Magnet Applications in Medicine and Spine

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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)
    - 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%)

- **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

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Magnetic Mini-Mover Procedure for Pectus Excavatum, I, II, III, IV

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
(3MP)
Magnimplant NdFeB, Ti-encased Ø1.5cm x 0.48 cm thick

Phenix Rod™

Postop AP

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

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**Rare Earth Magnets**

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

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**J MAG-Designer:**

Electromagnetic Simulation Software

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

- Geometry Modeling
  - Geometry Editor
  - CAD Link to SolidWorks

- Material Modeling
  - Material Database
  - Custom Properties

- Mesh Modeling
  - Automatic & Adaptive Meshes
  - Layered & Thin Plate Meshes

- Results
  - Force & Torque
  - Magnetic Field Analysis
  - Contour, Vector & Flux Line Plots
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

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

\[ \text{Design Concepts and Modeling} \]

- CAD design ideas in SolidWorks
  - Solid models
  - Export models to FEA software, JMAG
- Model using anatomical dimensions and magnet material properties
  - NS2 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

![Spinous Process Implant Repulsion Force Graph](image)

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

![Cervical Traction Diagram](image)

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**

<table>
<thead>
<tr>
<th>IDP Change per Pound of Traction (kPa/lb)</th>
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<tbody>
<tr>
<td>Crutin et al. (2001)</td>
</tr>
<tr>
<td>Wu et al. (2012)</td>
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<tr>
<td>Gudavalli et al. (2013)</td>
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</tbody>
</table>

- 10 pound traction load, IDP reduced by 14% to 28%
Magnetic Implant Technology: Spinal Traction

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

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**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

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**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
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

  - *Compress 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 (MCG), 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

<table>
<thead>
<tr>
<th>Offset Distance</th>
<th>Degree of Curvature</th>
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<tbody>
<tr>
<td>10 mm</td>
<td>14 deg</td>
</tr>
<tr>
<td>20 mm</td>
<td>27 deg</td>
</tr>
<tr>
<td>30 mm</td>
<td>37 deg</td>
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**Centering Force vs Offset Distance**

- Offset Distance
- 3-Level C-Curve
  - 2 magnets per vertebral body
  - 1 magnet per vertebral body

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

- Magnet Pole Direction
- Direction of Force on Vertebra

**Simulation of 5-level 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.
Effect of magnet thickness on repulsion force of magnets
Force is dependent on magnet size (diameter and thickness) and separation distance

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

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