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Implementation and validation of an implant-based coordinate system for RSA migration calculation

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ABSTRACT

An *in vitro* radiostereometric analysis (RSA) phantom study of a total knee replacement was carried out to evaluate the effect of implementing two new modifications to the conventional RSA procedure: (i) adding a landmark of the tibial component as an implant marker and (ii) defining an implant-based coordinate system constructed from implant landmarks for the calculation of migration results. The motivation for these two modifications were (i) to improve the representation of the implant by the markers by including the stem tip marker which increases the marker distribution (ii) to recover clinical RSA study cases with insufficient numbers of markers visible in the implant polyethylene and (iii) to eliminate errors in migration calculations due to misalignment of the anatomical axes with the RSA global coordinate system. The translational and rotational phantom studies showed no loss of accuracy with the two new measurement methods. The RSA system employing these methods has a precision of better than 0.05 mm for translations and 0.03° for rotations, and an accuracy of 0.05 mm for translations and 0.15° for rotations. These results indicate that the new methods to improve the interpretability, relevance, and standardization of the results do not compromise precision and accuracy, and are suitable for application to clinical data.

1. Introduction

The technical developments of radiostereometric analysis (RSA) (Selvik, 1989) continue to expand its capability as a research tool for describing the micromotion of orthopaedic implants *in vivo*. This highly accurate technique uses at least three tantalum markers inserted in both the implant and the host bone to define these rigid bodies. Stereo radiographs taken with a calibration box enable the calculation of three-dimensional movement of the implant relative to the bone. Micromotion can be measured as permanent migration of the implant over time or inducible displacement of the implant, an elastic deformation in response to an applied load (Selvik, 1989; Ryd, 1992).

One limitation of representing the implant with inserted markers for RSA micromotion calculation is that results are described as translations and rotations relative to a global coordinate system defined by the RSA calibration box. If the joint under examination is not aligned with the calibration box, the micromotion results will not correlate with the anatomical axes and will be inconsistent between subjects. Using implant landmarks to define an implant-based coordinate system for the calculation of RSA migrations may provide results that will be more clinically relevant since the measurement and anatomical axes are aligned.

Another issue that arises in radiostereometric analysis of total knee replacements (TKR) is that due to the narrow joint space in a total knee replacement, the markers in the tibial component polyethylene are often obscured by the metal implant components. This leads to different markers being visible in different exams, changing the location of the centroid of the markers which can lead to inconsistencies. In addition, since a minimum of three markers is required to define a rigid body, clinical cases may be lost when only two implant markers are visible. The identification of a reliable landmark of the metal tibial component can serve as an additional implant marker in all exams to provide improved marker distribution which encompasses the whole implant, not just the tibial plateau, and also recover otherwise unusable RSA cases.

A similar approach has been used successfully in RSA studies of the hip (Kiss et al., 1995; Kaptein et al., 2006) where easily identifiable features of the femoral component were used to create a geometric model of the implant, but to date, this approach has not been used for TKR.

Evaluations of new RSA techniques are commonly performed with phantom studies which assess the precision and accuracy of RSA systems and analysis methods (Valstar et al., 2000; Kaptein et al., 2006; Madanat et al., 2005). The objective of this study was

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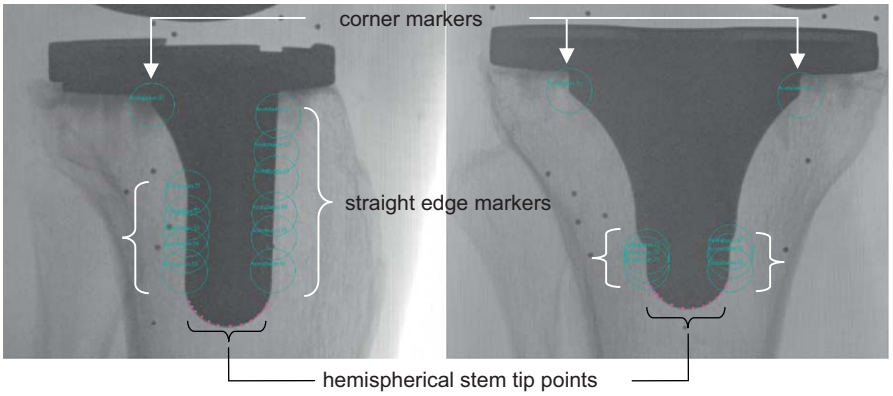

Fig. 1. Landmarks of the implant used to define the implant-based coordinate system identified on the stereo x-rays in the RSA software. Corners are identified by adding markers; the software matches the correct corner marker in the anterior–posterior view with the visible corner marker in the medial–lateral view. The straight edges are identified by placing a series of markers along the edges. The stem tip centre requires the user to add points along the periphery, which are used by the software to calculate the centre of a sphere.

to use an RSA migration phantom study to evaluate the effect of two modifications to the conventional RSA procedure intended to improve standardization of analysis and interpretation of results: (i) adding the centre of the hemispherical tip of the tibial component stem as an implant marker and (ii) using implant landmarks visible in the stereo X-rays to define an implant-based coordinate system for the calculation of migration results.

2. Methods

2.1. Radiostereometric analysis

A biplanar RSA set-up (Valstar et al., 2002) was used with two X-ray tubes (one fixed X-ray head: Model Ultranet-SA, GE Medical Systems, Monza, Italy; one portable X-ray head: Model 46-194759G1, General Electric Company, Milwaukee, WI, USA) oriented at 90° to each other and a biplanar calibration box (Tilly Medical Products AB, Lund, Sweden). X-rays were scanned from AFGA-Gevaert NV CRMD4.0 cassettes (35×43 cm) (Mortsel, Belgium) with an AGFA-Gevaert NV CR85-X digitizer, producing images with a spatial resolution of 6 pixels/mm and a greyscale resolution of 12 bits/pixel. Radiostereometric analysis was performed using commercial software (RSA-CMS, Version 4.3, MEDIS medical imaging systems BV, Leiden, The Netherlands).

2.2. Implant

The ADVANCE tibial component (Wright Medical Technologies, Inc., Arlington, TN) was used since the techniques developed in this study were to be applied to a clinical RSA study of this implant.

2.3. Addition of an implant landmark as a marker

The tip of the tibial component stem was selected as the landmark to be used as an additional implant marker. Specifically, the centre of the hemispherical tip of the tibial component stem was found by using the circle-finding feature of the RSA-CMS software. This function is intended for identifying the spherical femoral head of a hip replacement (Karrholm et al., 1997). The operator was required to place a series of points along the circular contour of the stem tip in both stereo X-rays which were used by the software to calculate the centre of a sphere. The centre point was then used as an implant marker. The allowable crossing line error of the centre point was set to 0.1 mm, the same limit was applied to the tantalum markers.

2.4. Definition of the implant-based coordinate system

Landmarks of the tibial component were used to define a coordinate system that was aligned with the implant, regardless of the orientation of the leg relative to the calibration box. Landmarks were selected that were reliably visible in the X-rays and which provided the necessary geometries to create an orthogonal coordinate system. These landmarks were identified in the commercial RSA software by manually placing software markers at these points. The landmarks used were (i) the centre of the stem tip as described in the previous section, (ii) the longitudinal axis of the stem defined by the straight edges in the X-rays, and (iii) the corners of the fins on the tibial component (Fig. 1). To determine the longitudinal axis of the stem, best-fit lines were generated through the points on the straight edges and the longitudinal axis of the stem was found by averaging the four visible straight edges, similar to methods used by Kiss et al. (1995) and Kaptein et al. (2006). A single fin corner was detected using the commercial RSA software to match the single point in the medial–lateral image with the correct point in the anterior–posterior image, providing the 3D location of this landmark. Crossing line errors for the corner were limited to 0.1 mm. The second corner was geometrically determined by finding the intersection of the projection line to the second corner point in the anterior–posterior view with the plane perpendicular to the longitudinal axis already determined, containing the first corner. The implant-based coordinate system was defined such that the *y*-axis was aligned with the longitudinal axis of the implant stem and the *x*-axis passed through the corners of the two fins (Fig. 2A). To ensure orthogonality of the coordinate system, the axis through the corners was used as a first estimate of the *x*-axis, the *z*-axis was calculated as a cross product of the *y*- and *x*-axis, and the true *x*-axis was recalculated as the cross product of the *y*- and *z*-axis. The origin of the coordinate system was placed at the centre of the hemispherical tip of the stem.

2.5. Migration calculations

Custom Matlab (The Mathworks, Inc., Natwick, MA) software was used to define the implant-based coordinate system based on these landmarks and to recalculate the migration results in this new coordinate system. For the custom software, the least squares optimization method as described by Challis (1995) was used to calculate transformations incorporating all marker information. All rotations and translations were calculated for a right-hand coordinate system with the signs later corrected to comply with the conventions proposed by Valstar et al. (2005) such that the *x*-axis points medially, the *y*-axis proximally, and the *z*-axis anteriorly.

Migration parameters calculated by the RSA system include translations and rotations of the implant about the *x*-, *y*-, and *z*-axis, and the maximum total point motion (MTPM) which is the length of the 3D vector of the implant marker which moved the most (Ryd et al., 1995).

To compare the effects of the two modifications to the RSA procedure, three measurement methods were used to calculate the migration parameters: (i) conventional RSA as calculated by RSA-CMS about the global coordinate system of the calibration box (*global*), (ii) conventional RSA including the stem tip centre as an implant marker (*global+stem*), and (iii) a local implant-based coordinate system defined by implant landmarks including the stem tip centre as an implant marker (*local+stem*).

2.6. Phantom study validation

Separate translational and rotational phantom studies were carried out to validate the implant-based coordinate system method and to quantify the system precision and accuracy. The phantom model for both studies was assembled to permit known movements of the implant with respect to a replica tibia. These known translations and rotations were the expected migration output of RSA-CMS.

The phantom model consisted of an ADVANCE tibial component and polyethylene insert mounted on a set of micrometers, and a fixed tibial replica bone (Sawbones, Pacific Research Laboratories, Inc., Vashon, WA) within the biplanar calibration box. Tantalum RSA marker beads (0.8 mm in diameter;

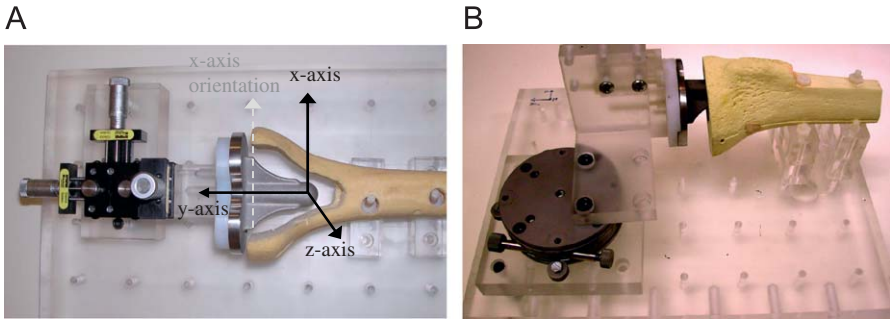

Fig. 2. The phantom study model with a replica tibia rigidly fixed to the base and the implant attached to the micrometers and implant-based coordinate system definition. (A) The translational phantom study configuration with three combined micrometers, able to translate the implant in the *x*-, *y*-, and *z*-directions. The implant-based coordinate system definition for the ADVNACE tibial component: the *y*-axis is parallel to longitudinal axis of stem, the *x*-axis passes through the corners of the fins, and the *z*-axis is perpendicular to both *x*- and *y*-axis. Positive directions for the axes are: x = medial, y = superior, z = anterior (Valstar et al., 2005). (B) An example of rotational phantom study configuration for *z*-axis rotation. The model configuration was changed by remounting the implant on the micrometer to allow rotations about *x*- and *y*-axis.

Table 1
Misaligned reference exams.

Exam	Axis misaligned about	Amount of misalignment (deg.)
1	*x*	−5
2	*x*	5
3	*x*	10
4	*y*	−10
5	*y*	−15
6	*y*	15
7	*z*	5
8	*z*	−5

Wennbergs Finmek AB, Gunnilse, Sweden) marked the implant polyethylene ($n = 5$) and proximal tibia ($n = 9$).

For the translational phantom study, a three-dimensional, linear translating micrometer from Parker Daedal (M3946M, Parker Daedal, Irwin, PA) was used to translate the implant in the *x*-, *y*- and *z*-directions (Fig. 2A). The resolution of the translating micrometers was 0.01 mm and the straight line accuracy was 0.002 mm for 25 mm of travel. Twelve zero-displacement exams were used to assess precision, and accuracy was assessed with twenty one known translational exams with the phantom model repositioned between each exam. For the translation exams, displacements of 0.05, 0.15, 0.20, 0.50, 1.00, 2.00, and 3.00 mm were conducted sequentially along the *x*-, *y*-, and *z*-axis such that the final position of the implant was $(x,y,z) = (3, 3, 3)$ from the reference position. Three millimeters of translation along a single axis is near the upper limit of clinical motions for knee replacements (Albrektsson et al., 1990; Ryd et al., 1983). The final zero-displacement exam from the precision series was used as the reference exam for all translational displacement exams for migration calculations with the RSA software.

The rotational phantom study used a single rotary micrometer (M-UTR80, Newport, Irvine. CA) with an accuracy of $\frac{1}{60}^\circ$ and a wobble rating of $\pm 0.003^\circ$. Three rotational configurations were used to allow rotation about each axis individually (Fig. 2B). For each configuration, a zero-displacement reference exam was followed by a series of displacements: $\frac{1}{6}^\circ$, $\frac{1}{3}^\circ$, 1°, 2°, 3°, and 6° for the *x*- and *z*-axes; and $\frac{1}{6}^\circ$, $\frac{1}{3}^\circ$, 1°, 2°, 5°, and 10° for the *y*-axis (Madanat et al., 2005). For each axis, migration was calculated between the reference exam and all displacement exams resulting in eighteen measures of rotational displacements.

To assess the ability of the implant-based coordinate system to correct for misalignments, eight reference RSA exams with the implant coordinate system purposely misaligned with the global coordinate system (Table 1) were used to analyse follow-up exams with 3 mm of translation along all three axes. The maximum misalignment was set to 15°, the maximum amount of misalignment seen in a clinical study at our centre.

2.7. Statistics

Precision was calculated as the standard deviation of the twelve repeated measurements of zero-displacement (Onsten et al., 2001; Madanat et al., 2005).

For the translational and rotational accuracy studies linear regression analyses were performed in SAS (SAS Institute Inc., Cary, NC, USA) to relate the translations and rotations measured with the RSA system to the actual displacements of the micrometers. Accuracy was defined as half the average width of the 95% prediction interval and was calculated for each axis (Onsten et al., 2001; Madanat et al., 2005).

Since our two modifications to the conventional RSA procedure were motivated by a desire to improve the interpretation of the results, our aim was to show equivalent accuracy of the new RSA measurement methods, not necessarily improvement. The procedure for assessing agreement between two methods of clinical measurement as described by Bland and Altman (1986) was used to compare the global method with the global+stem method and the global+stem method with the local+stem method. The difference between methods was judged by examining the limits of agreement calculated as $d \pm 2s$ where d is the mean of the differences and s is the standard deviation of the differences. If differences of $d \pm 2s$ were not clinically significant, the methods were considered to be interchangeable. Clinical significance was set at 0.2 mm, the amount of migration that predicts later loosening in TKRs at two years post-surgery (Ryd et al., 1995).

3. Results

For all phantom model exams, the mean errors of rigid body fitting were less than 0.1 mm and the condition numbers of the tibia and implant markers were less than thirty which are within the recommendations for RSA standardization (Valstar et al., 2005).

The precisions and accuracies calculated from the phantom study for the three measurement methods were similar (Tables 2 and 3). The precisions ranged from 0.017 to 0.044 mm for translations, and from 0.014° to 0.049° for rotations. The accuracies ranged from ±0.018 to ±0.075 mm for translations and between ±0.061 and ±0.153 for rotations. When comparing the differences between RSA measurement methods, the limits of agreement were low (Figs. 3 and 4) and did not exceed clinical significance (0.2 mm), showing equivalency of the methods.

The implant-based coordinate system was able to correct for misalignments of the implant with the global coordinate system in the reference exam when actual translations were 3 mm along each axis (Fig. 5). The maximum percent error for the global coordinate system was 31% (along the *x*-axis) which was reduced to 9% for the implant-based coordinate system. For the *y*- and *z*-axis, the maximum percent errors were reduced from 21% to 5% and 22% to 5% respectively.

4. Discussion

Our results are comparable to reported precisions and accuracies for previous RSA phantom studies. Madanat et al. (2005) reported translational precision of 0.002–0.006 mm, translational accuracy of ±0.006 mm, rotational precision of 0.025°–0.096°, and rotational accuracy ±0.073° with a biplanar calibration box. Onsten et al. (2001) reported precision of

Table 2
Precision for the 3 measurement methods, calculated as the standard deviation of twelve zero motion exams.

	Translation (mm)			Rotation (deg.)			MTPM (mm)
	x	*y*	*z*	*x*	*y*	*z*	
Conventional RSA *(global)*	0.021	0.027	0.044	0.049	0.025	0.014	0.032
Conventional RSA with stem tip centre *(global+stem)*	0.017	0.021	0.038	0.024	0.025	0.018	0.028
Implant-based coordinate system *(local+stem)*	0.018	0.020	0.041	0.024	0.025	0.018	0.028

Table 3
Accuracy for the three measurement methods, calculated as ±half the width of the 95% prediction interval (seven increments for translations, six increments for rotations).

	Translation (mm)			Rotation (deg.)			MTPM (mm)
	x	*y*	*z*	*x*	*y*	*z*	
Conventional RSA *(global)*	±0.025	±0.042	±0.075	±0.145	±0.093	±0.061	±0.056
Conventional RSA with stem tip centre *(global+stem)*	±0.018	±0.044	±0.054	±0.153	±0.092	±0.094	±0.049
Implant-based coordinate system *(local+stem)*	±0.021	±0.048	±0.047	±0.152	±0.093	±0.094	±0.049

0.030–0.104 mm and accuracies of ±0.047–±0.121 mm for translations.

The identification of implant landmarks for RSA has precedence in studies where implant landmarks were used to define the position of the femoral component for assessing hip migration (Kiss et al., 1995; Kaptein et al., 2006). These studies used the long axis of the femoral component and the centre of the femoral head as landmarks. The exact method of defining the implant-based coordinate system described for our study is only applicable to this specific tibial component but the overall concept can be translated to many implant designs provided suitable landmarks are consistently visible in the radiographs. Newly developed model-based RSA software uses shape matching to eliminate the need for markers attached to the implant (Valstar et al., 2001), but this method has decreased precision and accuracy compared to RSA using markers (Kaptein et al., 2003; Kaptein et al., 2006, 2007).

Using the stem tip centre as an additional implant marker offered a number of advantages: (i) the recovery of cases which may have otherwise had too few implant markers, (ii) increased number of markers and improved marker distribution for better rigid body estimation, and (iii) a marker that is in the same location in all subjects which can be used as the origin of the implant rigid body, as opposed to the variable centroid location, for migration calculations. In a clinical study of sixty five patients twelve cases were recovered with the addition of the stem tip centre as an implant marker, which would have otherwise been lost due to insufficient visible markers in the implant polyethylene (Laende, 2005). By examining the rigid body errors of the implant markers with and without the implant landmark

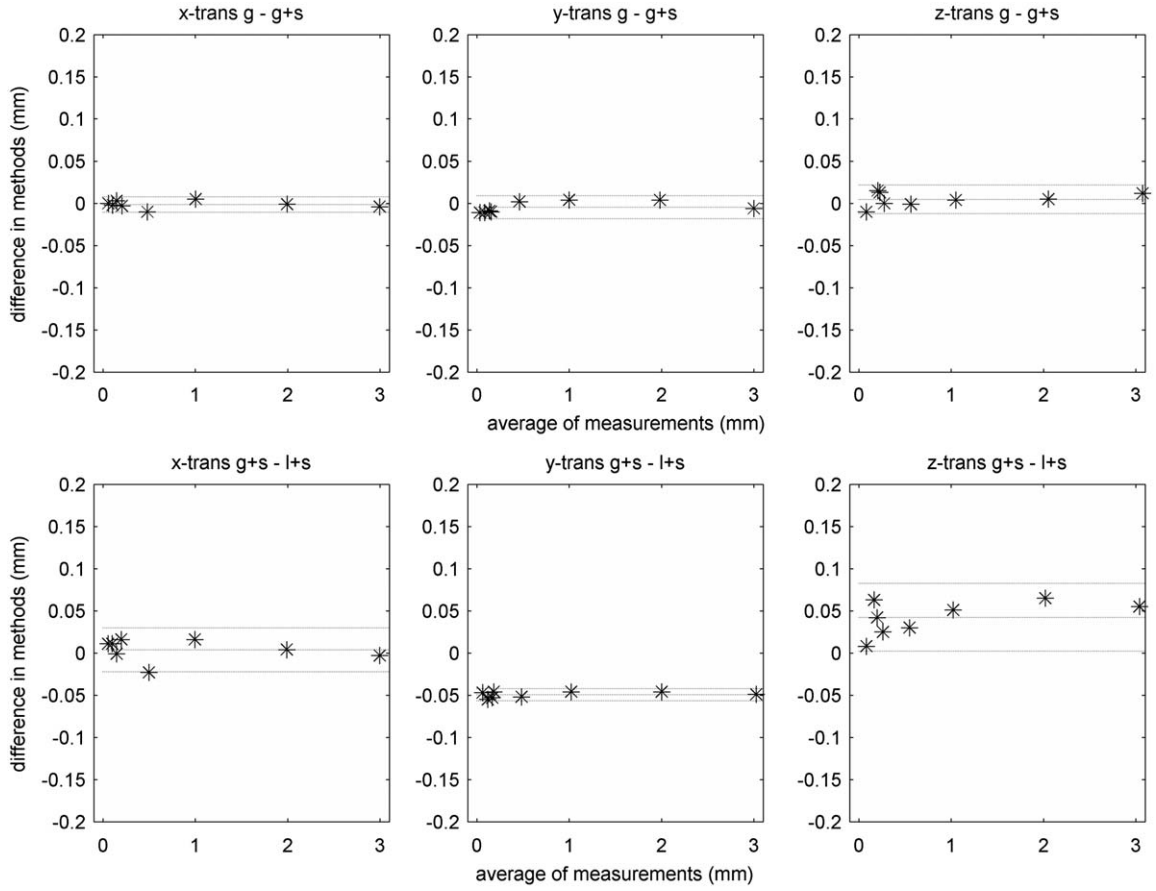

Fig. 3. Bland and Altman plots (Bland and Altman, 1986) for translations showing the difference of methods for individual translation components when comparing the global method to the global+stem method ($g-g+s$) and comparing the global+stem method to the local+stem method ($g+s-l+s$). Centre line = mean of differences (d), outside lines = limits of agreement = $d \pm 2s$ where s is the standard deviation of the differences.

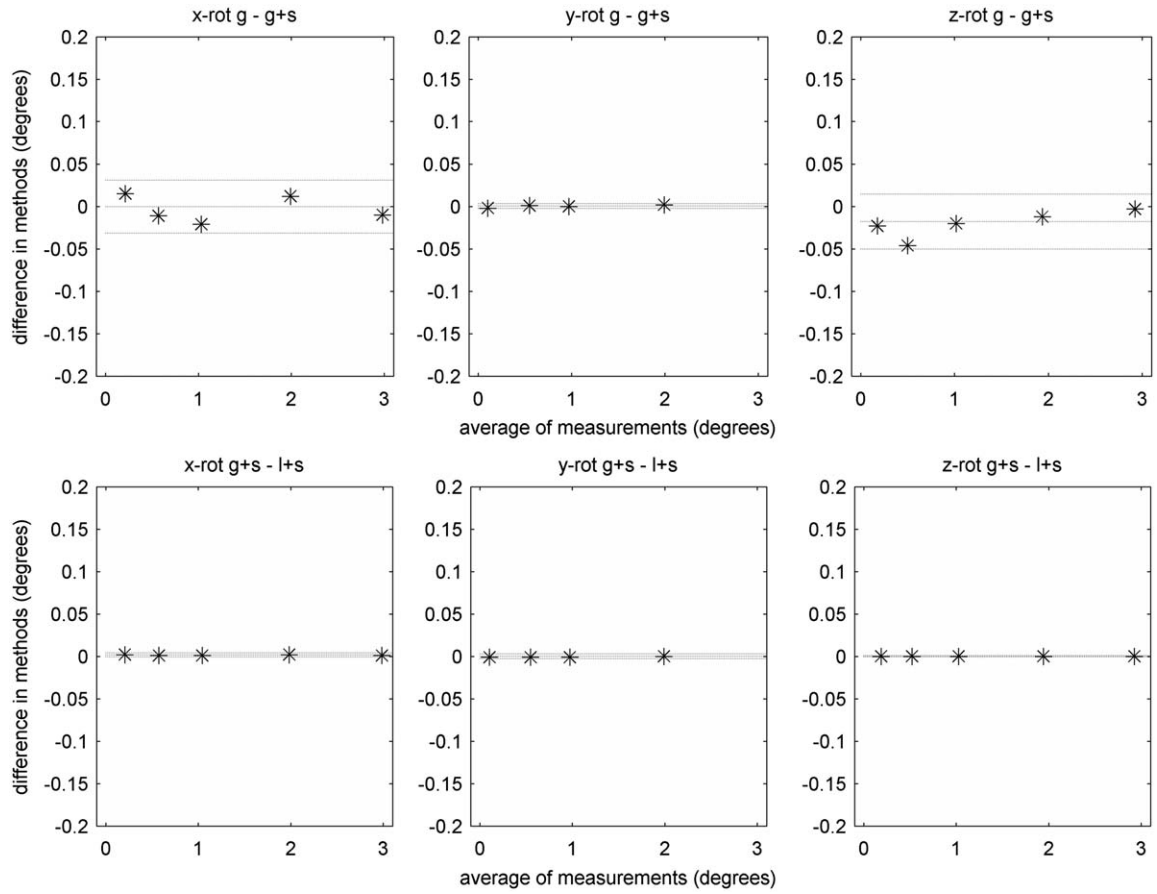

Fig. 4. Bland and Altman plots (Bland and Altman, 1986) for rotations showing the difference of methods for individual rotation components when comparing the global method to the global+stem method (g–g+s) and comparing the global+stem method to the local+stem method (g+s–l+s). Centre line = mean of differences (d), outside lines = limits of agreement = $d \pm 2s$ where s is the standard deviation of the differences.

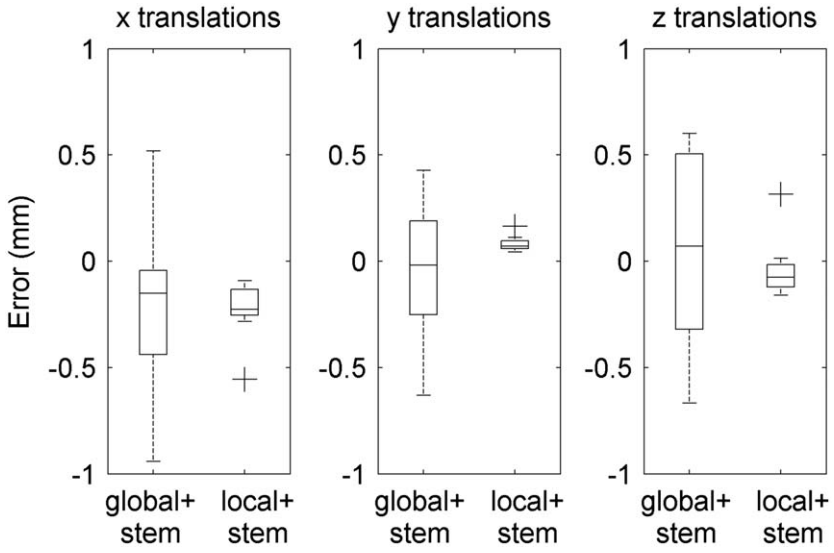

Fig. 5. Box plot of errors in calculating translations in the global and local coordinate systems for misaligned references exams and 3 mm of translation along all axes ($n = 8$). Boxes enclose the interquartile range (25th–75th percentile) with the centre line indicating the median, the whiskers showing the extent of the values with the exception of outliers, represented by the crosses, which exceed 1.5 times the interquartile range.

included as a marker, it will also be possible to assess the stability of the tibial plateau–polyethylene insert construct in clinical cases, which is generally assumed to be rigid for the purposes of RSA.

The implant-based coordinate system improved accuracies in cases where the implant in the reference exam was misaligned with the calibration box coordinate system, as can occur in clinical studies. With stable implant fixation the actual translations

themselves may be so small that misalignments will have negligible effects on the migration results. However, for implants showing large migrations, the correction for misalignments may improve measurement sensitivity by providing more consistent and anatomically relevant results. Note that migration would have to exceed 2 mm before the effect of a typical misalignment of 15° would exceed the detection limit of the RSA system.

The main advantage of the implant-based coordinate system is the assurance that the migration results reported about the *x*-, *y*-, and *z*-axes correspond to the anatomical medial–lateral, distal–proximal, and anterior–posterior axes. The implant-based coordinate system also positions the origin of the coordinate system at the stem tip centre rather than the centroid of the implant markers, as done with the commercial software, eliminating the variation associated with centroid location when some markers are obscured or not in standardized positions. Further, the implant-based coordinate system allows an additional refinement with the use of fictive markers for the implant (Nilsson et al., 1991). Fictive markers can be easily defined for each size of implant relative to the implant-based coordinate system based on the known dimensions of the implant, to eliminate the variation from implant markers placed in varying locations or obscured during some exams. This ensures that the implant markers being evaluated are in the same position in each patient, which is especially important for reducing the variation in the MTPM measurement, without the laborious task of manually adding fictive markers in the x-rays by physically drawing the fictive markers on each film as has been done in the past (Nilsson et al., 1991).

There have been numerous published protocols for RSA phantom studies (Onsten et al., 2001; Bragdon et al., 2002, 2004; Madanat et al., 2005; Ioppolo et al., 2007) with different approaches to assessing precision and accuracy, as well as different interpretations of these measures. Our study evaluated both precision, the closeness of agreement between independent test results obtained under stipulated conditions (Ranstam et al., 2000), and accuracy, the closeness of agreement between a test result and the accepted reference (the 'true') value (Ranstam et al., 2000; Valstar et al., 2005). The protocol used in this study was based on one described by Onsten et al. (2001) because it offered a balance between sufficient data and a reasonable data collection procedure.

The Bland and Altman plot limits of agreement provide an easily interpretable method of examining differences in measurements. These plots show that the difference between methods is well below clinical significance, meaning that the methods are interchangeable in well-aligned RSA exams. For translations there was a small bias between the global and local methods which may be attributed to the fact that a single reference exam is used to calculate all translations and, while the phantom model was visually aligned with the calibration box, the alignment may not have perfectly matched that found by the implant-based coordinate system.

While on its own, the use of an implant-based coordinate system may only have a minor impact on the values in an RSA study, it represents an incremental step in the improvement of RSA accuracy. The use of an implant-based coordinate system in combination with higher quality radiographs, standardized bead placements, fictive markers, and precise RSA exams may eventually lead to improved accuracies and increased sensitivity and interpretability of RSA data.

This study showed that the addition of the stem tip centre as an implant marker and the recalculation of migration parameters in an implant-based coordinate system was successful in providing a more meaningful and interpretable assessment of implant migration without increasing system errors. The phantom study results support the use of these methods in the analysis of clinical data.

Conflict of interest statement

The authors have no commercial affiliation with any product named in this article, nor will the authors or any institution or group with which the authors are associated receive any personal or professional financial benefit by naming any product in this article.

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