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Determination of Reference Geometry for Polyethylene Tibial Insert Wear Analysis

Matthew G. Teeter, BSc,*† Douglas D.R. Naudie, MD, FRCSC,*‡
Jaques S. Milner, BESc,* and David W. Holdsworth, PhD*†‡

Abstract: Geometric wear analysis techniques require unworn geometries to serve as a reference in wear measurement. A method to create a reference geometrical model is described for retrieval studies when the actual unworn geometry is unavailable. Never-implanted tibial inserts were scanned with micro–computed tomography. Two, 3, or 6 insert surfaces were coaligned and averaged to create reference geometries. Individual inserts were compared with each other (manufacturing variability) and with the reference geometries (reference variability). The 3-dimensional deviations between the surfaces were recorded. The reference variability was reduced to 8.3 ± 39 μm, vs manufacturing variability of 15 ± 59 μm. Deviations were smallest on the articular surfaces where most wear occurs and were significantly less than the reported insert wear rate of 20 μm/y. **Keywords:** total knee arthroplasty, polyethylene wear, micro–computed tomography, wear analysis, retrieval studies.

Wear of polyethylene tibial inserts is a significant detriment to the longevity of total knee arthroplasty [1]. Numerous designs and materials for total knee arthroplasty components have been studied to minimize wear and its effects, which include aseptic loosening and osteolysis [1-3]. Wear can be studied and analyzed in tibial inserts that have undergone wear simulator testing or in inserts that have been retrieved from patients undergoing revision knee arthroplasty due to failure of the original implant [4-8].

The tools used for wear analysis of the polyethylene components in total joint arthroplasties can include geometry-based techniques such as coordinate mapping machines (CMMs); optical laser scanning; and, more recently, micro–computed tomography (micro-CT) [5,9-12]. These techniques require an unworn reference geometry against which the worn geometry can be compared so that surface deviations (due to wear and creep) can be quantified [5,11]. In wear simulator studies, the tibial insert geometry is obtained before being loaded so that a perfect representation of its unworn self is available [5,9]. However, for tibial inserts retrieved from patients undergoing revision knee arthroplasty, the unworn geometry is generally unknown [11]. As there may be significant variability in the geometry of new, unworn inserts due to the manufacturing process, comparing a worn, retrieved insert to a single, separate unworn insert may overestimate or underestimate the amount of wear that has occurred [11]. In some cases, the unworn regions of a retrieved insert can be used to estimate the original, unworn insert surface geometry; but this may be difficult to impossible, depending on the complexity of the insert design [11].

We propose a reverse-engineering method whereby multiple (2-6) unworn inserts are used to construct an averaged, idealized unworn insert reference geometry. In this method, the unworn inserts are scanned with micro-CT; and the scans are reconstructed and processed to obtain surface meshes. The surfaces of the inserts are then coaligned and averaged to create the reference geometry. Surface deviations due to manufacturing variability would therefore be minimized in this idealized unworn insert. We hypothesize that this method will reduce the between-insert surface variability to a level significantly below the amount of surface deviation caused by wear and the manufacturing process, and thus

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*From the *Imaging Research Laboratories, Robarts Research Institute, The University of Western Ontario, London, Ontario, Canada; †Department of Medical Biophysics, Schulich School of Medicine and Dentistry, The University of Western Ontario, London, Ontario, Canada; and ‡Division of Orthopedic Surgery, Schulich School of Medicine and Dentistry, The University of Western Ontario, London, Ontario, Canada.*

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Reprint requests: Matthew Teeter, BSc, Imaging Research Laboratories, Robarts Research Institute PO Box 5015, 100 Perth Drive London, Ontario, Canada N6A 5K8.

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will be suitable for determination of the unworn insert reference geometry. The purpose of this study was to characterize the variability due to the manufacturing process and to determine the suitability of averaging scanned insert geometries to construct an accurate reference geometry.

Materials and Methods

Six new, nonimplanted Anatomic Modular Knee (DePuy, Warsaw, Ind) polyethylene tibial inserts were used for this study. All were the cruciate-retaining model of 10-mm thickness and were sterilized using gas plasma. Each insert was scanned 3 times with a laboratory cone beam micro-CT scanner (eXplore Vision 120; GE Health care, London, Ontario, Canada). Inserts were held in a radiotranslucent polystyrene foam holder at a double-oblique angle during the scans and were repositioned between scans. Scans were performed at an isotropic resolution of 50 μm over 1200 views with 10 frames averaged per view, with an x-ray tube voltage of 90 kV (peak) and current of 40 mA. Each scan was reconstructed at the full 50-μm isotropic resolution.

Dedicated 3-dimensional (3D) micro-CT analysis software (MicroView v2.2, GE Healthcare) was used to analyze the reconstructed scan images. The area of the insert geometry was set as a region of interest using a region-growing algorithm. Isosurface rendering was then performed using a threshold of −664 Hounsfield units. This threshold, which may vary with the type and manufacturer of the polyethylene, was selected using the method developed by Otsu [13]. The resulting surface was saved in stereolithography file format.

A custom script was written to coalign source insert surface files with a target surface file, to generate a new averaged surface based on the coalignment, and to create mean and standard deviation maps of the 3D deviations between the insert surfaces. Inserts were coaligned using an iterative closest-points algorithm, with convergence set for when the root mean square average distance dropped below 0.1 μm for the 1000 sample points. A pilot study (in which a linearly transformed insert was reregistered to its original model) revealed that the mean surface deviation was most efficiently minimized when 1000 sample points were used. The inserts were brought into alignment using a transformation matrix calculated by the script. Differences between the surfaces (ie, the 3D surface deviations) were calculated continuously across the entire 3D surfaces of the source and target files for the more than 4 million points forming each surface. The overall mean and standard deviation between the surfaces were calculated from all of the individually calculated deviations, and mean and standard deviation maps of the surfaces were generated based on the individual 3D surface deviations. ParaView (Kitware Inc, Clifton Park, NY) was used to visualize the mean and standard deviation maps.

Three potential sources of 3D surface deviation were evaluated: (1) intrainsert variability between scans of the same insert due to micro-CT scanner noise ("scan variability"), (2) interinsert variability between the surface geometries due to the manufacturing process ("manufacturing variability"), and (3) interinsert variability between the true surface geometry of the individual inserts and the idealized reference geometry ("reference variability"). The idealized reference geometries were constructed by the averaging of 2, 3, or 6 individually scanned insert surfaces. To eliminate the scan variability, the script was used to coalign and generate an averaged surface from the 3 scans for each of the 6 inserts (Fig. 1). These 6 surfaces were then used as the source surfaces in the determination of manufacturing and reference variability. This ensured that deviations due to scanner noise would not affect the calculations of the other 2 types of variation. As a measure of the scan variability, the overall absolute mean (ie, without regard to the positive or negative nature of the deviation) and standard deviation of the 3D deviations between the different scans of the same inserts were calculated.

Next, manufacturing variability was calculated. This was determined by selecting 1 of the 6 unworn inserts as a target surface and coaligning the remaining 5 inserts

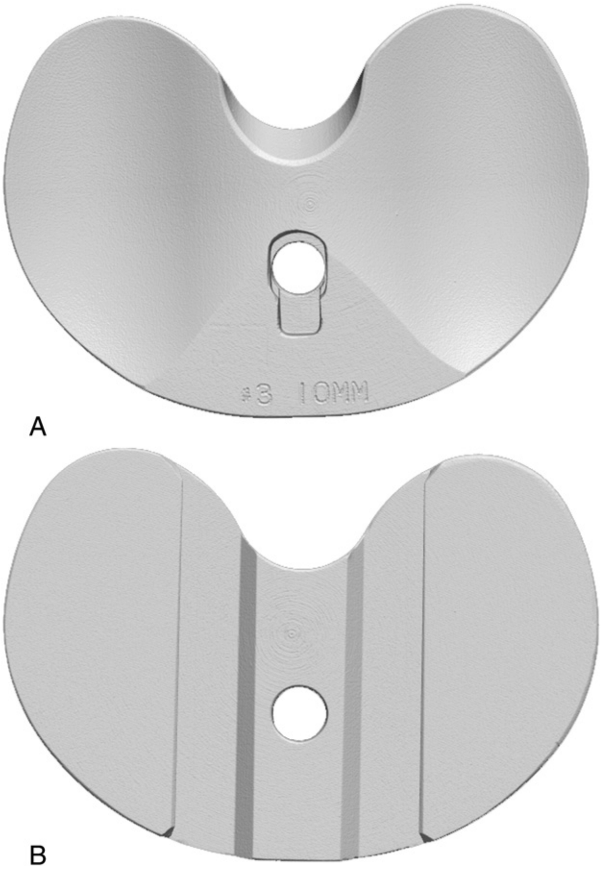

Fig. 1. Three-dimensional rendered image of an unworn polyethylene tibial insert, constructed by averaging 3 micro-CT scans of the insert. (A) Articular surface. (B) Backside surface.