. Implant positioning was assessed by measuring the inclination angles, and radiolucent lines were evaluated using the zones defined by DeLee and Charnley (15). Device-related adverse events were documented. Radiographic evaluations, including the status of the polar gap, were performed immediately postoperatively and at 1 and 2 years. All patients completed the study except one who was lost to follow-up due to non-compliance after 3 months. This patient’s data was used for the time period for which they were compliant.

**Statistical analysis**

A power calculation established the required sample size based on a standard deviation (SD) of migration of 0.5 mm (6). Practical equivalence limits were defined as ± 0.4 mm for translation or ± 0.4° for rotation (16). To demonstrate equivalence with a power of 80% and a p-value of 0.05, 20 patients in each group were needed. Cup migration of both groups at 2 years was first analysed with a graphical equivalence test that employed a null hypothesis of unequal means; rejection of the null hypotheses leads to the conclusion of equivalence and is achieved when the 95% CI lie completely within the practical equivalence limits defined for the study. Formal equivalence testing was done with two one-sided non-parametric Mann-Whitney tests because RSA data contained outliers. Post-hoc Holm-Bonferroni correction procedure was applied for multiple testing (17). The resulting significance level using this procedure was 0.0099, with all p-values equal or above considered non-significant. Migration patterns over time were compared using repeated measures analysis of variance.

**RESULTS**

**Patients**

Overall, 22 hips were assigned to the Ti group and 22 hips to the HA group (Tab. II).

**RSA measurements**

Results of the RSA analysis until 2 years postoperatively are presented in Figures 3 and 4.

After 2 years, 15 cups in the Ti group and 10 cups in the HA group had migrated in excess of the limits of detectable cranial (y-axis) migration (i.e. migration of more than 0.08 mm). Rotation around the x-axis (posterior tilt) exceeding the detectable limit of 0.23° was noted for 8 HA cups and 14 TI cups at 2 years (Fig. 4). The graphical equivalence tests at 2 years showed equivalent translation along each of the 3 car-
dinal axes and equivalent rotation around the x-axis for both the HA- and the Ti group. No conclusions could be drawn about rotation around the y- and z-axis (Fig. 5).

At 2 years, mean translation in the HA group and Ti group along the x-, y- and z-axes was 0.00 and 0.10, 0.10 and 0.11, and 0.02 and 0.01 mm, respectively. Mean rotation around the x-, y- and z-axes was -0.29 and -0.39, -0.09 and -0.36, and 0.28 and -0.01 degrees, respectively. Formal equivalence tests with post-hoc corrections confirmed that the null-hypotheses could be rejected for all translational movements. We could not reject the null-hypothesis for any of the axes for rotation and results were confirmed to be inconclusive (x; p = 0.00 / 0.099), (y; p = 0.00 / 0.04) (z; p = 0.00 / 0.07).

Three cups demonstrated increased migration. Two cups showed increased rotation around the z-axis after 2 years: one HA cup had rotated 2.1 degrees (adduction) and one Ti cup -2.4 degrees (abduction). Another cup of the Ti group showed increased rotation of -2.5 and -2.4 degrees along the x- and y-axes (external rotation with posterior tilt). Plotting the inclination angle of each cup against micromotion at 2 years did not reveal a linear relationship between these two variables for any of the movements.

With respect to the migration pattern over time, there was no evidence to suggest differences between the two groups. Variation from one subject to another was higher than variation over time or from one group to another.

Clinical and radiographic results

At two years, the mean Harris Hip Score was 96.7 (range 63 - 100) in the HA group and of 97.1 (range 81 - 100) in the Ti group. WOMAC scores were 87.2 (range 49 - 100) and 92.9 (range 74 - 100), respectively.

Gaps in the dome area were visible in 21 cases on the first postoperative radiograph. At final follow-up, these gaps were no longer detectable. One of the cups showed an isolated radiolucent line <2 mm in zone 1. None of the cups with an increased rotational movement showed radiographic signs of mechanical loosening. No implant-related adverse effects were observed.
DISCUSSION

The present study indicates that this flattened pole press-fit acetabular cup has excellent primary and secondary stability for at least 2 years. RSA has exhibited high precision in detailing early prosthetic migration (18-26), establishing it as the optimal analytic tool for measuring initial stability. Our results compare favourably to reports with hemispherical or dual-radius cups. In analysing 61 THAs with a porous-coated hemispherical titanium alloy press-fit cup, Zhou et al noted translations of less than 0.40 mm and mean rotations below 1.5° in all 3 axes (27). Onsten et al measured migration between 0.18 mm and 0.27 mm in all three cardinal axes with a HA-coated dual-radius press-fit cup after 24 months (6). The same authors also reported a 0.3 mm migration for a hemispherical press-fit cup undergoing RSA testing at 2 years, with no difference in migration between this implant and a cemented cup (28).

There are contradictory reports regarding whether migration occurs early (29) or later (30) in the stabilisation process. In our study, migration mainly occurred within the first 6 weeks postoperatively, with cup positions remaining almost unchanged thereafter, which is in accordance with the results by Zhou et al (27). The initial assessment of acetabular migration patterns is an essential tool for prognosticating medium- and long-term stability, as early migration predicts for both eventual aseptic loosening of the acetabulum and inferior clinical outcomes in different cup designs (31, 32). Conversely, low or no migration during the first 2 years following implantation of porous-coated cups was predictive of a stable fixation one decade later (5). Studies have also demonstrated that initial stability is a prerequisite for bone ingrowth into the porous coating (29).

The present results suggest that HA-coating had no significant effect on early cup migration. Differences between the groups were minor; however, the intragroup variability was high, leading to inconclusive results for rotational movement after 2 years. Although this highlights the excellent stability of the cup itself, it also points to a potential study limitation in that the sample size was not sufficiently powered. An analysis of maximal-total-point motion might lead to more conclusive results, but such methodology is not yet available for hemispherical or similar cups. This study has other potential limitations worth noting. The cohort was rather small and included only postmenopausal female patients. Therefore, the results might not be generalisable for all patients. Additionally, although both the lateral and posterior approaches offer excellent joint visualisation, the use of two different techniques may have had an impact on component placement.

Our results are in contrast with several reports in the literature, where the use of an HA coating on porous press-fit cups has led to a reduced migration (7, 32, 33). In comparing the migration of HA-coated to titanium-mesh coated press-fit cups with screw fixation, Thanner et al also found less rotation around the longitudinal axis of the cup in the HA-coated group (7). Three cups in the present series presented rotational movements in excess of 2°. However, at the time of last follow-up, these cases had no radiographic signs of loosening or clinical failure. These three cases will be closely monitored in the future. The radiographic analysis indicated excellent osseointegration of all cups over the study period. The disappearance of the initial polar gap at 2 years has been previously reported in cups with flattened poles of either a dual- or a triple-radius design and suggests that this occurs via osseointegration and not through subsidence (6, 34).

In conclusion, this study confirms the excellent initial stability of this triple-radius cup, with results at least comparable to those reported for more frequently used hemispherical and dual-radius components. Even with the use of RSA, currently the most sensitive tool for assessing migration, HA-coating was not observed to have a significant effect on the early stability of this cup.

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