FOR
Fellowship of Orthopaedic Researchers

Magnet Applications in Medicine and Spine

July 21-22, 2018

Part 2

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Advantages of Magnetic Force Transmission

- Non-contact (force at a distance)
- Strong and compact
- No power requirement
- Efficient signal path of static magnetic fields
- Damping for shock absorption
- 3-D characteristics of attraction/repulsion systems
  - Alignment control
  - Friction reduction

Potential Issues

- Corrosion / toxicity
- Force reduction with distance or mis-alignment
- Environmental interactions
- Brittle
- Exposure to heat

- Issues addressed:
  - Biocompatible coatings
  - Shielding of magnetic fields
  - Protection of implanted electronic devices
  - Factor of safety in design/application

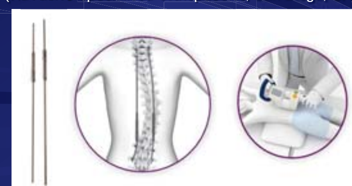
Current Use of Magnets in the Spine

- Pectus Excavatum
  - Magnetic Mini-Mover Procedure (3MP)
    Developed at UCSF Pediatric Surgery

- Early Onset Scoliosis
  - Magnetically controlled growing rods (MCGR)

Phenix Rod™
(Arnaud Soubeiran, PhD;
French designer and developer)

MAGnetic Expansion Control
(MAGEC) System
(NuVasive Specialised Orthopaedics, San Diego, CA)



Courtesy of NuVasive

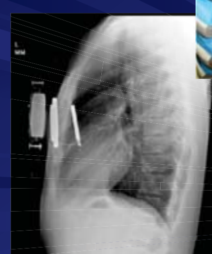
Pectus Excavatum

- Magnetic Mini-Mover Procedure (3MP)
  - Internal magnet implanted on sternum
  - External magnet in anterior chest wall brace
  - Magnetic forces used to move the sternum forward over time
- Phase 1 IDE pilot safety trial
  - 10 patients, ages 8-14 years, severe PSI>3.5
  - No detectable ill effects
  - Pectus severity index improved in early and mid-puberty patients
  - Weld failures of device (3/10, 30%)
- Multi-center safety & efficacy trial
  - 15 patients, 24-months treatment
  - Mixed efficacy based on Haller Index
  - Good satisfaction at one year
  - Device breakage, cables (7/15, 47%)

Magnetic Mini-Mover Procedure (3MP)

Magnimplant
NdFeB, Ti-encased
Ø1.5cm x 0.48 cm thick

1st Generation
Threaded stem to back plate
Prone to weld failures

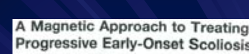


2nd Generation
Titanium cables wrap around sternum – connect magnet and back plate

Magnetic Mini-Mover Procedure for Pectus Excavatum, I, II, III, IV
Harrison MR et al (2007, 2010, 2012) and Graves et al (2017) J. Pediatric Surg

Early Onset Scoliosis

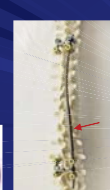
- Magnetically controlled growing rods (MCGR)
  - Expandable growing rod for children
  - Works only on the area of deformity
  - Rod is expanded externally with a magnet
  - Obtain and maintain correction as the child grows
- Phenix Rod™
  - 2005 1st implantations Europe
  - FDA approval on compassionate grounds (70 worldwide implanted)
  - 2012 1st two cases in USA reported by Wick & Konze (*AORN Journal*)
- MAGEC System (NuVasive)
  - 2009 CE Mark
  - 2012 Earliest results (Cheung et al, *Lancet*)
  - March 2014 FDA 510k approval
  - Safe and effective alternative to traditional growth rods
  - Reduced number of planned surgeries
  - Complications: failure of distraction, implant fracture, metallosis


A Magnetic Approach to Treating Progressive Early-Onset Scoliosis

Wick & Konze, *AORN Journal* 2012

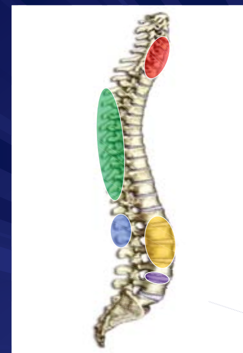
Phenix Rod™

MAGEC System



Magnet Technology
FOR Applications in the Spine

- Spinous process, stenosis
- Cervical traction
- "Dynamic" stabilized fusion
  - Adjacent segment protection
- Deformity correction, scoliosis
- Disc replacement
  - Non-contacting
  - Contacting

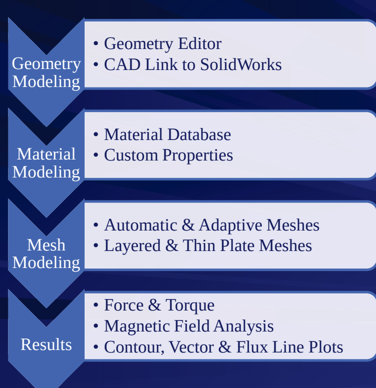


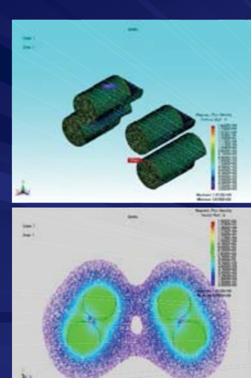
Rare Earth Magnets

- Neodymium-Iron-Boron (NdFeB) alloy
- Offers the highest *B*r and *H*ci values
- Strongest magnet available – up to 52 MGOe
- Susceptible to oxidation due to high iron content
- Use in environments up to 200°C

JMAG-Designer:
Electromagnetic Simulation Software

- High-speed, high-precision 3D FEA software used to simulate and optimize outputs of various implant and magnet configurations





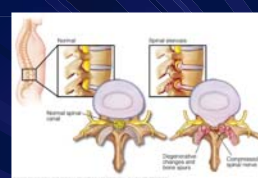
JMAG-Designer (Powersys Solutions, Southfield, MI)

Validation of FEA Results
Mechanical Testing

- Servohydraulic test systems used to measure repulsion forces of magnet configurations and evaluate strength/duration of magnetic implants

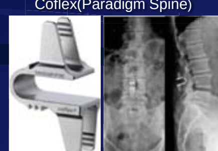
Lumbar Spinal Stenosis

- Interspinous Process Decompression
  - Relieve symptoms of lumbar spinal stenosis
  - Minimally invasive procedure
  - Alternative to decompression spine surgery, such as laminectomy



- Interspinous Process (ISP) Devices or Spacers
  - Implanted between spinous processes to distract or decompress the spine at the level of stenosis
  - Static (non-compressible) or dynamic (compressible)
  - Over 65 ISP devices currently in the market

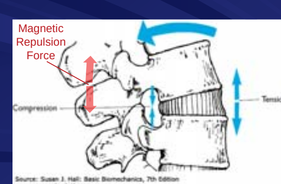
Coflex(Paradigm Spine)



Superion (Vertiflex)

Magnetically Levitated Spinous Process Implant

- Concept – Rare earth magnets inserted between adjacent lumbar spinous processes
  - Repulsion forces of magnets distract and separate vertebral bodies
  - Magnetic distraction increases foraminal height and alleviates nerve root impingement and pain
  - Magnetic force increases as distance between magnets shortens
  - “Dynamic” decompression

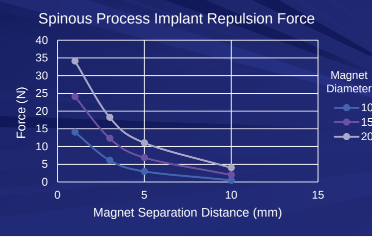


Magnetically Levitated ISP Device
Design Concepts and Modeling

- CAD design ideas in SolidWorks
  - Solid models
  - Export models to FEA software, JMAG

- Model using anatomical dimensions and magnet material properties
  - N52 grade NdFeB magnets
  - Disc shape, thickness (~3-5mm)
  - Separation distances

- Magnetic FEA modeling (JMAG)
  - Force and magnetic flux density results
  - Repulsion force (N) using various magnet diameters, separation distances and magnet thicknesses
  - Determine target distraction loads on spinous process



Cervical Pain / Traction

- Cervical Spine Injury or Neck Pain
  - Degenerative changes affecting disc, facet joints, or ligaments of spine
  - Symptoms include pain, headaches, stiffness, changes in neck ROM or gait, muscle weakness, or tingling sensations

- Cervical Traction or Manipulation
  - Nonsurgical treatment option: (1) discogenic pain; (2) degenerative disc disease; (3) radiculopathies; (4) facet joint syndrome; (5) joint hypomobility; (6) muscle spasms; (7) foraminal stenosis; and (8) post-laminectomy syndromes
  - Pneumatic neck pillows, over-door traction at home
  - Cervical manipulation/traction therapy





Traction Load and Intradiscal Pressures

- Manual Cervical Traction
  - Start 8 to 10 lbf, increase by 5-lbf intervals
  - ~25 to 40 lbf, not to exceed 45 lbf
  - Ideal effect, ~7-10% BW
  - Sustained or Intermittent, 15 to 20 min intervals
  - Daily, twice daily, 2-3 times weekly
- Effects of Traction on Intradiscal Pressure (IDP)
  - Typical resting disc, IDP ≈ 0.6 to 1.2 MPa
  - Increased disc compression, IDP ≈ 3.5 MPa (~250%)

Relative decreases in Intradiscal Pressure with applied traction forces

	IDP Change per Pound of Traction (kPa/lbf)
Cripton et al. (2001)	16.7
Wu et al. (2012)	1.6 – 1.9
Gudavalli et al. (2013)	1.6 – 7.2

  - 10 pound traction load, IDP reduced by 14% to 28%

Magnetic Implant Technology:
Spinal Traction

Targeted

Spinal Traction via Magnetic Suspension

Continuous

Low Force

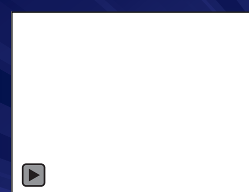
Potential Benefits

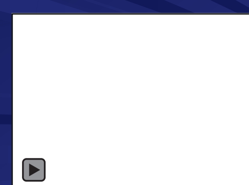
- ✓ Disc Height Preservation
- ✓ Minimal Tissue Disruption
- ✓ Pain Relief

Continuous Low Force Traction = Intermittent High Force Traction

Internal Magnetic Traction Device for the Cervical Spine

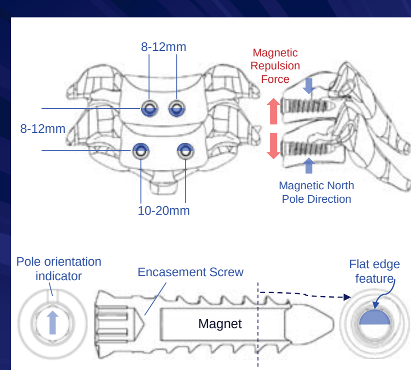
- Concept – Array of rare earth magnets placed in cervical vertebrae to produce vertical distraction force across the disc
  - Titanium implant or screws encapsulate magnets
  - Opposing repulsive magnetic fields provide distraction forces across spine segment
  - Sustained magnetic separation results in foraminal distraction, relief of any disc bulge, and alleviation of nerve root pressure thus reducing pain
  - Magnetic forces increase as distance between magnets shortens
  - “Dynamic” levitation or internal traction





Internal Magnetic Traction Device
Screw Design Features

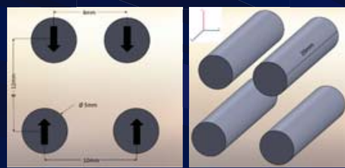
- Array of 4 Magnetic Screws
  - Screw: Ø 5–6 mm X 16–25 mm length
  - Magnet: Ø 3–5 mm X 10–20 mm length
  - Superior screws 8 to 12 mm apart
  - Inferior screws 10 to 20 mm apart
  - Diametrically magnetized
- Design Features
  - Typical cervical screw system
  - Ti-6Al-4V alloy body
  - Hex/torx drive mechanism
  - Flat edge feature to orient magnet pole
  - Magnet fully encased, tip welded

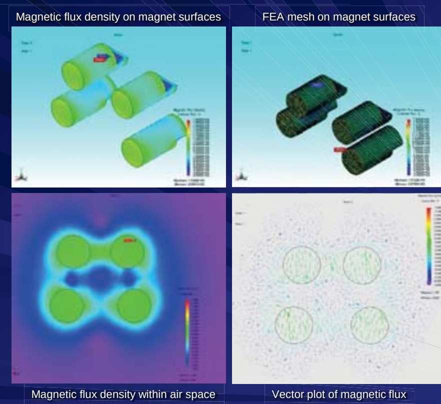


Internal Magnetic Traction Device

FEA Modeling of Magnetic Flux

Magnetic Traction Model



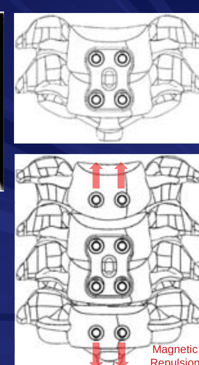


- Magnetic Cervical Traction, 5N separation force (range, 2 to 10N)

Magnetic Plate and Screw System

"Dynamic" Fusion

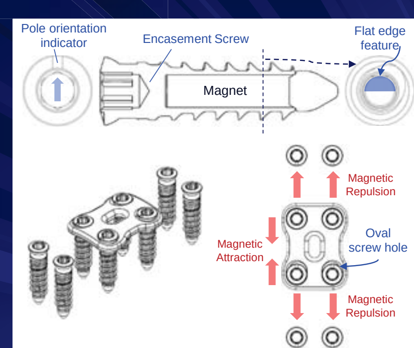
- Concept – Rare earth magnets in an anterior plate and screw fusion system to generate a compressive force across the fusion site
  - Attraction forces stabilize vertebrae across fusion site
  - "Dynamic" compression
  - Expandable to multiple levels
  - SMF may promote bone growth and enhance fusion mass
  - Repulsion forces at adjacent non-fused segments



Magnetic Plate and Screw System

Design Features

- Magnetic Screws
  - Screw: Ø 4–5 mm X 16–25 mm length
  - Magnet: Ø 3–4 mm X 10–20 mm length
  - Diametrically magnetized
  - Magnet fully encased, tip welded
  - Pole orientation indicator
- Plate Design Features
  - Typical anterior plate system
  - Contouring profile to vertebral body
  - Single plate: 2 or 4 screw holes
  - Multi-level plate
  - Round or oval screw holes to allow sliding of screw within plate
  - Provide compression to interbody implant and/or bone graft material

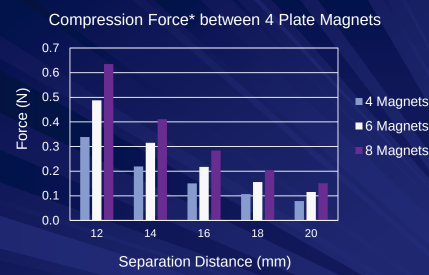


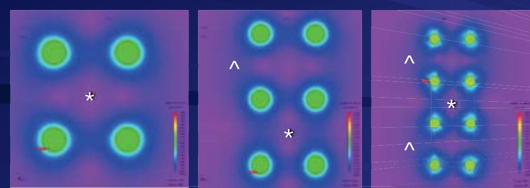
Prototype Magnetic Plate and Screws for Testing

Magnetic Plate and Screw System

FEA Modeling of Magnetic Flux

- Magnetic Plate and Screw System
  - Compression force doubles from 4 magnet to 8 magnet configuration
  - Larger forces possible as magnet diameter increases
  - Magnetic force increases as separation distance decreases
  - Repulsion forces^ generated at adjacent non-fused segments both cranial and caudal to fusion site





*Compression Force

^Repulsion Force

Magnetic flux density for 4, 6 or 8 magnet configurations

Early Onset Scoliosis (EOS)

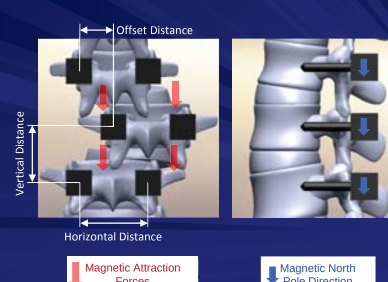
- Defined as a curvature of the spine greater than 10 degrees in children from birth to 10 years of age
- High risk of spinal deformity progression
  - Chest cavity malformation
  - Heart problems and impaired lung growth
  - Thoracic insufficiency syndrome (TIS)
- Non-surgical treatments
  - Observation
  - Bracing / Casting
- Surgical procedures
  - Distraction-based implants
    - Magnetically controlled growing rods (MCGR), i.e. MAGEC System
  - Guided growth implants
  - Compression-based implants
  - Fusion

Magnet Technology

Abnormal Spinal Curvature

EOS and Idiopathic Scoliosis

- Concept – Rare earth magnets used to realign and stabilize the spine and prevent further curve progression
  - Magnets housed in locking mechanism attached to head of pedicle screws
  - Magnetic screws placed in pedicles at level of curve, above and below
  - Attraction forces stabilize vertebrae across levels of spine
  - Magnet poles oriented to maintain desired vertical alignment
  - Can be combined with external magnets in a brace

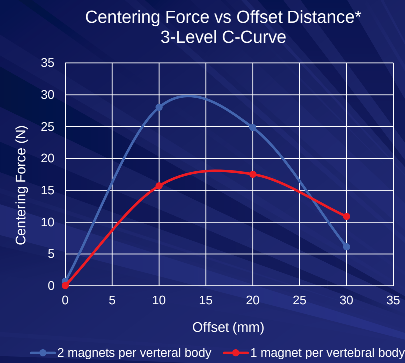


Magnetic Spine Curvature System

FEA Modeling of Centering Force

- Simulations of 3-level C-curve
  - 2cm x 2cm x 2cm magnet
  - 5cm horizontal separation
  - 4cm vertical separation
- Centering Force vs Offset Distance
  - Centering force affected by number of magnets per vertebral body
  - Centering force generated by magnet attraction and desire of magnets to align vertically

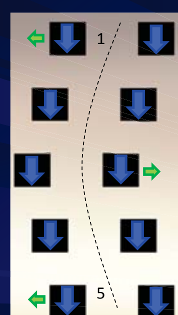
*Offset Distance	Degree of Curvature
10 mm	14 deg
20 mm	27 deg
30 mm	37 deg

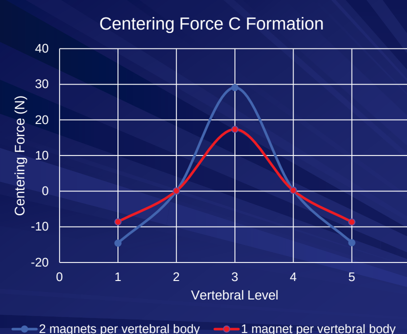


Magnetic Spine Curvature System

FEA Modeling of Centering Force

Simulation of 5-level C-curve with 10mm (14°) Offset Distances





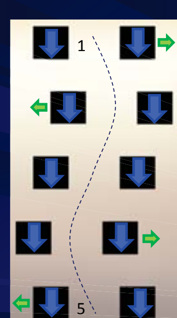
Magnet Pole Direction

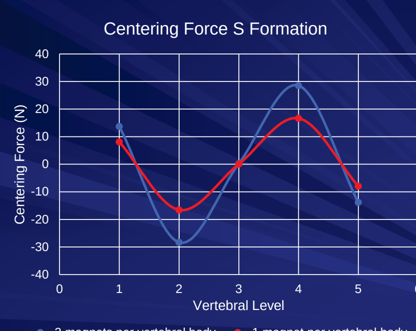
Direction of Force on Vertebra

Magnetic Spine Curvature System

FEA Modeling of Centering Force

Simulation of 5-level S-curve with 10mm (14°) Offset Distances



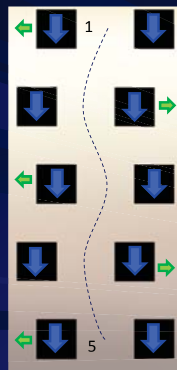


Magnet Pole Direction

Direction of Force on Vertebra

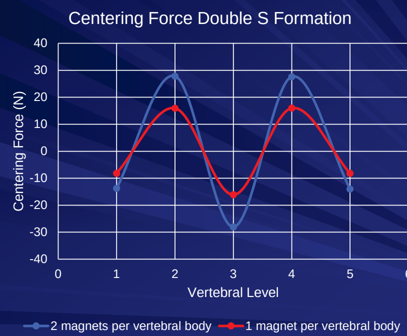
Magnetic Spine Curvature System
FEA Modeling of Centering Force

Simulation of 5-level Double S-curve with 10mm (14°) Offset Distances



Magnet Pole Direction

Direction of Force on Vertebra



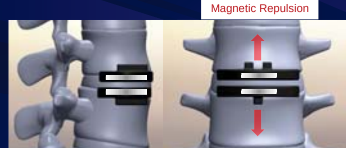
Artificial Disc Replacement

- Degenerative disc disease (DDD)
  - Most common cause of low back and neck pain
  - Replace diseased disc with artificial disc replacement
  - Provide pain relief and allow normal motion of spine
- Total disc replacement (TDR), cervical and lumbar
  - Unconstrained or semi-constrained
  - Articulating surface(s)
  - Fixation endplates

Magnets and Total Disc Replacement in the Spine

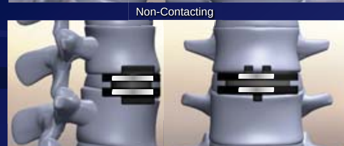
- Concept – Rare earth magnets placed in plates that are fixed to the vertebral endplates and oriented to generate a repulsive force across the disc space. Both non-contacting and contacting designs are possible.

Magnetic Repulsion



Non-Contacting

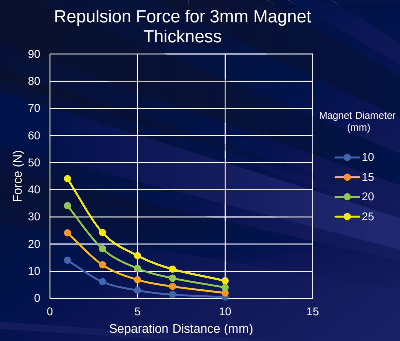
All-in-One Device

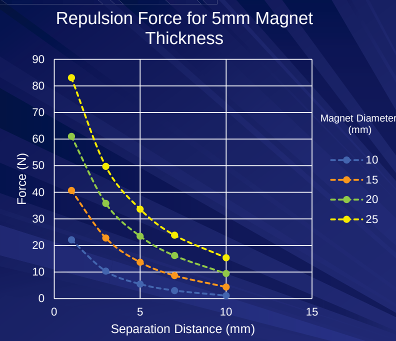


Multi-Component Spacer

Contacting Articulation

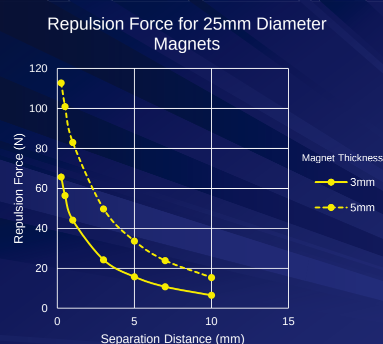
Magnetic Disc Replacement Repulsion Forces





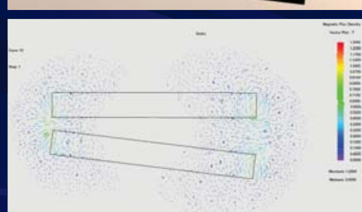
- Effect of magnet thickness on repulsion force of magnets
- Force is dependent on magnet size (diameter and thickness) and separation distance

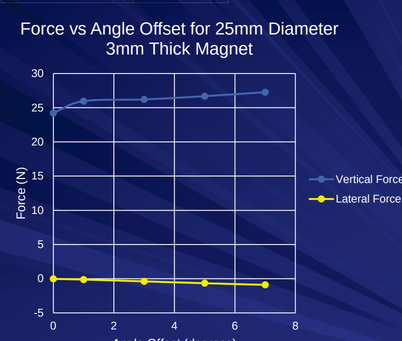
Magnetic Disc Replacement Repulsion Forces



- Repulsion forces approach 65 to 120 N as separation distance goes to zero (for Magnet Diameter 25mm)

Magnetic Disc Replacement Repulsion Forces

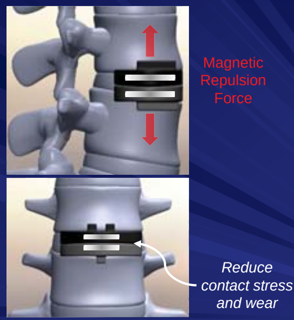




- Effect of angle offset of magnet on vertical and lateral repulsion forces
- Vertical forces increase slightly with increasing angle offset
- Lateral forces remain close to zero with slightly negative values at higher angle offset

Magnets and Total Disc Replacement in the Spine

- Contacting articulation design of an artificial disc replacement with magnets
  - Magnets housed in metal fixation plates attached to superior and inferior vertebral endplates
  - Magnets repel at the surface articulation and impart a repulsive force on the vertebra
  - Repulsive forces reduce contact stresses on the articulating surface of the device
  - Reduced wear due to reduction in contact stress



Review: Magnets in Medicine and Spine

- Magnet properties, strengths
- Advantages/disadvantages of magnets and magnetic field exposure
- Clinical uses of magnets – *Current and Future*
  - Diagnostic imaging
  - Potential therapeutic benefit
  - Dentistry, craniofacial applications, joint replacements, bone healing, prosthetic attachment
- Numerous spine applications for use of magnetic technology

THANK YOU