The Future of Spinal Fusion Procedures

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Department of Orthopaedic Surgery
Northwestern University Feinberg School of Medicine

Entity	Consulting	Advisory Board	Royalties	Research Grant
Medtronic	X			
Stryker	X		X	
Bioventus		X		
Asahi	X			
Surgalign		X		
Promimic		X		
CSRS		X		
Amphix Bio			X	

Disclosures

NEUROSURGICAL FOCUS

Neurosurg Focus 39 (4):E10, 2015

Lumbar pseudarthrosis: a review of current diagnosis and treatment

Danielle S. Chun, BA,[1] Kevin C. Baker, PhD,[2] and Wellington K. Hsu, MD[1]

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– Still a significant clinical problem

– 7 studies met inclusion criteria
– Plain radiographs and thin-cut CT used for diagnosis

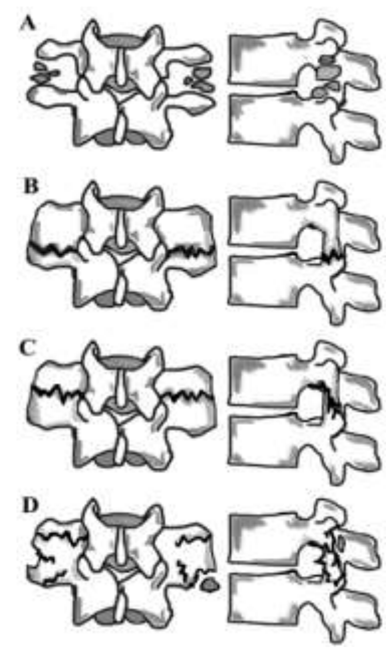


TABLE 2. Comparison of lumbar fusion techniques and fusion success rates

Authors & Year	Surgical Indication	Lumbar Fusion Technique	Fusion Success
Zdeblick, 1993*	DDD, spondylolisthesis	PLF alone	65%
		PLF + semi-rigid instrumentation	77%
		PLF + rigid instrumentation	95%
Christensen et al., 2002*	Degenerative lumbar disease	PLF + rigid instrumentation	80%
		ALIF + PLF + rigid instrumentation	92%
Madan & Boeree, 2003	Degenerative lumbar disease	ALIF + cage instrumentation	94.3%
		PLIF + PLF	100%
Kim et al., 2006	Degenerative lumbar disease	PLF + rigid instrumentation	92%
		PLF + PLIF + rigid instrumentation	95%
		PLIF + rigid instrumentation	96%
Strube et al., 2012	DDD, facet joint arthritis	ALIF	70.6%
		APLF	68.7%
Høy et al., 2013	Degenerative lumbar disease	PLIF + rigid instrumentation	88%
		TLIF + rigid instrumentation	94%
Berjano et al., 2015	DDD, spondylolisthesis, scoliosis, stenosis, revision, other	XLIF	87.1%
Fujimori et al., 2015	Degenerative spondylolisthesis	PLF + rigid instrumentation	84%
		TLIF + rigid instrumentation	96%

APLF = anteroposterior lumbar fusion; DDD = degenerative disc disease; TLIF = transforaminal interbody fusion; XLIF = extreme lateral interbody fusion.

* A statistically significant difference was noted between surgical groups.

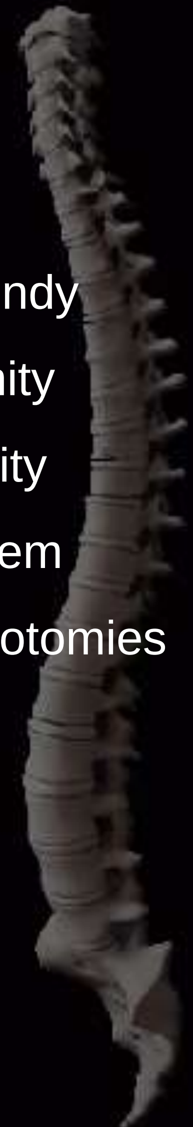
Patient-specific Considerations

Comorbidities

- High BMI
- Drug use
- Smoker
- Diabetes
- Previous revisions
- Osteoporosis
- Age

Spine structure

- High grade spondy
- Coronal deformity
- Sagittal deformity
- Multilevel problem
- Corrective osteotomies
- MIS approach



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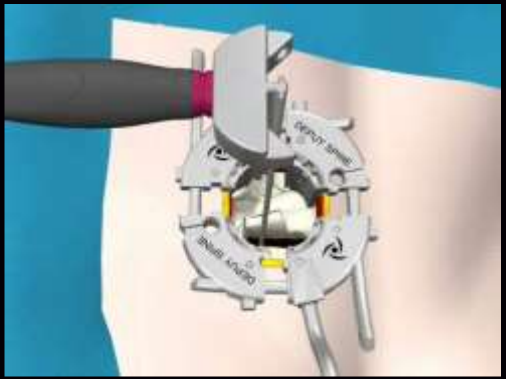
Controversies in Spine Surgery

Do Indications Change When You Decide to Do an MIS Case?

Erik Olsson, MD, D. Greg Anderson, MD,* and Wellington K. Hsu, MD†*

- Limited access
- Decreased surface area for bone bridging
- Lack of autograft
- Poor environment – less margin for error
- Handling properties of a biologic is critical



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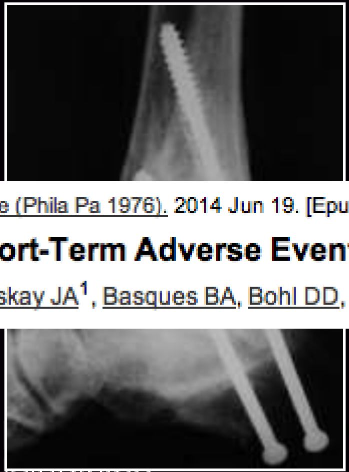
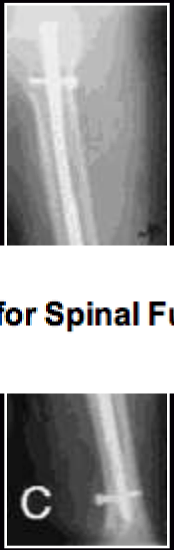
Where we have been…





Spine (Phila Pa 1976). 2014 Jun 19. [Epub ahead of print]

Short-Term Adverse Events, Length of Stay, and Readmission Following Iliac Crest Bone Graft for Spinal Fusion.

Gruskay JA[1], Basques BA, Bohl DD, Webb ML, Grauer JN.

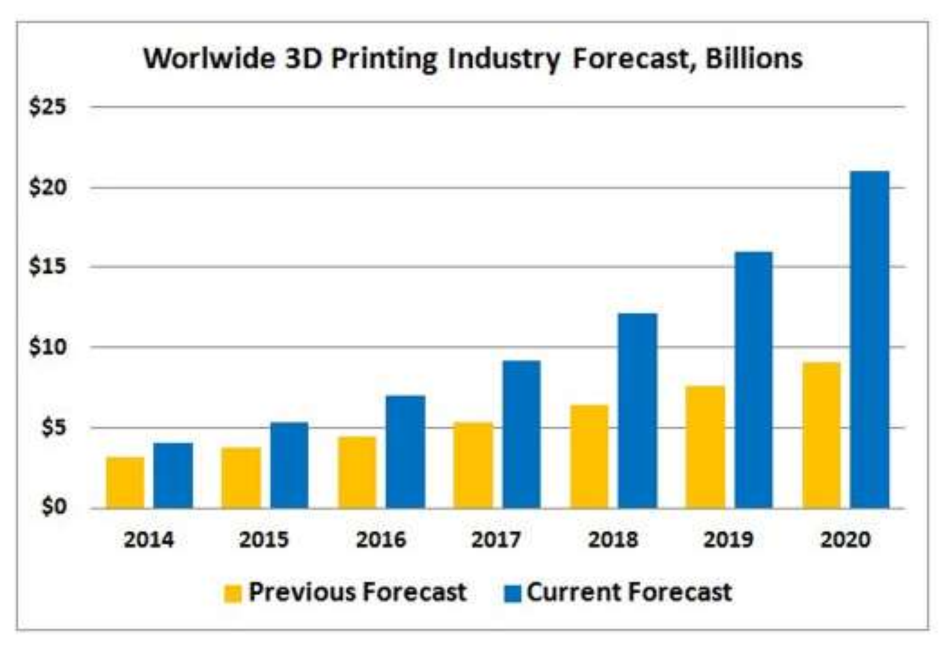
ICBG comprises 6% of spine fusions…

3D printing

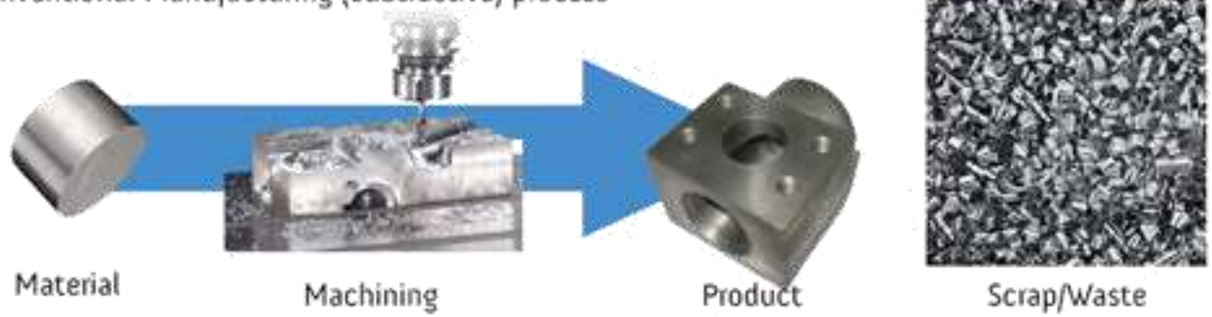
- Patented in 1983, expired in 2009
- Emergence of affordable printers
- Changing landscape like personal computers and internet

The New Industrial Revolution

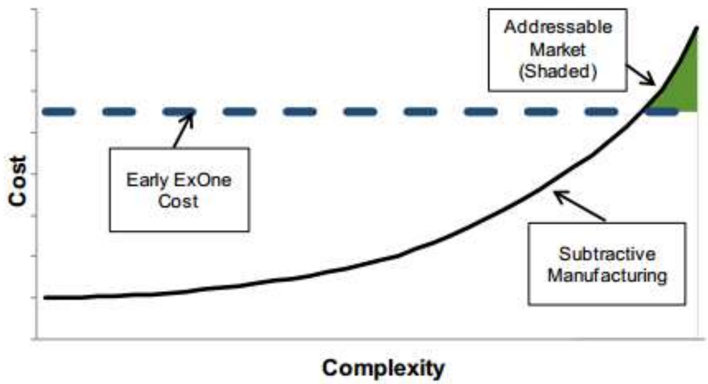
- Replacing mass with custom production
- Mass market for niche products
- Positive effect on environment
- Shapeways, Inc with 30 industrial-sized printers

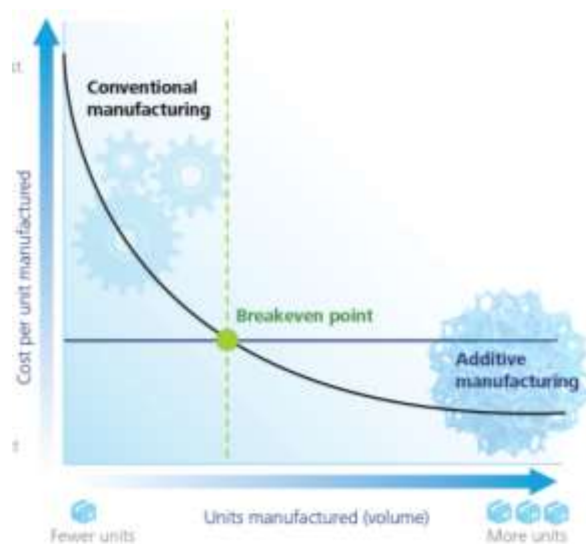


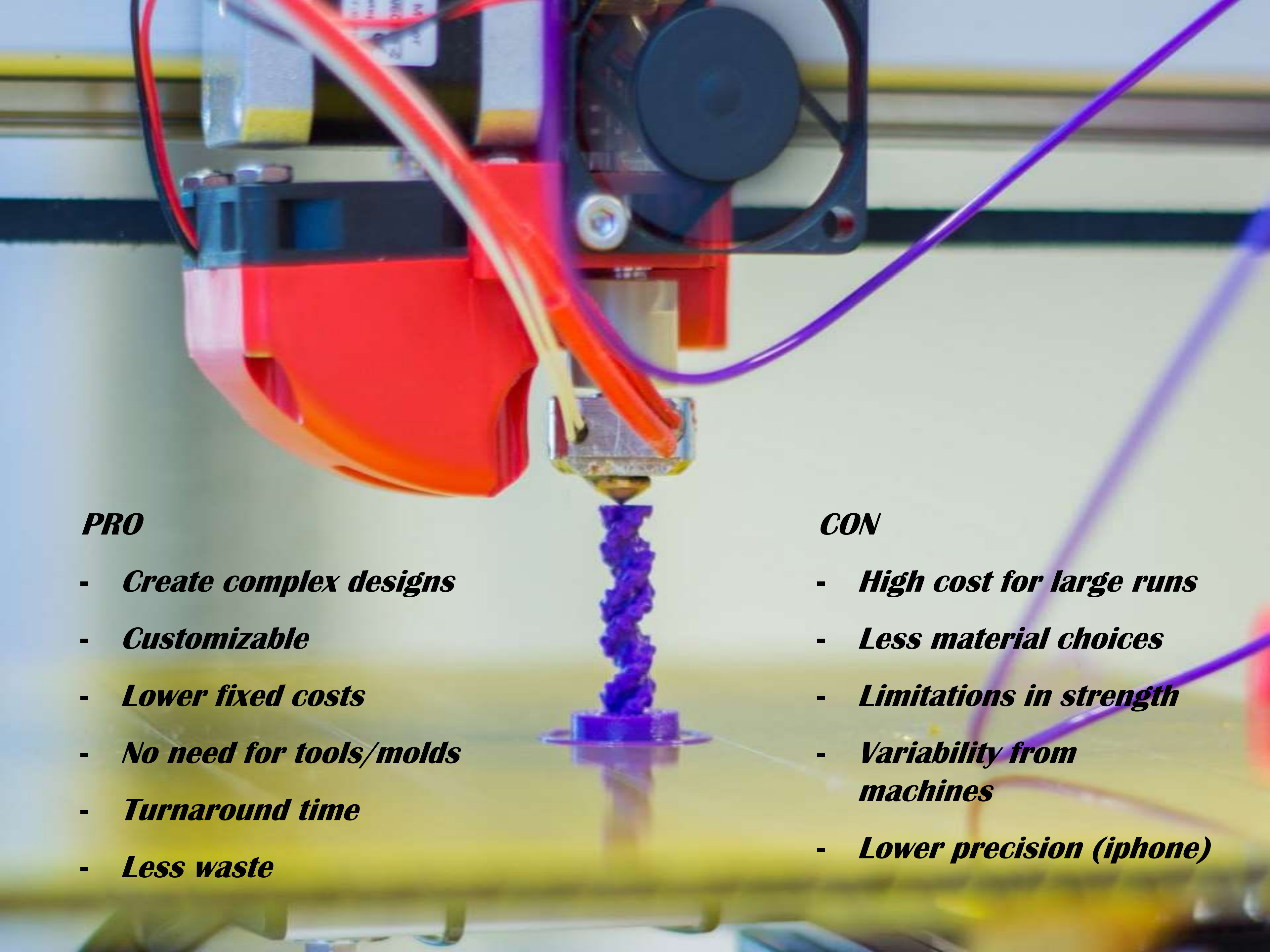
● Conventional Manufacturing (subtractive) process



- **Traditional Manufacturing**
  - Increasing complexity leads to increased costs







PRO

- **_Create complex designs_**
- **_Customizable_**
- **_Lower fixed costs_**
- **_No need for tools/molds_**
- **_Turnaround time_**
- **_Less waste_**

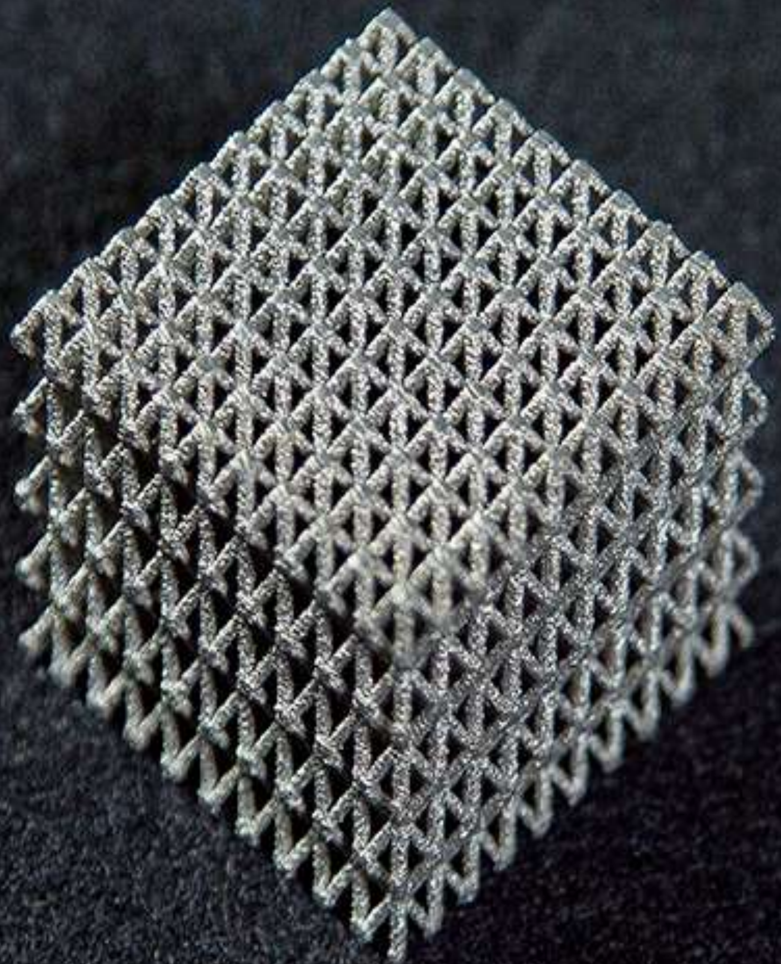
CON

- **_High cost for large runs_**
- **_Less material choices_**
- **_Limitations in strength_**
- **_Variability from machines_**
- **_Lower precision (iphone)_**

3D printing is everywhere

F1 car manufacturing

Jet engine fuel nozzles



Hearing aids

Movie props

Orthodontist braces

- Fused deposition modeling
  - Use of filament
  - Heated nozzle
  - Material extruded then instantly cools down and solidfies
  - Cheapest 3D printing technology on market

- Stereolithography
  - Liquid photopolymer resin
  - Laser light source to solidify the material
  - Uses a resin tank
  - DLP uses projector
  - Limited to resins

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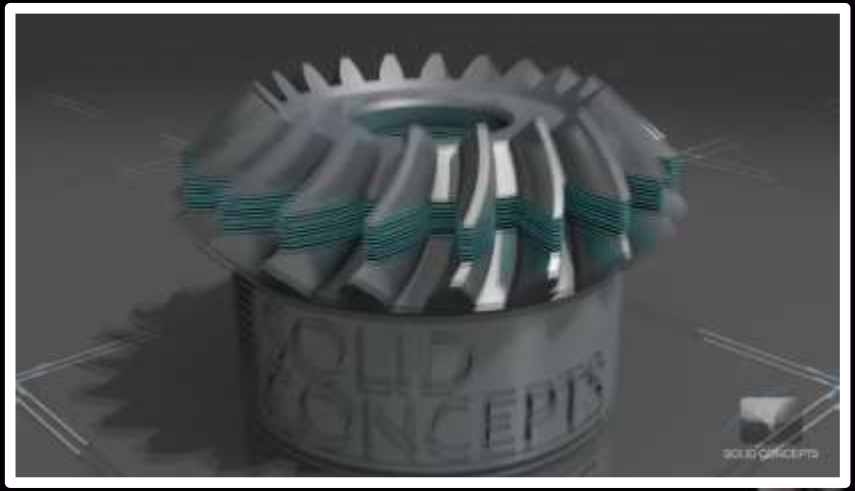

- Selective Laser Sintering
  - Laser to melt/sinter
  - Powdered material
  - Elastomers and plastics
  - Melts successive layers one by one
  - Industrial 3D printing applications
  - Complete design freedom
  - Ceramic, metal, glass, plastic

- Selective Laser Melting
  - Thin layers of powdered metal
  - Selectively melting using heat source – either high power laser or electron beam
  - Takes place in low oxygen environment or vacuum
  - Reduce thermal stresses
  - Holy grail of processes

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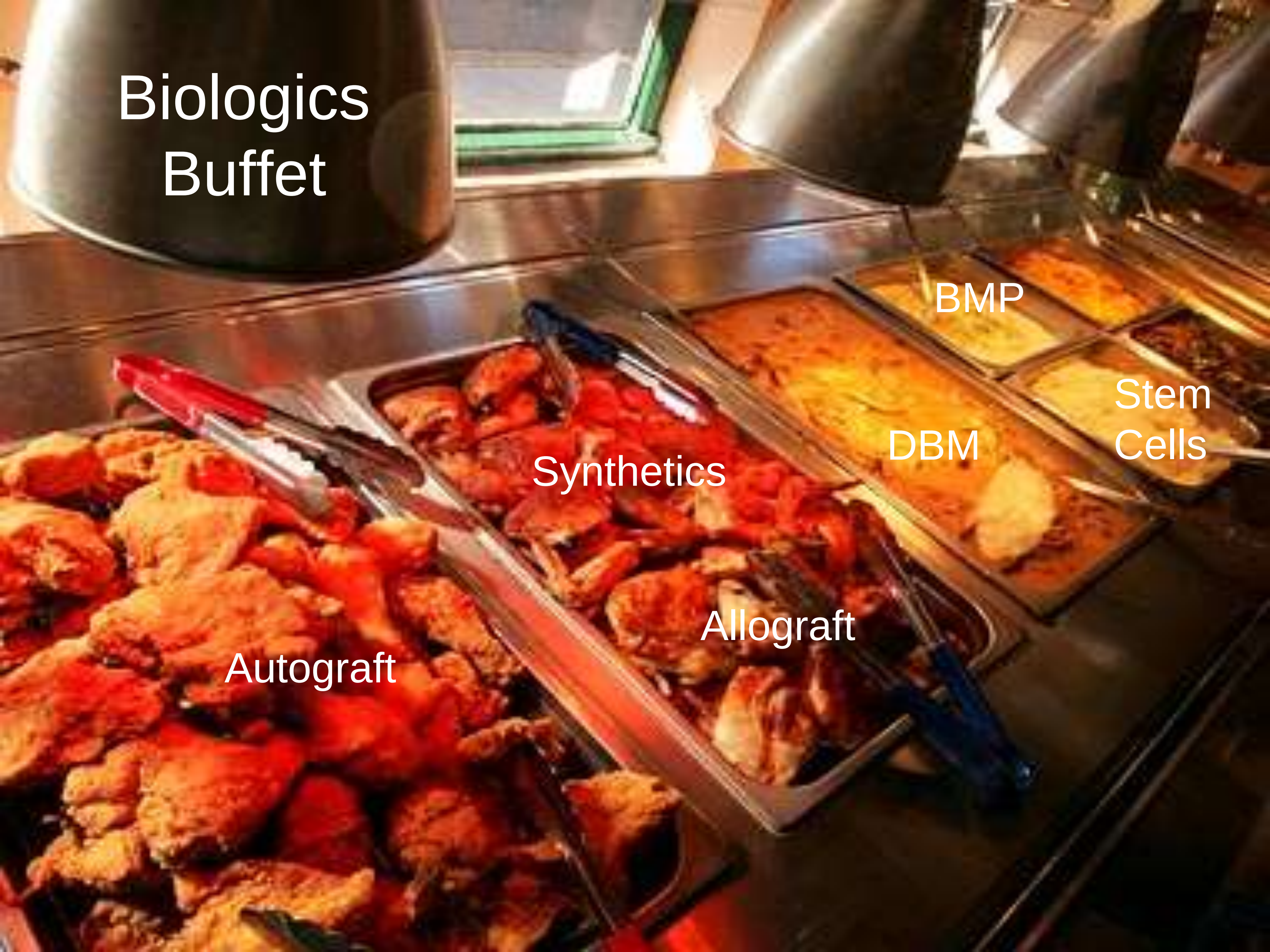
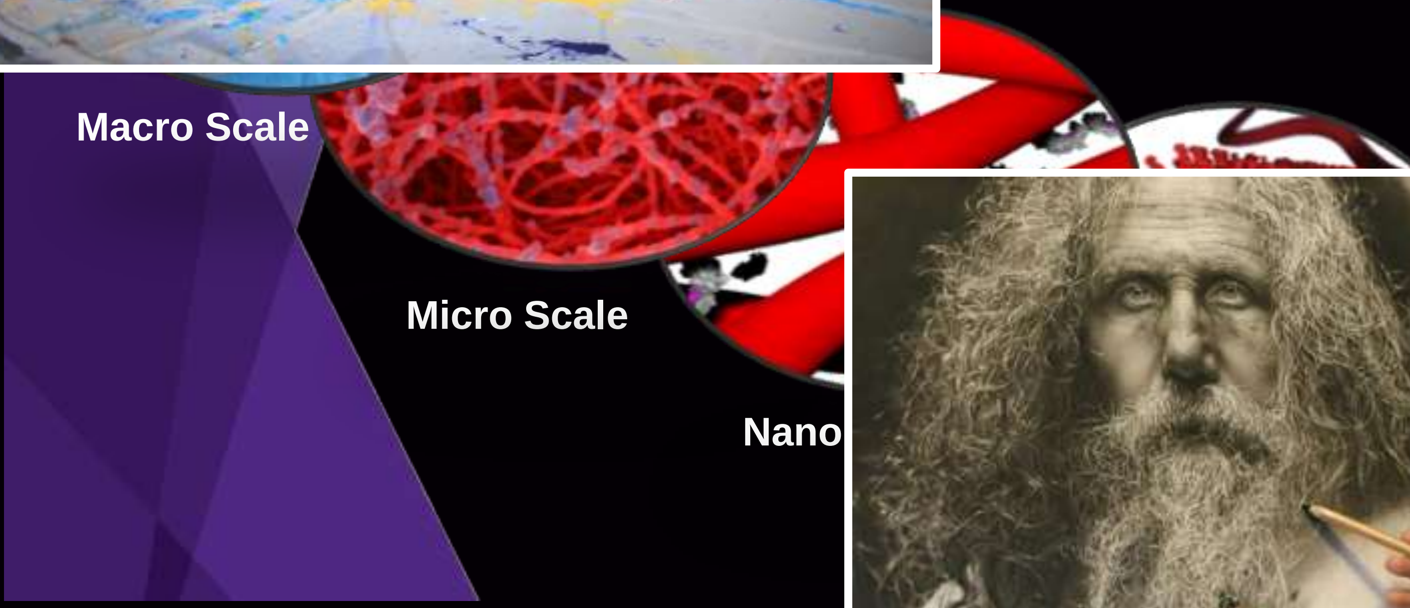

Biologics
Buffet
BMP
Stem
Cells
DBM
Synthetics
Allograft
Autograft


SQI
Simpson Querrey Institute
Northwestern
Medicine

nology in

egeneration



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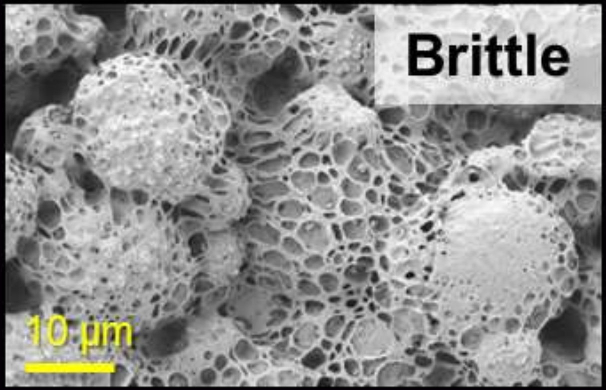
Synthetic carriers

- Silicates
- Ceramics
  - Calcium phosphate
  - Hydroxyapatite
- Bioglass
- Collagen-based



-More flexibility

-Less variability

-Better biomechanical properties

Hyperelastic “Bone” 3D-Ink

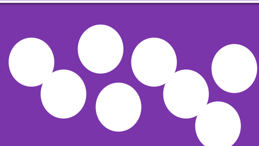
TRI-SOLVENT MIXTURE

+

ELASTOMER (10%)

+

HYDROXYAPATITE (90%)



10-50 μm

Mix and Thicken

Hyperelastic Bone 3D-Ink

(Scalable Ink Synthesis)

3D-Print

Room-Temperature, Extrusion 3D-Printing

Elevated temperatures are not used at any stage

3D-Printed material is 90% HA

SHAH TEAM LAB

Common material with uncommon properties

FEATURES

FDA approved materials

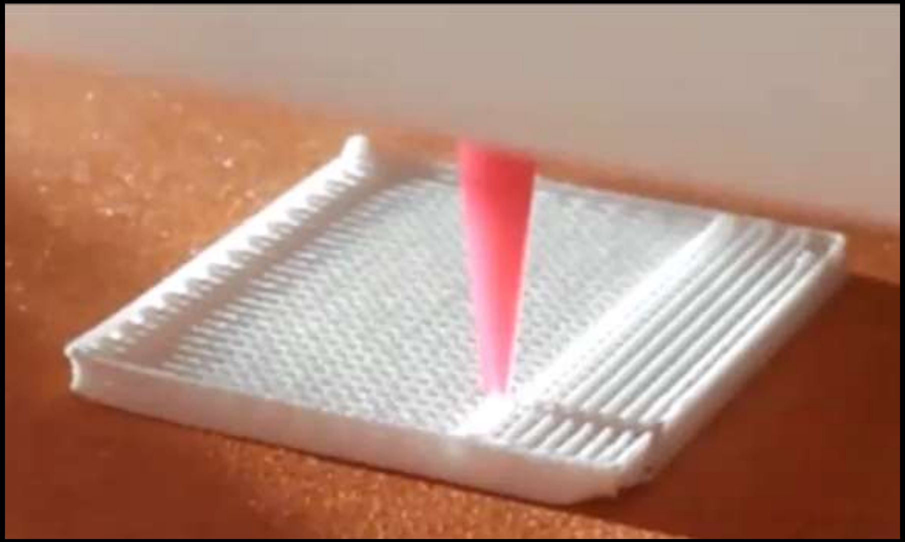
Mechanically Elastic

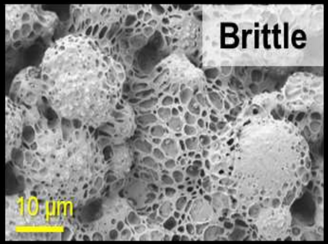
Absorbent

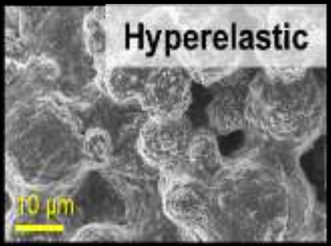
Osteoinductive

Fold, Roll, Cut, Fuse, Coat

Incorporate Bioactive Factors







Rapid liquid-to-solid transformation upon Deposition

Up to 150 mm/s print speeds

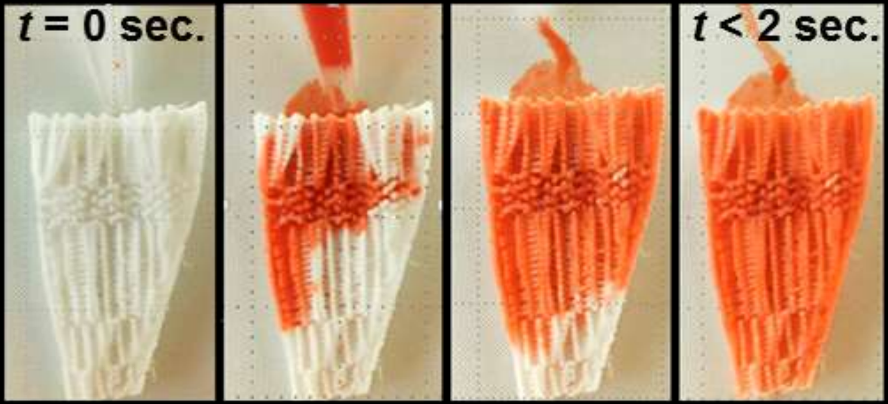
Objects can be handled immediately

No high-temperature processing required

Other advantages

3D-P "HB"

- absorbent
- room-temp printed from liquid ink
- 90 % HA
- hyperelastic
- ~50% porous

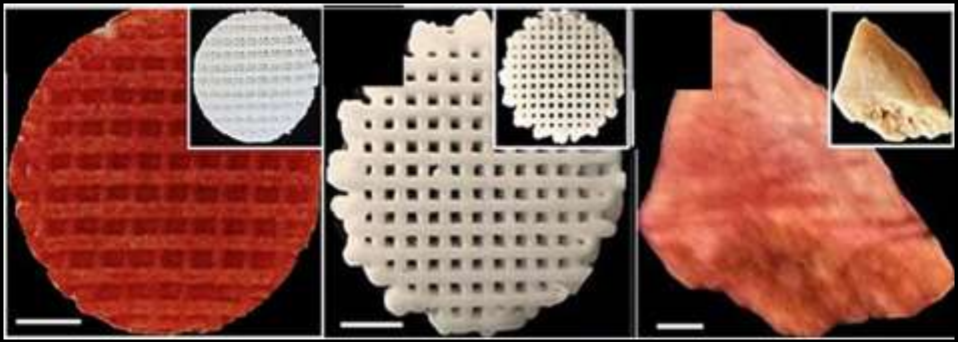


Standard 3D-P HA

- hot-melt printed from powder
- 50% HA
- brittle
- fully dense

Alizarin Red Stain → RED = Exposed Calcium (i.e. Hydroxyapatite)

HB **Hot-Melt** **Allograft Bone**

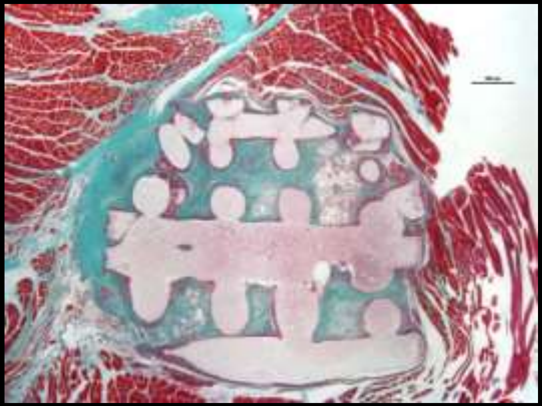


Hydroxyapatite dominates "HB" surface chemistry

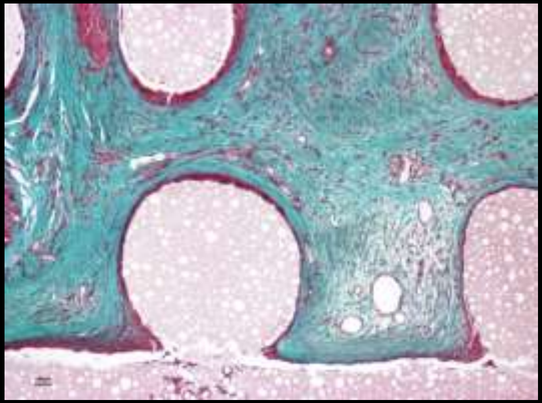
Hyperelastic "bone": A highly versatile, growth factor–free, osteoregenerative, scalable, and surgically friendly biomaterial

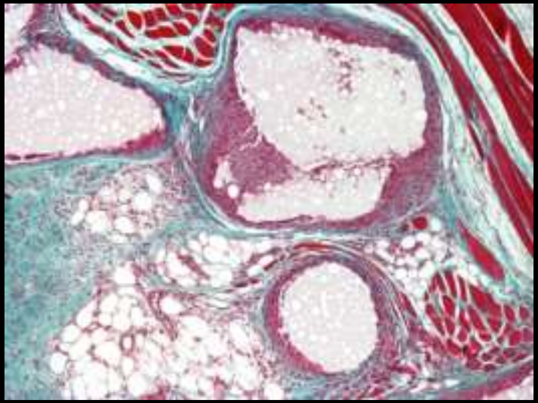
Adam E. Jakus,[1,2] Alexandra L. Rutz,[2,3] Sumanas W. Jordan,[4] Abhishek Kannan,[5] Sean M. Mitchell,[5] Chawon Yun,[5] Katie D. Koube,[1,2] Sung C. Yoo,[1,2] Herbert E. Whiteley,[6] Claus-Peter Richter,[7] Robert D. Galiano,[4] Wellington K. Hsu,[2,5] Stuart R. Stock,[8] Erin L. Hsu,[2,5] Ramille N. Shah[1,2,3,9,*]

2x



10x





Green = mineralized matrix

Red = non-mineralized collagen/cytoplasm

Demineralized Bone Matrix

What is it?

Acid extraction of mineralized phase of bone

Growth factors – *Urist MR 1965 Science*

Collagenous and non-collagenous proteins

Graft Properties

Osteoconductive

Osteoinductive

Advantages

Ease of Use and readily available

High Safety Factor

Disadvantages

Processing variability

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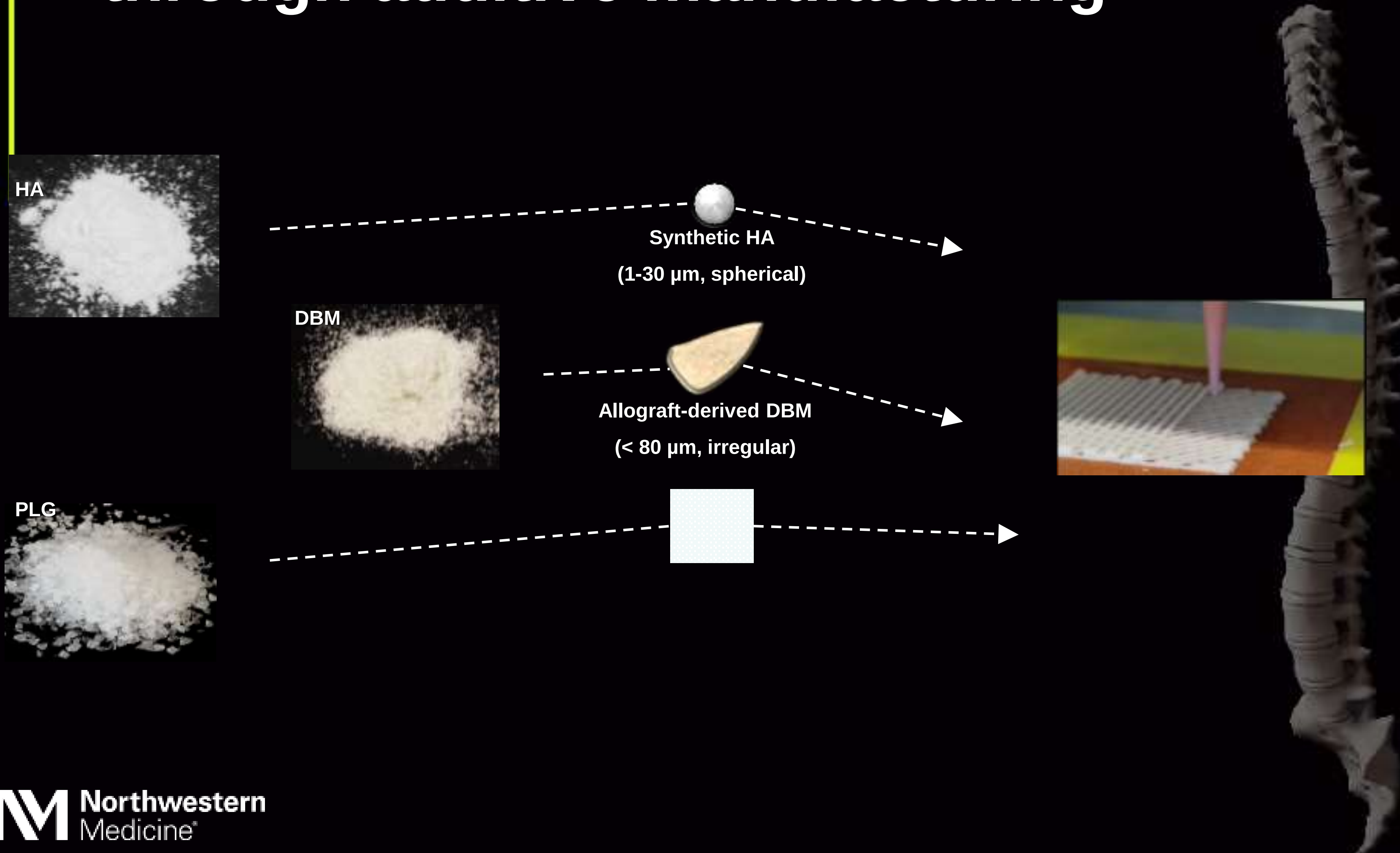
Combination biologic therapy through additive manufacturing



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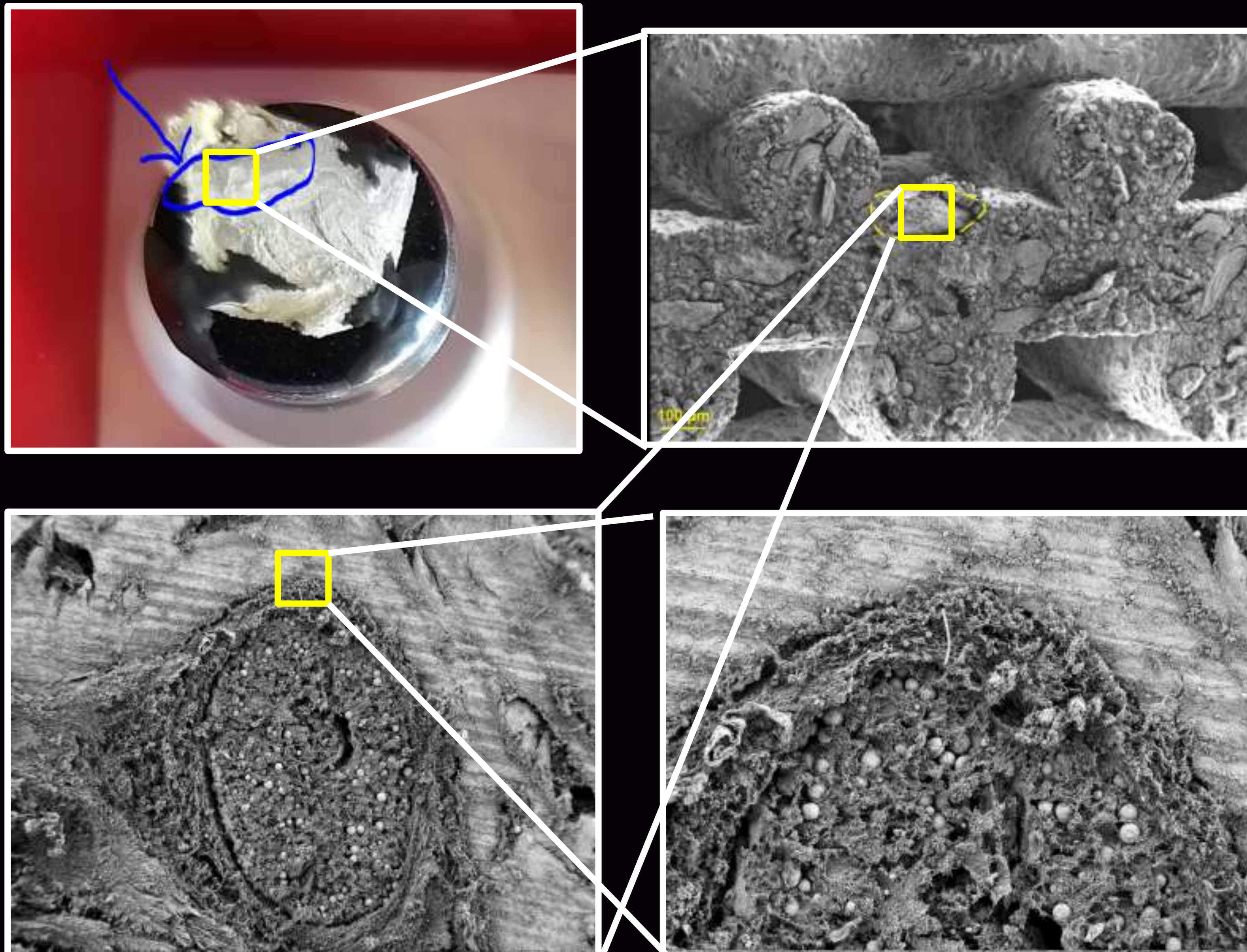

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3D-Printed Ceramic-Demineralized Bone Matrix Hyperelastic Bone Composite Scaffolds for Spinal Fusion

J. Adam Driscoll, MD,[1,2,*] Ryan Lubbe, MD,[1,2,*] Adam E. Jakus, PhD,[2–4] Kevin Chang, BS,[1,2] Meraaj Haleem, BA,[1,2] Chawon Yun, PhD,[1,2] Gurmit Singh, BS,[1,2] Andrew D. Schneider, MD,[1,2] Karina M. Katchko, MD,[1,2] Carmen Soriano, PhD,[5] Michael Newton, MS,[6] Tristan Maerz, PhD,[6,7] Xin Li, PhD, MD,[2] Kevin Baker, PhD,[6,8] Wellington K. Hsu, MD,[1,2] Ramille N. Shah, PhD,[2–4,6,9] Stuart R. Stock, PhD,[2,10] and Erin L. Hsu, PhD[1,2]

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termis.
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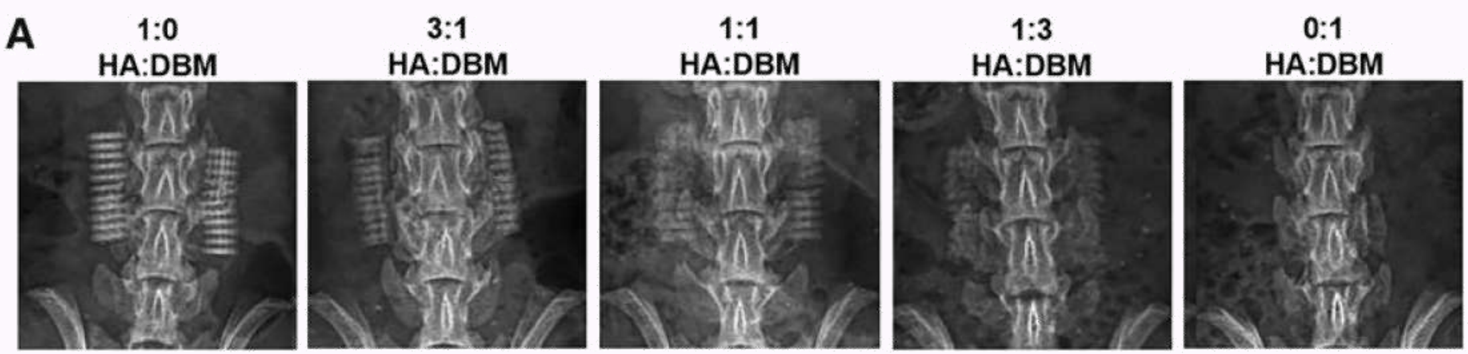

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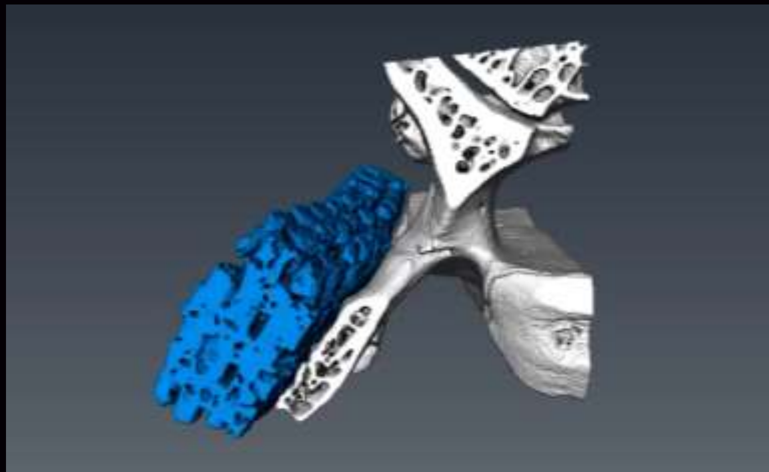

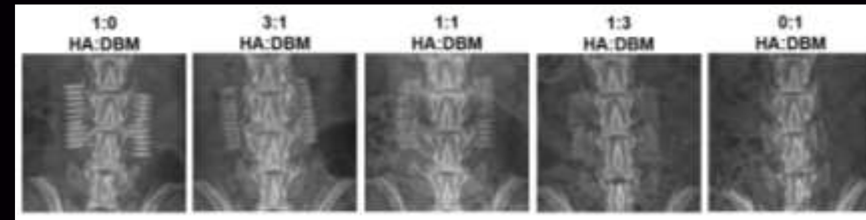

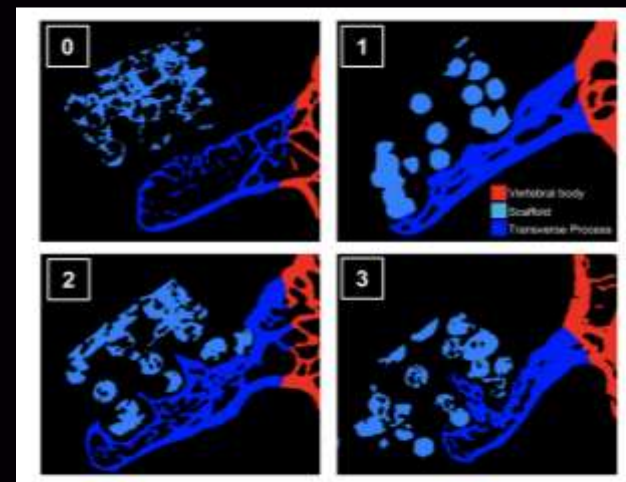

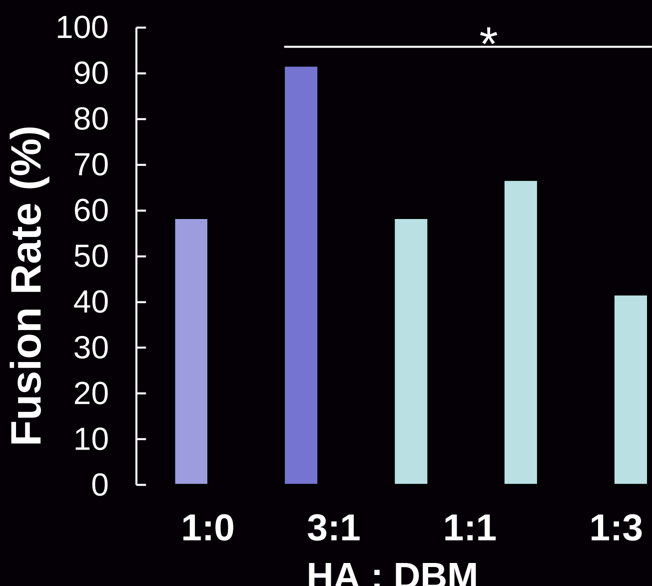

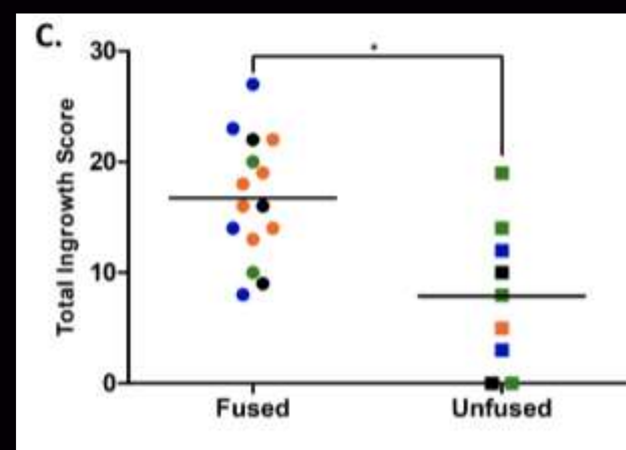

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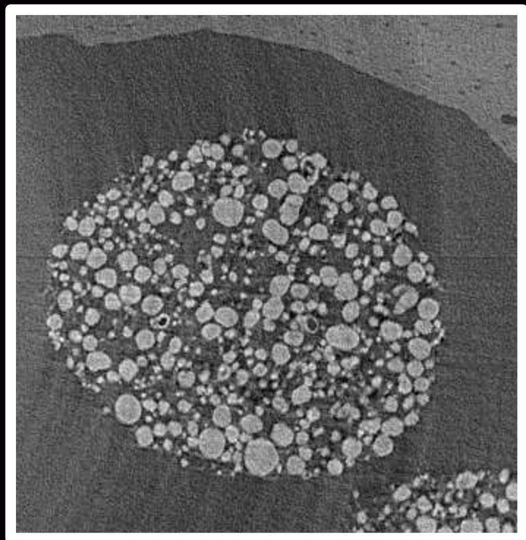
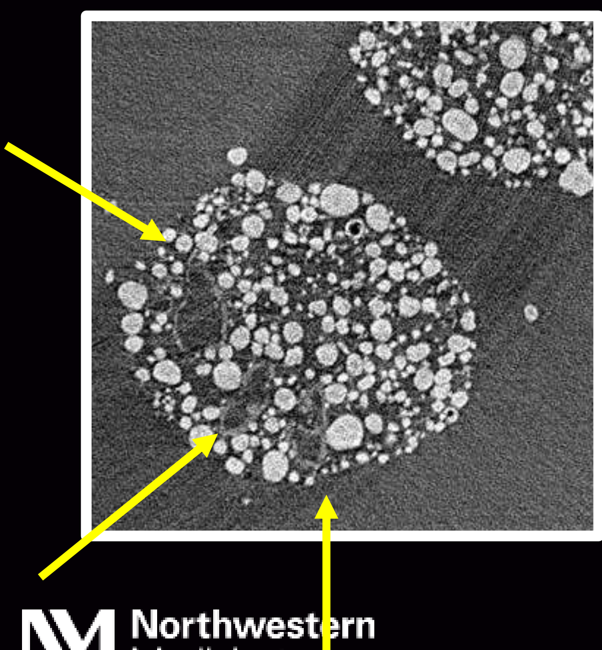
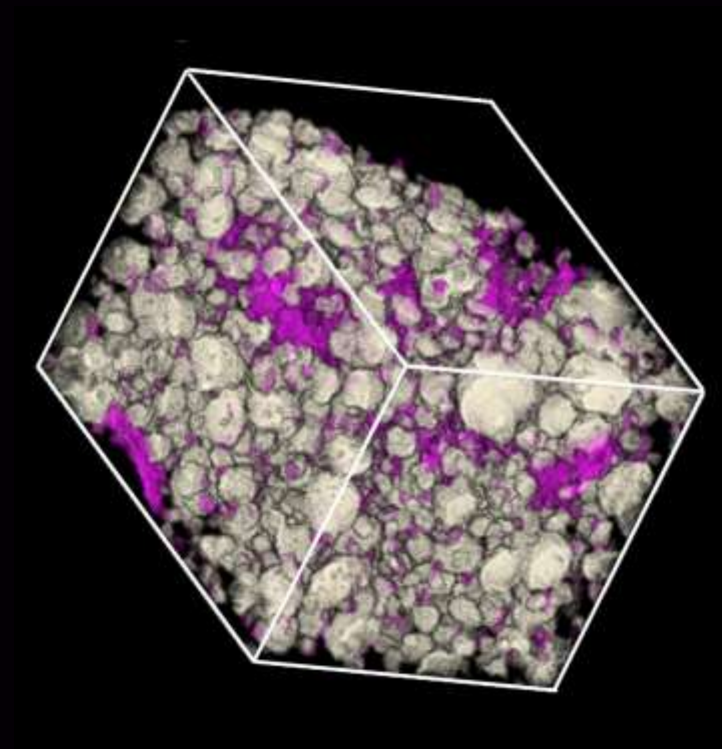
Synchrotron MicroComputed Tomography



100% HA



3:1 HA:DBM



White = HA

Magenta = Bone Spicule

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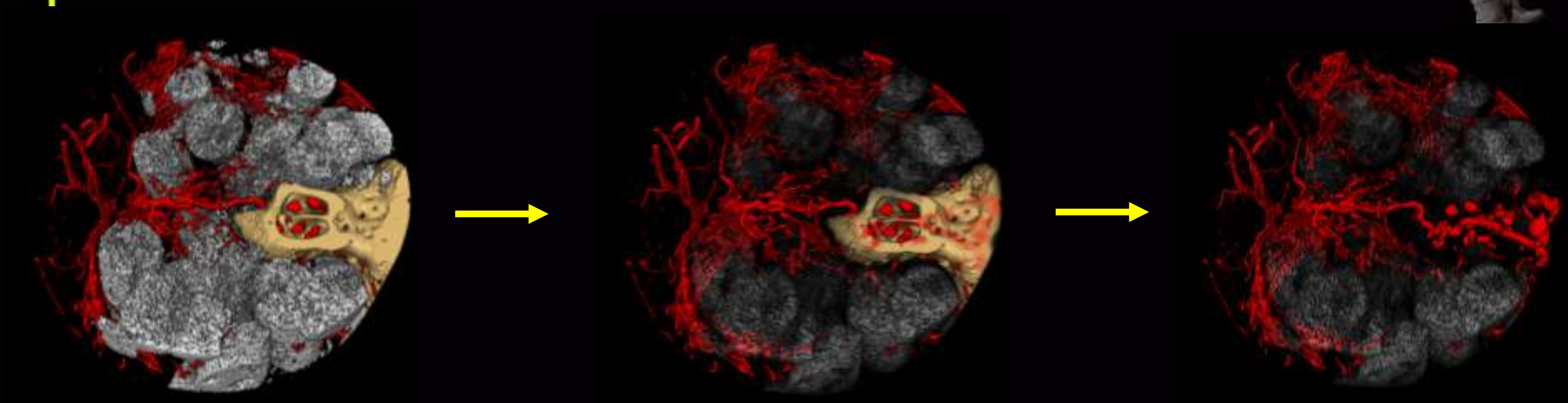
Influence of Geometry and Architecture on the *In Vivo* Success of 3D-Printed Scaffolds for Spinal Fusion

termis
Tissue Engineering & Regenerative Medicine International Society

Mitchell Hallman, MD[1,2] J. Adam Driscoll, MD,[1,2] Ryan Lubbe, MD,[1,2] Soyeon Jeong, MS,[1,2] Kevin Chang, MD,[1,2] Meraaj Haleem, MD,[1,2] Adam Jakus, PhD,[2–4] Richard Pahapill, BS,[1,2] Chawon Yun, PhD[1,2] Ramille Shah, PhD,[2–4,5,6] Wellington K. Hsu, MD,[1,2] Stuart R. Stock, PhD,[2,7,8] and Erin L. Hsu, PhD[1,2]



HA-DBM leads to abundant vascularization within the macropores

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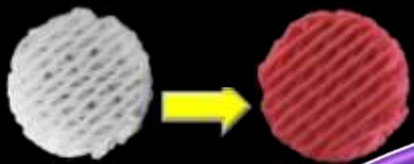
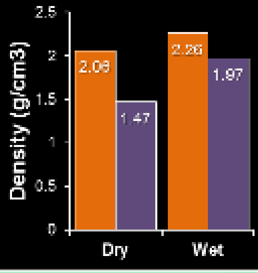
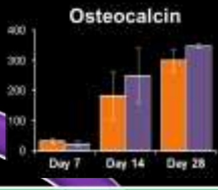
HYPERELASTIC BONE: A PROMISING NEW BIOMATERIAL







Processed at biological temps.

Porous structure and material

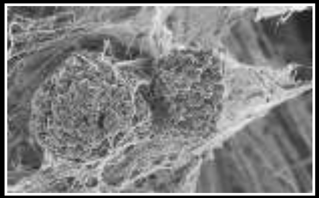
HAp exposed to surface: Bioactive

Hyperelastic Bone

Promotes osteogenesis

Biodegradable

Mechanically robust



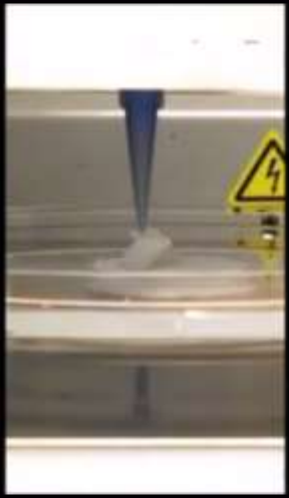
Economical

Scalable

Tailorable

Step 1…

- The future of spinal biologics may be synthetic, improving
  - processing methods
  - biomaterials
  - biodegradability
  - handling characteristics



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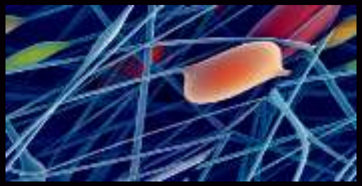
The Best of Both Worlds...

Biologics

Bony Fusion

Long-term stability

Needs rigidity



Instrumentation

Rigidity

Short-term stability

Needs bony fusion

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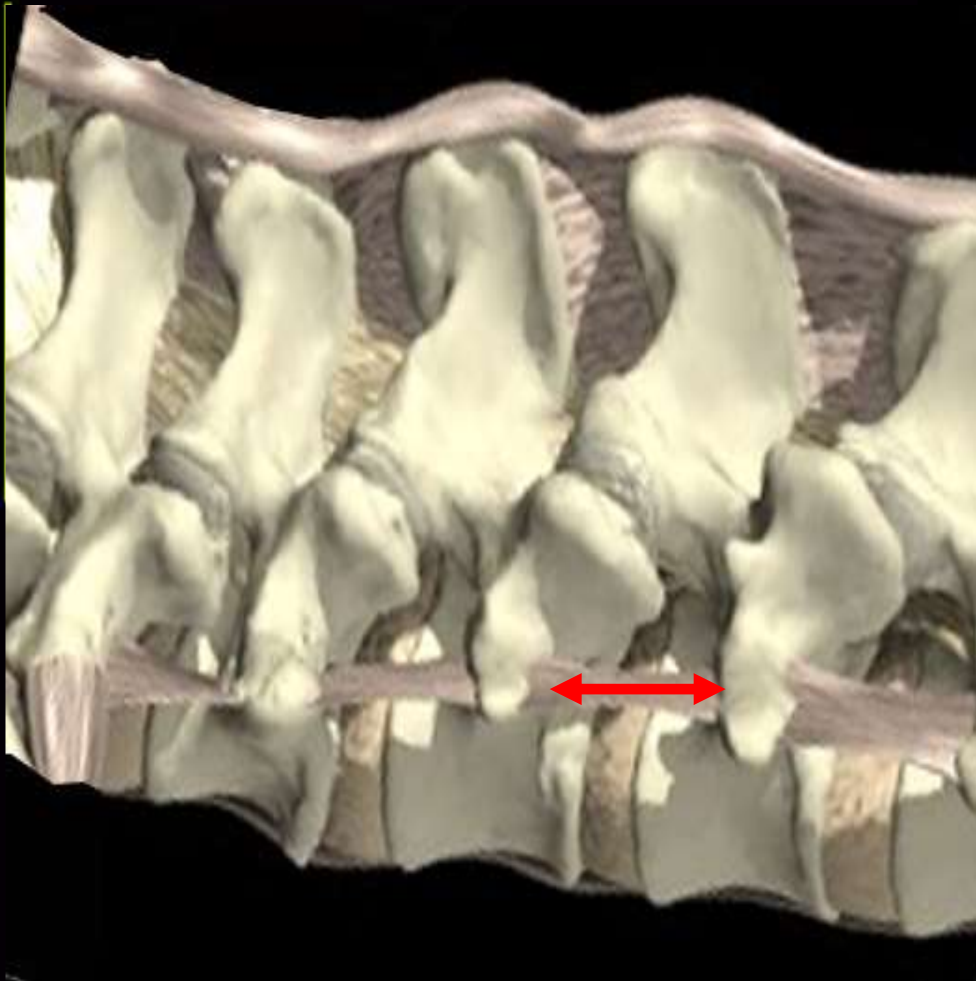

Long length

Under tension

No barriers

Contained space

Under compression

Defined borders

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Principles of Interbody Fusion

- Optimize compression
- Surface area, surface area, surface area
  - – Total discectomy
  - – Endplate preparation
  - – Filling the space
  - – Wide cage

1970

1980

1995

2000

2005

2010

2013

Variety of applications

ALIF

TLIF

LIF

ACDF

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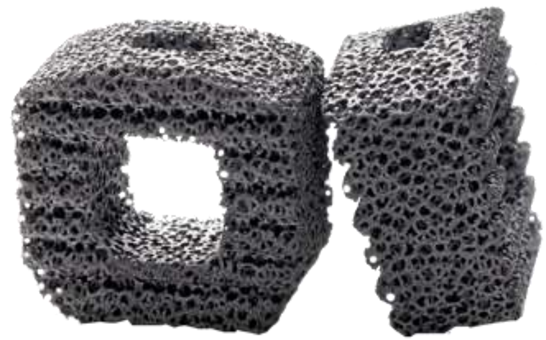
Principles of cage design

- Spacer/height restoration
- Stiffness
- Assessment of fusion
- Bony ingrowth
- Immediate stability
- Smooth edges for entry
- Accommodation of bone graft
- Restoration of lordosis

The Cage

- Radiolucent
- Young’s Modulus
- Durable

- No bony ingrowth



- Bony integration
- Surface friction

- Subsidence
- Radiopaque
- Sharp surface edges

- Delamination of surface

Basic Science

Does impaction of titanium-coated interbody fusion cages into the disc space cause wear debris or delamination?

Annette Kienle, MD[a,*], Nicolas Graf, Dipl-Ing (FH)[a], Hans-Joachim Wilke, PhD[b]
[a]SpineServ GmbH & Co. KG, Soeflinger Strasse 100, Ulm D-89077, Germany
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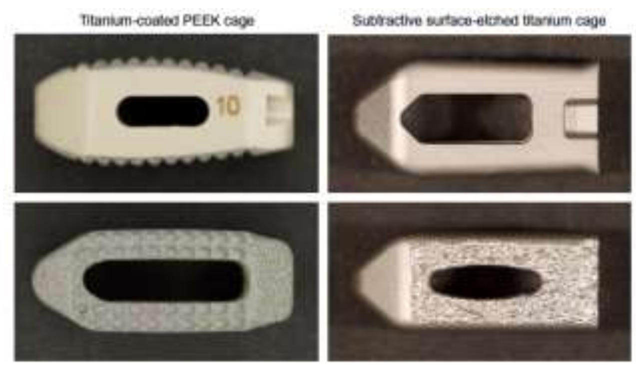
Received 11 June 2015; accepted 15 September 2015

- Test whether impaction of titanium-coated PEEK can result in delamination coating
- Compare to Titanium cages
- Vertebral body substitutes



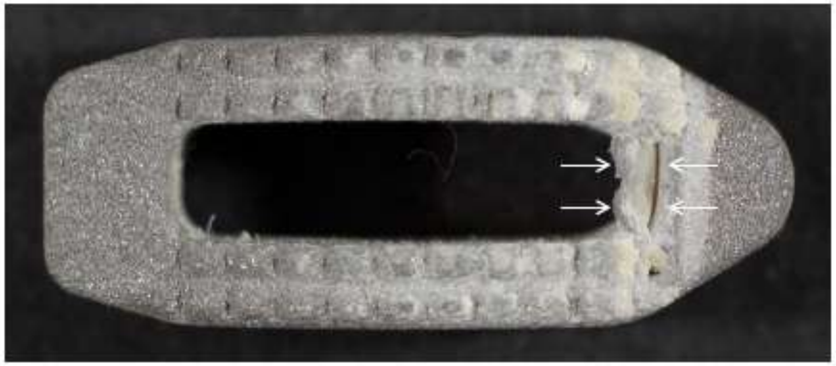
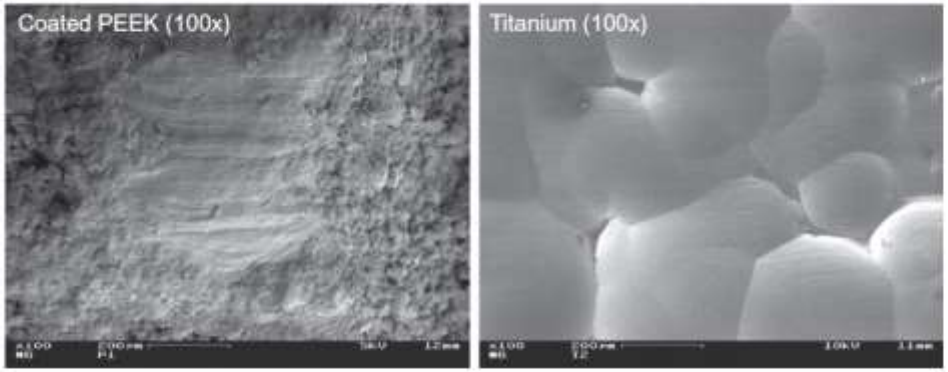
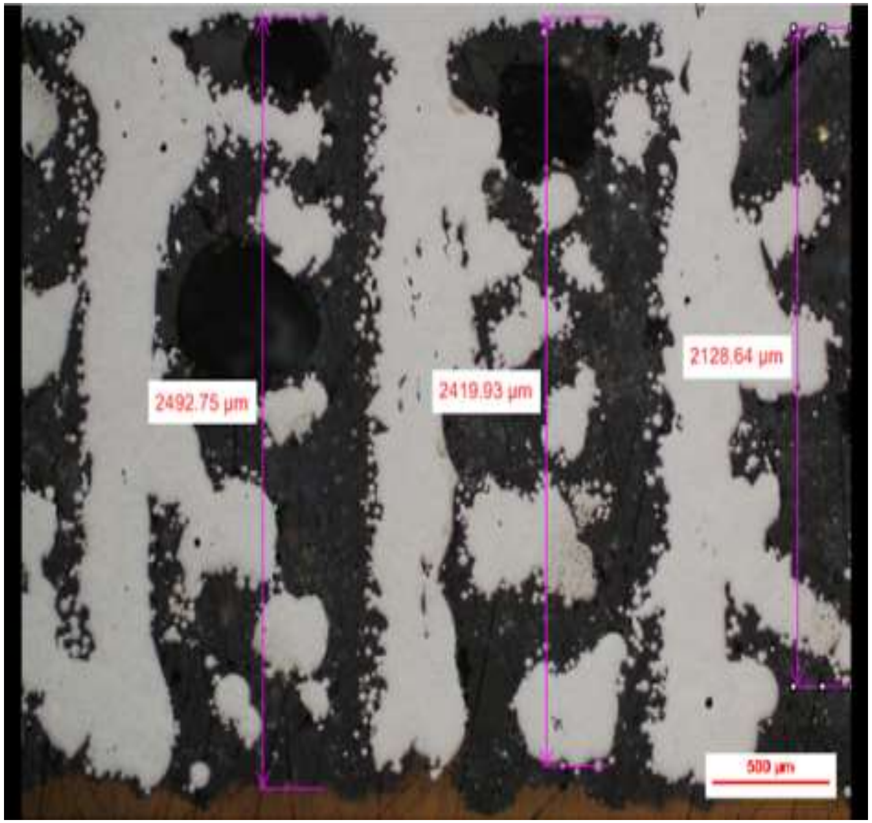
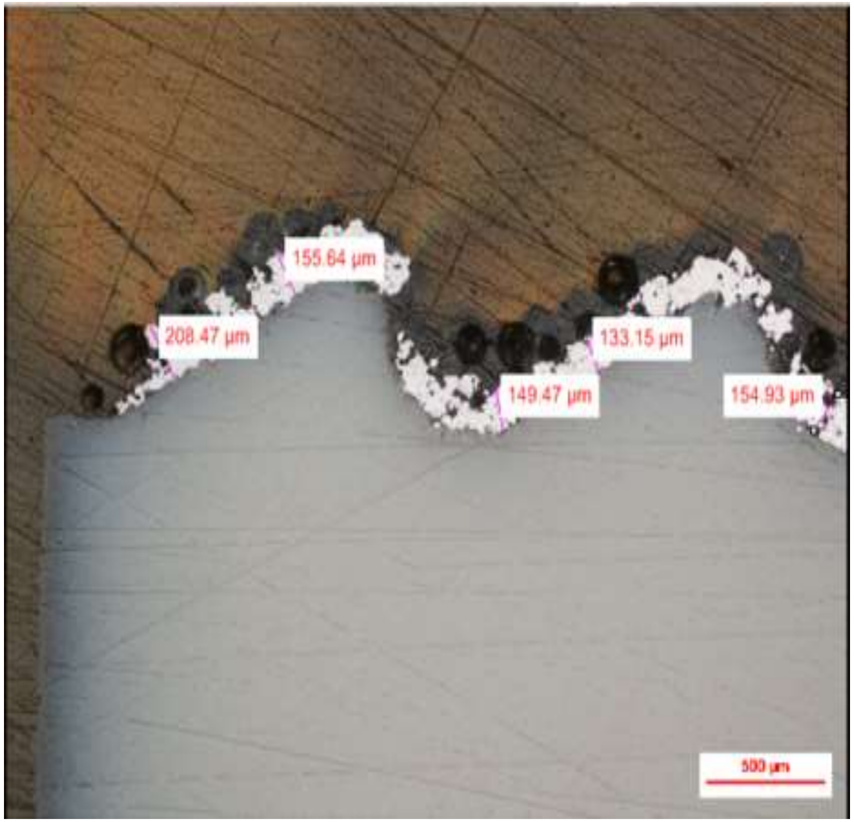


Fig. 7. One of the cages showed a cracking through the PEEK material at its anterior inner edge (arrows).





Tritanium Foam Thickness



Ti Plasma-Sprayed Coating Thickness on PEEK Implant

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| “titanium” and “bone healing”

DO HUMAN OSTEOBLASTS GROW INTO OPEN-POROUS TITANIUM?

U.Müller[1]*, T. Imwinkelried[2], M. Horst[3], M.Sievers[4] and U. Graf-Hausner[1]

[1] Institute of Chemistry and Biotechnology, University of Applied Science Winterthur, Switzerland
[2] Synthes, Oberdorf, Switzerland,
[3] Felmisweidstr. 2, 6048 Horw, Switzerland, and
[4]University of Applied Science Wädenswil, Switzerland

Titanium foam

↑ Col-1, alk phos, OC

Osteoblasts form trabecular bone bridge in titanium

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

Rene Olivares-Navarrete, DDS, PhD[a], Rolando A. Gittens, MS[b], Jennifer M. Schneider, MS[c], Sharon L. Hyzy, BS[a,d], David A. Haithcock, BS[a], Peter F. Ullrich, MD[e], Zvi Schwartz, DMD, PhD[a,f], and Barbara D. Boyan, PhD[a,*]

MG63 cells on PEEK, Ti

Titanium ↑ osteoblast maturation, ↑BMP prod

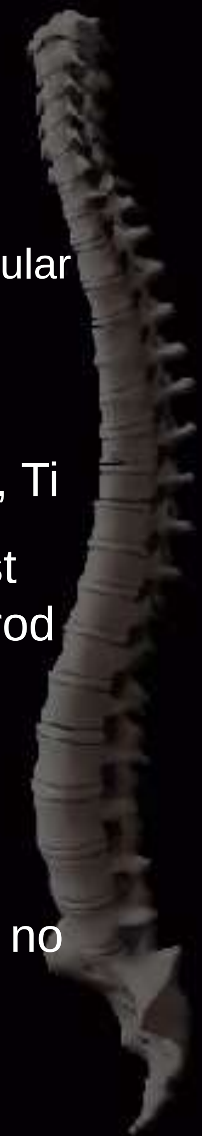
A novel synthetic material for spinal fusion: a prospective clinical trial of porous bioactive titanium metal for lumbar interbody fusion

Shunsuke Fujibayashi · Mitsuru Takemoto · Masashi Neo · Tomiharu Matsushita · Tadashi Kokubo · Kenji Doi · Tatsuya Ito · Akira Shimizu · Takashi Nakamura

Interbody – porous titanium

5 patient clinical trial, no BG

100% fusion rate



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Problems of Previous Metal Cages

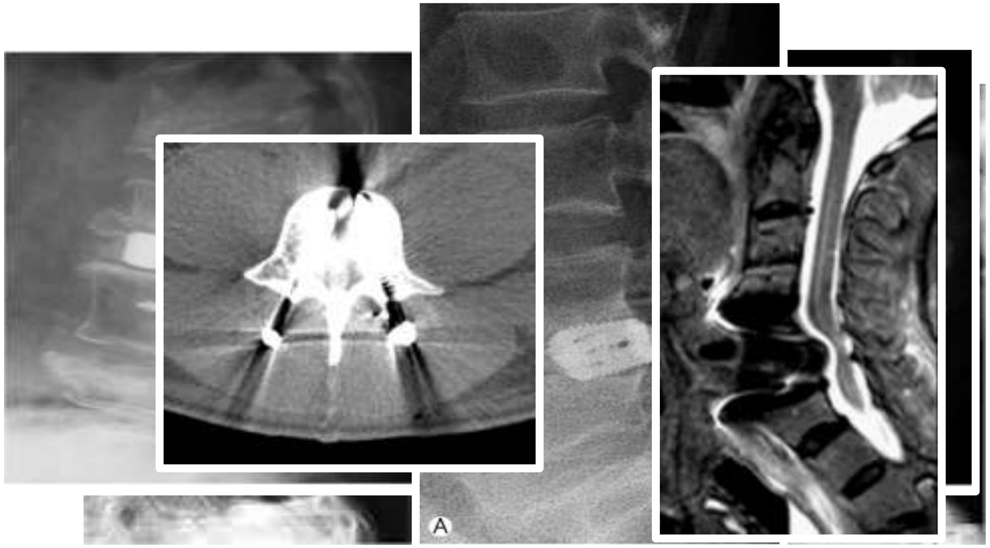
Radiographic footprint

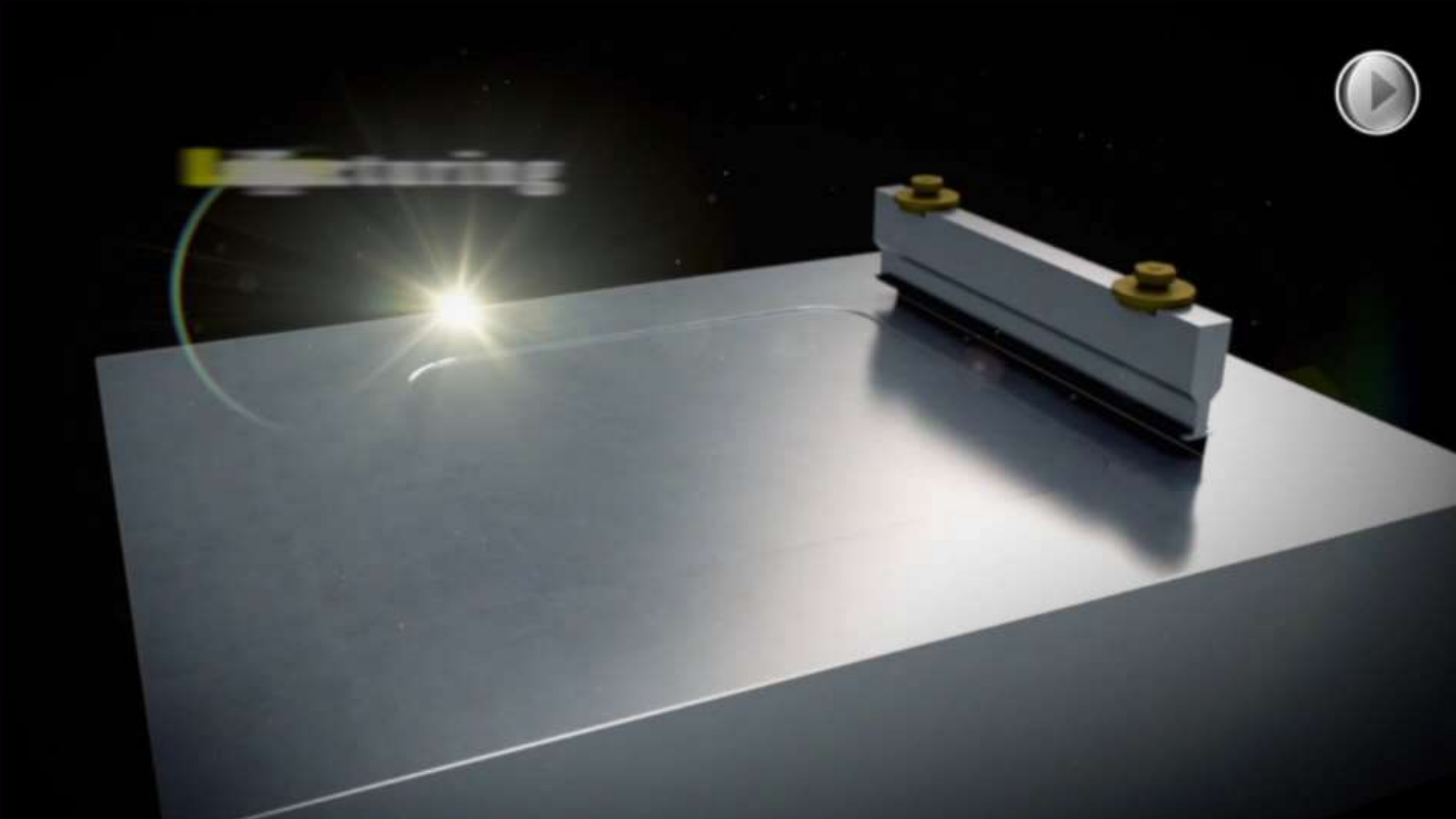
Cage Design

Subsidence

Migration

Imaging artifact



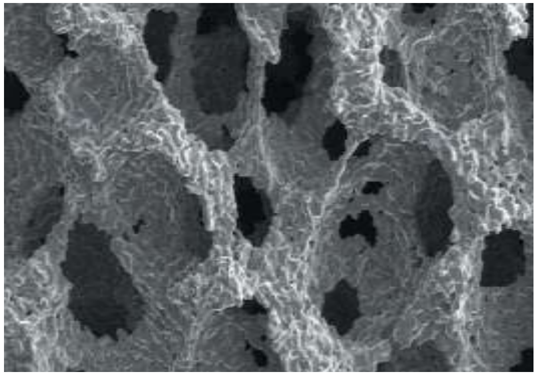


Tritanium Technology

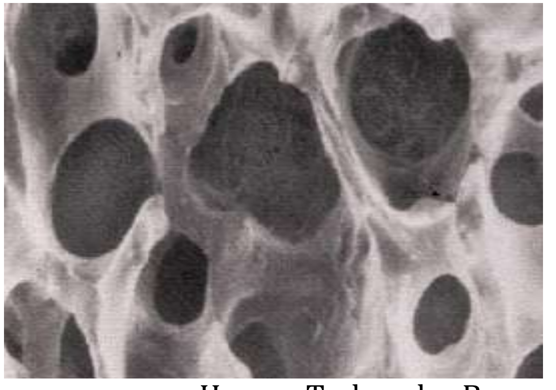
Tritanium = 3-Dimensional CP Ti or Ti Alloy

- Proprietary highly porous material designed for biological fixation

- **Tritanium closely resembles the structure of trabecular bone**
  - Pore size
  - Amount of porosity
  - Interconnectivity of pores



Tritanium Technology



Human Trabecular Bone

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Tritanium Pre-clinical Study

Bony Ingrowth

Stiffness

Subsidence

Expulsion

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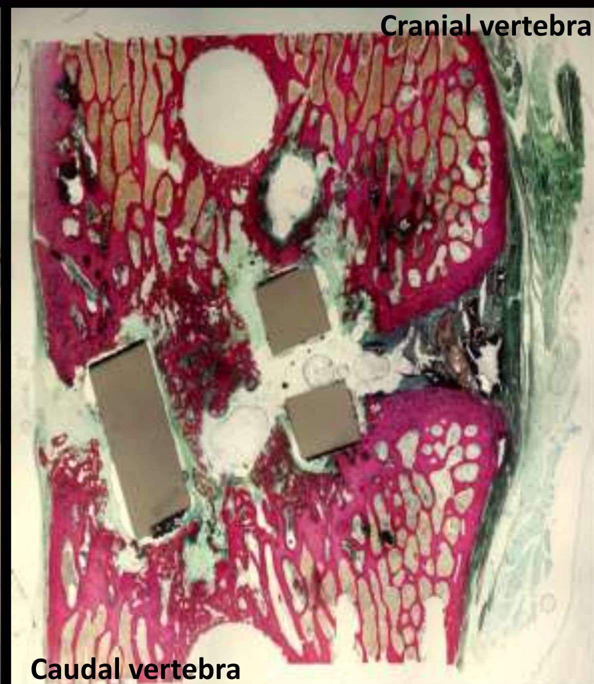
Tritanium Pre-clinical Study

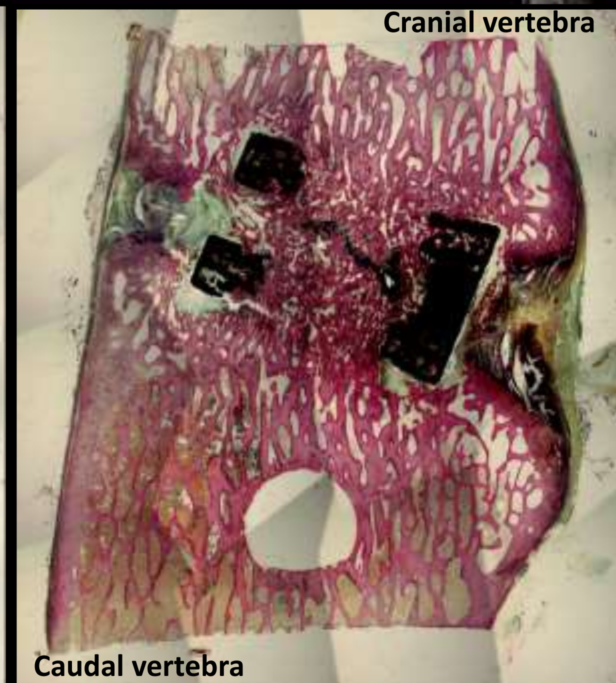
Bony Ingrowth | *Stiffness* | *Subsidence* | *Expulsion*

Sagittal View

PEEK Cage



Ti Plasma Sprayed PEEK Cage



Tritanium PL Cage

8 weeks post-op in an ovine model

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Tritanium Pre-clinical Study

Bony Ingrowth | *Stiffness* | *Subsidence* | *Expulsion*

Sagittal View

PEEK Cage

Ti Plasma Sprayed PEEK Cage

Tritanium PL Cage

16 weeks post-op in an ovine model

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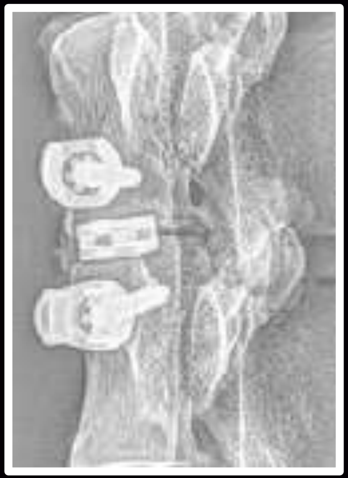
PEEK

Titanium



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The Power of Biomaterials…

- Increasing use of standalone cages

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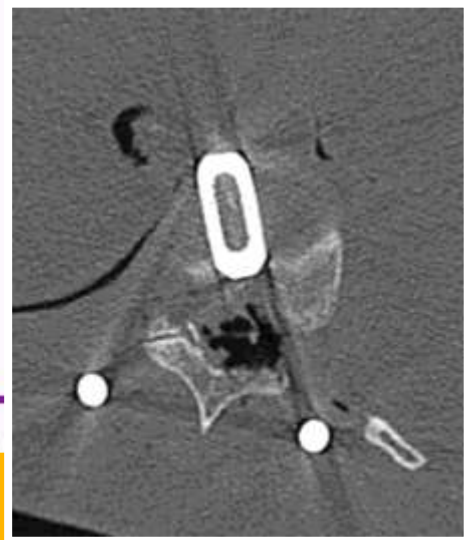
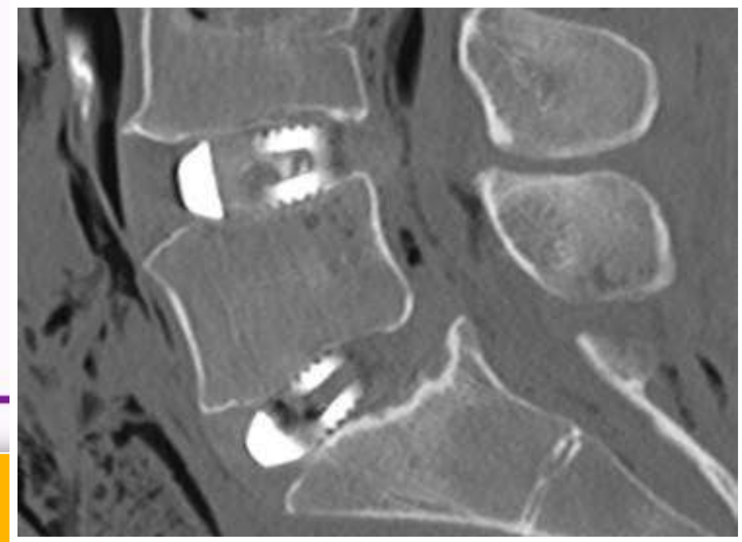
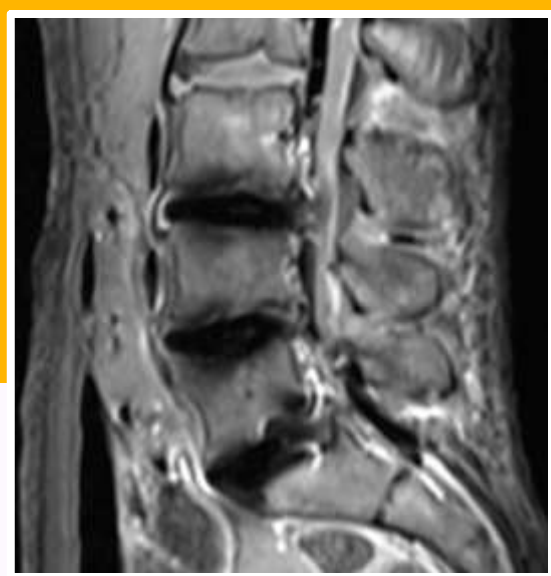
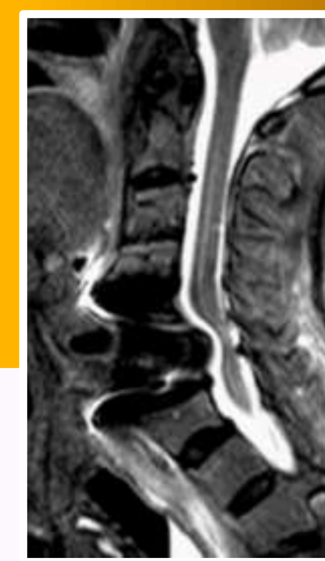



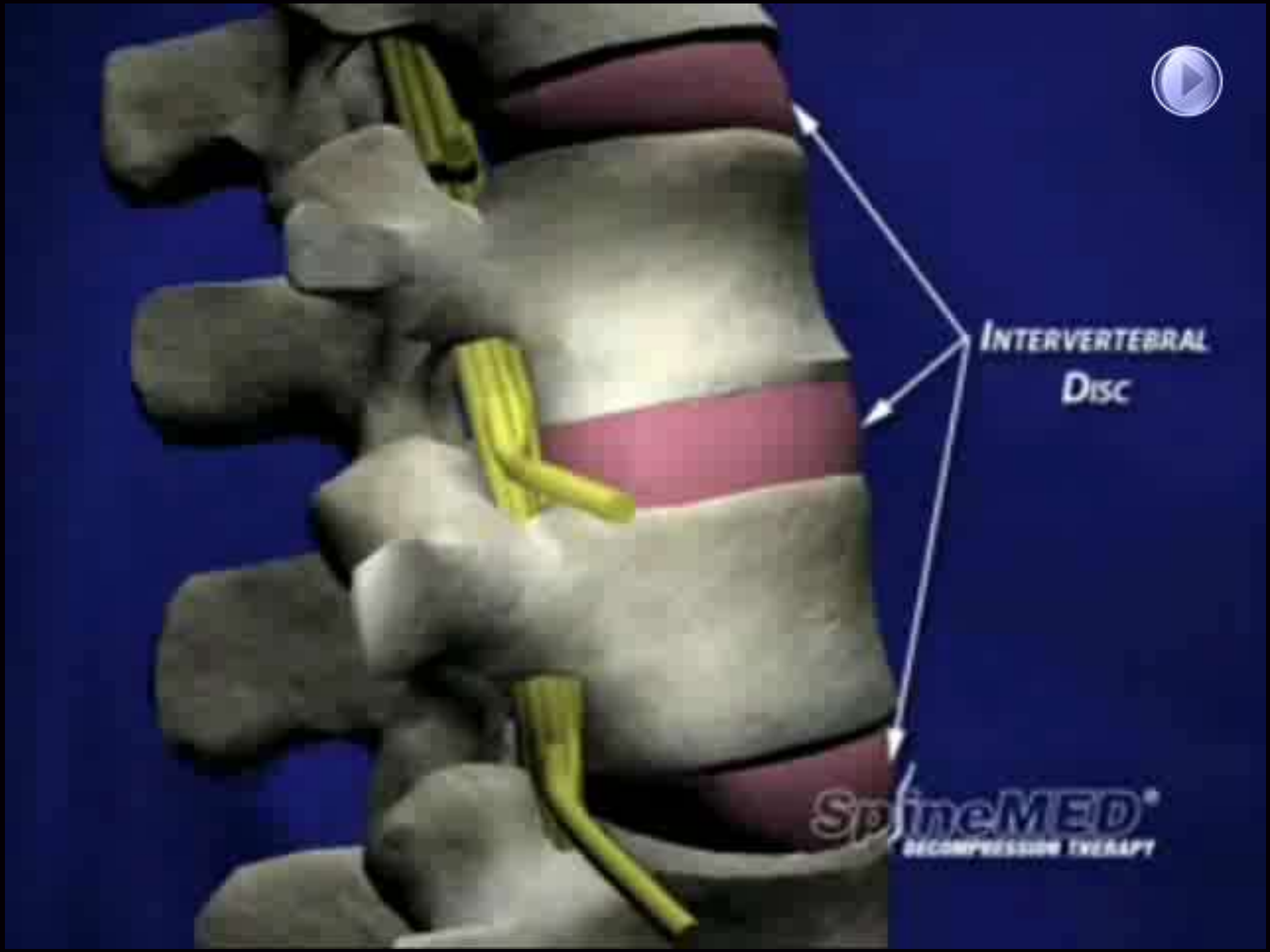



The Power of Biomaterials…

- Increasing use of standalone cages
- Can we improve biologic delivery to obviate the need for instrumentation?
  - Bone graft substitute inside the disc space
  - Surface area, surface area, surface area
- Cost-effectiveness

Northwestern Medicine

Degenerative Disc Disease



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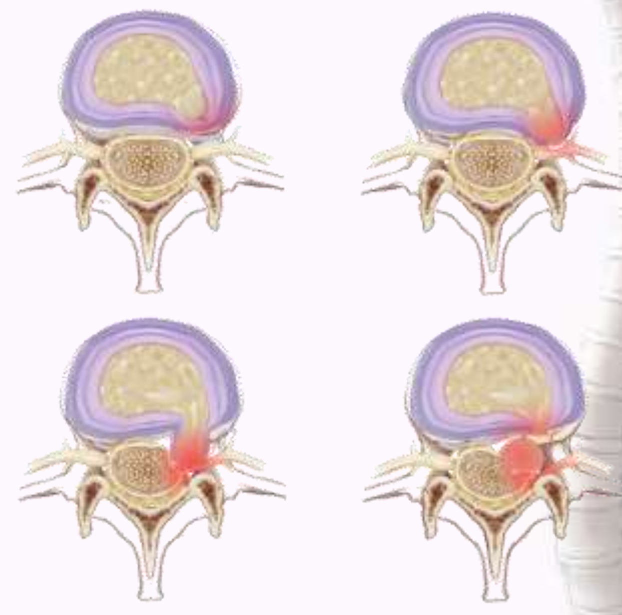
Prevalence of DDD

- MRI - Overly sensitive
  - 98% had DDD > 60 yr.
  - False positive imaging in up to 25%
  - Bulging discs
    - Increases with age
    - Only 36% 20-80 yr. had normal discs at all levels

Bulging *Protrusion*



Extrusion *Sequestered*

Jensen et al., *NEJM 331*, 1994.

Patient Outcomes After Lumbar Spinal Fusions

Judith A. Turner, PhD; Mary Ersek, RN, PhD; Larry Herron, MD; Jodie Haselkorn, MD, MPH; Daniel Kent, MD; Marcia A. Ciol, PhD; Richard Deyo, MD, MPH

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Spinal-Fusion Surgery — The Case for Restraint

Richard A. Deyo, M.D., M.P.H., Alf Nachemson, M.D., Ph.D., and Sohail K. Mirza, M.D.

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Rate of Spine Surgery Soars

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By JILIAN MINCER

A condition known as spina
for lower back pain, and the

Some orthopedic doctors ar
needs to be as some surge
fuse vertebrae. The more co
with more than one spinal d
chances of complications, including stroke and death, recent research shows.

"It has not been shown that the more complex surgery is better [for patients with simple stenosis], but people are willing to have it done," says Eugene J. Caragee, an orthopedic surgeon at Stanford University School of Medicine, who has written on the topic in medical journals. "The marketing is relentless," he says.

Painful Condition

Spinal stenosis is when bone spurs grow into the spinal canal, crowding nerves and causing pain.

Healthy vertebra (view from above)

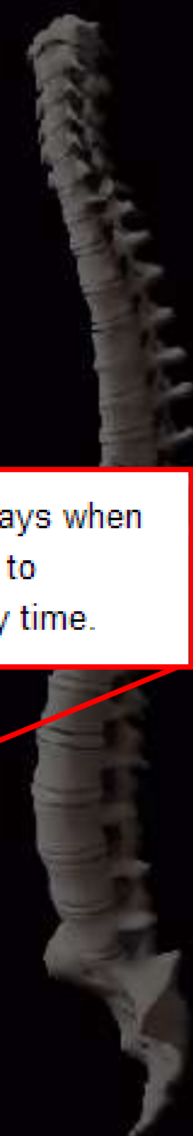
Vertebra with spinal stenosis

Disc

Nerve

Spinal stenosis occurs when bone spurs and other deposits cause the spinal canal to narrow, putting pressure on the spinal cord. Patients may experience pain or numbness in the back, legs and buttocks, and

Wellington Hsu, a professor at Northwestern University Feinberg School of Medicine, says when patients have stenosis that is limited to a small area of the spine, doctors may be able to perform less invasive surgery that uses a smaller incision and leads to a faster recovery time.



SPINE Volume 36, Number 4, pp 320–331

Spine

EPIDEMIOLOGY

Long-term Outcomes of Lumbar Fusion Among Workers' Compensation Subjects

A Historical Cohort Study

Trang H. Nguyen, MD, PhD,* David C. Randolph, MD, MPH,* James Talmage, MD,† Paul Succop, PhD,* and Russell Travis, MD‡

- Lumbar fusion in WC patients led to increased disability, increased opiate use, poor outcomes compared to preop
- Diagnosis: Degenerative Disc Disease

Study Design. Hi[illegible]

Objective. To de[illegible] (RTW), permanent [illegible] utilization, and reoperation status for chronic low back pain subjects with lumbar fusion. Similarly, RTW status, permanent disability, and opiate utilization were also measured for nonsurgical controls.

Summary of Background Data. A historical cohort study of workers' compensation (WC) subjects with lumbar arthrodesis and randomly selected controls to evaluate multiple objective outcomes has not been previously [illegible]

Methods. [illegible] subjects with chronic low back pain diagnoses with dates of injury between January 1, 1999 and December 31, 2001. [illegible] usage, and deaths were also determined.

Results. Two years after fusion surgery, 26% (n = 188) of fusion cases [illegible] reoperation rate was 27% (n = 194) for surgical patients. Of the lumbar fusion subjects, 36% (n = 264) had complications. Permanent disability rates were 11% (n = 82) for cases and 2% [illegible] surgery. Total number of days off work was more prolonged for cases compared to controls, 1140 and 316 days, respectively ($P < 0.001$). Final multivariate, logistic regression analysis indicated the number of days off before surgery odds ratio [OR], 0.94 (95% confidence interval [CI], 0.92–0.97); legal representation OR, 3.43 (95% CI, [illegible] predictors of RTW for lumbar fusion patients.

Conclusion. This Lumbar fusion for the diagnoses of disc degeneration, disc [illegible]

Key words: lumbar arthrodesis, workers' compensation, return to work, disability, opioids. **Spine 2011;36:320–331**

From the [illegible] Department of Environmental Health, University of Cincinnati College of Medicine, Milford, OH; †Meharry Medical College, Nashville, TN; and ‡Department of Physical Medicine and Rehabilitation, University of Kentucky College of Medicine, Lexington, KY.

Acknowledgment date: July 1, 2009. Revision date: October 25, 2009. Acceptance date: November 25, 2009.

The manuscript submitted does not contain information about medical device(s)/drug(s).

No funds were received in support of this work. No benefits in any form have been or will be received from a commercial party related directly or indirectly to the subject of this manuscript.

IRB Approval: This study proposal was approved by the Institutional Review Board at the University Of Cincinnati College Of Medicine prior to beginning the study.

Address correspondence and reprint requests to Trang H. Nguyen, MD, Division of Epidemiology and Biostatistics, Department of Environmental Health, University of Cincinnati College of Medicine, 3724 Signal Hill Center, Milford, OH; E-mail: [illegible]

DOI: 10.1097/BRS.0b013e3181ccc220

Lumbar arthrodesis (fusion) is a surgical procedure performed to unite spinal vertebrae to eliminate mobility. There have been few published studies evaluating lumbar fusion outcomes in US workers' compensation subjects.[1–4] [illegible] complications [illegible] were reported in only one study at 3 months after surgery.[1] Permanent or temporary disability results 2 years after fusion are variable among the studies, 18% to 68%.[1,2,4] Similarly, return to work status (RTW) also varied from 41% to 78%.[2,4]

True outcomes are difficult to determine when results are variable. The number of lumbar fusions for degenerative conditions has increased 220% in the United States from 1990.[5] A recent systematic review of randomized clinical trials comparing lumbar fusion to conservative care indicates solid conclusions cannot be reached due to the methodologic limitations and limited data.[6] In 2006, a different systematic review questioned the cost effectiveness of lumbar fusion.[7]

In this study, OH Workers' Compensation data from January 1, 1999 to January 31, 2006 was used to assess the

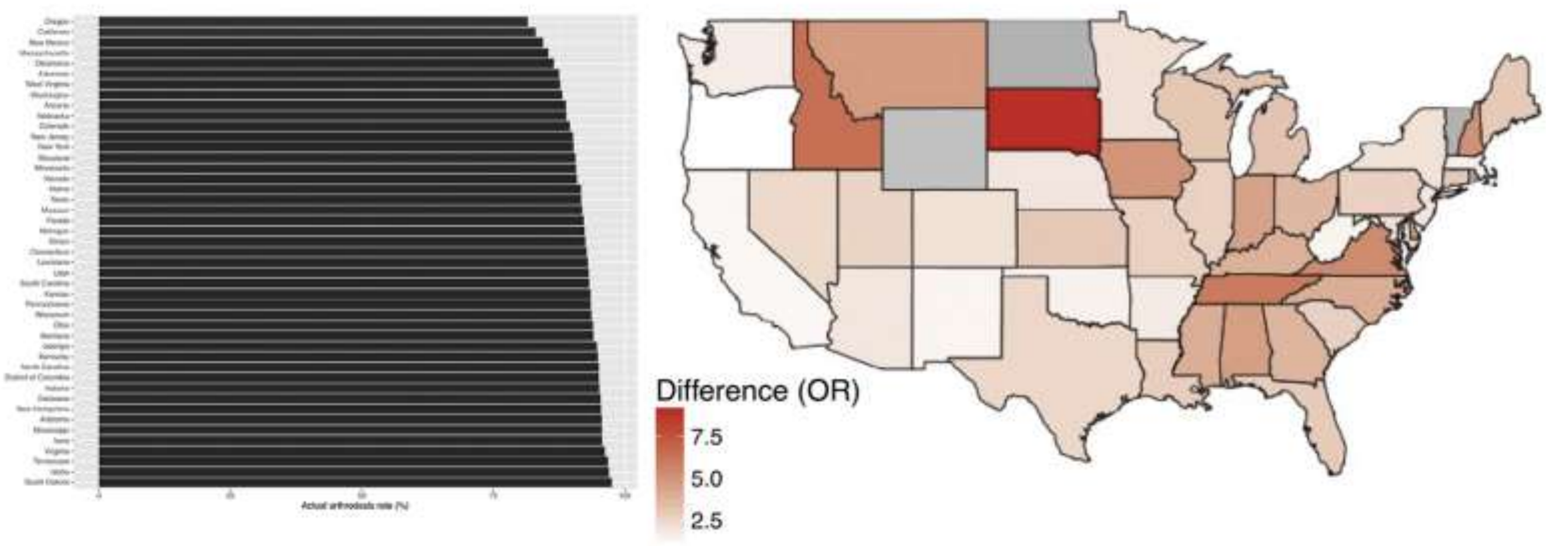


Fig. 1. (Left) Actual arthrodesis rates. (Right) Geographic variation in arthrodesis rates. OR, odds ratio.

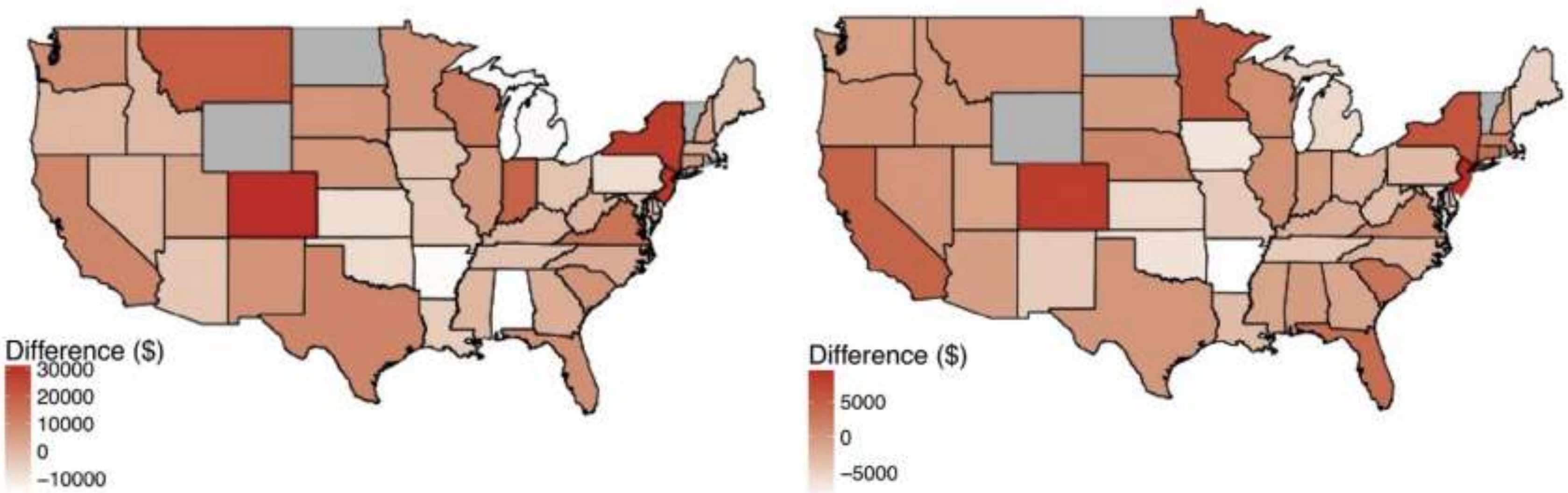
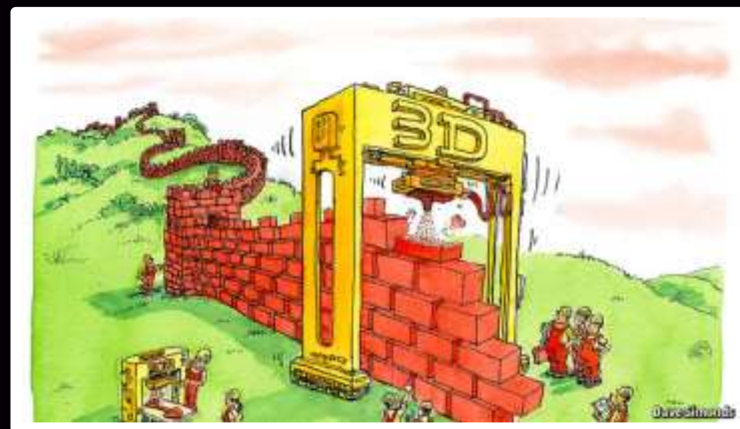


Fig. 2. Geographic variation in (Left) index costs and (Right) 2-year costs.

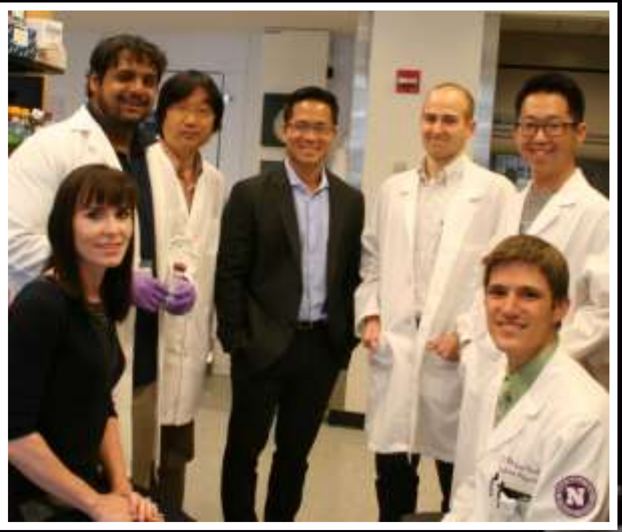
Diagnosis is key…

Success rate	90%	30%

Summary



- 3D printing may represent the new industrial revolution
- Enhances instead of replaces conventional manufacturing
- Spine surgery as a leading target for application



Wellington K. Hsu, MD

Clifford C. Raisbeck Distinguished Professor
Director of Research
Department of Orthopaedic Surgery
Northwestern University Feinberg School of Medicine
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