Accuracy of Model-based RSA Contour Reduction in a Typical Clinical Application

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Abstract Marker-based roentgen stereophotogrammetric analysis (RSA) is an accurate method for measuring in vivo implant migration, which requires attachment of tantalum markers to the implant. Model-based RSA allows migration measurement without implant markers; digital pose estimation, which can be thought of as casting a shadow of a surface model of the implant into the stereoradiographs, is used instead. The number of surface models required in a given clinical study depends on the number of implanted sizes and design variations of prostheses. Contour selection can be used to limit pose estimation to areas of the prosthesis that do not vary with design, reducing the number of surface models required. The effect of contour reduction on the accuracy of the model-based method was investigated using three different contour selection

schemes on tibial components in 24 patients at 3 and 6 month followup. The agreement interval (mean $\pm$ 2 standard deviations), which bounds the differences between the marker-based and model-based methods with contour reduction was smaller than -0.028 ± 0.254 mm. The data suggest that contour reduction does not result in unacceptable loss of model-based RSA accuracy, and that the model-based method can be used interchangeably with the marker-based method for measuring tibial component migration.

Introduction

Roentgen stereophotogrammetric analysis (RSA) is an accurate method for quantifying in vivo rigid body kinematics and has been used in investigations of implant migration, joint stability, fracture fixation, and realignment osteotomies [12, 21, 25]. The method is of particular importance because long-term followup studies show a correlation between early prosthesis migration and later aseptic loosening [13, 19]. Measurements with the RSA method reflect the current gold standard for assessing implant migration [22, 24] and can be used for early trials of new implant designs, potentially reducing the numbers of revisions.

Model-based RSA (MBRSA) is an approach by which pose estimation techniques are used to determine the three-dimensional (3-D) location of the implant relative to the surrounding bone (Fig. 1) [8, 10, 11, 23]. Pose estimation techniques are the digital equivalent of casting shadows, by which the location of objects is determined by the projection of a silhouette to the image plane or planes. The placement of tantalum implant markers required with marker-based techniques therefore is no longer necessary;

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Fig. 1 A typical view of an analysis using model-based and marker-based RSA (MBRSA 2.0 beta; Medis specials bv) is shown. The bone markers representing the reference rigid body for migration calculation are visible in circles. Three prosthesis markers also are visible, as is the geometric model of the prosthesis (foreground, middle). The projected contour of the implant (skewed), and the contour of the implant in the radiographs are visible (left and right), as are the fiducial and control markers used for calibration.

thus, the associated risks (initiation of cement cracking), technical problems (implant marker obfuscation), and cost (recertification cost) are eliminated [10, 14]. The MBRSA method can be distinguished from other shape-based methods [4, 8] in that it does not require specific implant geometries or shapes such as spherical femoral head and/or acetabular components. It also is comparable to fluoroscopic techniques for measuring joint kinematics [1, 17], with the distinction that higher-resolution, static stereoradiographs are used to determine implant migration. The theoretical accuracy and precision of the MBRSA method have been investigated in several experimental phantom studies using geometric models based on computer-aided design (CAD) data [23] and reverse-engineering techniques [10]. Reverse engineering is a process by which the 3-D geometry of existing objects is captured for replication of parts or devices or other purposes. Another study [11] of different pose estimation algorithms suggests the accuracy of MBRSA could be comparable to the classic marker-based method in detecting and quantifying *in vivo* implant migration.

Nonetheless, to apply the MBRSA technique, polygon surface models of the implanted prostheses are required. Obtaining proprietary CAD data of prosthesis geometries may not be possible for all prostheses or from all manufacturers. Even when available, subtle differences between the CAD geometry and the actual geometries of the prosthesis can result in a reduction in accuracy in comparison to reverse-engineering models [10]. To avoid problems with the availability and accuracy of CAD models, reverse engineering has been used to obtain surface models. The number of reverse-engineering models required in a clinical study depends on the number of different implanted prosthesis sizes and design variations; for example, the

tibial components of knee prostheses may vary according to the type of inlay used (fixed, mobile-bearing, cruciate-retaining, etc) (Fig. 2). An interesting property of the contour detection algorithms used with MBRSA is the ability to use partial contours, that is, selected regions of the contour of the implant. The partial contours used for pose estimation thus can be selected manually by the user.

The number of reverse-engineering models required in a given clinical study potentially could be reduced by limiting the selected contour to areas of the prosthesis that do not vary with design, for instance, the portion of the implant below the tibial plateau for knee prosthesis tibial components [11]. Furthermore, orthopaedic implants often possess functional areas of differing surface quality and/or manufacturing tolerances, and the use of partial contours allows areas of the implant that possess high geometric tolerances to be chosen for pose estimation and other areas to be ignored. Nonetheless, the applicability of contour reduction for prostheses of differing geometries still must be established and should be verified, not only under experimental conditions, but in particular under typical clinical conditions.

We asked whether contour selection (reduction) reduced the accuracy of the MBRSA method compared with marker-based RSA. The effect of contour reduction on the accuracy and precision of migration measurement was determined by comparison with marker-based RSA, which served as a standard for comparison. We hypothesized both methods were equivalent for measuring clinically relevant implant migration, regardless of the degree of contour reduction. The following question was addressed: can the difference between both methods be considered small enough such that both methods can be considered equivalent for prediction of later aseptic loosening?

Fig. 2A–B The photographs illustrate the (A) fixed-bearing and (B) rotational mobile-bearing implants investigated (Columbus[®] Knee System; Aesculap AG & Co KG). Both implants have the same geometry in the lower portion of the tibial plateau.

Materials and Methods

We analyzed tibial component migration using marker-based and MBRSA methods 3 and 6 months postoperatively in a cohort of patients treated with TKA (25 knees in 25 patients). The 25 patients were treated with the Columbus[®] Knee System prosthesis (Aesculap AG & Co KG, Tuttlingen, Germany) during a randomized, prospective clinical study. Details of that trial will not be reported here. The 25 implants investigated were fitted with three tantalum markers to allow the marker-based analysis to be performed. Up to 10 1.0-mm tantalum reference markers (Tilly Medical Products AB, Lund, Sweden) were placed in the cancellous bone surrounding the implant during the

implantation procedure. Four component sizes, ranging from 2 to 5, which included fixed (Fig. 2A) and rotational (Fig. 2B) inlay designs, were implanted.

Implant migration was measured using the marker- and model-based methods. A uniplanar RSA setup consisting of two manually synchronized roentgen tubes was used, whereby one was rigidly fixed to the ceiling (Philips Medio 50 CP-H; Philips Medical Systems GmbH, Hamburg, Germany), and the other was mobile (Philips MCD 105; Philips Medical Systems GmbH). Each roentgen tube was positioned at a 20° vertical angle, resulting in a 40° angle between the tubes. The roentgen tubes were placed approximately 160 cm above two conventional roentgen cassettes (350 mm × 430 mm), which were integrated into an RSA carbon fiber calibration box (Medis Medical Imaging Systems bv, Leiden, The Netherlands). We used AGFA Ortho Regular (400-System) film (Agfa-Gevaert NV, Mortsel, Belgium), and the analog RSA images were digitized at a 150 dpi resolution, eight-bit gray scale (ExpressionXL 1649; Epson Germany GmbH, Meerbusch, Germany). Tibial component migration was computed with respect to a coordinate system affixed to the calibration box, whereby translation along the mediolateral axis (x) and superoinferior axis (y) constitutes the in-plane motions and the posteroanterior axis (z) constitutes the out-of-plane translation. Rotation about the z axis represents in-plane rotation and rotation about the x and y axes represents out-of-plane rotations.

We analyzed the same sets of RSA radiographs with the marker- and model-based methods (MBRSA 2.0 beta; Medis specials bv, Leiden, The Netherlands) using the same calibration setting (roentgen-foci and image-plane determination). The MBRSA software used is a further development of the RSA-CMS[®] software (Medis Medical Imaging Systems bv) and is capable of both marker- and model-based analyses. The surface models required for each of the four prosthesis sizes implanted were generated using an optical noncontact digitizing system for small objects (ATOS II; GOM GmbH, Braunschweig, Germany). One model was generated for each size implanted with 0.08 mm spatial point spacing and 10 µm spatial resolution, which resulted in as much as approximately 380,000 polygons for the reverse-engineering models in the raw scanned state. Each surface model had to be reduced to 5000 polygons to be manageable for pose estimation using a quadric-based polygonal surface simplification algorithm embedded in the MBRSA software. We verified the quality of the reduced surface models using a nominal-actual comparison in the ATOS v5.4 software (ATOS v5.4; GOM GmbH), and found the differences between the raw and reduced models to be less than 0.05 mm in model areas that contribute to the projected contour of the implant (convex areas of the surface geometry).

Fig. 3 A schematic diagram shows each of the four analyses performed: one marker-based analysis (MBRSA-marker) and three different model-based analyses with different degrees of contour reduction (MBRSA-100, MBRSA-75, and MBRSA-50). RE = reverse engineering.

We performed four types of analysis (Fig. 3): a marker-based analysis (MBRSA-marker) and three model-based analyses with 100% (MBRSA-100), 75% (MBRSA-75), and 50% (MBRSA-50) of the prosthesis contour selected. The marker-based analysis served as the gold standard for comparison, and one observer (FS) performed all the analyses.

We used standard recommended thresholds [18] as acceptance criteria for calibration in this investigation: left-right translation error less than 0.2 mm and left-right focus error less than 1.0 mm. A possibility of making a correction for possible film bending, ie, the condition that the roentgen film is not a perfect plane, was not included in the analyses reported here. Additional analysis acceptance criteria used were that the condition number must be less than 80 to 90 and the rigid body error less than 0.3 mm for the bone markers [18]. Both of these criteria are related to the quality of the rigid-body motion determination of the bone markers [20].

The software computed rigid-body motion (migration) of the prosthesis based on different reference points for the two methods: the geometric center of the three tantalum markers for the marker-based analysis, and the geometric center of all the vertices of the geometric surface model for the model-based analysis. These reference points are not generally in the same location relative to the prosthesis. For purely translational prosthesis motions, translations reported with respect to both reference points are naturally identical. However, because prosthesis motions often contain some degree of rotational motion, it is essential to correct for the choice of reference points when making direct comparisons of the translations reported by both methods. To correct for

this difference in reference points, we recomputed translations computed using the model-based analysis reported by the MBRSA program (MBRSA-100, -75, -50) with respect to the reference point used by the marker-based (MBRSA-marker) analysis using rigid-body mathematics (program written for Mathematica 5.1; Wolfram Research Inc, Champaign, IL). Briefly, the rotation matrix and translation vector for the rigid-body motion of the implant relative to the bone from the model based analysis were determined. These then were used to compute motion of the same reference point that was used in the marker-based analysis. Thus, motion of the same point on the prosthesis could be compared using the two different methods.

To assess migration measurement agreement between the two methods, we used a specially adapted scatterplot technique as suggested by Bland and Altman [3] and Jorn et al. [7]. Using this approach, calculated migration differences between the marker- and model-based methods were plotted against their average values for each implant analyzed. We tested interchangeability of the two methods in a clinical setting by a bounding criterion defined as the mean ± 2 standard deviations of the measured differences (bounding approximately 98% of all measured differences). The smallest clinically relevant magnitude of migration is difficult to define, and several clinical investigations that have related early migration to later aseptic loosening have used thresholds ranging from 1.2 to 2.6 mm [5, 13, 15, 16, 19]. We therefore chose a conservative value of clinically relevant migration of ± 0.5 mm or greater in magnitude, ie, much less than thresholds that have been used to predict later loosening. According to this definition, the Bland and Altman interchangeability criterion would have to be within ± 0.5 mm for two measures of migration to be equivalent in a clinical setting. No agreement interval for rotations was defined because the criteria for predicting later loosening thus far has been based on measurements of translational migration alone.

The validity of all the analyses used for the comparisons in this study was assured; the calibration criteria for all the marker- and model-based analyses of the 25 patients ($n = 25$) were fulfilled for each analyzed pair of RSA radiographs. We observed somewhat larger rigid body error values for the bone markers of some patients, which reached a maximum of approximately 0.2 mm. For one patient, rigid body error was marginally larger than the limit (less than 0.3 mm) with a value of 0.334 mm, and we decided to remove this patient from the cohort resulting in a final sample size of 24 patient knees.

For convenience, and to provide a conservative bounding range for the accuracy of the RSA method for comparing the methods, the 95% confidence intervals (CIs) for migration measurement for the classic marker-based RSA method were assumed to range from 0.05 to 0.5 mm

and from 0.15° to 1.15° , as suggested by Valstar et al. [26] The differences between migration calculated using the classic marker- and model-based RSA methods were reported as mean, 95% CI (mean $\pm$ 1.96 standard deviations), and 2 standard deviations as calculated using SPSS 13.0 (SPSS Inc, Chicago, IL). We performed box plots of the calculated differences to illustrate the distribution of the data and identify possible outliers and extreme values.

Results

The maximum difference between the model-based method using contour reduction and the standard marker-based method was much smaller than what we considered to be clinically relevant. The Bland and Altman interchangeability criterion thus was much smaller than ± 0.5 mm. Using the full contour (MBRSA-100), the interchangeability criteria

were maximally -0.023 ± 0.076 mm and 0.002 ± 0.144 mm for in-plane and out-of-plane translations, respectively (Table 1), and $0.039^\circ \pm 0.218^\circ$ and $-0.078^\circ \pm 0.782^\circ$ for in-plane and out-of-plane rotations, respectively (Table 2). For the first contour reduction step, the comparison between marker- and model-based methods (MBRSA-75) resulted in maximum agreement criteria of -0.033 ± 0.210 mm and -0.002 ± 0.166 mm for in-plane and out-of-plane translations, respectively (Table 1), and $0.035^\circ \pm 0.232^\circ$ and $-0.102^\circ \pm 0.922^\circ$ for in-plane and out-of-plane rotations, respectively (Table 2). For the last contour reduction step (MBRSA-50), the maximum agreement criteria were -0.028 ± 0.254 mm and -0.027 ± 0.148 mm for in-plane and out-of-plane translations, respectively (Table 1), and $-0.006^\circ \pm 0.228^\circ$ and $-0.013^\circ \pm 0.906^\circ$ for in-plane and out-of-plane rotations, respectively (Table 2).

No systematic bias between the marker-based and the different model-based analyses was observed in the data

Table 1. Differences between analysis systems for translational degrees of freedom (n = 24)

Analysis system	Followup (months)	Statistic	In-plane		Out-of-plane
			x (mm)	y (mm)	z (mm)
MBRSA-100	3	Mean	0.005	-0.017	0.002
		95% CI lower	-0.058	-0.078	-0.140
		upper	0.058	0.076	0.141
		2 SD	0.060	0.078	0.144
	6	Mean	0.003	-0.023	-0.017
		95% CI lower	-0.061	-0.074	-0.133
		upper	0.061	0.073	0.131
		2 SD	0.062	0.076	0.134
	3	Mean	0.003	-0.010	-0.002
		95% CI lower	-0.086	-0.164	-0.163
		upper	0.086	0.162	0.163
		2 SD	0.088	0.166	0.166
	6	Mean	0.012	-0.033	-0.024
		95% CI lower	-0.090	-0.209	-0.151
		upper	0.091	0.202	0.147
		2 SD	0.092	0.210	0.152
MBRSA-75	3	Mean	-0.003	-0.013	-0.009
		95% CI lower	-0.102	-0.217	-0.140
		upper	0.102	0.214	0.139
		2 SD	0.104	0.220	0.142
	6	Mean	0.003	-0.028	-0.027
		95% CI lower	-0.096	-0.252	-0.147
		upper	0.096	0.245	0.143
		2 SD	0.098	0.254	0.148
MBRSA-50	3	Mean	-0.003	-0.013	-0.009
		95% CI lower	-0.102	-0.217	-0.140
		upper	0.102	0.214	0.139
		2 SD	0.104	0.220	0.142
	6	Mean	0.003	-0.028	-0.027
		95% CI lower	-0.096	-0.252	-0.147
		upper	0.096	0.245	0.143
		2 SD	0.098	0.254	0.148

MBRSA = model-based roentgen stereophotogrammetric analysis; CI = confidence interval; SD = standard deviation.

Table 2. Differences between analysis systems for rotational degrees of freedom

Analysis system	Followup (months)	Statistic	Out-of-plane		In-plane
			Rx (degrees)	Ry (degrees)	Rz (degrees)
MBRSA-100	3	Mean	0.020	−0.078	0.023
		95% CI lower	−0.420	−0.797	−0.136
		upper	0.429	0.737	0.139
		2 SD	0.434	0.782	0.140
	6	Mean	0.087	−0.073	0.039
		95% CI lower	−0.505	−0.680	−0.209
		upper	0.552	0.631	0.218
		2 SD	0.540	0.668	0.218
	3	Mean	0.067	−0.102	0.030
		95% CI lower	−0.471	−0.951	−0.152
		upper	0.505	0.857	0.157
		2 SD	0.498	0.922	0.158
MBRSA-75	6	Mean	0.068	−0.147	0.035
		95% CI lower	−0.587	−0.790	−0.223
		upper	0.629	0.680	0.231
		2 SD	0.620	0.750	0.232
MBRSA-50	3	Mean	−0.028	−0.013	−0.004
		95% CI lower	−0.588	−0.894	−0.206
		upper	0.572	0.882	0.205
		2 SD	0.592	0.906	0.210
	6	Mean	0.042	−0.070	−0.006
		95% CI lower	−0.485	−0.749	−0.224
		upper	0.507	0.697	0.223
		2 SD	0.506	0.738	0.228

MBRSA = model-based roentgen stereophotogrammetric analysis; CI = confidence interval; SD = standard deviation.

(Fig. 4). The data also illustrate generally better in-plane than out-of-plane translational and rotational accuracy (Fig. 5), with the exception of superoinferior translation with the contour reductions (MBRSA-75 and MBRSA-50; Fig. 5A–B).

Discussion

We investigated the effect of contour reduction on the accuracy of the MBRSA method in a typical clinical application. The model-based method, in particular when used with contour selection, provides significant practical and financial advantages in comparison to the marker-based method. In the setting in which our investigation was conducted, we found the model-based method in conjunction with contour reduction to be sufficiently accurate such that it can be used interchangeably with the marker-based method for measurement of implant migration.

Our results are valid only for the implant we investigated. Although we would expect similar results could be attained using other implants of similar geometry, materials, and manufacturing tolerances, this must be verified. We used one geometric model for each prosthesis size implanted and found the method sufficiently accurate. However, this may not be true with other implants that may not be manufactured to the same tolerances or are manufactured using other methods. Whether sufficient accuracy can be attained with implants of completely different geometries must still be investigated.

The MBRSA method, in particular when used with contour selection, provides considerable practical and financial advantages in comparison to the marker-based RSA method, although the effect of contour reduction on accuracy has to date only been investigated in experimental phantom studies. In the setting in which our investigation was conducted, we found the model-based method in conjunction with contour reduction to be sufficiently

Fig. 4A–F Scatterplots are shown for the MBRSA-marker versus MBRSA-50 migration in (A) mediolateral, (C) superoinferior, and (E) anteroposterior translation and rotation about the (B) mediolateral, (D) superoinferior, and (F) anteroposterior axes. Three-month (circles) and 6-month (stars) followup results are shown; each point represents the difference plotted versus the mean difference on the abscissa and ordinate, respectively, of migration computed with the two methods from the same image pair ($n = 24$). The solid horizontal line represents the mean of all the differences plotted, and the dashed lines represent the mean ± 2 standard deviations agreement interval. The plots show that the model-based method with contour reduction does not produce bias, and that the difference between the two methods (expressed by the agreement interval) is smaller than what we considered clinically relevant (± 0.5 mm).

accurate such that it can be used interchangeably with the marker-based method to measure implant migration.

We used the marker-based method as a standard of comparison in this study as it is a well-established method used as a basis of comparison for other techniques to measure implant migration. Although this may be viewed as a limitation, we believe our approach provides more information than a repeated (double) examination. The additional radiation exposure required by a double examination is, in our view, not justified in this context. The ability of early migration measurements to predict later aseptic loosening has been established [5, 13, 16, 19]. Marker-based RSA is considered the gold standard for measurement of implant migration, and it has been used as a standard of comparison for other radiographic methods,

such as the Sutherland, Wetherell, and Sulzer methods or EBRA (Ein-Bild-Röntgen-Analyse, single-image roentgen analysis) [2, 6]. Possible disadvantages of the marker-based RSA method, such as prosthesis marker occlusion or increasing cost of additional implant marking, could be compensated by the new model-based method [10, 14, 26]. The model-based method we used was validated in another clinical investigation of TKA implant migration [9]. A later version of the same software was used to perform the marker- and model-based analyses presented herein.

All computed differences between the marker-based analysis and each of the three model-based analysis protocols, as expressed by the agreement interval criteria (mean ± 2 standard deviations), were less than the ± 0.5 mm differences presumed clinically relevant. Thus,

Fig. 5A–D Box plots showing the calculated differences between the results of MBRSA-marker versus MBRSA-100, MBRSA-75, and MBRSA-50 along the mediolateral axis (white boxes), superoinferior axis (gray boxes), and anteroposterior axis (dark gray boxes). Translational motion at the (A) 3-month and (B) 6-month followups and rotational motion at the (C) 3-month and (D) 6-month followups

are shown. The dashed horizontal lines indicate minimum (large dash gap) and maximum (small dash gap) ranges of RSA accuracy reported in the literature (95% CI); outliers (circles) and extreme values (stars) are also indicated. The box plots show that reducing the contour somewhat increases variability in the measurement of migration.

using the full contour (MBRSA-100), the agreement interval is in a worst-case scenario 0.002 ± 0.144 mm in the anteroposterior direction, representing out-of-plane motion. Reducing the actual contour selection in the pairs of radiographs to the portion of the implant (MBRSA-75), which does not vary with design, resulted in an increase in the agreement in the worst case to -0.033 ± 0.210 mm; with the smallest contour selection (MBRSA-50), it was -0.028 ± 0.254 mm. Thus, in the worst case, the agreement interval is only approximately $\frac{1}{2}$ of what we considered clinically relevant (-0.028 ± 0.254 mm versus ± 0.5 mm). The data indicate additional reduction of the contour increases variability in the measurement of migration. Although the maximum contour reduction we analyzed did not result in unacceptable losses in accuracy, the effect of using additional reductions in contours could adversely affect the ability to measure clinically relevant migration.

The advantages of model-based analysis come only at a cost of requiring reverse-engineering models, which were necessary for analysis. The additional cost of digitizing reverse-engineering models increases with the number of applied prosthesis sizes and/or design variations implanted during a clinical study. The current cost for generation of surface models using the technique applied in this study (ATOS II; GOM GmbH) lies between €100 and €200 per scan, depending on implant complexity. An application of one reverse-engineering model size for an analysis of different design variations, eg, mobile-bearing arrangement, is generally possible, as we have shown. However, the results indicate accuracy decreases with dramatically reduced contours. Our results apply only to the prosthesis we investigated or to prostheses of similar geometry and manufacturing tolerances. Additional investigations must be performed in experimental phantom models or in a clinical setting to investigate the general applicability of

the model-based method to other prosthesis designs and geometries.

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