ISO Knee Testing Fails to Reproduce the Loads and Moments Imposed on the Knee by Active Patients

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Introduction
Despite advances in implant designs and prosthetic materials, the durability of knee prostheses is challenged by the demands of younger and more active individuals. Manufacturers and standards organizations have attempted to improve implant performance through pre-clinical testing using wear testing machines simulating normal gait. However, the pattern and severity of damage observed on retrieved implants often differs from that generated by laboratory testing using wear simulators. This suggests that either: (i) we do not appreciate the severity of the mechanical conditions imposed on knee prostheses, or (ii) that laboratory testing underestimates the loads and torques developed in vivo. In this study we use data collected from instrumented total knee prostheses to test the hypothesis that the ISO simulation of knee loading replicates the forces and moments imposed on knee prostheses during physiologic activities.

Materials and Methods
In-vivo data from five patients with instrumented tibial components were obtained from an open source database (www.orthoload.com). These data was used to determine the direction and magnitude of the six components of force and moment acting on the tibial tray during five common activities of daily living (stair descent, stair ascent, deep knee bend, one leg stance, and level walking). These data was compared to the loading profiles used to evaluate the performance of new materials and prosthesis designs through knee simulator wear testing (ISO 14243-1: Standards for Wear of Total Knee-Joint Prostheses). The combinations of the six components of force and moment at points of high knee joint loading were also documented to define the characteristic pattern of knee loading generated by each activity. These patterns were then compared with the loads and moments applied during ISO testing to assess whether this test at least recreated the combination of loads and moments seen in vivo.

Results
Of the 25 load cases examined (5 force/moment components during 5 activities), average values reported using instrumented prostheses exceeded the ISO values in 23 cases (92%). The maximum forces and moments measured during five activities of daily living exceeded ISO values by at least 50% in 20 cases (80%) and 100% in 13 cases (52%) (Fig 1).

Discussion
1. Current routines for laboratory wear testing of total knee joint prostheses fail to replicate the forces, moments, and magnitude present within knee prostheses and surrounding interfaces during physiologic activities. Moreover, the combinations of force and moment components generated during conventional wear testing fundamentally differ from those occurring in-vivo.

2. These discrepancies may explain the differences between the wear patterns seen in components retrieved upon revision vs. those generated by knee simulator machines.

3. Clearly, new testing protocols that impose more stringent loading conditions and variable loading patterns are required to simulate the diverse range of activities that active patients execute from day to day.

Significance
The loading profiles prescribed by current ISO wear testing protocols do not replicate the diverse range of activities encountered in everyday living. New more stringent testing protocols would better serve scientists and engineers when designing materials and implants for the more active patient.