Abstract: 453

Effects of Testing Parameter Perturbations in the ISO Standard for Wear of the ProDisc-L Total Disc Replacement

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Introduction: Consensus standards for wear testing of total disc replacements (TDRs) allow correlation of testing results across different laboratories, for a range of different implant designs. A necessary early step for these standards, given the difficulty of determining the *in vivo* kinematics of TDRs and the variability inherent in any such measures, is to determine the sensitivity of an implant's wear to perturbations of the proposed testing parameters. In this study, a numerical wear model incorporating cross-shear was used to test perturbations of the ISO standard for TDR wear (18192-1), for the case of the Prodisc-L implant.

Methods: A finite element model of the ProDisc-L TDR was developed in Abaqus (Figure 1). Wear was incorporated through Abaqus' adaptive meshing algorithm, with local surface topology progressively adjusted according to a modified Archard wear equation. The wear coefficient was dependent on cross-shear, calculated as the percentage of the total frictional work performed in a direction perpendicular to the principal molecular orientation.

The input recommended by ISO standard 18192-1 for lumbar implants was applied as a baseline case (Figure 1b). Following this, thirteen perturbations of the recommended input parameters were tested: the amplitude of each rotational input and the axial load was halved (Low) and doubled (High), and each rotation was set to zero (Null); and the axial load waveform was adjusted to double the dwell time in the lower range (Low), and to double the dwell time in the higher range (High).

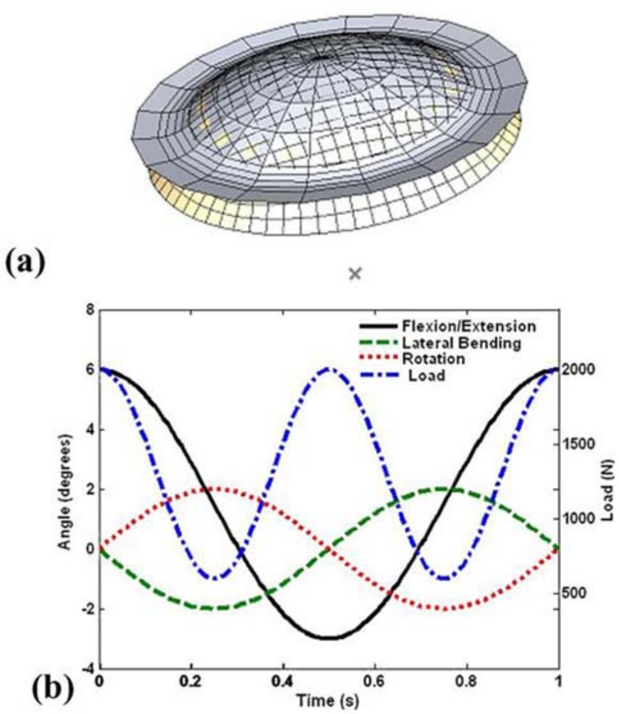

Figure 1. (a) Finite element model, and (b) baseline input waveforms for ISO testing of the Prodisc TDR.

[Figure 1]

Results: The magnitudes of the wear rate changed significantly in response to several of the perturbations, as shown in Figure 2a. Axial rotation and axial load amplitude had minimal influence on wear behavior, whereas flexion/extension amplitude and lateral bending had major effects.

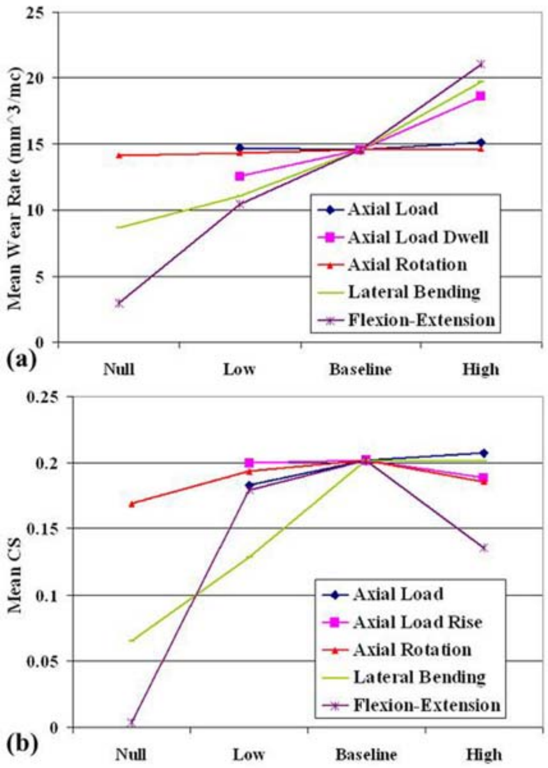

Figure 2. Variation in (a) mean wear rate, and (b) mean CS, as input waveforms were varied.

[Figure 2]

Discussion: Surprisingly, Changing the lateral bending input resulted in a factor-of-two difference in wear rate, despite the relatively small (±2^{o}) excursions involved. This is perhaps explained by the concomitant increase in cross-shear (Figure 2b). The effects of altering the flexion and extension range, on the other hand, appear to stem primarily from increasing or decreasing the total sliding distance involved. The negligible effect of changing the axial load waveform is likely due to the temporal mean load remaining unchanged. This study shows that differences in specific attributes of laboratory simulator protocol will greatly affect the resulting wear, suggesting that the most influential parameters are areas in which to focus attention for similarities to *in vivo* implant function.