



Durability Characterization of the Freedom[®] Cervical Disc



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White Paper

Durability
Characterization
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Cervical Disc

Abstract

The Freedom® Cervical Disc (FCD) is a viscoelastic total disc replacement (TDR) intended to restore function to the spine in patients with symptomatic degenerative cervical discs. The FCD 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 FCD 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 80 years of simulated significant bend cycles in both flexion/extension and lateral bending coupled with axial rotation with no failures. The FCD 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 Cervical Disc has demonstrated a fatigue life exceeding 50 years of simulated *in vivo* use.

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Introduction

FCD Description

The Freedom Cervical Disc is designed to restore function to the spine in patients with symptomatic degenerative cervical discs in order to reduce or eliminate disabling pain, promote recovery, and potentially avoid degeneration of the adjacent segments.

The FCD (Figure 1) is a one-piece viscoelastic total disc replacement (TDR) consisting of an elastomeric core bonded to titanium retaining plates using AxioLock™, a proprietary polymer-metal bonding technology. The FCD retaining plates 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 bodies. The FCD core material is CarboSil™ TSPU, a silicone polycarbonate urethane thermoplastic elastomer.

The asymmetric design of the FCD, with a larger rostral footprint, maximizes the bone-implant interface with minimal bone resection needed. Uncovertebral joints may be left intact for maximum segmental stability. Additionally, the asymmetric shape of the polymer core provides device stiffness and range of motion characteristic of the healthy human cervical disc; conversely, a symmetric design of the same size results in higher device stiffness. There is a chamber in the polymer core allowing for the target core stiffness range while providing stress relief. A wedge angle of 8° maintains cervical lordosis. Multiple sizes are available to allow for optimal fit in patient population.

FCD Function

The ideal TDR restores healthy function to the diseased segment. It reestablishes the physiologic stiffness in all loading modes, providing both physiologic motion and resistance to excess motions or loads. It restores the index level stability compromised due to the disease process and alteration of ligament structures during surgical intervention.

The FCD is a next generation TDR designed to mimic the function of the human disc. The Freedom Technology incorporates a bonded design and an exclusive proprietary polymeric material that provide the viscoelastic behavior like that of natural disc. The FCD's viscoelastic properties resist excessive motion which results in strains on the surrounding anatomy (facets, etc.) and resulting pain. The lordotic angle of the FCD will help sustain the normal lordotic curve, aiding in the prevention of segmental flat neck syndrome experienced after many fusion and TDR surgeries.

Durability Assessment

Dynamic biomechanical tests of the FCD 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 supra-physiologic, or extreme, loads and ranges of motion not typically observed *in vivo* to obtain functional failure of the FCD.

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 cervical disc, as published in the clinical literature.

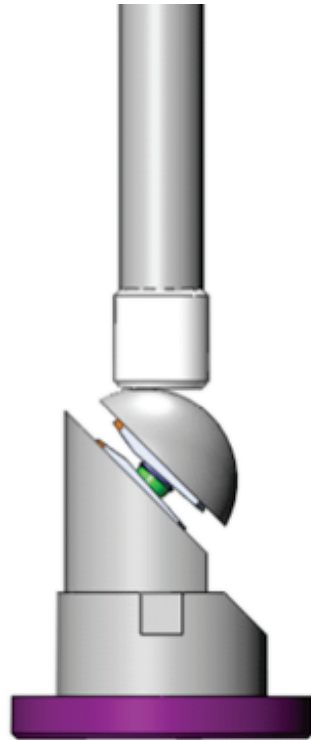


FIGURE 1:
FREEDOM CERVICAL
DISC (FCD)

The FCD is a next generation TDR designed to mimic the function of the human disc.

COMPRESSION FATIGUE / WALKING

Compression fatigue testing was used to predict long term *in vivo* performance of the FCD. 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.



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

Figure 2:
45° Compressive Shear Test Set-Up

45° COMPRESSIVE SHEAR / BOND DURABILITY

45° compressive shear fatigue testing was used to evaluate the durability of the bond between the FCD 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.

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

Wear testing is conducted to characterize the wear debris that may be generated by an artificial disc. 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. 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 FCD, C-55708. 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. (Colorado Springs, CO) according to ASTM F 2346-05, "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 F2423-11, "Standard Guide for Functional, Kinematic, and Wear Assessment of Total Disc Prostheses".

Compression and compressive shear fatigue tests were conducted in load control at a testing frequency of 3 Hz. A study of the FCD at different testing frequencies demonstrated that the response of the polymer core to the applied load did not change significantly from a frequency of 2 to 3 Hz. It should be noted that studies using higher frequencies with a viscoelastic polymer actually strain shield the polymer due to the deformation delay that occurs with viscoelastic polymers at high frequencies.



FIGURE 3: WEAR TESTING SET-UP

FCD test specimens were tested for 10,000,000 cycles in flexion/extension and 10,000,000 cycles in lateral bending coupled with axial rotation, all under the specified compressive pre-load. A test set up for two test devices is shown in Figure 3. Three discs were tested first in flexion/extension and then in lateral bending and rotation, all at a loading frequency of 2 Hz. Another three discs were tested in reverse order. All tests were conducted in displacement control, with applied flexion of 9°, extension to 6°, lateral bending of $\pm 6^\circ$, and rotation of $\pm 6^\circ$. All testing included a constant axial compressive load of 100 N. Test conclusion was defined per ASTM F2423-11 as 30 million device cycles (10M flexion/extension + 10M lateral bending + 10M rotation).

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.

A study of the FCD at different testing frequencies demonstrated that the response of the polymer core to the applied load did not change significantly from a frequency of 2 to 3 Hz.

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

Solutions for each test device were collected at 1, 3, 5, 10, 11, 13, 15 and 20 million machine cycles throughout testing, and analyzed by RJ Lee Group (Waynesburg, PA) and Orthokinetics (Shallotte, NC). Analyses included filtering of test solutions to collect debris, weight measurements of debris, and microscopy of particulate.

Results

All test results met the objective failure criteria.

In compression, the objective failure criterion was that the worst case device size must survive two times the average daily living (ADL) load for 50 million cycles with no mechanical or functional failure other than height loss of less than 33%. The average daily living load was estimated to be 100 N based on cadaver studies by Miura and Przybyla), and a height loss of < 33% represents mild disc degeneration (grade 1) per Kettler’s radiographic grading system for the human disc. Two devices were tested and survived 50 million cycles at twice the ADL load (200 N) with no mechanical or functional failures.

Based on the estimate of one million steps per year, ten million cycles in a compression fatigue test is considered to be the equivalent of 10 years simulated use. The Freedom Cervical 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 mechanical and/or functional failures. At loads from 2,100 N to 3,500 N, mechanical or functional failures were generated. Data is shown in Table 1 and Figure 4. One device completed 10 million cycles with no functional failures at 800 N, and another at 1,250 N. The dynamic stiffness of each test specimen was recorded throughout each long-term test. Figure 5 shows that the dynamic stiffness remains constant throughout testing, even at the supra-physiologic loads of 800 and 2,150 N. This finding demonstrates that the FLD retains its mechanical integrity and performance throughout the equivalent of 50 years of simulated walking loads.

TABLE 1: SUMMARY OF COMPRESSION FATIGUE RESULTS

APPLIED LOAD (N)	CYCLES TO FAILURE OR END OF TEST	DYNAMIC STIFFNESS @ 1,000 CYCLES (N/mm)
3,500	62,681	4,500.00
3,000	2,215,398	3,824.36
2,750	993,151	3,105.40
2,400	1,808,424	2,627.74
2,100	1,163,490	1,968.75
1,250	10,000,000 +	1,415.09
800	10,000,000 +	1,161.29
200	50,000,000 +	900.00
200	50,000,000 +	818.18

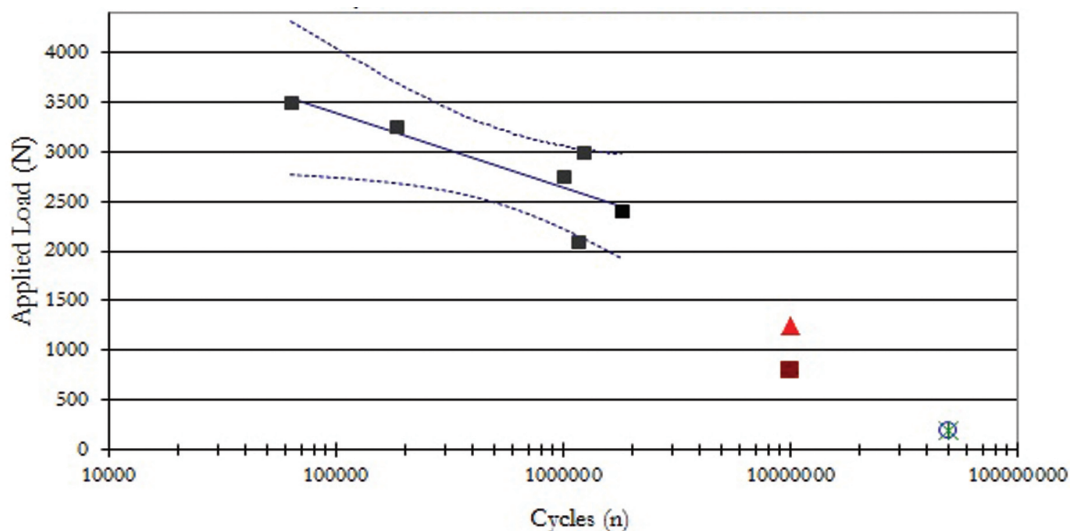


FIGURE 4: COMPRESSION FATIGUE CURVE WITH CONFIDENCE INTERVALS

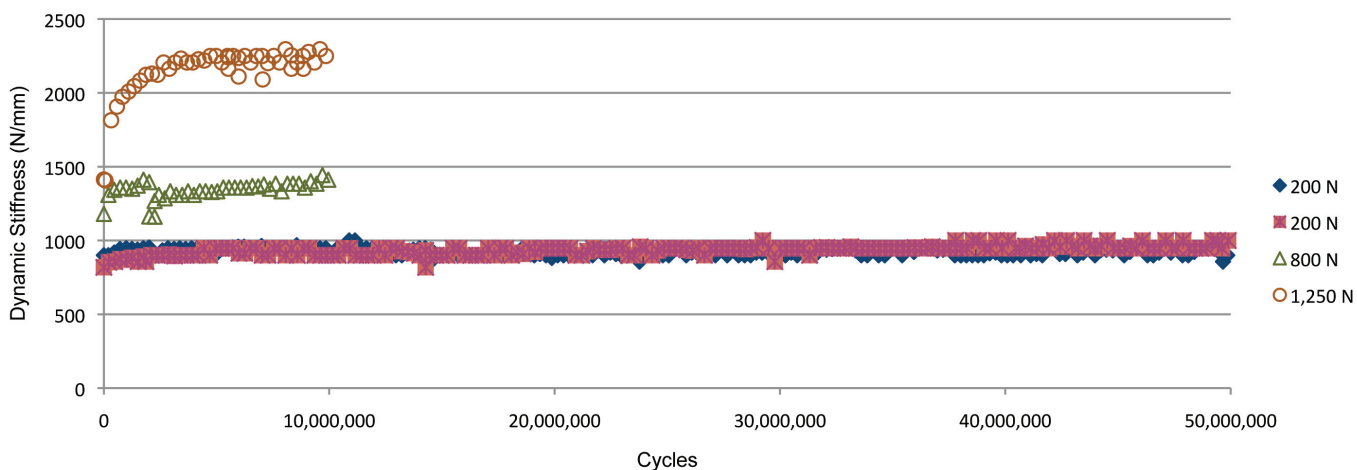


FIGURE 5: DYNAMIC STIFFNESS IN COMPRESSION

Objective failure criteria for dynamic compressive shear was to withstand twice the average daily living load (ADL) load of 20 N anterior shear, which translates to 28 N in 45° compressive shear, for 10 million cycles with no functional failure. This OFC is based on the findings documented by Patwardhan and Moroney that the shear loading component is approximately 10% of the compression load in the cervical spine. The average daily living compression load in the cervical spine is approximated at 100 N (Miura). Therefore, the shear load of 10% is 10 N. 20 N was chosen as a 2X safety factor for the OFC.

As in compression, it was desired to generate a fatigue curve, causing mechanical or functional failures of the device at all but the endurance limit load. The data is included in Table 2 and Figure 6. Note that tests which reached 10 million cycles were stopped without evidence of failure. 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 200 N in 45° compressive shear corresponds to an anterior shear load of 141 N, which is 7 times the OFC load of 20 N anterior shear.

TABLE 2: SUMMARY OF 45° COMPRESSIVE SHEAR FATIGUE TESTING OF FCD

APPLIED LOAD (N)	CYCLES TO FAILURE OR END OF TEST	DYNAMIC STIFFNESS @ 1,000 CYCLES (N/MM)
480	187,162	205.71
480	190,814	209.51
440	612,712	260.53
390	919,087	217.20
360	2,388,659	224.84
340	1,951,564	242.86
250	10,000,000 +	273.06
200	10,000,000 +	278.64

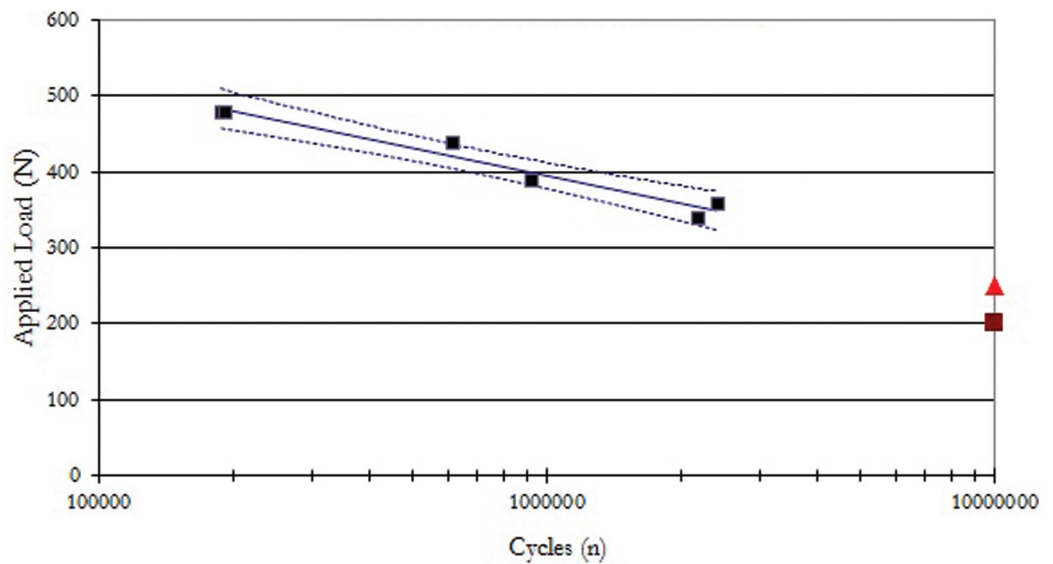


FIGURE 6: 45° COMPRESSIVE SHEAR FATIGUE CURVE WITH CONFIDENCE INTERVALS

The objective failure criteria for wear testing was to complete wear testing per ASTM F2423 with no functional failures and with wear amounts in the range of competitive products on the market. All six test specimens reached 30 million device cycles (10M flexion/extension + 10M lateral bending + 10M rotation) with no mechanical or functional failures. Per Hedman's estimate of 125,000 significant bends per year, 30 million device cycles corresponds to 240 years of simulated significant bends.

There were no mechanical or functional failures through 240 years of simulated significant bends, or 80 years of significant bends in each of flexion/extension, lateral bending and rotation.

Particulate analysis showed that the wear rate of the FCD is 0.028 mg/million cycles, with 0.016 mg being CarboSil polymer and 0.012 g being titanium. The average particle diameter is 1.73 µm for CarboSil polymer and 0.98 µm for titanium.

There were no mechanical or functional failures through 240 years of simulated significant bends, or 80 years of significant bends in each of flexion/extension, lateral bending and rotation.

The particulate generated by the FCD was compared to the wear data for other commercially available cervical total disc replacements for which wear data was available (Prestige, Bryan and ProDisc-C), shown in Table 3. The total particulate generated during wear testing of the FCD was lower than the particulate generated from commercially available cervical TDRs. Thus, the OFC have been met.

It should be noted that each device in Table 3 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 FCD falls well below the range of the wear rates of the three U.S. commercially available cervical total disc replacements.

TABLE 3: WEAR DATA FOR FCD VS. COMPETITIVE CERVICAL TDRs

	FREEDOM	PRESTIGE	BRYAN	ProDisc-C
Wear Rate (mg/million cycles)	0.028	3.3	1.2	2.59
Particle Size (µm)	Mean 1.73 polymer Mean 0.98 titanium	0.13 to 1.58	10 to 150	Mean 0.17 to 0.35 Total 0.04 to 1.65
Method Description	Total 30M cycles ASTM method: 10M +9°/-6° flex/ext + 10M ±6° lat bend coupled with ±6° rotation	Total 20M cycles Neither ASTM nor ISO method: 5M cycles ±4.7° lat bend coupled with ±3.8° rotation + 10M cycles ±9.7° flex/ext	Total 30M cycles Neither ASTM nor ISO method: ±4.9° flex/ext and/or lat bend coupled with ±3.8° rotation	Total 30M cycles ISO method: all motions coupled: ±7.5° flex/ext, ±6° lat bend, ±4° rotation

In summary, long term fatigue testing of the Freedom Lumbar Disc has demonstrated that the worst case device size can withstand at least 50 years worth of simulated walking loads as well as significant bends.

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Conclusions

The Freedom Cervical Disc demonstrated a fatigue life in excess of 50 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.

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