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Sidney Kimmel Medical College at Thomas Jefferson University

Endplate Technology: The Future of Fusion?

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Disclosures

- **Cerapeadics: Consultant**
- **Retropsoas Technologies: Consultant**

Objectives

- Pseudarthrosis Rates
- Biomaterials
- Advancements in materials
- Future implications

Lumbar Fusion

- **Rate of Lumbar Fusion Surgery Performed in the US steadily rising**
  - Up 62% on a population-adjusted basis between 2004 to 2015

Increase in Primary Fusions.

Increase in Revision Fusions

Lumbar Pseudoarthrosis

- Commonly defined as failure to achieve bony union >/= 1 year from Index procedure
- Rate in the literature variable
  - 5-15%
- Not all patients are symptomatic

ACDF

- Similar to lumbar fusions the rate of ACDFs performed continue rise
- As we see more ACDFs performed see more failures
- Overall >80% of patients are satisfied with their ACDF at 2 and 5 years post-operatively if surgery was done for radiculopathy.

Pseudarthrosis

- Lambrechts, Schroeder, et al. TSJ. 2022
  - Reviewed 597 ACDF patients and 1203 ACDF levels
  - Using Dynamic Flex ex films, Pseudarthrosis rate was 36.0% (215 patients)
    - However, only 4.9% (29 patients) required a revision

- No difference in HRQOL outcomes in patients with pseudoarthrosis to a solid fusion that did not undergo a revision

- Significant difference in HRQOL at 1 year in patients with pseudoarthrosis who required surgery, compared to those that had a solid fusion
  - NDI (38.0 vs. 23.7, p=.047) and delta VAS Arm (-0.22 vs. -2.97, p=.016) scores

Risk Factors for Pseudarthrosis

- **Common Risk Factors for Pseudarthrosis**
  - Metabolic Abnormalities – Diabetes
  - Excessive Motion at the fusion site
  - Smoking
  - Infection

Spine J. 2023 Jan;23(1):105-115. doi: 10.1016/j.spinee.2022.08.018. Epub 2022 Sep 2.

Revision lumbar fusions have higher rates of reoperation and result in worse clinical outcomes compared to primary lumbar fusions

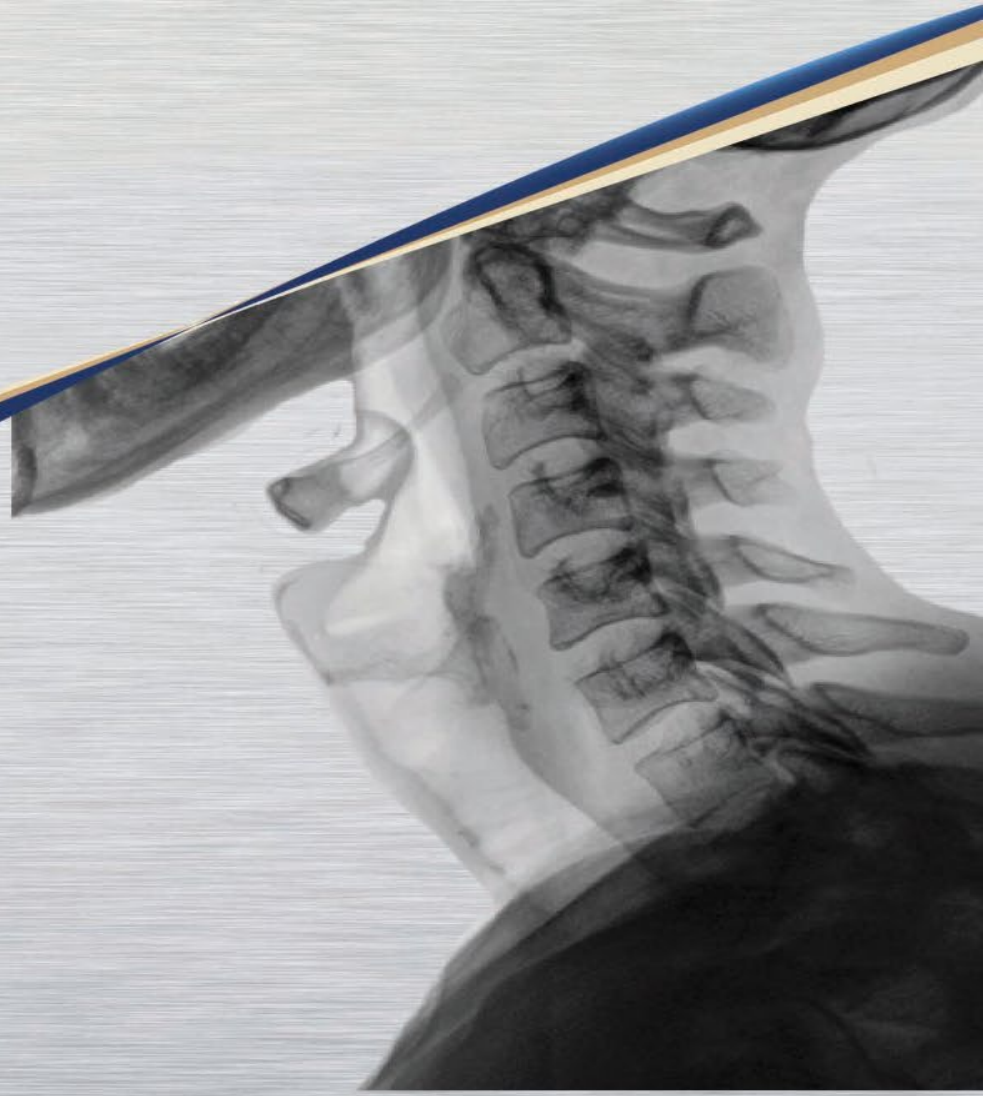
Mark J Lambrechts [1], Gregory R Toci [2], Nicholas Siegel [2], Brian A Karamian [2], Jose A Canseco [2], Alan S Hilibrand [2], Gregory D Schroeder [2], Alexander R Vaccaro [2], Christopher K Kepler [2]

- 892 Revision Spinal Procedures from from 2011- 2021
  - Indication for revision:
    - ASD: 56%
    - Pseudarthrosis: 17%
    - Recurrent Stenosis: 26%

- A revision procedure was an independent risk factor for worse improvement ΔODI, ΔVAS Back, ΔVAS Leg, and ΔPCS-12 and 1-year postoperatively. Regardless of the indication for revision lumbar fusion

- Higher rate of reoperation and future revision surgery

How Do We Optimize the Index Operation?



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Ways to Improve Fusion Success

Patients

Preoperative Optimization

Non-Smokers

Diabetic/Metabolic Optimization

Biologics

Allograft

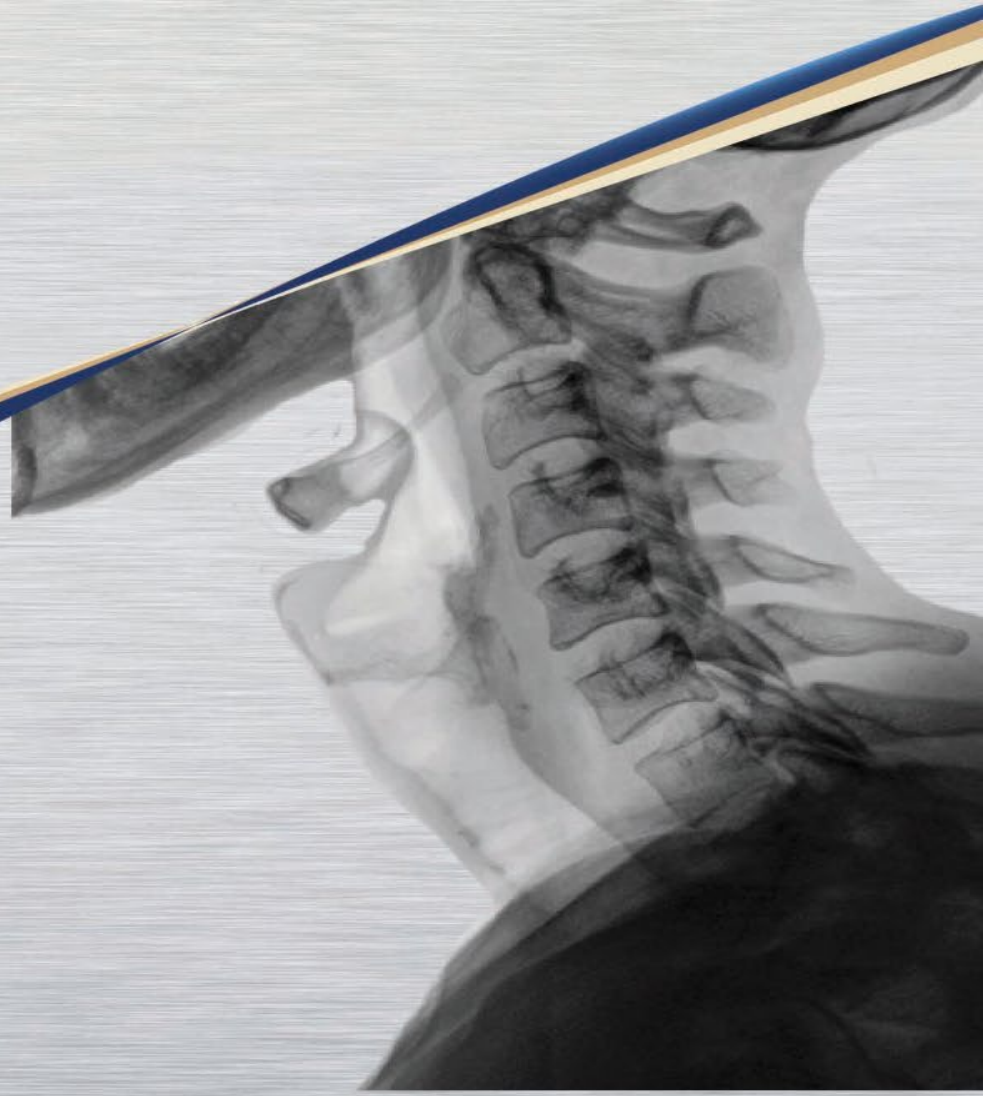
BMP

P15

Implants

Cage?

Implant Technology



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Ideal Interbody Device

- **Two Characteristics:**

- **The ability to produce a rigid construct that facilitates alignment correction and indirect decompression through disc-space distraction**

- **The ability to facilitate the bony fusion that is critical for long-term fusion success.**

Why Does the Implant Matter?

- **Implants that allow for integration within the device itself it is more likely to**
  - Aid in fusion
  - Improve the implant longevity +/- improve subsidence rates
  - Reduce stress shielding

Traditional Implants

- **Most commonly Used Implants**
  - PEEK
  - Titanium
- **Both offer good mechanical properties but traditional unprocessed endplates are generally inert and don't aid the direct fusion process**
- **Traditional implants with unaltered endplate states have very limited bioactivity to help promote or achieve fusion**

Poly- Ether-Ether-Ketone (PEEK)

Advantages

- **Biocompatibility**
- **Radiolucent**
- **Modulus of Elasticity**

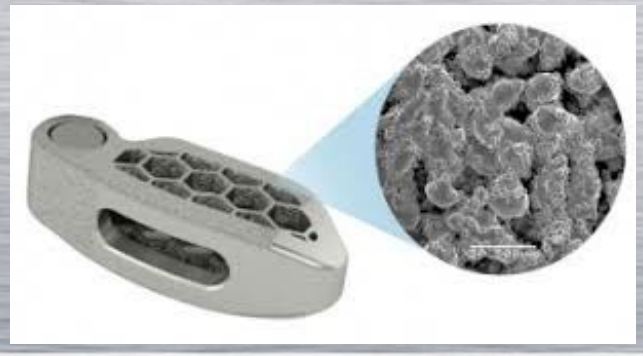
Disadvantages

- **Does not promote bone growth**
- **Poor Osteointegration**

Titanium and Ti Alloys

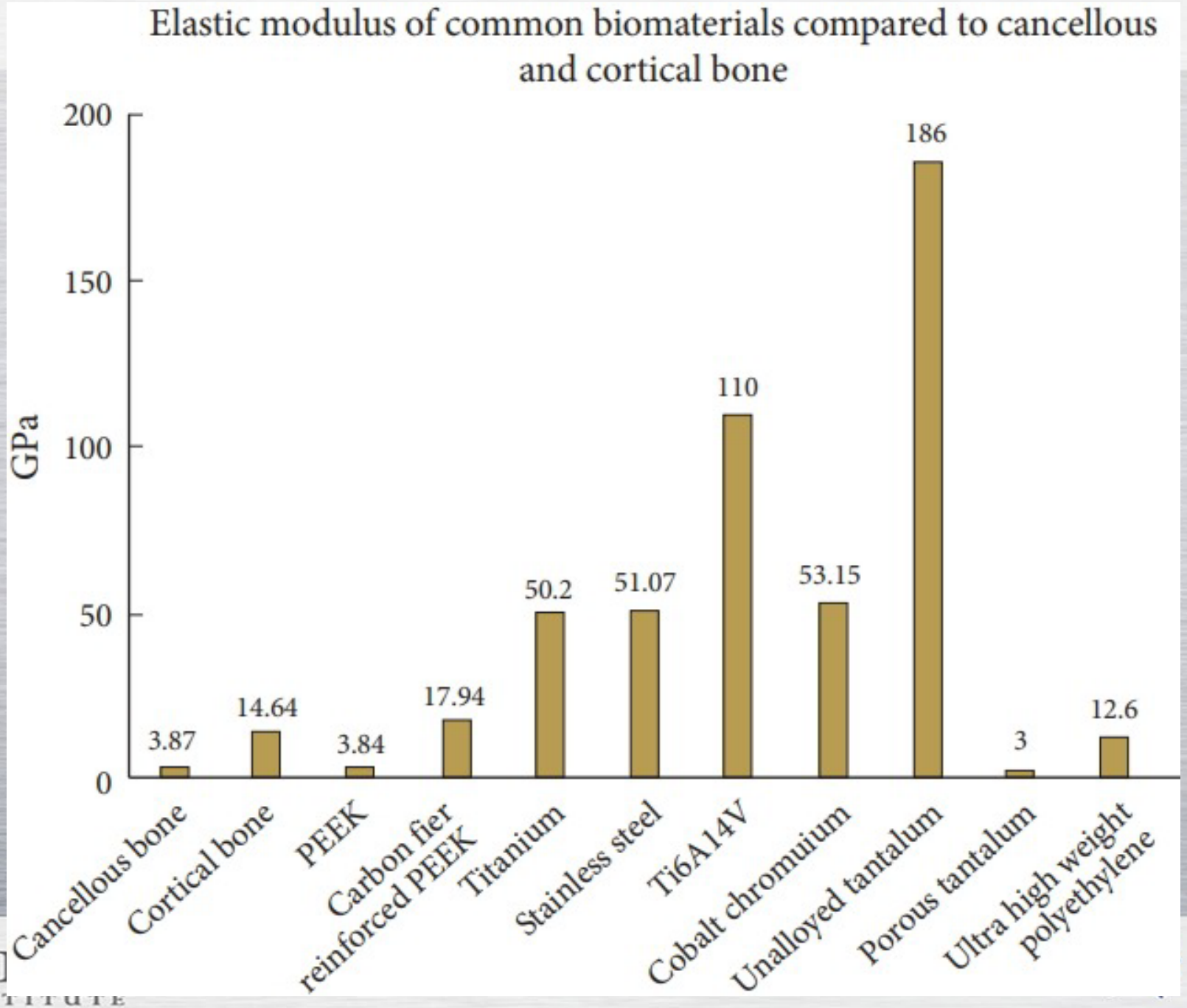
Advantages

- **Biocompatibility**
- **Corrosion resistant**
- **Low Density**
- **Osteointegration**

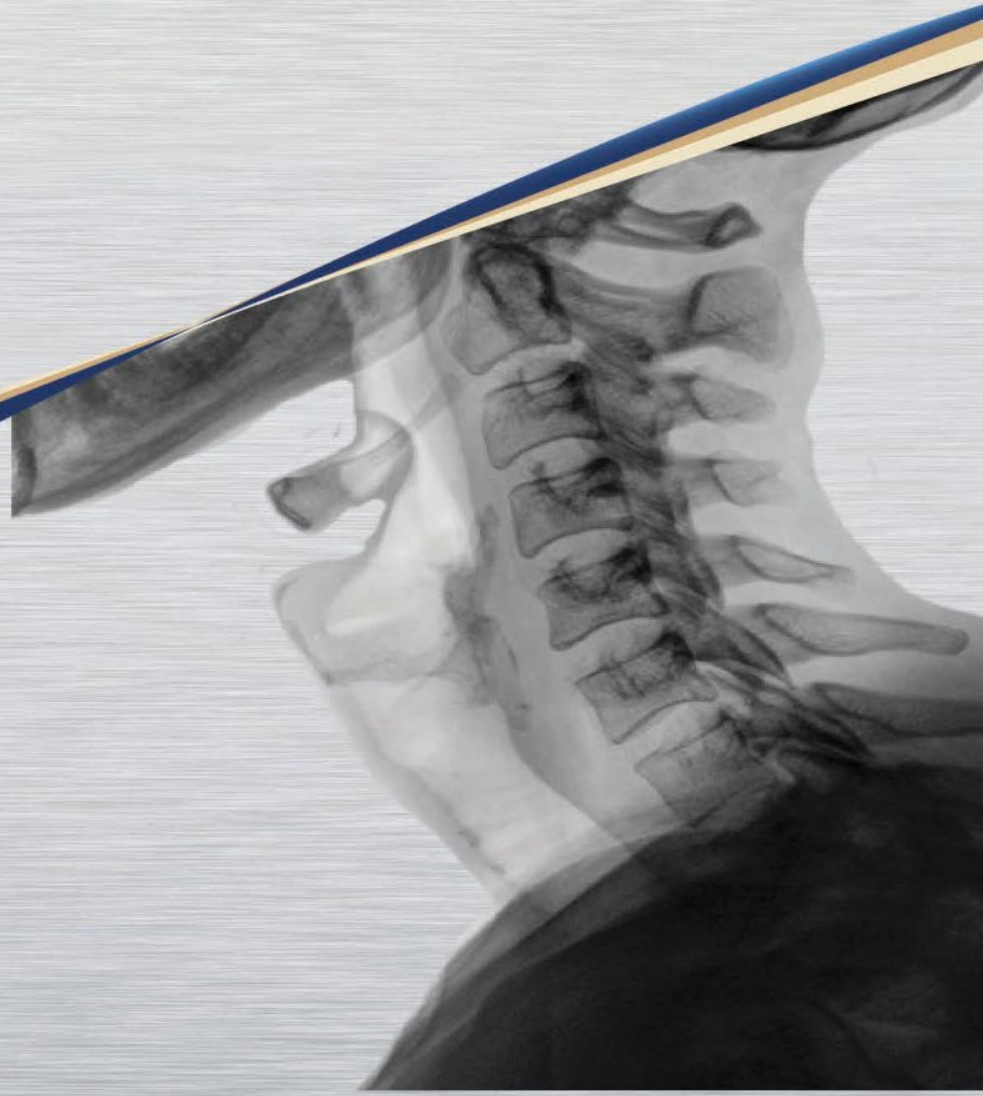


Disadvantages

- **High Modulus of Elasticity (110 GPa) compared to that of cortical bone (10-30 Gpa)**
- **Stress Shielding**
  - Bone atrophy
  - Subsidence
  - Implant failure
- **Can support bone growth but sufficient for true osteointegration (unprocessed surfaces)**


Elastic modulus of common biomaterials compared to cancellous and cortical bone
GPa
200
150
100
50
0
3.87
14.64
3.84
17.94
50.2
51.07
110
53.15
186
3
12.6
Cancellous bone
Cortical bone
PEEK
Carbon fier reinforced PEEK
Titanium
Stainless steel
Ti6A14V
Cobalt chromuium
Unalloyed tantalum
Porous tantalum
Ultra high weight polyethylene

Advancements in Cage Technology



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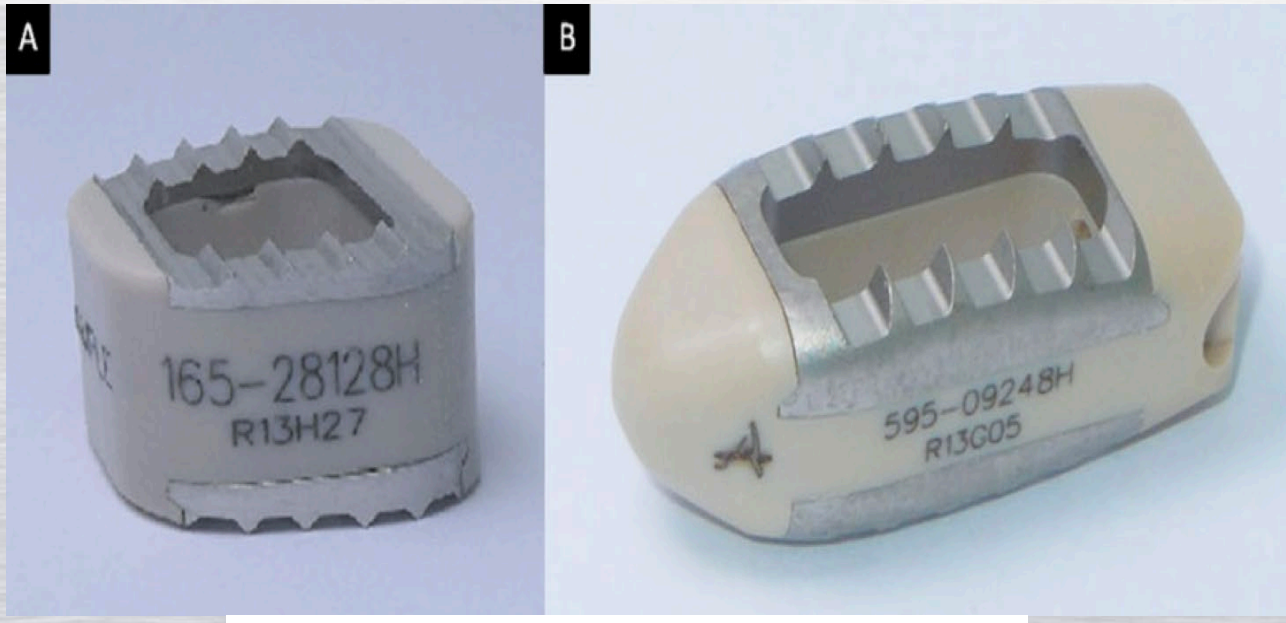
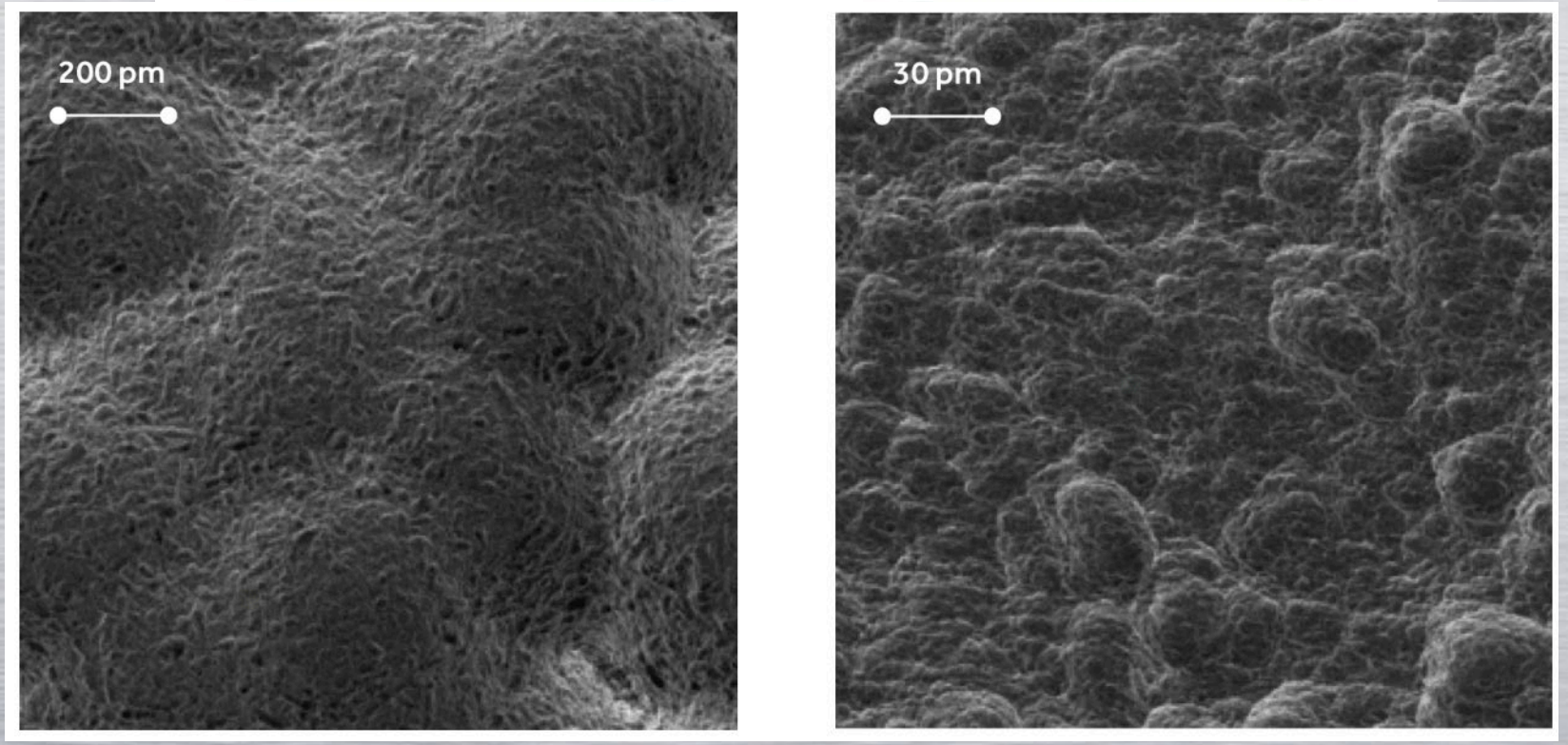
PEEK Cages

- TI-coated or dual material implants
- HA Coated Peek
- Expandable options



3D Printing



Surface Treatments

- Roughened Ti surfaces try to mimic the osteo-clastic like pits for cellular attachment
- Rough spike surfaces simulate osteoclast pit topography
- Induce bone growth factors

Spine (Phila Pa 1976). 2015 Mar 15;40(6):399-404. doi: 10.1097/BRS.0000000000000778.

Implant materials generate different peri-implant inflammatory factors: poly-ether-ether-ketone promotes fibrosis and microtextured titanium promotes osteogenic factors

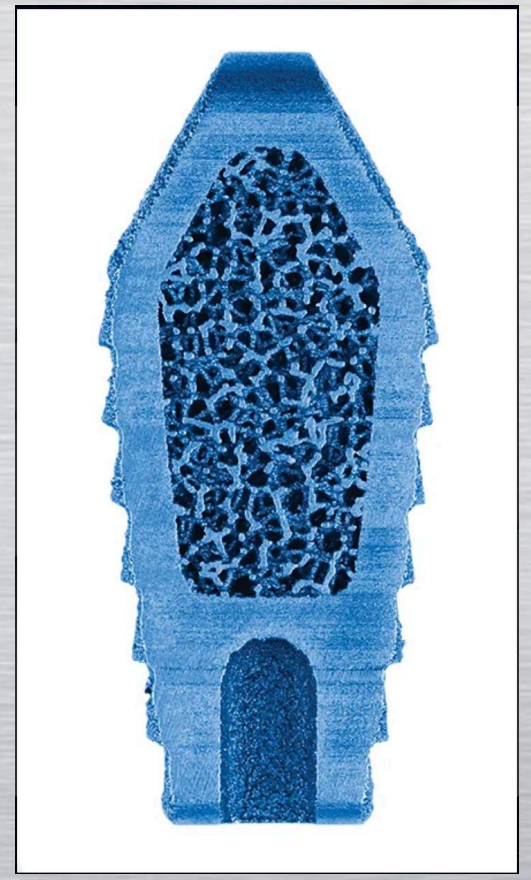
Rene Olivares-Navarrete [1], Sharon L Hyzy, Paul J Slosar, Jennifer M Schneider, Zvi Schwartz, Barbara D Boyan

- Goal of the study Inflammatory microenvironment generated by cells on surfaces is affected by surface microtexture and whether it differs from that generated on PEEK
- PEEK: reduced osteoblastic differentiation of progenitor cells and production of an inflammatory environment that favors cell death via apoptosis and necrosis
- TI: Surfaces with complex macro/micro/nanoscale roughness promote osteoblastic differentiation and foster a specific cellular environment that favors bone formation.

3D Printed Endplates

- Increased Osteoblastic Maturation
- Nanotechnology on surface allows for ingrowth
- Osteogenic Environment that produces Bone Morphogenic Proteins
- Lower Modulus of Elasticity Closer to that of Native Bone with porous 3D printed cages

↑ Pore Size ↑ Pore Density = ↓ Modulus



Olivares-Navarrete R. Spine J. 2013.

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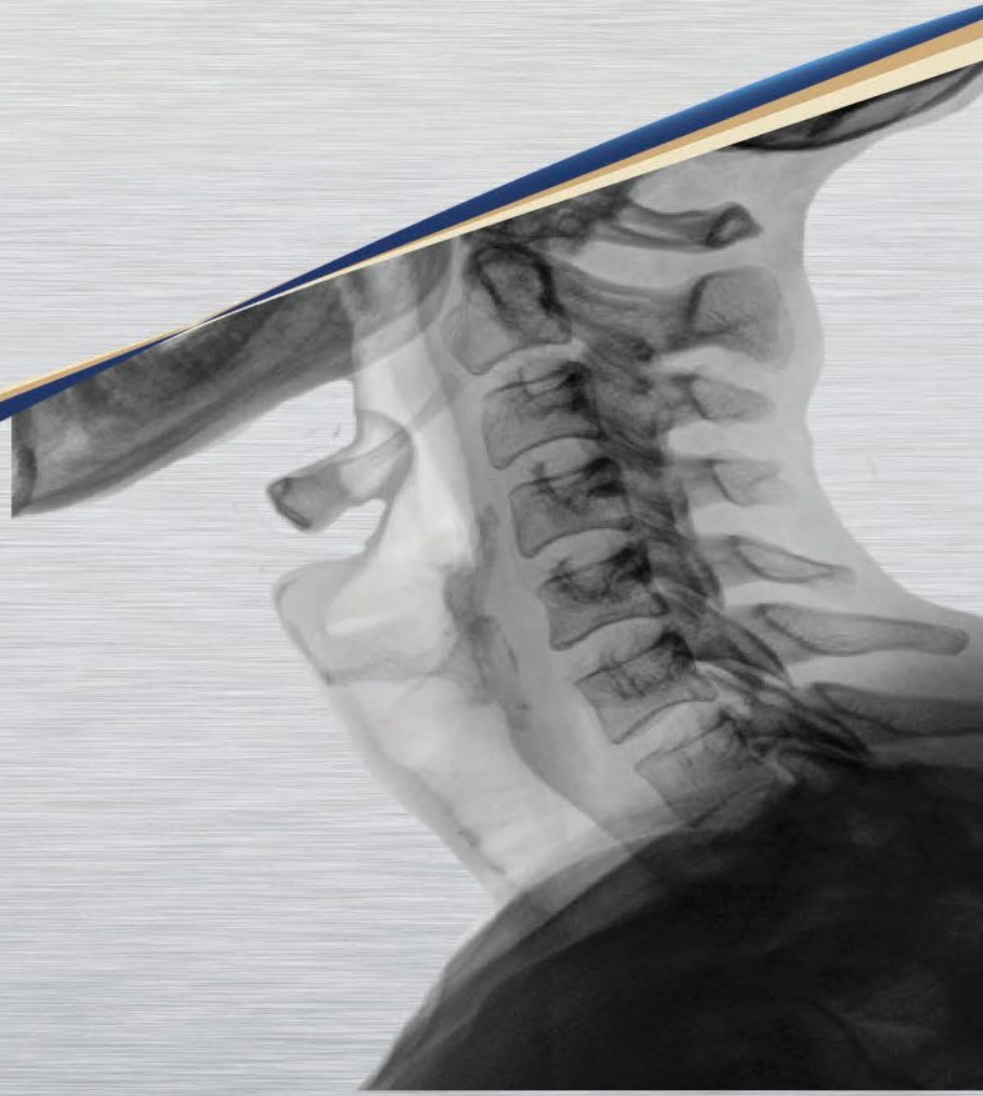
3D printed Ti

- **3D-pTi devices are designed to imitate trabecular bone with highly porous surfaces, which both facilitates bony ingrowth and lowers the elastic modulus to the point that it more closely emulates that of cancellous bone**

- **3D-pTi implants also have greater radiolucency relative to conventional Ti implants and so may allow for more accurate assessment of bony union**

Future Implications



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Will Cage Technology allow us to change our Strategy?

- **Decrease Revisions**
- **Improve Index fusions**
- **Decrease use of Biologics**

THANK YOU.

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