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The robustness and accuracy of measuring the minimum joint space width of TKA based on model-based RSA
The robustness and accuracy of measuring the minimum joint space width of total knee arthroplasty based on model-based RSA

E.A. van IJssel*d, E.R. Valstar*a,b, B.C. Stoelc, R.G.H.H. Nelissen*a, J.H.C. Reiber*c, B.L. Kaptein*a

*a Biomechanics and Imaging Group, Department of Orthopaedics, Leiden University Medical Center, PO Box 9600, 2300 RC Leiden, The Netherlands
*b Department of Biomechanical Engineering, Faculty of Mechanical, Maritime, and Materials Engineering, Delft University of Technology, Delft, The Netherlands
*c Division of Image Processing, Department of Radiology, Leiden University Medical Center, Leiden, The Netherlands

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Abstract

Introduction
Accurate in vivo measurements methods of wear in total knee arthroplasty are required for a timely detection of excessive wear and to assess new implant designs. Component separation measurements based on model-based Roentgen stereophotogrammetric analysis (RSA), in which 3-dimensional reconstruction methods are used, have shown promising results, yet the robustness of these measurements is unknown. In this study, the accuracy and robustness of this measurement for clinical usage was assessed.

Method
The validation experiments were conducted in an RSA setup with a phantom setup of a knee in a vertical orientation. 72 RSA images were created using different variables for knee orientations, two prosthesis types (fixed-bearing Duracon knee and fixed-bearing Triathlon knee) and accuracies of the reconstruction models. The measurement error was determined for absolute and relative measurements and the effect of knee positioning and true separation distance was determined.

Results
The measurement method overestimated the separation distance with 0.1 mm on average. The precision of the method was 0.10 mm (2*SD) for the Duracon prosthesis and 0.20 mm for the Triathlon prosthesis. A slight difference in error was found between the measurements with 0° and 10° anterior tilt. (difference = 0.08 mm, p = 0.04).

Conclusion
The mJSW can be measured with an accuracy of 0.1 mm and precision of 0.2 mm based on model-based RSA, which is more than adequate for clinical applications. The measurement is robust in clinical settings. Although anterior tilt seems to influence the measurement, the size of this influence is low and clinically irrelevant.
2-1 Introduction

Total knee arthroplasty (TKA) is highly successful in relieving pain and restoring joint function, yet implant failure remains a problem. One of the main causes of failure is excessive polyethylene wear. Wear particles can induce osteolysis that may provoke complications such as aseptic loosening. It has been reported that wear and osteolysis are the primary indications for revision in more than 44% of all revisions performed more than two years after surgery[22]. Excessive wear is related to the design of a prosthesis[25]. Therefore, new prosthesis designs are assessed with knee simulator studies before market introduction. Unfortunately these studies are limited in incorporating important factors such as patient activity and the incidence of misalignment[16, 26]. As an alternative, model-based Roentgen stereophotogrammetric analysis (MBRSA) may be used to assess wear in a clinical setting. This imaging and analysis method achieves sub-millimeter precision in assessing migration of prostheses[44-47], which is used to predict prosthetic loosening[34]. Wear measurements can be obtained with MBRSA and high accuracies were already obtained[42, 43, 48]. However, validation of these wear measurements has been restricted to individual prostheses or measurement protocols. The method’s robustness to variations in patient positioning has not been characterized.

The goal of this study is to determine the robustness of TKA wear measurements in MBRSA. The study uses an RSA setup and a knee phantom in which the separation distance between the tibial and femoral components is known exactly. The measurement method is applied for different variables such as prostheses type, actual separation distance, digital model accuracy and patient positioning. The robustness of the method is determined by assessing the measurement error as a function of these variables.

2-2 Materials and Methods

We now describe the phantom setup, the MBRSA analysis and the details of the separation measurements that were used in this study.
2-2-1 Phantom setup and acquisition of RSA images

A phantom setup was used with the total knee prostheses fixed into sawbones, to create more realistic images. RSA images of the phantom setup in standing position were acquired with a vertical RSA setup[32]. The setup consisted of a vertical rail on a base plate with two supports on which a tibial and a femoral sawbone could be fixed (Figure 2-3 Left). RSA images were obtained with two synchronized X-ray sources each aimed at a digital X-ray detector (Canon CXDI-series, 169dpi, 12BPP). The detectors were placed adjacently in a carbon calibration box (Medis Specials b.v., Leiden, Netherlands). The X-ray sources were positioned 1.5m from the detectors with a 40° angle between their respective beams. The phantom device was positioned as close to the detectors as possible (Figure 2-3 Right).

![Figure 2-3. of the phantom-set-up. Right: Schematic top view of the RSA set-up](image)

To validate the wear measurements, we analyzed the effect of different variables on the measurement error. In total 72 measurements were obtained using the variables in Table 2-1.

**Prosthesis type**

Two types of Stryker (Kalamazoo, USA) total knee prosthesis were used: the fixed-bearing Duracon knee (tibia size XL2, femur size XL) and the fixed-bearing Triathlon knee tibia (size 7, femur size 7).
Figure 2-4. Phantom device settings: (a) in resting position, (b) with a flexion angle and (c) with a positive anterior tilt

Flexion angle, anterior tilt and rotation
To test for different flexion angles and the effect of patient positioning, the setup contained mechanisms to adapt the flexion angle of the knee, the anterior tilt and rotation of the leg with respect to the imaging system (Figure 2-3).

Component separation distance
The component separation distance was set using cylindrical, radiolucent plates (Plexiglass/PMMA), which had an accurate thickness (tolerance 0.05mm). During the measurement a plate was placed in contact between the tibia plateau and the medial femoral condyle of the total knee. By repeating the measurements with plates of 5 and 10mm, we validated different component separation sizes.

2-2-2 Separation distance measurement
The separation distance measurement is based on 3D models of the tibial and femoral components. The first step of the measurement was creating a 3D reconstruction of the prosthesis component positions. An RSA analysis was done with MBRSA software
The robustness and accuracy of measuring the mJSW of TKA based on model-based RSA.

(Version 3.3, Medis Specials, Leiden, The Netherlands). The image contours of the components were selected semi-automatically. The user selected a region of interest in which the software program detected candidate edges (canny edge detection), which could be altered manually. Subsequently, the model poses were calculated by minimizing the difference between the image edges and the projected model silhouette. This is a standard procedure in MBRSA and the accuracy of the position and orientation estimation equaled 0.11 mm and 0.23°, respectively [33]. Next, the medial separation distance was calculated, which was defined as the shortest distance between the medial condyle of the femur and the tibial plane.

The RSA analyses were conducted with both computer aided design (CAD) models and models obtained by reverse engineering (RE), giving 144 measurement outcomes in total. The CAD models were provided by the prosthesis manufacturer. The RE models were created with a 3D laser scanner (Hyscan, Hymarc Tech, Ottawa, Canada) using the original components from this experiment. This scan had a tolerance of 0.020 mm.

<table>
<thead>
<tr>
<th>Order</th>
<th>Variable</th>
<th>Options</th>
<th>Procedure</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>Prosthesis type</td>
<td>1: Duracon 2: Triathlon</td>
<td>Place the sawbones with the protheses components into the phantom setup</td>
</tr>
<tr>
<td>2</td>
<td>Flexion angle</td>
<td>1: 0° 2: 30° 3: 45°</td>
<td>Adapt the angle with the lever on the phantom setup (Figure 2-4b)</td>
</tr>
<tr>
<td>3</td>
<td>Separation distance</td>
<td>1: 10 mm 2: 5 mm</td>
<td>Fix the plate with the appropriate thickness between the tibial and femoral components</td>
</tr>
<tr>
<td>4</td>
<td>Anterior tilt</td>
<td>1: 0° 2: 10°</td>
<td>Adjust the angle with the phantom setup (Figure 2-4c)</td>
</tr>
<tr>
<td>5</td>
<td>Rotation</td>
<td>1: 0° 2: 10° 3: -10°</td>
<td>Rotate the phantom device</td>
</tr>
</tbody>
</table>

**Table 2-1. List of variables used in the robustness validation experiment**

2-2-3 Statistical analysis

The accuracy and precision of the measurement method were analyzed based on
the measurement error, which is the difference between the measurement outcome and the separation distance set during the measurement. The means and standard deviations of the error were calculated for each subgroup of prosthesis type, model type and flexion angle. This was carried out to determine and compare systematic errors among these groups. Subsequently, tests were applied to determine whether mean errors were influenced by anterior tilt, actual separation distance and internal rotation (t-test/ANOVA). These tests were conducted with the data from RE models only, to avoid confounding due to model inaccuracies.

2-3 Results

Table 2-2 and Figure 2-5 show the average measurement error per group of prosthesis/model type and flexion angle. These groups consisted of 12 measurements combining all anterior tilt angles, rotation angles and separation distances.

Figure 2-5. Measurement errors of the absolute wear measurement for different subgroups of prosthesis and flexion angles. Each group consists of 12 measurements. The dashed horizontal line shows the average measurement error (0.11 mm).
The robustness and accuracy of measuring the mJSW of TKA based on model-based RSA

The results indicated that a systematic overestimation error of 0.1 mm was present in general (one sample \(t\)-test, \(p < 0.05\)) and in 11 out of 12 subgroups. As can be seen in Figure 2-5, the error of measurement with CAD models varied significantly over the flexion angles for both prosthesis types (ANOVA, \(p < 0.001\)). Measurements with RE models did not show this variation.

As shown in Table 2-2, the measurements were more precise with the Duracon prosthesis than with the Triathlon prosthesis (0.2 and 0.1 mm, respectively for the RE models). Levene’s test was applied on 6 equivalent subgroups (flexion*model type) and the outcome was significant (\(p < 0.05\)) for all but the Duracon 0° flexion case.

The mean errors between the groups of anterior tilt, knee rotation and real separation distance are displayed in Table 2-3. Only for anterior a significant difference in error was found (\(d=0.08, t\)-test, \(p < 0.05\)).

### Table 2-2. Mean measurement errors in the robustness experiment, comparison between model types, prosthesis type and knee flexion angle. Each subgroup consists of 12 measurements. Subgroups with a significant error (\(p < 0.05, t\)-test) are printed in bold.

<table>
<thead>
<tr>
<th>Flexion angle (deg)</th>
<th>0° N = 12</th>
<th>30° N = 12</th>
<th>45° N = 12</th>
<th>All N = 36</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Duracon CAD</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Mean + 2*SD</td>
<td>0.00 ± 0.08</td>
<td>0.06 ± 0.07</td>
<td>-0.05 ± 0.07</td>
<td>0.00 ± 0.06</td>
</tr>
<tr>
<td>Median</td>
<td>-0.012</td>
<td>0.046</td>
<td>-0.058</td>
<td>0.005</td>
</tr>
<tr>
<td>Total range</td>
<td>[-0.05 - 0.09]</td>
<td>[0.02 - 0.14]</td>
<td>[-0.09 - 0.01]</td>
<td>[-0.09 - 0.14]</td>
</tr>
<tr>
<td><strong>RE</strong></td>
<td>0.10 ± 0.08</td>
<td>0.13 ± 0.11</td>
<td>0.13 ± 0.10</td>
<td>0.12 ± 0.10</td>
</tr>
<tr>
<td>Mean + 2*SD</td>
<td>0.09</td>
<td>0.12</td>
<td>0.12</td>
<td>0.11</td>
</tr>
<tr>
<td>Median</td>
<td>[0.05 – 0.19]</td>
<td>[0.06 – 0.22]</td>
<td>[0.08 – 0.21]</td>
<td>[0.05 – 0.22]</td>
</tr>
<tr>
<td>Total range</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>Triathlon CAD</strong></td>
<td>0.30 ± 0.15</td>
<td>0.90 ± 0.18</td>
<td>0.10 ± 0.24</td>
<td>0.16 ± 0.27</td>
</tr>
<tr>
<td>Mean + 2*SD</td>
<td>0.31</td>
<td>0.06</td>
<td>0.11</td>
<td>0.18</td>
</tr>
<tr>
<td>Median</td>
<td>[0.19 – 0.40]</td>
<td>[-0.05 – 0.23]</td>
<td>[-0.12 – 0.29]</td>
<td>[-0.12 – 0.40]</td>
</tr>
<tr>
<td>Total range</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>RE</strong></td>
<td>0.13 ± 0.22</td>
<td>0.11 ± 0.20</td>
<td>0.07 ± 0.23</td>
<td>0.10 ± 0.20</td>
</tr>
<tr>
<td>Mean + 2*SD</td>
<td>0.15</td>
<td>0.15</td>
<td>0.05</td>
<td>0.09</td>
</tr>
<tr>
<td>Median</td>
<td>[-0.02 – 0.26]</td>
<td>[-0.06 – 0.20]</td>
<td>[-0.04 – 0.26]</td>
<td>[-0.06 – 0.26]</td>
</tr>
<tr>
<td>Total range</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>
Table 2-3. Average measurement errors and standard deviations (SD) for different values for anterior tilt, knee rotation and real component separation. The last column shows the difference test used and result for significance.

<table>
<thead>
<tr>
<th></th>
<th>N</th>
<th>Average (mm)</th>
<th>SD (mm)</th>
<th>Difference test</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Anterior tilt</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>0°</td>
<td>36</td>
<td>0.07</td>
<td>0.07</td>
<td>t-test p = 0.04</td>
</tr>
<tr>
<td>10°</td>
<td>36</td>
<td>0.15</td>
<td>0.06</td>
<td></td>
</tr>
<tr>
<td><strong>Separation distance</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>5 mm</td>
<td>36</td>
<td>0.09</td>
<td>0.09</td>
<td>t-test p = 0.06</td>
</tr>
<tr>
<td>10 mm</td>
<td>36</td>
<td>0.13</td>
<td>0.07</td>
<td></td>
</tr>
<tr>
<td><strong>Internal rotation</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>-10°</td>
<td>24</td>
<td>0.09</td>
<td>0.08</td>
<td>ANOVA p = 0.11</td>
</tr>
<tr>
<td>0°</td>
<td>24</td>
<td>0.11</td>
<td>0.07</td>
<td></td>
</tr>
<tr>
<td>10°</td>
<td>24</td>
<td>0.14</td>
<td>0.08</td>
<td></td>
</tr>
</tbody>
</table>

2-4 Discussion

We studied the accuracy and precision of a component separation measurement in MBRSA for TKA. The study was performed with a phantom setup, in which the measurement was repeated for various knee positions, separation distances and prosthesis types.

We found that the measurement had a small overestimation of 0.1 mm. For the CAD models, this seems to depend on the flexion angle, whereas the results for the RE models were more homogeneous. In addition, anterior tilt may influence the measurement, as a statistically significant effect size of 0.07 mm was observed over a tilt range of 10°. However, this effect is small and should pose little concern when patients are positioned carefully.

Other similar wear validation studies using perspex/acrylic plates also reported overestimations [43, 49]. We noticed that in many measurements the image contours of the prostheses were systematically smaller/more contracted than the contours based on the model projections. This difference may lead to a systematic error in the pose estimation, putting the models further apart and thus increasing the measured separation distance. This error is neutralized in relative measurements over time such as migration, which are usually performed in MBRSA studies.
The precision of the measurement seems related to the prosthesis type. With RE models, the precision of the Triathlon and Duracon prosthesis were 0.2 and 0.1 mm, respectively. Possibly, the Duracon prosthesis has a more salient geometry, giving a higher precision in the pose estimation.

An important question is how these results influence a wear measurement, which is the difference between two subsequent separation distance measurements. Assuming these measurements are independent, the overestimations will cancel out and a precision is expected of $\sqrt{2} \times 0.2 \approx 0.3$ mm. This shows the measurement is suitable for clinical research studies, as sub-millimeter difference can be detected with small patient groups.

A limitation of this study is the lack of experiments with in vivo data, in which soft tissue attenuation can deteriorate contours detection. Still, similar results are expected as attenuation is usually limited in knee X-rays. Besides, MBRSA analysis is robust even if only 10% of the contour information is used[50].

Some general limitations still exist for TKA wear measurements based on the separation distance. Wear is localized and liners can have a congruent geometry [25, 51]. Therefore, the outcome of the measurement depends on the contact location of the femur, which decreases the reproducibility of the measurement in vivo. In addition, the measurement cannot distinguish between wear and creep. Creep stabilizes in the first years after surgery [52, 53], after which period the wear measurement becomes reliable.

In conclusion, our data shows that the joint separation measurements based on model-based RSA are accurate enough for wear studies of total knee prostheses. Further research is needed for the usability in clinical practice. The use of RE models is recommended, as the measurement is more robust compared to CAD.

2-5 Acknowledgements

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