Freedom® Lumbar Disc Polymer-Metal Bond Integrity

CAUTION: Investigational device.
Limited by Federal law to investigational use.

Abstract

To re-establish function of the lumbar spinal segment, a total disc replacement (TDR) must: re-establish flexibility and natural resistance while creating stability; provide viscoelasticity to mimic the dynamic stiffness and load sharing in the natural disc; preserve physiologic range of motion (ROM) in flexion, extension, lateral bending, rotation, and compression, and; provide the correct spine alignment and lordosis. In order to provide all of these properties, the ideal TDR must incorporate a viscoelastic core to provide the appropriate mechanical properties and a boney ingrowth surface for fixation to the vertebral bodies. These individual critical components must be bonded to each other to ensure load transfer and resistance to excess motions or loads, as well as maintenance of lordosis.

The Freedom Lumbar Disc (FLD) utilizes metal retaining plates as a proven bone interface material and a viscoelastic core to mimic the mechanical properties of the healthy human intervertebral disc. The retaining plates are bonded to the polymer core, allowing for load transfer to the polymer which subsequently "controls" device performance and therefore segmental function. While the bond is critical in restoring function to the spinal segment, the bond is the potential "weak link" in product performance. For this reason, every aspect of the FLD bond between its retaining plates and core has been optimized and extensively tested.

The polymer-to-metal interface incorporates a composite bond; both chemical and mechanical bonds are employed that have been optimized to maximize bond strength and durability. Additionally, the FLD contains design features that shield the interface from stress during loading. Static and dynamic mechanical testing under both physiologic and supra-physiologic loads was conducted to characterize the strength and durability of the FLD bond.

Biomechanical testing has predicted an anticipated product life exceeding 40 years. The bond strength is 2.7 times that of the natural disc, and the device can withstand 7 times the amount of translation (sagittal shear) experienced by the human lumbar disc without failure. Dynamic testing demonstrated that the FLD has excellent bond durability, surviving 10 million cycles at a shear load more than three times the highest load anticipated in vivo. Additionally, clinical studies are underway, in which patients implanted for up to four years have had no device mechanical failures.

Figure 1: FLD

FLD Description

The Freedom Lumbar Disc (FLD, Figure 1) is designed with the goal of restoring function to the spine in degenerative disc disease (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 and facets.

The FLD is a one-piece viscoelastic total disc replacement (TDR) consisting of an elastomeric core bonded to titanium retaining plates. Each retaining plate also incorporates an end cap as part of its design. The FLD retaining plates and end caps are manufactured from titanium alloy and contain features on the bone-interface side to provide both short-term fixation (rails) and long-term fixation (beaded coating) 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 – a proprietary polymer exclusively licensed to AxioMed.

During manufacturing, the retaining plates are mechanically and chemically adhered to the core with proprietary bonding techniques. The chemical bond is achieved by meticulous cleaning and preparation of the titanium surface, followed by application of an adhesive. The mechanical bond is achieved by increasing the surface area of the plate's bonding area and including areas for the polymer to infiltrate and "lock in". This composite bond provides superior bond strength and durability along the metal-to-core interface compared to mechanical attachment of the polymer core to metal plate alone.

The FLD's patented design shields the bonded area against areas of increased internal stresses along the polymer-metal interface. The retaining plates are domed to optimize surface area with the core and minimize internal stresses. Additionally, the FLD retaining plates have a smooth flange around the periphery which supports the polymer core at higher loads and shields the bonded area.

The figure below shows a cross-sectional view of the FLD and a Finite Element Analysis (FEA) of the FLD under compression. The lowest stress areas are shown in dark blue. Higher stresses are seen in areas that are light blue and green, and the highest stress areas are shown in yellow.

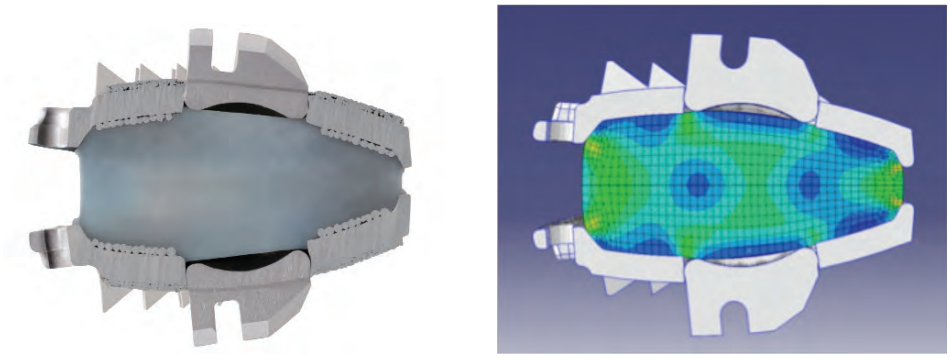

Figure 2: Cross section of FLD and cross section of FLD in FEA analysis

FLD Function: The Importance of a Bonded Device

The FLD system aims to re-establish the function of the lumbar spinal segment, augmenting the existing anatomical structures. 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.
- Provide the correct spine alignment and lordosis.

These aims are 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 end cap and retaining plate and expands radially along the polymer annulus, as shown in Figure 3. Both of these features are limited by the metal interface to control stiffness.

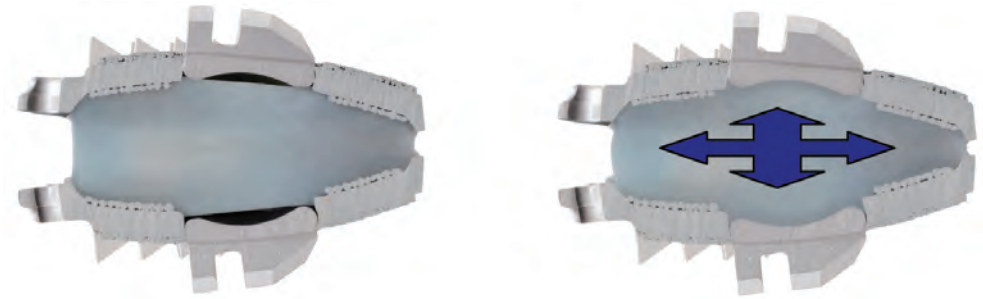

Figure 3: Cross-section of FLD unloaded (left) and under axial compression (right)

The core is bonded to the retaining plates to ensure load transfer from the spine to the core while allowing the core to respond viscoelastically. In non-bonded TDRs, compressive loads are transferred through the device to the next spinal level. The non-bonded device does not have the capacity to maintain stiffness and constrain excess motion. The bonded design allows the device to provide healthy segmental stiffness and motion while preventing excess motion of the segment, thereby maintaining stability.

Biomechanical Assessment

Static and dynamic biomechanical tests of the FLD were conducted to demonstrate the device's strength and durability, respectively, and characterize failure modes under different loading conditions. 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.

All mechanical testing was conducted on the worst case size FLD, which has a 26 x 36 mm footprint, 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, smallest polymer volume, and smallest bonding area. Many of the device's biomechanical capabilities, specifically device stiffness and range of motion, are provided by the polymer core 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.

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. All test results met the objective failure criteria.

Biomechanical testing of the worst case sized FLD showed that:

- The FLD survived 50 million simulated walking cycles at twice the average daily living (ADL) load (2,400 N) with no mechanical or functional failures, corresponding to 50 years of simulated walking.
- The FLD survived 30 million device cycles (10M flexion/extension + 10M lateral bending + 10M rotation) with no functional failures, which corresponds to 240 years of simulated significant bends.
- The FLD demonstrated a compressive strength more than three times the load required to fail a human disc.
- The FLD will withstand rotations in excess of ten times those seen in studies of the human disc without failing.
- The bond strength and durability were demonstrated in each of these testing modes, in that there were no failures of the bonded areas.

Although the bond strength and durability are evaluated during testing in the physiologic loading modes of compression, flexion, extension, rotation and lateral bending, a more severe compressive shear test is used to evaluate bond strength and durability specifically. 45° compressive shear testing was used to evaluate the strength (static test) and durability (fatigue test) 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. 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.

Static 45° compressive shear testing was conducted to determine FLD bond strength. The objective failure criterion was that the worst case sized device withstand 3,000 N anterior shear with no mechanical or functional failure, based on the clinical finding that failure of the human lumbar disc in anterior shear occurs at this load (Jager). Photos of a disc in the 45° compressive shear test fixtures are shown in Figure 4. The device retaining plates are held within the fixture and do not show in the photos.

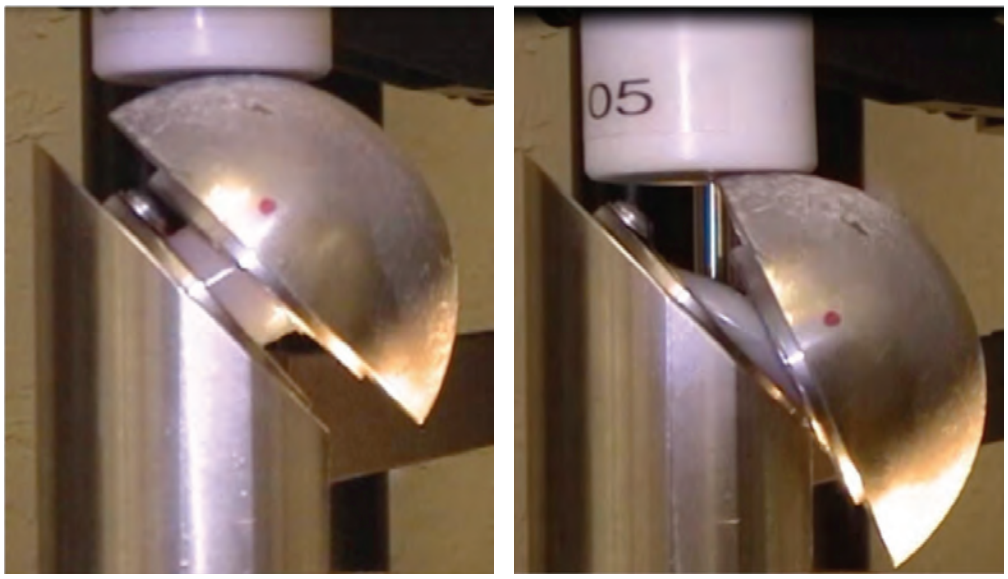

Figure 4: FLD at the start (left) and at the end (right) of a static 45° compressive shear test

There were no mechanical or functional failures at 3,000 N anterior shear. To address the OFC, the loads applied in 45º compressive shear were converted using geometry equations to the anterior shear and pure compression components. The ultimate strength of the FLD is 8,102 N (mean of the tested group), which corresponds to a 45° compressive shear load of 5,729 N. Thus the worst case FLD has an anterior shear strength 2.7 times higher than the OFC. The displacement of the top plate over the bottom at 8,102 N was an average of 19.6 mm. The range of motion of the human lumbar disc in sagittal shear has been reported to be from 0.6 to 2.8 mm (Berkson, Posner, Ashton-Miller); the FLD demonstrates more than 7 times that amount of motion before failing.

The objective failure criterion for dynamic 45º 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 presentation, Han). The average daily living load was estimated based on the loads on the lumbar spine for many activities reported by Nachemson. 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.

The FLD survived 10 million cycles in 45° compressive shear at a load of 1,200 N, corresponding to an anterior shear load of 1,697 N, or 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. These results demonstrate the excellent bond durability of the FLD.

Conclusions

The Freedom Lumbar Disc design – elastomeric core bonded to metal end plates – provides the properties needed to restore function to a lumbar segment with degenerative disc disease: spinal alignment, lordosis, flexibility and natural resistance (stability), and viscoelasticity to mimic the dynamic stiffness and load sharing in the natural disc, providing physiological range of motion in flexion, extension, lateral bending, rotation, and compression.

The polymer to metal bond is critical to the performance of the FLD. The bond technology incorporates both chemical and mechanical bonds developed and optimized to maximize bond strength and durability. Additionally, FLD design features were established to shield the bonded areas from stress during loading.

Static and dynamic mechanical testing under both physiologic and supra-physiologic loads was conducted to characterize the strength and durability of the FLD bond. Testing demonstrated that the bond strength is 2.7 times the load at which the natural disc fails in sagittal shear, and the device can withstand 7 times the amount of translation (sagittal shear) experienced by the human lumbar disc without failure. Dynamic testing demonstrated that the FLD has excellent bond durability, surviving 10 million cycles at a shear load more than three times the highest load anticipated in vivo.

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