Total knee arthroplasty wear simulation under varying component-to-simulator alignment

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INTRODUCTION: During preclinical testing of total knee arthroplasty (TKA) devices, physical wear simulation is often the most comprehensive evaluation of the entire knee system under clinically-relevant conditions. Wear testing of TKA devices is often performed using either ISO 14243-1 or ISO 14243-3, both of which are currently undergoing major revisions to clarify the many complexities of these test methods. Among the changes in these revisions, new definitions for component alignment with respect to the knee wear simulator actuator axes have been added, which may have an impact on the data produced by these methods. This study sought to investigate the impact on wear of femoral and tibial component alignment with respect to the flexion-extension axis and internal-external rotation axis, respectively, of the knee simulator.

METHODS: Cobalt chrome femoral components were tested against conventional polyethylene tibial inserts assembled to cobalt chrome tibial baseplates (Size 8, Triathlon CoCr, Triathlon CS N2Vac, Stryker, Mahwah, NJ). A knee joint simulator (MTS, Eden Prairie, MN) was used to test per ISO 14243-3 varying only in the alignment of the femoral component with respect to the flexion-extension axis and the tibial component with respect to the internal-external rotation axis of the knee simulator: a) 30° and 60° femoral contact normals and tibial sulcus (n=6), b) 30° and 60° femoral contact normals and 4 mm anterior to tibial sulcus (n=9), c) 0° and 58° femoral contact normals and tibial sulcus (n=9), and d) 0° and 58° femoral contact normals and 4 mm anterior to tibial sulcus (n=2). Volumetric wear rates (mm^3/mc) were reported after 5.0 million cycles (mc) of testing. A Levene's test was conducted to assess whether the variance of the groups differed. A one-way ANOVA was conducted, with a confidence level of 95%, to assess whether a difference in wear rate between the groups existed.

RESULTS SECTION: Representative images of the worn tibial inserts separated based on component alignment are shown in Figure 1. The main difference between the groups was in the location of the wear scar, with the 30° and 60° flexion/extension reference coupled with the 4 mm anterior to tibial sulcus position producing the most anteriorly-oriented wear scar. In contrast, the 0° and 58° flexion/extension reference coupled with the tibial sulcus led to the most posteriorly-oriented wear scar. Figure 2 shows the interval plot for the wear rate between different groups based on component alignment. The Levene's test produced a p-value of 0.644 and the one-way ANOVA produced a p-value of 0.804.

DISCUSSION: In summary, several wear tests were conducted to characterize the mean volumetric wear rate of a single TKA device varying only in the component alignment with respect to the knee simulator actuator axes. This testing was conducted to assess the impact of changing guidance within the ISO 14243-3 standard. Although the wear patch location varied between the component alignments, the results did not show a statistically significant difference in wear rate. This conclusion may not be valid for other materials and/or bearing designs, thus it is recommended, where feasible, to adopt the component position as defined in the proposed revision of ISO 14243-1 and ISO 14243-3.

SIGNIFICANCE/CLINICAL RELEVANCE: (1-2 sentences): Changing the orientation of the components with respect to the knee simulator axes during wear testing may impact wear and preclinical screening conclusions.

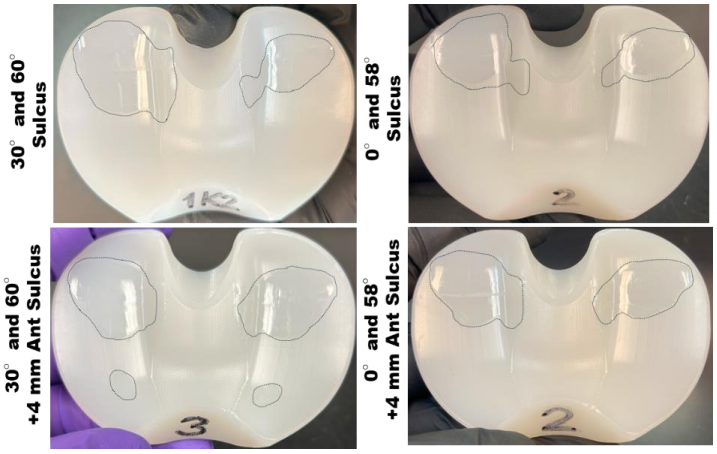

Figure 1: Representative images of the worn UHMWPE tibial inserts after 5.0 mc of testing, grouped based on component alignment. Wear scars have been outlined for clarity.

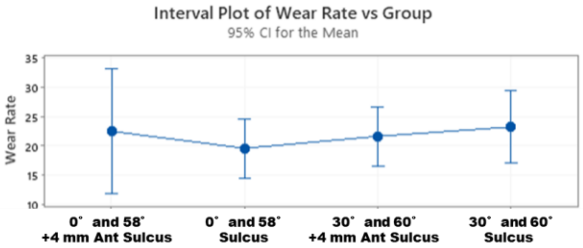

Figure 2: Interval plot for volumetric wear rate (mm^3/mc) after 5.0 mc of wear testing for each group