




**Metal vs PEEK vs Metal:
Points for Consideration**

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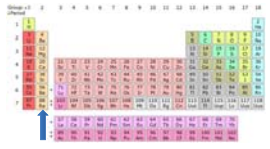
Disclosure


- Research Funding
 - Aesculap
 - Alphatec Spine
 - Globus
 - K2M
 - Medtronic
 - OrthoKinematics
 - Ratchiotek
 - Stryker Spine



The Same Old Story...

- Designer meets technology
- They fall in love
- Many new products designed with new technology
 - e.g., early 20th century, radium was a new technology
 - Discovered by Madam and Pierre Curie in 1898





Products Designed w/ Radium



Materials Technology: Design Factors

Component Design Changes

- Rigid Devices
 - Cage Thickness Changes
 - Corpectomy to Interbody Shift



- Material Choices
 - Titanium CP
 - Titanium Alloy
 - Allograft
 - Polyetheretherkeytone (PEEK)



Construct Design Philosophy Changes

- Compliant Mechanisms
 - Charite
 - Activ L



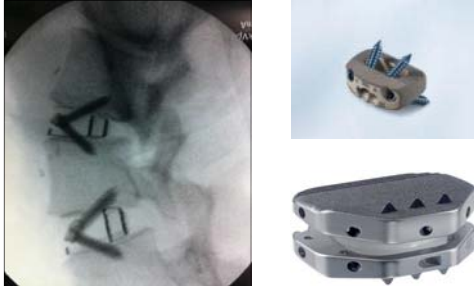
- Combined Mechanisms
 - FSU



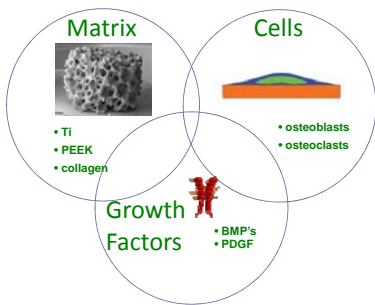
Competitive Interbody Products



Surface Material Technology



Essential Components of Arthrodesis

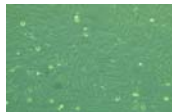


Titanium vs. PEEK: *in vitro* Evaluation

Objective: Evaluate the effect of the titanium coating on the *in vitro* adhesion, proliferation and differentiation of bone-forming cells as compared to non-coated PEEK surfaces.



Cells: Human MG-63 osteoblast-like osteosarcoma cells. 15mm diameter discs, 10,000 cell/cm².



Titanium Coating *in vitro* Evaluation

Assays:


- Cell Adhesion/Proliferation Assay: Cells seeded onto tissue culture plastic or disc substrates in 24 well plates in complete media containing serum at 37° C, 5% CO₂ until confluent (n=12 per surface).
- Cell Differentiation Assays: Transcriptional and translational analyses
 - Alkaline Phosphatase (ALP) activity, chromogenic assay.
 - qRT-PCR Analysis: osteoblast differentiation genes including type I collagen, osteocalcin, ALP, BSP, BMP-2.
 - ELISAs: Secreted bone morphogenetic proteins (BMP-2, BMP-4, BMP-7)

Rationale: Tracking 3 distinct phases of osteoblast maturation

Growth (proliferation):
BMP's

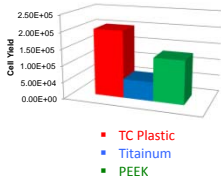
Extracellular matrix development:
ALP, Type I Collagen

Mineralization:
Osteocalcin



Cell Activity on Titanium Substrate

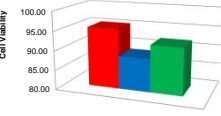
Average Cell Yield



| Surface | Approximate Cell Yield |
|------------|------------------------|
| TC Plastic | 1.50E+05 |
| Titanium | 2.20E+05 |
| PEEK | 1.20E+05 |


- Lower cell proliferation/growth on Ti
- Consistent with higher level of differentiation on Ti
- Differentiating cells divide slower

Average Cell Viability



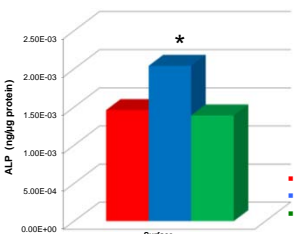
| Surface | Approximate Cell Viability |
|------------|----------------------------|
| TC Plastic | 95.00 |
| Titanium | 92.00 |
| PEEK | 93.00 |

- High cell viability on all surfaces



Cell Activity on Titanium Coated Implants


Average Alkaline Phosphatase Activity



| Surface | Approximate ALP Activity (ng/g protein) |
|------------|---|
| TC Plastic | 1.50E-03 |
| Titanium | 2.20E-03* |
| PEEK | 1.20E-03 |

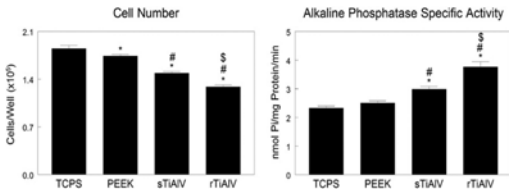
- Ti coating supports adhesion, growth and differentiation of osteoblast cells
- Ti coating significantly increases **early bone-forming activity** in osteoblast cells

* p<0.05, 2-sample T test and one-way ANOVA statistical analysis



Cell Activity on Rough Titanium Surfaces

- o Similar results published for roughened titanium surface (acid etched) compared to smooth titanium or PEEK.

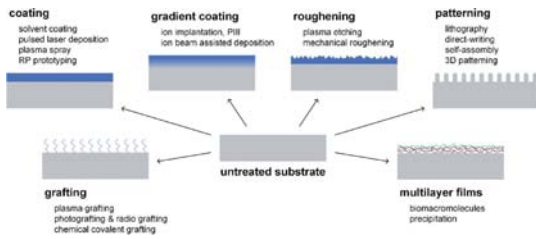


Taken from: Olivares-Navarette et al., *The Spine Journal* 12 (2012): 265-272.



Cell-Biomaterial Interaction: Harnessing the power

Medical Device Surface Modification Technology



Design Iteration: Utilizing a Hybrid Material Design

- Patients
 - Surgeon recognized need
- Manufacturer
 - Coating expertise
- Regulatory Agency
 - FDA



Other Radium Based Products



Failure Ti Coated PEEK

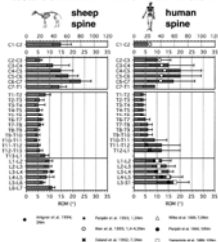
- Material Considerations
 - PEEK is radiolucent
 - PEEK is also less stiff and thus, decreases risk of subsidence
 - Ti is stiffer
 - Ti makes for excellent bone implant interface
 - Additional consideration for hybrid designs



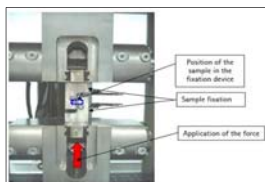
Additional Research: in vivo AND biomechanical studies

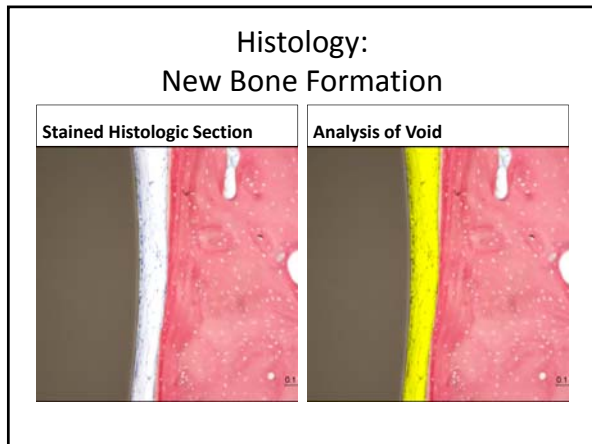
in vivo Animal Study

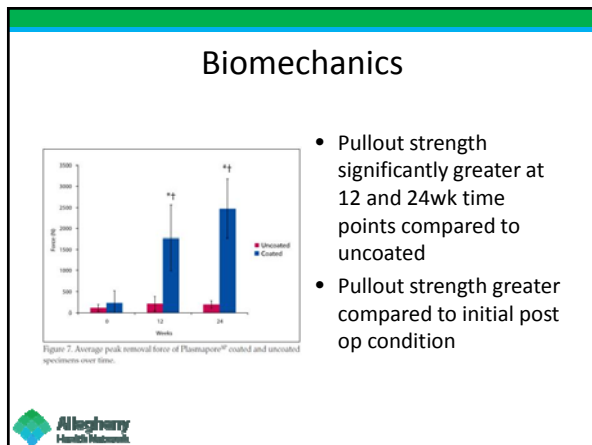
ROM COMBINED FLEXION / EXTENSION



Biomechanical Studies









Conclusions

- Different material substrates illicit different cellular responses
- Bone implant interface may dictate the success of the device and subsequently the procedure.
- Designs that incorporate different materials may impact clinical outcomes

