IMPLANT-TISSUE BONDING, MECHANICAL STABILITY, AND MODULUS MATCHING

M. Spector, Ph.D.
JOINT REPLACEMENT PROSTHESES
DESIGN PRINCIPLES

• Restoration of Kinematics
  – Range of motion
• Restoration of Joint Mechanics
  – Limb length (THA)
  – Angulation (TKA)
  – Vector of muscle force (abductor and patella)
• Mechanical Stability (Fit, Fixation, and Stiff.)
• Wear (and Friction) of the Articulation

FACTORS INFLUENCING PERFORMANCE

Micromotion\(^1\)  Stress Shielding\(^2\)

Fit

Fixation

Stiffness

\(^1\) pain
\(^2\) bone loss
FACTORS INFLUENCING PERFORMANCE

Fit

• Size and Shape
  – Computer-designed based on radiographs (viz., CTs) for standardized or individualized femoral stems; P.S. Walker
  – “Identifit”: a silicone mold used to intraoperatively construct a cementless femoral stem.

FACTORS INFLUENCING PERFORMANCE: FIT

Courtesy of Scandinavian Customized Prosthesis as. Used with permission.
FACTORS INFLUENCING PERFORMANCE: FIT

“Identifit”
- The surgeon creates the cavity in the femur.
- A silicone mold of the cavity in the femoral canal is made.
- While the surgeon proceeds to insert the acetabulum, in a laboratory located annexed to the hospital the mold is used to make a titanium stem in the same shape.
- The stem is anatomical with a mean value for bone to prosthesis contact equal to 94%.


FACTORS INFLUENCING PERFORMANCE

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\(^2\) bone loss
IMPLANT FIXATION
TISSUE INTEGRATION/TISSUE BONDING

- Cement
- Biological Fixation

“Bone Cement”
Self-Curing
Polymethylmethacrylate

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Problems with PMMA
- Low strength
- Exothermic reaction
- Toxic monomer
TYPES OF BIOLOGICAL FIXATION

- Frictional forces acting on a smooth surface (press-fit)
- Mechanical bond due to interdigitation of bone with irregular surface
- Interlocking mechanical bond due to bone ingrowth into porous coating
- Chemical bond of bone adhesion to calcium phosphate coating

MECHANICAL CHARACTERISTICS OF BIOLOGICAL FIXATION

<table>
<thead>
<tr>
<th>Strength</th>
<th>Shear Strength</th>
<th>Tensile</th>
</tr>
</thead>
<tbody>
<tr>
<td>Smooth Surface</td>
<td>+</td>
<td>0</td>
</tr>
<tr>
<td>Press-Fit</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Irregular Surface</td>
<td>++</td>
<td>0</td>
</tr>
<tr>
<td>Porous Coating</td>
<td>+++</td>
<td>++</td>
</tr>
<tr>
<td>Cal. Phos. Coating</td>
<td>+++</td>
<td>+++</td>
</tr>
</tbody>
</table>
# PROBLEMS OF BIOLOGICAL FIXATION

<table>
<thead>
<tr>
<th>Surface Type</th>
<th>Problem</th>
</tr>
</thead>
<tbody>
<tr>
<td>Smooth Surface (Press-fit)</td>
<td>Design/implantation that yields an interference fit</td>
</tr>
<tr>
<td>Irregular Surface</td>
<td>Obtaining sufficient bone apposition</td>
</tr>
<tr>
<td>Porous Coating</td>
<td>Obtaining sufficient bone ingrowth</td>
</tr>
<tr>
<td>Cal. Phos. Coating</td>
<td>Detachment/absorption of coating</td>
</tr>
</tbody>
</table>

# FUNCTION OF POROUS COATING

- Assist in stabilization
  - Not the primary means of stabilization (inherent mechanical stability of the design)
- Serve as rasp to enhance initial stability
**BIOLOGY OF BONE INGROWTH**

- Bone heals by regeneration
- Excessive movement of implant (>150 µm) can disrupt stroma, resulting in repair with scar (fibrous encapsulation of implant and fibrous ingrowth)
- Pore size must accommodate OBs (15-20 µm), capillaries (10 µm), and matrix; (pore size > 100 µm)
- Temporal sequence:
  - Bone ingrowth < 4–8 wks
  - Remodeling > 8 wks (stress related)

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**M. Spector, in Noncemented Total Hip Arthroplasty (Ed. R. Fitzgerald, Raven Press) 1988**

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**BIOLOGY OF BONE INGROWTH**

![Diagram showing the timeline of bone ingrowth](image-url)
FACTORS AFFECTING BONE INGROWTH

**Prosthetic Design Factors**
- Mechanical
- Stabilization
- Pore
- Characteristics

**Host Factors**
- Available
- Bone Stock
- Disease
- Aging

**Bone Ingrowth**

**Adjuvant Therapies**
- Bone graft material
- Synthetic calcium phosphate
- Collagen implants
- Demineralized bone matrix
- Bone growth factors
- Electricity

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EVALUATION OF BONE BONDING TO HA-COATED PROSTHESES

• To evaluate the percentages of hydroxyapatite (HA) and titanium surfaces to which bone was bonded, on HA-coated and non-coated titanium femoral stems retrieved from human subjects.

• Work was prompted by the supposition that as HA coatings dissolve or detach from the titanium substrate, the exposed metal becomes osseointegrated so as to maintain the fixation to bone.

MATERIALS AND METHODS

• Six implants used in this study from patients treated for a fractured femoral neck with a Bimetric hemi-arthroplasty (Biomet, UK).
  – 3 HA-coated specimens (duration 173, 261 and 660 days, post-op)
  – 3 non-coated specimens (40, 650 and 1094 days)

• The plasma-sprayed HA coating had an average crystallinity >85% and an average thickness of 50µm.
ESEM of a non-HA-coated specimen retrieved 40 days after implantation

Photos removed due to copyright restrictions.

ESEM of a non-HA-coated stem after 1094 days

Photos removed due to copyright restrictions.
RESULTS

• For the HA-coated stems:
  – 80±20% (mean±SEM, n=3) for the HA-coated regions versus 24±8% (n=3) for the titanium, originally underlying the HA and exposed with its loss (Student’s t test, p=0.01).

• For the non-coated titanium stems:
  – 24±5%; n=3, comparable with the bonding to the titanium regions on the HA-coated stems exposed by the loss of HA.

FACTORS INFLUENCING PERFORMANCE

Micromotion\(^1\)  Stress Shielding\(^2\)

Fit

Fixation

Stiffness

\(^1\) pain  \(^2\) bone loss
Defect in the Proximal Tibia Filled with Particles of Synthetic Hydroxyapatite, 1yr f-u
Failure Due to Lack of Modulus Matching

Potential for breakdown of the overlying art. cart. due to high stiffness of the subchondral bone? Photos removed due to copyright restrictions.

Region of high density and stiffness (cannot be drilled or sawn)

Bone loss due to stress-shielding?

Total Hip and Knee Replacement Prostheses

Photos removed due to copyright restrictions.
Bone Loss Due to Stress Shielding Around a Hip Prosthesis

Photos removed due to copyright restrictions.

Revision stem fills the canal and is bonded to bone by its porous coating; x-ray sign of thinning of the cortical bone; not painful

Undersized stem did not fill the medullary canal; no fixation of bone to the smooth stem; radiographic sign of stem toggling in the femur; painful

Normal thick.

Prosthesis removed from a patient at the time of revision

Photos removed due to copyright restrictions.
Decrease in the Stress in the Distal Femur after TKA due to the Stiffness of the Co-Cr Femoral Component: Finite Element Analysis

Courtesy of Orthopaedic Research Society. Used with permission.

Diagram removed due to copyright restrictions.
RADIOGRAPHIC BONE LOSS AFTER TKA*

- Retrospective radiographic analysis of 147 TKAs.
  - 3 designs
    - Cemented and porous-coated, non-cemented
- Determination of whether bone loss was evident in the post-op radiographs.
  - 3 examiners


Diagram removed due to copyright restrictions.
BONE LOSS UNDER THE FEMORAL COMPONENT OF TKA

- Bone loss occurred in the majority of cases (68% of patients).
- Bone loss occurred within the first post-operative year and did not appear to progress.
- Bone loss was independent of implant design and mode of fixation (*i.e.*, cemented vs. non-cemented).

EFFECT OF BONE LOSS ON BONE STRENGTH

How much bone loss needs to occur before it is detectable in a radiograph?

- Radiographic evidence of bone loss in the distal femur = 30% reduction in bone density.*

How does bone loss affect bone strength?

- Bone strength is proportional to density$^2$.
- Therefore a 30% decrease in bone density means a 50% decrease in bone strength.


BONE LOSS UNDER THE FEMORAL COMPONENT OF TKA

Conclusion

- Bone loss occurs in the distal anterior femur post-TKA due to stress shielding related to the stiffness of the cobalt-chromium alloy component.

Potential Problems

• Complicates revision arthroplasty due to the loss of bone stock.
• May place the prosthesis at risk for loosening.
• May place the distal femur at risk of fracture.

Solution

• Oxinium TKA.
  – Oxinium has approximately ½ the stiffness of Co-Cr alloy, therefore there should be less stress shielding and less bone loss.
BENDING STIFFNESS

\[ = \text{Modulus} \times \text{Cross Section of Elasticity} \times \text{Moment of Inertia} \]

\[ = E \times \pi D^4/64 \]
BENDING STIFFNESS

= Modulus \times Cross Section
of Elasticity \times Moment of Inertia

= E \times \pi D^4/64

Porous Polysulfone-Coated Titanium Femoral Stem

Photo removed due to copyright restrictions.
Photos removed due to copyright restrictions.

Stems that reduce the cross-sectional moment of inertia

Photos removed due to copyright restrictions.
FACTORS INFLUENCING PERFORMANCE

Micromotion\(^1\)  Stress Shielding\(^2\)

- Fit  -
- Fixation  -
- Stiffness  ?

\(^1\) pain  
\(^2\) bone loss