

# No effect of additional screw fixation of a cementless, all-polyethylene press-fit socket on migration, wear, and clinical outcome

## A 6.5-year randomized radiostereometric analysis follow-up report

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Submitted 2015-10-08. Accepted 2016-03-21.

**Background and purpose** — Additional screw fixation of the all-polyethylene press-fit RM cup (Mathys) has no additional value for migration, in the first 2 years after surgery. However, the medium-term and long-term effects of screw fixation remain unclear. We therefore evaluated the influence of screw fixation on migration, wear, and clinical outcome at 6.5 years using radiostereometric analysis (RSA).

**Patients and methods** — This study involved prolonged follow-up from a previous randomized controlled trial (RCT). We analyzed RSA radiographs taken at baseline and at 1-, 2-, and 6.5-year follow-up. Cup migration and wear were assessed using model-based RSA software. Wear was calculated as translation of the femoral head model in relation to the cup model. Total translation, rotation, and wear were calculated mathematically from results of the orthogonal components.

**Results** — 27 patients (15 with screw fixation and 12 without) were available for follow-up at 6.5 (5.6–7.2) years. Total translation (0.50 mm vs. 0.56 mm) and rotation (1.01 degrees vs. 1.33 degrees) of the cup was low, and was not significantly different between the 2 groups. Wear increased over time, and was similar between the 2 groups (0.58 mm vs. 0.53 mm). Wear rate (0.08 mm/year vs. 0.09 mm/year) and clinical outcomes were also similar.

**Interpretation** — Our results indicate that additional screw fixation of all-polyethylene press-fit RM cups has no additional value regarding medium-term migration and clinical outcome. The wear rate was low in both groups.

ever, the value of additional screw fixation of press-fit acetabular cup implants on implant survival is questioned. On the one hand, additional screws can increase short-term fixation (Heller et al. 2013). On the other hand, there are reasons to believe that additional screws may cause increased micromotion in several regions of the cup (Won et al. 1995). Furthermore, screws may also cause stress shielding, which, in turn, can result in increased implant mobility in the long term due to bone resorption (Wolff 1986). Moreover, additional screw stabilization could facilitate migration of polyethylene debris into the pelvis through and along the screw tracts, resulting in osteolysis (Schmalzried et al. 1997). It is therefore conceivable that wear and wear rate of cup implants are important factors in this process, as more wear leads to more debris (Young et al. 2002).

Previously, our group reported on the short-term effects of additional screw fixation of the cementless, all-polyethylene RM press-fit cup (Mathys AG, Bettlach, Switzerland), measured by radiostereometric analysis (RSA). At 2-year follow-up, no clinically relevant differences in cup stability and clinical outcomes were seen between patients with additional screws and patients without (Pakvis et al. 2012). These findings were confirmed by a meta-analysis of studies in the literature, which focused on the effect of additional screw fixation on the stability of press-fit cups (Ni et al. 2014). This meta-analysis included studies with a follow-up of up to 5 years. Along with our previous study, only 2 other RCTs were included. Both investigated titanium alloy cups with a polyethylene liner (Thanner et al. 2000, Röhrli et al. 2004). Recently, the results of long-term follow-up in the latter study were published—again showing no difference between the groups (Otten et al. 2016). The results on migration and wear from these studies using titanium implants are difficult to compare with the results with the titanium-coated all-polyethylene cup in the present study.

Primary fixation of the acetabular cup in total hip arthroplasty (THA) is vital for long-term stability (Pilliar et al. 1986). In cementless press-fit cups, this initial stability is achieved by the press-fit fixation. Additional primary fixation may be obtained by the use of extra screws (Tabata et al. 2015). How-

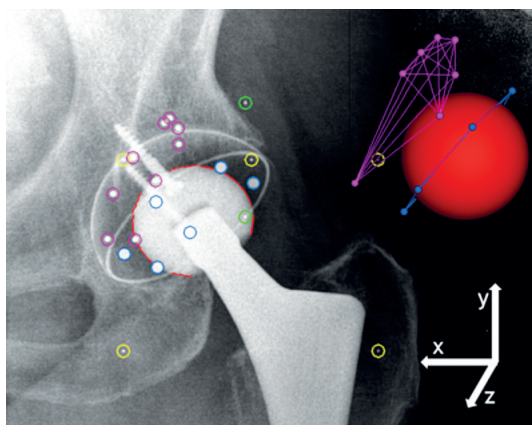


Figure 1. Pelvic radiograph showing the RM press-fit socket with additional screw fixation, tantalum RSA markers, and the marker models generated: acetabular bone markers and model (pink); cup implant markers and model (blue); femoral head contour and model (red); fiducial calibration box markers (yellow); and control calibration box markers (green).

In this study, we assessed the medium-term effect of additional screw fixation of this all-polyethylene cup on migration, wear, and clinical outcome.

## Patients and methods

### Study design and patients

This paper describes the prolonged follow-up of a previous, single-center, patient-blinded, randomized controlled trial (RCT) performed at Sint Maartenskliniek in Nijmegen, the Netherlands (Pakvis et al. 2012). Briefly, patients with primary osteoarthritis of the hip received a cementless, all-polyethylene, press-fit acetabular cup with titanium coating (RM press-fit; Mathys AG, Bettlach, Switzerland). Patients were randomly allocated to 2 groups: (1) with no additional screw stabilization, and (2) with additional screw stabilization using two 4.0-mm screws of variable length (Figure 1). Details of the study design and surgical technique have been described before (Pakvis et al. 2012). Patients who completed the follow-up of the previous study were invited to participate in the current study. Written informed consent was obtained from all the patients who participated.

### RSA

A marker-based RSA technique was used to analyze implant migration and wear. Exact procedures have been described elsewhere (Pakvis et al. 2012).

### Implant migration

Migration of the cup was calculated as micromotion of the cup model in relation to the acetabular bone model according to methods described earlier (Pakvis et al. 2012). Total migration was calculated as the vectorial sum of the 3 translations

(total translation  $(TT) = \sqrt{(T_x^2 + T_y^2 + T_z^2)}$ ) and the 3 rotations (total rotation  $(TR) \approx \sqrt{(R_x^2 + R_y^2 + R_z^2)}$ ) (Selvik 1989). RSA radiographs obtained during hospitalization after THA and after a median of 6.5 years of follow-up were assessed to calculate cup migration. Migration detection limits and clinically relevant amounts of migration have been published elsewhere (Pakvis et al. 2012).

### Implant wear

Wear of the cup was defined as translation of the femoral head model in relation to the acetabular cup model. Total wear was calculated as the vectorial sum of wear in the 3 orthogonal components (total wear  $(TW) = \sqrt{(Wear_x^2 + Wear_y^2 + Wear_z^2)}$ ) (Selvik 1989) and wear rate (in mm/year) was calculated. RSA radiographs obtained during hospitalization after THA and after 1 year, 2 years, and a median of 6.5 years of follow-up were assessed to calculate implant wear. In order to correct for initial creep and wear-in of the femoral head into the cup, wear was calculated from 1-year follow-up to 6.5 years ( $TW_{corrected}$ ), and also from baseline to 6.5 years.

95%-precision limits of wear measurements were determined in accordance with ISO 16087:2013, from double RSA radiographs obtained at 2 months of follow-up (X-wear: 0.17 mm; Y-wear: 0.20 mm; Z-wear: 0.34 mm; TW: 0.20 mm).

### Clinical outcomes

The Harris hip score (range 0–100 with 100 being the best score) (Harris 1969) and the Dutch validated version of the Oxford hip score (range 0–48 with 48 being the best score) (Gosens et al. 2005) were collected by the research nurse (Pakvis et al. 2012). Serious device-related adverse events since completion of the 2-year follow-up were recorded.

### Statistics

Differences between groups (screws vs. no screws) in migration and clinical outcomes at 6.5 years of follow-up were tested using Mann-Whitney U-test, because the data were not normally distributed. The differences between groups in numbers of patients exceeding the clinically relevant amount of translation ( $> 1$  mm) and rotation ( $> 2^\circ$ ) were tested with Fisher's exact test. The difference in wear over the course of follow-up was tested with repeated-measures ANOVA, with time as the within-subject factor and with/without screws as the between-subjects factor. Any p-values less than 0.05 were regarded as being statistically significant. Data are presented as median (range) or mean (SD), as appropriate.

### Ethics

The study protocol was approved by the medical ethical committee, region Arnhem-Nijmegen (amendment on dossier 2006/032). The study was conducted in accordance with the Declaration of Helsinki, CONSORT guidelines, and ISO 16087:2013 for RSA.

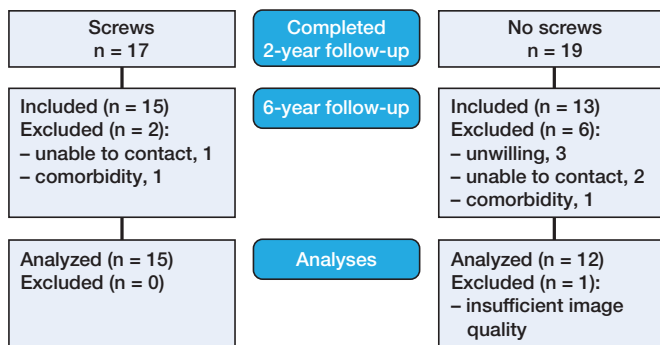


Figure 2. Flow chart of patient inclusion.

## Results

### Patients included

The 36 patients who completed the 2-year follow-up (Pakvis et al. 2012) were invited to participate in the current study. Data from 27 patients were available for analysis of translation and wear (Figure 2 and Table 1); in 1 patient, the acetabular marker model only consisted of 2 markers and rotations could not be calculated. Measurements were performed between March and October 2014 at Sint Maartenskliniek, Nijmegen. At the 2-year follow-up, data from patients who were not analyzed in the current study did not differ statistically significantly from the data from patients who were analyzed. No serious device-related adverse events occurred after the 2-year follow-up; 1 hip stem was revised because of loosening.

### RSA

Mean condition numbers of the cup marker and the acetabular bone models were 32 (SD 5.3) and 33 (SD 17), respectively. All values were below the ISO guidelines criterion of 120. Mean rigid body errors of the markers of the cup and the acetabulum were 0.25 (SD 0.09) and 0.09 (SD 0.19) mm, respectively. These mean values satisfy the criteria in ISO guidelines ( $< 0.35$  mm). However, the values were exceeded in 3 and 5 patients, for cup and acetabulum, respectively. Rigid body error was higher in these patients, due to suboptimal radiograph quality as result of large volumes of soft tissue around the hip. The data from these individuals were not excluded.

### Implant migration

At 6.5 years, total translation (TT) and total rotation (TR) were not significantly different between groups ( $p = 0.8$  and  $p = 0.2$ , respectively) (Table 2 and Figure 3). For the individual migration axes, only internal rotation (y) was significantly different between the groups (screws:  $0.33^\circ$  (SD 0.50); no screws:  $-0.61^\circ$  (SD 0.97);  $p = 0.004$ ). However, the differences between the groups did not exceed the clinically relevant rotation of  $2^\circ$ . No statistically significant differences in the number of patients exceeding the clinically relevant translation (1 mm) and rotation ( $2^\circ$ ) were observed between groups.

Table 1. Patient demographics

	Screws	No screws
No. of patients	15	12
Male / Female	5 / 10	6 / 6
Mean age (SD), years	70 (5.5)	69 (8.4)
Median follow-up, years	6.4 (5.6–7.0)	6.3 (5.5–7.2)

Table 2. Translations and rotations at 6.5-year follow-up in individual directions, and total translation (TT) and total rotation (TR)

	Screws	No screws
Translation, mm	(n = 15)	(n = 12)
$T_x$	-0.09 (-0.60 to 0.71)	0.06 (-0.91 to 0.59)
$T_y$	0.15 (-0.34 to 0.79)	0.13 (-0.06 to 0.82)
$T_z$	0.01 (-0.67 to 0.74)	-0.02 (-1.02 to 0.56)
TT	0.36 (0.12 to 0.98)	0.39 (0.06 to 1.59)
Rotation, degrees	(n = 14)	(n = 12)
$R_x$	0.13 (-1.10 to 0.77)	-0.02 (-0.65 to 2.47)
$R_y$	0.41 (-0.56 to 0.97)	-0.54 (-2.43 to 1.47)
$R_z$	0.03 (-1.54 to 1.90)	-0.07 (-0.94 to 1.47)
TR	0.77 (0.28 to 2.21)	1.13 (0.30 to 2.8)

Values are median (range).

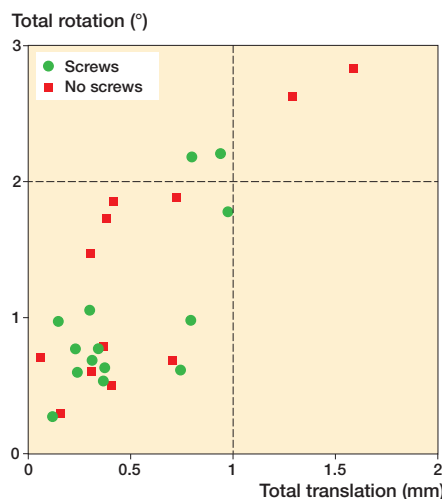


Figure 3. Total translation (TT) and total rotation (TR) at 6.5-year follow-up. Dashed lines indicate clinically relevant rotation and translation.

### Implant wear

At 6.5 years of follow-up, TW was similar in both groups (0.57 (SD 0.24) mm and 0.53 (SD 0.20) mm for cups with and without screws, respectively;  $p = 0.6$ ) (Figure 4). TW increased over time ( $p < 0.001$ ), and was similar in both groups ( $p = 0.5$ ). For the individual components of TW, only an interaction between the groups and medial wear (x) was found ( $p = 0.002$ ). Post-hoc analysis showed a statistically significant difference in medial wear (x) between groups at 6.5 years of follow-up (0.19 (SD 0.22) and  $-0.04$  (SD 0.12) for the groups

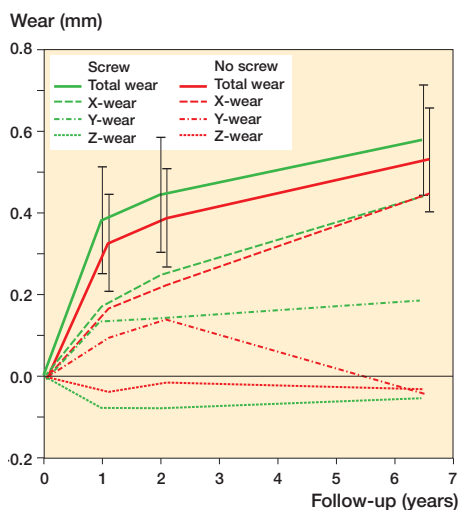


Figure 4. Mean wear (in mm) over time for individual directions, and total wear. Error bars show 95% confidence intervals.

with and without screws, respectively;  $p = 0.003$ ). When corrected for initial creep and wear-in (by taking 1-year follow-up as reference), the analyses showed similar results.  $TW_{corrected}$  was 0.41 (SD 0.21) mm in the group with additional screws and 0.47 (SD 0.19) mm in the group without, at 6.5 years of follow-up ( $p = 0.4$ ). Corrected medial wear (x) was 0.05 (SD 0.14) mm for the group with additional screws and  $-0.14$  (SD 0.14) mm for the group without additional screws ( $p = 0.002$ ).

The wear rate (baseline to 6.5 years) was similar for cups with additional screws and for cups without: 0.09 (SD 0.04) mm/year and 0.08 (SD 0.03) mm/year, respectively ( $p = 0.7$ ). The corrected wear rate (1 year to 6.5 years) was 0.07 (SD 0.04) mm/year for screws and 0.09 (SD 0.04) mm/year for no screws ( $p = 0.3$ ).

### Clinical outcomes

At 6.5 years of follow-up, Harris hip score (97 (48–100) and 99 (55–100);  $p = 0.6$ ) and Oxford hip score (16 (14–45) and 15 (14–43);  $p = 0.6$ ) were similar in the group with screws and in the group without screws.

### Discussion

This is the first paper to report on the medium-term effects of additional screw fixation on the migration, wear, and clinical outcome of a cementless, all-polyethylene press-fit cup—as assessed with RSA. No clinically relevant differences in migration, wear, and clinical outcomes were found between the 2 groups. The average levels of translation, rotation, and wear after 6.5 years were well below the clinically relevant limits (Pakvis et al. 2012). Furthermore, the wear rate of the all-polyethylene cup was below 0.1 mm/year for both groups. No serious device-related adverse events had occurred in either group since the completion of the 2-year follow-up.

To our knowledge, only 2 other RCTs investigating the effect of additional screw fixation of press-fit cups have been performed, with 2-year and 14-year follow-up, respectively (Thanner et al. 2000; Otten et al. 2016). Both studies used titanium alloy cups with polyethylene liners, in contrast to the all-polyethylene cups used in the current study. In accordance with our findings, both studies found no difference in migration and wear between cups with additional screws and cups without. Nevertheless, an increased wear rate of 0.21 mm/year was found by 1 study over the 14-year follow-up (Otten et al. 2016). This is more than twice the wear rate that we found. This can be explained by the ethylene oxide- (EtO-) sterilized polyethylene liner that was used in that study, which has shown a higher wear rate compared to the gamma-sterilized polyethylene that we used (Digas et al. 2003); probably because of the formation of larger wear particles (Röhrl et al. 2004).

Increased proximal (y) translation and adduction (z-rotation) of acetabular cups during the first 2 years have been described as strong risk factors for component failure in the long term (Nieuwenhuijse et al. 2012). However, this may not be relevant to the current study, in which the cups showed no relevant migration after the 2-year follow-up. The underlying process of migration in the short term and in the medium term is possibly different (initial implant fixation as opposed to stress shielding and polyethylene debris osteolysis).

A concern with the all-polyethylene press-fit cup may be a possibly increased wear rate. As the diameter of the cup is oversized compared to the reamer, to ensure initial press-fit stability, the cup is likely to be deformed to a certain extent during placement. Consequently, the space for the femoral head might be reduced, possibly leading to increased wear. However, we did not find that the wear rate was increased compared to press-fit cups with a metal alloy shell, which are possibly less subject to deformation. Thus, we believe that there is no reason for concern about a high wear rate with this cup.

The study had some limitations. First, the sample size of the study was small, and possibly had low power to detect differences in migration or wear between the groups. However, the RSA precision limits were low and a great overlap in TT and TR was seen between the groups (Figure 3). We therefore believe that we would have found the same results in a larger study population. Secondly, no measurements of radiolucent lines were performed. However, as no statistically significant difference in migration was seen between groups, radiolucent lines are of less interest. A third consideration may be the fact that the RSA measurements were performed with patients in supine position, with unloaded joints during the measurements. This might have influenced the wear measurements, which were calculated as migration of the femoral head in relation to the cup implant. However, previous RSA research has not shown any difference in femoral head penetration between supine and standing position (Bragdon et al. 2006). Thus, we believe that our wear measurements were

accurate. Lastly, previous research found that a more vertical orientation of the cup was associated with more migration and increased wear (Kennedy et al. 1998). Unfortunately, standard pelvis radiography images were not taken in all patients, so cup inclination angle could not be measured.

In conclusion, this medium-term study showed no statistically significant or clinically relevant differences in migration, wear, and clinical outcome between all-polyethylene press-fit cups with additional screw fixation and all-polyethylene press-fit cups without.

This study was funded by Mathys Orthopaedics, Bettlach, Switzerland, and prior to the study there were no limitations described by either party regarding publishing of the data resulting from the study.

PH and MS contributed to the conception and design of the study. MM and PH contributed to data acquisition and analysis. All the authors were involved in preparing the manuscript.

The study protocol and further information concerning this study are available from the corresponding author (PH).

We thank research nurse Saskia Susan for her efforts in patient recruitment and Jolanda Rubrech-van As for data management.

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