Is a hollow centralizer necessary when using a polished, tapered, cemented femoral stem?

A randomized, controlled RSA study of 60 hips with 10 years of follow-up

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Background and purpose — A tapered, polished and collarless stem is normally equipped with a hollow centralizer to prevent the stem from becoming end-bearing in the cement as the stem subsides. In a randomized clinical trial, we evaluated such a stem (MS-30), which was initially introduced with a solid centralizer but was later recommended to be fitted with a hollow centralizer. We hypothesized that while the stem would sink more, it would become rotationally stable and have less retroversion with a hollow centralizer than with a solid centralizer.

Patients and methods — We randomized 60 patients with primary hip arthritis to receive either a hollow centralizer or a solid centralizer with the stem. The effect was evaluated over a 10-year follow-up period with repeated RSA examinations, conventional radiographs, and clinical follow-ups using the WOMAC and SF-12 questionnaires.

Results — At 10-year follow-up, the group with hollow centralizers had subsided more than the group with solid centralizers (1.99 mm (hollow) as opposed to 0.57 mm (solid); $p < 0.001$). However, rotation was similar at 10-year follow-up (mean retroversion 1.34° (hollow) and 1.30° (solid)). Both groups showed excellent 10-year results, with similar clinical outcome, and none of the stems were radiographically loose or had been revised.

Interpretation — As expected, there was more subsidence in the group with hollow centralizers, and with similar magnitude to that reported in earlier RSA studies on conceptually similar prostheses. Interestingly, there was no difference in the rotational behavior of the prostheses. This stem type appears to have a design that, regardless of the type of centralizer and the possibility of subsidence, withstands the rotational forces it is subjected to very well. This study does not support the need for a hollow centralizer for these types of stems.

A distal stem centralizer acts to center the distal tip of the femoral stem within the intramedullary canal of the proximal femur, and it thereby facilitates an evenly distributed cement mantle surrounding the stem (Berger et al. 1997). The role of modern centralizers, however, is not necessarily restricted only to the positioning of the stem, but must be considered in light of the femoral stem design, stem surface, cement characteristics, and postoperative migration. It is therefore essential to clarify the historical design features of both stems and centralizers that have influenced the theories behind this study.

During the early 1970s, a new concept for a femoral stem was introduced: the collarless, tapered Exeter stem. In 1986, the previously matte-finish Exeter stem (1976–1985) was made highly polished instead, and at the same time a new invention, the hollow centralizer, was introduced in order to prevent distal cement "punch-out" fractures (Lee and Ling 1982). These 2 changes, introduced simultaneously, have been credited as being a major part of the success of the Exeter type of stem system.

The introduction of a hollow centralizer was a radical measure. The role of the centralizer was to enable the stem to subside continuously; it was no longer constrained to function solely as an intraoperative tool. The concept was later referred to as the "force-closed" system, including a polished, tapered, collarless stem used with a hollow centralizer to avoid end-bearing in the cement (Huiskes et al. 1998). It has been confirmed that cemented force-closed stems with very good long-term results continue to subside, probably throughout the entire lifetime of the stem (Stefansdottir et al. 2004, Nieuwenhuijse et al. 2012, von Schewelov et al. 2014).

The MS-30 (Morscher/Spotorno) femoral stem (Zimmer), introduced in 1990 (Figure 1), was initially designed with a

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Figure 1. Left: MS-30 with hollow centralizer; right: MS-30 with solid centralizer. Both stems were fitted with tantalum marker towers at the tip and in the proximal section, supplied by the manufacturer.

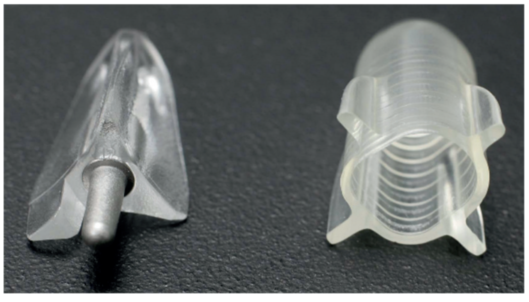

Figure 2. Left: the solid, 3-winged, peg-fitted asymmetrical centralizer; right: the hollow, 4-winged open-ended centralizer. The centralizers were available in 2 sizes for each stem size (large and small) and were selected depending on the width of the femoral canal.

solid centralizer. The design of the stem is characterized by features of a "force-closed" stem. It is triple-tapered, highly polished (Ra < 0.22 µm) and collarless, with lateral wings to provide rotational stability. The solid polymethylmethacrylate (PMMA) centralizer was 3-flanged and was fixed to the taper using a metal pin (Figure 2).

The hollow centralizer for the MS-30 stem was introduced in 2001 (Figure 2). It is made of PMMA and integrates with the cement mantle during polymerization. The main reason for recommending the hollow centralizer was—based on the clinical success with the Exeter concept—that it was thought to be desirable to have a centralizer that allowed subsidence of the stem within the cement. Other theoretical advantages, using computational fluid dynamics (CFD), would be a reduced amount of air bubbles in the transition zone of the taper and the centralizer, reducing cement delamination (Klabonde, personal communication 2001).

Table 1. Patient characteristics

Variable	Hollow	Solid	Total
No. of patients	30	30	60
Mean age, years (range)	69 (55–85)	71 (60–82)	70 (55–85)
Sex (male / female)	17 / 13	10 / 20	27 / 33
Mean BMI (SD)	29.0 (5.9)	27.0 (3.7)	28.0 (5.0)

BMI: body mass index.

The main purpose of this study was to examine the 3D migratory pattern of the MS-30 stem fitted with a solid centralizer or a hollow centralizer, using radiostereometric analysis (RSA). We hypothesized that the MS-30 used with a hollow centralizer would subside more but resist the important rotational migration and have less retroversion than the MS-30 with a solid centralizer.

Patients and methods

Study group and randomization

60 patients (mean age 70 years, 33 women) (Table 1) with primary hip osteoarthritis who were scheduled for a cemented total hip arthroplasty (THA) were recruited for this study. Surgery was performed by 1 of 3 experienced hip surgeons (GF, CO, and UK) between February 2003 and February 2004. The study was completed in November 2014. It was a collaboration study between Skåne University Hospital and Blekinge County Hospital with 30 patients, 15 in each group, being operated at each center. Patients between 55 and 85 years old with Charnley classification A or B were included. The exclusion criteria were rheumatoid arthritis, malignant disease, severe osteoporosis with extensive bone loss in the acetabulum, previous fracture or operation to the hip, ongoing corticosteroid or immunosuppressive medication, dementia, and drug or alcohol abuse.

16 patients died during the 10-year follow-up, all for reasons unrelated to the operated hip. 54 patients completed the 5-year follow-up, and 26 patients completed the 10-year follow-up (Figure 3, see Supplementary data).

Block randomization was used. The randomization forms were prepared and mixed in sealed envelopes, which were opened intraoperatively, with 15 forms for hollow centralizer and 15 forms for solid centralizer at each surgery center. The MS-30 femoral stem was used for all patients.

Table 2. Precision of the RSA measurements [a]

Axis	Translation, mm	Rotation, degrees
Transverse (X)	0.14	0.24
Longitudinal (Y)	0.08	0.34
Sagittal (Z)	0.14	0.14

[a] The precision is based on 60 double examinations of the patients in the study. The value given represents the smallest migration that is considered statistically significant and is based on 2 standard deviations of the error obtained. This therefore corresponds to the 95% confidence limit.

Surgery

A posterolateral approach was used. According to the guidelines for standardization of RSA (Valstar et al. 2005), the proximal femur was marked before cementation with 8–10 well-scattered 0.8-mm diameter tantalum markers. 5 or 6 markers were implanted in the greater trochanter, and 3 or 4 in the lesser trochanter. We used pre-chilled Palacos with Gentamycin bone cement, mixed in an Optivac vacuum mixing system (Biomet Cementing Technologies AB, Sweden). The cement was marked with 6–8 tantalum markers of 0.8-mm size. 3 or 4 markers were put in the cement distal to the stem from the tip of the cement gun, and a further 3 or 4 in the proximal cement mantle after introduction of the stem, but before the cement solidified. The prostheses were provided by the manufacturer pre-marked with tantalum markers of 1.0-mm diameter at the tip, shoulder, and medial border of the stem (Figure 1). The femoral head was used as the fourth marker. All patients received antibiotics (Cloxacilline; 3-dose regime) and an anticoagulant (Enoxaparine; at least 10 days of treatment) postoperatively.

Radiostereometry

All RSA examinations were performed according to the guidelines for standardization of RSA of implants (Valstar et al. 2005). The patients underwent RSA examinations and conventional radiographic examinations on the first postoperative day before weight bearing, and thereafter at 6 months, 1 year, 2 years, 5 years, and 10 years. For calculation of the precision value in this study, all patients had at least 1 double examination during the follow-up period (Table 2), normally at the 1- or 2-year follow-up, which was obtained during a standard follow-up RSA examination. An upper limit for the mean error, i.e the mean difference between measurements of the same marker in different examinations, was set at 0.30. An upper limit for the condition number, which describes the 3-D distribution of the tantalum markers in each segment (rigid body), was set at 120. However, when measuring segment motion of the stem in relation to the cement, a higher condition number for the cement markers was accepted due to the technical difficulty of obtaining an even scatter of the tantalum markers in the cement. The results of migration of the stem in relation to the cement were therefore regarded as reliable for the measurement of subsidence, but not for measurement of rotation.

The RSA examinations were performed using a biplanar technique with the patient in supine position and the calibration cage below the patient. We used UmRSA software for the RSA analysis (version 6.0; RSA Biomedical, Umeå, Sweden), and a type 41 calibration cage (Tilly Medical AB, Lund, Sweden). We analyzed the 3-D segment motion of the stem in relation to both femur and cement. Stem subsidence (Y-translation) and retroversion (Y-rotation) were considered to be the primary effect variables.

After the first RSA examination had been performed, the patients were mobilized on the first day, and were allowed full weight bearing. The patients filled out the general health questionnaire SF12 (Short Form survey) preoperatively, and at 1- and 10-year follow-up, and the hip-specific questionnaire WOMAC (Western Ontario and McMaster Universities osteoarthritis index) before surgery, and then at 1-, 2-, 5-, and 10-year follow-up.

Statistics

Based on earlier studies, we considered that a difference in mean distal migration of 0.25 mm and a posterior rotation of 0.5 degrees might have clinical significance (Karrholm et al. 1997). A pre-study power analysis was performed with available data, and with an alfa-value of 0.05, with 30 patients in each group, was considered sufficient to achieve a power of 90%.

To analyze the primary endpoints (retroversion and subsidence), a mixed-effects linear regression model was used with a random intercept (at the patient level) and slope (for time transformed to a logarithmic scale) specified along with independent covariance matrix structure. 95% confidence intervals (CIs) were calculated.

To compare differences between groups at a given time, Student's t-test was used. All results are given as signed values for migration. For analysis of the outcome questionnaires SF12 and WOMAC, the Mann-Whitney U-test was used.

IBM SPSS statistics software version 21.0 and STATA version 12.1 were used for the statistical analysis. Any p-value of < 0.05 was considered significant.

Ethics, registration, funding, and potential conflict of interests

The study was approved by the ethics committee of Lund University and was carried out according to the Helsinki Declaration of 1975, as revised in 2000. All the patients gave their informed written consent. The study was registered at ClinicalTrials.gov (identifier NCT01918540).

Zimmer unconditionally sponsored part of the RSA analysis work, but no other benefits have been received or will be received from any commercial party related directly or indirectly to the subject of this article.

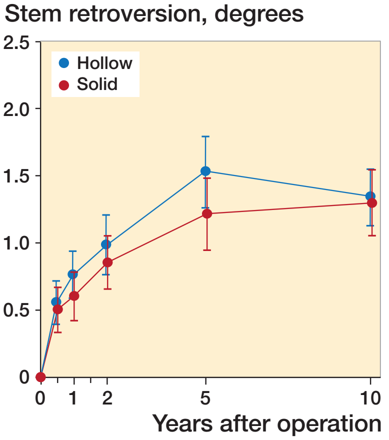

Figure 4. Graph showing mean retroversion (Y-rotation) measured with RSA technique, including confidence intervals (bars).

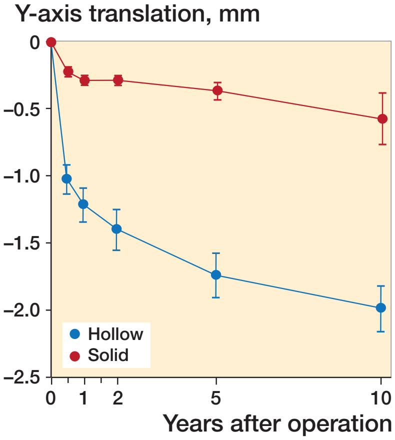

Figure 5. Graph showing mean stem subsidence (Y-translation) measured with RSA technique, including confidence intervals (bars).

Results

In the analysis of primary endpoints for the whole 10-year follow-up period, we found no statistically significant differences between the stem types in terms of retroversion (Figure 4) (slope coefficient = 0.0035 degrees, 95% CI: –0.25 to 0.26; p = 1.0). However, both groups analyzed together showed a statistically significant retroversion over time with an estimated slope coefficient of 0.39 degrees (CI: 0.32–0.46). The interaction term (time versus group) was not statistically significant (slope coefficient = –0.05 degrees, CI: –0.15 to 0.05).

In terms of subsidence over time (Y-translation, stem in relation to the femur), there was a statistically significant difference between the 2 groups as measured with mixed-model analysis (slope coefficient = 0.40 mm, CI: 0.27–0.55) with hollow centralizer as reference. Analyzed together, both groups had subsidence over time (coefficient = –0.30 mm, CI: –0.34 to –0.26)) but the statistical significance of the centralizer type and time interaction (coefficient = 0.22 mm, CI: 0.16–0.27) suggested that the hollow centralizer group had a higher rate of subsidence. The hollow centralizer group had more subsidence (mean 1.02 mm, CI: –1.42 to –0.62)) than the solid centralizer group (mean 0.2 mm, CI: –0.24 to 0.20) within the first 6 months ($p < 0.001$). At 10 years, the mean subsidence was 0.57 mm for the solid centralizer group and 1.99 mm for the hollow centralizer group (Figure 5).

The mixed-model analysis was also applied and analyzed from 2 to 10 years, and indicated that there was no statistically significant difference in rotation between the 2 types of centralizer. However, each group showed statistically significant rotation over time, with an estimated slope of 0.47 degrees (CI: 0.34–0.60) for the hollow centralizer group and 0.39 degrees (CI: 0.28–0.51) for the solid centralizer group. There was a statistically significant difference in subsidence between 2 and 10 years (coefficient = 1.05 mm, CI: 0.88–1.22).

Regarding the secondary outcome measures of translation along and around the X-axis and Z-axis, there were no statistically significant differences between the 2 groups at any time point or when measured over the entire follow-up period (Table 3, see Supplementary data).

Most stem subsidence occurred in the stem-cement interface. At 10 years, the mean subsidence of the cement mantle inside the femoral canal was 0.11 mm for the hollow centralizer (SD 0.15 mm) and –0.01 mm (SD 0.14 mm) for the solid centralizer. The cement mantle was considered to be stable within the femur, according to the plain radiographs and overall RSA data.

The 10-year follow-up radiographs showed no signs of punch-out fractures of the distal cement, and no radiolucent zones. All cement mantles were graded as Barrack A or B. 1 stem in the solid centralizer group might, however, have been graded as a Barrack D, as there were no cement between the tip of the centralizer and the cement restrictor. None of the stems were revised during the 10-year follow-up period.

There were no statistically significant differences between the 2 groups when we analyzed the WOMAC and SF12 outcome questionnaires at any time point during the follow-up (Figures 6 and 7, see Supplementary data). Both groups, however, showed significant improvement in scores (preoperatively to postoperative follow-up) and they were consistent during the 10 year follow-up period.

Discussion

Consistent with our hypothesis, the hollow centralizer group had more subsidence than the group with a solid centralizer within the cement mantle, and showed a pattern of continuous, but declining subsidence over the first 10 years similar to that for other force-closed femoral stems (Stefansdottir et al. 2004, Nieuwenhuijse et al. 2012, von Schewelov et al. 2014). On the other hand, the end-bearing group with a solid centralizer clinically stabilized and almost no further subsidence was seen after a year. In contrast to our hypothesis, the solid centralizer group did not have more retroversion than the hollow centralizer group. When we started the study, our hypothesis was that end-bearing stems with solid centralizers would have more retroversion because retroversion is the second highest load vector to which the stem is subjected (Bergmann et al. 2001). The fact that it did not have more retroversion according to the RSA results, would indicate that the stem is stable in spite of its inability to fully act as a force-closed stem, and it can well withstand the rotational forces to which it is subjected.

We observed 1 stem in the solid centralizer group that subsided from 0.93 mm to 2.50 mm between 5 and 10 years.

When we reviewed the radiographs, we found that the tip of the stem was not end-bearing. The distal cement restrictor plug was set too high during surgery, leaving the solid centralizer in direct contact with the restrictor plug with no cement in-between. One can speculate that this error would have changed the concept behind the stem, so that the stem was not "shape-closed" by the cement distally, and thereby functioned as a self-locking taper when the plug was pushed distally by axial forces into the femur canal. The subsidence of this particular stem thereby resulted in a wider confidence interval in the 10-year results of the solid group, but it did not affect the overall results (Table 3, see Supplementary data).

The use of a solid centralizer instead of a hollow centralizer might be beneficial in reducing the risk of periprosthetic fracture. A study with data from the Swedish Hip Arthroplasty Register showed an increased risk of periprosthetic fracture when using tapered, polished, and collarless stems (Leonardsson et al. 2012). Using an end-bearing solid centralizer, one can speculate that the stem would be prevented from sudden subsidence—and thereby cracking of the proximal femur during a fall.

According to our results, the MS-30 stem can be used with a solid centralizer. Our study should, however, not be considered to be a recommendation to use solid centralizers with all force-closed stems, but it shows that this particular force-closed cemented stem has some of the migrational characteristics of a shape-closed stem when a solid centralizer is used, without signs of increased retroversion, punch-out fractures, or loosening. Our results are consistent with the fact that, during the period 1990–2000, solid centralizers were mainly used with the MS-30 stem. During that period, the revision rates were no higher than they are today (Morscher et al. 2005). In fact, many of the stems implanted during these years had a matte surface, thus giving the MS-30 even greater characteristics of a shape-closed stem.

In the past, it has proven risky to mix stem design philosophies as done in our study, but our results should also make us humble to the fact that the field of stem migration—and, even more importantly, the linkage between stem migration and stem survival—is far from being fully understood. In fact, most studies on a particular stem are not always comparable to other studies of the same stem type because one or several parameters in the studies have varied. For example, the design of the centralizer may have changed, the surface roughness or flexibility (change in the modulus of the material) of the stem may have changed over time, the stem may come in a more lateralized version, the cement and/or cementing technique may have changed, the patient characteristics—and thereby bone quality—may be different, and last but not least; subtle changes may have been made to the stem design. A change in one of the parameters is perhaps unlikely to alter the stem migration, but a combination of changes could alter stem migration over time. However, an alteration in stem migration is, as our study shows, is not synonymous with an alteration in stem survival.

Our results raise a certain amount of scepticism regarding the concept of dividing stem types into strict categories, such as force-closed and shape-closed stems. The scepticism towards the concept of shape-closed stems has been raised previously, due to the fact that all stems appear to migrate after surgery (Breusch and Malchau 2005). Several attempts have been made to see what happens when the concepts of force-closed and shape-closed stems are altered. Karrholm et al. (2000, Scientific exhibition) carried out several in vitro examinations where the concepts were changed—for example, by polishing the cemented anatomical Lubinus SPII stem and removing the collar. Few attempts, however, have been made in vivo—as in our study—to change only one of the parameters, while keeping all the others constant. One should be cautious in altering a functioning concept, but we believe that our rather surprising results could call for further studies investigating whether the proven success of tapered, highly polished, and collarless cemented stems is due to the actual stem design and not to the combination with a hollow centralizer. Our results thereby raise doubt over the validity and applicability of the popular force-closed vs. shape-closed paradigm.

Supplementary data

Table 3 and Figures 3, 6, and 7 are available as supplementary data in the online version of this article, http://dx.doi.org/10.1080/17453674.2017.1315553.

Design of the study, recruitment of patients, and performance of the operations were done by GF, UK, and CO. The data were analyzed by EW and GF. The paper was written by EW and reviewed by GF.

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Berger R A, Seel M J, Wood K, Evans R, D'Antonio J, Rubash H E. Effect of a centralizing device on cement mantle deficiencies and initial prosthetic alignment in total hip arthroplasty. J Arthroplasty 1997; 12(4): 434-43.

Bergmann G, Deuretzbacher G, Heller M, Graichen F, Rohlmann A, Strauss J, Duda G N. Hip contact forces and gait patterns from routine activities. J Biomechanics 2001; 34(7): 859-71.

Breusch S J, Malchau H. The well-cemented total hip arthroplasty. Springer: Heidelberg 2005.

Huiskes R, Verdonschot N, Nivbrant B. Migration, stem shape, and surface finish in cemented total hip arthroplasty. Clin Orthop Relat Res 1998; (355): 103-12.

Karrholm J, Herberts P, Hultmark P, Malchau H, Nivbrant B, Thanner J. Radiostereometry of hip prostheses. Review of methodology and clinical results. Clin Orthop Relat Res 1997; (344): 94-110.

Lee A J C, Ling RS M. Spacer for intra-medullary implant. United Kingdom; 1982.

Leonardsson O, Karrholm J, Akesson K, Garellick G, Rogmark C. Higher risk of reoperation for bipolar and uncemented hemiarthroplasty. Acta Orthop 2012; 83(5): 459-66.

Morscher E W, Clauss M, Grappiolo G. Femoral components: Outcome with the MS-30 stem. In: The well-cemented total hip arthroplasty. (Ed Breusch SJ , Malchau H). Heidelberg: Springer; 2005. p. 235-40.

Nieuwenhuijse M J, Valstar E R, Kaptein B L, Nelissen R G. The Exeter femoral stem continues to migrate during its first decade after implantation: 10-12 years of follow-up with radiostereometric analysis (RSA). Acta Orthop 2012; 83(2): 129-34.

Stefansdottir A, Franzen H, Johnsson R, Ornstein E, Sundberg M. Movement pattern of the Exeter femoral stem; a radiostereometric analysis of 22 primary hip arthroplasties followed for 5 years. Acta Orthop Scand 2004; 75(4): 408-14.

Valstar E R, Gill R, Ryd L, Flivik G, Borlin N, Karrholm J. Guidelines for standardization of radiostereometry (RSA) of implants. Acta Orthop 2005; 76(4): 563-72.

von Schewelov T, Carlsson A, Sanzen L, Besjakov J. Continuous distal migration and internal rotation of the C-stem prosthesis without any adverse clinical effects: an RSA study of 33 primary total hip arthroplasties followed for up to ten years. Bone Joint 2014; 96-B(5): 604-8.