The handle http://hdl.handle.net/1887/42759 holds various files of this Leiden University dissertation.

Author: IJsseldijk, E.A. van
Title: Model-based wear measurements in total knee arthroplasty: development and validation of novel radiographic techniques
Issue Date: 2016-09-01
Validation of a model-based measurement of the minimum insert thickness of total knee arthroplasty
Validation of a model-based measurement of the minimum insert thickness of total knee arthroplasty


a Biomechanics and Imaging Group, Department of Orthopaedics, Leiden University Medical Center, PO Box 9600, 2300 RC Leiden, The Netherlands
b Clemson University, Department of Bioengineering, 301 Rhodes Engineering Research Center, Clemson, 29634, USA.
c University Hospital Carl Gustav Carus, Department of Orthopaedic and Trauma Surgery, TU Dresden, Fetscherstrasse 74, 1307 Dresden, Germany.
d Division of Image Processing, Department of Radiology, Leiden University Medical Center, Leiden, The Netherlands

Published as “Validation of a model-based measurement of the minimum insert thickness of total knee prostheses”, Bone and Joint Research, 2014, 3(10), pages 289-296
Validation of a model-based measurement of the minimum insert thickness of total knee prostheses

Abstract

Introduction
Wear of polyethylene inserts plays an important role in failure of total knee replacement and can be monitored in vivo by measuring the minimum joint space width in anteroposterior radiographs. The objective of this retrospective cross-sectional study was to compare the accuracy and precision of a new model-based method with the conventional method by analysing the difference between the minimum joint space width measurements and the actual thickness of retrieved polyethylene tibial inserts.

Method
Before revision, the minimum joint space width values and their locations on the insert were measured in 15 fully weight-bearing radiographs. These measurements were compared with the actual minimum thickness values and locations of the retrieved tibial inserts after revision.

Results
The mean error in the model-based minimum joint space width measurement was significantly smaller than the conventional method for medial condyles (0.50 vs 0.94 mm, $p < 0.01$) and for lateral condyles (0.06 vs 0.34 mm, $p = 0.02$). The precision (standard deviation of the error) of the methods was similar (0.84 vs 0.79 mm medially and both 0.46 mm laterally). The distance between the true minimum joint space width locations and the locations from the model-based measurements was less than 10 mm in the medial direction in 12 cases and less in the lateral direction in 13 cases.

Conclusion
The model-based minimum joint space width measurement method is more accurate than the conventional measurement with the same precision.
5-1 Introduction

Polyethylene is used as bearing material in total knee arthroplasties (TKAs) and its wear plays an important role in TKA failure [22]. Remarkably, standardized (computer assisted) tools for the in vivo assessment of polyethylene wear in TKA do not exist. Rather, planar radiographs are the medical standard for routine monitoring of TKA performance and they are used to estimate changes in polyethylene insert thickness during clinical follow-up. This thickness is quantified with the minimum joint space width (mJSW), which is the apparent distance between the metal tibial tray and the femoral condyles in standard frontal plane radiographs [27, 29, 30]. The insert thickness and its change over time can predict TKA failure [23, 24]. However, the conventional mJSW method is applied to image projections, which is subject to parallax errors that occur when the metal tibial baseplate surface is not aligned with the X-ray beam during sequential radiographic assessments. mJSW measurement errors of up to 2 mm are not exceptional and numerous follow-up visits are required to obtain a reliable estimation of the wear rate [28, 29].

In our earlier work a novel, model-based method was presented to measure the mJSW in standard anterioposterior radiographs using highly accurate model-based roentgen stereophotogrammetric analysis (RSA) software [72, 76]. This method has two advantages over the standard mJSW measurements: the effect of parallax errors is reduced by applying a 3-dimensional reconstruction of the prosthesis components using surface models and it gives insight into both the magnitude and location of the mJSW. For a fixed bearing prosthesis, in vitro validation showed that the model-based method is superior in accuracy (mean = -0.03 mm vs. 0.20 mm), precision (Standard Deviation = 0.19 mm vs. 0.40 mm) and absolute error (mean = 0.14 mm vs. 0.35 mm) compared with the conventional method [76]. Thus, this method has the potential to improve the accuracy of mJSW measurements, enabling more accurate detection of wear-related complications and improving the power of clinical studies evaluating differences in wear rates between different TKA designs.

In this retrospective cross-sectional study the actual thickness of retrieved polyethylene tibial inserts was compared with the mJSW measurements acquired using the model-based and conventional methods applied to weight-bearing pre-revision radiographs. The primary objective is to compare the accuracy and precision of these mJSW measurement
methods using the insert thickness measured from TKA retrievals as a “gold standard”. The secondary objective is to investigate whether the mJSW location determined in the model-based method corresponds to wear locations evident on the explanted polyethylene inserts.

5-2 Method

5-2-1 Data

We searched a database of explanted TKAs catalogued in an Implant Retrieval Program previously established with institutional review board approval (clinical protocol number in Germany EK348112009; retrieval analysis protocol number in USA IBC2011-26) and patient informed consent. Wear scars on polyethylene tibial inserts of 60 fixed-bearing TKAs retrieved from a single clinic (University Hospital Carl Gustav Carus, Dresden) were grossly assessed using optical microscopy to visualize the damage modes and physical touch to detect changes in the articular surface contour. Fifteen posterior cruciate ligament retaining TKAs ultimately were selected to represent a wide range of articular wear scar sizes and shapes, ensuring that the validation study was meaningful for the extensive wear scar variations that can occur in clinical practice[78].

Table 5-8 lists clinical information such as the TKA design, duration of in vivo TKA function, the reasons for revision surgery and the grade of the wear scar (mild, moderate or severe). Wear scars were graded as mild if the damage modes visibly disrupted the machine marks on the articular surface without causing a perceptible change in the articular geometry (6 TKAs); moderate if the damage modes visibly disrupted the machine marks on the articular surface and the wear scar was tangible when physically touching the articular surface (5 TKAs); and severe if there was visibly gross material loss (e.g. delamination) and a notable tactile change in the articular geometry due to gross disruption of the bearing surface (4 TKAs).

For each TKA, the most recent anteroposterior planar radiograph was selected from those acquired during routine clinical exams prior to the revision surgery. The radiographs were acquired with a Siemens Arisost FX Axiom imaging device (0.143 mm per pixel). All patients were instructed to remain fully weight-bearing on both limbs. The selected radiographs include unilateral (n=11) and bilateral (n=4) exposures. The radiographs were transmitted in DICOM format following a de-identification process to protect patient privacy in preparation.
for the radiographic assessments.

Individual 3-D surface models (triangulated meshes) of the explanted components (metal tibial baseplate, polyethylene tibial insert, metal femoral component) were generated using reverse engineering software and a 3-D laser scanner (Next Engine, Santa Monica, CA, USA). These scans had an accuracy of 0.1 mm.

Table 5-8. Description of the fifteen TKAs used in this study.

<table>
<thead>
<tr>
<th>Case</th>
<th>TKA Design</th>
<th>Wear degree</th>
<th>TKA Lifetime (months)</th>
<th>Lifetime after radiograph&lt;sup&gt;b&lt;/sup&gt; (months)</th>
<th>Reason for revision</th>
</tr>
</thead>
<tbody>
<tr>
<td>K2004</td>
<td>TC-Plus</td>
<td>Mild</td>
<td>41</td>
<td>0.7</td>
<td>Infection</td>
</tr>
<tr>
<td>K2133</td>
<td>TC-Plus</td>
<td>Mild</td>
<td>17</td>
<td>0.2</td>
<td>Pain</td>
</tr>
<tr>
<td>K2145</td>
<td>TC-Plus</td>
<td>Mild</td>
<td>24</td>
<td>3.0</td>
<td>Infection</td>
</tr>
<tr>
<td>K2154</td>
<td>Zimmer NK</td>
<td>Mild</td>
<td>50</td>
<td>12.1</td>
<td>Infection</td>
</tr>
<tr>
<td>K2171</td>
<td>TC-Plus</td>
<td>Mild</td>
<td>34</td>
<td>0.0</td>
<td>Painful flexion, infection</td>
</tr>
<tr>
<td>K2178</td>
<td>TC-Plus</td>
<td>Mild</td>
<td>19</td>
<td>2.5</td>
<td>Infection</td>
</tr>
<tr>
<td>K2035</td>
<td>TC-Plus</td>
<td>Moderate</td>
<td>23</td>
<td>0.0</td>
<td>Infection</td>
</tr>
<tr>
<td>K2132</td>
<td>TC-Plus</td>
<td>Moderate</td>
<td>86</td>
<td>0.2</td>
<td>Infection</td>
</tr>
<tr>
<td>K2137</td>
<td>TC-Plus</td>
<td>Moderate</td>
<td>130</td>
<td>23.6</td>
<td>Suspected osteolysis later diagnosed as metastasis</td>
</tr>
<tr>
<td>K2144</td>
<td>TC-Plus</td>
<td>Moderate</td>
<td>132</td>
<td>3.1</td>
<td>Aseptic loosening</td>
</tr>
<tr>
<td>K2175</td>
<td>TC-Plus</td>
<td>Moderate</td>
<td>60</td>
<td>0.0</td>
<td>Infection</td>
</tr>
<tr>
<td>K2046&lt;sup&gt;a&lt;/sup&gt;</td>
<td>Encore Foundation</td>
<td>Severe</td>
<td>144</td>
<td>4.0</td>
<td>Aseptic loosening</td>
</tr>
<tr>
<td>K2156&lt;sup&gt;a&lt;/sup&gt;</td>
<td>Stryker 7000</td>
<td>Severe</td>
<td>77</td>
<td>0.2</td>
<td>Infection</td>
</tr>
<tr>
<td>K2159&lt;sup&gt;a&lt;/sup&gt;</td>
<td>Sulzer Protek</td>
<td>Severe</td>
<td>108</td>
<td>1.6</td>
<td>Infection</td>
</tr>
<tr>
<td>K2161</td>
<td>TC-Plus</td>
<td>Severe</td>
<td>108</td>
<td>0.2</td>
<td>Infection</td>
</tr>
</tbody>
</table>

<sup>a</sup> For these TKAs, double-leg standing radiographs were used for measuring mJSW, for all other TKA a single-leg standing radiograph was used.

<sup>b</sup> The period between the radiograph acquisition and revision surgery

List of manufacturers: TC-Plus (Smith & Nephew, London, UK); Zimmer NK (Zimmer, Warsaw IN, USA); Encore Foundation (DJO Surgical, Vista CA, USA); Stryker 7000 (Stryker, Kalamazoo MI, USA); Sulzer Protek (Protek Medical Product Inc., Coralville, IA, USA).
5-2-2 Assessment methods

The mJSW was measured on the pre-revision radiograph using both the conventional (C) and Model-based (MB) methods; the true insert thickness \(d_0\) and position \(p_0\) on the medial and lateral compartments were measured from the scanned models of the polyethylene inserts. The details of these assessments are described below and depicted in Figure 5-13. Last, the articular wear scar on the insert was identified by digitizing the periphery of the worn area.

**Figure 5-13. Overview of the measurement methods applied for a single total knee replacement (TKR). The rows in the figure represent the measurement methods that were compared: 1) the input radiograph; 2) the conventional insert thickness measurement; 3) 2D/3D matching of the component models; 4) model-based mJSW measurement; 5) the minimum insert thickness and location based on the 3D laser scan of the insert.**

**Conventional mJSW method**

In the conventional mJSW method, the insert thickness \(d_C\) was assessed directly in the radiographic image, based on the metal-to-middle method\[28\]. This assessment was conducted by an experienced orthopaedic surgeon and an experienced researcher (HvdL & EvIJ) and the average values of the observations were used in
the further analysis. Commercially available software was used (Digimizer, MedCalc software, Mariakerke, Belgium) for annotation, image processing and measurement of distances. A reference line was drawn that annotated the superior rim of the metal tibial baseplate at its largest medial-lateral width. The shortest, tibiofemoral distances between this line and the distal femoral condylar edges were measured. The tibial component rim is used for the capture mechanisms securing the polyethylene tibial inserts to the metal baseplate. Therefore, the height of the rim above the tibial baseplate surface was measured by one observer (EvIJ) at three locations using Magics (Materialize, Leuven, Belgium). The mean height was added to the tibiofemoral distances, yielding the final estimate of the insert thickness.

Image magnification was calculated using the ratio between the tibial tray widths in the image silhouette and in the scanned model. This was used to convert all image-based mJSW measurements to real-world dimensions, recorded as the medial $d_c$ and lateral $d_c$.

**Model-based mJSW method**

In the model-based method, the mJSW ($d_{MB}$) was assessed using triangulated surface models of the components (tibia, insert and femur) and using model-based RSA software (Version 3.34, RSAcore, Leiden, The Netherlands)[32]. The tibial model and the insert model were aligned in such a way that the insert’s inferior surface and the tibial baseplate’s superior surface coincided with the 0xz-plane of the model coordinate systems.

Assessment of the TKAs was initiated with an image-focus calibration step. The pixel size was obtained from the DICOM data and the focus position was set at a 115cm distance to the center of the image, in accordance to the hospital’s imaging protocol. Next the tibial and femoral models were matched with the radiographs using 2D-image/3D-model registration. The mJSW was measured by detecting the femoral condylar model with the shortest distance to the tibial baseplate ($d_{MB}$). The projection of the points ($p_{MB}$) was stored and expressed in anterio-posterior (AP) and medio-lateral (ML) coordinates with respect to the center of the tibial baseplate. The measurement was repeated by two researchers (EvIJ and BLK), who independently conducted the registration
and measurement processes. The average values of the observations were used in further analysis.

**Insert measurements**

Using the 3D laser scan of the explanted polyethylene inserts, the minimum insert thickness in millimeters ($d_0$) was measured as the minimum perpendicular distance between the inferior backside surface and the articular surface of the insert. The scans were aligned with the tibia models and the locations of the minimum insert thickness ($p_0$) were expressed in the same coordinate system as in the model-based mJSW method.

One experienced observer (MKH) analyzed the wear scar area of the inserts using the following approach: The wear scar areas were visually identified using an optical stereomicroscope (model Z30L, Cambridge Instruments, Cambridge, MA, USA). Subsequently, the circumference of the insert periphery and the circumference of the wear scars were digitized on calibrated digital images of the articular surface using published photogrammetry methods[79, 80]. The insert circumference was used to map these data to the tibia model coordinate system.

**5-2-3 Statistical Analysis**

The values $\Delta_c$ and $\Delta_{MB}$ were calculated as the difference between the respective mJSW assessment $d_c$ and $d_{MB}$ and the reference insert thickness $d_0$ ($\Delta_c = d_c - d_0$, $\Delta_{MB} = d_{MB} - d_0$). The mean and standard deviation of these differences over the 15 cases were calculated and compared (paired t-test). In addition, the mean measurement errors were calculated as the mean of the absolute difference $|\Delta_c|$ and $|\Delta_{MB}|$ and the number of cases having an absolute difference smaller than 1 mm was counted, similar to the analysis by Collier et al[28]. Inter-observer agreement was analyzed with the limits of agreement and Bland-Altman plots per condyle and mJSW measurement method[81].

To investigate whether the model-based mJSW measurement can accurately determine the location of the minimum insert thickness, the locations of the model-based mJSW assessment ($p_{MB}$) and minimum insert thickness ($p_0$) were compared. The mJSW accuracy could be associated with the difference these locations and this
was tested by computing the correlation between these outcomes. The number of TKAs was counted for which the model-based measurement points \( p_{MB} \) were within the wear scar periphery.

### 5-3 Results

#### 5-3-1 mJSW measurements

After enduring functional lifetimes of approximately 1.5 to 12 years, the actual minimum insert thickness measured on these explanted polyethylene bearings ranged from \( d_0 = 1.99 \text{ mm} \) to \( 7.86 \text{ mm} \) medially and \( 4.97 \text{ mm} \) to \( 7.92 \text{ mm} \) laterally (Figure 5-14). The mean difference between the mJSW \( d_{MB} \) or \( d_C \) and insert thickness \( d_0 \) was positive for both methods (Table 5-9), meaning that both methods tended to overestimate the actual minimum insert thickness that was measured from the explanted tibial inserts. The standard deviations of the mJSW measurement methods were similar. The mean measurement error was significantly smaller for the model-based measurement than for the conventional measurement for both the medial condyle \((0.50 \text{ mm versus } 0.94 \text{ mm}, p < 0.01)\) and lateral condyle \((0.06 \text{ mm versus } 0.34 \text{ mm}, p = 0.02)\); (paired \( t \)-tests).

![Figure 5-14. Barplots of the estimated insert thicknesses \( d_c \) from the conventional mJSW method, \( d_{MB} \) from the model-based mJSW method, and actual minimum insert thickness \( d_0 \) for each case. The cases are ordered as in Table I and grouped by wear grade.](image-url)
Table 5-9. Statistics of the differences between the mJSW measurements (conventional $D_C$ and model-based $D_{MB}$) with respect to the true minimum insert thickness $d_0$.

<table>
<thead>
<tr>
<th></th>
<th>Medial condyle (N=15)</th>
<th>Lateral condyle (N=15)</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>$\Delta_C$</td>
<td>$\Delta_{MB}$</td>
</tr>
<tr>
<td>Mean (mm)</td>
<td>0.94</td>
<td>0.50</td>
</tr>
<tr>
<td>Standard deviation (mm)</td>
<td>0.84</td>
<td>0.79</td>
</tr>
<tr>
<td>Mean measurement error (mm)</td>
<td>1.02</td>
<td>0.66</td>
</tr>
<tr>
<td>N(err &lt; 1 mm)</td>
<td>9 (60%)</td>
<td>11 (73%)</td>
</tr>
</tbody>
</table>

1 Paired $t$-test for equal means
2 Levene’s test for homogeneity of variance

The limits of agreement between the observers over the 15 cases were calculated for both mJSW measurement methods. For the model-based mJSW the values were $0.00 \pm 0.45$ and $0.00 \pm 0.54$ (mean $\pm$ 1.96 * standard deviation) for the medial and lateral condyles respective. For the conventional mJSW these values were $-0.22 \pm 0.48$ and $-0.21 \pm 0.45$. For both condyles a systematic difference was found between the observers for the conventional method (Student $t$-test, $p < 0.01$). The Bland-Altman plots of the outcomes (Figure 5-15) showed no other trends for either mJSW measurement method. Two outliers (K2154 and K2156, both condyles) were found in the distribution of the observer difference for the model-based measurement. For the conventional measurement case a single outlier was found (K2154).
Figure 5-15. Bland–Altman plots A) of the model-based mJSW and B) of the conventional mJSW method

5-3-2 Evaluation of the measurement points

The locations of the measurement point (pMB) was compared with the minimum insert thickness location (p0) and the wear scar area (Figure 5-16) and the difference between the points in terms AP and ML distance was computed (Table 5-10). The largest distances were found in the AP direction, where the differences ranged between -18 mm (anterior) and +6 mm (posterior). The Euclidean distance was smaller than 10 mm for 12 out of 15 cases medially and 13 out of 15 cases laterally. The median Euclidian distance was 6 mm and the largest Euclidean distance was 18 mm. For all cases the locations were inside the wear scar area or at the edge of the wear scar area. No significant correlation was found between the Euclidian distance and the measurement error of the model-based mJSW measurement (Spearman’s ρ= 0.07, P =0.70).
Validation of a model-based measurement of the minimum insert thickness of total knee prostheses

Figure 5-15. Bland–Altman plots A) of the model-based mJSW and B) of the conventional mJSW method.

5-3-2 Evaluation of the measurement points

The locations of the measurement point (p_{MB}) was compared with the minimum insert thickness location (p_0) and the wear scar area (Figure 5-16) and the difference between the points in terms AP and ML distance was computed (Table 5-10). The largest distances were found in the AP direction, where the differences ranged between -18 mm (anterior) and +6 mm (posterior). The Euclidean distance was smaller than 10 mm for 12 out of 15 cases medially and 13 out of 15 cases laterally. The median Euclidian distance was 6 mm and the largest Euclidean distance was 18 mm. For all cases the locations were inside the wear scar area or at the edge of the wear scar area. No significant correlation was found between the Euclidian distance and the measurement error of the model-based mJSW measurement (Spearman’s rho= 0.07, P =0.70).

Table 5-10. The differences in position between the femoral contact locations p_{MB} and the minimum insert thickness locations p_0 (as seen in Figure 5-16). Values are expressed in millimeters.

<table>
<thead>
<tr>
<th>Case</th>
<th>condition</th>
<th>Medial Compartment</th>
<th>Lateral Compartment</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td>AP</td>
<td>ML</td>
</tr>
<tr>
<td>K2004</td>
<td>Mild</td>
<td>5.98</td>
<td>-1.84</td>
</tr>
<tr>
<td>K2133</td>
<td>Mild</td>
<td>5.98</td>
<td>-0.22</td>
</tr>
<tr>
<td>K2145</td>
<td>Mild</td>
<td>-7.47</td>
<td>3.88</td>
</tr>
<tr>
<td>K2154</td>
<td>Mild</td>
<td>0.52</td>
<td>0.76</td>
</tr>
<tr>
<td>K2171</td>
<td>Mild</td>
<td>2.02</td>
<td>-6.38</td>
</tr>
<tr>
<td>K2178</td>
<td>Mild</td>
<td>1.67</td>
<td>-1.06</td>
</tr>
<tr>
<td>K2035</td>
<td>Moderate</td>
<td>-1.95</td>
<td>-7.26</td>
</tr>
<tr>
<td>K2132</td>
<td>Moderate</td>
<td>-8.97</td>
<td>-8.80</td>
</tr>
<tr>
<td>K2137</td>
<td>Moderate</td>
<td>2.32</td>
<td>-6.57</td>
</tr>
<tr>
<td>K2144</td>
<td>Moderate</td>
<td>-9.04</td>
<td>-2.06</td>
</tr>
<tr>
<td>K2175</td>
<td>Moderate</td>
<td>-12.88</td>
<td>-1.16</td>
</tr>
<tr>
<td>K2046</td>
<td>Severe</td>
<td>-11.02</td>
<td>-3.69</td>
</tr>
<tr>
<td>K2156</td>
<td>Severe</td>
<td>0.14</td>
<td>-1.07</td>
</tr>
<tr>
<td>K2159</td>
<td>Severe</td>
<td>0.03</td>
<td>-0.53</td>
</tr>
<tr>
<td>K2161</td>
<td>Severe</td>
<td>4.89</td>
<td>-4.30</td>
</tr>
</tbody>
</table>

5-4 Discussion

The primary objective was to compare the accuracy and precision of the model-based mJSW measurement and the conventional mJSW measurement using minimum insert thickness measured from TKA retrievals as a “gold standard”. The accuracy (proximity to the truth) and precision (measurement reproducibility) of both methods was determined by applying the methods to pre-operative radiographs and comparing the outcomes with the minimum thickness of the retrieved inserts. The results showed that the model-based measurement method was more accurate than the conventional method for both condyles (0.50 vs 0.94 mm medially and 0.06 vs 0.34 mm laterally). The precision of the methods was similar (0.84 vs 0.79 mm medially and both 0.46 mm laterally). Both mJSW measurements were more accurate
Figure 5-16. Illustrations of the articular surfaces of each explanted insert, showing the wear scar peripheries and locations of the minimum insert thickness ($p_0$) and the femoral contact ($p_{MB}$). These illustrations are plotted as looking down on the superior surface of a right knee, with the medial condyle always at the left side of the image. Inserts originating from left TKR are mirrored in this illustration to fit this convention; (indicated with an asterisk (*)).
Validation of a model-based measurement of the minimum insert thickness of total knee prostheses

and precise for the lateral condyle than for the medial condyle. Since this occurred for both methods, this is not a measurement error. Apparently a physical difference existed between the femorotibial distance and the insert thickness, which can be related to various clinical conditions such as varus malalignment.

Concerning the observer reproducibility, the model-based method the mean difference was 0.0 mm and for the conventional method the mean difference between the observers was 0.2 mm. The limits of agreements of the mJSW measurement methods were similar. For the cases K2154 and K2156 a large difference (> 0.5 mm) was found between the model-based observers mJSW measurements. For K2154 some bone cement was still attached to the backside of the tibia baseplate when it was scanned. This introduces a model inaccuracy and complicates the matching procedure, as the respective contours of the tibial metal baseplate should then not be used in the 2D/3D matching. One observer deselected these particular contours, whereas the other observer included this contour part, which may explain the measurement difference. For K2156 one observer did not apply the 2D/3D matching process for the tibia component correctly. This resulted in an out-of-plane positioning error that affected the measurement outcome. Still, the average measurements for these cases were not remarkably far from the actual minimum insert thickness. The outlier for the conventional mJSW measurement (K2154) was related to a difference in setting the height of the reference line at the tibial baseplate.

Four cases stand out (K2137, K2159, K2171 and K2178) as relatively large overestimations (more than 1 mm) of the medial insert thickness for both methods. For K2137 this seems to be related to the image calibration: in the model-based optimization the posterior edge of the femoral component models is approximately 3 cm away from the X-ray detector plate, which is physically unlikely. For K2159 there is a large difference between the measurement location \( p_{MB} \) and the actual minimum insert thickness location \( p_0 \). For the other cases no obvious explanation could be found, and it may be possible that for these patients there was no actual contact at the mJSW position \( p_{MB} \) at the medial side.

Our secondary objective was to investigate whether the explanted inserts truly show wear scars at the points measured by the model-based mJSW technique. The analysis showed that this was true for all inserts. It should be noted that for some cases,
such as K2156 and K2132, the wear scar covers the majority of the inserts’ articular surface area, which dilutes the information of this observation as any measurements is bound to reside in the wear scar area. Still, this finding supports the proposition that the mJSW measurement is suitable to detect wear.

Concerning the difference between the minimum insert thickness location ($p_o$) and the femoral contact location ($p_{MB}$), the findings were volatile. The findings were similar for the medial and lateral condyles: the Euclidean difference was smaller than 10 mm for twelve cases medially and thirteen cases laterally. When this difference was larger than 10 mm, the measurement point always was more anterior than $p_o$. This could be related to the patient positioning: patients are standing with extended knees during the image acquisition whereas the femoral condyles reposition during dynamic activities\[77\]. In posterior cruciate ligament retaining TKA, knee flexion during activity can contribute to posterior contact of the femoral condyles and posterior wear scars\[82\]. This is supported by the observation that three out of four cases with severe wear had a relatively posterior location for $p_o$. The anteroposterior direction also corresponds to the film-focus direction for a frontal plane radiograph, for which the 2D-3D model matching algorithm is the least accurate. Therefore, the difference in location can also be related to measurement error.

Collier et al. found that conventional mJSW measurements had an accuracy within 1 mm for 82% medially and 58% laterally\[28\]. This is comparable to the findings with the conventional method in the current study (60% medially and 87% laterally within 1 mm), although the accuracy numbers for the condyles are interchanged. Differences between these results could be caused by the type of prosthesis that was evaluated. Whereas Collier et al. used a single, flat-surfaced Anatomic Modular Knee (Depuy, Warsaw, IN, USA), the measurements in the current study were applied to five different implant designs as to validate our measurement technique as a more generic application to different implant models. This also included designs having a metal rim capture mechanism on the tibial baseplate, which can distort the projection image and for which an alternative approach of the conventional mJSW method had to be used. Moreover, Collier, et al. achieved good measurement accuracy only when TKR were well-aligned relative to the projection plane, necessitating that 28%-39% of their radiographs be discarded from the measurement analysis due to
Validation of a model-based measurement of the minimum insert thickness of total knee prostheses

excessive anteroposterior tilt of the tibial baseplate [28, 29]. For the current study all radiographs were utilized regardless of baseplate tilt.

In our prior validation study the model-based mJSW measurement showed a standard deviation of 0.2 mm in case of fixed-bearing TKAs, against 0.79 mm medially and 0.46 laterally in the current study [76]. An explanation for this difference is that repeated measurements for a single TKA were used in the validation study, whereas fifteen different TKAs were measured in our current study. Moreover, in the validation study the inserts were replaced with a flat acrylic block [76]. This approach removed the possibility that sagittal plane curvature of the articular surface could lead to large variations in thickness with only slight deviations in the anteroposterior position of the femoral condyle.

This study was set up in an attempt to capture a representative range of wear severity in a limited number of implant designs and to obtain a first impression of the accuracy that can be obtained with the model-based mJSW method \textit{in vivo}. In future work the data need to be augmented to include a wider range of prosthesis designs with varied insert curvature and to determine the precision of the method when longitudinal data are analyzed.

The model-based mJSW measurement requires accurate tibial and femoral models. In this study, models were generated by reverse engineering prosthesis components that were retrieved from the cohort of included patients. This resulted in the best possible model accuracy for the model-based method [32]. In practice, it will not be possible to use such patient-specific models, as longitudinal assessments of polyethylene wear are conducted without availability of retrieved components. In that case scanned models (reverse engineered models) are recommended, that can be produced based on matching components (i.e. of the same type and size) and the costs of production are relatively low.

Contour detection and optimization can be time-consuming tasks of the model-based mJSW measurement, which might limit the use in clinical evaluation studies. A topic of further research is to reduce the measurement time using further automation of the measurement procedures. Furthermore the measurement could also be improved
by reducing the out-of-plane error of the optimization. For example, this could be realized by restricting the freedom of the model pose using prior knowledge on the allowed range of motion of the TKA [83].

In conclusion, the model-based mJSW measurement method delivers a more accurate estimation of the *in vivo* insert thickness from planar radiographs compared with the conventional measurement. In addition, it provides information on the mJSW location, which is indicative for the site of the wear. Further research is required to come to a standardized measurement protocol and to investigate whether the model-based mJSW can hold its accuracy gain in longitudinal data and for a broader range of prosthesis designs.

**REFERENCES**


