The Benefits of a Viscoelastic Lumbar Total Disc Replacement

CAUTION: Investigational device.
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Abstract

The natural disc provides for tri-planar (three-dimensional) motion: flexion and extension (sagittal plane); lateral bending (frontal plane); rotation, and compression (axial plane). It is viscoelastic, in that the degree of stiffness varies with the frequency of any load, and is complaint under loading (shock absorber). To restore the disc function to a degenerated segment, an artificial disc should mimic the properties of the natural disc as closely as possible, including viscoelasticity.

The Freedom® Lumbar Disc, by incorporating these essential properties of the normal disc, has the potential of improving on the mediocre clinical results of first generation technologies which are not viscoelastic. 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.

The viscoelastic properties of the FLD allow this TDR to provide the properties of the natural disc – restoration of lordosis, restoration of natural motion, resistance to excess motion (or provision of stability), and protection of the surrounding anatomy from excess stress – which are not provided by the lumbar TDRs currently available.

Degenerative Cascade

Low back pain (LBP), secondary to DDD of the lumbar spine, is the leading cause of pain and disability in adults in the U.S. It is estimated that direct and indirect expenditures for LBP in the U.S. exceed 40 billion dollars annually. The vast majority of LBP patients will respond to one or more conservative therapies such as medications, bracing, physical therapy, etc. However, approximately 20% of patients are unresponsive and develop chronic LBP. It is this 20% of chronic LBP patients that are ultimately responsible for 80% of the markedly accelerating expenditures for treatment of what some have termed an "epidemic" of LBP. For patients who cannot be treated successfully with conservative care, lumbar spinal arthrodesis and lumbar disc arthroplasty are surgical options.

Degenerative changes in the intervertebral discs have been defined in three phases by Kirkaldy-Willis; dysfunction, instability and stabilization. The progressive degenerative changes to the discs and facet joints in these phases are illustrated in Figure 1.

Facet Joints		Intervertebral Disc
Synovitis Hypomobility	**Dysfunction**	Circumferential Tears Radial Tears
Continuing Degeneration Capsular Laxity Subluxation	**Unstable Phase**	Internal Disruption Disc Resorption
Enlargement of Articular Processes	**Stabilization**	Osteophytes

Figure 1: Kirkaldy-Willis Degenerative Cascade

The ideal treatment for degenerative disc disease (DDD) will provide stabilization and function similar to those of a healthy segment.

Fusion

Fusion has been the standard surgical treatment for chronic LBP for over 50 years. Advances in technology such as pedicle screw fixation, bone graft substitutes to avoid the pain and risk of iliac crest bone grafting, and minimally invasive techniques have led to fusion rates approaching 100%, shorter hospital stays and fewer complications. However, despite these advances and the attainment of safer and more predictable fusions, there has been little if any improvement in patient-assessed health status. In fact, there seems to be little correlation between a radiographically successful fusion and relief of pain or diminished disability.

Published data indicate that only about 75% of fusion patients experience any clinical benefit. Only half will experience major or complete relief of pain or recovery of function. Anticipated re-operation rates within ten years are reported to be between 10% and 25%. Additionally, fusion may increase the incidence of degeneration of adjacent levels.

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Total Disc Replacement

Patient and physician dissatisfaction with fusion has intuitively led to the concept that removal of the symptomatic disc with maintenance of motion will improve clinical results. In contrast to fusion, TDR is designed to preserve motion of the diseased segment and possibly provide greater pain relief, diminished disability and earlier return to activity. Fusion treatments of symptomatic lumbar DDD have been shown to increase intradiscal pressure and motion at levels adjacent to the fusion. These two factors are thought to be contributory to the clinical occurrence of radiographic and symptomatic DDD at the levels adjacent to lumbar fusion. However, there are those who would argue that the adjacent level degeneration (ALD) seen post-fusion is the natural progression of DDD in the lumbar spine rather than the consequence of fusion. Nonetheless, preservation of motion with TDR has the theoretical advantage of diminishing the incidence of adjacent level degeneration seen post-operatively in lumbar fusion patients.

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First Generation Technologies

History

The concept of TDR is not new. Fernstrom implanted stainless steel balls into the disc spaces of patients with symptomatic DDD in the 1960s and is credited with being the first disc replacement surgeon. Follow-up of his 191 patients is very much incomplete, but it is known that there was some early pain relief. However, many patients failed to improve because the implants subsided into the vertebral endplates.

The success of hip and knee replacement over the past half decade for disorders previously treated with fusion of the joint is at least partially responsible for not only the surge in interest for TDR but many if not most of the early designs.

Since Dr. Fernstrom's first attempt to develop a surgical alternative to fusion for symptomatic DDD, there have been a plethora of TDR designs from the very simple to the very complex in an attempt to simulate normal intervertebral disc function by preserving motion. Inherent in most current designs is also restoration of disc space height and varying degrees of stability. The success of hip and knee replacement over the past half decade for disorders previously treated with fusion of the joint is at least partially responsible for not only the surge in interest for TDR but many if not most of the early designs. However, hips and knees differ vastly from the intervertebral disc in their energy absorption and kinematics.

Although clinical trials have been initiated with a multitude of designs, currently complete data is available from only three randomized controlled trials (RCTs) for lumbar TDR (Charite, Prodisc, Flexicore – Figures 1-3). These three non-inferiority trials randomized to fusion suggest that complication rates and patient generated outcome measures are at least as good as those for fusion (non-inferiority). The studies also show maintenance of disc space height and motion at the operated level. Longer term follow-up will be required to determine if the theoretical advantage of TDR over fusion to diminish the incidence of ALD will come to fruition.

These metal on metal or metal on polyethylene articulations lack the viscoelasticity necessary to replicate the shock absorbing function of the native disc.

The core materials utilized in almost all of the TDRs currently in the pipeline are either ultra-high molecular weight polyethylene (UHMWPE) or metal. These metal on metal (Maverick, Flexicore, Kineflex – Figures 4-6) or metal on polyethylene (ProDisc, Charite – Figures 2, 3) articulations lack the viscoelasticity necessary to replicate the shock absorbing function of the native disc.

Figure 2: Charite Disc (DePuy Spine)

Figure 3: ProDisc Lumbar (Synthes Spine)

Figure 4: Flexicore (Stryker)

Figure 5: Maverick Disc (Medtronic)

Figure 6: Kineflex (Spinal Motion)

Long term European experience has been reported by a number of authors. Lemaire (1997) described his experience with the Charité. Although he calls the Charite the "best disc replacement compromise yet", he also observed that the Charité provided only mobility and fell short of full restoration of the lumbar functional spinal unit. Furthermore, even though mobility and short-term results were favorable, he opined that the long-term clinical implications appeared to be sub-optimal. The factors that impeded the Charité from achieving long-term clinical success were described as facet arthritis and secondary facet pain.

Lemaire's observations have been confirmed more recently by a variety of analytical and clinical evidence suggesting that long-term implantation of the Charité or ProDisc device places the facets under abnormal and excessive loading, creating an environment for facet degeneration and reoccurrence of localized pain (Denoziere, Park, Phillips, Punt, van Ooij). This occurs because the first generation discs do not restore stability, but instead maintain the unstable phase in the degenerative cascade. Segmental stiffness similar to that of the natural disc is needed to prevent excess motion.

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Charite devices have been shown to become impinged on one area of the core and move at only one or neither of the two articulating surfaces (O'Leary 2005). Polyethylene based devices have also shown deformation and failure of their cores, while patients with metal on metal devices demonstrate increased levels of the metallic ions from the metals used to manufacture them. Although these first generation devices restore motion to the spinal segment, it is not natural motion and, as such, has potentially negative effects such as facet degeneration, failure to relieve pain and diminish disability with a resultant need for revision surgery.

Solution: Next Generation Technology

The natural disc provides for tri-planar (three-dimensional) motion: flexion and extension (sagittal plane); lateral bending (frontal plane); rotation, and compression (axial plane). It is also viscoelastic, in that the degree of stiffness varies with the frequency of any load, and is compliant under loading (shock absorber). The first generation discs restore only two-dimensional motion, provide no axial compression, and have no viscoelastic properties. Therefore, while current generation discs can maintain motion and restore disc height, they cannot replicate the natural motion and viscoelastic properties which are the primary native functions of the healthy intervertebral disc. The FLD, by incorporating these essential properties of the normal disc, has the potential of improving on the mediocre clinical results of first generation technologies.

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

Overview

The Freedom® Lumbar Disc (FLD) is a one-piece viscoelastic artificial disc consisting of an elastomeric core bonded to titanium alloy retaining plates with end caps. The FLD system intent is 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.

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 end cap and retaining plate and expands radially along the polymer annulus (Figure 7). Both of these features are limited by the metal interface to control the stiffness of the FLD.

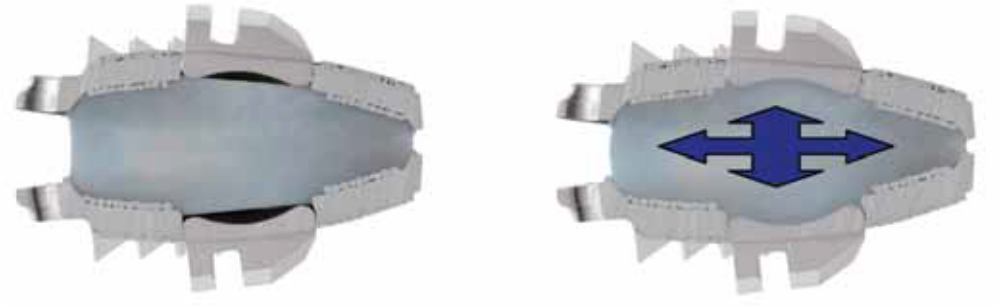

FIGURE 7: CROSS-SECTION OF FREEDOM LUMBAR DISC BEFORE AND AFTER COMPRESSIVE LOAD IS APPLIED

÷the segment implanted with the FLD has similar quality and quantity of motion to the intact spinal segment.

The ability of the FLD to re-establish function in the spine was demonstrated in a cadaver study. The intact spine was cycled through 8 Nm in flexion and 6 Nm in extension. Then, a disectomy was performed, and the FLD was implanted at L3/4. The overlying curve demonstrates that the segment implanted with the FLD has similar quality and quantity of motion to the intact spinal segment. The quality of motion is demonstrated by the shape of the curve.

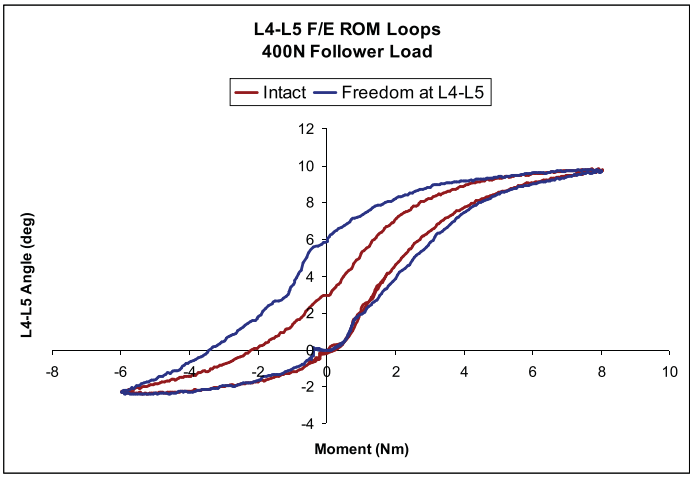

FIGURE 8: MOMENT VS. ANGLE OF THE FLD COMPARED TO THE NATURAL DISC IN FLEXION AND EXTENSION
(Patwardhan A, Voronov L, Havey R; Musculoskeletal Biomechanics Laboratory at Loyola University Chicago Stritch School of Medicine, Chicago, IL.)

Biomechanically, the device has demonstrated strength surpassing that of the surrounding anatomy, without failure. Additionally, devices have shown excellent durability under extreme loading conditions.

The FLD device has been shown to have properties similar to the natural human lumbar disc.

The FLD device has been shown to have properties similar to the natural human lumbar disc. The FLD core is a viscoelastic polymer, exhibiting higher stiffness with higher load or higher frequency of loading. The natural disc is also viscoelastic. The stiffness of the FLD has been found to be in the ranges of stiffness for the natural disc which are published in the clinical literature.

Property	Ball & socket discs	Freedom Lumbar Disc
Restoration of Disc Height	✓	✓
Restoration of Disc Angle		✓
Stiffness of the Natural Disc		✓
Motion	✓	✓
Shock Absorption		✓
Passive Restraint (Stability)		✓
Quality of Motion (mimicking that of the natural disc)		✓

Table 1: Freedom Lumbar Disc compared to Current 1st Generation Discs

A summary of the technologies for surgical treatment of DDD, with their advantages and disadvantages, is shown in Figure 9.

Stability	Stability + Function	Motion
Fusion	Natural Disc Freedom Disc	Ball & Socket Discs
		
Advantages Restoration of height Stabilizes segment	**Advantages** Viscoelasticity Restoration of height Restoration of lordosis Restoration of natural motion Resists excess motion (stability) No excess stress on surrounding anatomy	**Advantages** Restoration of height Provides motion
Disadvantages No motion Excess stress to adjacent levels No shock absorption	**Disadvantages**	**Disadvantages** Excess motion (instability) No shock absorption Excess stress to facet joints Excess stress to adjacent levels

Figure 9: Summary of Technologies for Treatment of DDD

Prior Elastomeric Lumbar Disc Clinical Trials

Polymeric disc clinical experience began with Dr. Arthur Steffee, the inventor of the AcroFlex lumbar disc. Three generations of the AcroFlex lumbar disc (DePuy Spine, a Johnson & Johnson company) were utilized in several pilot studies and/or custom implantations. All three generations of the device incorporated titanium alloy endplates and an elastomeric core bonded to the metal plates.

The first generation disc incorporated a hexane based polyolefin rubber and adhesive system and was implanted in six patients (Enker 1993). Satisfactory results (one excellent, two good and one fair) occurred in four of the six patients to three years follow up. The second generation device was approved by FDA in 1993 for implantation into 13 patients, but results have not been published (Traynelis & Haid, www.spineuniverse.com). The second generation device had a silicone elastomer core. The company abandoned silicone technology due to concerns for the public acceptance of silicone as a suitable biomaterial.

The 3rd generation AcroFlex lumbar artificial disc also used a hexane based polyolefin rubber and adhesive. These discs had either flat endplates with a raised crescent (Version A, Figure 10) or slightly domed endplates with six teeth for short term fixation to bone (Version B, Figure 11). Both 3rd generation discs had a sintered bead coating for boney in-growth.

Figure 10: Version A

Figure 11: Version B

Three prospective, non-randomized pilot studies were conducted with the 3rd generation AcroFlex disc (Fraser 2004).

1. Eleven patients received a one level disc replacement with version A (Figure 10) in 1998 and 1999 in Adelaide, Australia (Pilot 1).
2. Seventeen patients received version B (Figure 11) in 2000 in Adelaide, Australia, with either one or two level disc replacement (Pilot 2).
3. Thirteen patients received version B (Figure 11) in 2001 in Manchester UK (Pilot 3).

Results:

- There was a partial anterior displacement of a device in one Pilot 1 patient, but revision surgery was not required.
- Serial thin section CT found rubber tears in the devices in 36% of patients in Pilots 1 and 2. Seven patients from pilots 1 and 2 underwent revision surgery.
- Cracking of the rubber and osteolysis were found in all of these patients. The devices were removed from three patients prior to fusion, while the other four patients were fused around the devices.
- In pilot 3, there were seven cases of anterior displacement of the implants, with revision surgery required in three patients within two years.
- The outcome instruments demonstrated significant improvement from baseline to 12 months follow up and to two years follow up in pilot 1 patients, and the overall clinical results up to two years appeared to be satisfactory. Planned randomized studies were not carried out for the third generation AcroFlex disc due to the finding of mechanical failures in the elastomer cores (Freeman 2006).

The Freedom™ Lumbar Disc (FLD) system recognizes the strengths of the AcroFlex disc while incorporating advanced technology to overcome recognized weaknesses. The Freedom Lumbar Disc incorporates a vastly superior polymer, design features that improve the implant's long-term viability, and well established methods for manufacturing and sterilization.

Points to Consider

- The natural disc is viscoelastic and constrains motion.
- Fusion provides no motion or function, only stability.
- First generation TDRs:
  - Are not comprised of viscoelastic materials.
  - Do not provide shock absorption and passive resistance, but transfer load through the spine.
  - Do not have the same stiffness as the human disc and will therefore not provide the quality and appropriate range of motion.
- A one-piece elastomeric TDR comprised of a viscoelastic material with the same stiffness as the natural disc will:
  - 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.
  - Restore natural function to the lumbar spine:
    - Natural function = relief of pain and disability
    - Natural function = stability + compression + motion

	Stability	Compression	Motion
Human Disc	✓	✓	✓
Fusion	✓		
1st Generation TDR			✓
Freedom®	✓	✓	✓

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