CLINICAL RETRIEVAL AND SIMULATOR COMPARISON OF AN INVESTIGATIONAL CERVICAL DISC REPLACEMENT: *AN A PRIORI REQUIREMENT*

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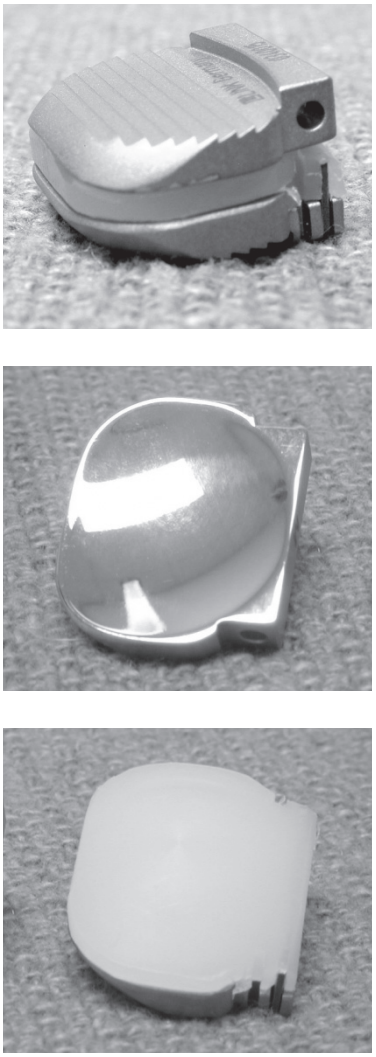
INTRODUCTION

The evolvement of cervical and lumbar disc replacement designs as alternatives to spinal fusion has resulted in a significant number of ongoing United States Food and Drug Administration (USFDA)-sponsored clinical trials. While these seek to establish "safety and effectiveness", they are of limited *in vivo* duration and benefit from long-term benchtop comparison. To assure implant durability, mechanical and biological evaluation of these devices, particularly long-term fatigue behavior, is necessary.

Both the American Society of Testing and Materials (ASTM) in (ASTM F2423-05) *Standard Guide for the Functional, Kinematic, and Wear Assessment of Total Disc Prostheses* and the International Organization for Standardization (ISO) in (ISO 18192-1:2008) *Implants for surgery -- Wear of total intervertebral spinal disc prostheses -- Part 1: Loading and displacement parameters for wear testing and corresponding environmental conditions for test* have provided guidance in the evaluation of the performance of artificial spinal discs. These guides propose the biochemical environment, motions, and loading appropriate to simulate long-term use of prostheses employed in total disc arthroplasty. The parameters evaluated include wear measured by gravimetric weight loss, as well as, changes in the articular surface shape and roughness to the extent that these may influence function.

This exhibit describes the wear characteristics of an articulating cervical disc replacement during approximately 80 years of simulated loading in an electro-mechanical, multi-axial spinal disc simulator (US Patent No. 7,493,828 B2) with comparison to clinical retrievals. These results are useful in demonstrating the safety and effectiveness of this device and also present a pre-clinical evaluation methodology for future disc replacement designs.



PCM® Artificial Spinal Disc Prosthesis

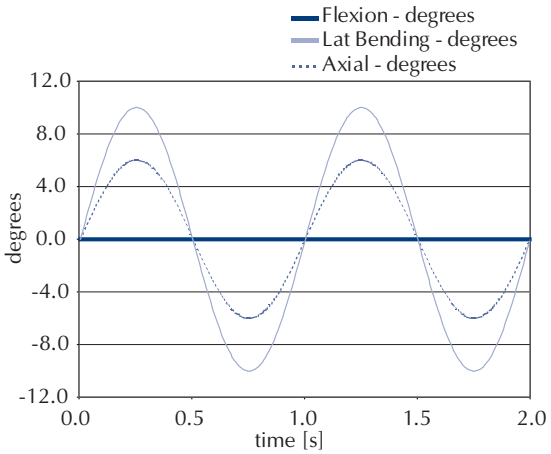
THE DESIGN

Testing was performed on the PCM® artificial spinal disc prosthesis (NuVasive, Inc., San Diego, CA, USA). The PCM® is a two part device with a spherical articulating interface. The convex/caudal portion of this articulation is ultra-high molecular weight polyethylene (UHMWPE) attached to a cobalt chrome molybdenum (CoCrMo) base plate. The concave/cephalic portion of the articulation is composed entirely of CoCrMo. This investigational device is specified for clinical application in the cervical spine as an alternative to fusion for patients suffering from degenerative disc disease and herniated discs, and has just completed a two-year USFDA-approved clinical trial.

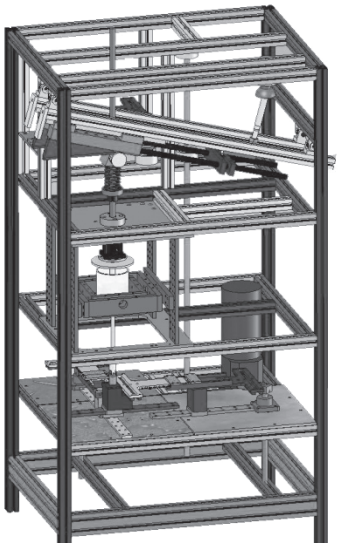
THE SIMULATION

The challenge with any simulation design is the accuracy to which it replicates physiologic human motions and loads such that information derived is predictive of anticipated *in vivo* performance. Compliance with current USFDA, ASTM, and ISO guidelines suggests that spinal device simulators have multiple simultaneous rotations, joint compression, and a hydrated, temperature-controlled environment. Patient daily activities, including walking, running, and stair climbing, are translated to realistic simulations of flexion-extension, lateral bending, and axial rotation under load.

Each specimen was aligned in an anatomical position for an erect patient and loaded statically to 100 ± 2 N of joint compression through the center of rotation of the prosthesis via a compression spring. Under displacement control, the prosthesis was articulated simultaneously through 6.0 ± 0.5 degrees of fully reversing axial rotation (R = -1) and 10.0 ± 0.5 degrees of fully reversing lateral bending (R = -1) about the center of rotation of the prosthesis. All motions were sinusoidal and in phase. The vector of the compressive force tracked the bending motion as a follower load. Test frequencies were 1 Hz for the first 2 million cycles and 1.35 Hz from 2 million to 10 million cycles.



Cervical disc simulator motion profile demonstrating extensive lateral bending and axial rotation, but without flexion.



Multi-Axial Spinal Disc Simulator

Five specimens (n = 5) were tested in a series of identical, custom, single-station motion simulators for 10 million motion cycles (Mc). All tests were conducted in 37 ± 3ºC filtered and sterilized bovine calf serum lubricant diluted to a total protein concentration of 20 grams per liter with phosphate buffered saline following ASTM F1714-96. The lubricant contained 0.2% sodium azide and ethylene-diaminetetraacetic acid (EDTA) at a concentration of 20 mM. Distilled water was added as needed to correct for lubricant evaporation.

Wear was determined by the gravimetric weight loss method described in ASTM F1714. Specimens were evaluated before testing, every 500,000 cycles for 1 million cycles, and every 1 million cycles thereafter. Individual components were weighed on a Sartorius ME235S analytical balance (Sartorius AG, Goettingen, Germany) with a resolution of 0.01 mg. The cumulative weight loss and wear rate were reported for each specimen at each interval after correcting for fluid absorption in the load soak controls (n=2). At each of the test intervals the lubricant was exchanged to enable wear particle analysis.

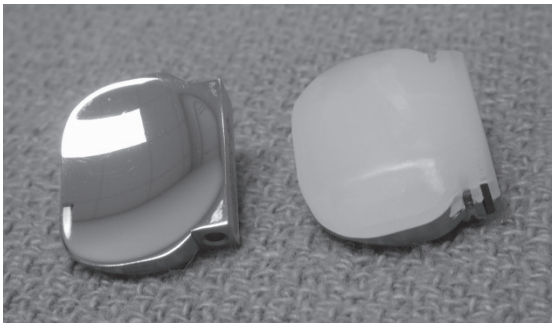
THE CLINICAL RETRIEVALS

Over the past three years, twenty-five retrievals were received for analysis of wear damage based on the classification by Hood et al.[11] The damage modes were defined as burnishing, abrasion, pitting, surface deformation, delamination, scratching, debris capture, track scratching, biologic skiving, fracture and explantation. The retrieval population was compared to the simulator results.

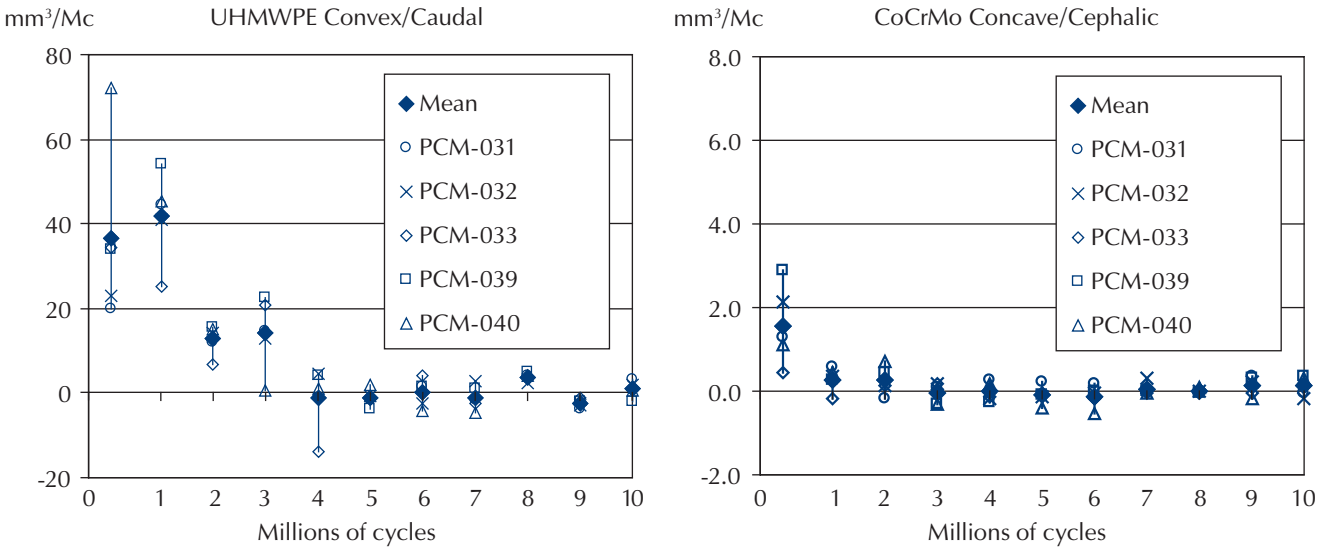
RESULTS

THE SIMULATION

All five devices completed 10 million cycles of simulated activity without functional failure and minimal debris generation. The UHMWPE convex/caudal articular surface of the specimens presented with considerable areas of polishing while the CoCrMo concave/cephalic articular surface presented with a few, long and isolated scratches, 3 to 5 mm in length. The mean volumetric wear rates were 9.5 mm^3 per million cycles and 0.2 mm^3 per million cycles for the UHMWPE convex/caudal and CoCrMo concave/cephalic components, respectively. Further, surface evaluation of the UHMWPE convex/caudal components demonstrated that the articulations remained spherical with only a slight flattening detected in most specimens.



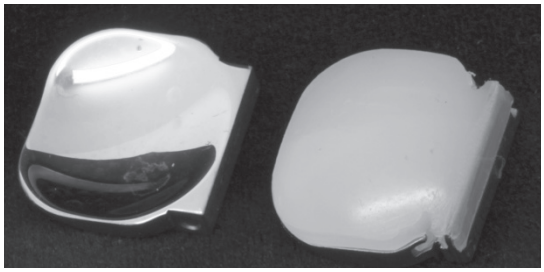
The PCM® artificial spinal disc prosthesis (PCM-040) after 10 million cycles.



Volumetric wear rate of the PCM® cervical disc prostheses.

THE CLINICAL RETRIEVALS

The majority of the UHMWPE convex/caudal components demonstrated wear defined as areas where an absence of machine marks was evident. Severe gouging marks associated with explantation were observed on several components and confined to the anterior region. Fracture did not occur in any of the specimens and third-body particulate was found embedded in five of the twenty-five (5/25) retrievals. Separation of the UHMWPE from the metal-backing (1/25) and damage to the locking mechanism (1/25) were noted, however, whether these occurred *in vivo* or during explantation cannot be clearly determined.



A PCM® UHMWPE convex/caudal clinical retrieval displaying surface polishing, mimicking the damage patterns of the simulator components.

DISCUSSION

The etiology of mechanical back and neck pain is not well understood and is among the more difficult problems encountered by the spine surgeon. Specific pain generators may include the disc as well as the facet joints at any given or multiple level of the spinal column. Treatment goals, not unlike hip and knee reconstruction, seek to eliminate pain, maintain or restore stability, correct height loss, and in the case of disc arthroplasty, offer motion preservation. Fusion is the accepted gold standard of treatment, but lacks the latter prospect of intervertebral mobility. Successful patient outcomes for both lumbar and cervical fusion range from 60-85%, but report complications of adjacent spinal disc disease, incomplete pain relief, and morbidity arising from the surgical approach.[3,6-10,12,13,15]

This study demonstrates that within an approximate 80-year period of simulated function (ASTM F2423), the volumetric wear debris generated is less than what has been reported in previous hip and knee simulator reports at shorter time periods.[1,5] Although variance in simulator and prosthetic design can account for data differences, the findings support a reduced UHMWPE particle load as well as a reduction in wear rate employing conventional UHMWPE.

The emergence of disc arthroplasty as an alternative to fusion is dependent on careful patient selection. Cervical replacements are currently indicated in the absence of instability after discectomy and decompression for radiculopathy/myelopathy or for axial neck pain. These current indications will likely be modified as experience with these devices is gained.[2,4,14,16]

CONCLUSION

The PCM® cervical disc replacement demonstrated a volumetric wear rate per million cycles less than that reported for contemporary hip and knee arthroplasty designs in the simulator study. The components exhibited functional durability suggestive of long-term *in vivo* use. Similar wear patterns, particular to the removal of machine marks on the UHMWPE convex/caudal component, were noted in the majority of retrievals. Several damage modes were observed on the retrieved components that were not captured in the simulator study. This is suggestive of future studies to correlate individual surgical factors with the goal of identifying causation.

These laboratory simulator evaluations assist an understanding of anticipated performance of cervical and lumbar spinal disc replacements particular to their material wear characteristics, and should be required of all future designs, both articulating and elastomeric, to assure their functional and mechanical integrity.

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