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
Discussion
8-1 General discussion

Total Knee Arthroplasty (TKA) is an effective treatment for end stage symptomatic osteoarthritis with good long-term outcomes and patient satisfaction\cite{10, 11, 14, 108}. Survival analysis taking revision of the implant as end-point shows a mean survival at 10 years of 90%. The main cause for revision is loosening of the tibial or femoral components, which is related to wear of the polyethylene liner insert\cite{9, 12, 13, 15, 20}. As the rate at which the polyethylene insert thickness decreases can predict failure\cite{23}, an accurate and precise method is required to assess the progression of this wear \textit{in vivo}. This will not only support clinical decision making on when to exchange a liner before component loosening occurs but also enables the accurate comparison of wear resistance of different (new) prosthetic designs\cite{25}.

In current clinical practice and research, the progression of the polyethylene wear is measured in planar radiographs using minimum joint space width (mJSW) measurement as a surrogate measure for the remaining insert thickness\cite{27}. Measurement errors of up to 2 mm are not exceptional and multiple follow-up visits are required to obtain a reliable estimation of the wear rate\cite{28, 29, 31}. Model-based measurement methods based on matching a 3D model of the prosthesis on its 2D projection in the roentgen image are less prone to human errors or
parallax errors resulting from the alignment of the radiographic beam. It is therefore expected that a better accuracy and precision can be achieved using model-based wear measurement techniques.

The primary aim of this work was to develop novel model-based mJSW measurement methods and validate the accuracy and precision of these methods using conventional measurement methods as a reference. Next to the validation of the model-based measurements this work assessed the reliability of the mJSW measurement as a surrogate for the actual insert thickness as this reliability can be influenced by numerous factors. In this study, the influence of the image set-up and patient positioning were assessed.

**mJSW measurements for TKAs**

Chapters 2 and 3 focus on *in vitro* validation of the developed model-based mJSW measurement for TKAs using either stereo-images acquired from RSA or anteroposterior (AP) plain radiographs: RSA is typically used to assess or compare new implant designs and is known for its high accuracy in 2D/3D pose reconstruction [33, 46]. AP radiographs are used in daily clinical practice (e.g. for the assessment of wear progression in TKA).

As expected, the highest precision and accuracy (0.2 mm and 0.1 mm respectively) can be achieved when stereo images are used (Chapter 2). The accuracy of model-based mJSW measurements with RSA was studied in a few existing studies where similar findings were reported [42, 43, 48]. This is the first study in which the influence of patient positioning on the accuracy of wear measurement was evaluated. Only anterior tilting showed a statistically significant effect (0.07 mm versus 0.02 mm accuracy for 0° versus 10° tilt). The use of reversed engineered (RE) models is preferred over CAD models because of the large increase in measurement accuracy and precision and the lower sensitivity for patient positioning and flexion angle. Recently, in a similar study no significant effects of variances in patient positioning were found, corresponding with our findings when using RE models [109].

For AP radiographs, the model-based technique has been applied using a standard imaging set-up without calibration object (Chapter 3). Compared to older studies
that describe a similar model-based measurement method[41, 65], this has the advantage that the model-based technique can be immediately applied to any standard AP radiograph in clinical practice.

The model-based technique significantly improves the accuracy (0.2 versus 0.5mm) and reproducibility (0.3 versus 1.0mm) of mJSW measurements compared to the conventional measurements. These results indicate that a direct improvement of the mJSW measurement can be attained when applying the model-based measurement technique in clinical practice.

**The mJSW measurement as a reliable estimator of the insert thickness**

The mJSW is an indirect measurement of the insert thickness, which may not be reliable if the femoral component loses contact with the insert[110]. Furthermore, the insert thickness should be measured at the same location in successive follow-up images for reliable wear detection. This can be challenging as the femur generally performs a sliding and rolling motion over the articulating insert surface during flexion, yet only a single contact location is captured in an X-ray image. To detect wear, the contact location should coincide with the damaged area of the insert in the baseline radiographs as well as the successive follow-up radiographs. Capturing the damaged area can be challenging also as the location and size of this area can vary among patients[82].

The work presented in Chapters 4 and 5 improves our insight in the reliability of the mJSW as a wear indicator. Chapter 4 showed that the mJSW was larger in non-weight-bearing (NWB) than in weight-bearing (WB) images, with a mean difference of 0.28 mm and 0.20 mm for the medial and lateral condyle respectively. This difference can be explained by the possible loss of contact between the tibial and femoral components in NWB positions and differences in contact location between the WB and NWB positions. In NWB positions, the femoral contact location is more anterior with respect to the tibia due to gravity. As the insert is thicker at this location, this also explains the larger mJSW measured in NWB position. Patient positioning thus influences the mJSW measurement outcome and should be taken into account when interpreting these measurements.
In Chapter 5, the insert thickness of retrieved inserts was compared to model-based and conventional mJSW measurements in pre-operative weight-bearing radiographs. The model-based measurement has a higher accuracy than the conventional measurement, but the measurement precision was similar. This findings on precision differ from those in Chapter 3, where the model-based measurement was significantly more precise was (0.8 vs 0.2 mm standard deviation). In the study of Chapter 3 the thickness of flat acrylic blocks was measured in vitro whereas in Chapter 5 the measurement was used in vivo on actual inserts with a more complex articular surface. Therefore, the measurement precision in Chapter 5 can be influenced by differences between the insert measurement location and minimum insert location and by loss of tibiofemoral contact. In support of this, for five cases the medial mJSW measured by either technique was much larger (> 1 mm difference) than the actual insert thickness. We believe that the mJSW was measured accurately, but that the influences above resulted in a difference between measured and actual minimum insert thickness. The limited number of cases in this study did not allow for a detailed analysis of these effects, leaving the subject as an important topic for future work.

**Insight in tibiofemoral location from model-based mJSW measurement**

A major advantage of model-based mJSW measurement methods over the conventional method is the possibility to deduct the tibiofemoral contact location, i.e. the projection of the lowest point of each femoral condyle to the transverse plane of the tibial plateau. The mJSW measurement itself is conducted at this contact location. This information can be related to differences in the tibiofemoral contact location between subsequent measurements and can therefore be useful in clinical practice, e.g. to quantify the repeatability in successive follow-ups.

The accuracy and precision of this mJSW location measurement has not been assessed in this work. However, the tibial surface areas at which the mJSW locations were measured in our studies correspond to kinematics descriptions as well as retrieval studies describing insert surface damage patterns[79, 111, 112]. Moreover, in Chapter 5 we have shown that the mJSW location had a good correspondence with the location of the minimum insert thickness. In future work, the precision of the location measurement could be determined based on double examinations (test-retest image acquisition) with weight-bearing images.
Volumetric wear measurement for TKAs

Model-based reconstruction techniques can also be used to estimate the volume of wear debris as was already theorized by Gill et al. [48, 49]. This could be applied to in vivo performance testing as part of prospective evaluation of new implant designs in premarket release study, after in vitro wear simulator studies have been done. We developed such a volumetric wear measurement for TKAs and studied its accuracy using artificially worn liners. Measurements at different flexion angles (0, 30 and 45 degrees) were performed to investigate the influence of tibiofemoral contact and whether these measurements provide complementary information (Chapter 6). We found that the accuracy of this volumetric measurement is currently limited. Given the absolute outcomes of volumetric wear measurements, the influence of model positioning error is larger than for linear wear measurements. For example, bias in the pose estimation of the 3D models has a larger influence than in relative (baseline vs follow-up) linear wear measurements where this bias is cancelled out. In addition, the volumetric wear measurement also relies on the accuracy of the 3D insert model. The use of generic (non-prosthesis specific) 3D models results in a limited accuracy due to differences in the actual insert thickness from tolerance in the manufacturing process. In a similar experiment using a physiological phantom and inserts from retrievals, only half the volume of the total wear volume could be detected [113]. Given the current limitations in measurement accuracy, obtaining reliable volumetric wear measurements with this technique is not yet possible and linear wear measurements should be used instead.

Model-based mJSW measurement for native knees

The mJSW measurement is also used in radiographs of native knees to assess the progression of osteoarthritis [2, 114]. However, false readings may occur if the tibial plateau is skewed with respect to the X-ray beam [2, 115]. Moreover, cartilage defects are best detected when the images are acquired in a weight-bearing set-up and during in a flexion position of the knee. Due to this, the general opinion in literature is that this measurement lacks sensitivity and different approaches are advised such as measuring cartilage thickness on MRI or the use of a (fluoroscopy) guided imaging protocol to standardize patient positioning improving reproducibility [2, 35, 88, 100, 102, 115, 116].
In Chapter 7, we proposed a model-based mJSW measurement technique that could alleviate the problems related to tibial plateau alignment and patient positioning. The proposed technique resembles the one which is presented for TKAs in previous chapters. The main difference is that patient-specific bone geometries (the tibia and the femur) have to be reconstructed whereas the geometry of TKAs components is generally easy to obtain. To reconstruct patient-specific bone geometries without resorting to CT scans (due to i.e. radiation exposure and costs), statistical shape models were used. These models generate shapes by matching the edges of the femoral and tibial silhouettes found in planar radiographs, constrained by a likelihood condition of the expected shape learned from a training set of example shapes.

The validation in Chapter 7 showed that the smallest detectable difference in thickness was higher for the model-based measurement than for the conventional measurement (0.82 mm vs 0.70 mm). This means that the model-based measurement does not improve (early) wear detection. The predominant cause of this result was the modelling error resulting from the reconstruction of the bone structures with SSMs. Despite this finding, the results are encouraging for further research, which should focus on improvements in model and matching accuracy. For instance, advanced matching algorithms using multiscale information or edge orientation could be used to improve edge detecting and selection, leading to a higher precision [36, 117]. Also, the shape generation could be extended with non-linear shape deformation modules, which will reduce matching error especially when the SSM is too constrained to match unseen shapes [118]. In our opinion such improvements are feasible, thus encouraging for future work on the application of SSMs for native knees. The quantitative shape-analysis capabilities of SSMs can be highly valuable for both mJSW measurements and shape related osteoarthritis-research. Our model-based technique would then provide an economic alternative to MRI-based assessments [107, 119].

8-2 Future Work / Recommendations

This work presents convincing evidence that the knee mJSW measurement accuracy and precision is improved using model-based measurement techniques in RSA images as well as in standard AP radiographs. The next steps towards clinical application
are to improve the measurement software and to conduct further research on the influence of knee flexion and implant design on the reliability of insert thickness measurements.

Measurement software
The current measurement software was a prototype adequate for experimental purposes. A single measurement takes several minutes for an experienced user and requires a cascade of different applications. For clinical practice, an integral application is required in which the measurement can be conducted within approximately 30 seconds and in a user-friendly manner. Especially relevant steps are the automation of the contour detection and visualization of the mJSW measurement. Integration in the existing model-based RSA software seems a good candidate since most of the analyses required are already at hand.

The model-based measurement software requires precise scanned 3D models of implant components to obtain reliable mJSW measurements. These models are not always available thus increasing the cost and complexity of this measurement compared to the conventional approach. Yet, it is expected that this disadvantage will diminish as the use of 3D models becomes more common in medicine, increasing cost efficiency. Optionally, the number of required scans can be reduced by using a single model per component size and type. Patient-specific component differences do exist (e.g. due to manufacturing tolerance and polishing of the components), but the influence is marginal.

The influence of flexion and implant design on measurement reliability
The findings from the retrieval study (Chapter 5) suggest that the loss of tibiofemoral contact or differences in tibiofemoral contact location influence the reliability of the measurement of the insert thickness based on the mJSW. Since reliability and accuracy of measurement are prerequisites for use in a clinical application, further research into this topic is necessary. This is closely related to the articulation pattern of a TKA and therefore knee flexion and implant design are important factors in this research.

For this research, using RSA instead of plain radiographs is recommended. The main reason is the more accurate reconstruction of the tibiofemoral contact location in
RSA due to the higher accuracy in the out-of-plain direction. This tibiofemoral contact location could be used as an indicator of measurement precision: In case implant designs are less congruent (i.e. more mobility at the articular surface), differences in flexion angles of the knee will cause large variations in contact location between femur and tibial insert. Due to this a lower precision of the mJSW measurement is expected to be present. Differences in contact location between successive measurements throughout follow-up could therefore indicate a limited measurement precision.

The findings from this research can be translated into conditions that should be met when conducting model-based mJSW measurements in RSA as well as in standard radiographs.

**Model-based measurements as a diagnostic toolbox**

In potential, model-based reconstructions and measurements allow for several diagnostics from a single image. Model-based techniques could thus provide a diagnostic toolbox for an integral, *in vivo* assessment of TKAs from radiographs. Examples of such an automated analysis are already found in the literature [120, 121]. For example, model-based RSA is already used to predict failure rates of new implant designs related to loosening. With addition of the model-based mJSW measurement, wear-related complications of total knee replacements could be predicted at the same time. Furthermore, model-based reconstructions could be used to model the bone geometry and herewith measure the alignment of the prosthetic components.

The main challenges of realising such an integrated toolbox are to reduce the processing workload using more automatic and faster procedures and to improve the model accuracy to obtain an acceptable measurement precision when deformable models are used. Given the rapid improvements in image quality, segmentation techniques and model accuracy as well as the fast developments in user friendliness, processing speed and reduction of costs of imaging software, we foresee that model-based wear measurements for native knees and TKAs will be common practice in the future.

**REFERENCES**

Chapter 8


[22] Mintz, A.D., C.A. Pilkington, and D.W. Howie, A comparison of plain and fluoroscopically guided radiographs in the assessment of arthroplasty of the


[115] Kinds, M.B., et al., Influence of variation in semiflexed knee positioning during image acquisition on separate quantitative radiographic parameters


