Fatigue Characterization of the Freedom® Lumbar Disc

Abstract

The Freedom Lumbar Disc (FLD) is a one-piece viscoelastic total disc replacement (TDR) intended to restore function to the spine in patients with degenerative disc disease (DDD). The FLD is designed to: re-establish flexibility and natural resistance while creating stability within the functional spinal unit (FSU); provide viscoelasticity to mimic the dynamic stiffness and load sharing in the natural disc; preserve physiological range of motion (ROM) in flexion, extension, lateral bending, rotation, and compression; and, provide correct spine alignment.

The objectives of dynamic biomechanical testing of the FLD were to predict in vivo performance by characterizing device performance under physiologic test conditions and to demonstrate the device's durability and characterize failure modes under different loading scenarios using more severe test conditions. Biomechanical testing in compression, 45° compressive shear, flexion/extension, lateral bending and rotation was conducted by independent laboratories according to ASTM standards. All testing was conducted in physiologic environments, and all testing was conducted on the worst-case device size.

The worst case device size survived 50 years of simulated walking cycles and 40 years of simulated significant bend cycles in both flexion/extension and lateral bending coupled with axial rotation with no failures. Also, the FLD demonstrated an endurance limit of more than five times the amount of anterior shear that the device would be expected to experience during average daily living *in vivo*.

Overall, the Freedom Lumbar Disc has demonstrated a fatigue life exceeding 40 years of simulated *in vivo* use.

Introduction

FLD Description

The Freedom Lumbar Disc (FLD) is designed to restore function to the spine in DDD patients in order to reduce or eliminate disabling pain, promote recovery (and return to work, when applicable), and potentially avoid degeneration of the adjacent lumbar segments.
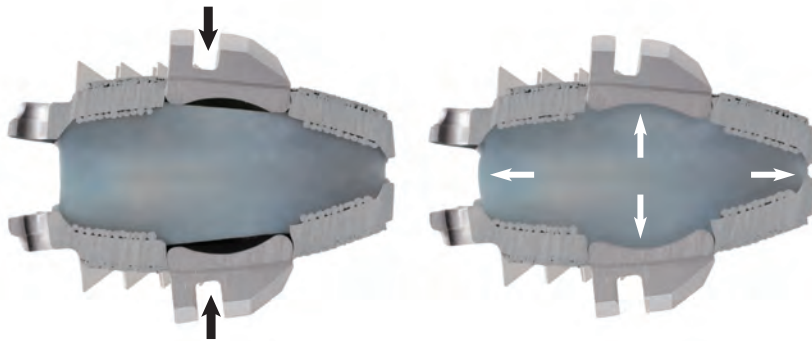
The FLD is a one-piece viscoelastic total disc replacement (TDR) consisting of an elastomeric core bonded to titanium retaining plates. The FLD retaining plates and endcaps are manufactured from titanium alloy and contain features on the bone-interface side to provide both short- and long-term fixation of the device to the vertebral body. End caps are locked into the retaining plates prior to implantation. The FLD core material is CarboSil™ TSPU, a silicone polycarbonate urethane thermoplastic elastomer.

In the assembled device, the retaining plates are mechanically and chemically adhered to the core with proprietary bonding techniques. This provides superior bond strength along the metal-to-core interface and low internal retained stresses within the core.

FLD Function

The FLD is intended to work in conjunction with the surrounding anatomy and mimic the biomechanics of the human disc. This is achieved through the combination of the viscoelastic polymer core and the overall design of the FLD. The polymer core is able to expand both radially and axially. This axial feature, along with the mechanical characteristics of the polymer, allows the FLD stiffness to approximate the stiffness of natural human disc. As the FLD compresses, the polymer expands into the chamber formed by the endcap and retaining plate and expand radially along the polymer annulus (Figure 1). Both of these features are limited by the metal interface to control the stiffness of the FLD.

FIGURE 1: CROSS-SECTION OF FREEDOM LUMBAR DISC BEFORE AND AFTER COMPRESSIVE LOAD IS APPLIED

The Freedom Lumbar Disc (FLD) is designed to restore function to the spine.

The FLD is intended to work in conjunction with the surrounding anatomy and mimic the biomechanics of the human disc.

Biomechanical Assessment

Dynamic biomechanical tests of the FLD were conducted to demonstrate the device's durability and characterize failure modes under different loading scenarios. Some test methods were intended to represent physiologic loads, while others were designed to utilize non-physiologic, or extreme, loads and ranges of motion not typically observed in vivo to obtain functional failure of the FLD.

Assessment of functional failure is important to establish the ultimate performance characteristics of the device. **Functional failure** is defined as permanent deformation or wear that renders the intervertebral disc prosthesis assembly ineffective or unable to resist load/motion or any secondary effects that result in a reduction of clinically relevant motions or the motions intended by the device (ASTM F2423-05). **Mechanical failure** is defined as failure associated with a defect in the material (for example, fatigue crack) or of the bonding between materials that may or may not produce functional failure (ASTM F2423-05). A device can exhibit mechanical failure without functional failure.

Objective Failure Criteria (OFC), or clinically relevant conditions for each testing mode under which the device must perform, were established for each test. Clinically relevant conditions were defined using the properties of the human lumbar disc, as published in the clinical literature.

Compression fatigue testing was used to predict long term in vivo performance of the FLD. At axial compressive loads in the range of average daily living loads, each cycle simulates a walking step. Since it is generally believed that the average person takes one million steps per year (Morlock, Schmalzried), a ten million cycle compression fatigue test is used to predict 10 years of simulated *in vivo* loading.

a ten million cycle compression fatigue test is used to predict 10 years of simulated in vivo loading.

45° compressive shear fatigue testing was used to evaluate the durability of the bond between the FLD retaining plates and polymer core. The compressive shear loading mode has limited value for predicting physiologic performance, as neither a human or artificial disc is loaded in this manner *in vivo*. When the spine is in motion (i.e., flexion and extension), the primary loading is compressive. The follower load theory describes the interaction of the muscles, ligaments and spinal system during loading and physical activities at a segmental level. Patwardhan et.al. (2001) contend that "muscle activation causes the internal force resultant to follow a path approximating the tangent of the spinal curve, thereby minimizing the internal shear forces and bending moments and loading the whole lumbar spine in nearly pure compression". The discal shear loading that does occur is instantaneous and is subsequently mitigated by the surrounding muscles and ligaments that force changes in the lordotic curve (vertebral body translation) and disc geometry to eliminate shear stress. Multiple follower load studies, such as those by Patwardhan, Goel, Panjabi, and Stanley, have supported this finding.

compressive shear loading provides a severe test of both the polymer and the bond.

However, while 45° compressive shear is not a physiologic loading mode, it is an extreme loading scenario which, while compressing the device as a whole, translates the top of the device over the bottom and places the anterior and posterior sides of the polymer core into tension. As a result, compressive shear loading provides a severe test of both the polymer and the bond.

Wear testing is conducted to characterize the wear debris that may be generated by an artificial disc. The ASTM method for wear testing combines a high lifting compressive load with maximum ranges of motion in flexion, extension, lateral bending and rotation. Studies have shown that the range of motion of the lumbar spine decreases with increasing compressive load (Janevic). As a result, the ASTM method places the device under range of motion and load combinations that neither the natural disc or TDR devices would be expected to experience *in vivo*. For this reason, it is believed that the ASTM wear test dramatically exaggerates the functional, kinematic and wear response of the FLD.

Per the estimate of 125,000 significant bends per year, each 5 million cycles is equivalent to 40 years of significant bends, ten million cycles is equivalent to 80 years of significant bends, etc., and 30 million cycles is equivalent to 240 years worth of significant bends.

In order to predict *in vivo* wear, a correlation of the number of wear testing cycles to the number of years in vivo is desired. Hedman et.al., estimated that the average person experiences 125,000 significant bends in flexion/extension per year. This is believed to be a high estimate because it is generally not believed that the average person has 342 significant bends per day, as this estimate predicts. It is assumed that a significant bend in flexion/extension is a full-range of motion bend. It is also assumed that a full-range of motion bend in rotation or lateral bending is a significant bend. The loads and motions defined in the ASTM method are considered by the authors to be significant bends. It is arguable that these are not actually significant bends, but extreme non-physiologic motions. However, for purposes of testing and interpreting the results, the load/motion combinations in the ASTM method will be designated significant bends. As such, each cycle of any of flexion/extension, lateral bending and rotation is equal to one significant bend. Therefore, a test which includes 10 million cycles of each of flexion/extension, lateral bending and rotation produces 30 million total cycles. Per the estimate of 125,000 significant bends per year, each 5 million cycles is equivalent to 40 years of significant bends, ten million cycles is equivalent to 80 years of significant bends, etc., and 30 million cycles is equivalent to 240 years worth of significant bends.

Materials and Methods

All mechanical testing was conducted on the worst case size FLD, which has a 26 x 36 mm retaining plate, 13 mm anterior height, and 12° angle. This device size is the worst case for biomechanical testing because it has the combination of the smallest footprint, smallest posterior height and smallest polymer volume. Many of the device's biomechanical capabilities, specifically device stiffness and range of motion, are provided by the polymer material properties and geometry. The polymer core acts as a dampening mechanism to absorb energy produced by the loading and motion of the spine, and the stresses on the device are reduced because of this inherent ability of the polymer core to absorb energy. The lower the polymer volume, the greater the stresses on the device during testing.

All test specimens were manufactured per AxioMed standards, including ethylene oxide sterilization. All test specimens were preconditioned in 37°C saline for a minimum of three days prior to testing. All testing was conducted in 37°C saline environment.

Fatigue testing was conducted according to ASTM International Standards. Dynamic testing in compression and compressive shear was conducted by Empirical Testing Corp. (ETC, Colorado Springs, CO) according to ASTM F 2346, "Standard Test Methods for Static and Dynamic Characterization of Spinal Artificial Discs". Wear testing was conducted by MarTest Inc. (Cincinnati, OH) following the guidelines of ASTM F2423-05, "Standard Guide for Functional, Kinematic, and Wear Assessment of Total Disc Prostheses", although the method was in draft form when testing was conducted. Steel fixtures and test blocks were used for testing to remove flexibility from the system so that all stiffness measurements were device stiffness only.

All fatigue tests were conducted at a testing frequency of 3 Hz or less. A previous study of the FLD at different frequencies demonstrated that the response of the polymer core to the applied load and the core temperature did not change significantly at frequencies between 1 and 3 Hz. Conversely, at frequencies of 4 Hz and higher, the polymer response decreased and temperature increased. It should be noted that studies using higher frequencies with a viscoelastic polymer actually shield the polymer from being exposed to the command load due to the deformation delay that occurs with viscoelastic polymers at high frequencies.

The ASTM method for wear testing allows several different testing configurations; however, the preferred configuration of the FDA is a simple motion test for flexion/extension and a coupled motion test of lateral bending and axial rotation, all under the specified compressive pre-load. This testing scenario was used for the FLD. Three discs were tested in flexion/extension to 10 million cycles and then in lateral bending and rotation to 10 million cycles, all at a loading frequency of 2 Hz. Another three discs were tested in reverse order. All testing included a constant axial compressive load of 1,200 N. Flexion/extension tests were conducted in load control to ±10 Nm, lateral bending was conducted in load control at ±12 Nm, and rotation was controlled to ±3°. Flexion/extension and lateral bending tests were conducted under load control because load control is more physiologic; the discs are loaded during daily activities and respond to those loads with motion. Rotation tests were conducted in displacement control because load control, as specified in the ASTM standard (± 10 Nm), resulted in excessive, supra-physiologic motion of the FLD. *In vivo*, rotation of the intervertebral disc is limited by the facets to approximately ± 3°; therefore, this was felt to be the more appropriate testing option.

Two additional devices were tested as unloaded controls. Controls were not loaded because an earlier study found no significant difference between device weights for loaded vs. unloaded controls.

One specimen in the group tested first in lateral bending/rotation was lost during the first 10 million cycles due to part damage caused by a power outage. The remaining five test specimens all reached test conclusion at 30 million device cycles (10M flexion/extension + 10M lateral bending + 10M rotation).

Solutions for each test device were collected by MarTest every five million cycles throughout testing, for a total of 20 solution samples, and analyzed by BioEngineering Solutions Inc. (Oak Park, IL). Laser diffraction particle analysis (LALLS) was conducted for quantitative analysis of particle size. Scanning electron microscopy (SEM) with EDAX was conducted for qualitative analysis of particle shape. All particle sizes were given in equivalent spherical diameter (ECD) based on a volume analysis and a number analysis.

Results

All test results met the objective failure criteria.

In compression, the objective failure criterion was that the worst case device size must survive the average daily living (ADL) load of 1,200 N for ten million cycles with no mechanical or functional failure. The average daily living load was estimated based on the loads on the lumbar spine for many activities reported by Nachemson (1981). Two devices survived 50 million cycles at twice the ADL load (2,400 N) with no mechanical or functional failures.

The Freedom Lumbar Disc demonstrated a 50 year fatigue life with no failure at twice the average daily living load.

Studies have shown that hip and knee joints undergo approximately 1 million (0.9 to 1.1 million) cycles per year during walking and stair climbing (Morlock, Schmalzried). It is our contention that one walking cycle (right step + left step) is equal to one cycle on the lumbar discs. Ten million cycles in a compression fatigue test is thereby considered to be the equivalent of 10 years simulated use. The Freedom Lumbar Disc demonstrated a 50 year fatigue life with no failure at twice the average daily living load.

Additional tests were conducted at higher, non-physiologic loads to cause functional failures. At loads from 7,000 N to 17,500 N, functional failures were generated, as shown in Figure 2. At 6,000 N, three devices completed 10 million cycles with no functional failures. One of the devices that survived 6,000 N for 10 million cycles is shown in Figure 2, next to another untested disc from the same production lot.

FIGURE 2: AXIAL COMPRESSION FATIGUE CURVE FOR THE FREEDOM LUMBAR DISC (ETC TECHNICAL REPORT 194-114410-27, REV.B)

Axial Compression Fatigue Curve for the
26mm x 36mm, 13mm 12° Freedom Lumbar Discs
$r^2 = 0.935449632$ DF Adj $r^2 + 0.892416053$ FitStdErr = 1410.065894 Fstat = 57.96711345
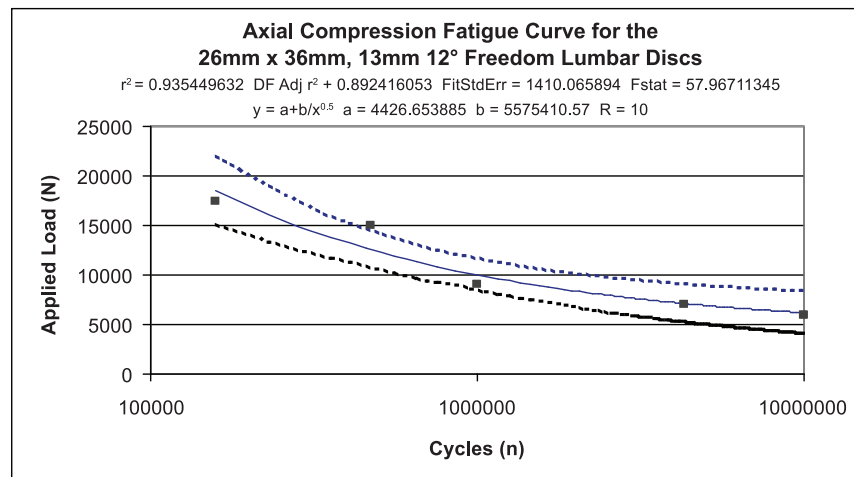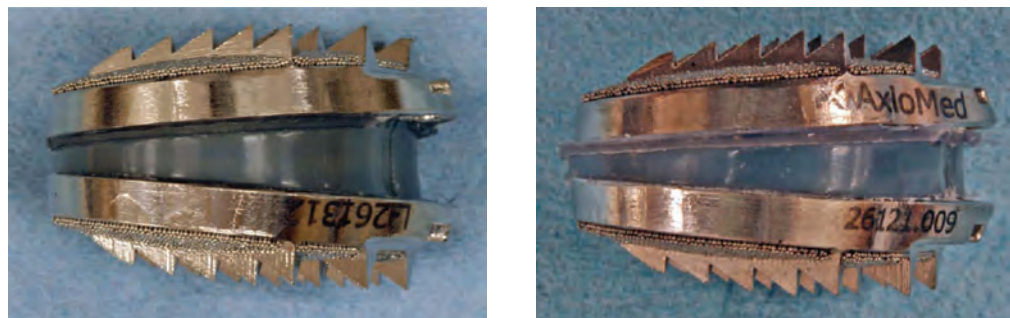$y = a+b/x^{0.5}$ a = 4426.653885 b = 5575410.57 R = 10

FIGURE 2: PHOTO OF UNTESTED FLD (LEFT) COMPARED TO FLD AFTER 10 MILLION CYCLES AT AN AXIAL COMPRESSION LOAD OF 6,000 N. (ETC TECHNICAL REPORT 137-203409-27)

The dynamic stiffness of each test specimen was recorded throughout each long-term test. Figure 3 shows that the dynamic stiffness remains constant throughout testing, even at the non-physiologic loads of 6,000 and 7,000 N. This finding demonstrates that the FLD retains its mechanical integrity and performance throughout long term fatigue testing.

FIGURE 3: DYNAMIC STIFFNESS OF THE FLD OVER 10 AND 50 MILLION CYCLES
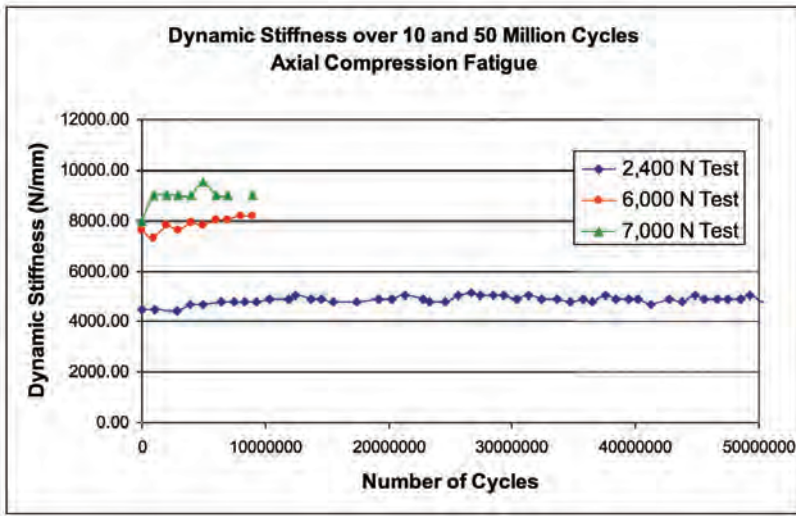
the dynamic stiffness remains constant throughout testing, even at the non-physiologic loads of 6,000 and 7,000 N.…
the FLD retains its mechanical integrity and performance throughout long term fatigue testing.

The objective failure criterion for dynamic 45° compressive shear testing was that the worst case sized FLD withstand 300 N in anterior shear for 10 million cycles with no mechanical or functional failure. The OFC was developed based on two clinical references: first, the fatigue strength of the human lumbar disc in anterior shear is 100 N (Eijkelkamp); second, the maximum shear load on the lumbar spine is 20 to 25% of the compressive load on the spine (Patwardhan 2005 Han). Twenty-five percent of the ADL of 1,200 N is 300 N, which is higher than the load noted by Eijkelkamp and therefore the conservative choice for the OFC.

As in compression, it was desired to generate a fatigue curve, causing functional failures of the device at all but the endurance limit load. The fatigue curve is show below in Figure 4. Note that tests which reached 10 million cycles were stopped without evidence of failure. One device, which survived 1,200 N for 10 million cycles, is shown in Figure 5, next to another untested disc.

FIGURE 4: DYNAMIC COMPRESSIVE SHEAR FATIGUE CURVE FOR THE WORST CASE SIZED FLD (ETC TECHNICAL REPORT 167-299201-27)
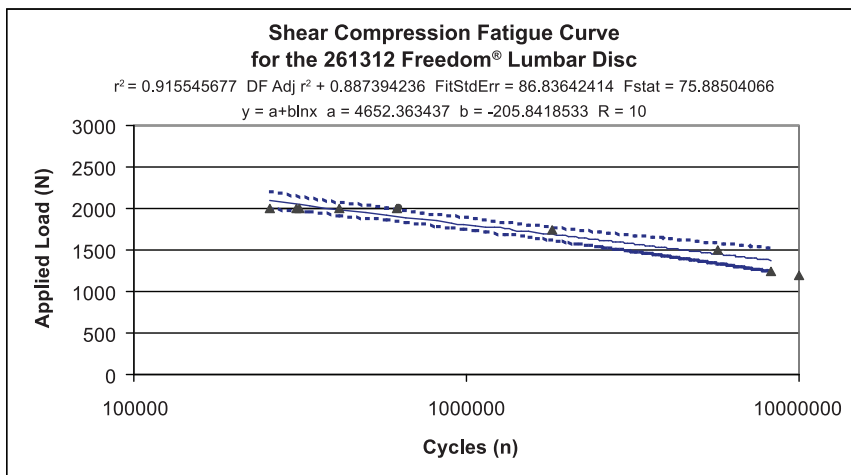
FIGURE 5: PHOTO OF UNTESTED FLD (LEFT) COMPARED TO FLD AFTER 10 MILLION CYCLES AT A COMPRESSIVE SHEAR LOAD OF 1,200 N. (ETC TECHNICAL REPORT 167-299201-27)

The endurance limit load of 1,200 N in 45… compressive shear corresponds to an anterior shear load of 1,697 N, which is 5.7 times the OFC load of 300 N anterior shear.

To address the OFC, the loads applied in 45° compressive shear were converted using geometry equations to the anterior shear and pure compression components. The endurance limit load of 1,200 N in 45° compressive shear corresponds to an anterior shear load of 1,697 N, which is 5.7 times the OFC load of 300 N anterior shear. The anterior shear forces on the lumbar discs are expected to be between 25 N and 525 N (Eijkelkamp, Patwardhan, Han, Nachemson). Therefore, in addition to surpassing the OFC with a 5.7X safety factor, the FLD has a performance safety factor of more than three times the highest load anticipated *in vivo*.

For wear testing, the objective failure criteria was: either 1) to complete testing with a wear rate less than or equal to that of a commercially available artificial disc; or, 2) for the worst case sized FLD to survive 5 million cycles each of flexion/extension of ±7 Nm and lateral bending of ±7.2 Nm coupled with axial rotation of ±1.7°, all under an axial compressive pre-load of 1,200 N, with no mechanical or functional failures. Because wear testing places constrained devices under non-physiologic combinations of load and range of motion, the OFC were developed to represent a more physiologic test of simulated significant bends. However, because the FDA desires wear testing according to the ASTM method, this was used for FLD wear testing. Therefore, results cannot be directly compared to the second OFC criterion.

Five test specimens reached 30 million device cycles÷with no functional failures.

÷240 years of simulated significant bends.

Five test specimens reached 30 million device cycles (10M flexion/extension + 10M lateral bending + 10M rotation) with no functional failures. One specimen in the group tested first in lateral bending/rotation was lost during the first 10 million cycles due to part damage caused by a power outage. Per Hedman's estimate of 125,000 significant bends per year, 30 million device cycles corresponds to 240 years of simulated significant bends.

Although the second OFC cannot be addressed directly due to the chosen testing conditions, it can be reasonably assumed that, if the FLD can survive the more severe test with no functional failures, it could be expected to survive the OFC test conditions with no mechanical or functional failures.

Test specimen analysis data shows that the devices lost an average of 0.07 g weight over 30 million device cycles of wear testing. Dimensionally, the parts lost an average of approximately a quarter of a millimeter in height over 30 million cycles, while the periphery dimension increased by approximately three quarters of a millimeter. These small dimensional changes after a simulated 240 years worth of significant bends demonstrate the good hysteresis, or recovery, of the FLD.

Twenty solution samples were collected and analyzed. The number average particle diameter was 1.90 µm, with a range of 0.80 to 6.92 µm, and the weight average particle diameter was 48.66 µm, with a range of 23 to 76 µm. The average mass of particulate per million cycles of wear testing was 1.70 mg.

To address the first objective failure criterion, a comparison of the wear of FLD, Charite and ProDisc was made and is presented in Table 1. Charite and ProDisc data was extracted from their respective Summaries of Safety and Effectiveness (SS&Es).

TABLE 1: SUMMARY OF FLD WEAR RATES VS. PRODISC-L VS. CHARITE

DEVICE	TEST DESCRIPTION	TOTAL NUMBER OF DEVICE CYCLES	WEAR RATE (MASS LOSS PER MILLION CYCLES)	AVERAGE PARTICLE DIAMETER
FLD	ASTM, 10M flex/ext + 10M lat bend + rotation	30 million	1.70 mg	1.90 µm
ProDisc-L	ISO, 10M flex/ext + lat bend + rotation	30 million	5.73 mg	0.44 µm
Charite	ASTM, 10M flex/ext + rotation, OR 10M lat bend + rotation	20 million	0.11 mg	0.2 µm

It should be noted that each device was tested under a different methodology, resulting in different combinations of load and range of motion, as well as different numbers of total device cycles. Although the results are not directly comparable, they indicate that the wear rate of the FLD falls within the range of the wear rates of the two U.S. commercially available total disc replacements, meeting the first objective failure criterion. The wear rate of the FLD was more than three times lower than that of the ProDisc-L. The FLD wear debris also had significantly larger particle diameter than did the ProDisc-L and Charite particulate. As noted by Dr. Nadim Hallab of BioEngineering Solutions, a decrease in particle size has been found to result in an increase in bioreactivity (resultant biologic pro-inflammatory activity). Thus, the smaller particles from the ProDisc-L or Charite devices would be more likely to induce a pro-inflammatory response than the larger FLD particles.

the smaller particles from the ProDisc-L or Charite devices would be more likely to induce a pro-inflammatory response than the larger FLD particles.

Conclusions

The Freedom Lumbar Disc demonstrated a fatigue life in excess of 40 years simulated
walking and simulated significant bends with no mechanical or functional failures.
The polymer did not crack or permanently deform, and the bond retained its integrity.

References

Eijkelkamp MF, van Donkelaar CC, van Horn JR, Huyghe JM, Verkerke GJ. Requirements for an Artificial Intervertebral Disc. The International Journal of Artificial Organs 24; pp 311-21, 2001.

Goel VK, Grauer JN, Patel TC, Biyani A, Sairyo K, Vishnubhotla S, Matyas A, Cowgill I, Shaw M, Long R, Dick D, Panjabi MM, Serhan H. Effects of Charite Artificial Disc on the Implanted and Adjacent Spinal Segments Mechanics Using a Hybrid Testing Protocol. Spine 30 (24); pp 2755-64, 2005.

Han JS, Goel VK, Ahn JY, Winterbottom J, McGowan D, Weinstein J, Cook T. Loads in the Spinal Structures During Lifting: Development of a Three-Dimensional Comprehensive Biomechanical Model. Eur Spine J 4; pp 153-168, 1995.

Hedman TP, Kostuik JP, Fernie GR, Hellier WG. Design of an Intervertebral Disc Prosthesis. Spine 16 (6); pp S256-S260, 1991.

Janevic J, Ashton-Miller JA, Schultz AB. Large Compressive Preloads Decrease Lumbar Motion Segment Flexibility. Journal of Orthopaedic Research 9; pp 228-236, 1991.

Morlock M, Schneider E, Bluhm A, Vollmer M, Bergmann G, Muller V, Honi M. Duration and Frequency of Every Day Activities in Total Hip Patients. J Biomech 34 (7); pp 873-81, 2001.

Nachemson AL. Disc Pressure Measurements. Spine 6 (1); pp 93-97, 1981.

Panjabi M, Malcolmson G, Teng E, Tominaga Y, Henderson G, Serhan H. Hybrid Testing of Lumbar Charite Discs Versus Fusions. Spine 32 (9); pp 959-66, 2007.

Patwardhan AG, Meade KP, Lee B. A Frontal Plane Model of the Lumbar Spine Subjected to a Follower Load: Implications for the Role of Muscles. Journal of Biomechanical Engineering Vol 123: pp 212-217, 2001.

Patwardhan AG. The Follower Load Concept and its Implementation. Presentation to AxioMed Spine Corp. Medical Advisory Panel, March 18, 2005.

Patwardhan AG, Carandang G, Ghanayem AJ, Havey RM, Cunningham B, Voronov LI, Phillips FM. Compressive Preload Improves the Stability of Anterior Lumbar Interbody Fusion Cage Constructs. JBJS 85-A (9); pp 1749-56, 2003.

Patwardhan AG, Havey RM, Carandang G, Simonds J, Voronov LI, Ghanayem AJ, Meade KP, Gavin TM, Paxinos O. Effect of Compressive Follower Preload on the Flexion-Extension Response of the Human Lumbar Spine. Journal of Orthopaedic Research 21: pp 540-546, 2003.

Patwardhan AG, Havey RM, Meade KP, Lee B, Dunlap B. A Follower Load Increases the Load-Carrying Capacity of the Lumbar Spine in Compression. Spine 24 (10); pp 1003-9, 1999.

Schmalzried TP, Szuszczewicz ES, Northfield MR, Akizuki KH, Frankel RE, Belcher G, Amstutz HC. Quantitative Assessment of Walking Activity after Total Hip or Knee Replacement. J Bone Joint Surg Am 80 (1); pp 54-9, 1998.

Stanley SK, Ghanayem AJ, Voronov LI, Havey RM, Paxinos O, Carandang G, Zindrick MR, Patwardhan AG. Flexion-Extension Response of the Thoracolumbar Spine Under Compressive Follower Preload. Spine 29 (22); pp E510-14, 2004.

AxioMed®LLC

Overlook Pointe
5350 Transportation Blvd., Suite 18
Garfield Heights, OH 44125
USA

Phone: 216.587.5566
Fax: 216.587.3388

www.axiomed.com