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Short communication

# The robustness and accuracy of *in vivo* linear wear measurements for knee prostheses based on model-based RSA

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ABSTRACT

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. 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 seperation distance was determined. 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, $p = 0.04$). The accuracy of 0.1 mm and precision of 0.2 mm can be achieved for linear wear measurements 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.



## 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 (Sharkey et al., 2002).

Excessive wear is related to the design of a prosthesis(Dennis and Komistek, 2006). 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 (Lavernia et al., 2001; Naudie et al., 2007).

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 (Garling et al., 2005; Nelissen, 1995; Nilsson and Kärrholm, 1996; Soballe et al., 1993), which is used to predict prosthetic loosening (Ryd et al., 1995). Wear measurements can be obtained with MBRSA and high accuracies were already obtained (Gill et al., 2006; Kellett et al., 2004; Short et al., 2005). 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 tibia and femur is known exactly. The measurement method is applied for different settings 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 parameters.

## 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.

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### 2.1. Phantom setup and acquisition of RSA images

A phantom setup was used of sawbones with a total knee replacement in standing position. RSA images of the phantom setup were acquired with a vertical RSA setup (Kaptein et al., 2003). 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 (Fig. 1). The total knee prostheses were fixed into sawbones, to create more realistic images. 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 1.5 m from the detectors with a 40° angle between their respective beams. The phantom device was positioned as close to the detectors as possible (Fig. 2).

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 1.

#### 2.1.1. Prosthesis type

Two types of Stryker (Kalamazoo, USA) total knee prosthesis were used: the fixed-bearing Duracon knee (sizes: tibia—XL2, femur—XL) and the fixed-bearing Triathlon knee (sizes: tibia 7, femur 7).

#### 2.1.2. 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 (Fig. 3).

#### 2.1.3. Component separation distance

The component separation distance was set using cylindrical, radiolucent plates (Plexiglass/PMMA), which had an accurate thickness (tolerance 0.05 mm). 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 10 mm, we validated different component separation sizes.

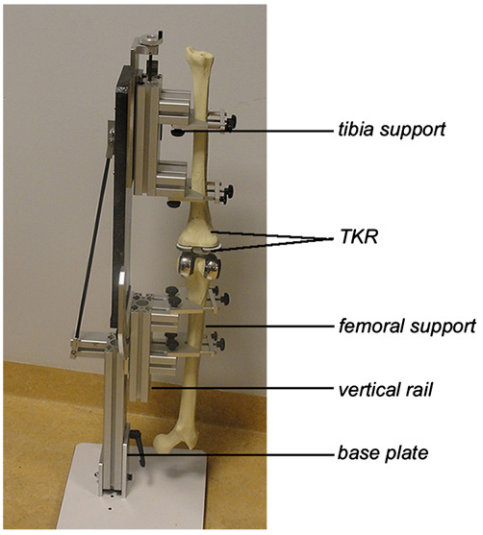


**Fig. 1.** Image of the phantom setup.

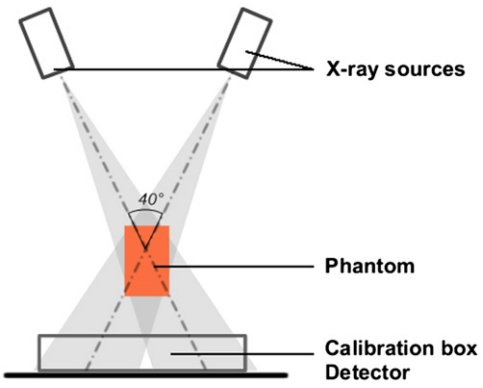


**Fig. 2.** Schematic top view of the RSA setup.

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

| Order | Variable | Options | Procedure |
|---|---|---|---|
| 1 | Prosthesis type | 1: Duracon<br>2: Triathlon | Place the sawbones with the prostheses components into the phantom setup |
| 2 | Flexion angle | 1: 0°<br>2: 30°<br>3: 45° | Adapt the angle with the lever on the phantom setup |
| 3 | Separation distance | 1: 10 mm<br>2: 5 mm | Fix the plate with the appropriate thickness between the tibia and femur component |
| 4 | Anterior tilt | 1: 0°<br>2: 10° | Change the anterior tilt level in the phantom setup, by pivoting the system |
| 5 | Rotation | 1: 0°<br>2: 10°<br>3: −10° | Adjust the rotating platform to the designated angle |

### 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 (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 program detected candidate edges (canny edge detection), which could be altered manually. Subsequently, the model poses were calculated by minimizing the difference between the 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 (Kaptein et al., 2007). Next, the medial separation distance was calculated, which was defined as the shortest distance between the medial condyle of the femur model 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.

### 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.

## 3. Results

Table 2 and Fig. 4 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.

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 Fig. 4, 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.