Compliant Pre-Stress Osseointegration: Basic Science and Engineering Principles

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Disclosure:

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Commercial Relationship
What does **Compliance** mean?

- The opposite (inverse) of **stiffness** $K$
- Word chosen to emphasize relative deformability, compared to bone
- “Extensive property”, ie a segment of bone, or a whole blood vessel, or a whole spring (S. Tepic 1985)
- Units: $C = \frac{1}{\text{stiffness}} = \frac{1}{K} = \frac{\partial}{F}$
  - emphasizes deflection $\partial$ of spring element, rather than resistance to deflection
Compliant Prestress Offers Prosthesis Attachment at the Sheep Femur Mid-Diaphysis  
Loads Carried by Bone and Stem are Proportional to Relative Stiffness

Fraction of Cyclic Load $\Delta F$ Carried by Bone

$$\frac{\Delta F_B}{\Delta F} = \frac{\Delta L K_B}{\Delta F} = \frac{\Delta L (K_B + K_S)}{\Delta F}$$

$$K_S = 0.01 K_B$$

$$\frac{\Delta F_B}{\Delta F} = 0.99$$
Cross Pins

Anchor

Porous Ti/HA

Smooth Stem

Spring
Belleville Spring Washers

Flattening of conical washer provides high spring forces
CPS Sheep Implant
Unrestricted Postoperative Activity
CPS and Cement Comparison—One Year
BSEM of CPS Interfaces

- Sagittal sectioning
- Ingrowth quantitation
  (R. Holmes, UCSD)

BSEM Results

- 75% ± 2.6% SE ingrowth
  n = 8 (2 interfaces/sheep)
- Extensive remodeling noted
- Dense cortical ingrowth
Prosthesis OI Needs

- Interface Stability 6-12 wks (<10-30\(\mu\))
- Cyclic Load Transfer
- OI Interface, Morphology and Chemistry
- Metallic Substrate -- all we’ve got
Challenges

- Interface stability under cyclic load
- Metallic Prosthesis
  1. Strength
  2. Bond to porous interface
But:
  1. Will not tolerate 2000 μstrain
  2. 5-10x stiffer than bone
CPS: Primary Bone Healing was first
- Bypass Callus with “Rigid” fixation
- Plates and Screws both apply elastic prestress (Martin, ORS, 1980)

“Rigid” fixation? Not really; only at interface
Porous Stem Arthroplasty

- Works amazingly well
- Huge porous surface area
- Preserved load transfer only very limited locations, "spot welds", trabeculation normal to stem
Contradiction of Strains in Bone and Metal

- 75% drop in Ti fatigue strength with porous coat.
  Fatigue strength is only 125 MPa
  Corresponds to 1500 μstrain
- 2000 μstrain required to sustain bone
Conundrum: Transfer load in axial shear from hard to soft material

- Bone needs 2000 \( \mu \)strain (0.2%)
- Prosthesis needs less, for safety and practical design

It is impossible to sustain bone with load transfer in axial shear!
Force transfer must be orthogonal to stiff prosthesis.
Transverse interface is special for load transfer

- Principal load vector normal to interface plane
- The *only* geometry which allows a natural load transfer pattern from metal into bone.
Optimize Interface

- Prestress, prevent movement
- Planar interface, normal to mechanical axis
Early Goal:
Prevent interface movements

- Milled bone surfaces
  Perfect geometric fit
  Axi-symmetric
- Compressive force exceeds distractive force
- Block torsional shear movements
Late Goal: Prevent late Stress Protection

- **Planar Interface**
  - High load/area:
    - High strain in bone
    - Safe strain in metal

- **Fixation elements**
  - Near bone axis
  - Low stiffness compared to bone (springs)
Milled Interface, Precise Fit

- Ream to fit milling stem
- Anchor and traction bar placed *before* milling, to define axis of mill

anchor position defines final length
- Sharp edge is essential
- Low rake (0°) and relief (2°) prevent grabbing and splitting
- Rapid bone removal
- If edge will not raise a chip on your fingernail, it is too dull!
How much compressive force needed?

Bending Moment to cause lift-off:

\[ M = F \times \frac{D}{2} \]
\[ F = \frac{2M}{D} \]

M = 2000N \times 0.015 \text{ m} = 30\text{Nm} = 3 \text{ kg held by outstretched hand}

Hard to resist bending moments at mid-diaphysis! Smooth stem used.
Other Factors in Force Choice

- Strength of traction bar; 4.7 mm, 1000 lbs
- Strength of bone has usually not been a problem in tibia and femur
- Limited benefit in preventing torsion (“spinning”).

Sheep had 1x body wt. Estimate 2x body wt probably enough
Is Traction Bar alone compliant enough to avoid stress protection?

\[
\frac{K_{bone}}{K_{bar}} = \frac{A_{bone}/L_{bone}}{A_{bar}/L_{bar}} \cdot \frac{E_{bone}}{E_{Ti}} \approx 10
\]

For: 24mm bone tube, 5mm Ti bar.

- Bone is much stiffer than traction bar
- Bar cross section is small
Spring Constant $K$

- Deliver force 2x body weight
- Deflection needed ~ 4 mm
- Spring Constant $K < 0.1 K_{\text{bone segment}}$

For 100 Kg individual:

$$\frac{100\text{Kg} \cdot G}{4\text{mm}} = \frac{2000N}{4\text{mm}} = 500 \frac{N}{\text{mm}}$$

Deflection requirements define the spring compliance
Spring Constant << Bone

- If deflection is adequate, the spring cannot be too stiff.
New Slide, similar to force-deflection graph slide

- Show bone on opposite side of ordinate, reverse neg-pos scale on abscissa
- Show traction bar at 10x deflection as bone
- Show deflections in mm for bone and other elements
- Show how many μ bone deflects, bar deflects, and springs deflect
- Show drop in force from 20μ resorb in bone, 20μ and 100μ in bar, and 1000μ in 2mm and 4mm deflection springs
Spring Constant

Who cares if spring causes 1% or 2% stress protection?

Bigger issue is having adequate deflection to take up absorption from movement at interface.

Interface stability is most important.
Torsional Shear at Interface

- Hardest to control.
  Divergent intramedullary pins
  Friction
  Stems keyed into anchor - 1st two sheep
  Pins into cortex - sheep series and 1st five human
  Rough porous surface
  Splines - under investigation by vendor

- Limits widespread reconstructive application
Torsional Shear “Spinning” Control: Sheep and Early Human Cases
Summary

- Sheep model was the ideal
- Reality:
  Accommodate various bone morphologies
  Make it simple enough to gain acceptance and still work.
  Regulatory barriers
  Human factors, team building
Summary

Keys:
- Machined fit
- Interface orthogonal to axis
- High forces stabilizing interface
- Compliant attachment elements
- Stability to bending and torsional shear
How are CPS-OI and Brånemark-style -OI different?

- Brånemark relies on biologic healing before initiating cyclic load transfer.
- CPS relies on interface pre-stress to immobilize interface in the face of cyclic loading, while biologic healing is progressing.
OI Technique Differences

- Brånemark model originates in non long-bone. Similar to acetabular cup.
- CPS design addresses long bones with mechanical axis.
Why is Acetabular Cup the easiest OI model?

- Load vector produces no interface shear; load transfer normal to interface
- Contained from sides
- Large surface area
- Cancellous bone
Review Questions

What is the most favorable location of fixation elements to avoid stress protection?

1. In the bone axis
2. On the bone surface
3. External fixator
Unique Offering of CPS-OI?

- Isthmus available for press-fit porous stem:
  CPS prevents osteopenia adjacent to stem.
  Clinical outcome no better than porous stem.
- Divergent canal, short segment.
- Diaphyseal segment
- Resurfacing ends of longbones:
  TKA tibial component was original goal of this project.
What is the relative stiffness of Ti compared to cortical bone?

1. 5x
2. 10x
3. 20x
4. 50x
What is the greatest function of the spring in CPS-OI?

1. Prevent stress protection.
2. Provide high interface preload force.
3. Accommodate settling at interface.
4. Prevent lift-off under bending moment.
What is the function of the interface preload force? (three correct)

1. Prevent lift-off of interface under bending.
2. Accelerate osseointegration.
3. Inhibit torsional shear (“spinning”).
5. Prevent small interface movements.
What is the function of the stem?

1. Center the implant.
2. Resist extreme bending moments.
3. Prevent torsional shear.
What is the best means to block rotational shear (spinning)?
(two correct)

1. Creating a rough porous surface
2. Macro-interdigitation of implant with bone near interface.
3. Applying high interface prestress force.
Osseointegrated bone adjacent to an implant and transmitting loads to the implant only in shear -

1. Remodels to transmit load nearly orthogonal to the implant surface.
2. Disappears.
3. Forms a “spot weld”.
What prevents the facing mill from grabbing and splitting the bone?

1. Avoid a very sharp tool.
2. Run mill at slow speed.
3. Low rake and relief angles.
4. Avoid applying excessive force.
In AO “rigid internal fixation”, what is rigid? (ie. without cyclic elastic or sliding movement)

1. The plate.
2. The bone.
3. The screws.
4. The healing interface.
In a stemmed CPS implant, where does the host bone experience the greatest bending moment?

1. At the interface.
2. At the stem.
3. At the anchor plug.
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