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ME 598 - Orthopedic Biomechanics
December 12, 2018

Spine Implant + FEA

I. Introduction

I.1 Clinical Problem

Clinical Need for Implant

Lower back pain (LBP) is the leading cause of long-term disability worldwide.[1] Degenerative disc disease (DDD) is a spinal condition involving the natural deterioration of the intervertebral disc, requiring an artificial disc implant. It is one of the most common causes of LBP alongside lumbar spine osteoarthritis, the degeneration of synovial facet joints.[2] Other causes of LBP include: disc herniation, spondylolysis, and spondylolisthesis; however, isolating a single cause is often difficult as multiple conditions may be present at the same time.[3]

Prevalence, Incidence, Burden, Secondary effects

The cost associated with medical treatment for LBP in the United States is estimated at $26 billion annually, with an additional $25-50 billion in indirect or societal costs due to lost wages and workers' compensation related to the duration of the treatment and recovery.[4] The direct costs come from approximately 19 million office visits, 225,000 medical admission, 300,000 laminectomies, and 300,000 lumbar spinal fusion procedures.[5] In United States, back pain is the fifth leading cause of admission to the hospital and the third most common cause for surgical procedures.[6] The intervertebral discs are flexible at a young age, but naturally stiffen leading to an increase in LBP in adolescence and again around age 40-50, declining thereafter.[7] It is also more prevalent in women; however, the difference is not significant.

Alternative Treatment Options

Left untreated, lower back pain will persist and potentially worsen as degradation continues. Patients may adapt to the pain by developing inappropriate postures. Prolonged periods of inappropriate postures cause the muscles to adapt by lengthening or shortening to accommodate the unnatural state. This may lead to a muscle imbalance, inducing further structural damage and subsequent pain.[8]

With the high incidence of LBP, non-invasive treatment options such as physical therapy and anti-inflammatory medications are preferred. When unsuccessful, severe pain persists and structural damage may continue. Depending on the cause of the LBP, a laminectomy or discectomy may be performed. These procedures relieve pressure on the spine, but do not always resolve the issue. The most common method of stabilizing the lumbar spine is fusion or fixation of the associated segments. The consequences of this procedure are a limited range of motion, adjacent segment degradation, and sagittal imbalance. The surgical methods require extensive exposure and a longer recovery time.[8a] A soft interspinous spacer was introduced as a solution for this issue in 1997.[9] This spacer improved range of motion, but was not able to restore flexion-extension to a normal working range.[10] The best method to relieve pain and restore joint function is a total lumbar disc replacement, which is accompanied by its own set of negative side effects.

I.2 Joint Description

General Anatomy (bones, relevant ligaments, other tissues)

The spine is made up of 33 vertebrae divided into 5 sections. The lumbar spine is a section of the lower back where the spine curves inward towards the abdomen. It consists of five vertebrae (L1-L5) and resides below the thoracic spine, extending down into the sacral spine (A.2, Figure 1). The lumbar vertebrae support the weight of the entire torso while allowing for lifting, twisting, and bending. In between vertebrae are intervertebral discs which provide shock absorption, stability, slight movement within the spine, and maintain proper spacing. Posterior to the disc, there are also two facet joints in between vertebrae. These synovial joints guide and limit movement within the spine. The intervertebral disc is made up of an outer fibrous ring known as the anulus fibrosus surrounding the gel-like nucleus pulposus (A.2, Figure 2). The anulus is made up of several layers of fibrocartilage with type I cartilage on the edge as the stiff laminae can withstand compressive forces. The nucleus pulposus helps distribute pressure evenly across the disc while also absorbing shock. A third component of the intervertebral disc joint are the vertebral end plates. It is debatable whether they belong to the vertebrae or the discs, however, they are still important, as they separate the disc from the vertebral bodies.[11]

Degrees of Freedom and Joint Kinematics

The vertebrae and disc allow for motion in all 6 degrees of freedom. In the sagittal plane, the lumbar region can rotate about 40-60 degrees in flexion and 20-35 degrees in extension. In the coronal plane, the lumbar region can rotate about 15-20 degrees in lateral bending. Lastly, the lumbar region can rotate about 3-18 degrees axially (A.2, Figure 3 and 4).[12] The facet joints restrict the rotation of the vertebrae, protecting the segment from anterior shear forces and excessive rotation and flexion. The angulation and geometry of these joints differ along and even within the sections of the spine (A.2, Figure 5). For example, the facets in the L2-L3 and L3-L4 are oriented relatively more parallel to the sagittal plane, allowing limited rotational movements while aiding in flexion and extension. However, the L4-L5 facet joints have increased coronal angulation, facilitating greater rotational movements.[13] For translation, the spine can move in laterolateral shear, anteroposterior shear, and axial compression/decompression. Compression of the disc causes pressure within the nucleus pulposus in all directions, placing the anulus fibrosus under tension, which can lead to deformation near the center of the endplate (see A.2, Figure 6). Shear and twisting forces tense the fibers in the direction of movement and relax the fibers in the opposite direction while tension tenses all fibers, regardless of direction (see A.2, Figure 7).

Age, Gender, Training or Culture Effects on Range of Motion

While LBP is prevalent in a wide range of age groups, severe pain is commonly associated with those around 50-years or older. The curve of the lumbar spine is more pronounced in females, resulting in an increased ROM in individual lumbar vertebrae (A.2, Figure 8).[13] Muscles in the lumbar region are more prone to injury than their opposing muscle group, the abdominal muscles. The lower back muscles have a shorter moment arm because they are close to the spine. These muscles must generate relatively more force to keep the body balanced, inducing stress on the spine. Gradually, the discs will bulge and irritate the nerves, causing lower back pain. Lower

back muscles are often injured due to bad form during heavy lifting or poor posture. Being seated for extended periods is also associated with increased disc pressure and spinal hypomobility.[8]

II. Implant Design

II.1 Market Analysis

Possible Candidates

Artificial disk replacement is not appropriate for all patients with low back pain Generally, good candidates should have back pain caused by **one or two problematic intervertebral disks** in the lumbar spine since the TDR is replicating the spinal function of a single spinal disc. Partially constrained implants reduce the burden on facet joints, however, there are still significant facet joint loads. **Facet joint disease or bony compression on spinal nerves** will expedite degeneration of these joints. Since TDRs are mainly compressive load bearing, a lighter load is better for the implant durability, therefore body size that is **not excessively overweight** is recommended. Another exclusion criteria is **high pelvic incidence (more than 65 degrees)** since this will lead to arthritis and expedited degeneration of facet joints, thus reducing the integrity of the implant. **Translational deformities (spondylolisthesis or scoliosis)** are not be treated with a TDR as it is intended to restore spinal function, not stabilization. A candidate with **impaired motion due to segmental autofusion or poor bone quality** is not recommended since this will lead to fixation failure and vertebral body fracture.[3]

Implant History: Success Rate and Causes for Failure

The Total Disc Replacement (TDR) is a relatively old procedure, first taking place in the 1950s. However, it was recently adopted in the United States, where the first procedure was not performed until 2000. The TDR substitutes both the anulus fibrosus and nucleus pulposus of the affected disc with a mechanical device simulating spinal function. Typically, the implant is comprised of two cobalt chromium or titanium alloy end-plates with a polyethylene core in-between, a decision inspired by the more common knee and hip replacements.[14] There have been multiple design failures, allowing ample room for improvement on almost every design on the market to date. Disc replacements are classified by their range of motion: unconstrained, semiconstrained and fully constrained. Unconstrained TDRs reduce stress concentrations on the two bearing surfaces of the implant by allowing translation of the disc. They do not require perfect alignment because of a mobile center of rotation. The drawback of unconstrained designs is that they rely on surrounding structures for restraint during the extremes of typical range of motion, potentially increasing stresses on the facet joints. Semiconstrained implants began to replace unconstrained implants in the early 2000s because of their ability to withstand larger applied loads, reducing facet joint degeneration. However, the fixed center of rotation requires a more exact anatomic placement.[3] Fully constrained implants anchor the joint through stability. A list of existing implants, photos, and a short set of notes can be found in Appendix A.3, Market Research.

The most successful unconstrained implant was the Charite, created in the 1980s. In October 2017, the manufacturer of Charite, Johnson & Johnson, was sued due to multiple implant failures in patients, permanent health issues, as well as some life-threatening complications caused by the implant. European doctor, Dr. van Ooij, tracked hundreds of surgeries in Europe and treated at least 49 Charite patients who "suffered terrible leg and back pain after the device was implanted and many [who were] unable to undergo a surgical revision of the disc due to the dangers involved in spinal surgery". Mechanical testing revealed two component failures: the polyethylene cores were found to be flattened and broken creating wear debris and the press-fit fixation of the metal base failed through dislocation or bone fracture over time.[15] This unconstrained design proved to be problematic, leading to the partially constrained implants dominating the current TDR market.

Partially constrained disc replacements reduce the loading on surrounding structures, thereby reducing facet joint degeneration, one of the leading causes of lower back pain. Despite this improvement, these implants still have their own issues and failures. Design considerations with any implant are: durability, prosthesis migration, dislocation and debris particles from wear. Historically, implants have failed due to the loads and stresses on the vertebrae. The first disc replacement in 1950 comprised of a steel ball as a replacement for the nucleus pulposus. This design failed due to the excessive compressive load concentration which resulted in subsidence of the implant into the subchondral bone. A follow-up design involved the use of a silastic ball bordered by a horseshoe-shaped plateau; however, this design also failed due to subsidence.[15a] There were a few other designs that went through animal testing but never made it to clinical trials (A.2, Figure 10). An example is shown in Figure XX, Kostuik's articulating hinge on the posterior end of the disc with a spring maintaining spacing and providing shock absorption between the endplates. The next design was the SB Charite, created in the 1980s, comprising of a sliding ultra-high molecular weight polyethylene (UHMWPE) core between two metallic end plates. Once again, this implant failed due to stress concentrations resulting in subsidence of the shell-like end plates into the vertebral body.[3] The Prodisc and Prodisc II were released in the late 1980s, utilizing a single articulating interface between the superior metallic end plate and the polyethylene core which was fixed to the inferior end plate.[16] All partially constrained designs since have utilized this design with improvements revolving around increasing the lifetime of the implant durability and fixation methods. Johnson & Johnson's implant division, now Depuy Synthes, developed a new implant and acquired FDA approval through a PMA supplement; however, the device is not available on the US market. There are only two FDA implants that are available on the market in the US -- the activL by Aesculap Implant Systems and the ProDisc-L by Centinel Spine. Total disc replacements are one of the most involved solutions to degenerative disc disease. They allow for a greater range of motion than joint fusion but have not been adopted due to the complexity of the procedure and failure of the implants.

Market Analysis

Annual rates of lumbar ADR have decreased from 3059 cases in 2005 to 420 cases in 2013.[17] However, the North American artificial disc market is projected to reach $614.5 million by 2023

according to a report published by GlobalData.[18] Globally, The artificial disc market is projected to reach $3.3 billion by 2024 according to a report published by P&S Research (https://www.psmarketresearch.com/press-release/artificial-disc-market). Cervical discs make up approximately 68% of the market as they facilitate early postoperative neck motion and have a lower failure rate. Lumbar ADR have not achieved significant market adoption due to poor clinical evidence demonstrating superiority over spinal fusion along with a more complicated implantation procedure. The cost of an artificial disc varies around $10,000 (ProDisc-L) per device with a surgical cost between $12,000 (inpatient) and $40,000 (outpatient).[3]

II.2 Design Proposal

Design Decisions

Information was not found on the exact cost to manufacture implants; however, profit should not be an issue with the growing market. LBP is a huge drain on the economy and finding a solution which limits pain long-term while restoring joint function is critical for an individual to return to work. We decided to follow the success of previous implants in using a semiconstrained, metal on polymer design. Inspiration was drawn from the general shape of existing implants as manufacturing techniques are likely standardized. The novelty of our design comes from the surgical technique and the shape of the artificial disc. This unique design will require intensive computational and experimental testing before it can be considered for pre-market approval.

Implant Design CAD

Engineering drawings along with CAD images can be found in appendix A.3 “Our Design’.

Design Concept

Our design is an improvement inspired by implants that are on the market and FDA approved -- the *activeL* from Aesculap Implant Systems and the *ProDisc-L* from Centinel Spine. We decided to use a trapezoidal ridge that is 24mm long with 3 equally spaced holes to encourage bone growth through device, improving fixation. The ridge is not sharp and is short relative to the height of vertebrae to minimize stress concentrations. The superior and inferior plate are similar in shape. The inferior plate has a rectangular trench while the superior plate has a semicircle trench to allow rotation of the superior plate relative to the artificial disc and inferior plate. This design does not require a sheath to hold the core disc in place -- as found in the M6-L -- and is still constrained to prevent migration.

For the artificial disc, we wanted to restore kinematics in the same way as traditional spherical discs while eliminating known risk factors. The unique shape of the core restores joint function while limiting frictional wear during rotation. The decrease in contact area increases the stress in the top of the core, however, the components will not rub against each other during flexion-extension or lateral bending. The most wear will occur during rotation. Sharp edges were smoothed with fillets to avoid potential stress concentrations.

Surgical Tissue Removal

The spine is a difficult location for surgery. Lining the front of the spine is the aorta and vena cava, the main artery and vein directing blood to and from the heart. Behind the spine, traveling through the epidural space, is the spinal cord. Mistakes during a spinal procedure may lead to permanent reduction in mobility, paralysis, or severe blood loss. Most artificial discs use an anterior approach to the spine which includes retraction of the aorta and vena cava, ligation of several arteries and veins, and an incision in the anterior longitudinal ligament. This approach is inherently dangerous due to the proximity of major arteries and veins. It has also been shown to allow hypermobility in the joint, leading to facet joint degeneration, the leading cause of revisions after a TDR.[19] The surgical method for our implant is a lateral approach based on existing techniques for spinal fusion procedures and the XL-TDR implant. During the surgery, the only soft tissue that will need to be removed will be the diseased disc of interest. The disc will be accessed through the lateral side of the abdomen and all organs and tissues will be retracted. The diseased disc can then be removed. First, the outer anulus fibrosus is removed and then the interior nucleus pulposus. The joint is then distracted to visualize and remove any remaining disc tissue. Once the diseased disc is removed, the artificial disc will be implanted. The vertebral body will remain intact; however, a small cut will be made along the midline of the vertebral body to align the ridge of the endplate within the spine. This alignment is crucial for both joint mobility and protection of surrounding tissue. A lateral approach makes the measurements and incisions more difficult, however, the XL-TDR has an established procedure (A.2, Figure 9). One major drawback of the XL-TDR is dislocation due to poor fixation (A.2, Figure 11). Multiple x-ray's will also be taken during the procedure to ensure proper alignment.

Material and Fixation Specifications

Our implant design is constructed of three components manufactured from two different materials. Much like the current successful spinal implants found on the market, our implant will consist of two cobalt chromium end-plates with an ultra-high molecular weight polyethylene core. This material decision was motivated other successful joint implant designs such as total knee and hip arthroplasties. Metal-polyethylene implants have succeeded with long lifespans and relatively low revision rates. A metal-on-metal design could be a viable option for the artificial disk as it has little to no movement between components compared to joints like the knee or hip. However, the only metal-on-metal spinal implants -- Maverick, FlexiCore, and Kineflex-L -- have not been FDA approved most likely due to the increased wear debris which caused neurological problems in metal-on-metal hip replacements.[20] The lumbar spine carries the load of the entire spine, so it is safer to select materials that produce toxic particles in the event of wear.

The fixation method for our design is similar to current implants on the market. The implant will be a hybrid between partially and fully constrained since both ends of the polyethylene core are fixed into the end-plates, however, the superior connection is free to rotate but not translate. The inferior side of the polyethylene core will snap-fit into the superior side of the inferior end-plate. The implant in its entirety will be press-fitted into the bone via the ridges located on the superior side of the superior end-plate and the inferior side of the inferior end-

plate. This connection is made by cutting a slit into the bone through the midline of the vertebrae. The joint will then be distracted and the implant will be pressed into place using a mallet.

Negative Design Considerations

Our goal is to reduce the need for revision surgeries while restoring joint function. As with any new product, there are flaws that need to be addressed. Our complex artificial disc will be more expensive to produce, however, our end plates should align with market standards. The biggest issue with the core is the load distribution. The hemispherical core design distributes the load across a larger area. Our "X" shape design will see increased stresses at the points of contact with the end-plates. The shape eliminates wear during flexion-extension and lateral bending since the core itself will bend like a spring. The larger stress this will produce on the corners of the design may lead to shearing the polyethylene core. Overall, our implant is innovative and succeeds in eliminating key issues related to spinal implant failure: facet joint degeneration and implant dislocation.

III. Preclinical Testing

III.1 Virtual Surgery

Bone Loss

Our implant will be hammered into the bone. We do not plan on removing any bone before implantation, however, the impaction of the device will result in the destruction and displacement of some bone. For our preclinical testing, we simulated implantation at 3 different levels. The implant was moved further into the bone until the strain results of the FEA were below the fracture limit. Volumetric estimations of bone loss at all implantation levels are in tables 1 and 2 of appendix A.3.

Anticipated Regions of Failure

The most innovative aspect of this design is also most susceptible to failure. The constant flexion and extension of the polyethylene core may cause creep or fatigue failures. There is also a possibility for the disc to shear at the fixation trenches. The endplates must be extremely thin in some areas in order to fit the exact geometry of the spine and replicate the lordotic curve precisely. These regions could shear under extreme load or also from fatigue where the polyethylene is held in place. The vertebrae are made up of relatively low density bone. This means that a misalignment or improper implantation could result in a high stress concentration which could result in a catastrophic compression fracture.

III.2 Computational Assessment

Loading Scenarios

Our implant is meant to replicate full range of motion and most loading scenarios. A quiet stance could be used to determine the lowest loading condition required for our implant, however, the including motion is more reasonable when determining the lowest level of function in our implant. For this, we choose a simple gait, walking, and a more strenuous gait, walking up stairs. The data for these conditions came from an instrumented implant inserted at the L2-L3 level (Rohlmann, 2014).

Boundary Conditions

After meshing each components, boundary condition and constraints were applied. The bottom surface of L5 vertebrae was fix as the boundary condition, and all other parts were connected through tie constraints on all contact surfaces. Finally, the force was applied on the top surface of L4 vertebrae. Two different loading conditions were applied: stair walking (1000N) and normal walking (500N).

Material Selection

Upon completing the design, FEA was performed to simulate different loading condition as an actual implant in the patient's body. Boolean cut was made to replicate the bone ongrowth. Material properties were assigned to each components. The L4, and L5 vertebrae have Young's modulus of 9.98 GPa. and Poisson ratio 0.32 (Nicholson, 1997), which were based on the material properties of real vertebral bones. The end-plates have Young's modulus of 210 GPa, and Poisson ratio of 0.29 (Despa, 2013 and Odahara, 2008) as cobalt-chromium alloy, and the artificial disc has Young's modulus equal to 1 GPa and Poisson ratio of 0.4 as UHMWPE (Malito, 2018). Since artificial disc was less stiff compared to the alloys and bone, we chose the UHMWPE that had the highest Young's modulus to ensure minimum deformation under the load.

Failure Criteria

Bone is estimated to fracture catastrophically at around 8-10 thousand microstrain. For the cobalt-chrome, we used a yield strength of 480 MPa and for the polyethylene we used a tensile strength of 38 MPa. The yield limit was selected to prevent plastic deformation of the components.

Results

First, we analyzed the design under normal walking conditions. The results indicated that the maximum principal stress on the superior end-plate was 315.3 MPa in tension (Fig. 12A), and on the artificial disc, the maximum principal stress was 6.196 MPa in tension (Fig. 12B). The

maximum strain of 7378 micro-strain at the edge of the tie constraint on L4 vertebrae (Fig. 12C). The maximum strain was very close to the limit of bone fracture, which usually occurs at approximately 8000 micro-strain (Ref). However, since it was only a point on the edge of the constraint and the rest part of the bone was well below the limit, we considered this as a defect of the FEA analysis.

Next, we proceeded to the stair walking condition. As the load increased to 1000N, the maximum principal stress on the superior end-plate increased to 630.7 MPa (Fig. 13A), which exceeded the tensile yield stress. On the other hand, the maximum tensile on the disc was 12.4 MPa (Fig. 13B), which was in the safe range. The maximum strain appeared as 14,760 micro-strain (Fig. 13C) as the FEA defect. In this model, our design only had a very shallow Boolean cut on both L4 and L5 vertebrae which represented a low bone on growth scenario. Therefore, we decided to test another model with deeper insertion of the implant in order to replicate a better bone on growth condition.

In this model, the maximum tensile stress on the superior end-plate was 201 MPa (Fig. 14A). The maximum tensile stress on the artificial disc was 106 MPa at a point on the edge of the constraint (Fig. 14B), and thus we considered this as a defect as well as the maximum strain on bone occurred at the same location in previous model with 8496 micro-strain (Fig. 14C). The maximum stress on the end-plate was decreased to below the yield strength.

In all three analysis, the compression stresses on each components were much lower in magnitude compared to the tensile stress, and hence we did not consider them as critical factors.

Discussion

Our results were difficult to interpret due to errors caused by the time constraints. However, future design changes may consider an increased contact area between the disc and superior endplate to reduce stress concentration. There should also be a slope towards the posterior end of the implant to prevent rubbing during spinal extension. The polyethylene piece is small compared to the endplates. Once again, the stress concentration could be reduced by widening the disc to fill the entire endplate. Our experimentation was limited to finite element analysis of a simple loading condition due to time and budget constraints. For future development, the components should be fatigue tested and wear due to bending and rotation should be explored.

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Appendix A.1 List of Abbreviations

CCM - cobalt-chromium-molybdenum
CC - cobalt-chromium
UHMWPE - ultra-high molecular weight polyethylene
PCU - polycarbonate urethane
Ti - Titanium
AP - Anterior-Posterior
ML - Medial-Lateral

Appendix A.2 Figures

(A) **(B)**

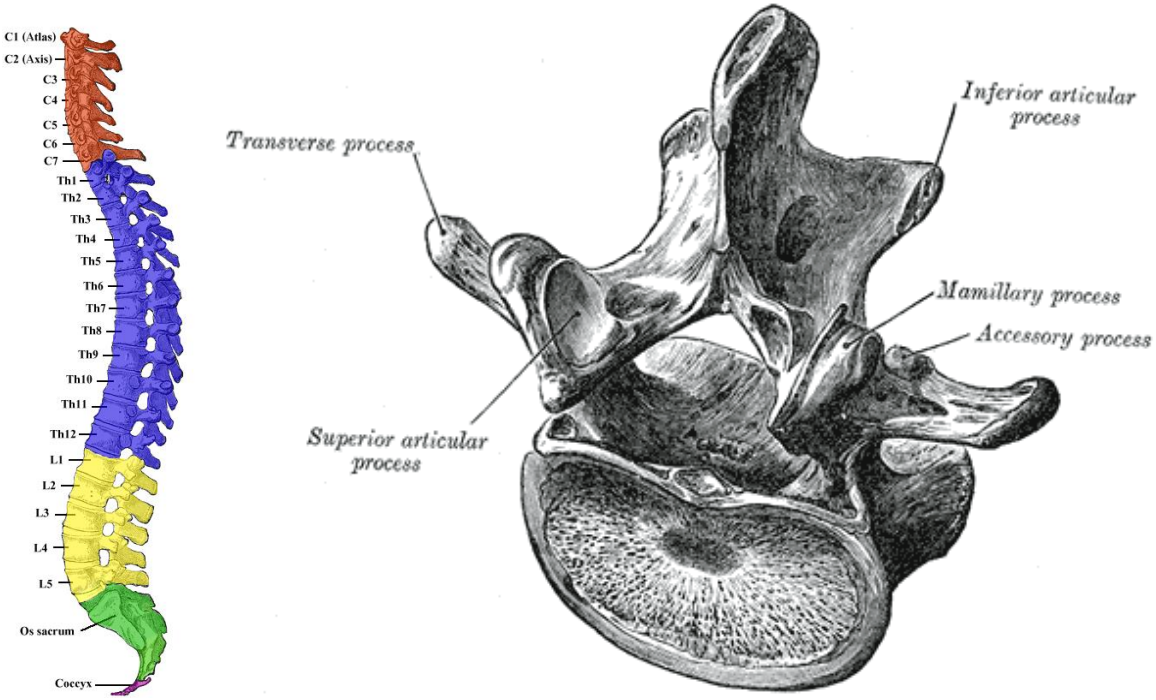


Figure 1. Location of the lumbar spine in the spinal column (a) and a typical lumbar vertebra (b) (Source: Gray's Anatomy)

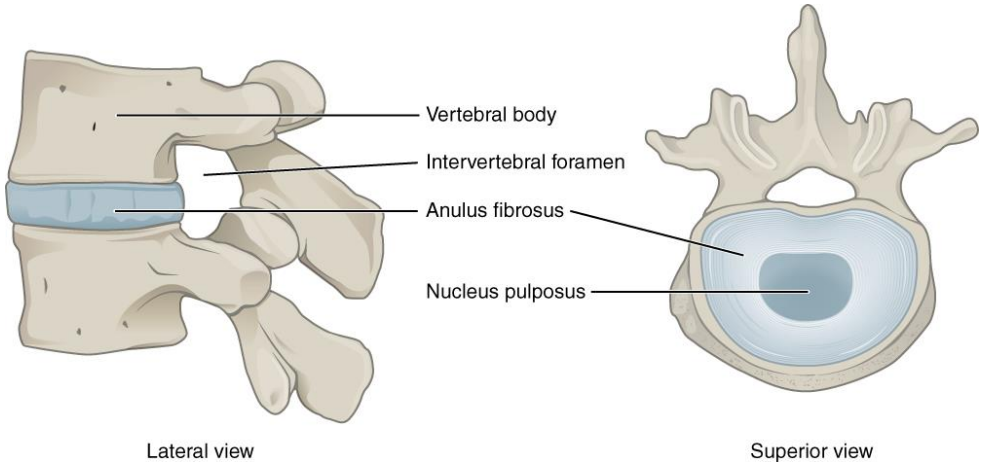


Figure 2. Intervertebral disc (Source: Anatomy & Physiology, Connexions Website)

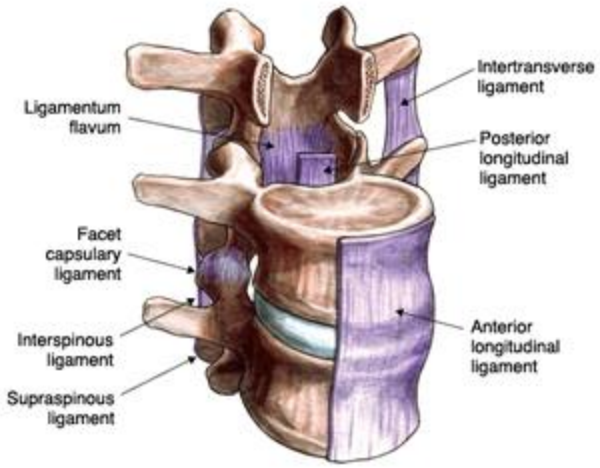


Figure 2AA. Ligaments of the spine (Spine Universe Website)

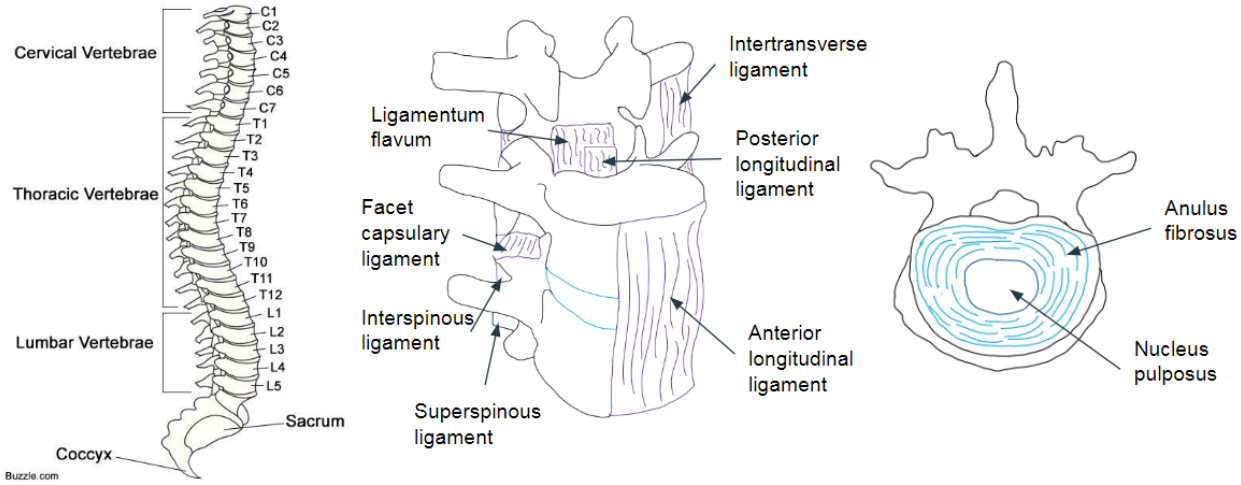


Figure 1-3. Replacement photo for these figures

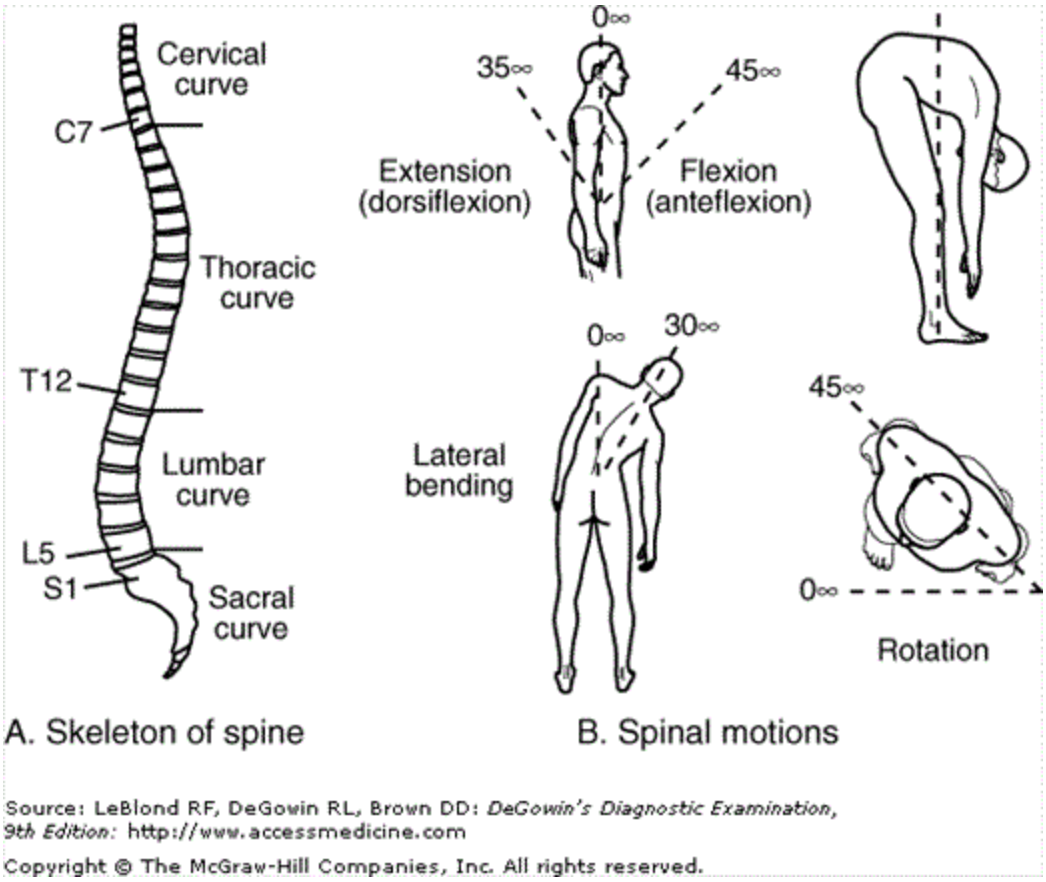


Figure 3. Rotational degrees of freedom of the spine (Source: DeGowin's Diagnostic Examination, 9e)

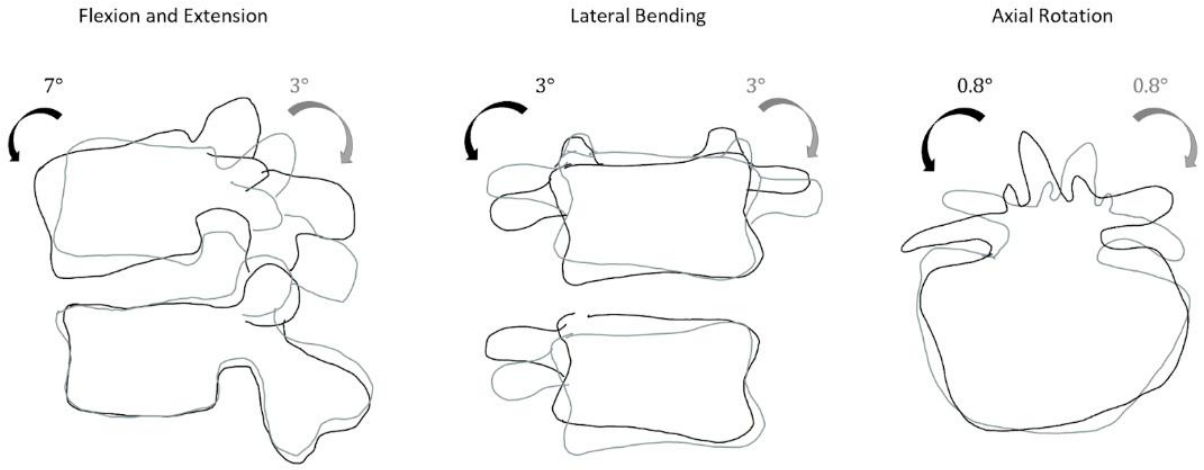


Figure XX (PREVIOUSLY FIGURE 8). Range of motion of the L4-L5 vertebrae (Source: Cook et. al.)

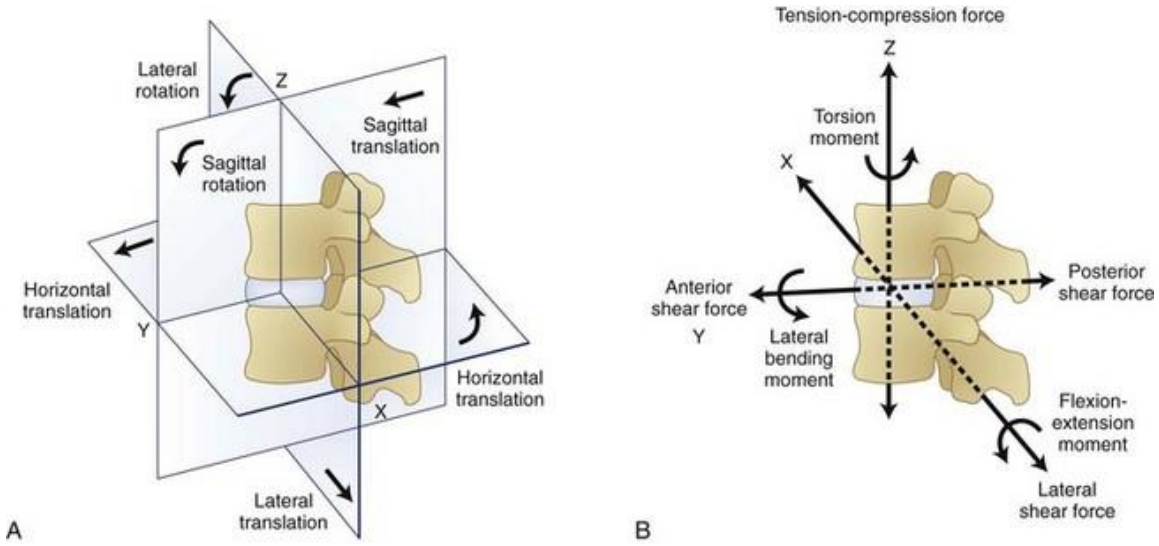


Figure 4: Full 6 degrees of freedom of a vertebrae (Source: https://clinicalgate.com/biomechanics-of-the-spinal-motion-segment/)

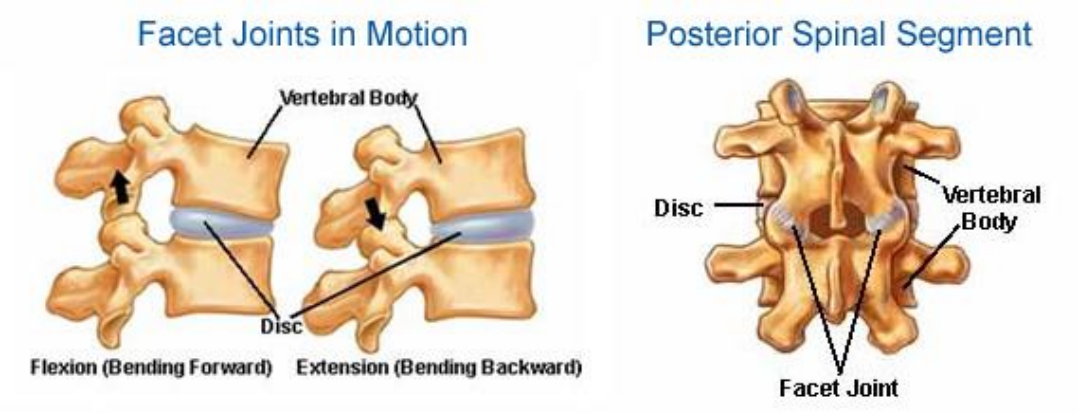


Figure 5. Location of facet joints and their effects on rotation in the vertebrae

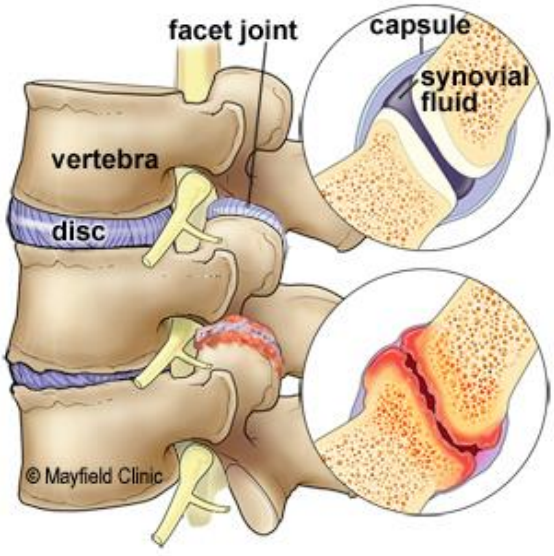


Figure XX. Close up of facet joint and degeneration

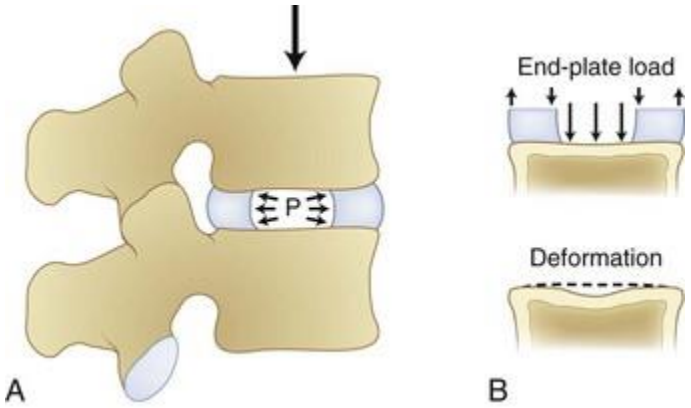


Figure 6. Compression of disc leading to increased pressure in disc nucleus and deformation of endplate. (Source: https://clinicalgate.com/biomechanics-of-the-spinal-motion-segment/)

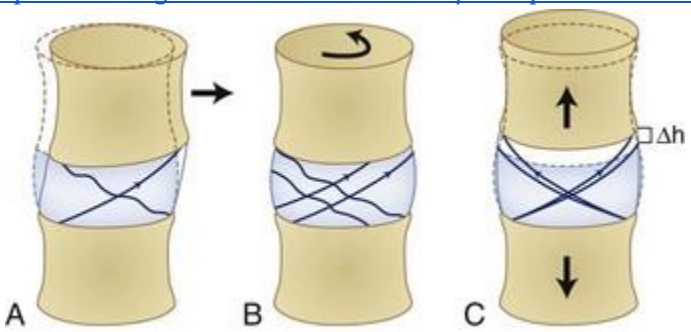


Figure 7. The effects of shear (A), torsion (B), and tension (C) on the fibers of the anulus fibrosus. (Source: https://clinicalgate.com/biomechanics-of-the-spinal-motion-segment/)

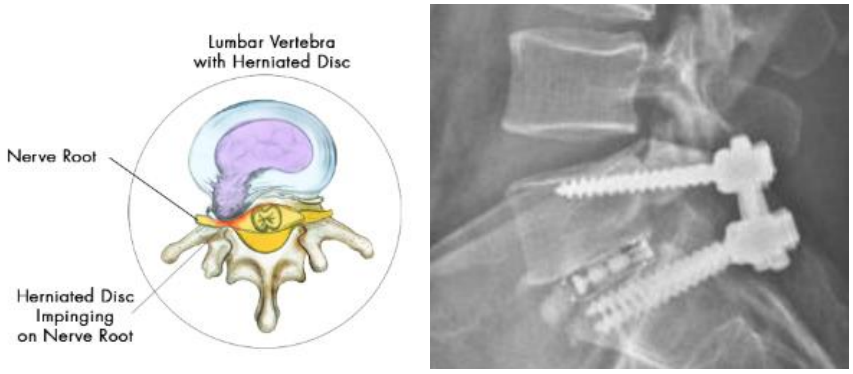


Figure XX. (left) Disc herniation, (right) Spinal fusion of L5/S1 and pelvic fixation

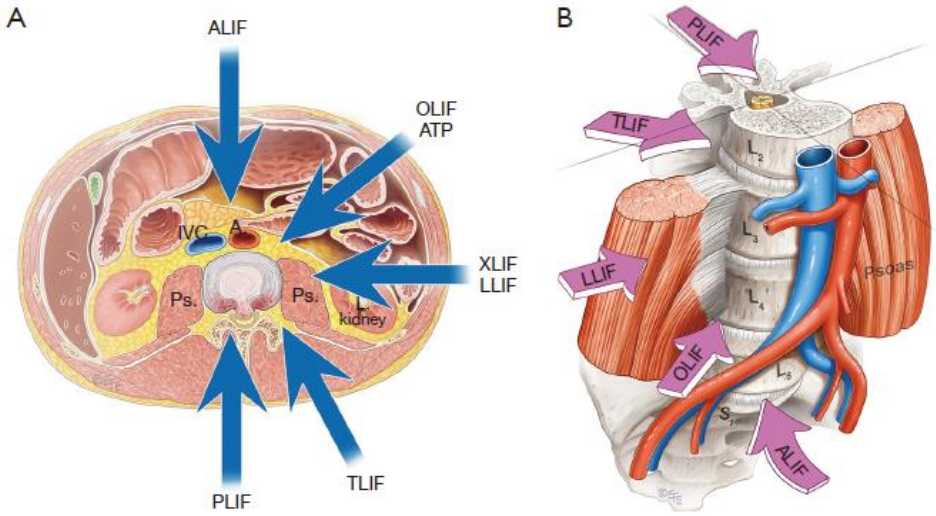


Figure 9. Lumbar interbody fusion surgical techniques (Mobbs - 2015, Journal of Spine Surgery)

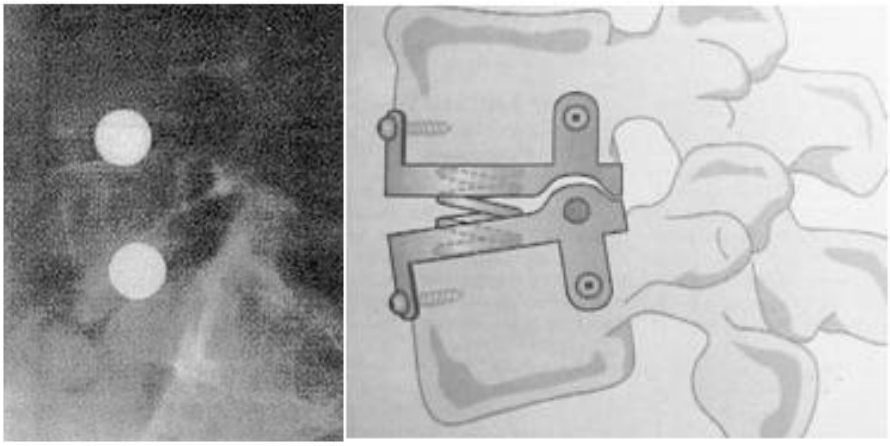


Figure 10. Fernstrom's steel balls which failed by subsidence into the vertebral body endplates (left) and Kostuiks posterior hinge and spring (right)

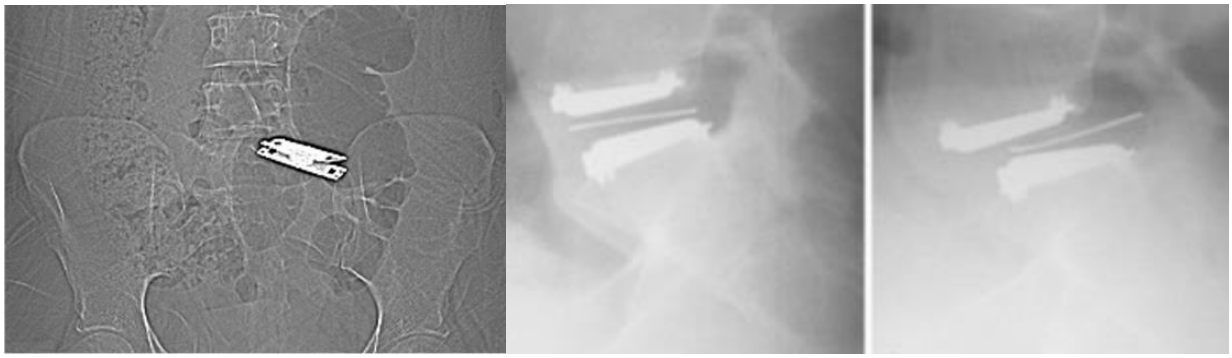


Figure 11. (Left) Dislocation of L4/5 XL-TDR into the left ipsilateral psoas muscle (Malhalm - 2017) (Right) SB Charite dislocation failure

Appendix A.3 Our Design

Table 1. L4 vertebra implantation volume loss

Model (units)	Original Volume	Implanted Volume	Volume Loss
Least-inserted (in^3)	5.22	5.17	0.05
Less-inserted (mm^3)	85,486.31	84,795.13	691.18
Most-inserted (mm^3)	85,484.60	83,785.77	1,698.83

Table 2. L5 vertebra implantation volume loss

Model (units)	Original Volume	Implanted Volume	Volume Loss
Least-inserted (in^3)	5.17	5.16	0.01
Less-inserted (mm^3)	84,739.75	84,169.82	569.93
Most-inserted (mm^3)	84,739.74	83,624.72	1,115.02

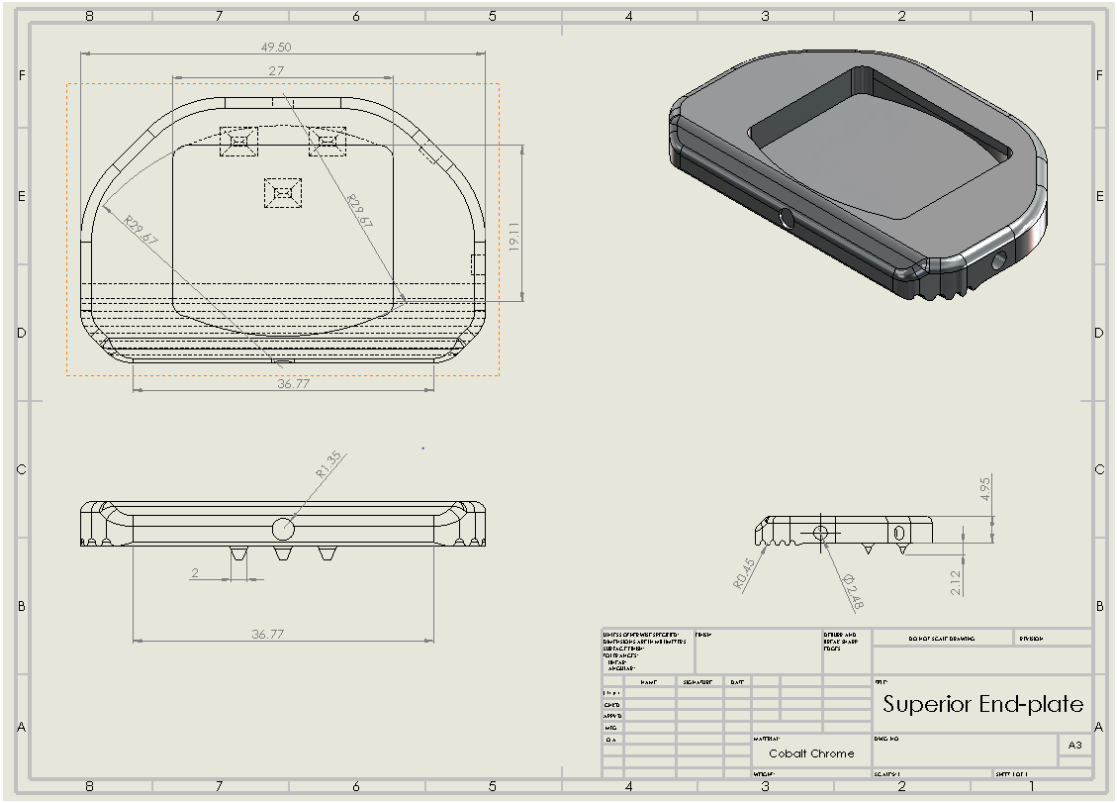


Figure 12. Engineering Drawing for Superior End-plate

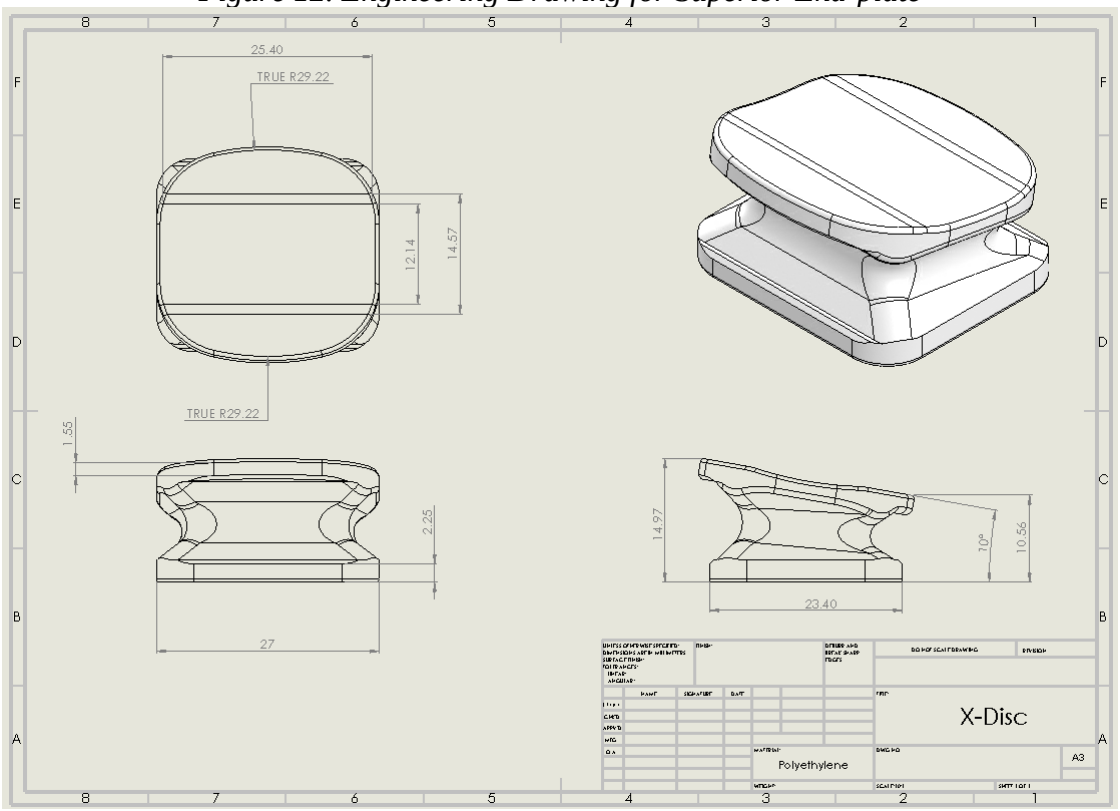


Figure 13. Engineering Drawing for the X-Disc

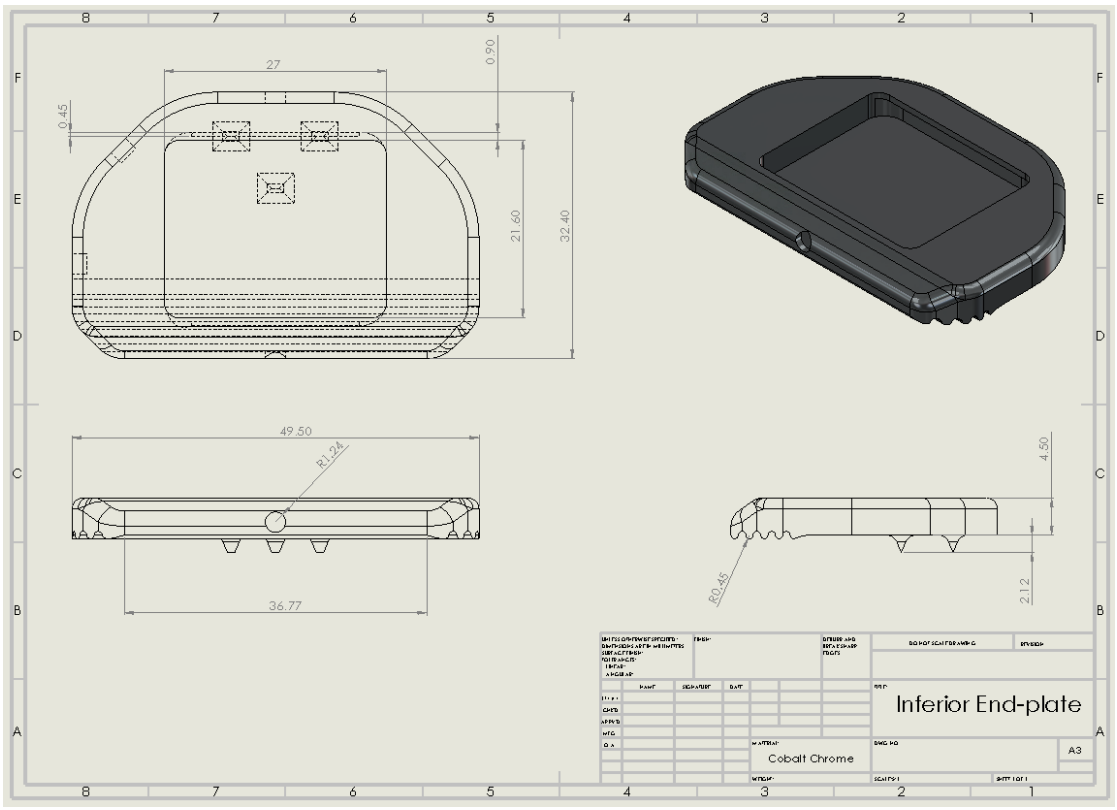


Figure 14. Engineering Drawing for the Inferior End-plate

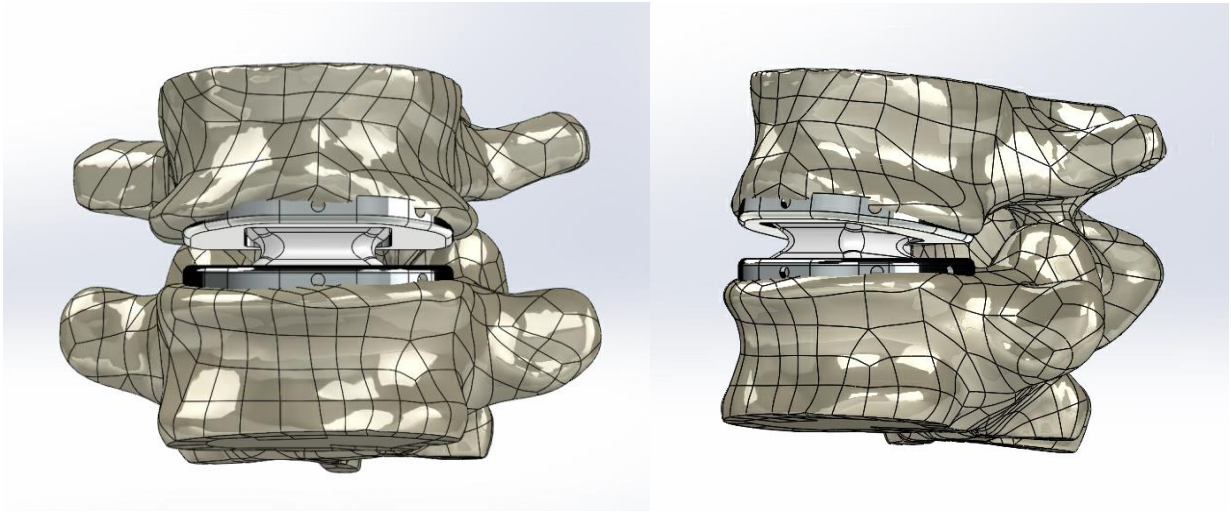


Figure 15. (Left) Anterior view of Implant (Right) Isometric view of Implant Virtual Implantation

Figure 15. (Left) Anterior view of Actual Bone Implantation (Right) Sagittal view of Actual Bone Implantation

Figure 15. (Left) Anterior view of Implant (Right) Isometric view of Implant Virtual Implantation

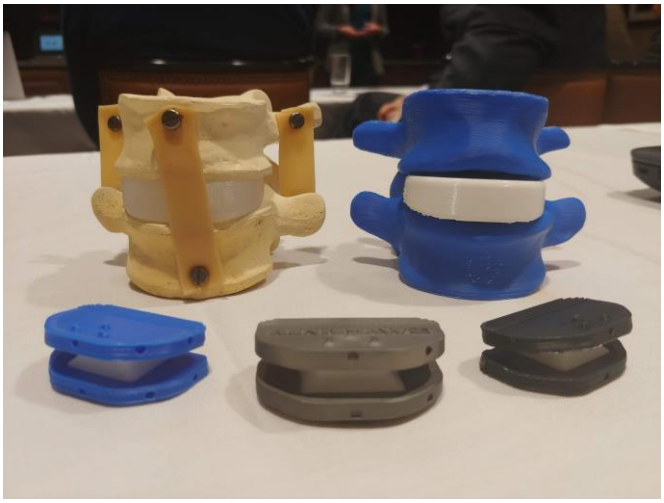


Figure 16. Prototypes, Bone Implantations and Final Lumbar Disc Replacement Implant

Appendix A.4 Finite Element Analysis

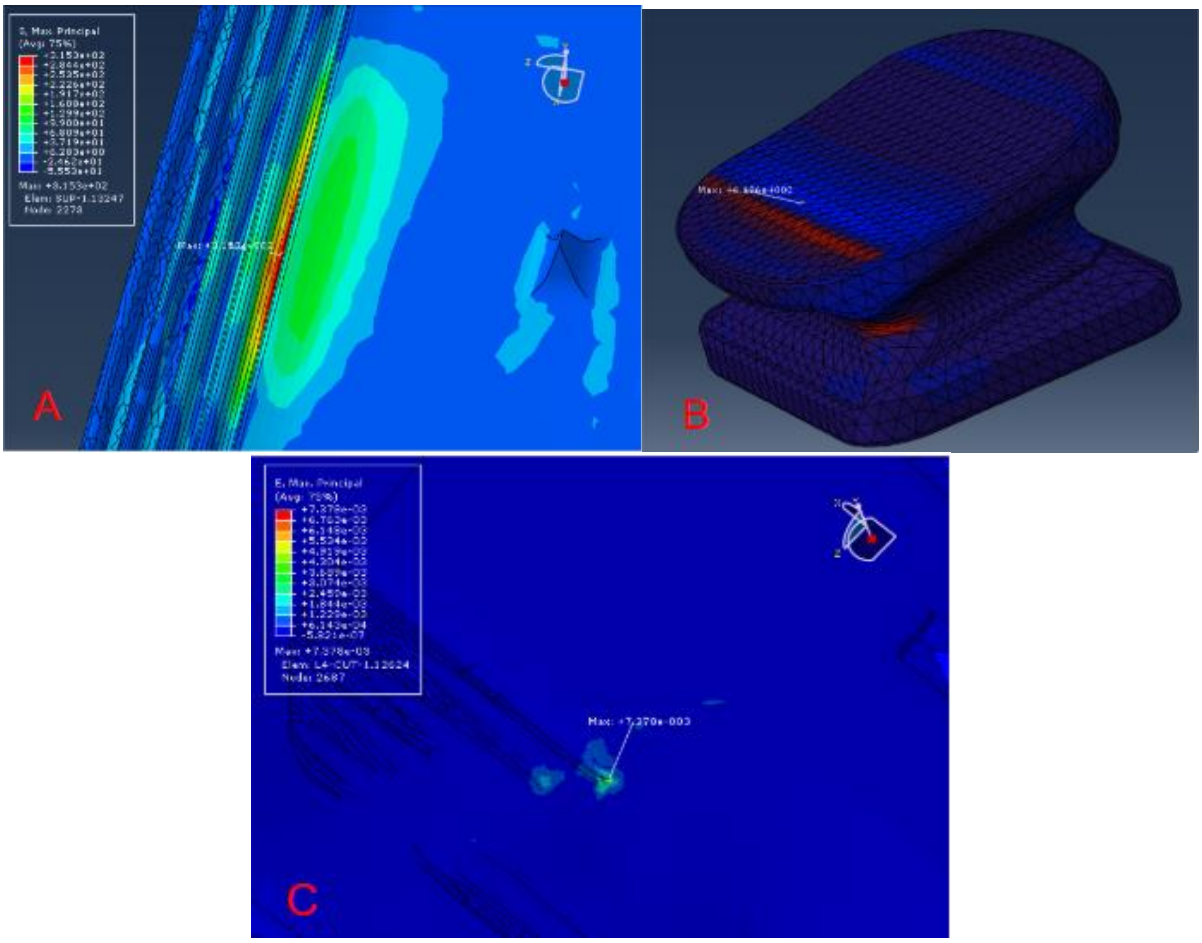


Figure 17. A. Maximum tensile stress on superior end-plate; B. maximum tensile stress on disc; C maximum strain on L4 vertebrae in normal walking condition.

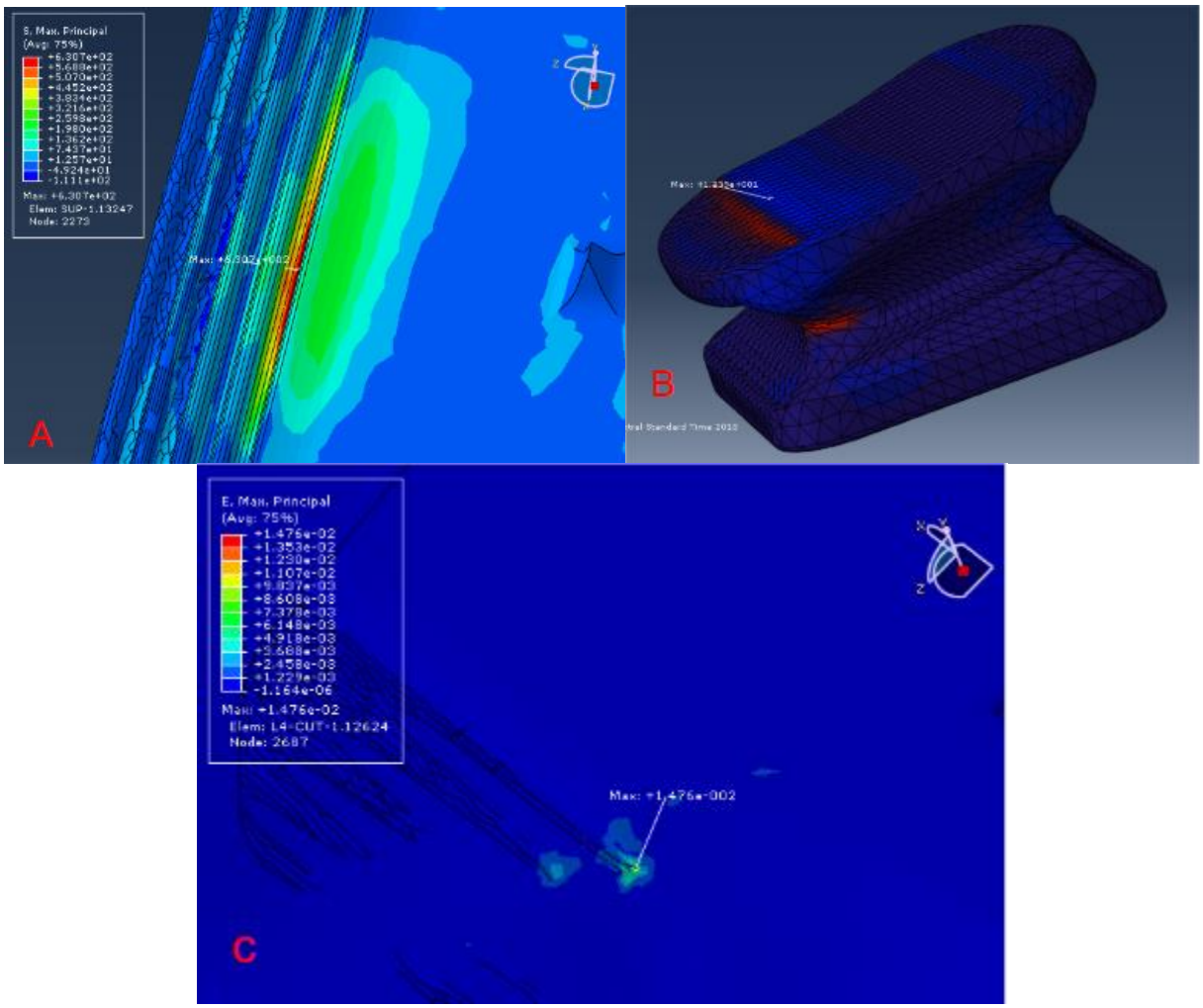


Figure 18. A. Maximum tensile stress on superior end-plate; B. maximum tensile stress on disc; C. maximum strain on the L4 vertebrae in stairwalking condition.

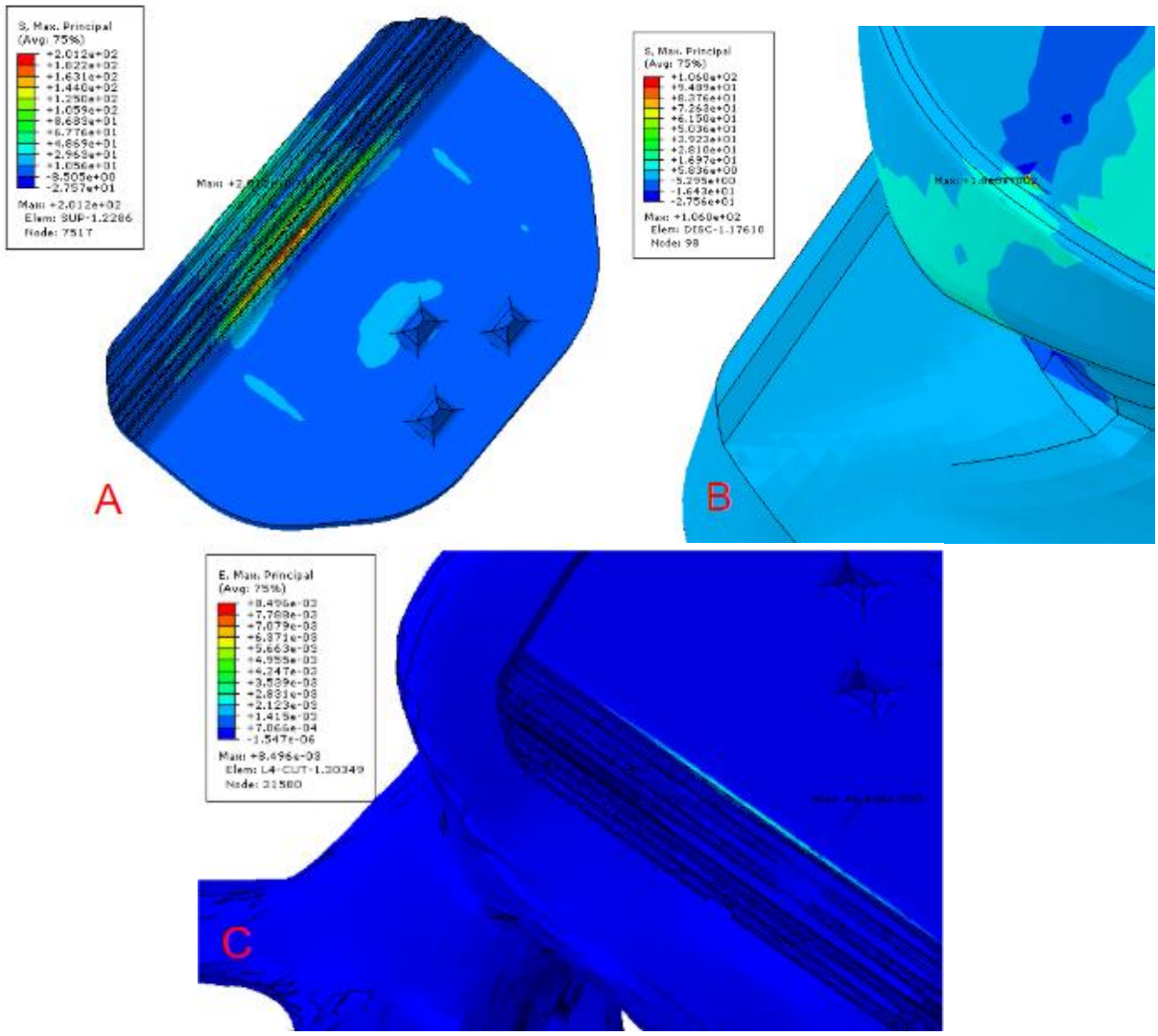


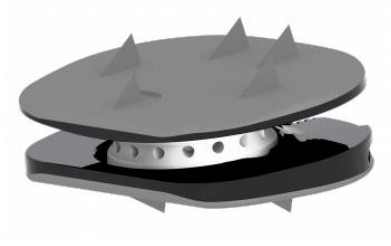
Figure 19. A. Maximum tensile stress on superior end-plate; B. maximum tensile stress on disc; C. maximum strain on the L4 vertebrae in stairwalking condition with deeper insertion.

Appendix A.5 Market Research

Implant Name/Manufacturer	Image	Notes
Implant: activL Artificial Disc *Manufacturer:* Aesculap Implant Systems, LLC *First Used*: 2006		*Type:* Semiconstrained *Status:* FDA Approved 2015 *Material:* CCM alloy with a titanium coating endplates and a UHMWPE insert *Fixation:* 1 ML keel and ridges
Implant: ProDisc-L *Manufacturer:* Centinel Spine (Formerly Depuy Synthes) *First Developed:* 1980 *First Used*: 2006		*Type:* Semiconstrained *Status:* FDA Approved 2006 *Material:* CCM alloy endplates and an UHMWPE inlay *Fixation:* 1 AP keel and lateral spikes with plasma-sprayed Ti surface *Failure:* lack of significant long-term pain relief
Implant: SB Charite III *Manufacturer:* Depuy Synthes *First Developed:* 1980 *First Used*: 2004		*Type:* Unconstrained *Status:* FDA Approved 2004 -- WITHDRAWN from market *Material:* CCM endplates and an UHMWPE sliding core *Fixation:* 6 raised teeth *Failure:* facet joint degeneration, lack of significant long-term pain relief, subsidence, and adjacent segment degeneration
Implant: In Motion *Manufacturer:* Depuy Synthes		*Type:* *Status:* FDA Approved -- not available on market *Material:* *Fixation:* 6 raised teeth
Implant: Maverick *Manufacturer:* Medtronic *First Used*: 2002		*Type:* Semiconstrained *Status:* Outside US only *Material:* CCM alloy endplates and disc *Fixation:* 1 AP keel with holes for bone ingrowth *Failure:* wear debris of chromium and cobalt ions

Implant: Flexicore *Manufacturer:* Stryker		*Type:* Fully Constrained *Status:* Withdrawn From Market *Material:* CCM alloy endplates and disc *Fixation:* 2 AP keels and ridges
Implant: Kineflex *Manufacturer*: Spinal Motion		*Type:* Semiconstrained *Status:* Withdrawn from market *Material:* CCM alloy endplates and disc *Fixation:* 1 AP keel with holes for bone ingrowth
Implant: Mobidisc *Manufacturer:* Zimmer Biomet		*Type:* Unconstrained *Status:* Withdrawn from market *Material:* CCM endplates and a UHMWPE core *Fixation:* 1 AP keel with spikes
Implant: XL TDR *Manufacturer:* NuVasive		*Status:* Clinical Trials *Material:* 2 CCM endplates with a Ti plasma spray coating *Fixation:* 3 ML keels Inserted through a XLIF approach
Implant: Freedom *Manufacturer:* AxioMed		*Type:* Elastomeric *Status:* Outside US only *Material:* Ti plates, silicone PCU core *Fixation:* 4 AP keels with spikes

Implant: Acroflex *Manufacturer:* AcroMed Corporation		*Type:* Unconstrained *Status:* Withdrawn from market
Implant: M6-L *Manufacturer:* Spine Kinetics *First Used*: 2009		*Type:* Elastomeric *Status:* Outside US only *Material:* PCU core surrounded by UHMWPE fibers between 2 Ti endplates *Fixation:* 2 AP keels
Implant: LP-ESP *Manufacturer*: FH Orthopaedics *First Used*: 2005		*Type:* Elastomeric *Status:* Outside US only *Material:* Ti plates with a PCU cushion and a silicone core loaded with compressible beads *Fixation:* 5 raised teeth and a porous, rough hydroxyapatite coating. Ribs on the metal end plates transform the rotational movements between the two plates into compression and traction of the inner deformable core
Implant: Cadisc-L *Manufacturer:* Ranier Technology		*Type:* Elastomeric *Status:* Outside US only *Material:* PCU graduated modulus with physiological, progressive bending stiffness *Fixation:*

Implant: eDisc *Manufacturer:* Integra Spine (formerly Theken Spine)		*Type:* Elastomeric *Status:* Outside US only *Material:* Ti plates, elastomeric core *Fixation:* 1 central keel
Implant: Baguera L *Manufacturer:* Spineart		*Type:* Semiconstrained *Status:* Outside US only *Material:* Diamolith-coated Ti plates and UHMWPE core *Fixation:* 5 raised teeth
Implant: Physio-L *Manufacturer:* NexGen Spine		*Type:* Elastomeric *Status:* Outside US only *Material:* Ti plates, elastomeric core *Fixation:* 1 AP Keel
Implant: Triumph *Manufacturer:* Globus Medical		*Status:* IDE study ongoing *Material:* 2 metallic endplates Inserted through a posterolateral approach

Appendix A.4 Edited Sentences

Deleted sections are struck through, added sections are in {}

1. [Clinical Problem: para 1] ~~Lumbar~~ {Lower} back pain (LBP) is the leading cause of long-term disability worldwide.
2. [Clinical Problem: para 1] ~~LBP may also be caused by~~ {Other causes of LBP include:} disc herniation, spondylolysis, and spondylolisthesis; however, isolating a single cause is often difficult as multiple conditions ~~are~~ {may be} present at the same time.

3. [Clinical Problem: para 2] The intervertebral discs are flexible at a young age, but naturally stiffen ~~with age.~~ {leading to an increase in} LBP ~~has been shown to increase~~ in adolescence and again around age 40-50, declining thereafter.
4. [Clinical Problem: para 4] {The consequences of} this procedure ~~results in~~ are a limited range of motion, adjacent segment degradation, and sagittal imbalance.
5. [Clinical Problem: para 4] The best method to relieve pain and restore joint function is a total lumbar disc replacement{, which is accompanied by its own set of}~~. These also have~~ negative side effects~~, leaving room for improvement~~.