Evaluation of in vivo Wear Measurement Technique in Total Knee Replacements Using Model-Based Radiostereometric Analysis

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Disclosures:

Introduction
Total knee arthroplasty is a successful treatment for end-stage knee arthritis. Various improvements to the polyethylene (PE) bearing material have increased the clinical success of total knee replacements (TKR). Clinical investigations of bearing performance are very expensive as they typically require long-term radiographic follow-up of large numbers of patients. Model-based radiostereometric analysis (MBRSA) is a radiographic method which can be used to examine the performance of new bearing materials in vivo, after short implantation periods [1, 2]. Until recently, there has been limited research into optimization or validation of the methodology [3, 4]. The objective of this study is to evaluate the ability of MBRSA to estimate the volumetric change occurring to the PE insert due to both wear and creep in a TKR by comparison to the retrieved PE inserts.

Methods & Materials
Ten patients were recruited for this pilot study, each requiring revision surgery of their Genesis II TKR (Smith & Nephew, Mississauga, ON) which was in situ for a minimum of 2 years. Five MBRSA examinations of each patient’s TKR were obtained. Two repeat images were obtained of the patients in a standing, full weight bearing position to determine MBRSA precision through double exams. A single non-weight bearing image was obtained to determine the effect of weight bearing on measured PE volumetric change. Two lateral images were obtained with the patient’s knee mildly (20°-35°) flexed and moderately (35°-50°) flexed, to increase the measured area of the articulating surface, thereby improving volumetric measurement, as demonstrated by as Gill et al., 2006 [1]. New PE inserts were purchased from the manufacturer to serve as the unworn reference geometry of the 10 retrieved PE inserts.

All components (new and explanted) were reverse-engineered (RE) using a laser scanner (SG-102, ShapeGrabber Inc., Ottawa, ON) for volume computation and pose estimation with the MBRSA software suite (RSACore, Leiden, The Netherlands). The pose data from MBRSA was applied to the RE models to virtually reconstruct the replaced knee joint in Geomagic Studio (Geomagic Inc., Morrisville, NC). Volumetric PE deviation was estimated from these models as the overlap between the femoral condyles and the unworn PE insert; termed RSA-deviation. The wear of the retrieved inserts was estimated as the volumetric difference between the retrieved insert and its matching unworn insert; termed retrieval-deviation. Only the volumetric deviation of the articular surfaces was analyzed in an attempt to reduce the effect of manufacturing tolerances. The linear penetration depth of the PE inserts was also examined. The thinnest point of the medial and lateral sides of each retrieved insert was measured with a micrometer (Mastercraft, Canada) and compared to the MBRSA-estimated depth of penetration measured as the closest point of the femoral condyles normal to the plane of the tibial tray surface.

Results
The average retrieval-deviation rate was 87 mm³/yr (95% CI: 35 mm³/yr), whereas the average RSA-deviation rate was 94 mm³/yr (95% CI: 52 mm³/yr) when standing and flexed MBRSA examinations were combined. Combination of standing and flexed examinations improved volumetric change measurement by an average of 23 mm³/yr (95% CI: 18 mm³/yr; p=0.011), Figure 1. Weight bearing exams improved wear estimation by an average of 37 mm³/yr (95% CI: 44 mm³/yr) compared to non-weight bearing exams, although not significantly, p=0.058. The precision of volume deviation measurement was 70 mm³ based on double examinations in the standing, weight bearing position. The average linear penetration rate measured on the retrieved inserts was 0.082 mm/yr (95% CI: 0.025 mm/yr) compared to 0.174 mm/yr (95% CI: 0.119 mm/yr) as measured from weight-bearing MBRSA exams. Weight-bearing exams typically overestimated PE penetration depth for the medial condyle (Figure 2), whereas non-weight bearing exams had more condyle lift-off and therefore underestimated PE penetration (Figure 2).

Discussion
The group of patients in the present study experienced approximately 90 mm³/yr of PE volume deviation, which is similar to previous reports [1]. While there is apparent agreement between the average retrieval and MBRSA measured volume deviation, there was an average disagreement of 60 mm³/yr for each individual case. Therefore, the present study was not able to validate in vivo MBRSA measurement of PE wear and creep as a result of several limitations; firstly, the calculation of retrieval-deviation is highly dependent on manufacturing tolerances and yearly design changes between manufactured insert lots [5]. Secondly,
virtual positioning of the PE insert within the locking mechanism of the tibial tray may not have been representative of the in vivo case. Thirdly, the subjects analyzed were pre-revision patients, thus their TKRs were not representative of well-functioning TKRs with typical volumetric change patterns. Despite the significant errors of volume deviation measurement, some valuable outcomes were gained from this study; weight bearing examinations are ideal as the prevent condyle lift-off and combining volume deviation data from multiple knee flexion angles provided improved overall volume estimation as previously described by Gill et al [1]. Future in vivo TKR wear studies must focus on longitudinal measurement over multiple follow-up periods, in order to cancel out the effect of manufacturing tolerances and other errors, thereby improving the accuracy of wear/creep measurement.

Significance
This research presents the first in vivo evaluation of model-based radiostereometric analysis of polyethylene wear and creep in total knee replacements. This imaging and analysis technique has the potential be used for rapid, in vivo assessment of new designs of total knee replacements and novel bearing materials.

References
Figure 1: Average volumetric change (time normalized) of different MBRSA images. Error bars represent 95% confidence intervals.
Figure 2: Average condyle penetration depth and the effect of weight bearing. Error bars represent 95% confidence intervals.