Vertebral Motion Segment Dynamics Influence Prodisc-L Wear Performance

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Introduction: The goal of TDR is to replace the degenerated disc with a new bearing unit to enable pain free motion. Several current TDR designs consist of metal on polyethylene (PE) bearings. An ISO input parameter set, based on the latest biomechanical understanding, has been proposed for a relevant TDR wear simulation [1]. Various simulator concepts have been introduced to achieve ISO inputs using differing motion and load actuation methods. Several studies reported wear rates of TDR, but these have not been based on the most current ISO standard [2-4]. A limited number of PE wear rates generated by the ISO TDR test have been published [5]. The effect of varying actuation techniques has not yet been documented.

The purpose of this investigation was to examine the in–vitro wear performance of the Prodisc-L TDR when experiencing ISO specified load and motion conditions actuated using two different vertebral motion segment simulation concepts.

Materials and Methods: A spine simulator (Endolab, Germany), designed according to [1], was mounted with 8 Prodisc-L (Synthes, USA) TDRs. Another 7 station spine simulator (MTS, Eden Prairie MN), designed according to [1], was mounted with 7 Prodisc-L TDRs. The implant articulating surface is a CoCr alloy/UHMWPE couple. The implants were fixed in polyurethane, ensuring proper rotation center alignment and a 10° shear angle on both simulators. Both simulators tested n=6 dynamic test specimens and included loaded soak controls.

A "cross-shear" motion profile according to [1] for lumbar TDR testing, as shown in Fig 1, was employed by both simulators.

Results: The two actuation techniques resulted in different wear rates: 4.64 mg/Mc cycles for MTS and 5.30 mg/Mc cycles for Endolab simulator concepts. Fig 3 shows mean wear plots and mean wear rates. The mean wear rates were the same order of magnitude, although the differences between the two simulators were statistically significant (α=0.05). The PE articulating surfaces for all implants tested showed highly polished areas, machine mark residuals, and light surface scratches. No plastic deformation or total implant failure occurred.

Discussion: Wear is highly dependent on the loads, motions, and environment to which the components are subjected. In this study, a single input parameter set (ISO) was applied on two different simulators. All variables were held constant, except the load and motion actuation positions. Results of this study show a significant difference in calculated wear rates. This result is consistent with previous THA studies which have shown that kinematics influence wear results[6]. Additionally, TDR wear rates for both simulators were lower than standard PE THA results (30–40 mg/Mc).

Although statistically different, caution should be used when interpreting this data. These results are from a single set of tests on each simulator type. The affect of minor gamma irradiation differences, lubricant, and machine variability may have affected overall wear rates.

This study shows that caution should be used when comparing results across TDR simulation platforms. Researchers must report all aspects of the simulation including loads, motions and how they are applied, as well as complete details about test specimens (materials etc) and the test environment.

A more complete understanding of the TDR biomechanical environment will lead to advancement in spinal motion preserving technologies. A better understanding of spinal biomechanics during TDR patient daily activities should be pursued. Simulator inputs should move closer to the in–vitro situation as the body of knowledge increases.


Fig 1: ISO 18192 lumbar input parameters

The Endolab and MTS spine simulators actuated the ISO parameters using two different methods. Fig 2 illustrates the motion actuation concept similarities and differences.

All PE inlays were pre-soaked in distilled water at a temperature of 37°C for at least 14 days. Calf serum according to ISO/DIS 14242-1 with a protein content of 30 g/l, and EDTA content 20 mMol was used. Patricin (50µg/ml) was added to retard bacteria-induced degradation. Test serum was exchanged and a gravimetric wear rate was determined.

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Fig 2. MTS (left) & Endolab (right) spine simulator actuation techniques. Lateral bending (LB) and flexion-extension rotation (F/E) were applied at the top segment on the MTS simulator. Internal-external rotation (Rot) and vertical loading (Faxial) were applied at the bottom segment. Motions were applied at the bottom segment on the Endolab simulator, and loading was applied to the top segment.

Fig 3: Prodisc linear gravimetric wear rate determined on two simulators

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