Magnet Applications in Medicine and Spine

July 21-22, 2018

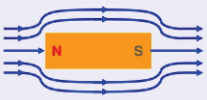
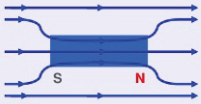
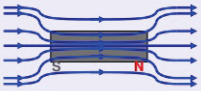
Part 1

Stephen D. Cook, PhD
Executive Director

Fellowship of Orthopaedic Researchers
320 Hammond Highway
Metairie, Louisiana

Magnet Basics

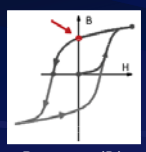
Comparison of Magnetic Materials

DIAMAGNETIC	PARAMAGNETIC	FERROMAGNETIC
1. Diamagnetic substances are those substances which are feebly repelled by a magnet. Eg. Antimony, Bismuth, Copper, Gold, Silver, Quartz, Mercury, Alcohol, water, Hydrogen, Air, Argon, etc.	Paramagnetic substances are those substances which are feebly attracted by a magnet. Eg. Aluminium, Chromium, Alkali and Alkaline earth metals, Platinum, Oxygen, etc.	Ferromagnetic substances are those substances which are strongly attracted by a magnet. Eg. Iron, Cobalt, Nickel, Gadolinium, Dysprosium, etc.
2. When placed in magnetic field, the lines of force tend to avoid the substance. 	The lines of force prefer to pass through the substance rather than air. 	The lines of force tend to crowd into the specimen. 

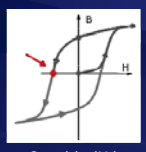
Magnet Basics

Magnet and Magnetic Field Properties

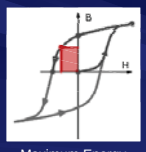
- Magnetic Field Strength, or Flux Density (*B*)
- Magnetizing Force (*H*)
- B/H Curve
  - Plot of Magnetic Force (H) vs resultant Flux Density (B)
  - Residual Induction, or Remanence (*Br*)
  - Coercive Force, or Coercivity (*Hc*)
  - Maximum Energy Product (BH_{max})



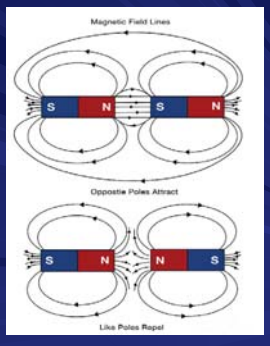
Remanence (*Br*)



Coercivity (*Hc*)

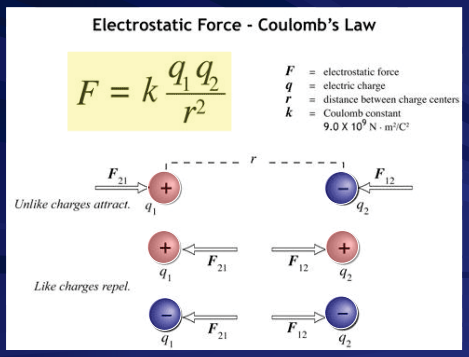


Maximum Energy Product (*BH*max)

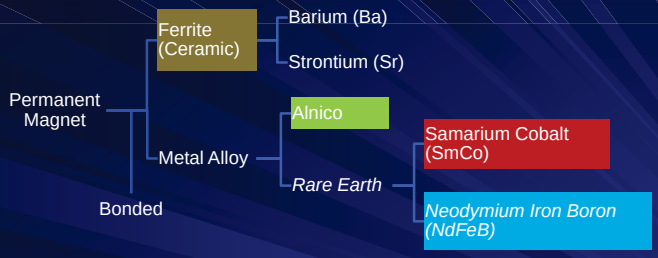


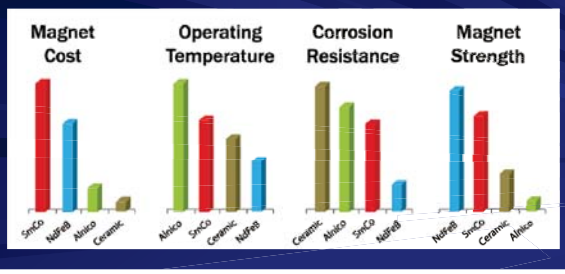
Coulomb's Law of Magnetism

- *"The force of attraction/repulsion between two magnetic poles is directly proportional to the strength of the poles and inversely proportional to the square of the distance between them."*

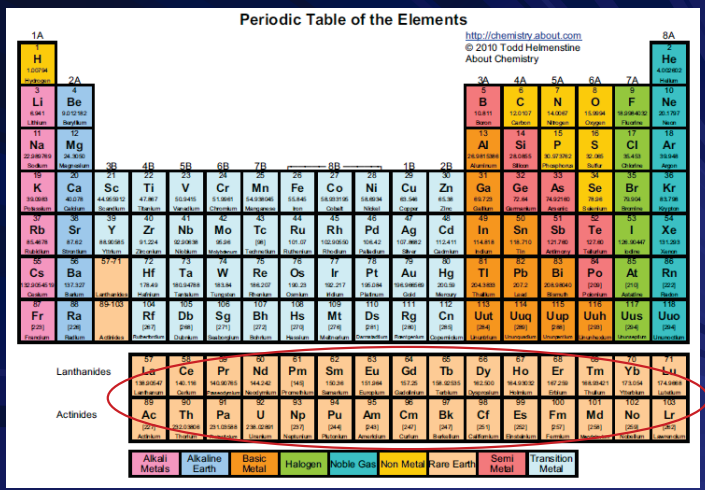


Permanent Magnetic Materials





Rare Earth Metals



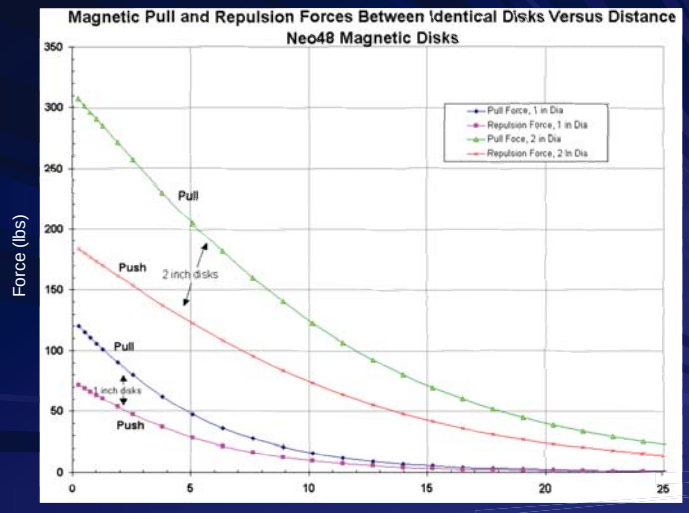
Neodymium Iron Boron (NdFeB)

- Rare Earth magnet
- 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

Advantages of Magnetic Force Transmission

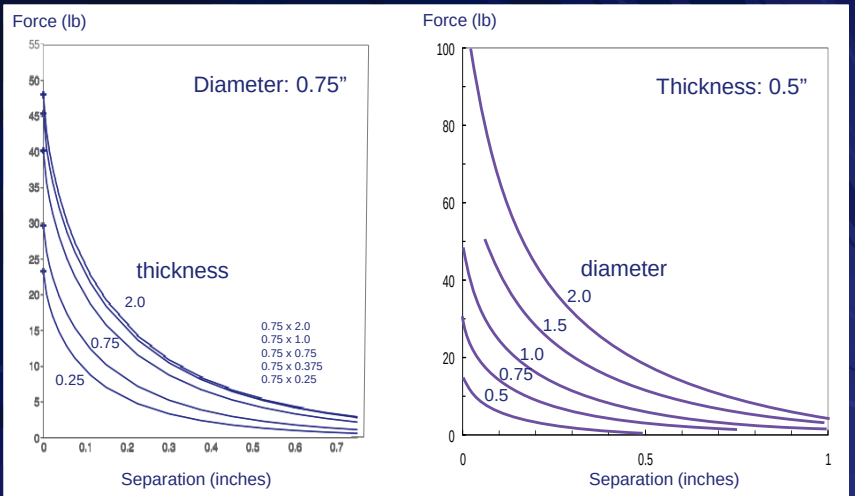
- Non-contact (force at a distance)
- Strong and compact
- No power requirement
- Efficient signal path of static magnetic fields
- Damping for shock absorption
- 3-D characteristics of attraction/repulsion systems
  - Alignment control
  - Friction reduction

Magnetic Forces



Magnetic Forces

Calculated forces between two identical magnets



Potential Issues

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

Corrosion / Toxicity

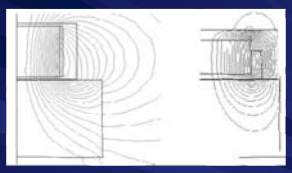
- Cytotoxicity of raw material, corrosion products
- Biocompatible coatings
  - Polymers (PTFE, Parylene, Epoxy)
  - Stainless steel
  - Titanium
  - Tin
  - Palladium
  - Titanium nitride
  - Chromium nitride
  - Laser-welded seal

Environmental Interactions

- Avoid external magnets or ferrous metallic objects
  - Shielding of magnetic field
  - Soft magnetic keeper (Pd-Co-Ni, Pd-Co-Pt alloys)

Containment of magnetic flux

Open Field

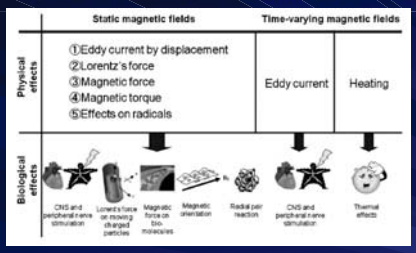


Closed Field

- Protection of implanted electronic devices, Pacemaker/ICD
  - Distance & field strength

Safety of Static Magnetic Fields

- Physical & biological effects of SMFs/EMFs*



High SMF (>3T) exposure in humans:

- Transient temporal sensations caused by subject motion
- No lasting or negative effects on cognitive functions, cardiac function, or body/skin temperature

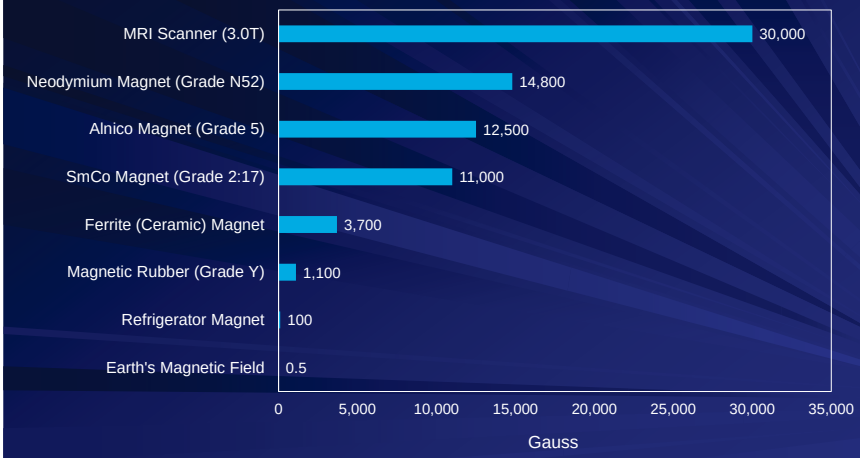
*Yamaguchi-Sekino, et al. *Magn Reson Med Sci* (2011): Biological effects of electromagnetic fields and recently updated safety guidelines for strong static magnetic fields.

- *No compelling evidence for long-term health effects of static magnetic fields up to 8 Teslas*

"Guidelines on Limits of Exposure to Static Magnetic Fields" (2009) by ICNRP (*International Commission on Non Ionizing Radiation Protection*)

Exposure	Magnetic Flux Density Limit
Occupational	
Head and trunk	2 T
Limbs	8 T
General Public	
Any part of body	400 mT

Relative Gauss Measurements



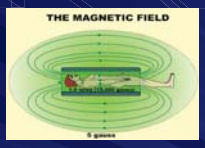
10,000 Gauss = 1 Tesla

Magnets in Medicine

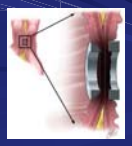
- Dentistry and Prosthodontics
  - Denture retention
  - Teeth movement

- Craniofacial Prosthetics
  - Attachment

- Magnetic Resonance Imaging (MRI)
  - 0.5 to 3.0 Tesla
  - 10.5T (U of Minn.)



- Surgical GI Tract
  - Compression anastomosis



Magnets in Medicine

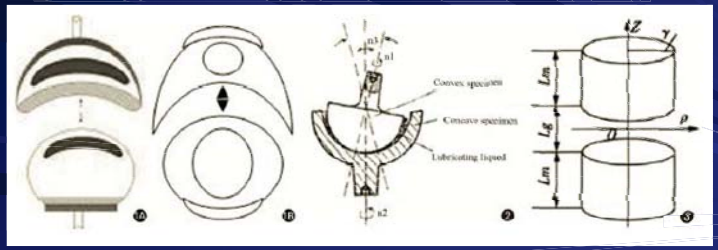
- Effects of SMFs on bone formation and healing[#]
  - Mostly *in vitro* and *in vivo* animal studies
  - Low to moderate field strengths (4 mT to 100 mT, <1T)
  - Exposure duration (15 days to 12 weeks)
  - Effects of applied SMF using magnets:
    - Enhanced bone formation and healing
    - Increased BMD
    - Inhibited bone loss in OVX rats
    - Faster peri-implant bone formation
  - No side effects or adverse reactions

- Limited study in humans on SMF effects on bone
  - Hypo-magnetic fields (<5μT), i.e. astronauts in deep space
  - High strength fields (>3T), i.e. diagnostic imaging

[#]Zhang J, et al. *Prog Biophysics Mol Biol* (2014): The effects of static magnetic fields on bone.

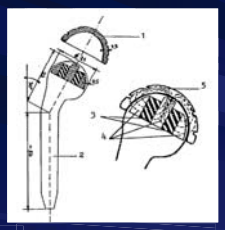
Magnets in Orthopaedics

- Magnetic Suspension Hip Joint
  - Dai & Nie, *Chinese Medical Journal*, 2010
  - Opposing magnets in concave and convex mating implants
  - Titanium nitride plating of magnets
  - Friction wear tests
  - Magnetic poles repel, joint load & friction are reduced

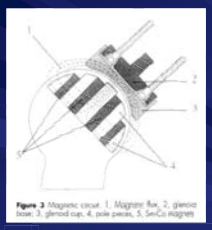


Magnets in Orthopaedics

- Magnetic Total Hip & Total Shoulder Replacement
  - Doursounian et al, 1988 and 1998
  - Combined Sm-Co magnets & F-17 steel poles in polyacetal ball joint
  - Titanium nitride-coated SS “keeper” in socket/glenoid



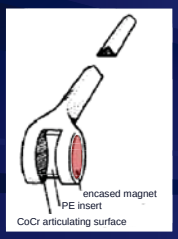
- THA model, 7 ewes
- Good biocompatibility
- Femoral fractures (4)
- Dislocation (1)



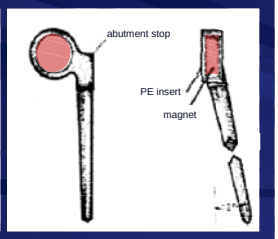
- TSR, 66yo female cancer patient
- Breakaway force, 40N
- Good radiographic & functional results at 24 months
- Late subluxation of device

Magnets in Orthopaedics

- Magnetic Elbow Prosthesis
  - Esformes et al, 1981
  - Prototype with magnetically constrained axis
  - Greater stability than non-hinged devices
  - Reduced tensile and rotatory forces on prosthetic fixation
  - Prevent loosening and breakage



Humeral component



Ulnar component

Elbow prosthesis

Magnets in Orthopaedics

- Leg Lengthening / Expandable Rods
  - JTS® Extendible Implant (Stanmore Implants, UK)
    - FDA 510K approvals 2011, 2014
    - Internally implanted magnet/gear box
    - External drive unit with rotating magnetic field
    - Growth rate: 1mm in 4 minutes
  - PRECICE® System (NuVasive)
    - Adjustable intramedullary nail (magnet/gear box)
    - Femur and tibia, limb length discrepancy
    - External Remote Control (ERC)
    - Precise non-invasive expansion

Magnetic Coupling & Direct-to-Skeleton Prosthesis Attachment

- One in 200 Americans living with a limb loss
  - In 2008, ~1.7 million persons…By 2050, estimated 3.6 million
  - 82% amputations secondary to dysvascular disease
    - 40% comorbidity – Diabetes mellitus
  - Decline in trauma- and cancer-related amputations
- Increase in U.S. military amputation rates
  - War-related injuries & major limb amputations
  - Return of amputees to service
  - High activity levels

Amputation Rates: *Percentage of U.S. Battle Injuries**

	Percentage	*Number*
American Civil War	12.0%	50,000 +
World War I	1.7%	2,610
World War II	1.2%	7,489
Korean War	1.4%	1,477
Vietnam Conflict	3.4%	5,283
Global War on Terrorism[#]	2.6%	1,600 +

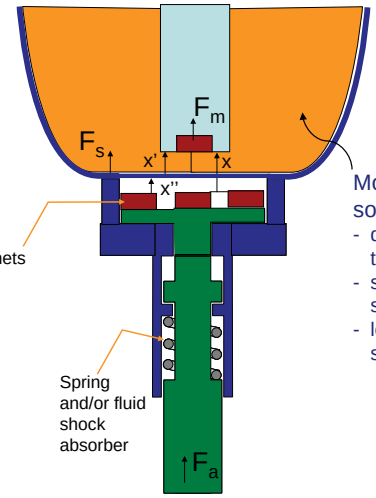
[#]Statistics for September 2001 to September 2010; CRS Report RS22452 (September 28, 2010).
*Isaacson BM et al: IEEE 2011, p2991-2994; CRS Report RL32492 (February 26, 2010).

Direct-to-Skeleton Prosthesis Attachment

- Amputees need recovery to normal functions
  - Walking, running, daily activities
- Benefits of magnetic prosthetic attachment system
  - Reduce load transmission through soft tissues
  - Avoid infections via skin-penetrating anchor devices

Magnetic-Mechanical System Concept

When loaded, magnets approach and transmit force to skeleton



Modified traditional socket
- distributed load on soft tissue
- suspension: vacuum, straps
- load onto proximal skeleton through skin

When unloaded, spring pushes external magnets away, minimizing push-off force

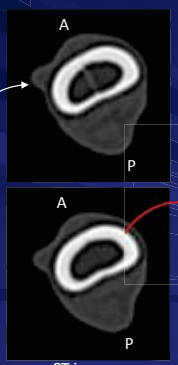
Neodymium-Iron-Boron (Nd-Fe-B)

- Rare earth magnetic material
  - Military defense applications, motor design, MagLev train
  - Clinical use in artificial valves, inner ear devices, craniofacial attachment, dentistry
- Strong magnetic properties
  - High retentive capacity
  - High resistance to demagnetization
- Toxic, not biocompatible
  - Low corrosion resistance
  - Needs biocompatible coating
    - i.e. titanium, titanium nitride, palladium, stainless steel, Teflon, gold

Goat Amputation Model

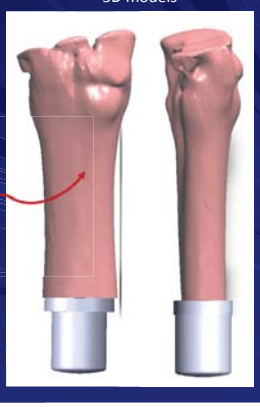
- Anatomical measurements – metacarpal bone
- Radiographic and CT imaging studies
- 3D models of goat forelimb

Mid-metacarpal resection



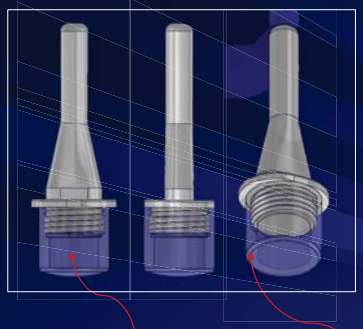
CT images

3D models



Design of Implantable Magnet System

Design Concept for Goat Metacarpal Implant



Titanium Stem

Threaded Attachment – *Well for magnet; Mechanical seal*

Magnet

PEEK Cap – *Magnet Enclosure*

HA-coated Plasma-sprayed Titanium – *Bone Fixation*

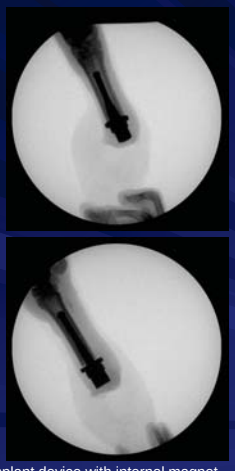
Implant Collar – *Support against Resected Bone*

Nd-Fe-B Magnet *Ni-Cu-Ni Coated / Gold Plated* *1/2" Diameter x 5/8" Height*

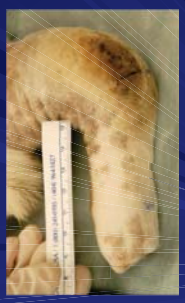
Implantable Device – 2 Sizes: Small & Large

Surgical Amputation & Implantation

1) Mid-metacarpal amputation



2) Surgically implant device with internal magnet



3) Healing period – *2 to 4 Weeks*

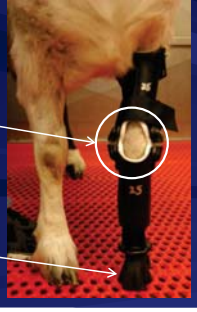
Prototype Prosthesis for Goat

carpus

metacarpal

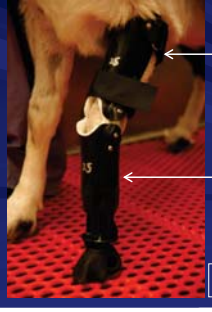
Cast molding of residual limb

CONCEPT



Hinge for carpus

Anatomical "hoof"

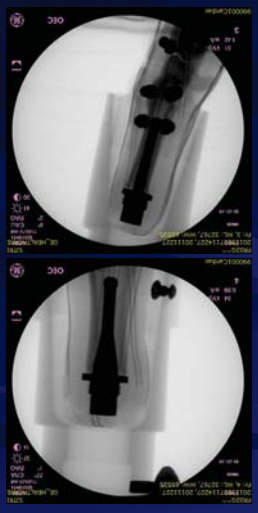


Velcro straps for upper limb suspension

Custom-fit socket with foam liner

CUSTOM

Goat Prosthesis Trials



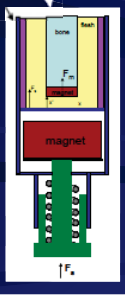
C-arm image of limb in prosthesis

Video of goat wearing prosthesis

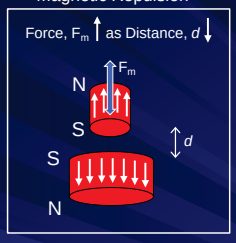
Prosthesis With Magnetic Suspension

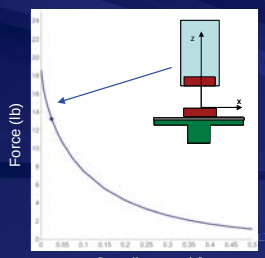
Replace Lower Socket –

Magnetic suspension control mechanism

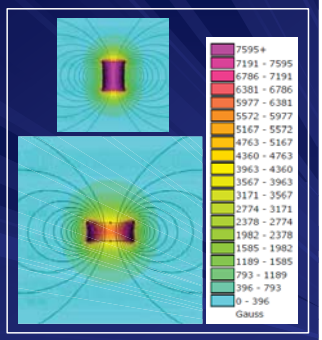


Magnetic Repulsion





Gap distance (d)

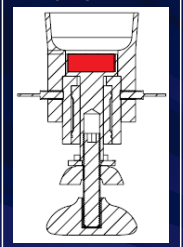


Magnetic Field Visualization

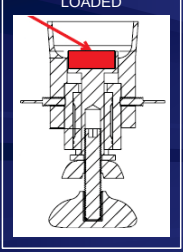
Prosthesis With Magnetic Suspension

Design Schematic

UNLOADED

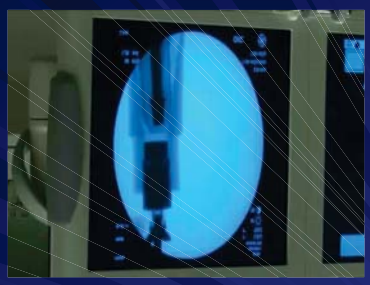


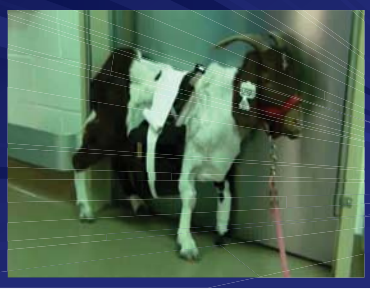
LOADED



Fabricated Prosthesis

Prosthesis With Magnetic Suspension

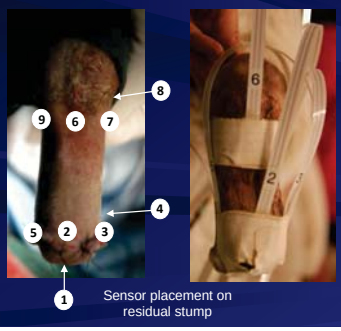





Instrumented Prosthesis
Measurement of Dynamic Contact Pressures

Thin Film Polymer Sensors
Static & Dynamic Force

Wireless transmission of live data to PC



Sensor placement on residual stump

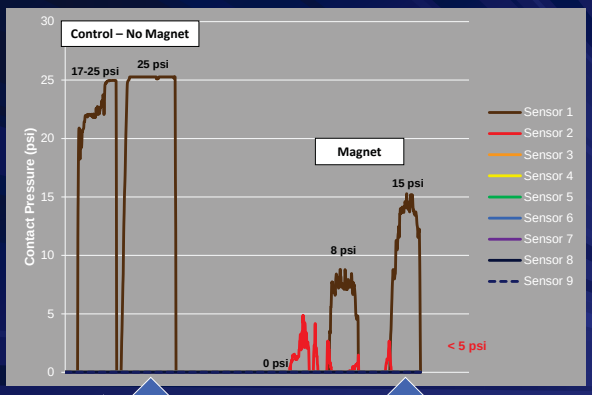
Measure Contact Pressures in Socket

1) *External Magnet in Lower Prosthesis*

versus

2) *Non-Magnetic Control*

Load Reduction & Re-Distribution of Pressure
Effects of Magnet



40 – 50% Reduction in Contact Pressure

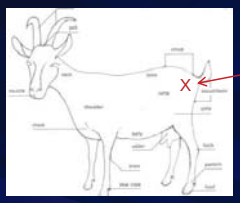
Shift in Pressure: End of Stump to Anterior Socket

Applied Force (lbf)

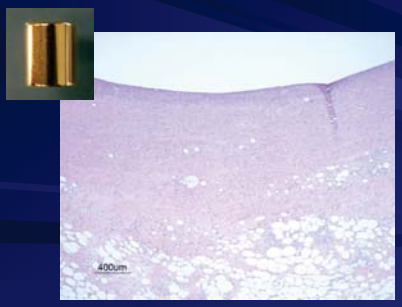
4 6 8 10

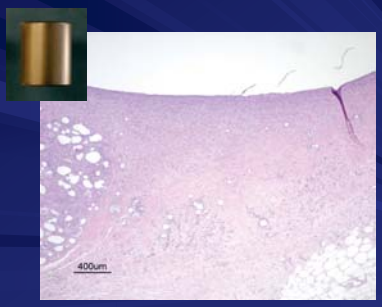
4 6 8 10

Biocompatibility Tissue Test



Nd-Fe-B Magnet
vs.
Titanium Control



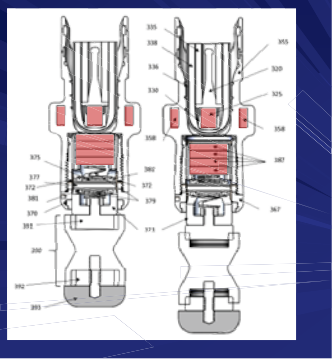


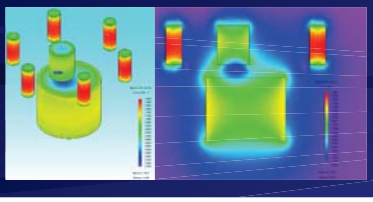
Nd-Fe-B Magnet | Titanium Control

Histopathology Results

Current Prosthetic Design

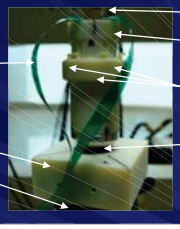
- U.S. Patent 9,707,105 *"Magnetic Prosthetic Implants and Methods Thereof"* (Issued Jul. 18, 2017)
- U.S. Patent 15/707,937
  - Internal implant magnet
  - Adjustable pilon
  - Housing for larger lower magnets
  - Arrays of magnets incorporated into prosthesis socket
  - Magnetic modeling analysis of magnetic flux density and forces (JMAG, Powersys-Solutions)

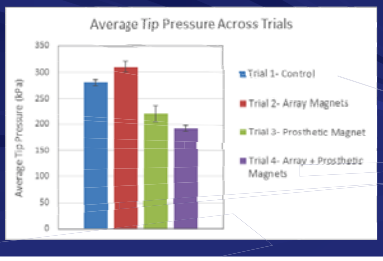




In Vitro Testing of Magnetic Arrays

- Reduced peak pressures on limb
- Enhanced distribution of contact stresses





- Self-centering motion
- Lateral forces reduced
- Increased stability
- Dynamic levitation

Review: Magnets in Medicine

- Magnet properties, strengths
- Advantages/disadvantages of magnets and magnetic field exposure
- Clinical uses of magnets
  - Diagnostic imaging
  - Potential therapeutic benefit
  - Dentistry, craniofacial applications, joint replacements, bone healing, prosthetic attachment
  - Current and future spine applications:

Magnet Applications in Medicine and Spine, Part 2
Sunday, July 22
8:00 – 9:00am