

High-precision measurements of cementless acetabular components using model-based RSA

An experimental study

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Background In RSA, tantalum markers attached to metal-backed acetabular cups are often difficult to detect on stereo radiographs due to the high density of the metal shell. This results in occlusion of the prosthesis markers and may lead to inconclusive migration results. Within the last few years, new software systems have been developed to solve this problem. We compared the precision of 3 RSA systems in migration analysis of the acetabular component.

Material and methods A hemispherical and a non-hemispherical acetabular component were mounted in a phantom. Both acetabular components underwent migration analyses with 3 different RSA systems: conventional RSA using tantalum markers, an RSA system using a hemispherical cup algorithm, and a novel model-based RSA system.

Results We found narrow confidence intervals, indicating high precision of the conventional marker system and model-based RSA with regard to migration and rotation. The confidence intervals of conventional RSA and model-based RSA were narrower than those of the hemispherical cup algorithm-based system regarding cup migration and rotation.

Interpretation The model-based RSA software combines the precision of the conventional RSA software with the convenience of the hemispherical cup algorithm-based system. Based on our findings, we believe that these new tools offer an improvement in the measurement of acetabular component migration.

Radiostereometric analysis (RSA) (Selvik 1989) is a well-established method for evaluation of micro-motion of orthopedic implants in clinical trials, and is considered to be the most precise measuring method (Kärrholm 1989, Snorrason and Kärrholm 1990, Vrooman et al. 1998). The conventional RSA method of migration measurement involves the attachment of tantalum markers to the implant in order to create a rigid body. However, in conventional RSA analysis of metal-backed acetabular cups, the tantalum markers attached to the prosthesis are often difficult to detect on stereo radiographs due to the high density of the metal—resulting in occlusion of the tantalum markers (Kaptein et al. 2005). Even if a sufficient number of markers are visible, the analysis is difficult because each individual marker has to be identified and corresponding pairs must be matched. However, within the last few years new software systems have been developed in an attempt to solve this problem (Kaptein et al. 2005, Borlin et al. 2006).

Marker-free RSA systems are convenient in clinical trials involving assessment of the migration of acetabular components. The migration can be evaluated without alteration of the original cup design; such alterations are costly and may influence the cup migration. In addition, it can be difficult to obtain approval from national authorities in some countries if the implant has been subject to even small modifications.

We compared conventional marker-based RSA software (QBone RSA 4.3; Medis, Leiden, the

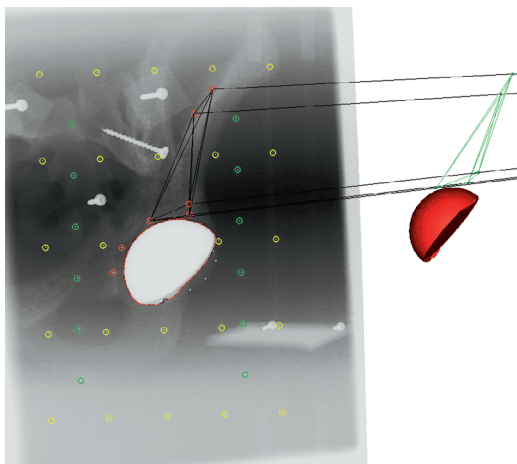


Figure 1. Model-based RSA. On the left, a stereo image. The contour of the cup is marked in red. The 3D model of the acetabular component is shown on the right.

Netherlands), with two marker-free RSA software systems in terms of precision of migration measurement. The first marker-free software system tested against conventional RSA was the hemispherical cup algorithm of QBone RSA 4.3, which provides the option of using the geometry of the acetabular component in the migration analysis (Valstar et al. 1997). The hemispherical cup algorithm calculates the position of the cup and the orientation of the base of the cup based on the assumption that the implant has a hemispherical shape.

The second system tested was Model-based RSA 3.0 (MbRSA) (Medis). MbRSA requires a 3D surface model of the prosthesis in order to estimate accurately the position and orientation of the implant from a stereo pair of radiographs images by minimizing the difference between the 3D surface model and the acetabular component as it appears on the radiographs (Figure 1) (Kaptein et al. 2003, 2005). These models can be obtained either from the manufacturer's CAD models or by reverse engineering of the prosthesis using optical 3D scanning.

Material and methods

Experimental setup

Two different acetabular components were used in this study. One of them was a 56-mm Trilogy acetabular component (Zimmer Inc., Warsaw, IN)



Figure 2. Trilogy cup with markers attached.

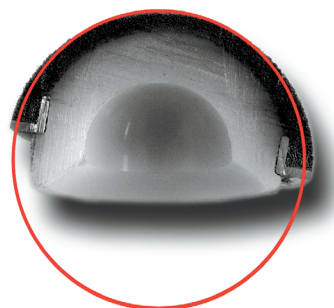


Figure 3. Cross-sectional view of the Monoblock cup. The red line describes a perfect circle.

(Figure 2). This hemispherical-shaped cup had 6 titanium towers 5 mm in length mounted on the front of the metal shell. The towers were produced in two different profiles and positioned in a specific pattern. Either a 0.8-mm or a 1.0-mm tantalum marker was affixed on top of each tower; thus, all cup markers were of unique appearance. It was possible to penetrate the titanium fiber-mesh with a radiation dose equivalent to a radiostereometric exposure of the hip (150 kV, 3 mAs) and make all tantalum markers visible. The other acetabular cup to be analyzed was a 54-mm Trabecular Metal Monoblock component (Zimmer) (Figure 3). This hemi-elliptical shaped cup was left unchanged except that 12 tantalum markers were inserted into the liner material.

The prostheses were positioned in a pelvic phantom (Sawbones no. 1301-1; Pacific Research Laboratories, Vashon, WA), which was mounted on a 14-mm Plexiglas plate in a normal anatomical pelvic position. In addition, 8 1.0-mm tantalum markers were inserted in the periacetabular

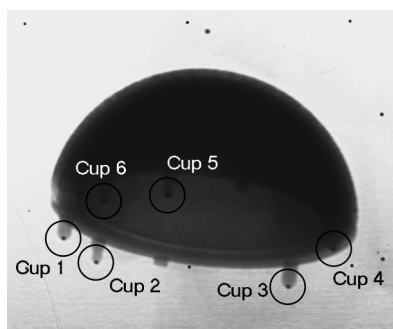


Figure 4. Trilogy cup using markers (marker-based RSA).



Figure 5. Trilogy cup dots marking the contour of the cup (hemispherical cup algorithm).

bone, forming a reference rigid body in the phantom bone. Beneath the phantom, a calibration box (large calibration box: Aarhus; Medis) was located with two phosphor plates using the uniplanar technique (Kärrholm et al. 1997). Two stationary radiographic tubes were positioned with crossing X-ray beams at an angle of approximately 40 degrees. The exposure was set to 150 kV and 3 mAs.

For both cup types, 10 RSA radiographs were obtained. Between each exposure, the alteration of the pelvic phantom was done systematically using wedges with different angles placed beneath the phantom. The cup inclination and anteversion was changed in stepwise increments of 2 mm, which was marked on both the cup and the phantom pelvis.

Before exposure, the X-ray tubes were adjusted to optimal position with respect to the position of the cup. All radiographs were fully digitized and saved in a standard dicom file format (200 DPI, 10 gray-level resolution) and uploaded to a workstation. During the analysis of the Trilogy cup, the conventional QBone-RSA software automatically detected and combined all 6 tantalum cup markers correctly in all 10 pairs of radiographs (Figure 4). The result of the migration was therefore based on all 6 markers. On average, 30 dots were manually placed to mark the shape of the acetabular component in the QBone RSA software. It was possible to apply the dots creating the contour of the cup to all radiographs (Figure 5).

Evaluation of the precision of the software systems was based on repeated analysis of the 10 pairs of radiographs. Amongst other considerations, the precision of the different RSA software systems

depends on whether it is manually or automatically operated, on differences in mathematical algorithms, and on the accuracy of the 3D-scanned prosthesis (Valstar et al. 2000, Kaptein et al. 2003). To determine the impact of these factors on the precision of the migration results, we used a method regarding reproducibility described by Bland and Altman (1986). In this study, we were only interested in the level of precision achieved by each of the software systems and not the errors due to physical setup. Each set of radiographs was uploaded to the different RSA systems 2 × 2 times. This resulted in 2 migration calculations for each set of radiographs. In order to assess the precision of the software systems, the difference between the 2 migration calculations was obtained. Ideally, the migration/rotation between the first and second analysis was zero since true migration had not occurred. Deviations from 0 reflect the measurement error of the RSA system. Afterwards, we calculated the means and standard deviations of the differences in migration results from all 10 radiographs.

The same procedure was applied to the radiographs of the Monoblock cup; however, it was not possible to perform conventional RSA because there were too few prosthesis markers visible. It is important to emphasise that we were measuring the precision—which is a measurement of how closely the migration results can be duplicated—and not the accuracy. Accuracy is a measure of reliability, defined as the difference between the true value of a measured quantity and the most probable value, which has been derived from a series of measurements.

Table 1. Precision of the marker, hemispherical cup and MbRSA systems applied to the Trilogy and Monoblock cups. Migration is expressed in mm and rotation in degrees

	X	Y	Z	X ROT	Y ROT	Z ROT
<i>Trilogy cup</i>						
Marker-based RSA						
Mean	-0.01	0	-0.02	-0.01	-0.07	-0.01
95% tolerance limits	-0.02–0.01	-0.01–0.01	-0.05–0.02	-0.05–0.03	-0.15–0	-0.06–0.03
Algorithm-based RSA ^a						
Mean	0.01	0.04	0.04	0.53	-0.09	-0.37
95% tolerance limits	-0.03–0.05	-0.07–0.16	-0.10–0.18	0.10–0.96	-0.38–0.19	-1.62–0.88
Model-based RSA						
Mean	-0.01	0	0	0.02	-0.02	
95% tolerance limits	-0.02–0.01	-0.13–0.05	-0.04–0.04	0–0.05	-0.06–0.01	-0.06–0.06
<i>Monoblock cup</i>						
Algorithm-based RSA ^a						
Mean	0.01	-0.02	-0.08	0.09	0.02	-0.08
95% tolerance limits	-0.06–0.07	-0.1–0.05	-0.27–0.11	-0.09–0.27	-0.11–0.15	-0.33–0.17
Model-based RSA						
Mean	0	-0.01	0.01	0.01	0.01	0.01
95% tolerance limits	-0.01–0.01	-0.02–0	-0.02–0.04	-0.01–0.03	-0.09–0.11	-0.04–0.05

^a Hemispherical cup algorithm-based RSA

Statistics

To describe the precision of measurement, the upper and lower limits of the differences of the first and second migration calculation are presented as 95% confidence intervals (CIs) around the mean value. CIs are calculated as shown below:

CI = $1.96 \times \text{SD}/\text{square root } (n)$ (SD: standard deviation; n: number of objects).

Migrations and rotational values, and the difference between the first and second measurements were assumed to be normally distributed, based on probability plots.

Results

The migration results for all three software systems are shown in Table 1.

Hemispherical cup

Comparison of the different measurement techniques applied to the hemispherical-shaped Trilogy cup showed narrower confidence intervals, implying that more precise measurement occurred when the conventional marker system or MbRSA were used with regard to translation or migration.

Looking at the migration along the x-axis with the hemispherical cup algorithm RSA system, a

reduction in precision was seen compared to conventional RSA and MbRSA, and the same tendency, even to a greater extent, was seen along the two other axes. A reduction in precision was also seen in rotations around all axes of the acetabular cup, being most pronounced around the sagittal axis comparing MbRSA and conventional RSA with the hemispherical cup algorithm RSA system.

Non-hemispherical cup

Comparison of the hemispherical cup algorithm RSA system with MbRSA revealed that the latter had a narrower confidence interval for differences between measurements regarding migration along all 3 axes, but also regarding rotation around all 3 axes. Note that the hemispherical cup algorithm RSA system was not designed to analyze cups that are not of hemispherical shape.

Discussion

The aim of this study was simply to compare the RSA software systems. We did not want to take the hardware setup into account, since the main objective was to quantify the precision of the software systems. Direct comparisons between precision values from clinical studies and the results of our

Table 2. Calculated precision in a number of clinical RSA studies

Study	CI limits %	x-axis mm	y-axis mm	z-axis mm
Flivik et al. 2005	99	0.19	0.12	0.22
Önsten et al. 1994	99	0.2	0.2	0.3
Thanner et al. 2000	99	0.22	0.15	0.37
Valstar et al. 1997	95	0.09	0.07	0.34

study are not possible. They can only give an indication of the magnitude of the variation in migration. The results from repeat examinations done in clinical trials are usually based on 2 consecutive X-ray exposures, and will be influenced by confounders arising from the clinical setup.

The precision values in a number of clinical RSA studies have been compared in Table 2. The study by Flivik et al. (2005) revealed the precision with a cemented cup, and the subsequent studies by Önsten et al. (1994), Valstar et al. (1997), and Thanner et al. (2000) reported the precision with an uncemented acetabular component. All studies were performed with the use of tantalum markers, with the exception of the study by Valstar et al. (1997) who used the hemispherical cup algorithm-based RSA system. Note the different standard deviations expressing the precision. To facilitate comparison between the studies, we have taken the liberty to convert the standard deviations to 95% tolerance limits.

The 95% confidence intervals of the difference between the first and second measurements show that the highest precision of a cup migration analysis will be obtained using MbRSA or tantalum markers. Unfortunately, the conventional RSA system has limitations when applied to a metal-backed cup. The location of the tantalum markers on the acetabular cup has previously been discussed (Bragdon et al. 2004). These authors found no significant difference in accuracy and precision of the RSA system, no matter whether the markers were positioned on the back of the cup, protruding into the acetabular cavity, or inserted into the rim of the acetabular liner. Based on that study, it appears reasonable to attach the markers at the convexity of the cup since free projection of the tantalum markers is then achieved. However, protrusion

of several pegs into an acetabular cavity will affect the apposition of the uncemented cup and possibly bias the migration analysis.

Attachment of the markers to the base of the cup is preferable, as it will not interfere with the cup-bone interface. This technique was used in cup studies performed by Önsten et al. (1994) and Thanner et al. (2000). On the other hand, insertion of tantalum markers into the periphery of the polyethylene liner can be complicated and care must be taken, if the cup is of a modular design—as with the Trilogy cup. Relative motion between the metal shell and the inserted liner may introduce a source of error. If titanium towers are affixed to the shell, the length of the titanium towers must also be taken into account. High towers will increase the numbers of visible markers; however, there is a trade-off between the number of markers and the risk of femoro-acetabular impingement, and possible damage to the towers.

In addition to this, we encountered severe problems in this study with prosthesis marker occlusion; thus, we had to give up the migration analysis of the Monoblock cup using conventional RSA. The tantalum markers in the work by Önsten et al. (1994) and Thanner et al. (2000) were easily identifiable because both papers were based on either the Trilogy cup or the Harris-Galante cup, both of which have low radiodensity. This contrasts with the Monoblock cup used in the present study, which consists of the highly radiopaque tantalum metal. Flivik et al. (2005) used an all-polyethylene cup, the Opticup, where all markers could be identified in a straightforward manner. When the hemispherical cup algorithm RSA software was applied to the hemispherical cup, the confidence interval of the translation along all axes was wider than with the conventional RSA system or the MbRSA system. When the hemispherical cup algorithm RSA system was applied to a non-hemispherical cup, a wider confidence interval of some of the translation was observed for the x- and z-axes than with the hemispherical cup.

The sizes of the cups tested may also have influenced the results, especially with the marker-based system. The number of tantalum markers attached to the periphery of the polyethylene liner can be increased in large cups, leading to a large rigid body. In that way, measurement precision

is increased in comparison to smaller cups. An important difference between the hemispherical cup algorithm software and the MbRSA software is that in the latter, the contour detection is automatic, while in the Qbone RSA system the contour detection is done by manually placing points on the contour of the cup. Previous RSA studies have shown substantial differences between automated and manually achieved measurements—in favor of the automated approach (Vrooman et al. 1998, Borlin et al. 2002). This may have caused greater variation in the results of the hemispherical cup system.

In a recent review article (Valstar et al. 2005), the authors suggested that as little as 15–25 patients in each group in a randomized trial are sufficient to achieve valid results, due to the high accuracy of the RSA method. However, even if a marker-free RSA system such as the hemispherical cup algorithm RSA system will eliminate concerns regarding marker location and use of titanium towers, it is reasonable to assume that due to its lower precision, the hemispherical cup algorithm RSA system will require a higher number of patients to reveal a significant difference.

It is important to emphasise that we describe results obtained under an optimal laboratory setting, which is far from the conditions in clinical practice. Tantalum markers and implant edges are not blurred by soft tissue. Markers are located with no consideration of surgical approach. The femoral head is not positioned in the cup and does not influence the number of visible implant markers or reduces the edges of the acetabular component.

The MbRSA software brings together the advantages of the conventional RSA software with regard to precision and the convenience of the hemispherical cup algorithm RSA system software. However, the MbRSA software does require 3D surface models (CAD models), which can be obtained from the implant manufacturer or from reverse engineering. A previous study (Kaptein et al. 2003) compared the reverse-engineered models and the manufacturer's CAD models for a knee prosthesis. The results showed that the reverse-engineered models provided more accurate results than the CAD models. The cups we used in the present study have been subject to optical 3D measurement to determine the exact dimensions. We

did not use the CAD models supplied by the manufacturer. Inaccuracies in size and shape of the cups as a result of the manufacturing process are known to occur in the case of these two cups in particular. In a clinical study, this procedure cannot be used, as optical 3D measurement leads to unsterile implants. In such situations, one has to rely on CAD models of the implants, or alternatively reverse-engineered cup models similar to the implanted cups. Intolerances between the implanted cup and the 3D model may therefore affect the data.

Until now, methods that have been available for determining the migration of metal-backed cups have been technically demanding, which may lead to exclusion of otherwise relevant patient material. We found that a new RSA system, the MbRSA, can overcome the technical challenges without compromising the precision that can be achieved using conventional methods. However, MbRSA still remains untested on data from clinical trials. This must be done before implementation in orthopedic practice.

Contributions of authors

TBH: protocol, experimental setup, analysis, and writing of manuscript. SK: experimental setup, protocol, and revision of manuscript. BLK: analysis and revision of manuscript. KS: protocol and revision of manuscript.

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