EVALUATION OF TOTAL DISC REPLACEMENTS WITH A NOVEL MULTI-AXIS SPINE SIMULATOR: *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 Food and Drug Administration (FDA)-sponsored clinical trials. While these seek to establish "safety and effectiveness", they are of limited *in vivo* duration. To assure implant durability, mechanical and biological evaluation/testing of these devices, particularly long-term fatigue characteristics, is necessary.

The American Society of Testing and Materials (ASTM) has expressed an interest in the performance of artificial spinal discs in Standard Guide for the Functional, Kinematic, and Wear Assessment of Total Disc Prostheses, (F 2423-05). This guidance proposes 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 a novel, electro-mechanical, multi-axial spinal disc simulator whose operation supplements the above and establishes long-term fatigue and particulate characteristics for both articulating and non-articulating (elastomeric) spinal implant devices *(US Patent Application Serial No. 11/498,313)*. It enables performance comparisons between devices, and fulfills the pre-clinical evaluations required of every FDA-sponsored clinical device trial.

DEVELOPING THE SIMULATOR

The challenge with simulator design is to create a system that replicates physiologic human motions and loads such that information derived is predictive of anticipated *in vivo* performance. Compliance with current FDA, ASTM, and International Organization for Standardization (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 dynamic load.

Based on these criteria, an electro-mechanical, multi-axial spinal disc simulator has been designed and manufactured to determine the long-term wear and durability characteristics of articulating and non-articulating (elastomeric) spinal disc prostheses (Figure 1). *In vivo* loading conditions are simulated through optimized independent control of compressive loading up to 3000N, as well as, flexion/extension, lateral bending and axial rotational up to 40 degrees. All motions and loading can be applied simultaneously and at any phasing allowing the investigation of the motion interactions over millions of cycles.

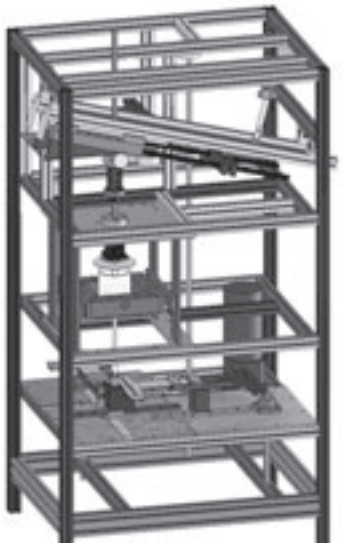

Figure 1: Single station, electro-mechanical, multi-axial spinal disc simulator.

DEFINING THE MOTION

With the mechanical requirements of the simulator defined, motion profiles need to be examined to determine their influence on device performance. In spinal disc arthroplasty this is of particular importance for articulating designs because material wear is sensitive to several factors including friction, lubrication, sliding velocity, and crossing pattern. Current intervertebral disc designs employ a variety of articulating materials, including metal on polyethylene, metal on metal, and ceramic on ceramic. Wear in each of these material couples will be influenced by the simulated motion pattern. Elastomeric designs are also susceptible to accelerated failure under multi-axial motion due to debonding and material rupture. Examples of motion profiles for the cervical and lumbar spine are shown in Figures 2-5. Each profile details the input motion function in terms of the individual flexion/extension, lateral bending, and axial rotation angle. In addition, a graph plotting a single articular contact point and its respective sliding velocity is shown.

THE NITTY GRITTY

The ASTM guide (F 2423) calls for the reporting of changes during simulation of a spinal disc that may influence its function; these include 1.) Wear determination by gravimetric weight loss (ASTM F 1714) and particle analysis, 2.) Identification of changes in articular surface contours, and 3.) Assessment of articular surface roughness (ASTM F 2083-01a).

Gravimetric Weight Loss and Articular Surface Examination

Fully hydrated specimens are inspected and weighed before testing, every 500,000 cycles for 1 million cycles, and every 1 million cycles thereafter including photographic documentation of the articular surfaces. Weight loss is corrected for fluid absorption. At each test interval fresh lubricant is replaced and the used lubricant is analyzed for particulate debris.

Articular Surface Contour Examination

For articulating spinal arthroplasty devices, profilometric analysis is completed both before and after 10 million loading cycles to generate three-dimensional digital scans of the surfaces for geometric comparison.

Articular Surface Roughness Examination

Component surface roughness is determined using a non-contact imaging surface structure analyzer, which employs a precision microscope in combination with scanning white light interferometry techniques to detect differences between a highly qualified reference surface and the specimen.

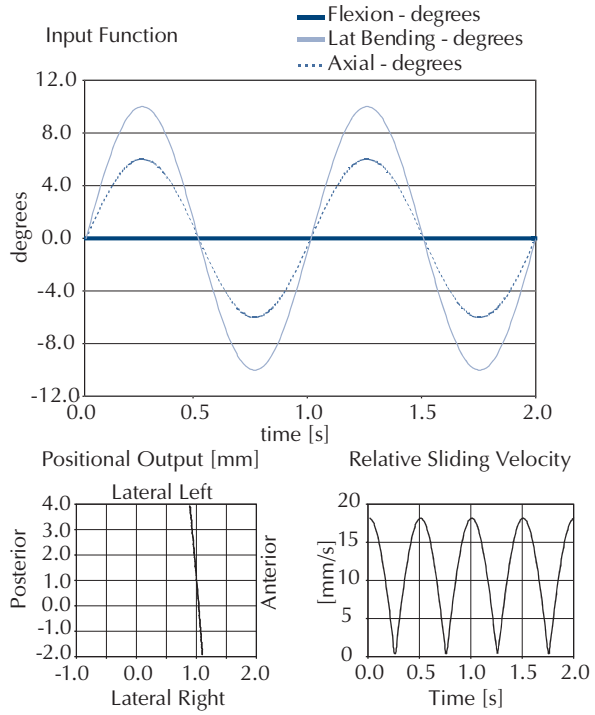

Figure 2. Sample motion profile for a cervical disc demonstrating extensive lateral bending and axial rotation, but without flexion. Note the high relative sliding velocities and the linear stop/start character. Wear results using this profile in the PCM® cervical disc are presented.

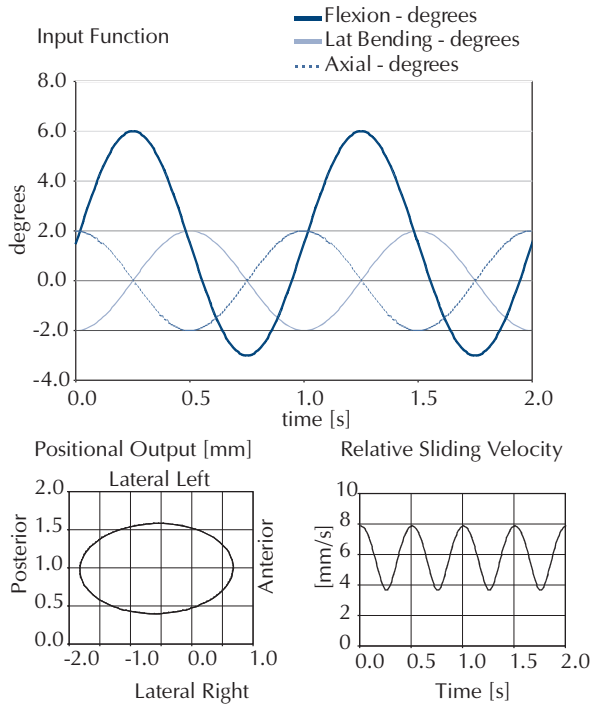

Figure 3. Sample motion profile for a lumbar disc demonstrating simultaneous flexion/extension, lateral bending, and axial rotation at levels corresponding to the ASTM F 2423 recommendations. Note the continuous motion without any path crossing.

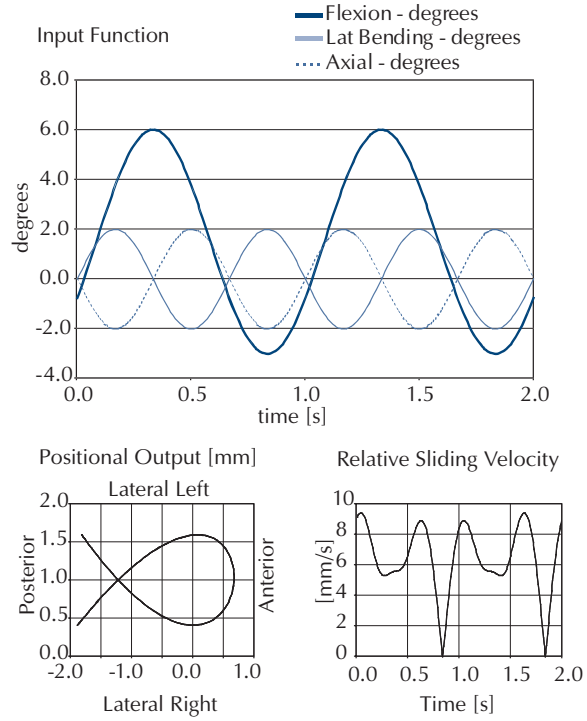

Figure 4. Sample motion profile for a lumbar disc demonstrating simultaneous flexion/extension, lateral bending, and axial rotation at levels corresponding to the ASTM F 2423 recommendations. Simple changes in frequency and phasing have resulted in a single path crossing and dual start/stop events.

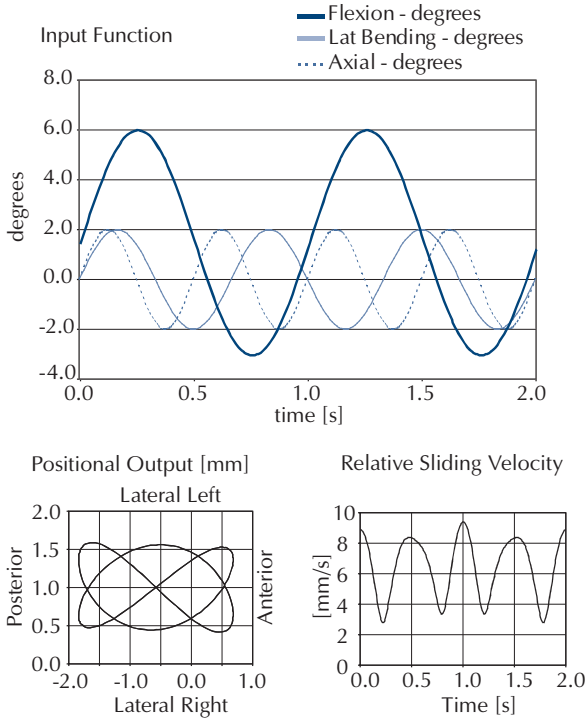

Figure 5. Sample motion profile for a lumbar disc demonstrating simultaneous flexion/extension, lateral bending, and axial rotation at levels corresponding to the ASTM F 2423 recommendations. Simple changes in frequency and phasing have resulted in continuous motion and multiple path crossings.

THE PROOF IS IN THE PUDDING

As part of a FDA-sponsored clinical trial, five PCM® cervical disc prostheses (Cervitech, Inc., Rockaway, NJ) (Figure 6) were mounted in an identical series of the spinal disc motion simulators for evaluation (Figure 7).

Figure 6. The PCM® artificial spinal disc prosthesis produced by Cervitech, Inc.

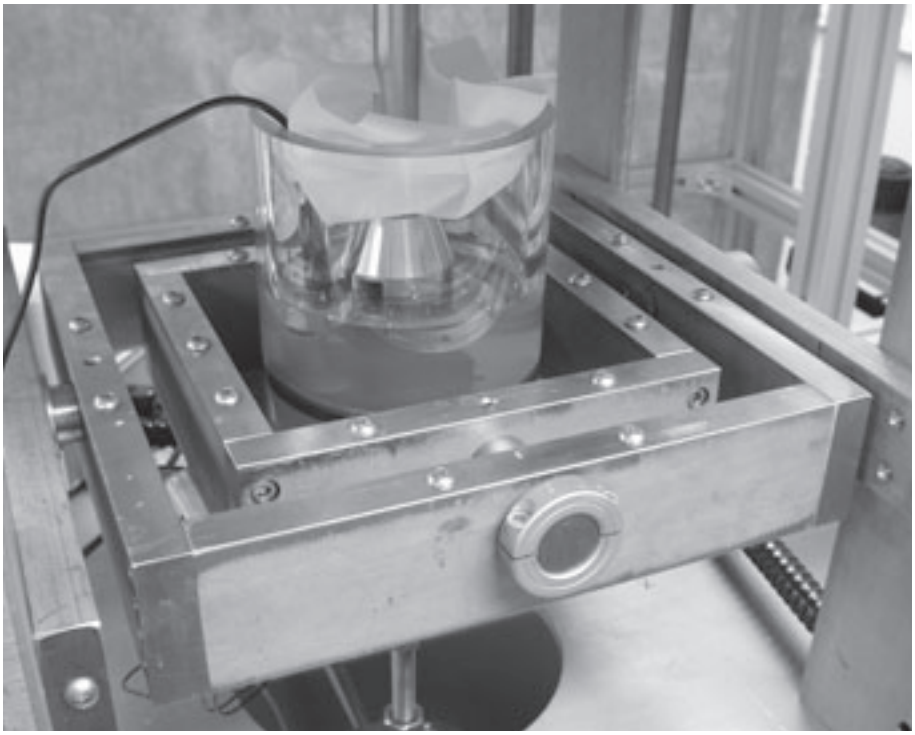

Figure 7. Single station, electro-mechanical, multi-axial spinal disc simulator with PCM® artificial spinal disc prosthesis.

All tests were conducted in 37 ± 3°C 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.

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 (Figure 2). 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.

RESULTS

All specimens survived 10 million cycles of simulated activity without functional failure and minimal debris generation (Figure 8).

Figure 8. The PCM® artificial spinal disc prosthesis (PCM-040) after 10 million cycles.

Gravimetric Weight Loss and Articular Surface Examination

The weight loss at each testing interval was determined for all specimens with correction for fluid absorption. No significant wear was detected after 3 million cycles on either the PE or CoCrMo articulations (Figures 9-11).

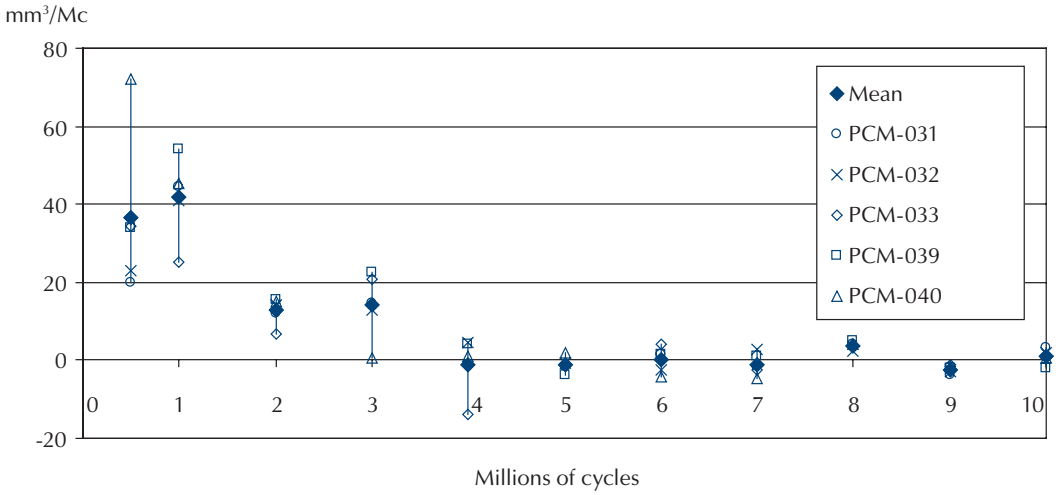

Figure 9. Volumetric wear rate of the PE articulation of the PCM® cervical disc prostheses.

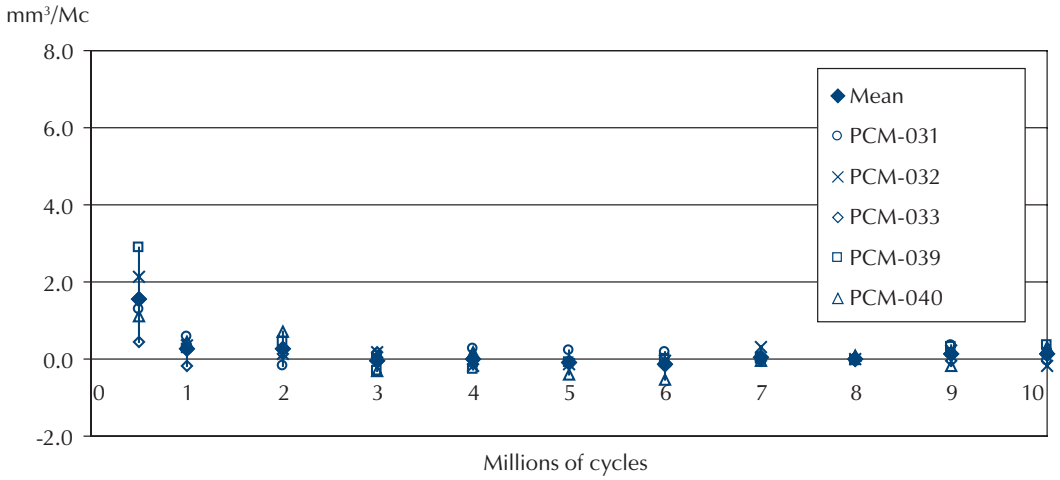

Figure 10. Volumetric wear rate of the CoCrMo articulation of the PCM® cervical disc prostheses.

Articular Surface Shape and Roughness

Surface evaluation by laser profilometry and scanning white light interferometry was completed on all PE articulations before testing and after reaching 10 million cycles. Articulations remained spherical with only a slight flattening detected in most specimens. The roughness measurements for all specimens were within the ASTM F2083-01a recommendations for polymeric and metallic articulation of orthopaedic devices. Polishing of the PE articulation and some minor, isolated scratching of the CoCrMo articulation were observed.

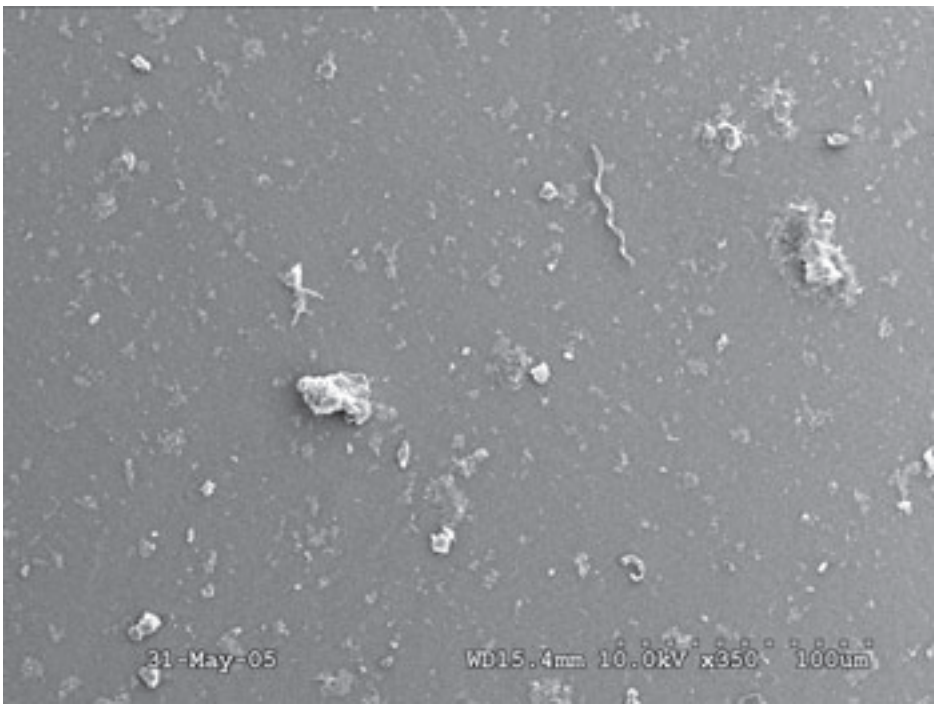

Figure 11. Sample particulate PE debris retrieved during simulation of the PCM® cervical disc prostheses. (Particulate analysis completed by Bioengineering Solutions, Inc., Oak Park, IL)

TAKE HOME MESSAGE

The concurrent use of hip and knee simulators has led to significant advances in articulating materials and design. This has now been extended through the development of a novel, electro-mechanical, multi-axial spinal disc simulator, whose dedicated function provides necessary assurance of long-term durability for these devices. As example, aspects of the pre-clinical evaluation of the PCM® cervical disc arthroplasty, which is currently in a FDA-sponsored clinical trial, has been utilized. The complexities of spinal motion, its repetitiveness during human function, as well as an evolving appreciation of its loading environment represents a challenge, which if met in pre-clinical evaluation, ultimately contributes to the safety and effectiveness of these devices.

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