Clinical Relevance of ISO 18192-1 Spinal Disc Wear Parameters to the PCM Cervical Disc System

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Statement of Purpose: Cervical total disc replacement (CTDR) has been proposed as a motion preserving surgical alternative to spinal fusion. Compared to fusion, CTDR have the theoretical advantage of limiting hyper-physiologic motion and degeneration at the adjacent levels. In order to preserve motion, CTDR devices contain articulating surfaces. As with other arthroplasty devices, wear of the articulating surfaces is a concern.

Testing standards were developed by ASTM and ISO organizations to address wear, however they were developed with limited information from actual device clinical kinematics and retrievals. Therefore the clinical relevance of these standards is not known. The ISO wear standard is intended to allow comparison between devices by applying the same motions that "simulate average loading conditions rather than the extremes"; however it does not consider how device design affects in vivo kinematics. Therefore ISO motions parameters and cross-shear phasing may not be applicable to all devices, and may be extreme in some cases.

PCM (NuVasive, Inc., San Diego, CA) has 2 CoCr endplates, a large bearing radius UHMWPE core, and is a semi-constrained CTDR device. The bearing radius and articulating surface area both increase with implant footprint size. In this study, wear testing was performed using the ISO standard with the smallest height, small and large footprint PCM sizes, and standard and clinically-derived modified motion parameters.

Methods: Wear tests were performed to evaluate PCM as follows:

(1) ISO, size 6.5 S (small footprint device, SFD),
(2) ISO, size 6.5 L (large, footprint device, LFD),
(3) Modified ISO, size 6.5 L (LFD).

Modified ISO parameters were based on: clinical data (95th percentile full flexion-extension ROM at 2 years follow-up from the PCM IDE study), assumptions about the motion proportion of activities of daily, and using worst-case (highest cross-shear) coupled lateral bending-to-axial rotation motion.

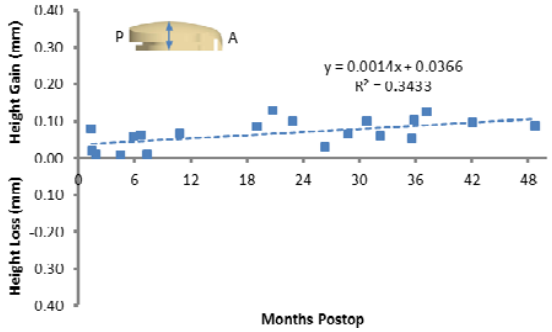
Table 1.Wear Test Motion Parameters

Test	Flexion-Extension	Lateral Bending	Axial Rotation	Axial Load
SFD-ISO	±7.5°	±6.0°	±4.0°	50-100 N
LFD-ISO	±7.5°	±6.0°	±4.0°	50-100 N
LFD-ISO Modified	±3.25°	±1.75°	±1.17°	50-100 N

Implants were gamma-sterilized and pre-soaked. UHMWPE core dimensions were measured. Wear tests were performed to 5 million cycles (MC) at 1 Hz on a 6-station spine wear simulator per the parameters in Table 1. Wear was calculated gravimetrically per ISO 14242-2. Height change was determined and compared with height loss from clinical retrievals out to over 48 months in vivo.

Results: Height loss measured in the ISO wear tests was 0.45 ± 0.01 mm for the SFD, 0.19 ± 0.03 mm for the LFD, and 0.096 ± 0.008 mm for the LFD with modified, clinically-derived motions. Visual examination of explanted UHMWPE bearing surfaces revealed polishing/removal of machining marks in the articulation region. Measurement of UHWMPE central core height changes with respect to the nominal height revealed no apparent trend of height loss with time in vivo (Figure 1).

Figure 1. Explanted Devices: UHMWPE Core Central Height Change vs. Time In Vivo.



Total gravimetric wear at 5 MC was 32.6 ± 1.84 mg for the SFD, 38.2 ± 0.70 mg for the LFD, and 15.8 ± 0.87 mg for the LFD with modified motions. One LFD sample with the ISO standard motions was noted to have worn through the UHMWPE core over the locking plate at 5 MC. Wear through to the locking plate was not detected in any clinical retrieval.

Conclusions: Wear was highest for the LFD under standard ISO motions. Compared to the SFD, the LFD has a larger bearing radius which equates to a longer wear cycle sliding path under the same input motions, and it has a larger surface area. These factors contribute to the higher wear rate. The SFD had the greatest height loss since lower wear was over a smaller area. One LFD test sample was noted to wear through to the locking plate at 5 MC under standard ISO motions. However, the significant height loss measured during wear testing (for LFD-ISO or SFD-ISO) did not correlate with height change from clinical retrievals. Therefore core wear-through during clinical use is unlikely. Further, clinically-derived motion parameters still produced significantly greater height loss on the LFD than seen in vivo, likely due to high cross-shear in the test.

For the same ISO motions, small radius devices are subjected to less sliding distances during a wear cycle than large radius devices, and therefore less severe testing. In contrast, in vivo kinematic data from clinical studies reveals that small radius devices actually move through larger ranges of motion when compared with larger radius devices. This suggests that the ISO test is biased towards small bearing radius devices, which due to hypermobility and impingement concerns, potentially may not perform well in vivo. Input parameters for in vitro wear tests should be determined for specific device designs, rather than using ISO standard motions, since they may not be clinically relevant for all devices such as large bearing radius designs like PCM.