Influence of Gait on Polyethylene Wear Particle Size and Morphology - A Knee Simulator Study

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Disclosures:

Introduction: In an ongoing effort to make knee wear tests more predictive of the clinical performance of total knee replacements (TKR), our laboratory has engaged in a detailed study of knee kinematics and kinetics to generate realistic load and motion protocols for knee wear testing. A gait study [1]of 28 TKR patients with well-functioning PCL retaining prostheses led to the separation of the subjects into two distinct anterior-posterior (AP) motion categories: a low motion group (LMG) and a high motion group (HMG), with AP ranges of 13 mm and 25 mm, respectively. Load and motion protocols based on the kinematic and kinetic data for these two groups were implemented in a knee simulator, with the purpose of comparing the effect of these two protocols on total and backside tibial insert wear [2]. As a control, the load and motions protocol for the displacement controlled ISO14243-3 standard for knee wear testing was also run. A trend toward higher wear rates was found in going from the ISOG to the LMG and from the LMG to the HMG. Here we report on the effect of the ISO, LM, and HP load and motion gait protocols on the particle size and shape (morphology) of the polyethylene wear debris because this information can lead to insights on polyethylene wear mechanisms [3] and potential biological effects [4]. We hypothesized that the three different gait protocols will produce significantly different wear particle size and shape distributions.

Methods: Four NexGen® CR TKRs (Zimmer Inc, Warsaw, IN) with tibial liners made from conventional polyethylene gamma-sterilized in nitrogen were tested in a 4-station Endolab knee wear simulator, where they were subjected sequentially to three load and motion protocols: ISO displacement [ISO Std], a low motion protocol (LM) and a high motion protocol (HM), as reported previously [1, 5]. Each protocol was applied for 2 million cycles (Mc), with the serum lubricant changed every 0.5 Mc. Wear particles were retrieved from the bovine calf serum lubricant used in the 1.5 to 2 Mc run. The serum was digested with 10.5 M HCl for one hour at 50°C, diluted with methanol (1:100) [6], and filtered under vacuum through a 0.1 µm pore polycarbonate membrane (Whatman). The membranes were gold sputtered and viewed under a scanning electron microscope (SEM). SEM micrographs at a magnification of 20,000x were analyzed with Image J for particle area and perimeter, from which the equivalent circle diameter (ECD) and shape ratio of the particles were calculated [7]. At least 1000 particles per sample were analyzed. Particles were defined as rounded, elongated, or fibrillar based on their length-to-width ratio: <1.5, 1.5 to 5, or greater than 5, respectively. The ECD size distributions were compared using a 2-tailed heteroscedastic t-test after log-transforming the data to achieve normality. The shape distributions were compared using a chi-square test.

Results: The particle size (ECD) distributions were skewed toward the larger particles (positive skew) for all three groups (Fig. 1) and followed a lognormal distribution (Fig. 2). For all three protocols, more than 99.5% of the particles were submicrometer. The HMG exhibited the largest mean particle size (185 ± 138 SD ± 3 SE nm), followed by the ISOG (175 ± 137 SD ± 2 SE nm), and the LMG (168 ± 141 SD ± 3 SE nm). These means are significantly different from one another (p = 80%), followed by fibrillar particles (~14%) and rounded particles (<= 6.5%) (Fig. 3). Although the three groups were comparable with respect to the fibrillar particles (p = 0.762), they differed markedly with respect to the proportion of rounded particles (Fig. 3). Thus, the LMG generated 6.5% rounded particles, which was more than twice the proportion for the ISOG (3.1%) and more than quadruple the proportion for the HMG (1.5%) (p < 0.0001).

Discussion: The three load and motion protocols led to significantly different mean particle size and shape distributions, supporting our hypothesis. Although the differences between the particle size means were small (<=10%), they need to be coupled with the wear rates to obtain the total effect. Given wear rates of 11, 15, and 29 mm3/Mc for ISO, LM, and HM groups, respectively, the corresponding estimated number of particles released per million cycles is roughly 2.2, 3.9, and 4.4 trillion/Mc for ISO, LM, and HM groups, suggesting that the ISO protocol underestimates substantially the particle load. Because particle shape also affects the immune system response [8], the higher proportion of rounded particles and correspondingly lower proportion of elongated particles for the low motion group compared to the other groups may also be biologically significant.

The larger particle mean size for the high motion group is not unexpected because higher wear rates tend to be associated with larger particles. That the low motion group had a smaller particle size, yet a higher wear rate than the ISO group, indicates that not only is the sliding distance important but also the phase relationship between the secondary motions, anterior-posterior translation and internal-external, as expected from the well established path-dependence of polyethylene wear. The three groups also differed in the relative amount of backside wear, namely, 3% (ISO), 16% (LM), and 20% (HM) of total wear, but the effect of this wear on particle size and shape is unknown. The results from this study suggest that other activities, such as running, biking, and stair climbing and descent, as well as joint misalignment, need to be examined for their influence on wear
particle size and morphology using in vivo-determined load and motion protocols. The influence of some of these activities might be much greater than found here for the three walking gait protocols.

**Significance:** Using in vivo-based load and motion curves as gait input for knee wear tests is necessary to make simulator tests more clinically relevant. This comparative study addresses the effect of simulator input on polyethylene debris particle size and shape.

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**References:**

![Graph](image)

**Fig. 1.** Particle size (ECD) distributions for the three gait groups: ISO, low motion (LMG), and high motion (HMG).
**Fig. 2.** Log-transformed particle distribution for the high motion group (HGM), shown as an example. The envelope is the fitted lognormal distribution.

**Fig. 3.** Wear particle shape distributions for the three gait groups: ISO, low motion, and high motion.

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