Advancements in Implant Surface Technologies to Enhance Fusion: What Really Matters?

Robert Isaacs, MD

Duke UNIVERSITY

Disclosures

Duke UNIVERSITY

- Other scientists data
  - Data is published in the scientific literature
  - No conflict
- Porous PEEK data
  - Collaborative research from Duke, Emory, and Georgia Tech
  - Data published or to be published under peer review
- Spinal cages
  - On Vertera Spine Scientific Advisory Board

2

What Really Matters?

Duke UNIVERSITY

- What's more important: implant material or topography?
- Is porosity needed or is surface roughness enough?
- What about nanotopography?
- Can we make PEEK porous and osseointegrate without any additive material flaking off?
- What would be the clinical impact?

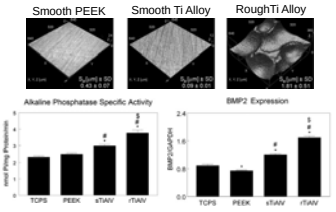
Review of the independent peer-reviewed literature and preliminary data provides insight.

3

Implant Material or Topography?

Beginning of the Ti vs. PEEK debate was an apples to orange comparison.

Osteoblasts exhibit a more differentiated phenotype and increased bone morphogenetic protein production on titanium alloy substrates than on poly-ether-ether-ketone



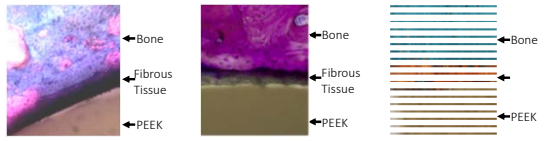
this study, because the contact angles were similar, this suggests that the surface texture was the main reason for the difference in osteoblast behavior between the materials

-Boyan et al, The Spine Journal (2012)

4

Implant Material or Topography?

All negative clinical and preclinical data is on smooth PEEK!



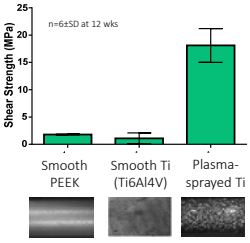
Toth et al. Biomaterials (2006) | Walsh et al. Spine (2014) | Evans et al. Acta Biomater (2015)

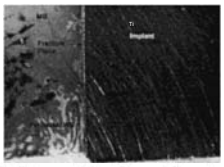
Prior studies show fibrous tissue integration on smooth PEEK

5

Implant Material or Topography?

Any smooth surface is bad, even titanium.





Histologic examination of the smooth specimens (S) revealed limited bone contact and a fibrous interface

- Implants placed line-to-line in cortical bone of adult sheep, "pushed out" after 12 weeks.
- Both smooth Ti and PEEK form fibrous tissue.

Walsh et al. J Biomed Mater Res (2000); Walsh et al. Spine (2015)

6

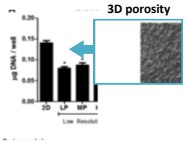
Is Porosity Needed?

Porosity facilitates a stronger osteogenic response at the cell level and stronger integration at the implant level than roughness alone.

Cellular Level

"....we propose that the 3D constructs provide a distinct structural advantage over 2D surfaces that increases osteoblast response."

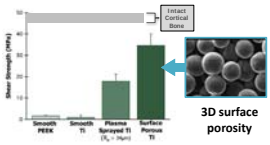
~Cheng, Boyan et al. 3D Printing and Additive Manufacturing (2016)



Implant Level

...three-dimensional material for bone integration achieve high shear strength values...because of mechanical interlocking between bone an the geometry of the material."

~Walsh et al. The Spine Journal, 2015.



Walsh et al. JBMR (2000); Walsh et al, The Spine J, (2015)

7

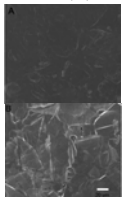
What About Nanotopography?

Porosity overwhelms any effect nanotopography may have at the cellular level.

"...submicron scale roughness, while contributing to the overall response of the cells, is not a major determinant of cell behavior in the absence of the larger craters."

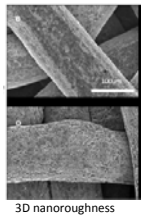
-Boyan et al. Biomaterials (2007)

Smooth (PT)

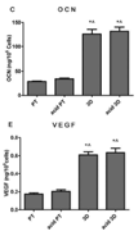


2D nanoroughness (acid PT)

3D micro-pores



3D nanoroughness (acid 3D)



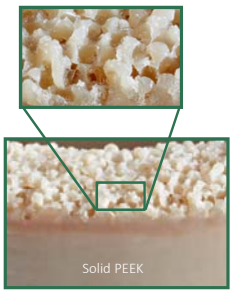
Boyan et al. JBMR (2015)

8

Porous PEEK Scoria™

Porosity is grown directly from the base PEEK device.

Porous PEEK Scoria



New Wettable Surface

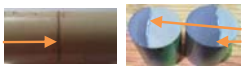
Physical Characteristics	
Porosity	63 ± 1%
Pore Size	220 ± 5 µm
In-Growth Depth	690 ± 150 µm
Interconnectivity	99.8 ± 0.2 %

9

Porous PEEK Will Not Flake Off

Porous PEEK structure is more durable than coatings and will not flake off under clinical loading.

- Scoria exhibits superior wear and abrasion properties compared with smooth PEEK.
- Compared with titanium coatings that delaminate, porous PEEK Scoria will not shear or "flake" off under *in vivo* fatigue loading.

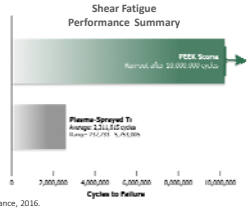


Wear Abrasion Performance Summary

Sample	Mass Loss (mg)	Particle Size (μm)
Scoria	27.6 ± 12.3	0.28-20.09**
Smooth PEEK	39.0 ± 18	

**Comparable to reported values for biomedical-grade PEEK

Shear Fatigue Performance Summary



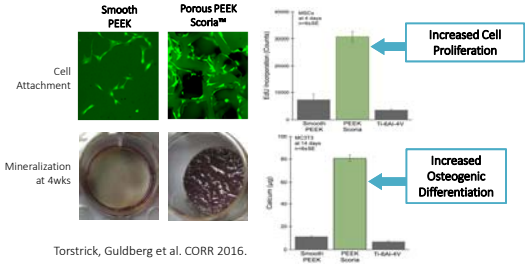
White Paper 1: Shear Mechanical Performance, 2016.

10

Porous PEEK is More Osteoconductive

Porous PEEK Scoria's osetoconductive porosity stimulates osteogenic cell differentiation resulting in improved osseointegration.

In Vitro: Increased Osteogenic Differentiation → In Vivo: Improved Osseointegration



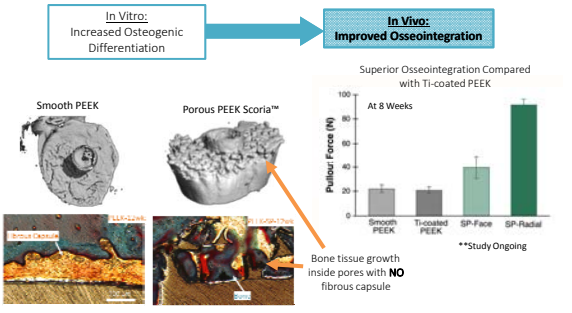
Torstrick, Guldberg et al. CORR 2016.

11

Porous PEEK is More Osteoconductive

PEEK Scoria's osetoconductive porosity stimulates osteogenic cell differentiation resulting in improved osseointegration.

In Vitro: Increased Osteogenic Differentiation → **In Vivo: Improved Osseointegration**

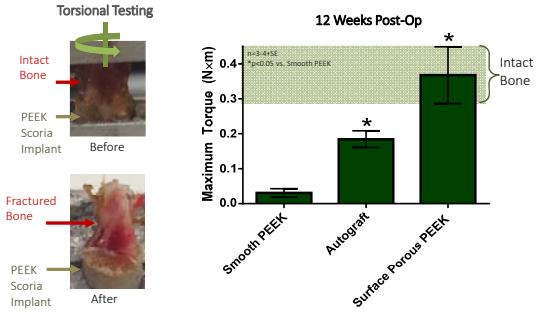


Evans, Gall et al. Acta Biomater (2015)

12

Stronger Integration Faster

Porous PEEK Scoria integrates better with bone compared with smooth PEEK and has a higher interfacial strength than autograft bone by 12 weeks.



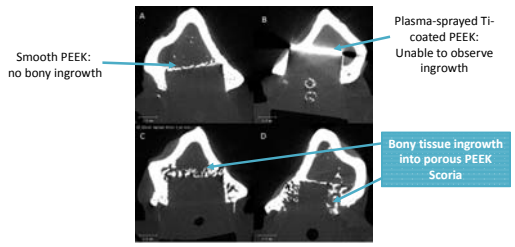
**Ongoing study

Torstrick, Guldberg et al. ORS 2016.

13

Imaging Ingrowth: A New Paradigm?

Not only does Porous PEEK Scoria allow for better imaging and assessment of fusion, x-ray and CT can now be used to assess bony tissue ingrowth directly into the device porosity.



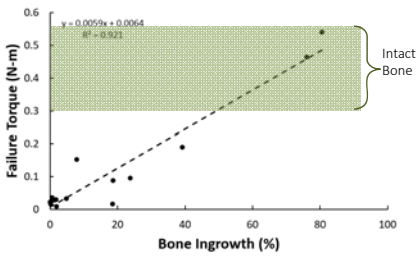
8 Weeks in Rat Tibial Model

**Ongoing study

14

Imaging Ingrowth: A New Paradigm?

CT-measured bony tissue ingrowth over time is directly correlated to implant integration strength, providing a new way to potentially assess fusion strength at early time-points post-op.



**Ongoing study

Torstrick, Guldberg et al. ORS 2016.

15

Conclusions

Duke UNIVERSITY

- Implant material or surface topography?
  Topography is the dominant factor in osseointegration at the cell and implant levels regardless of the base material.
- Porosity or surface roughness?
  Porosity induces significantly stronger osteogenic response and integration compared to roughness alone at the cell and implant levels.
- What about nanotopography?
  Nanotopography alone does not elicit a significant osteogenic response and requires larger topography such as porosity.
- Porous PEEK and clinical impact?
  - **Porous PEEK is osteoconductive, facilitating bony tissue ingrowth and stronger implant integration faster.**
  - **Imaging bony tissue ingrowth into porosity over time may provide a direct way to assess implant-mediated fusion at early time points.**

16