

BIOMECHANICS OF THE SPINE AND IMPLANT FIXATION

ORTHOKINETIC TECHNOLOGIES & ORTHOKINETIC TESTING TECHNOLOGIES

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DISCLOSURES

- OKT – Strategic Planning & Regulatory Consulting
- OKT² – ISO 17025 A2LA Accredited Test Facility

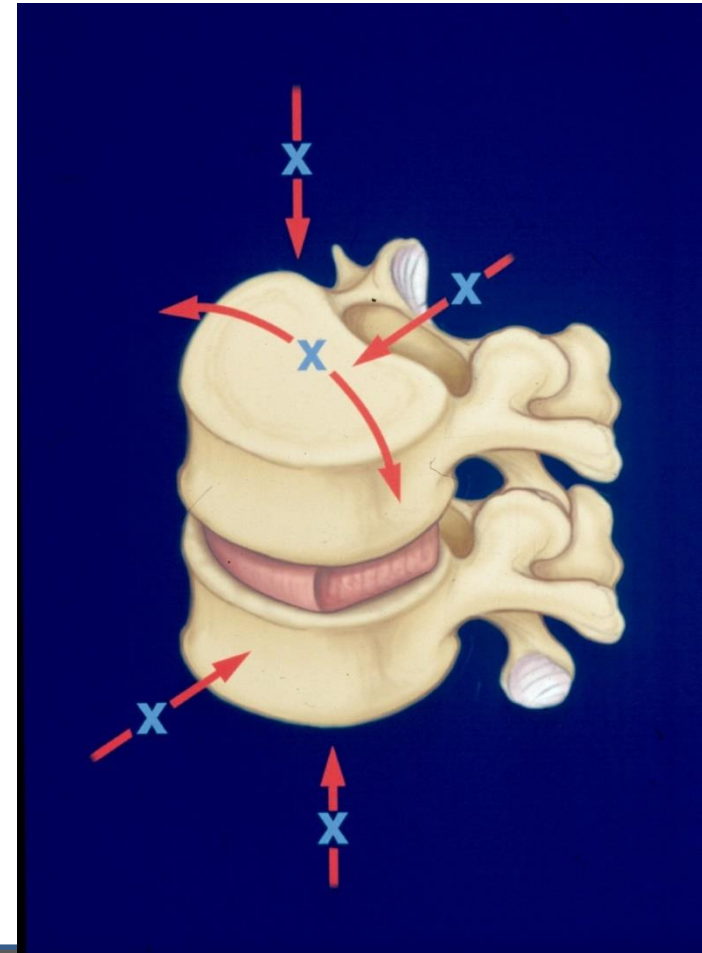


MECHANICS 101



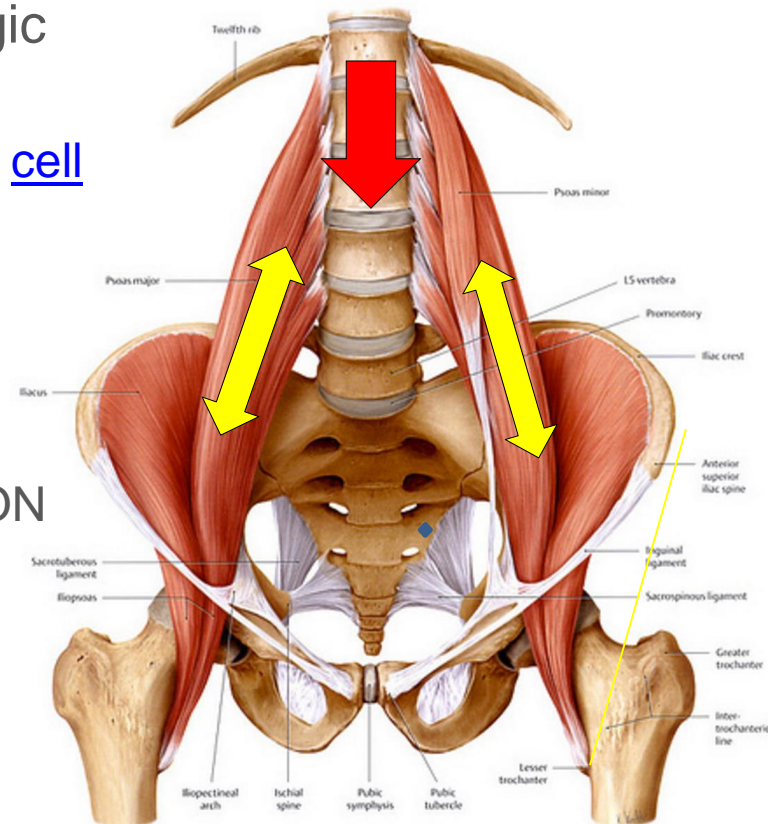
Spinal Motion

- Motion along 3 planes
- 6° Freedom
- Dynamic IAR
- Bending in Disc:
 - Compression & tension on annular fibers
 - Displacement of nucleus
 - Flexion – dorsal
 - Extension - ventral



BIOTENSEGRITY

- Application of tensegrity principles to biologic structures
 - muscles, bones, fascia, ligaments, tendons, cell membranes
- Superior strength from unison tension + compression of tissue structures
- Muscular-skeletal system
 - Muscles & connective = continuous TENSION
 - Bones = discontinuous COMPRESSION
- Maintains homeostasis



MUSCULATURE

- Intrinsic & Extrinsic Muscles serve as pulleys to spine for stabilization
- Apply constant tension for mobilization
- Transfer stress to surrounding structures – load sharing



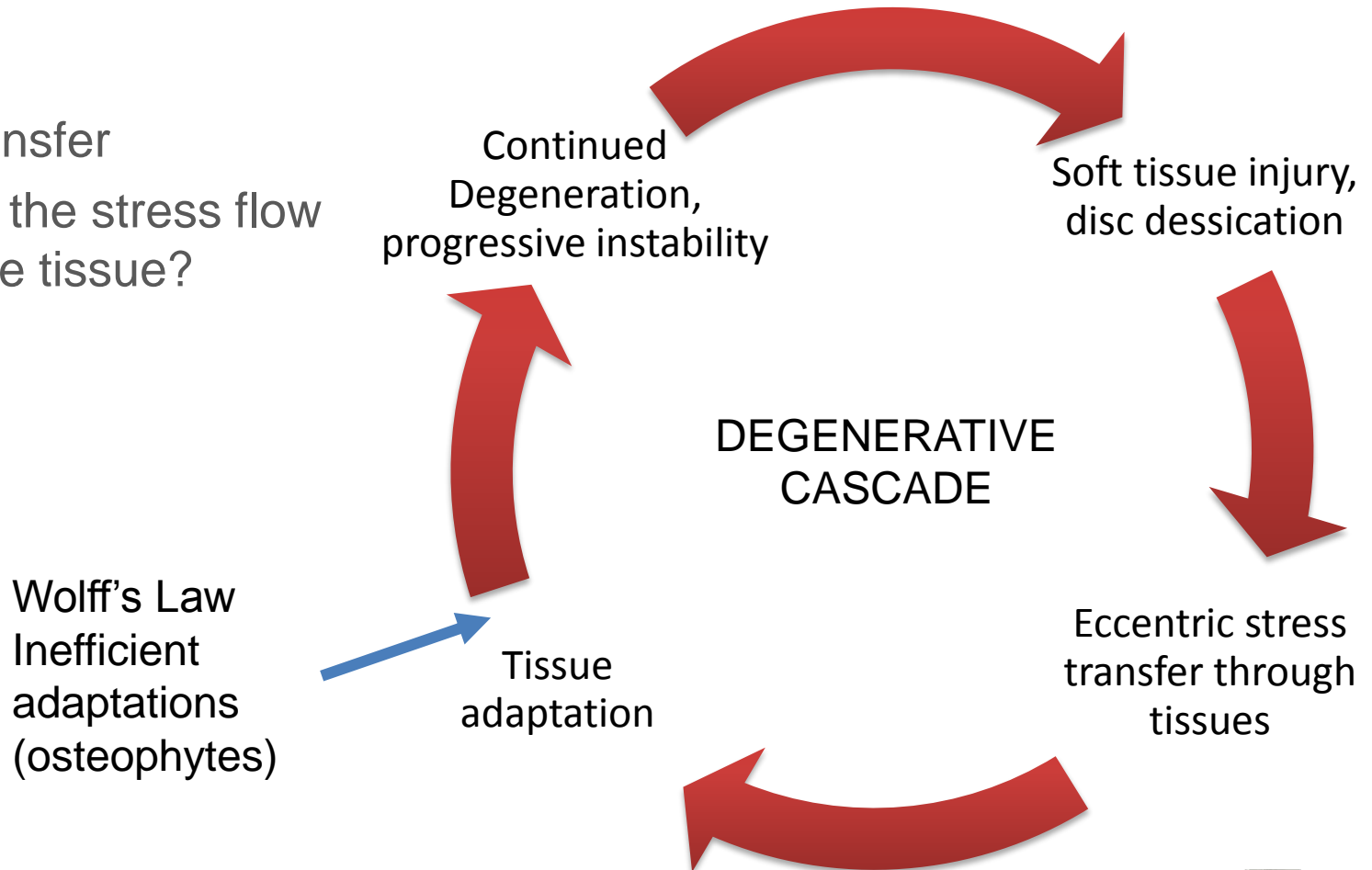
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STRESS & DEGENERATION

- Stress Transfer
- How does the stress flow through the tissue?



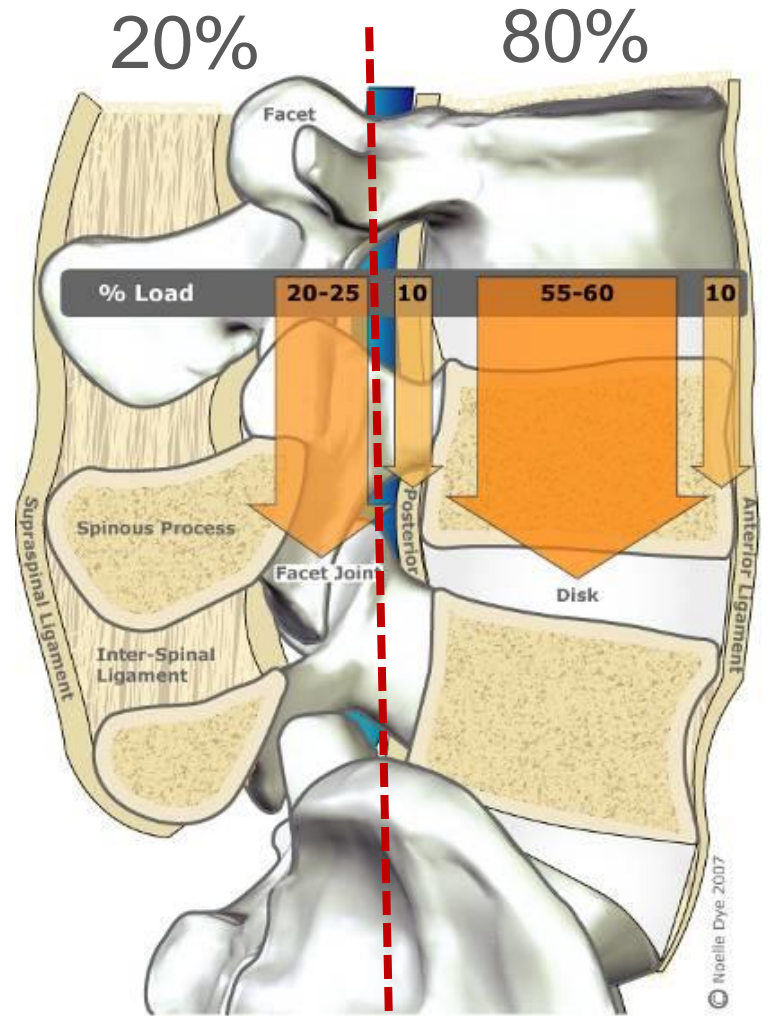
LOAD BALANCE AND CENTER OF ROTATION FOR FSU



LOAD BALANCE (STRESS TRANSFER) – HEALTHY

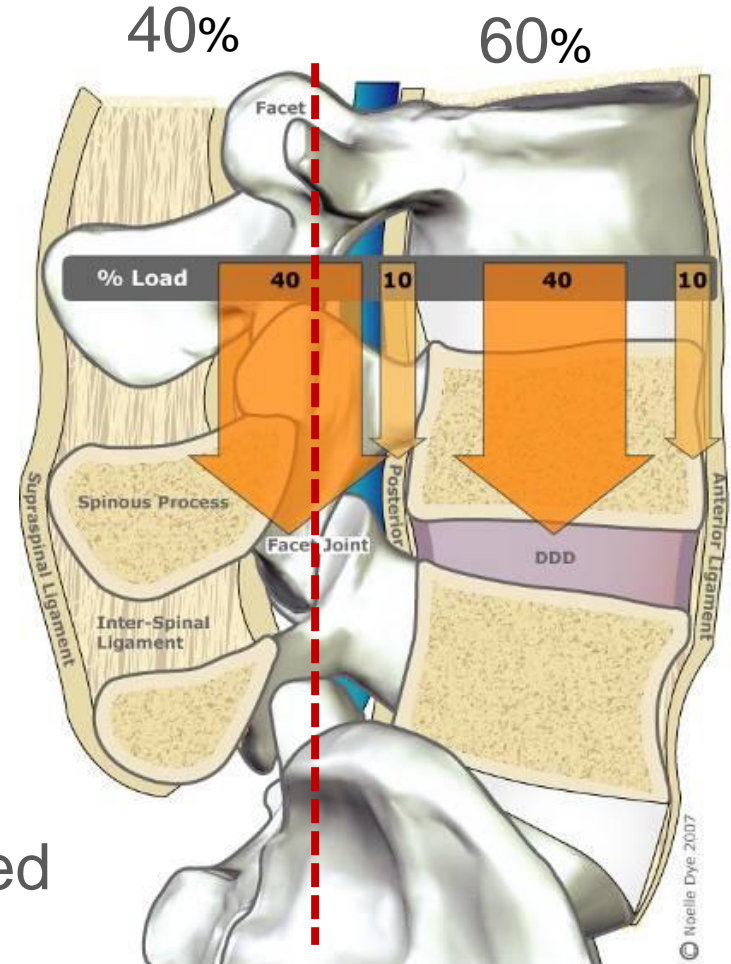
- Vertebra + Disc = 55 - 60%
- Cortical shell = 10%
- Posterior Ligaments = 10-15%
- Facets = 20-25% Load transmitted uniformly across endplates & disc
- Uniform load transmits to annulus
- Isotropic stress profile
- Ligaments pull stress away from disc
- 80% Anterior : 20% Posterior

} 80%



LOAD BALANCE - DEGENERATIVE

- Less Efficient
- Vertebra + Disc = 40%
- Cortical shell = 10%
- Posterior Ligaments = 10%
- Facets = 40%
- Facets > load transmission
- Stress profile anisotropic
- Excessive stress & COR transmitted posteriorly

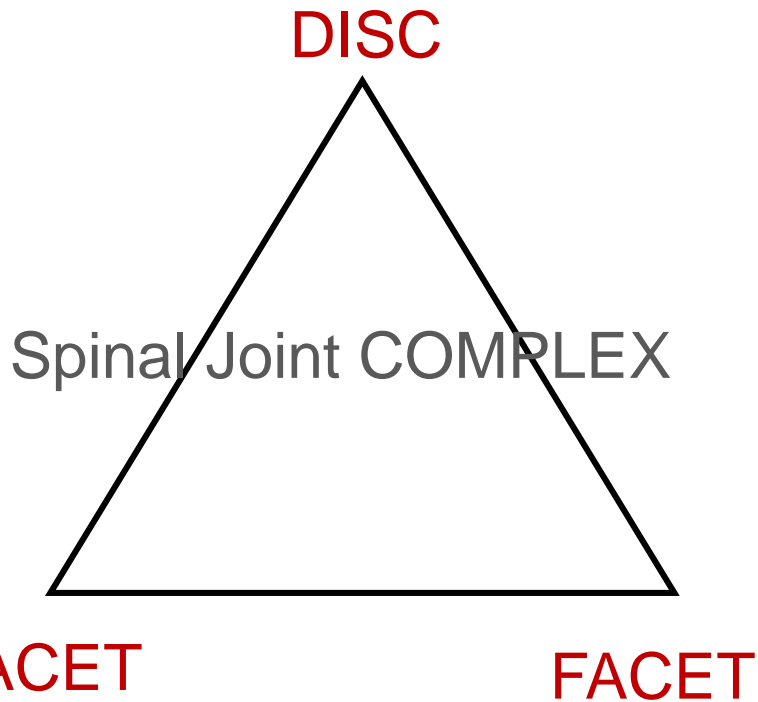


CURRENT CHALLENGES FOR BIOFIDELIC IMPLANT DESIGN



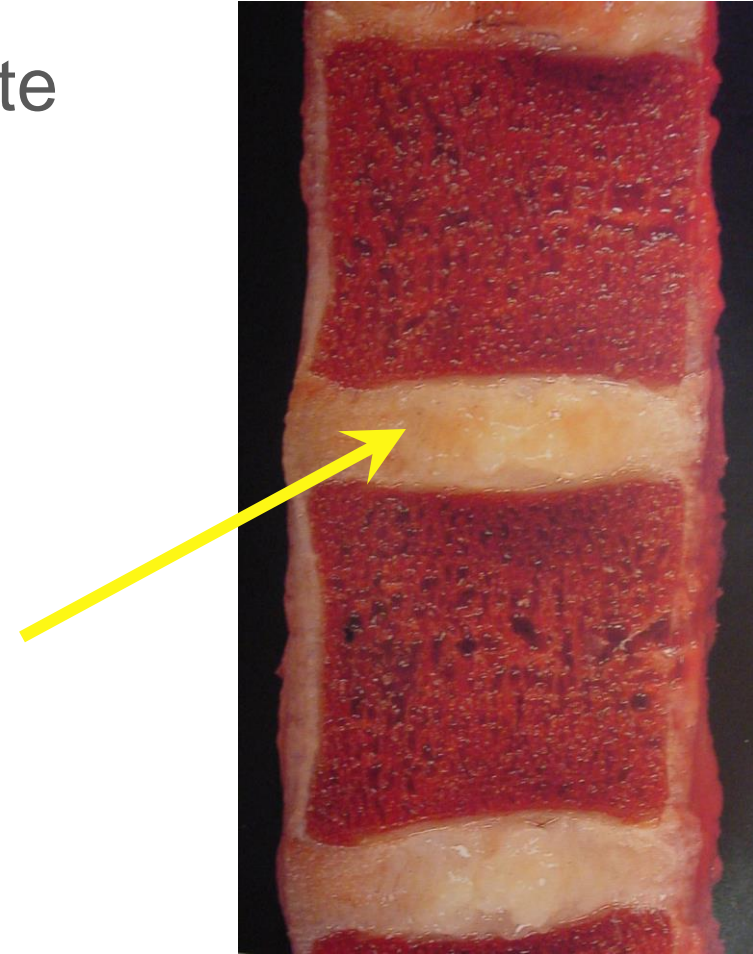
FACET JOINT – COMPLEX JOINT

Interdependence of disc + facets
Soft + Hard tissue



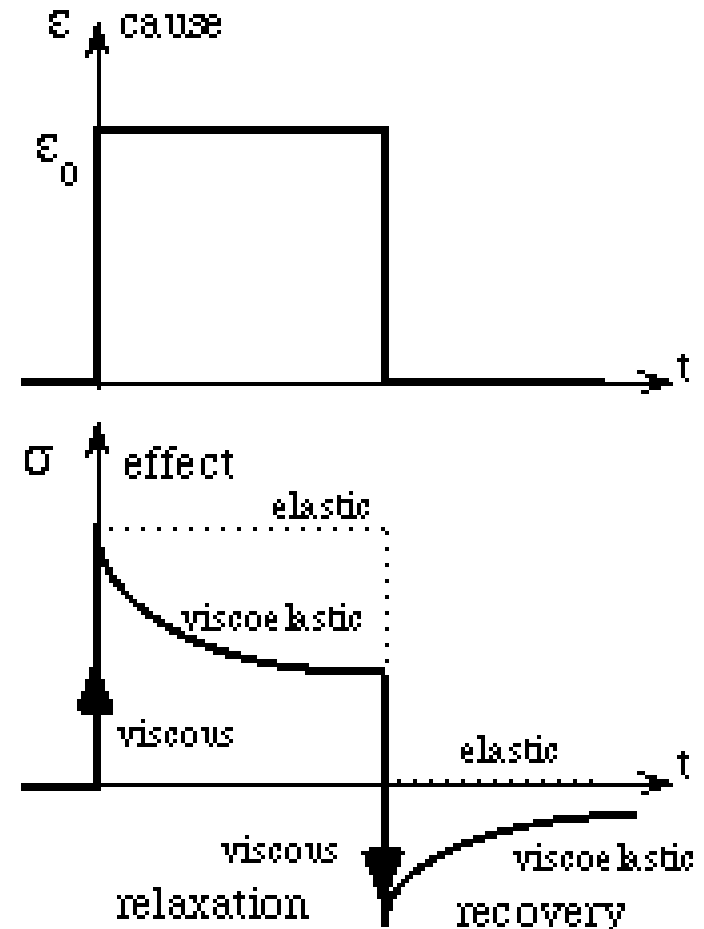
Challenges with Designing Intervertebral Implants

- Unique disc structure & endplate anatomy
- Bone Integrity
- Fit of implant within interspace
 - Cortical Margining
 - Avoid centrum = stress riser
 - Endplate viscoelastic



VISCOELASTICITY

- Behaves like fluid & solid
- Stress relaxation
- Load rate dependent
 - Intervertebral Disc
 - Bone
 - Soft tissue
- Ex: Silly Putty



ELASTIC MODULUS

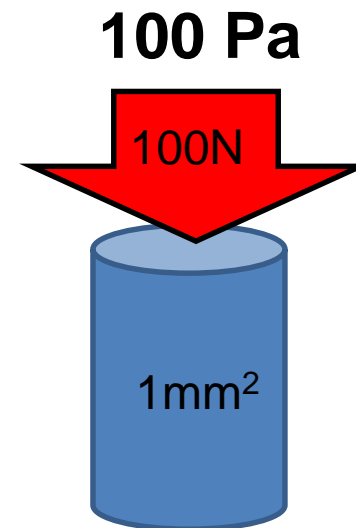
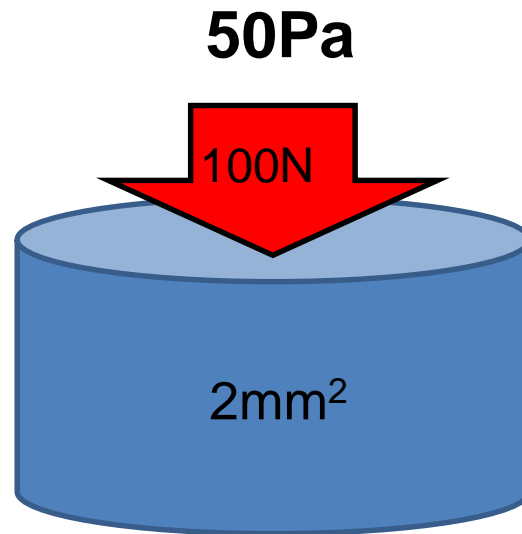
- Defines compliance 'elasticity' of material
- **EM = Stress / Strain**
- Material Modulus – Ti = Stress/strain of bulk material
- Global modulus – Stress/Strain of implant
- Localized modulus – Stress/strain of strut member



STRESS

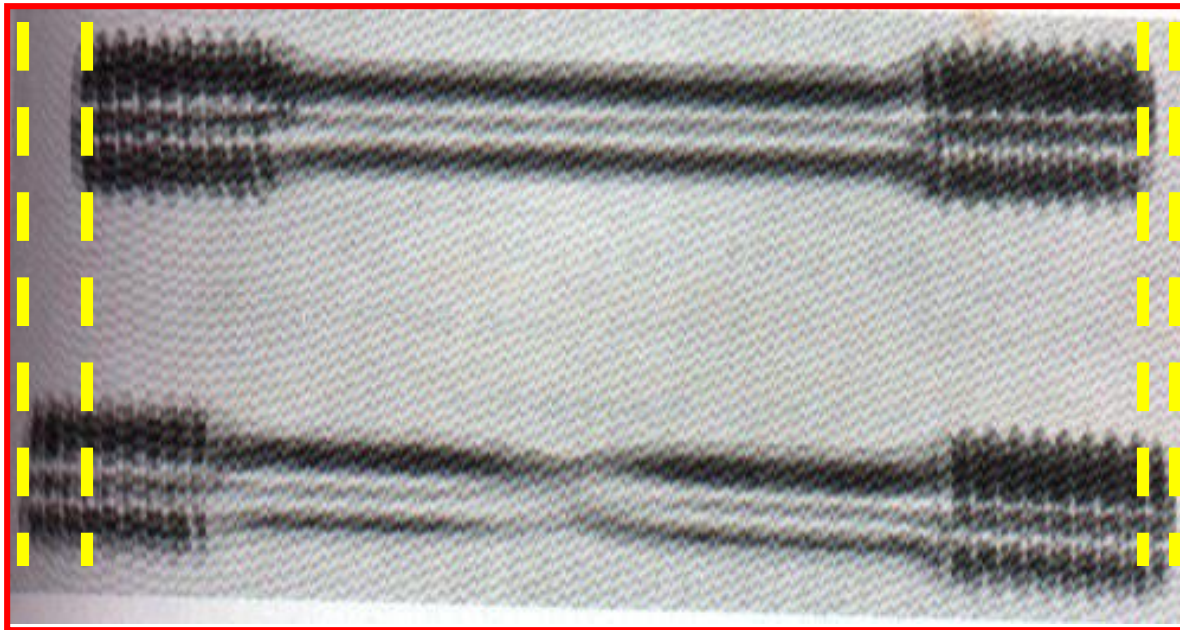
- Force / Area
- Units: N/mm², Pascals
- $\sigma = \text{Force} / \text{Area}$

Z



STRAIN

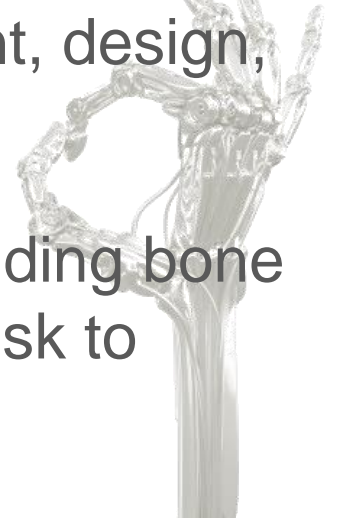
- Linear: $\Delta \text{ length} / \text{original length}$
- Rotational: $\text{angle} / \text{original angle}$
- $\epsilon = \Delta L / L_0$



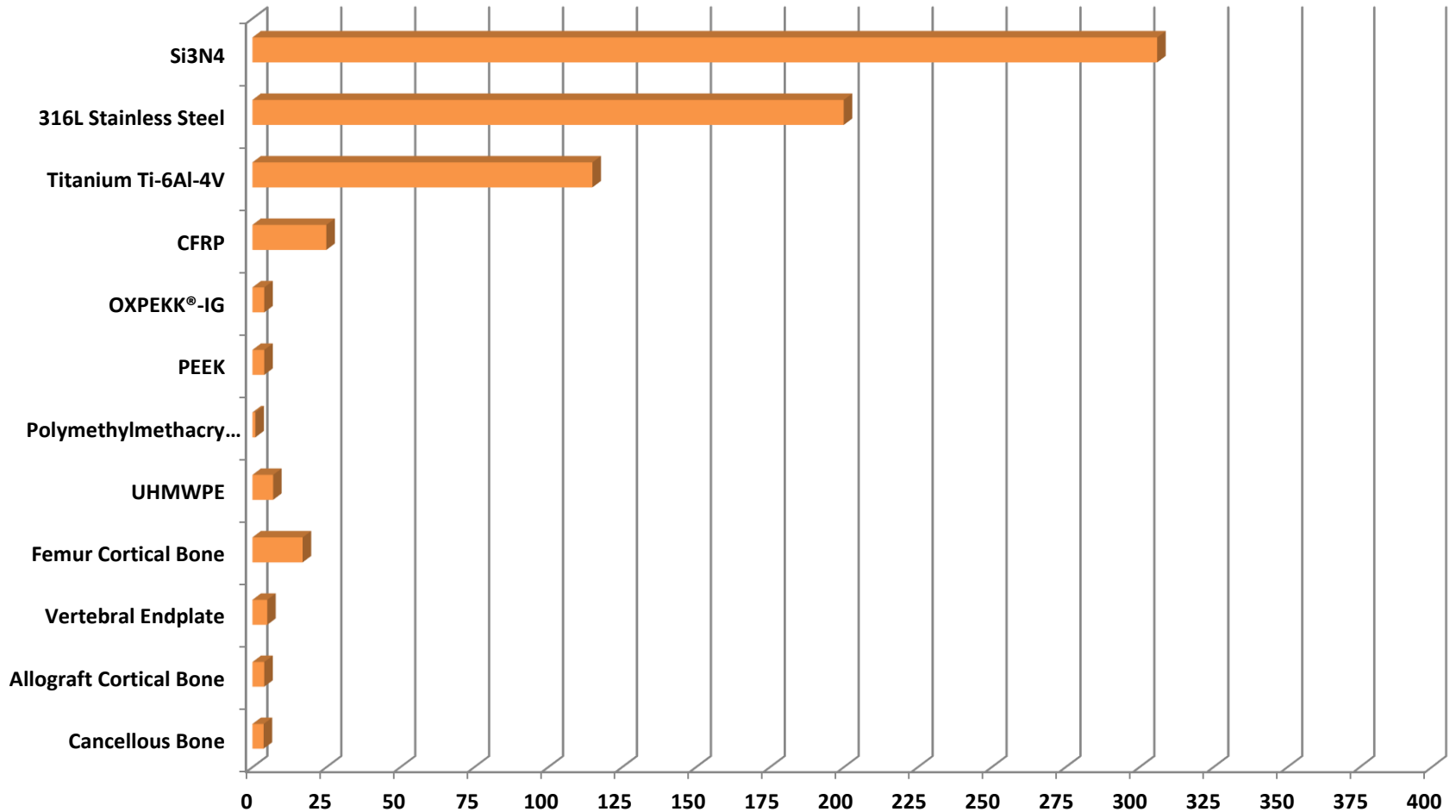
BIOMECHANICAL MYTHS

- **Modulus Matching – PEEK vs. Titanium**

- **Myth** - Believed to be necessary to provide improved load sharing, reduce incidence of stress risers/shielding
- **Fact** – Behavior at the bone-implant interface affected by many factors; bone quality, implant footprint, design, geometry, edges.
- Large footprint will decrease stress to surrounding bone and capture stronger peripheral bone = less risk to subsidence

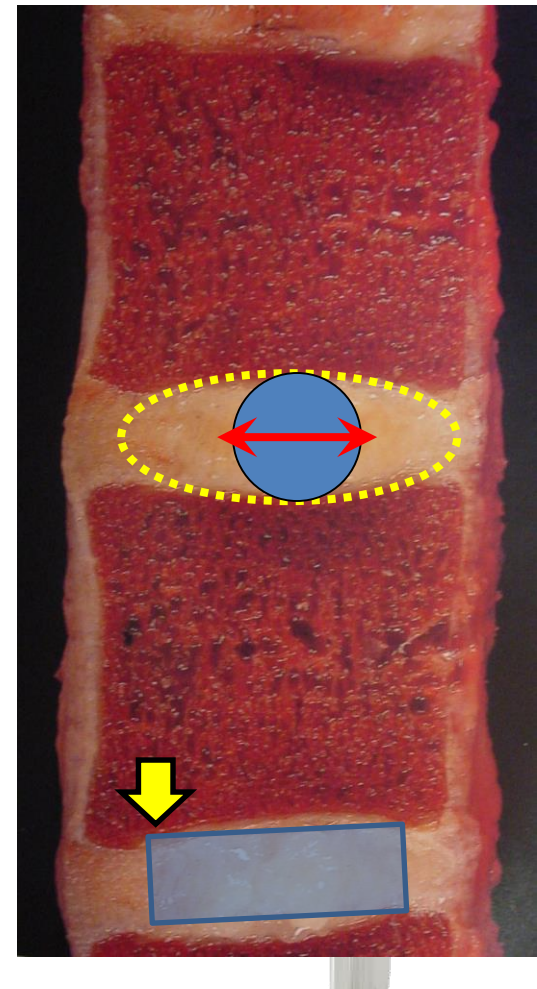


BULK ELASTIC MODULUS (GPa)



Biomechanical Challenges for Implants

- Matching elastic moduli (??)
 - Increase implant footprint
 - Engage cortical margin
 - Avoid implant stress risers
 - Understand implant EM
- Matching endplate shape (curvature)
 - Increase contact surface area
 - Reduce stress (or stress risers) to endplate
 - Avoid abrupt interfaces
- Avoid concentrated stress at centrum
 - Endplate weakest at center



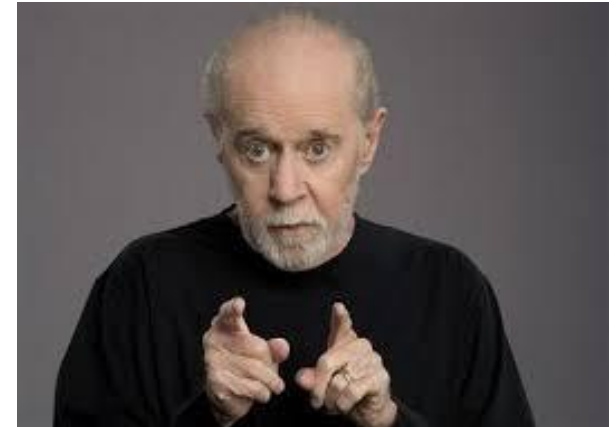
SETTLING VS. SUBSIDENCE

• Settling

- Natural occurrence of the human tissue to creep under compressive loads due to the viscoelasticity of the tissue
- Natural settling 1- 2mm - cervical fusion / 1.5-2.5mm lumbar / viscoelastic endplates

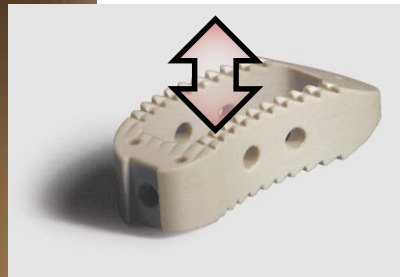
• Subsidence

- Exceeds the natural viscoelastic limit of the tissue
- Enters the plastic deformation stage
- Potential ‘penetration’ into the weaker substrate
- Footprint greatest influence on subsidence
- But there is balance between footprint & other factors (EM, design, shape)
- **STRESS TRANSFER**



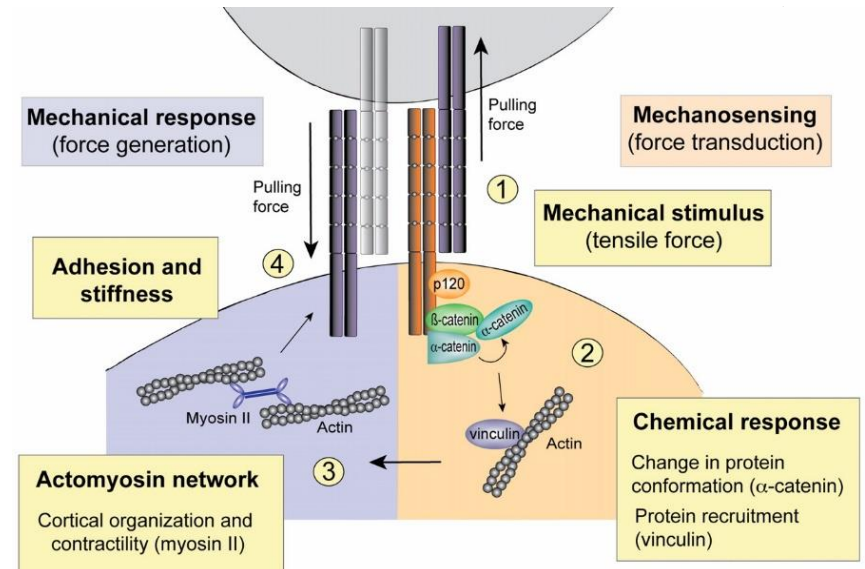
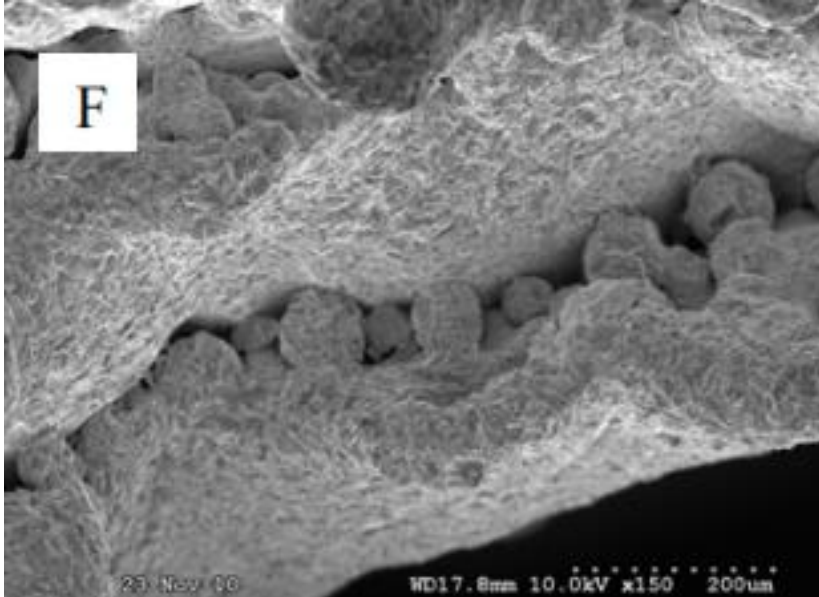
IMPLANT FOOTPRINT & FUSION STABILITY

- Multi-directional bone exchange & incorporation = better biomechanical stability
- Improved stability allows for further ingrowth towards center- throughout implant
- Greater fusion footprint – better stress distribution throughout implant
- Surface texture can aid with attachment – earlier stability



Surface Finish / Biomechanics / Mechanotransduction

- Surface finish / texture correlates with grip strength of implant component
- Improves bone attachment
- Rough = high coef. of friction – reduces sliding of substrate on material
- Process where mechanical energy is converted -electrical & biochemical.
- Mechanical stimuli ↔ Tissue ↔ individual Cells



Cellular Mechanotransduction

- All eukaryotic cells - mechanosensitive
- Forces (gravity, tension, compression, shear,) influence cell behavior (growth and tissue remodeling).
- Cellular Mechanotransduction – the mechanism by which cells convert mechanical signals into biochemical responses.
- Cells respond to applied force stimuli to tissue --- AND---
- Internal forces generated from cell cytoskeleton respond by generating contractile forces for motility, matrix formation
- Continuous, dynamic cyclical process



BIOMECHANICAL MYTHS

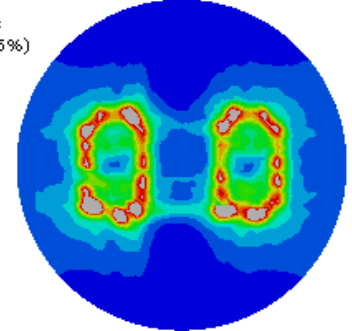
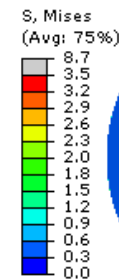
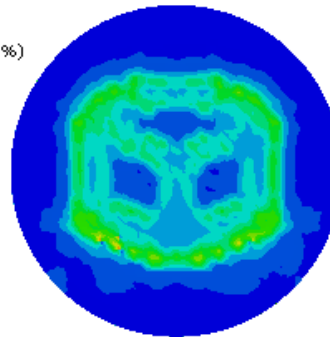
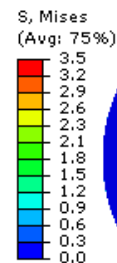
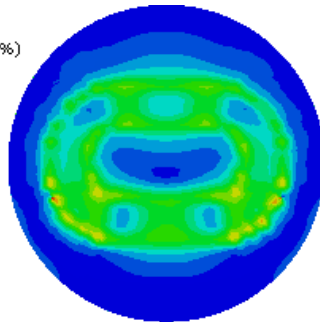
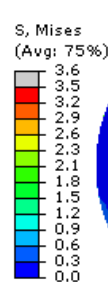
- **Stiffness – Ex: PEEK vs. Titanium**
 - **Myth** - A stiff implant will have increased risk to stress shielding & subsidence
 - **Fact** – stiffness is related to combination of material properties + implant design (footprint) + stress transfer through implant



STIFFNESS & STRESS

Loading Mode	Ti ALIF	PEEK ALIF	Ti Cylinder
Axial Compression (KN/mm)	6.3	4.1	3.8
Flexion (Nm/Deg)	8.3	5.5	2.7
Lateral Bending (Nm/Deg)	15.5	7.1	8.3
Axial Rotation (Nm/Deg)	48.7	36.2	24.6

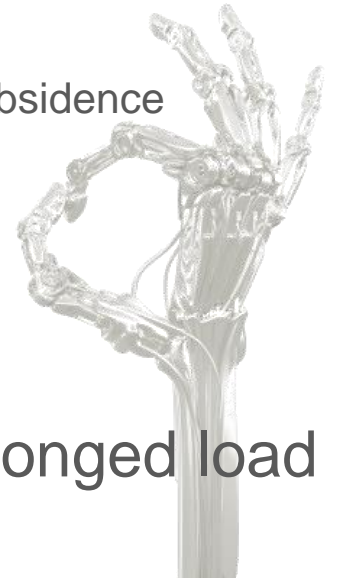
FEA of STRESS
PROFILE FOR
ENDPLATE



The larger Ti ALIF highest stiffness, largest bone volume containment = less stress at endplate, less stress than Ti cylinders

SUMMARY

- Understand your biomechanical environment
 - Bone & soft tissue integrity (tissue stiffens with desiccation)
 - Implant design & position within space
 - Stress transfer to surrounding structures
 - Bigger IBF footprint = less stress to endplates = less risk to subsidence
 - Too rigid can be as bad as not rigid enough
 - Implantation - More is not always better
 - Strive for load balance
 - Implants should load share with tissue – prolonged load bearing will = IMPLANT FAILURE



THANK YOU





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IMPLANT DESIGN CHALLENGES

- Biocompatibility
- Optimized material & design for osteoblast recruitment
- Balance – re-establish a healthy loading pathway along the spine to slow the degenerative cascade.
 - Ideal stress transfer to surrounding tissues within biomechanical thresholds
- Implant mechanics should match the kinetics of spine for site specific performance
- Ease of Fabrication in reproducible, consistent manner
 - Adequate Sterilization, surface finish, cost of production
- Ease of Repair / Revision for failed implants

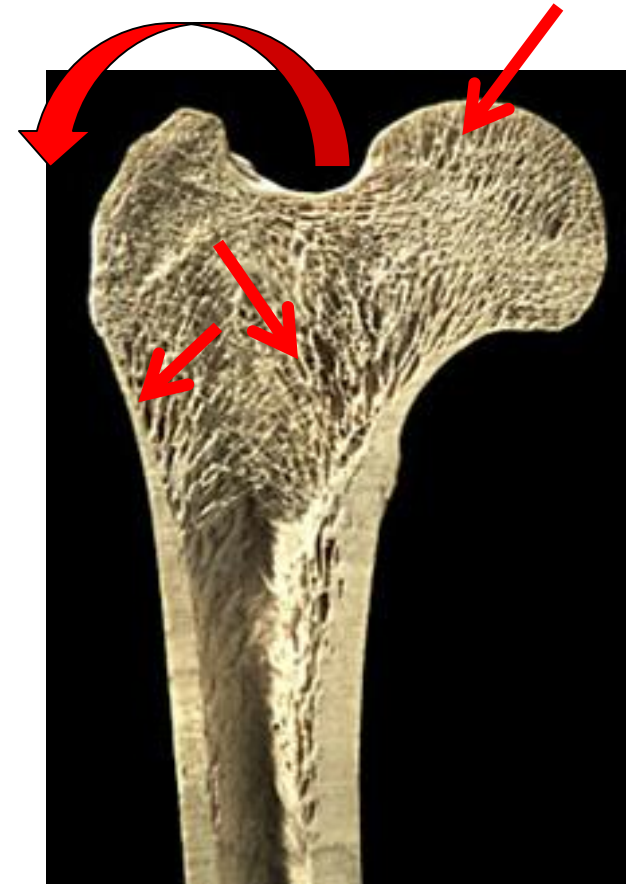


THE GOOD, THE BAD, THE UGLY



OPTIMIZING OSSEOINTEGRATION

- RESPECT & UNDERSTAND WOLFF'S LAW
 - Bone growth responds to stress and strain
 - Region specific – different bone responds to different stress/strain
- MATERIAL + DESIGN = OSSEOINTEGRATION
 - Cascade of events for bone integration
 - Immobilize/stabilize – optimal strain for osteoblast differentiation/recruitment
 - Material favored by osteoblasts
 - Design provides uniform distribution of optimal strain + allows for multiplanar bone ingrowth = early anchoring for stability and continued



BULK MODULUS (MATERIAL)

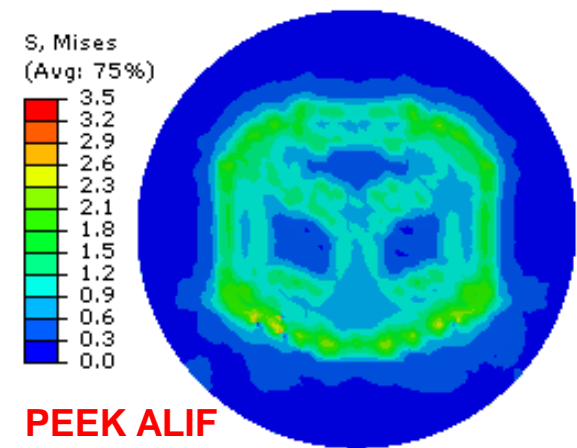
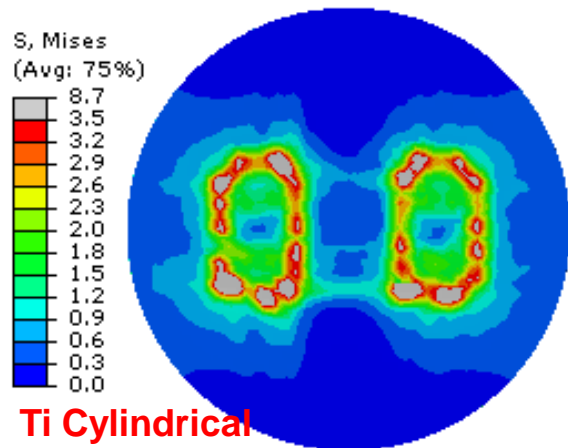
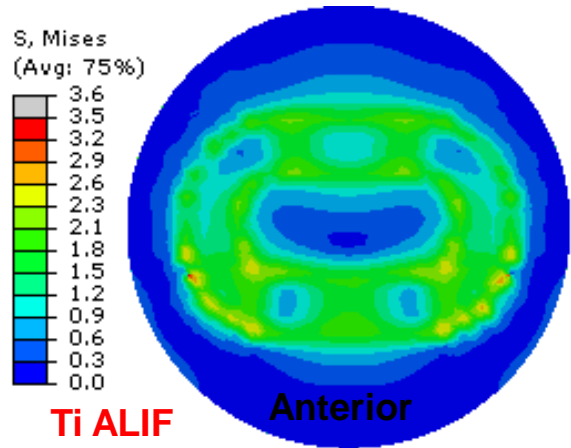
Material	Elastic Modulus (GPa)
316L Stainless Steel	200
Titanium Ti-6Al-4V	115
Allograft Cortical Bone	4.0-8.0
PEEK	4.0
PEKK	4.0
Polymethylmethacrylate	1.0
Cancellous Bone	0.1

FORCE DISTRIBUTION AT BONE-IMPLANT INTERFACE

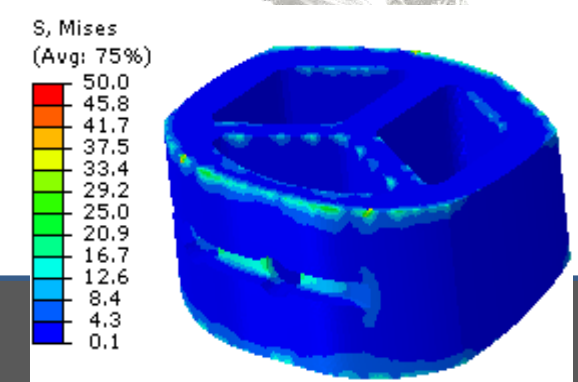
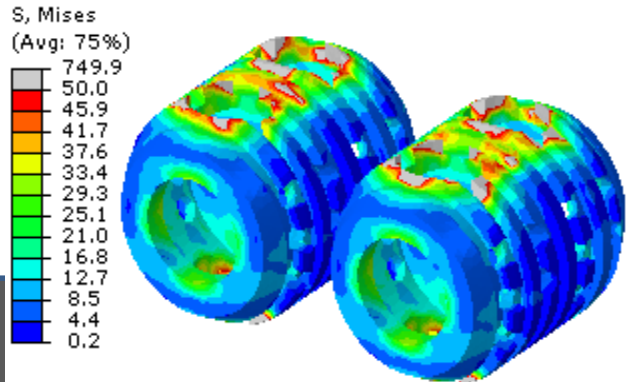
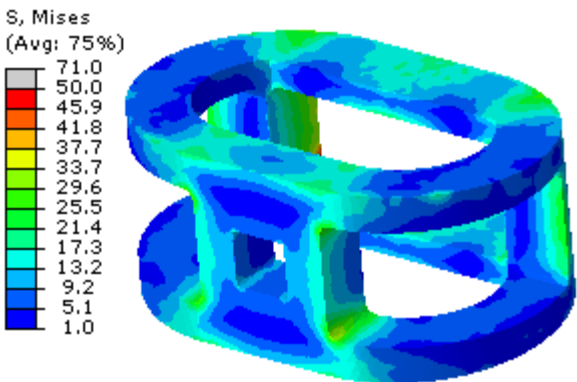
GEOMETRICAL INFLUENCES (vs. modulus matching)

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TECHNOLOGIES, LLC

ORTHOKINETIC TESTING
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- Stress risers – small geometry at bone interface
- Result in subsidence, pistoning through bone
- Stress risers at bone and implant interface



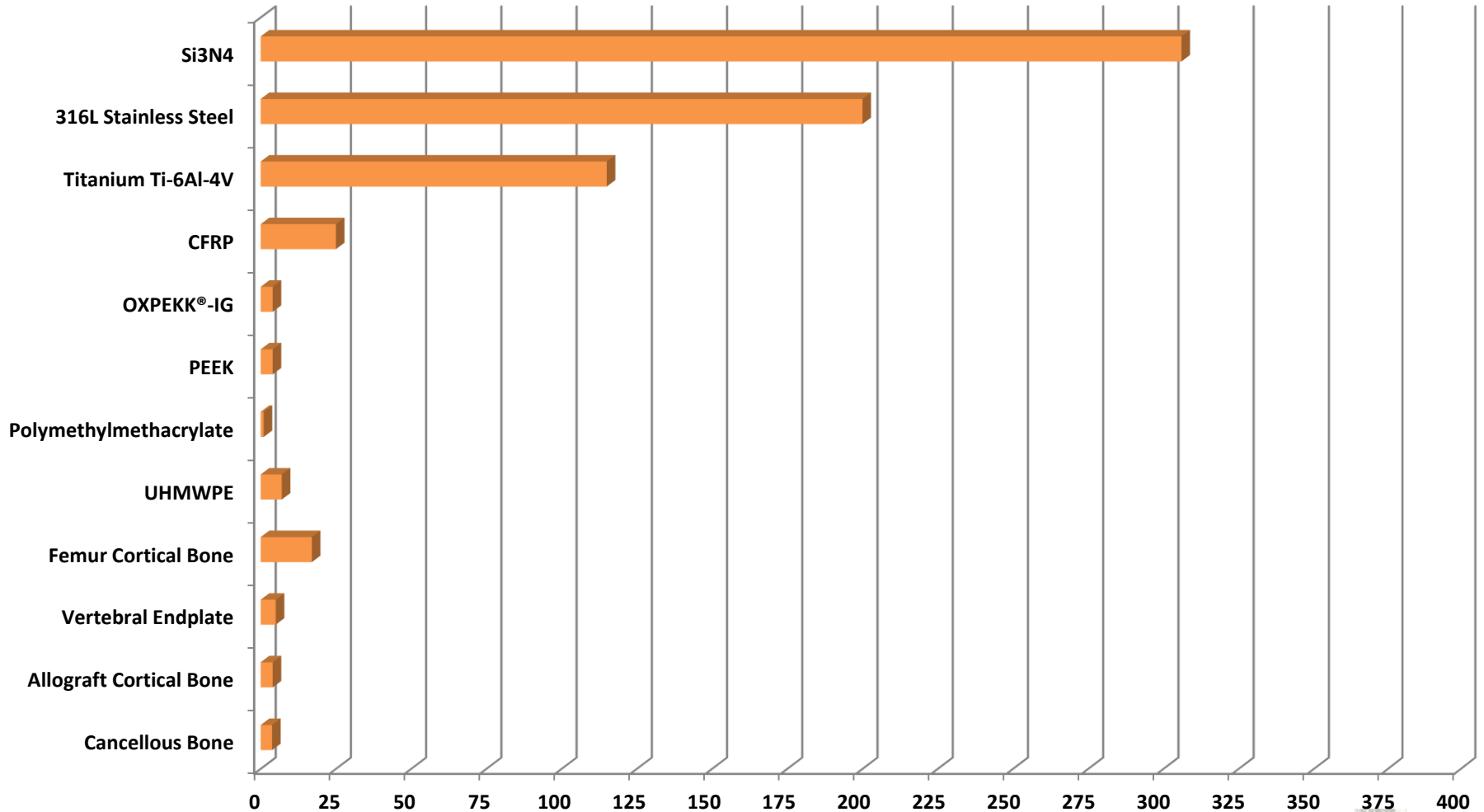
BIOMECHANICAL MYTH 2

Stiffness of the Implant:

- A stiff implant will have increased risk to stress shielding and subsidence
- Fact – stiffness is related to the combination of the material properties + implant design



ORTHOKINETIC TECHNOLOGIES, LLC ELASTIC MODULUS (GPa)



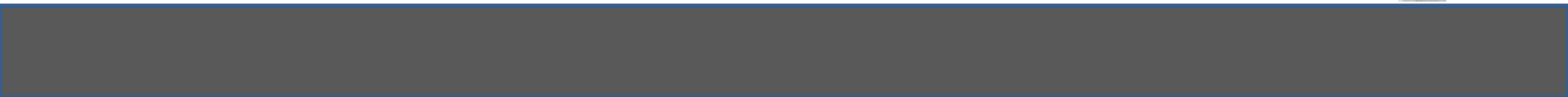
● Si₃N₄

● 100X stiffer than Cancellous Bone





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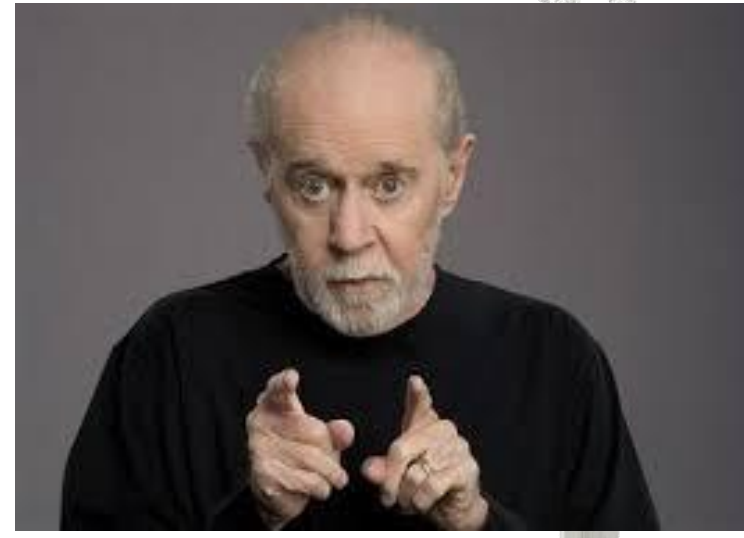






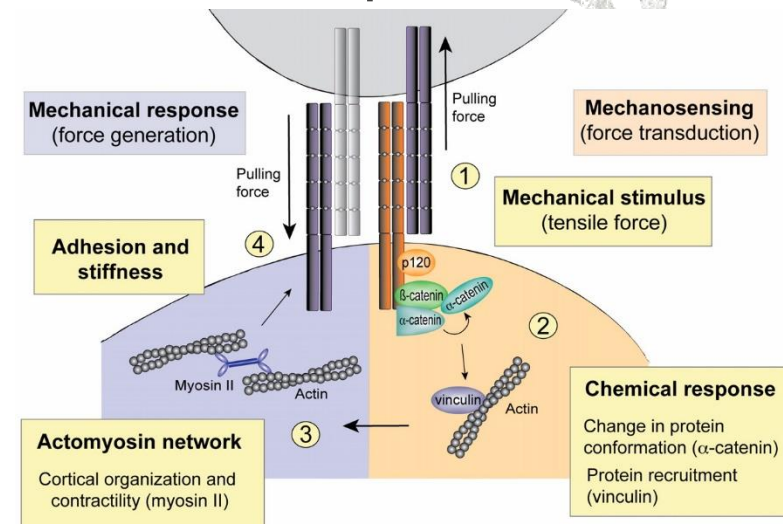
7 WORDS YOU CAN'T SAY TO THE FDA

1. Micromotion
2. Subsidence



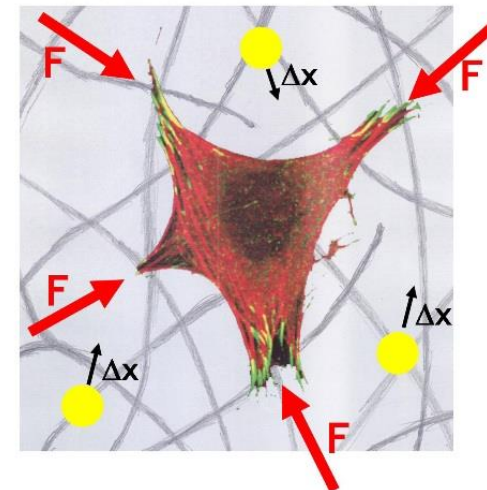
Mechanotransduction

- Process where mechanical energy is converted into electrical and biochemical signals.
- Mechanical stimuli ↔ Tissue ↔ individual Cells
- Cellular Mechanotransduction – the mechanism by which cells convert mechanical signals into biochemical responses.



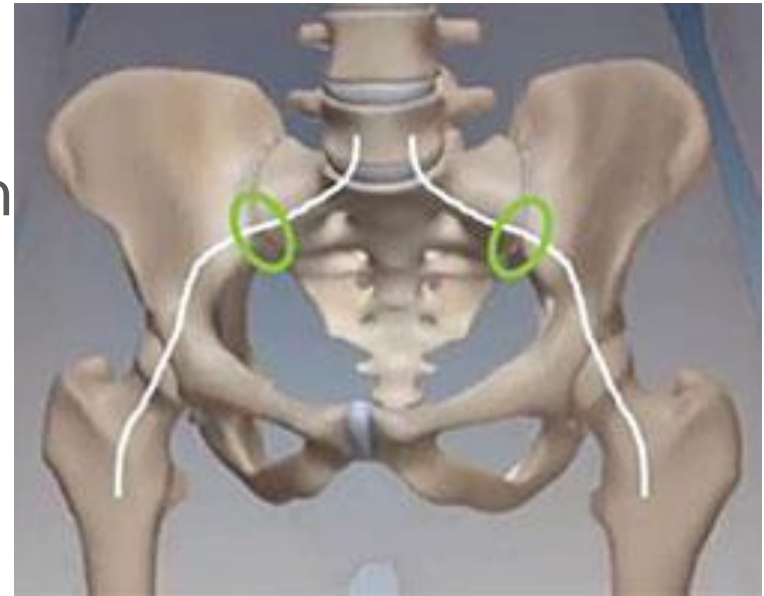
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- Forces (gravity, tension, compression, shear,) influence cell behavior (growth and tissue remodeling).
- Cells respond to applied force stimuli to tissue --- AND---
- Internal forces generated from cell cytoskeleton respond by generating contractile forces
- Continuous, dynamic cyclical process



FORCE CLOSURE

- Forces created by contraction of stabilizing muscles
- produce a “self-locking” mechanism for joints,
- resulting in increased joint stability.
- For SIJ - occurs through contraction of deep muscles in low back, hip, pelvis
- controls translation & shear by compressing joint

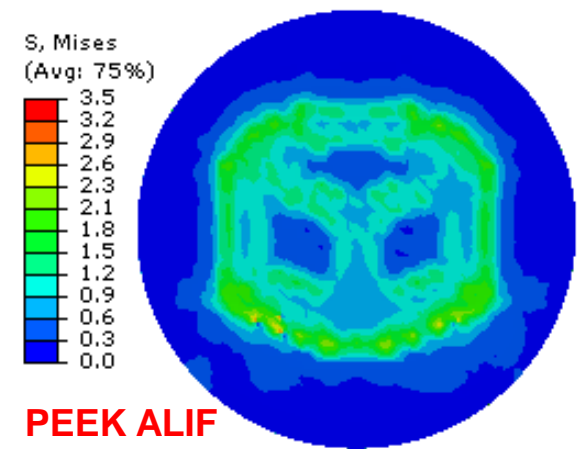
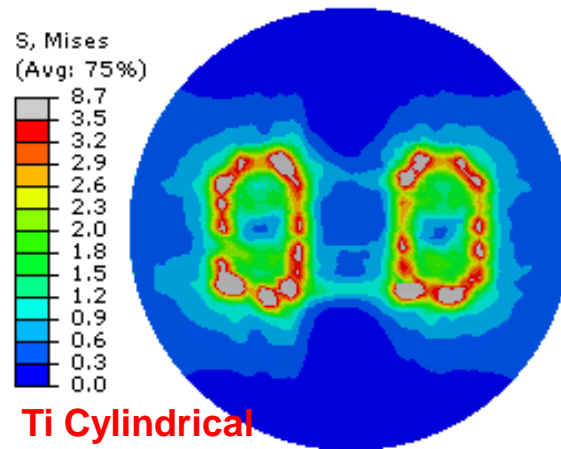
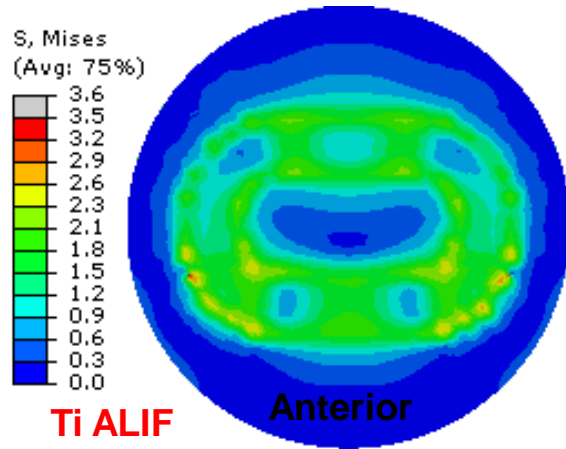


FORCE DISTRIBUTION AT BONE-IMPLANT INTERFACE

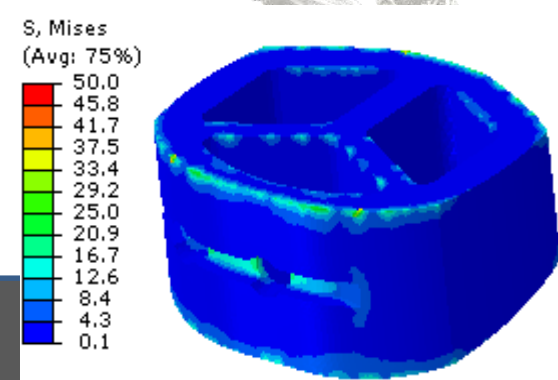
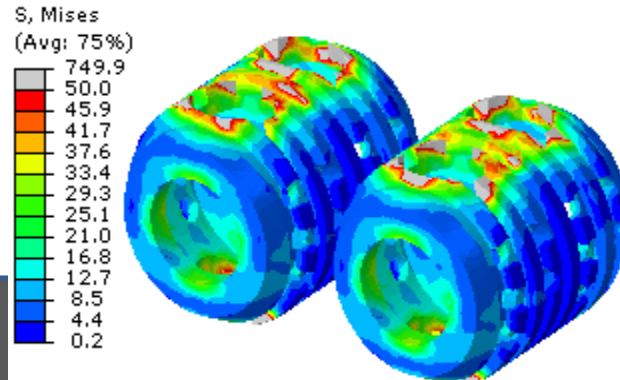
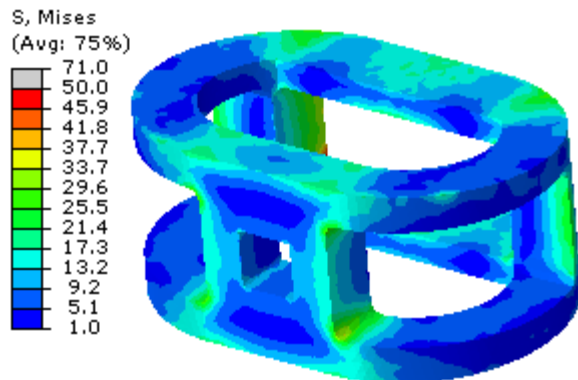
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WOLFF'S LAW

Form Follows Function

- Bone will remodel along lines of stress / resorb in lack of stress-strain
- **Function** – Walking
- **Form** – Results in Bone remodeling along lines of greatest stress during function
- Dynamic System – Bone remodeling is a constant process responding to constant stimuli

