Artificial Spinal Discs

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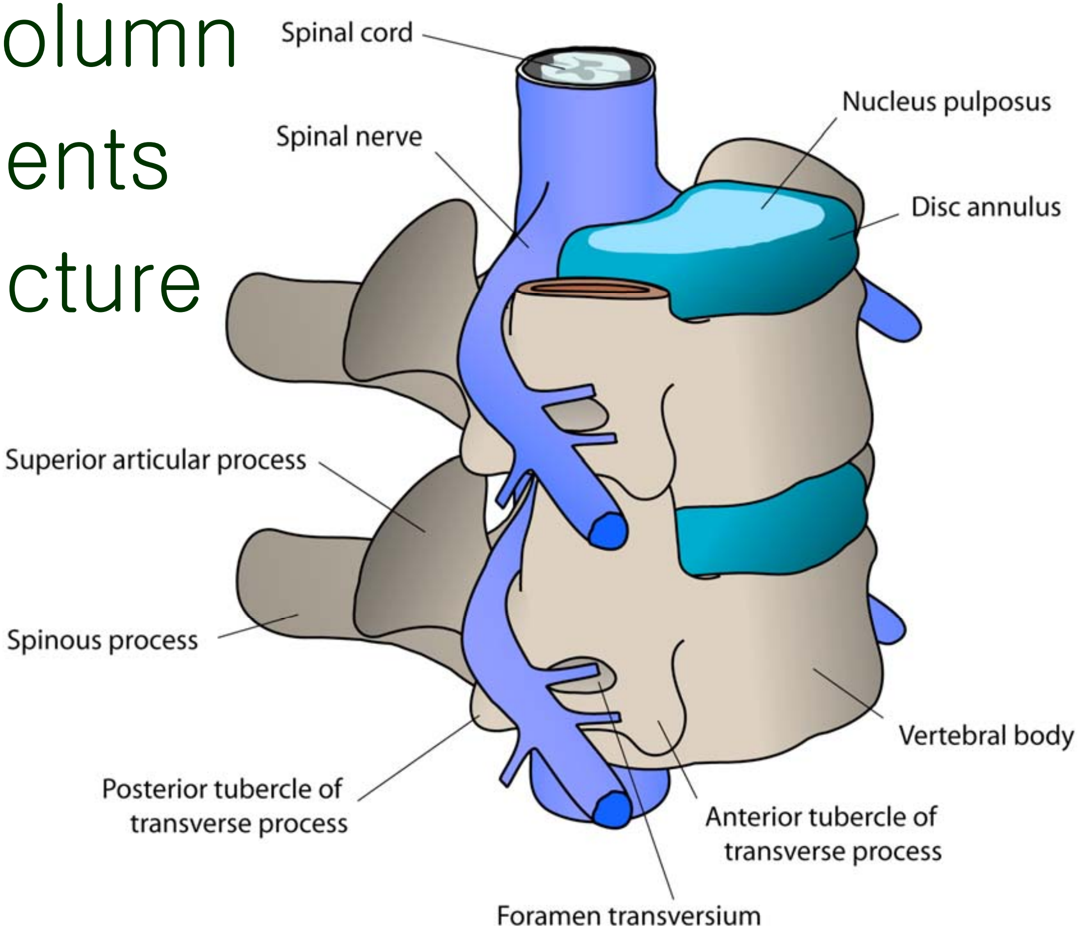
Introduction

- Statistics
  - In the U.S. almost 700,000 spinal procedures are performed every year [1]
  - $50 Billion spent on back pain treatment per year [2]
  - 14% of new patient visits to physician office every year [3]

Our Spinal System

- The Vertebral Column
- Neural Components
- Supporting Structure



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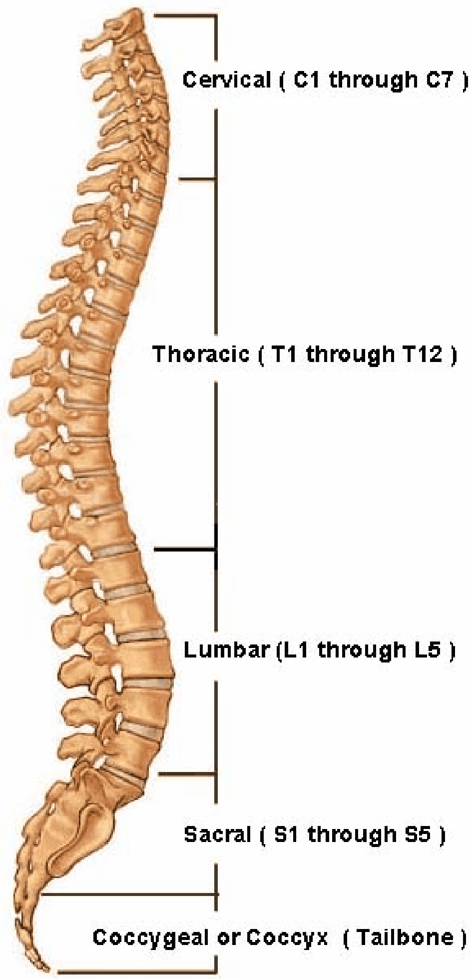
The Vertebral Column

- Cervical : 7 cervical vertebrae
- Thoracic: 12 thoracic vertebrae
- Lumbar: 5 lumbar vertebrae
- Sacrum: five bones
- Coccyx: tailbone (3–5 bones)



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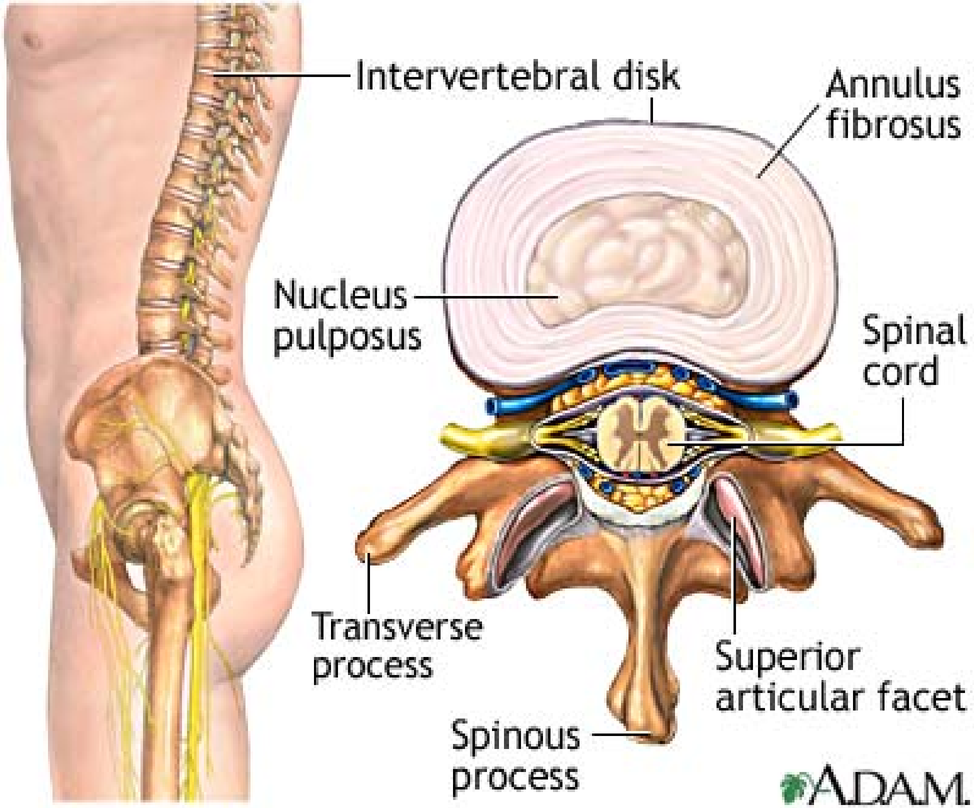
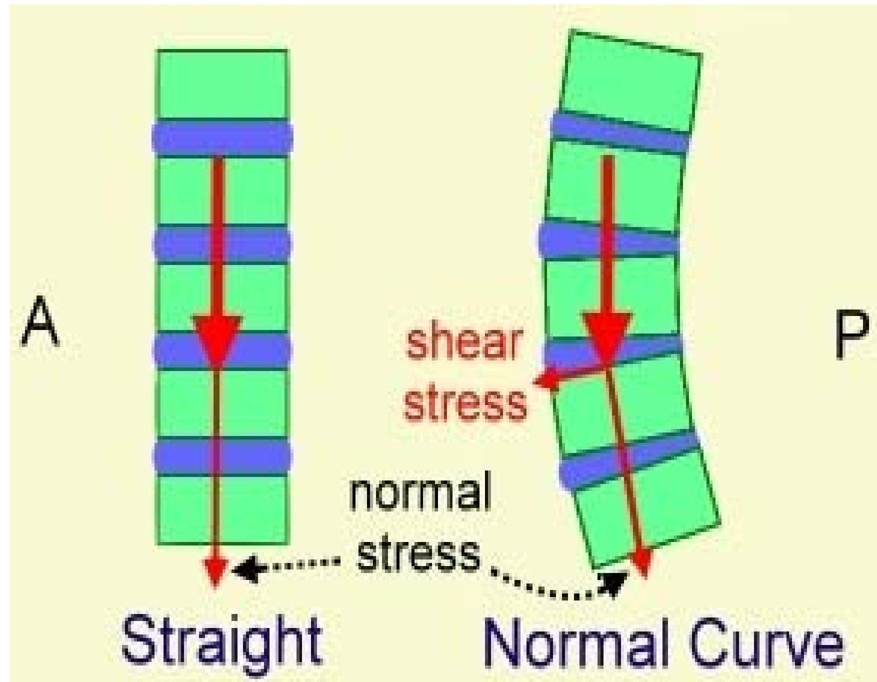
Intervertebral Disc

- Three Components
  - Annulus Fibrosus
    - Distributes even pressure on the disc
  - Nucleus Pulposus
    - Acts as a shock absorber
  - End Plates
    - Contacts adjacent vertebrae body [6]



Biomechanics of Spine Column

- Natural Curvature
  - Transmit forces from upper to lower extremities
  - Distributes mechanical forces/stress on the spine
  - Reduce the ground reaction forces



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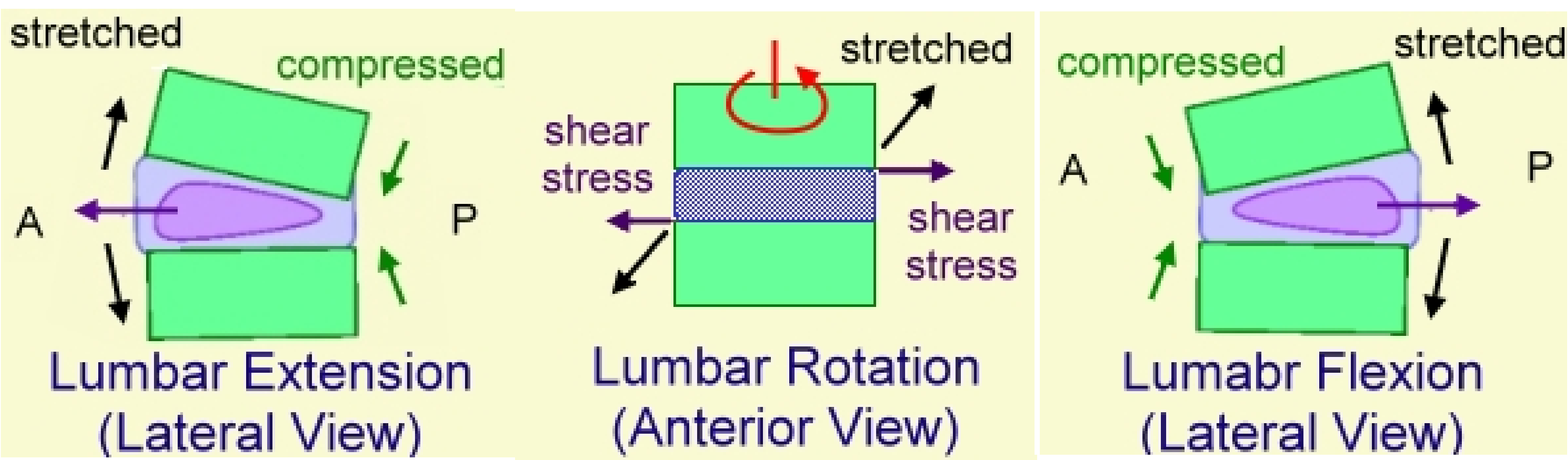
Biomechanics of Intervertebral Disc

- Like a Jelly Donut!
- Distributes Sheer Forces
- Absorbs forces through gel-like mechanism

[7]



Disease / Disorder

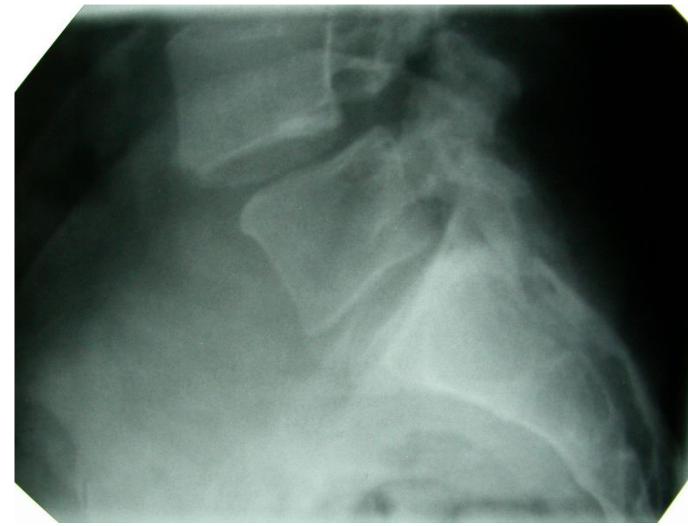
- Degenerative Disc Disease
  - Part of the aging process, where the intervertebral discs wear and tear off.
  - DDD can affect any part of the spine.
  - Lumbar and Cervical Spine are affected the most

[8]

Other Disorders

- Spondylolisthesis:
  - Forward slippage of the disc and the vertebra.
  - Can be categorized into 5 different levels.
- Retrolisthesis:
  - Backward slippage of the disc and vertebra.

[9]



What causes DDD?

- Age
  - Dehydration of Disc
  - Bones and Ligaments become less flexible
  - Thinning Disc
- Bad natural habits
- Herniated Discs

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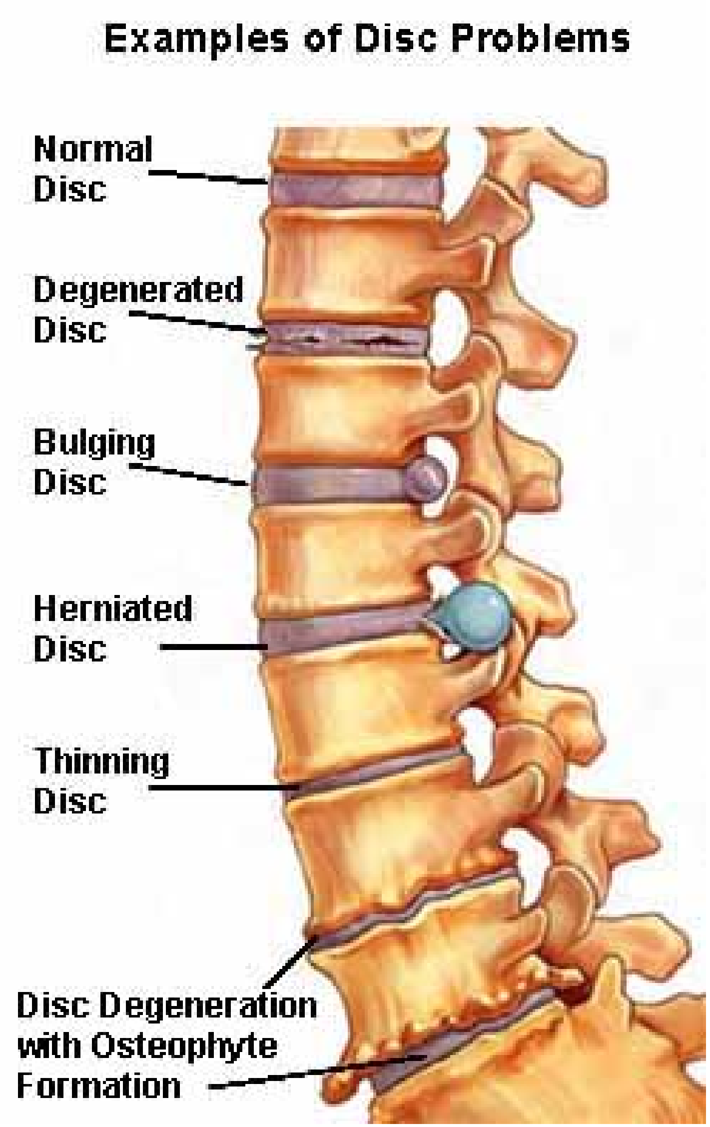
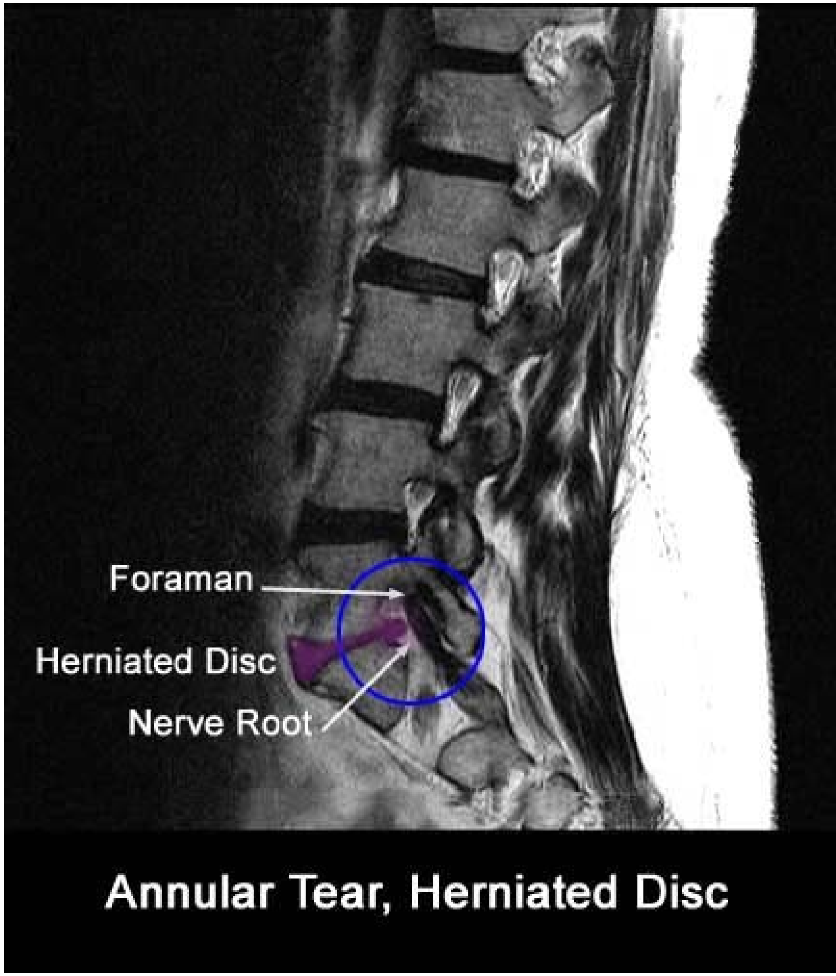


Herniated Disc

- Main reason behind DDD
- A tear on the Annulus Fibrosus
  - Leak of nucleus pulposus
  - Nucleus “Bulges Out”
  - Could result in “Drying Out”
- Occurs usually in the thirties or the forties



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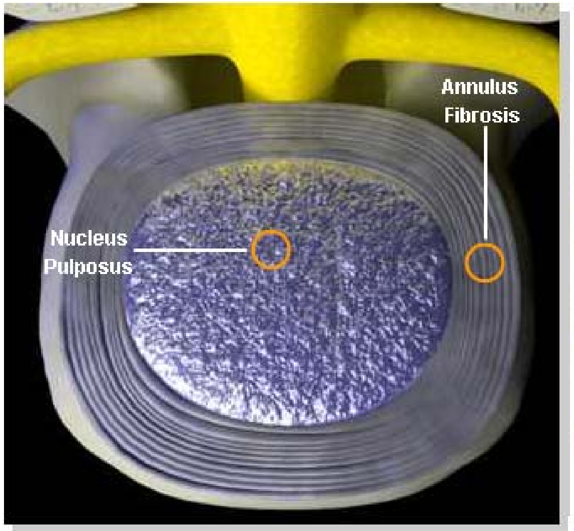
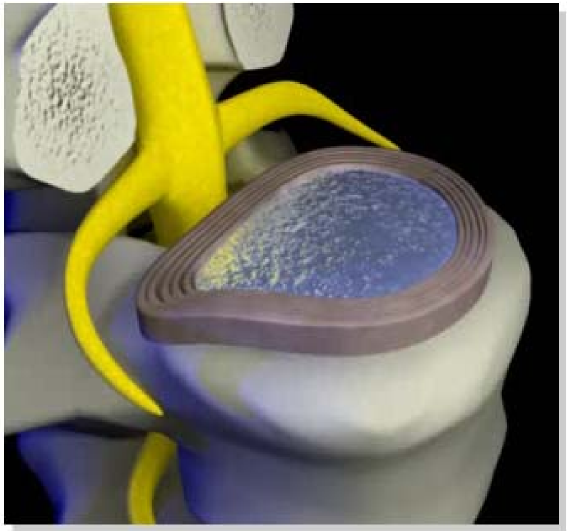
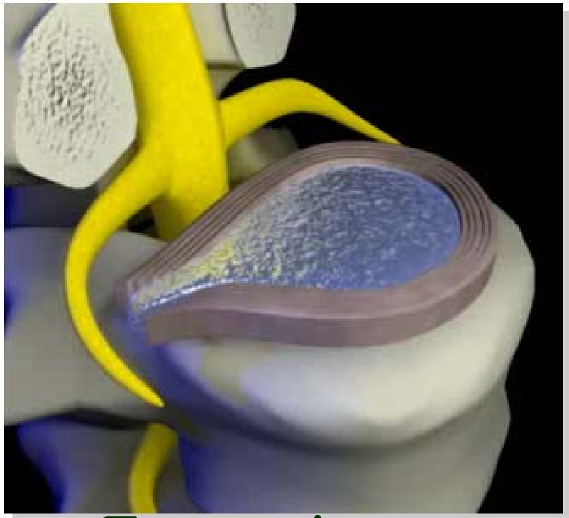
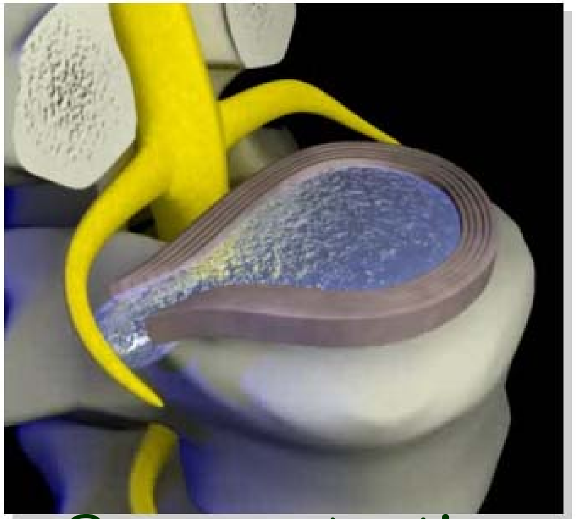
Stages of Herniated Disc





- Normal
- Prolapse



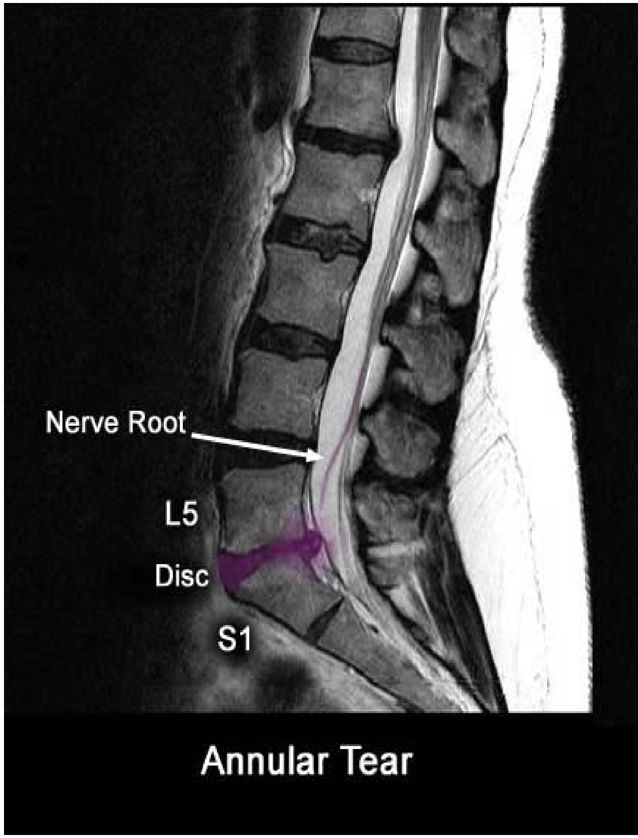


- Extrusion
- Sequestration

[12]

Why does it hurt?

- Pressure:
  - Leaked Nucleus presses on spinal cord and nerve roots
  - Pain signals are sent to CNS
- Weakness or numbness:
  - Lumbar: Legs, Thighs, buttocks
  - Cervical: Shoulder, Arm, Hand



[11]

Symptoms of Spinal Disorder

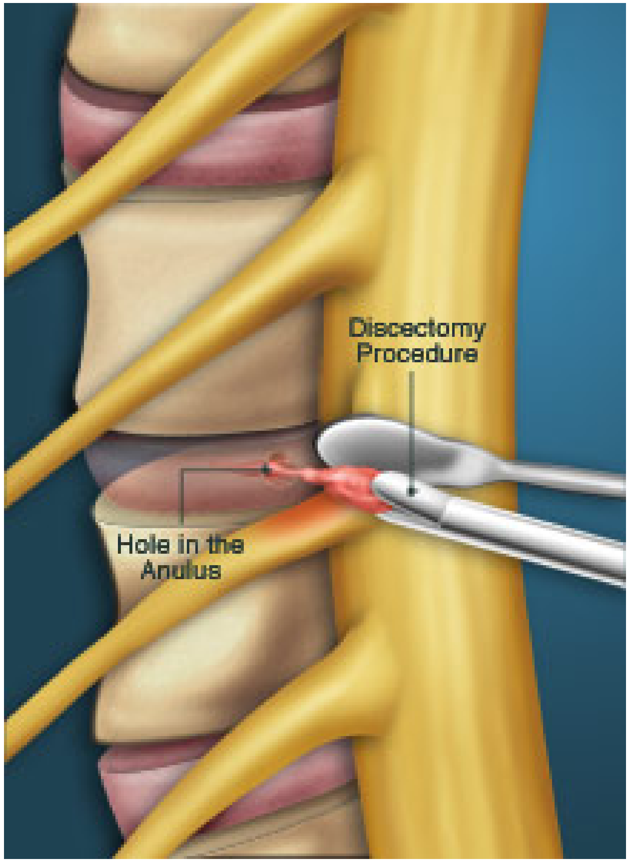
- Common Symptoms:
  - Pain when sitting for a long time.
  - Pain through daily activities, such as running, lifting, twisting, etc.
  - Pain when you lie down, or change posture.
- Severe Symptoms:
  - Worsening of spine pain, (Chronic pain)
  - Disabling pain
  - Weakness, numbness or tingling in parts like legs, arms, neck.
  - Loss of bladder control

What can be done?

- 3 Common Surgical Procedures:
  - Discectomy
  - Spinal Fusion
  - Artificial Disc Replacement

Discectomy

- Dissection of the leaked nucleus
- Relieves pressure on nerves, ligaments



- Pros:
  - Short-term pain relieving effect
  - High success rate
- Cons:
  - Disc height reduction
  - Increase of instability in structure
  - Possibility of Spinal Stenosis, facet pain [13]

Spinal Fusion

- Joining of two or more vertebrae
- Pedicle screws and interbody cages required
- Bone graft is placed between the vertebrae

- Pros:
  - Relieves back pain
  - 75% success rate
  - Great knowledge on the surgery procedures
- Cons:
  - Alters intervertebral disc functions
  - Increase of stress/strain on other discs
  - Limited movement [14]

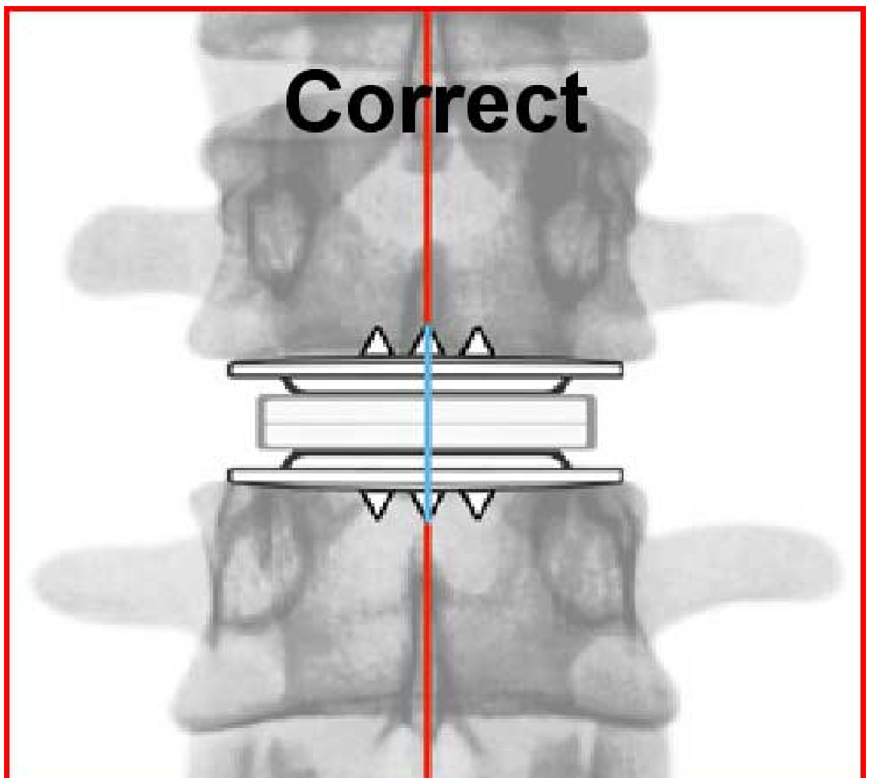
Artificial Disc Replacement

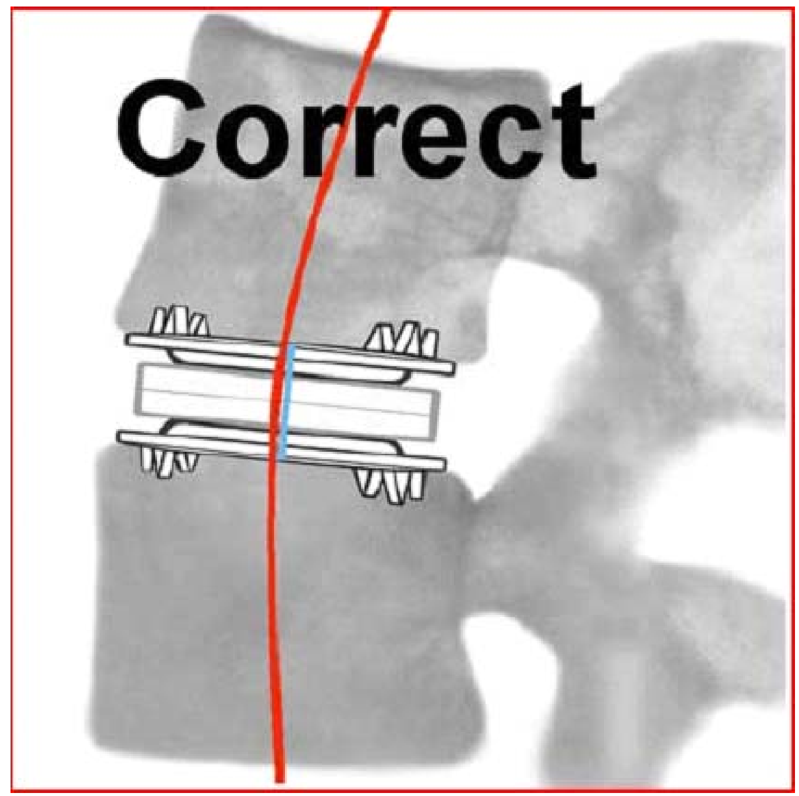
- Anterior approach
- Damaged Disc is removed
- Space is heightened to relieve pressure on nerve cords
- Debris is freed
- Artificial Disc is inserted
- Spinal height is re-adjusted

[15]

Artificial Disc Replacement Cont…

- Alignment with Center of the Posterior Spinal axis
- Anatomic alignment in lordosis [16]





Pros/Cons

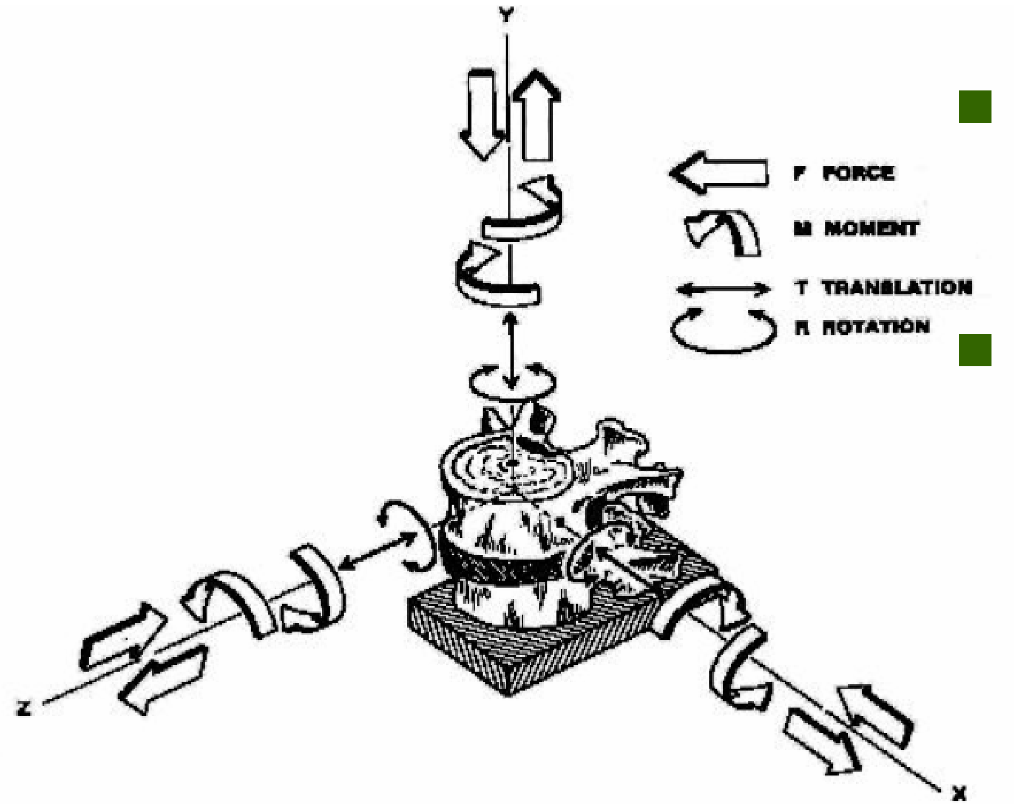
- Advantages:
  - Successful Pain Relief
  - Stabilization of Spine
  - Independent integrity of the annulus
  - Full restoration of Original Disc function
  - Promising for severe cases of DDD

- Disadvantages:
  - Long & Difficult process (108 ~ 300min)
  - Still in "Learning Curve" phase
  - Possibility of nerve damaging
  - Very specific patient requirement are needed

[16]

Biomechanical Properties of Intervertebral Disc & Artificial Disc

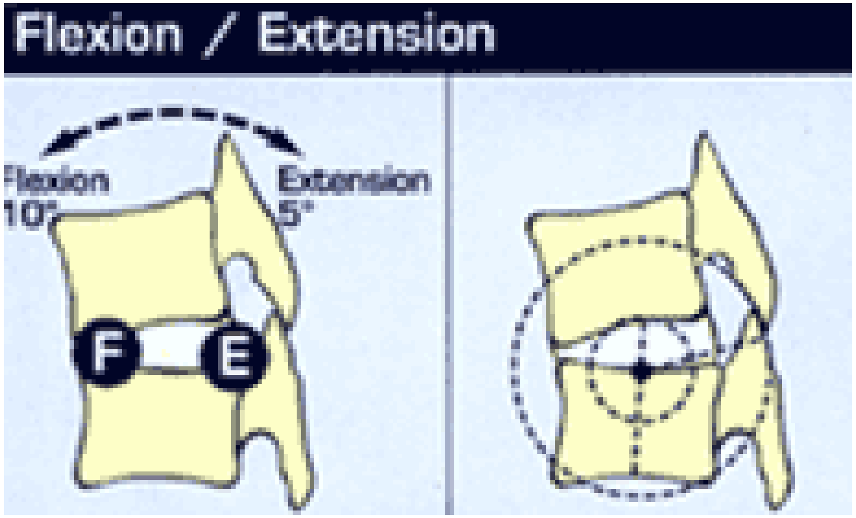
Spinal Unit



- Six degrees of freedom
  - 3 Rotational
  - 3 Translational
- Total of five motions
  - Axial compression
  - Flexion & Extension
  - Lateral Bending
  - Axial Torsion

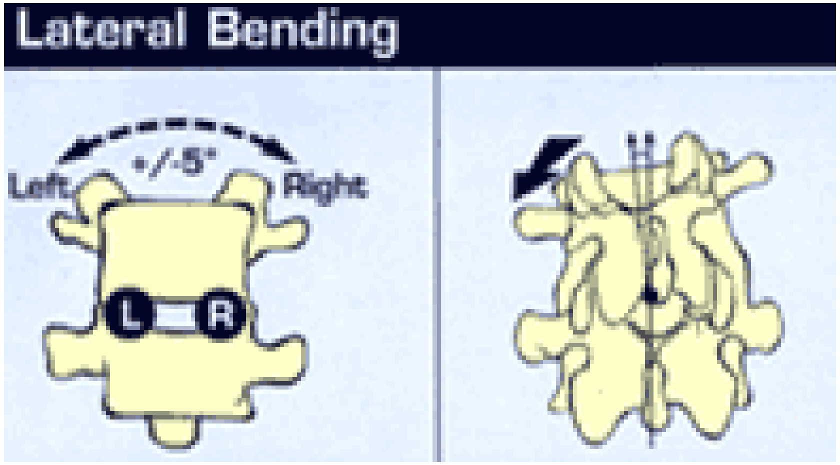
[17]

Flexion/Extension



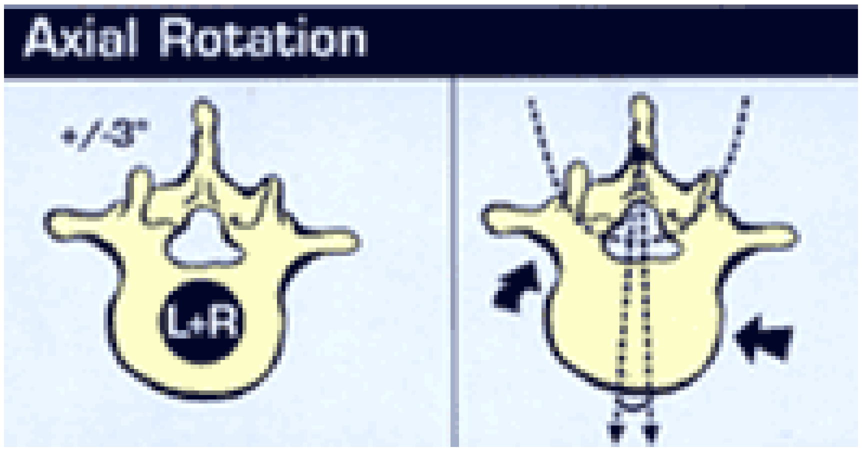
- Allows 10^{o} flexion freedom and 5^{o} extension freedom
- Annulus layers in the direction of the motion are under compression
- Tension on the opposite side of annulus layer
- Nucleus will move with tensile force [19]

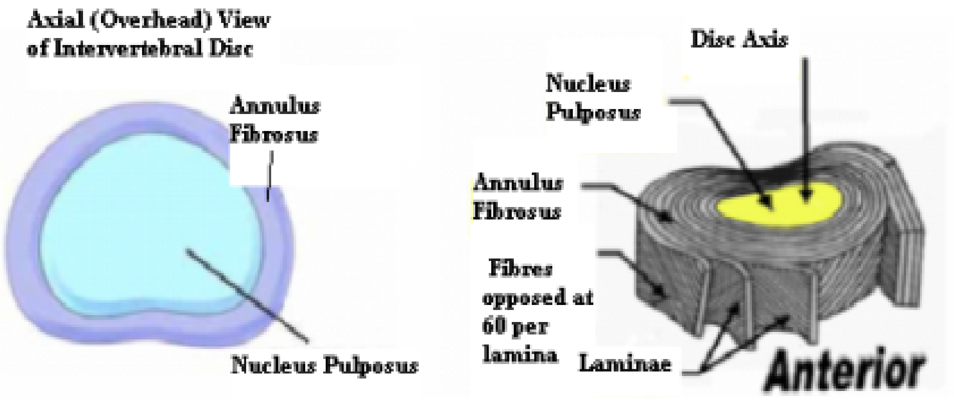
Lateral Bending



- Allows +/− 5^{o} of freedom to lateral bending to both left and right
- Tension is highest on the opposite side of bending
- Again, works like a jelly-donut [19]

Axial Rotation / Torsion



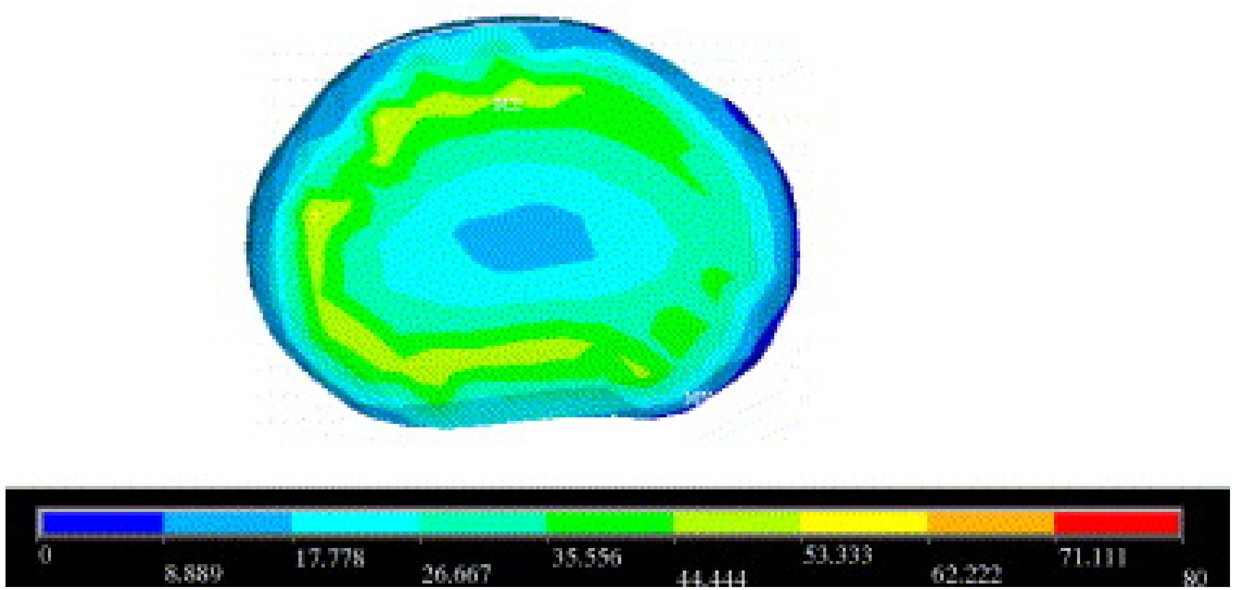


- Allows +/- 3^{o} of freedom to rotate around spinal axis
- In the Anterior & Lateral annulus region:
  - Tensile forces on fibers lie in the direction of axial torque
  - No stress on fibers lie in the opposite direction
- In the Posterior annulus region:
  - Annulus fibers are always in tension regardless of torsion direction

[19]

Axial Compression

- 1000N axial compressive loads on Lumber Disc
- Intensity of Stress weakening towards nucleus
  - Annulus fiber shows in Green
  - Nucleus Pulposus shows in Blue
- Nucleus Pulposus absorbs some loads
- Stress/Strain distributed mainly on posterior of annulus fibers [20]

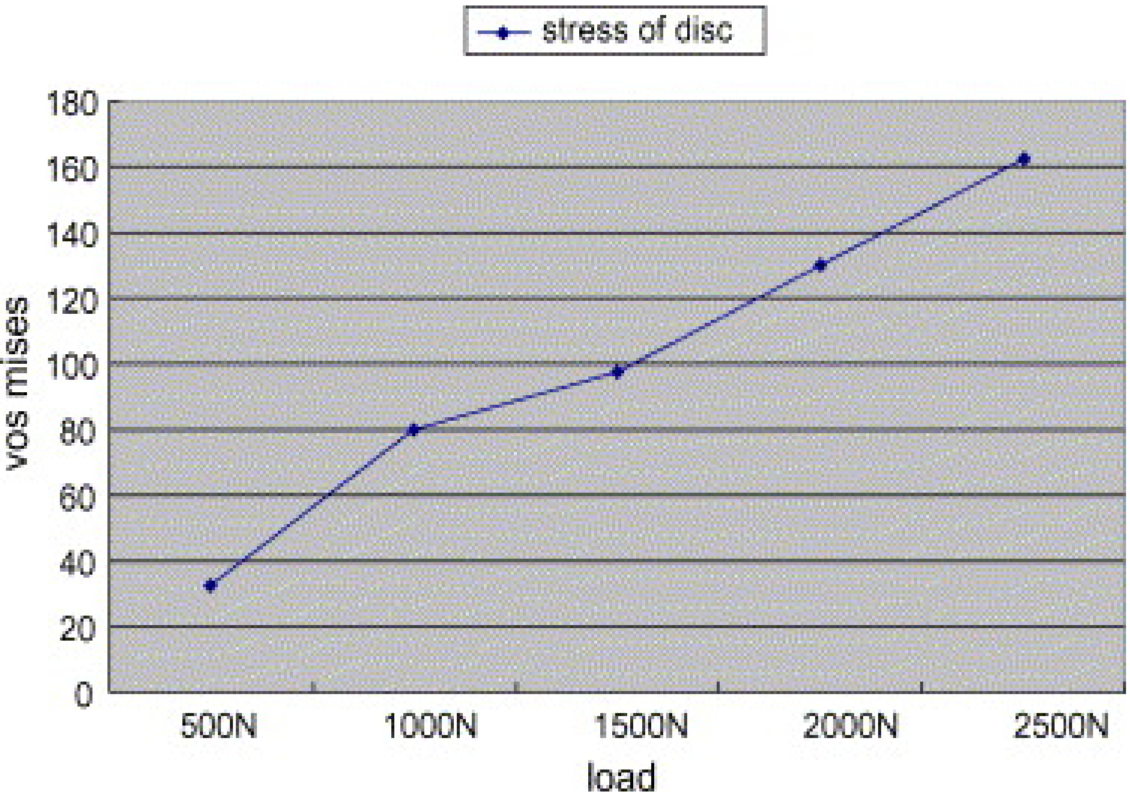


Composition of Intervertebral Disc

- Collagen:
  - Main protein of connective tissue
  - 50%, in annulus fibrosus, 20-30%, in nucleus, of dry weight.
  - Annulus Fibrosus contains Type II and 40% of Type I
  - Nucleus Pulposus contains Type II
  - Type II collagen fibers have greater intermolecular spacing than Type I
    - Nucleus has higher hydration level and better withstand compressive forces than annulus fibrosus
- Proteoglycans:
  - Found in Nucleus and Endplates
  - Regulates transportation of solutes into and out of the disc
- Water:
  - Main component of an intervertebral disc
  - Annulus Fibrosus contains 60-70% of water
  - Nucleus Pulposus is composed of 70-90% water

[17]

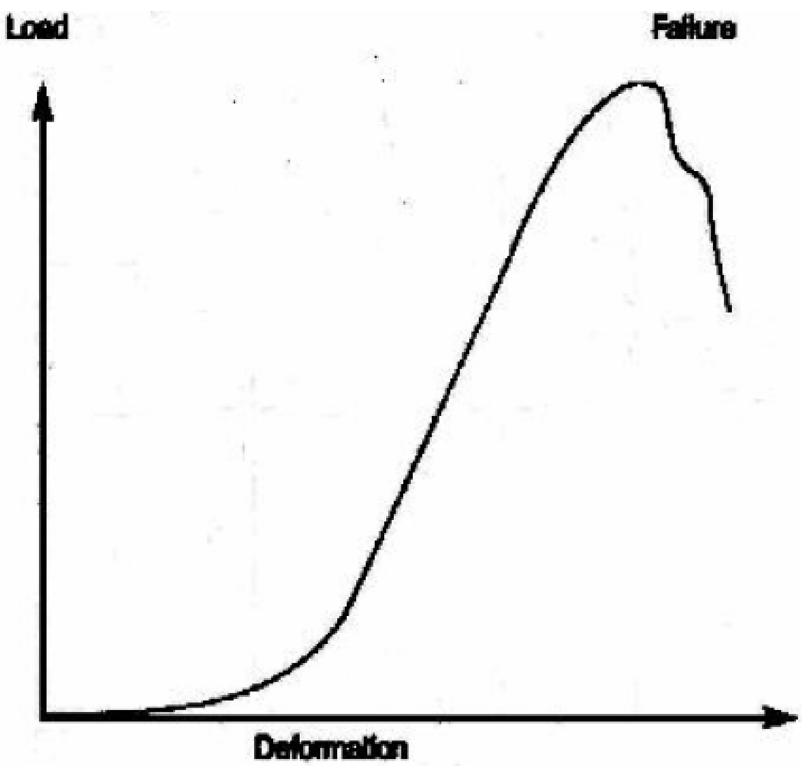
Intervertebral Disc



- Stress Vs. External load
- Linear Relationship
- Load increases as Stress increases
- Flexible properties to a certain extent

[18]

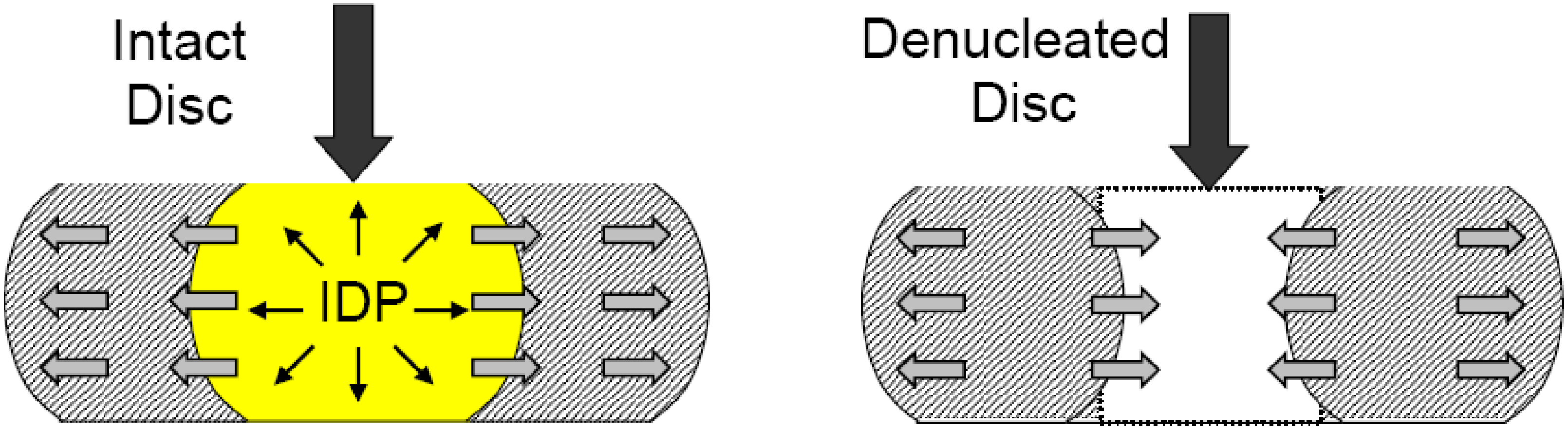
Intervertebral Disc



- Linear Relationship B/W Load and Deformation
- After Max.peak, disc will damaged
  - Herniated Disc
- As the load increases, the disc stiffens
  - At low loads, disc provides flexibility
  - At intense loads, disc provides stability

[17]

Nucleus Pulposus



- With Nucleus
  - Force pushes down
  - Nucleus absorbs shock
  - Evenly distributes pressure & force
- Without Nucleus
  - Annulus Fiber pushes inwards
  - Forces are not distributed evenly

[17]

Desired Biomechanical Properties of Artificial Disc

- Flexibility
- Good Range of Axial & Lateral rotation
  - Range of Motion: 5º of flexion-extension
- Fatigue Strength / Life
  - Estimated that individual takes 2 million steps/year, or bends 125,000 times.
  - Over 50 year of life expectancy of artificial disc = over 106 million cycles
- High Tensile & Torsional Strength
- Minimization of Contact Stress
  - Cross Sectional area of Intervertebral Disc

[14,16,17]

What types of Artificial Disc?

- Metal on Metal
- Non-Metal on Non-Metal
- Metal on Non-Metal

Biomaterials

- Inflammatory, Organotoxic or carcinogenic
- Imaging Friendly

- Metal
  - Titanium Based Alloy
    - Poor bearing surface
    - Good Imaging artifact
  - Cobalt – Chromium Based Alloy
    - Superior bearing surface
    - Poor imaging artifact
  - Stainless Steel Alloy
    - Great ductility
    - Poor biocompatibility
- Nonmetal
  - Rubber
  - Elastomers
    - Silicone
    - Polyurethane
    - Polyethylene

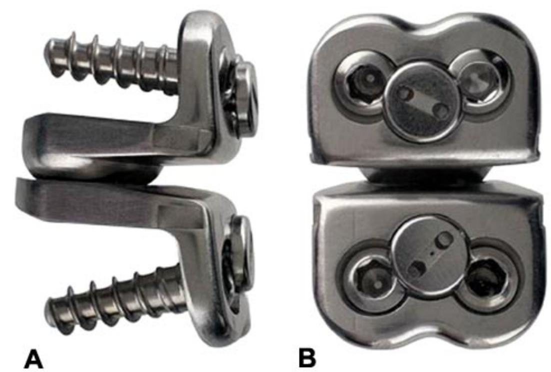
Metal on Metal Design

- Design Pros:
  - Entire cross sectional area minimizes contact stress
  - High fatigue strength
  - High tensile strength
  - High Corrosion resistance
- Design Cons:
  - Metallic/Metal ionic debris
  - Stiffness of the system
  - Lack in flexibility

[21]

Metal on Metal:
Bristol/Cummins Disc

- "Ball in socket" design secured to anterior vertebral body by screws
- Prestige ST disc
  - Titanium carbide
  - Size:
    - Lengths: 14 to 18 mm
    - Heights: 6 to 8 mm
  - Greater degree of rotation
  - Undamaged vertebrae required
  - For soft disc herniation patients [22]



Metal on Metal Design Cont…

- Kineflex–C disc
  - Cobalt chrome molybdenum endplates & core
  - “Ball in socket” design
  - Rough endplate surfaces grabs on to the surfaces of vertebrae
  - Preserve motion with low wear

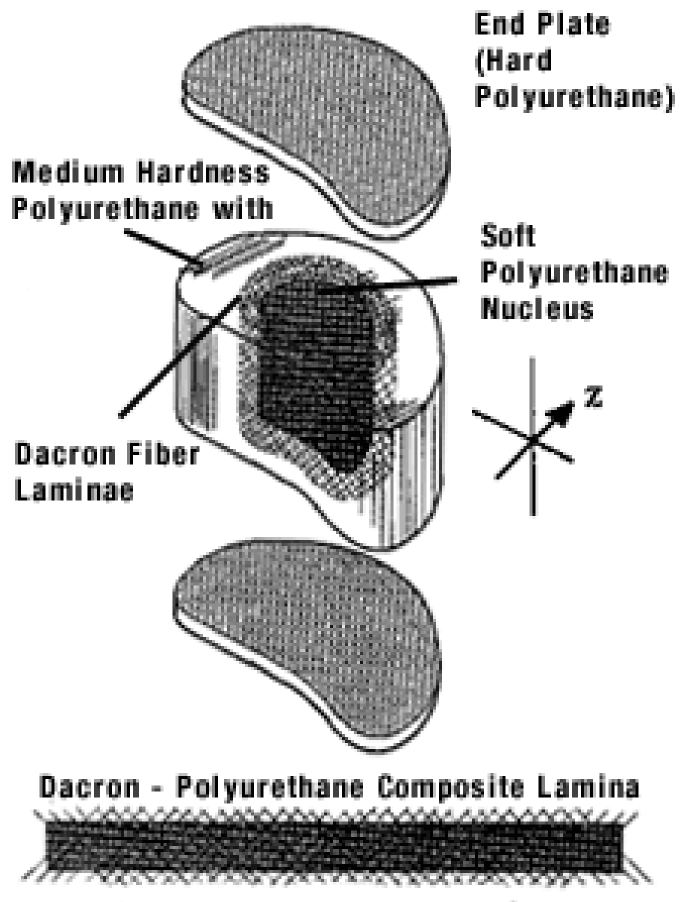
[23]

Nonmetal on Nonmetal Design

- Design Pros:
  - Mechanical similarity to the natural disc
  - Low elastic modulus
  - Close replication of disc kinematics
- Design Cons:
  - Difficult to develop long lasting device (>40 years)
  - Lack of adequate implant method
  - Lack in vertebrae fixation
  - Difficult promoting in-growth of bone implant [21]

Nonmetal on Nonmetal: Lee Disc

- Center:
  - Soft Polyurethane central core
  - Mimics the structure and the function of natural nucleus
- Outside:
  - Reinforcing the structure of central core
  - Sheet of Polyurethane with specific alternating fiber orientation
  - Mimics the function of Annulus fibrosus
- Endplates:
  - Moderately stiff
  - More similar to the bony endplates [17]



Nonmetal on Nonmetal Cont…

- Successful:
  - Portraying the compressive modulus of the natural disc
  - Mimics the compressive-torsional stiffness of the natural disc
- Failed:
  - Lack of adequate implant method
  - Poor Vertebrae fixation
  - Poor life expectancy

[18]

Metal on Nonmetal

- Design Pros:
  - High fixation rate of metal plates
  - Close replication of nucleus mechanics
  - Entire cross sectional area minimizes contact stress
  - Excellent range of motion in all direction
  - Experimentally proven to last longer
  - High Biocompatibility
- Design Cons:
  - More experimental data needs to be gathered on existing designs
  - More costly to design with variety of materials
  - Complex design including fusion of different materials

[24]

Metal on Nonmetal: Sandwich Design

- The CHARITÉ® Artificial Disc
  - First ever to be approved by FDA
  - Cobalt Chromium alloy end plates
  - Spikes for better fixation of disc
  - Sliding core is made of polyurethane and fits between the end plates
  - Allows good motion:
    - 0^{o} to 20^{o} of flexion/extension

[23]

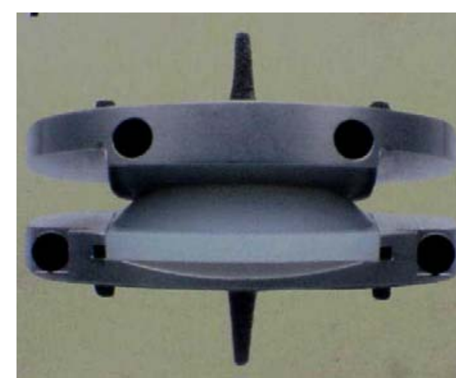
Metal on Nonmetal: CHARITÉ® Artificial Disc Cont...

- Good?
  - Designed to restore disc space height
  - Fully restores motion segment flexibility
  - Biocompatible and durable
    - Expected life span of 40 years (85 million cycles)
- Test?
  - Long term cyclical motion simulating for less than 11 years:
    - No wear debris particles identified
    - Minimal deformation of the core: with less than 8% height loss expected in 10 years of use

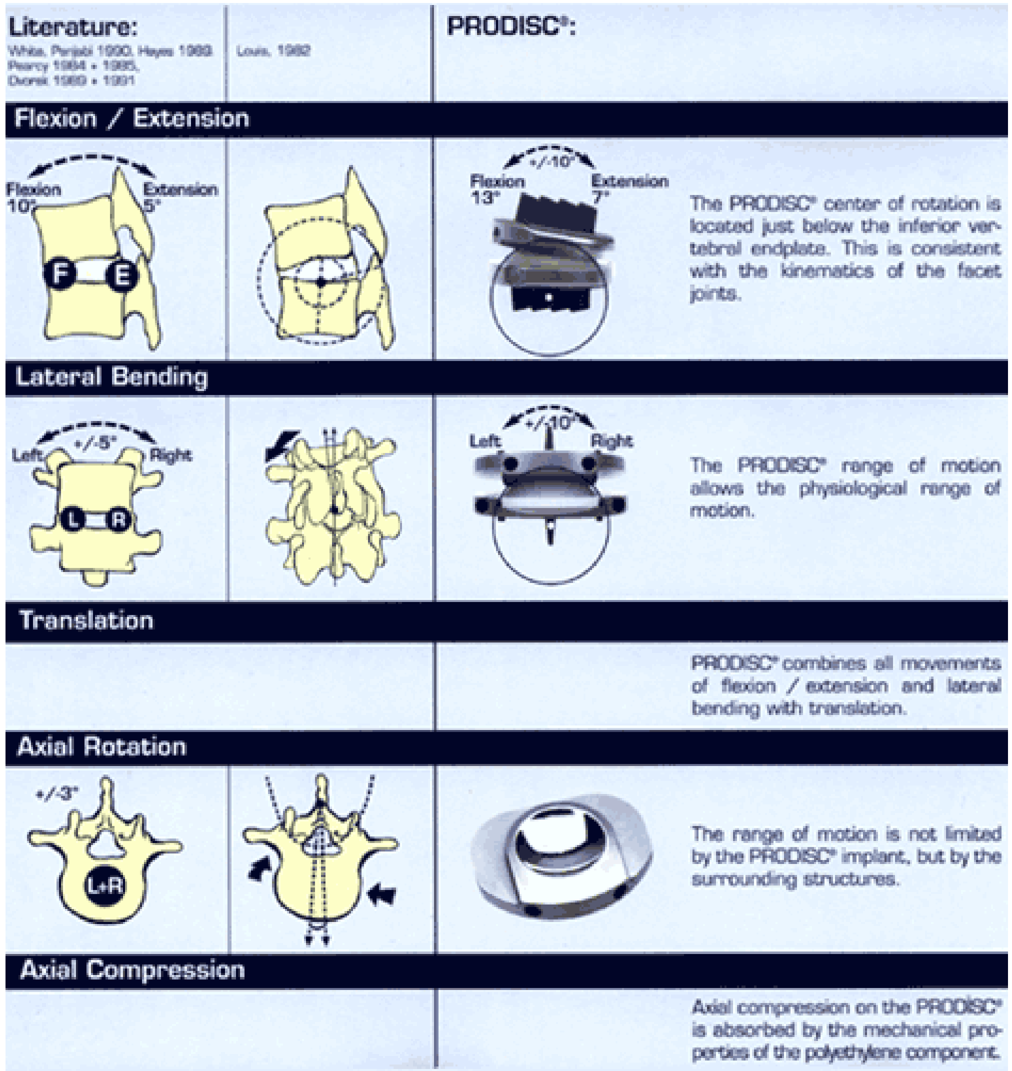
[23]

Metal on Nonmetal Cont…

- ProDisc-C:
  - Cobalt Chromium Molybdenum alloy endplates
  - Ultra-high molecular weight polyethylene
  - Connected through large central keel and spikes on each endplate
  - Sizes:
    - Two endplates: medium and large
    - Three heights of nucleus: 10, 12, 14mm
    - Three lordosis angles: 6 and 11 degrees [23]

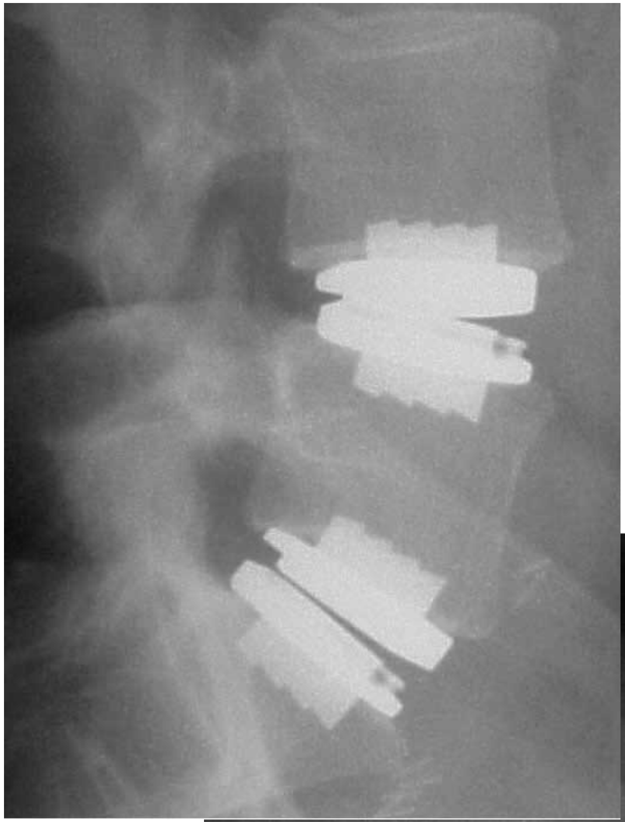


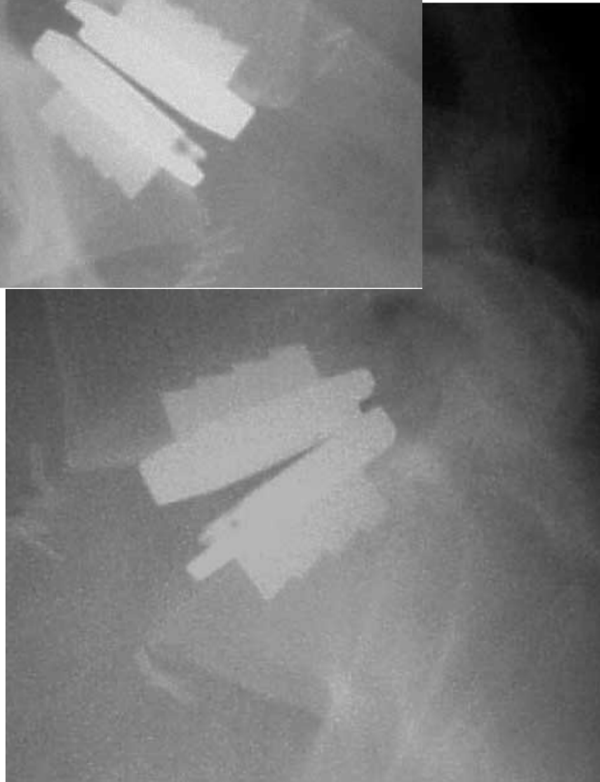
Metal on Nonmetal: ProDisc Cont... [19]



Metal on Nonmetal: ProDisc Cont...

- Durability:
  - In 7 – 11 years, 95% of patients had no implant removals, revision or failures
  - A significant reduction in back and leg pain
  - Still being tested to be improved





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Future: What is left?

- New design of Artificial Disc are being released every year
- More design needs to be approved
- Longer experiment needs to be conducted
  - More accurate data on Life Expectancy
- Improvement on surgical method
  - Easier Fixation method

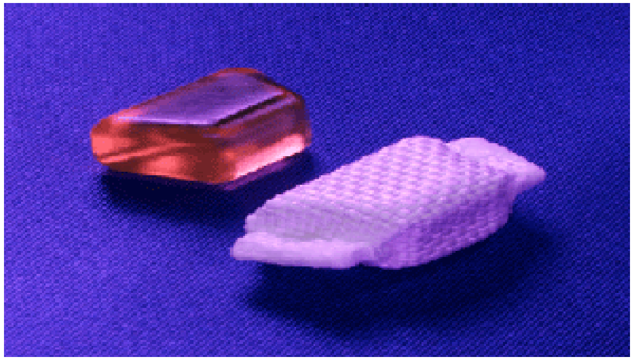
Artificial Nucleus Implantation

- Polycarbonate Urethane
- Nucleus Pulposus replacement called the Newcleus.
- Absorb water up to 35% of it's net weight
- An elastic memory spiral design allows for easy uncoiling and coiling to facilitate a minimally invasive implantation.

[19]

Artificial Nucleus Implantation

- Hydraulic Artificial Discs
  - Gel-like core covered with a tightly woven polyethylene jacket
  - Before implantation, the pallet shaped core is compressed and dehydrated
    to minimize its size
  - After implantation, the woven allows fluid to pass through the core
  - Allowing fluid to pass through in 24 hours
  - It makes 4 – 5 days for maximum expansion
  - Two hydraulic implants are needed, in most cases, to provide the necessary height [26]



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