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Author: Prins, A.H.
Title: Model-based shape matching of orthopaedic implants in RSA and fluoroscopy
Issue Date: 2015-06-04
CHAPTER 3

HANDLING MODULAR HIP IMPLANTS IN MODEL-BASED RSA: COMBINED STEM-HEAD MODELS

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Journal of Biomechanics 2008 41 (14), 2912–2917
Abstract

Migration measurements of hip prostheses using marker-based Roentgen Stereophotogrammetric Analysis (RSA) require the attachment of markers to the prostheses. The model-based approach, which does not require these markers, is, however, less precise. One of the reasons may be the fact that the spherical head has not been modelled. Therefore, we added a 3D surface model of the spherical head and estimated the position and orientation of the combined stem-head model. The new method using a combined stem-head model was compared in a phantom study on five prostheses (of different types) and in a clinical study using double examinations of implanted hip prostheses, with two existing methods: a standard model-based approach and one using elementary geometrical shapes. The combined model showed the highest precision for the rotation about the longitudinal axis in the phantom experiments. With a standard deviation of 0.69° it showed a significant improvement ($p = 0.02$) over the model-based approach (0.96°) on the phantom data, but no improvement on the clinical data. Overall, the use of elementary geometrical shapes was worse with respect to the model-based approach, with a standard deviation of 1.02° on the phantom data and 0.79° on the clinical data. This decrease in precision was significant ($p < 0.01$) on the clinical data. With relatively small differences in the other migration directions, these results demonstrate that the new method with a combined stem-head model can be a useful alternative to the standard model-based approach.
3.1 Introduction

Roentgen Stereophotogrammetric Analysis (RSA) is a well-known method for measuring micromotion of joint replacement prostheses and can be used to detect prosthesis loosening [Kärrholm et al., 1994]. It is used to measure the position and orientation of attached prosthesis-markers with respect to markers inserted into the bone [Selvik, 1989]. This marker-based approach is very accurate, with standard deviations ranging from 0.03 mm to 0.35 mm for translations [Mjöberg et al., 1986, Kärrholm, 1989, Kärrholm et al., 1994] and from 0.05° to 0.58° for rotations [Kärrholm, 1989, Börlin et al., 2002]. But, the marker-based approach has the disadvantage that the implant may obscure these markers in the radiograph making pose estimation impossible. Furthermore, it is expensive to attach the markers to the implant.

To prevent the requirement of attaching markers to the prosthesis, elementary geometrical shape models (EGS) can be used to determine the position and orientation of a prosthesis. For example, the center of a sphere can be used to measure the position of the spherical head [Baldursson et al., 1979, Kärrholm, 1989, Önsten et al., 1995, Kärrholm et al., 1997], while the position and orientation of a cylinder or a cone can be used to measure the position and orientation of the stem of the implant [Valstar, 1996, Valstar et al., 2001, Kaptein et al., 2006].

The method cannot be applied, however, if these elementary geometrical shape models do not fit the implant properly. Therefore, a so-called model-based approach was developed to overcome this problem. It uses a 3D surface model of the stem of the prosthesis to measure its position and orientation with respect to the bone [Valstar, 2001, Kaptein et al., 2003].

In a comparison-study [Kaptein et al., 2006] the precision of three RSA methods (marker-based, EGS-based and model-based) has been assessed using the Mallory/Head prosthesis (Biomet, Inc, Warsaw, IN). The analysis showed that both the model-based approach and EGS-based approach were not as precise as the original marker-based approach. In general, the rotation about the longitudinal axis, also known as internal rotation, and the subsidence (translation along the longitudinal axis) are the two most impor-
tant early indicators of loosening [Kärrholm, 1989, Nistor et al., 1991, Gill et al., 2002] and precise measurements of these two migration directions are important. Unfortunately, both elementary geometrical shapes and model-based RSA show relatively large standard deviations for the rotation about the longitudinal axis.

The lower precision of the model-based approach may be explained partially by the fact that it uses a 3D surface model of the stem only, without the spherical head. This makes the 3D surface model relatively symmetric about its longitudinal axis, making estimation of rotation about the longitudinal axis difficult. The head was not included in the 3D surface model, however, because dimensional tolerances in the manufacturing process influence the exact position of the head with respect to the stem.

In this paper, a new method is proposed that models the dimensional tolerances by adding a spherical head to the 3D surface model in such a way that the relative position of the head is optimised during the estimation of position and orientation of the prosthesis. This method with a combined stem-head model (CM-RSA) was validated in a phantom study and a clinical study using double examinations of implanted hip prostheses. In this study, the new method (CM-RSA) was compared with the standard model-based approach (MB-RSA) and the method using elementary geometrical shapes (EGS-RSA).

### 3.2 Methods

To estimate the position and orientation of the prosthesis, the following three methods were used.

#### 3.2.1 Elementary Geometrical Shapes

This method (EGS-RSA) uses elementary geometrical shapes, identified by the user, to estimate the position and orientation of a small number of landmarks [Kaptein et al., 2006] as illustrated in Figure 3.1a. Contours are
detected in the roentgen images using the Canny Edge detector [Canny, 1986]. Shapes corresponding to the spherical head of the prosthesis are identified by the user and the position of the spherical head is computed from these shapes and the two focus positions. The mid-point of the shortest line-segment connecting these two projection lines forms the estimation of the center of the spherical head, i.e. the first landmark.

The left side of the distal part of the stem is estimated as follows. The user identifies the corresponding lines in the two roentgen images. Two planes are formed from these images using the two focus positions. The crossing line of these two planes forms the left side (in 3D) of the stem. The right side of the distal part of the stem is estimated similarly. These two 3D lines are then used to compute a central axis through the distal part of the stem.

The second landmark is obtained by projecting the first landmark, the center of the spherical head, onto this central axis.

The third landmark is defined by the most distal tip of the stem. The user identifies an initial guess of the tip in the two roentgen images. The corresponding 3D point is computed as the mid-point of the two projection lines.

**Figure 3.1:** EGS-RSA: The first landmark (1) is formed by the estimation of the center of the spherical head. An axis \(a\) is estimated through the most distal part of the stem. The second landmark (2) is obtained by projecting landmark 1 onto the axis \(a\), while the third landmark (3) is formed as the projection of the tip of the stem onto axis \(a\). MB-RSA: The 3D surface model of the stem is used to minimize the distance between a virtually projected contour and the detected contour. CM-RSA: A combined head-stem model is used to minimize the distance between a virtually projected contour and the detected contour, while allowing the position of the spherical head to vary during the minimization.
through the focus positions and the initial guesses of the tip. The projection of the 3D tip position onto the central axis of the stem results in the third landmark. With three landmarks, sufficient information is available to compute the position and orientation of the prosthesis in 3D.

### 3.2.2 Model-based RSA

This method (MB-RSA) uses a 3D surface model of the stem. This 3D surface model is used to determine the position and orientation of the prosthesis, by aligning it with the detected contours of the prosthesis in the image (Figure 3.1b): Contours are detected using the Canny Edge detector [Canny, 1986], after which the contour parts of the stem are manually selected. To reduce the computation time, 25% of the detected contour is used for the alignment of the surface model. The alignment of the surface model is performed by calculating a contour of the virtually projected 3D surface model, followed by a calculation of the distance between this virtual contour and the actual, detected, contour. The correct pose of the surface model is then determined by searching through the six-dimensional parameter (position + orientation) space for an optimal pose, which minimizes the distance between the contours.

### 3.2.3 Combined stem-head model

In this new method (CM-RSA), the reverse-engineered 3D surface model of the stem is combined with a 3D triangulated surface model of a sphere with a diameter of 28 mm. The vertices of the triangulated surface model of the stem corresponding to the tapered neck are manually selected and a cone is matched in a least squares manner through these vertices. The sphere model is allowed to move along the axis of this cone, resulting in a 3D surface model with seven degrees of freedom: six parameters describing the general position and orientation of the stem and an additional seventh parameter describing the position of the sphere on the estimated axis (Figure 3.1c). The default position of the sphere is specified manually by setting a suitable initial value for this seventh parameter.
Contours are detected using the Canny Edge detector [Canny, 1986], after which the correct contour parts are manually selected. Because the 3D surface model is now composed of a stem and a head, contour parts for the head are selected as well. To reduce the amount of computation time, 25% of this detected contour is used for the aligning of the surface model. Equivalent to the MB-RSA method, the alignment of the surface model is performed by calculating contours of the virtually projected combined model, followed by a calculation of the distance between this virtual contour and the actual, detected, contour. The correct pose is then determined by searching through the seven-dimensional parameter space for an optimal pose which minimizes the distance between these contours.

### 3.3 Experimental setup

The new method (CM-RSA) was validated in both a phantom study and on clinical data, where it is compared to MB-RSA and EGS-RSA.

#### 3.3.1 Phantom experiment

The phantom study was performed on five prostheses (of three different hip stem designs).

- Mallory/Head size 9 and size 12 (Biomet, Inc, Warsaw, IN, USA)
- SL-Plus size 4 (Plus Orthopedics AG, Rotkreuz, Switzerland)
- Two straight Stanmore prostheses size 3 (Biomet, Inc, Warsaw, IN, USA)

A spherical head with a standard diameter of 28 mm was attached to each prosthesis and each prosthesis was rigidly fixed in a sawbone. Between 5 and 8 marker beads were inserted into each sawbone, resulting in a distribution of the markers with conditions number varying between 13 and 19 [Söderkvist
and Wedin, 1993]. For the SL-Plus prosthesis, a cup was added in which the spherical head was placed.

Eleven RSA-images were made of each prosthesis. Between exposures, the entire phantom was placed in a position and orientation mimicking the clinical situation. Furthermore, between exposures, the phantom was repositioned manually, each time in a similar clinically relevant position, but with an overall variation of roughly $15^\circ$ orientation. The RSA-setup consisted of two synchronized roentgen tubes at 1.5 m above the roentgen film and were directed towards the roentgen film, each one making an angle of $20^\circ$ with the vector perpendicular to the roentgen film. Migrations between pairs of consecutive scenes were computed. I.e. the migrations were computed between the following scene-pairs: $(1, 2), (2, 3), (3, 4)$.

### 3.3.2 Clinical data

In addition to the phantom experiment, the CM-RSA method was applied to clinical double-examination data. 11 double stereo roentgen-images were available for the Mallory/Head prostheses (sizes 7−14) with a metal-backed cup. For the standard Stanmore-prostheses (size 2 and size 3), eleven double images were available with a polyethylene cup. In both cases, migrations were computed between corresponding image pairs.

### 3.3.3 Validation

Laser-scanning (TNO Industry, Eindhoven, The Netherlands) with a spatial resolution of 0.05 mm, was used to generate reverse-engineered 3D surface models for the prostheses. The images were analyzed using Model-based RSA 3.12 (Medis specials, Leiden, The Netherlands) using standard methods for calibration and the described three methods (MB-RSA, EGS-RSA and CM-RSA) for the estimation of the position and orientation of the prosthesis.

Between exposures a prosthesis is considered to be rigidly fixed and no migration is expected of the prosthesis with respect to the tantalum markers.
in the (saw)bone. Therefore, the measured migration represents the measurement error. The mean migrations give an indication of the systematic error of the measurements, while the standard deviations give an indication of the precision of the measurements. Migrations were computed using the calibration box as the global coordinate system: the reference coordinate system is illustrated in Figure 3.1a, with the x- and y-axes in the image plane and with the z-axis perpendicular to the image plane.

Levene’s test for equality of variances was used to compare the standard deviations of the three methods.

### 3.4 Results

The time needed for the analysis of a pair of roentgen-images was comparable between the three methods and ranged from three to five minutes. For each method and each prosthesis, means and standard deviations for both the translational and rotational components of the measured migrations were computed. The results from the phantom-experiment and the clinical double-examinations are presented in Table 3.1.

<table>
<thead>
<tr>
<th>Method</th>
<th>Translations</th>
<th>Rotations</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>x (mm)</td>
<td>y (mm)</td>
</tr>
<tr>
<td>Phantom</td>
<td></td>
<td></td>
</tr>
<tr>
<td>MB-RSA</td>
<td>-0.01 [0.05]</td>
<td>0.00 [0.06]</td>
</tr>
<tr>
<td>CM-RSA</td>
<td>-0.01 [0.05]</td>
<td>0.00 [0.06]</td>
</tr>
<tr>
<td>Phantom SL</td>
<td></td>
<td></td>
</tr>
<tr>
<td>MB-RSA</td>
<td>-0.01 [0.04]</td>
<td>0.01 [0.07]</td>
</tr>
<tr>
<td>CM-RSA</td>
<td>-0.01 [0.07]</td>
<td>0.01 [0.11]</td>
</tr>
<tr>
<td>Stannmore</td>
<td></td>
<td></td>
</tr>
<tr>
<td>MB-RSA</td>
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<td>0.00 [0.03]</td>
</tr>
<tr>
<td>CM-RSA</td>
<td>-0.00 [0.03]</td>
<td>0.00 [0.02]</td>
</tr>
<tr>
<td>Clinical</td>
<td></td>
<td></td>
</tr>
<tr>
<td>MB-RSA</td>
<td>-0.02 [0.12]</td>
<td>0.11 [0.21]</td>
</tr>
<tr>
<td>CM-RSA</td>
<td>-0.05 [0.14]</td>
<td>-0.03 [0.19]</td>
</tr>
<tr>
<td>Stannmore</td>
<td></td>
<td></td>
</tr>
<tr>
<td>MB-RSA</td>
<td>-0.02 [0.08]</td>
<td>-0.02 [0.11]</td>
</tr>
<tr>
<td>CM-RSA</td>
<td>-0.03 [0.14]</td>
<td>-0.03 [0.19]</td>
</tr>
</tbody>
</table>

Table 3.1: Migration results (mean [standard deviation]) for each method applied to each prosthesis.

For the two most important indicators of prosthesis loosening, longitudinal translation and rotation, the measurements for these migration directions are gathered into two groups: clinical and phantom. This overall dataset
is presented in figure 3.2. The standard deviations show that CM-RSA performed significantly better ($p = 0.02$) on the $y$-rotation than MB-RSA ($0.69^\circ$ vs. $0.96^\circ$), while on the clinical dataset, there was no significant difference (0.41 vs 0.35). For the translation along the $y$-axis, there is a slight increase (from 0.05 mm to 0.06 mm) on the phantom data, while there is a significant increase (from 0.09 mm to 0.14 mm, $p = 0.04$) on the clinical data. EGS-RSA performs similar to MB-RSA ($1.02^\circ$ vs. $0.96^\circ$) on the phantom data for the rotation about the longitudinal axis and significantly worse ($0.10$ mm vs. $0.06$ mm, $p < 0.01$) for the translation along the longitudinal axis. On the clinical data, it appeared to perform worse than MB-RSA. Its standard deviations ($0.15$ mm and $0.79^\circ$) were significantly larger ($p = 0.02$ and $p < 0.01$, respectively) than MB-RSA.

For the individual experiments, it can be seen that for the phantom data the mean translation errors were all below 0.1 mm, indicating small systematic errors. For the clinical experiment these values were in general slightly higher, with values below 0.12 mm.

Similarly, the mean rotation errors were mostly below $0.1^\circ$, with some exceptions: in the clinical data a mean $y$-rotation of $0.49^\circ$ was measured for EGS-RSA applied to the Mallory/Head data. All three methods had a relatively large mean $y$-rotation on the clinical Stanmore data, with $0.12^\circ$, $0.20^\circ$ and $0.17^\circ$ for EGS-RSA, MB-RSA and CM-RSA, respectively.

The standard deviations for the translations are in general below 0.2 mm, with the exception of EGS-RSA and CM-RSA applied to the SL-Plus, which show standard deviations for the $z$-translation of 0.29 mm and 0.49 mm respectively. In the clinical data of the Mallory/Head, EGS-RSA has a standard deviation of 0.30 mm. The standard deviations for the rotations, however, show different results. Although performance on the $z$-rotations (values between $0.04^\circ$ and $0.20^\circ$) appears to be similar to those of the translations, larger standard deviations can be seen for the $x$-rotation and $y$-rotation. In the most extreme case, EGS-RSA has a standard deviation of $2.22^\circ$ $y$-rotation when applied to the SL-Plus. Only on the clinical data for the Stanmore, standard deviations comparable to those for translation are obtained, with values of $0.32^\circ$, $0.24^\circ$, $0.20^\circ$ for EGS-RSA, MB-RSA, CM-RSA,
For each prosthesis, Levene’s test for equality of variances was used to determine if CM-RSA or EGS-RSA showed a significant improvement over MB-RSA. Several significant differences were found. E.g., when considering the y-rotations, EGS-RSA performed significantly better than MB-RSA on both the phantom and clinical data of the Mallory/Head, but at the same time it performed significantly worse on the phantom data for the SL-Plus. CM-RSA performed significantly better on the phantom data for the Stanmore prosthesis.

3.5 Discussion

Overall, the results from figure 3.2 demonstrate that the new CM-RSA method, using a combined stem-head model, can yield more accurate results than the original MB-RSA method with a surface model of the stem only.

When considering the standard deviations for rotation about the y-axis of
EGS-RSA on the phantom data of the Mallory/Head prosthesis, EGS-RSA performs very well, with a factor two improvement for the standard deviation for the rotation about the y-axis (from 1.01° for MB-RSA to 0.51° for EGS-RSA, \( p = 0.01 \)). At the same time, it also may perform better on the phantom data of the Stanmore prosthesis (from 0.94° for MB-RSA to 0.66° for EGS-RSA). The overall worse performance of EGS-RSA with respect to MB-RSA on the phantom data can probably be explained by its poor performance on the SL-Plus prosthesis. On the phantom data of the SL-Plus, EGS-RSA performs a factor two worse (\( p < 0.01 \)) than MB-RSA, with a standard deviation of 2.22° for EGS-RSA, compared to 1.00° for MB-RSA. The SL-Plus stem design has a rectangular cross-section, as opposed to the curved cross-sections of the Mallory/Head and Stanmore designs. For certain stem orientations, this rectangular cross-section can make the estimation of the orientation troublesome. This suggests that the performance of EGS-RSA depends partially on the shape of a particular prosthesis.

In clinical practice the precision is usually worse than the precision in a controlled phantom experiment. For the Mallory/Head and the Stanmore prostheses, this is not visible in the results. The improvement of CM-RSA with respect to MB-RSA as visible in the phantom data, is not clearly present in the clinical data. For the Mallory/Head prosthesis, there is a small non-significant improvement from 0.54° to 0.40° and for the Stanmore prosthesis MB-RSA already achieves good results and CM-RSA yields only a marginal improvement over MB-RSA from 0.24° to 0.204°.

For the Mallory/Head prosthesis, the phantom experiment was performed using a size 9 and a size 12 Mallory/Head prosthesis. During analysis, it appeared that pose estimation on the size 12 prosthesis was much less accurate. Apparently, the MB-RSA and CM-RSA methods have problems with the Mallory/Head size 12 prosthesis, while not having those problems with the other sizes of the Mallory/Head. This can possibly be explained by the fact that the 3D surface model was not reverse-engineered from the actual prosthesis used in the study but from another size-12 prosthesis. This could have resulted in a difference between the 3D surface model of the scanned size 12 Mallory/Head prosthesis and the actual prosthesis used, which in turn could result in relatively large migration errors for the size 12
Mallory/Head prosthesis.

For the discrepancy between phantom and clinical data for the Stanmore prosthesis a simpler explanation can be given. Most Stanmore prostheses in the clinical dataset were standard curved Stanmore prostheses, while the ones from the phantom experiment were straight Stanmore prostheses. The straight Stanmore prosthesis is much more symmetric around its longitudinal axis and will therefore result in a larger standard deviation for the rotation about that axis. As the standard curved Stanmore prosthesis is far less symmetrical and thus less sensitive for measurement error on axial rotation, the addition of the spherical head will not yield a noticeable improvement in the double examinations. This is in line with the initial hypothesis that the addition of the spherical head will yield more precision, because the symmetry along the longitudinal axis is reduced.

The results for the phantom experiment with the SL-Plus prosthesis and the results for the clinical double-examination data for the Mallory/Head prosthesis demonstrate that even with a partial overlap of the head by a metal cup, CM-RSA shows smaller standard deviations (0.84 mm vs. 1.20 mm and 0.40 mm vs. 0.54 mm) for the rotation about the y-axis than MB-RSA. In clinical practice, such a cup will often be present and cause large parts of the spherical head to be occluded.

Kaptein et al. [2006] presented an analysis of the precision of the model-based approach and reported standard deviations for translations ranging from 0.03 mm to 0.21 mm and standard deviations for rotations ranging from 0.04° to 1.76°, with the largest error found for rotation about the y-axis. As can be seen from Table 3.1, the results for MB-RSA presented here are similar.

The results for EGS-RSA are similar to the data presented by Kaptein et al. [Kaptein et al., 2006] with standard deviations for translations ranging from 0.07 mm to 0.14 mm and from 0.10° to 0.61° for rotations. Both results have the largest error for rotation about the y-axis.

The results of CM-RSA can also be compared to the results of marker-based RSA. With standard errors ranging from 0.03 mm to 0.35 mm for
translations [Mjöberg et al., 1986, Kärrholm, 1989, Kärrholm et al., 1994] and from 0.05° to 0.58° for rotations [Kärrholm, 1989, Börlin et al., 2002], the marker-based approach is currently considered the most accurate method for migration measurements.

The results in Table 3.1 show that CM-RSA and EGS-RSA can still have problems with measuring the rotation about the y-axis. Considering the magnitudes of the errors, the small increase in translation error is probably justified by the decrease of the error in the other directions. It can also be seen that there is indeed an increase in accuracy with CM-RSA as opposed to MB-RSA.

### 3.5.1 Conclusion

It was demonstrated that using a combined stem-head model, with optimisation of the head position during estimation of the pose of a prosthesis, yields more precise migration measurements on the phantom data when compared to a model-based approach with surface models of the stem only. On the same phantom data was demonstrated that elementary geometrical shapes can also be a feasible method for migration measurements on some implant designs.

Overall, CM-RSA appears to be a feasible alternative to MB-RSA. As opposed to CM-RSA and MB-RSA, EGS-RSA eliminates the need for an accurate (reverse engineered) surface model, but it is only applicable in cases where the shape of the implant can be described by elementary geometrical shapes.

Because the precision of the model-based methods - MB-RSA, CM-RSA or EGS-RSA - is shape dependent, it is recommended that before using one of these methods as an alternative for marker-based RSA, an in-vitro validation experiment is carried out to assess the precision of these methods. When the precision of these methods is not sufficient, it is advised to use the marker-based approach, with the disadvantage that markers have to be attached to the prosthesis.
3.5.2 Future Work

One of the reasons for adding the spherical head to the model of the prosthesis was to show that pose estimation using a combined model is feasible. Now that this is demonstrated, the method can be applied to other modular prostheses. E.g. when focusing on knee prostheses, a combined tibial stem-plateau model can be constructed and used to increase the accuracy of RSA.

3.5.3 Acknowledgement

This project was sponsored by European Community project DESSOS IST-2004-27252