The Effect of Surface Chemistry and Topography on Spinal Implant Material Osseointegration

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Overview/Disclosures

• Introduction: PEEK versus Titanium
• Cell culture and animal studies
  – Review of other scientists data (no disclosures)
• Porous PEEK
  – Published work (no disclosures)
  – Work in progress by two PhD students (no disclosures)
  – Spinal Cages (Equity ownership in Vertera Spine)

Beginning of the PEEK-Ti Debate

[Graphs and images showing cell number, Alkaline Phosphatase Specific Activity, and BMP-2 Expression]

This study because the contact angles were similar, this suggests that the surface texture was the main reason for the difference in osteoblast behavior between the materials.
Animal Data: All on smooth PEEK!

Prior studies show fibrous tissue integration on smooth PEEK

Reinventing the Wheel: Surface Topography

Some Fundamental Questions:
- How do smooth PEEK and smooth Ti osseointegrate?
- Regardless of material, is a rough surface enough for osseointegration or is the porosity necessary for mechanical interlock?
- How does a biologic like hydroxyapatite affect osseointegration?

In Titanium 3D topography favors cells
Animal work: Effect of Surface on Osseointegration

- Implants placed line-to-line in cortical bone of adult sheep
- “Pushed out” after 4 or 12 weeks

Smooth surfaces are bad for Ti and PEEK

In Ti, Surface Porosity is Far Superior to Roughness

Bony ingrowth into surface porosity maximizes osseointegration, and while HA helps, the porosity is most critical
What about HA inside or coated onto PEEK?

HA Has a Minor Effect on Integration

- Hydroxapatite and surface chemistry are not significant drivers for implant integration in light of surface porosity.

Surface Porous PEEK Scoria™

- Porous Surface Grown Directly from Base Material
  - Fully interconnected
  - >500µm thick
  - >60% porosity
  - Wettable surface
Stronger than Trabecular Bone

Cyclic Fatigue Resistance

Cell Study Data
Bony Tissue Ingrowth

12 Week Bony tissue ingrowth

Porous PEEK Scoria™ Side

Smooth PEEK Side

Blood wicking into porous layer


Osseointegration of Porous PEEK

Torsional Testing

Intact Bone

PEEK Scoria Implant

Fractured Bone

PEEK Scoria Implant

As bone grows into porous PEEK failure torque increases

Osseointegration of Porous PEEK

12 Weeks Post Op

Autograft

Surface Porous PEEK

0.0

0.1

0.2

0.3

0.4

Maximum Torque (N\*m)

*
Surface topography is the dominant factor in osseointegration (evaluated through cellular and mechanical means) regardless of base material
- Porous: high strength
- Rough: moderate strength
- Smooth: weak

Surface porous PEEK can provide implant osseointegration while coating and composite alternatives only provide “ongrowth”

Conclusions

Comparative large animal study with Dr. Scott Boden at Emory on porous PEEK osseointegration
Cellular and small animal studies with Dr. Bob Guldberg at Georgia Tech
- Use of Atomic Layer Deposition (ALD) TiO2 coatings to fundamentally separate chemistry and roughness effects
- Small animal models to understand osseointegration mechanisms in porous PEEK

Work in Progress

Cervical Cage Product Line
- Heights 6 through 10 mm in 1 mm increments
- Footprint areas 12x14 mm, 14x16mm
- Lordotic profile
- Sterile packaged
- Product launch in Q1 2016