



Machined vs. 3D Printed Titanium

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OVERALL GOAL

- Subtractive vs. Additive Manufacturing
- Pros & Cons of Manufacturing
- Advantages of AM for medical devices
- The Future

MANUFACTURING & MEDICAL IMPLANTS PAST – PRESENT - FUTURE

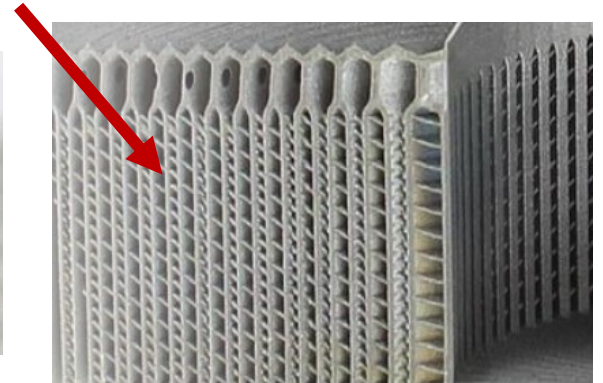
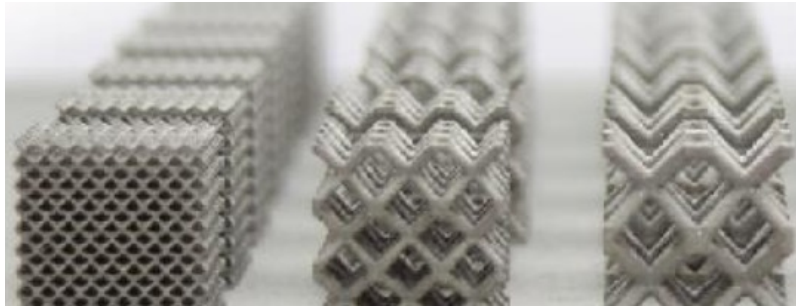
Subtractive Technology

- Machining, grinding, milling
- Lengthy time to production
- Lacks efficiency
- Design, material & equipment limitations
- Material waste
- Difficult to create lightweight components
- Need for multiple machines
- Post-processing increase time & cost
- Mistakes lead to significant cost & time increase
- Lack control of manufacturing (if outsourced)
- Revisions, iterations, new features - increase cost & time to market
- Slower innovation to market
- Cost & time prohibitive for multiple designs



Additive Manufacturing - Innovative Products

- Complex matrices
- Graded structures (dense core to porous surface)
- Open architectures
- Repetitive microstructures
- Lightweight components
- Increased surface area = Increased efficiency for fluid, thermal exchange



Additive Manufacturing – 3D Printing

- CAD 3D model of Design
- Create parasolid files that are then sliced – layered build
- Multiple software packages (Mimics, 3Matic, ProEngineer, Anatomics)
- Layered build process from powder or liquids (Ti, CoCr, Polymer)

3D CAD file



3D CAD File



3D STL File

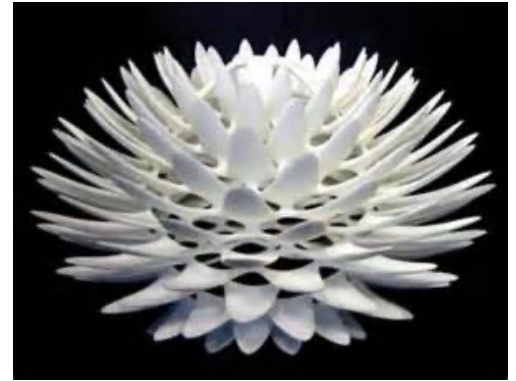


Sliced File



AM: Value Added

- Can build complex structures that are difficult to machine
- Characterized by rough surface quality – improved cellular response
- Designed, controlled, interconnected porosity
- High processing velocity – rapid serial production of implants
- Customize fit to patient anatomy



ADDITIVE MANUFACTURING

- AM is ONLY a mechanism to allow fabrication of open architectures and complex structures
- BUT – it's about the DESIGN, MATERIALS, ENVIRONMENT, BUILD PROCESS, and more.....
- 3D printing serves as a vehicle for manufacturing complex designs

ADDITIVE MANUFACTURING

- Pros
 - Create complex open architectures
 - Rapid process
 - Metals & polymers & Ceramics
 - Customize surfaces, graded densities & porosities
- Cons
 - Speed of build can alter mechanical integrity
 - Tolerances not as tight – must validate each lot
 - Internal voids can form – early failure

Disadvantages of AM

- Must design the build process to achieve design criteria
 - Greater risk of inducing residual stresses into component
- Orient component in build minimize need for supports during build
 - Integrate into design
 - Optimal orientation uses less material during build
- Complex matrices
 - Lack crisp edges or interfaces – good & bad
- Tolerances are not held as tightly as subtractive manufacturing
- Larger ranges in structure dimensions
- Surface structure designs must be considered
 - May generate debris or could break
- Higher risk for contamination to materials (powder)
- Potential for large learning curve

BENEFITS OF ADDITIVE MANUFACTURING FOR MEDICAL DEVICES

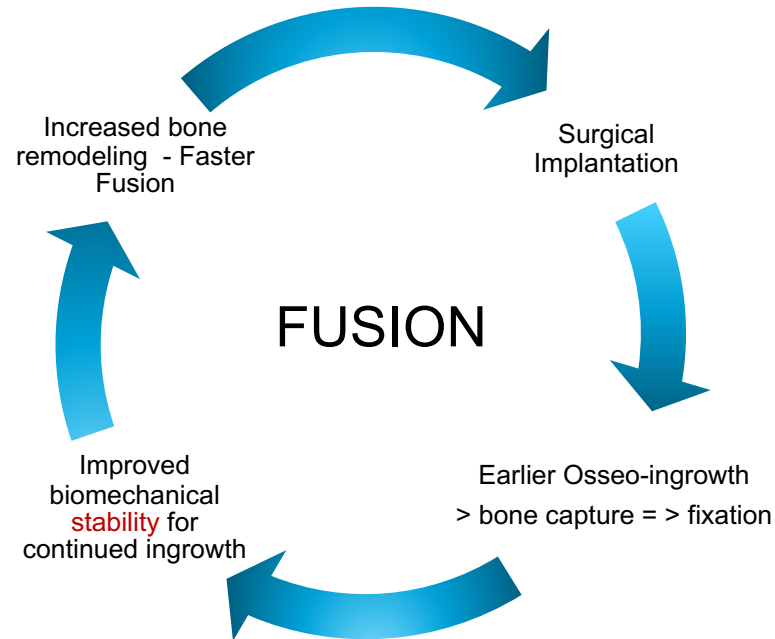
IMPROVE INTERFACE MECHANICS

- Why? - Balance between Time & Stabilization: Fixation α Stability
- Decrease Healing Time = Decrease Failure Risk
- Improved Interface mechanics



BIOMECHANICAL FUSION CASCADE

- Improvement of Bone Interface fixation
- Enhanced Osseointegration – early stabilization
- Early biomechanical stability = faster fusion

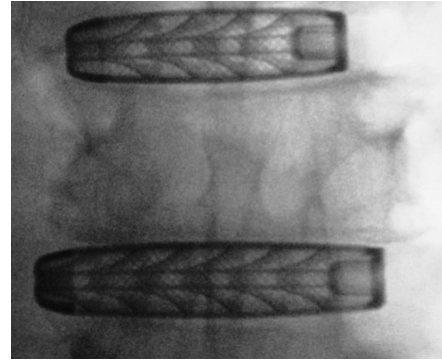


Bone and Implant Interface - Improved Fixation

- Osseointegration
 - Controlled, repeatable, structures
 - Open architectures – bone ingrowth
 - Multiplanar ingrowth = earlier stability
- However conventional manufacturing cannot machine/mold/cast such designs in costly efficient manner

AM - Design Advantages

- Can image through Titanium to view bone
- Lightweight implant (vs. machined) w/ less waste
- Greater area for bone graft
- Increased surface area for bone exchange
- Rough surface = mechanotransduction
- Increased friction = Reduced device migration^{1,2}
- Allows bone ingrowth from multiple points of entry
- Visualization through Ti cage – 'radiolucent'



Radiolucency of Ti-6Al-4V cages. Courtesy of Tsunami Medical Srl.



Courtesy of 4Web Medical & Camber Spine

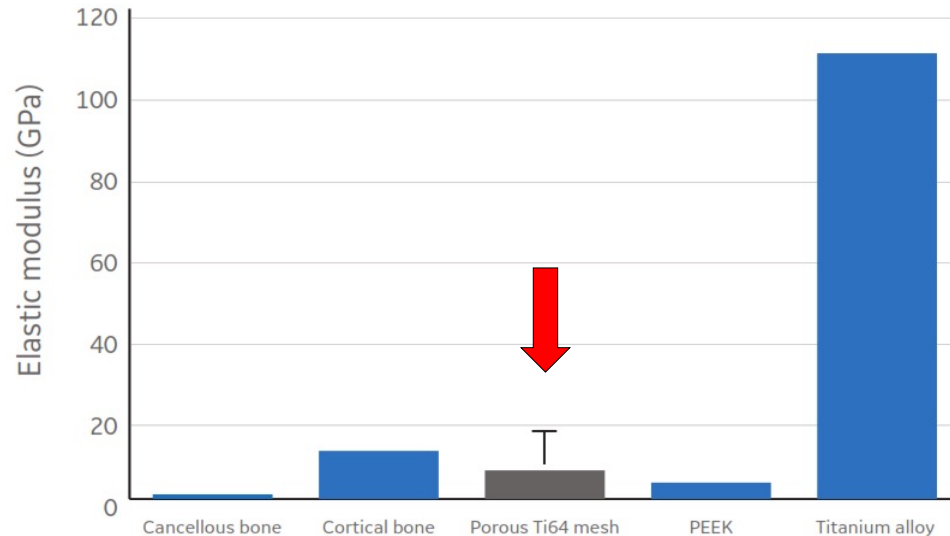
¹ McGillvray K.C., Easley J., Seim H.B., Bony ingrowth potential of 3D-printed porous titanium alloy: a direct comparison of interbody cage materials in an in vivo ovine lumbar fusion model. The Spine Journal. 2018; Volume 18. Issue 7: 1250-1260.

² Abbushi A., Cabraja M., Thomale U.W. et al. The influence of cage positioning and cage type on cage migration and fusion rates in patients with monosegmental posterior lumbar interbody fusion and posterior fixation. European Spine Journal. 2019; Issue 18: 1621-1628.



AM - Design Advantages

- Design porosities into structure
- Roughened surface for mechanotransduction
- Tailored Elastic Modulus - design stiffness to mimic bone stiffness



Surface Textures for Mechanotransduction

- Induce mechanotransduction
- Global mechanical stimuli = response at cell level
- Biomimicry – roughness mimics cancellous bone
- Coefficient Friction increase

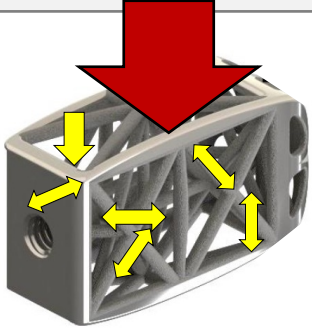
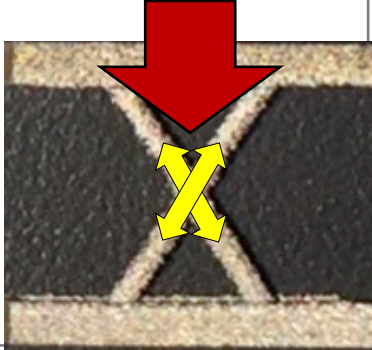
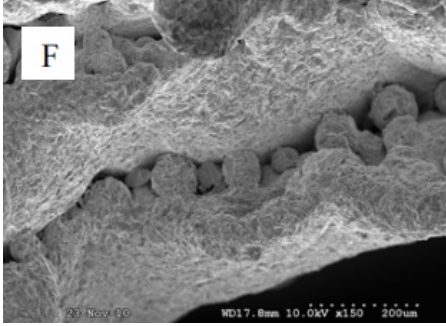


Printed Ti – Trabecular Pattern
Courtesy of Camber Spine

NEW TECHNOLOGIES LEAD TO NEW ERA OF IMPLANT EVALUATION

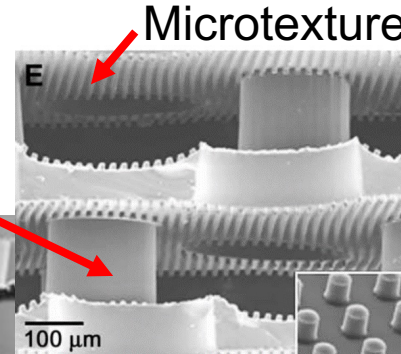
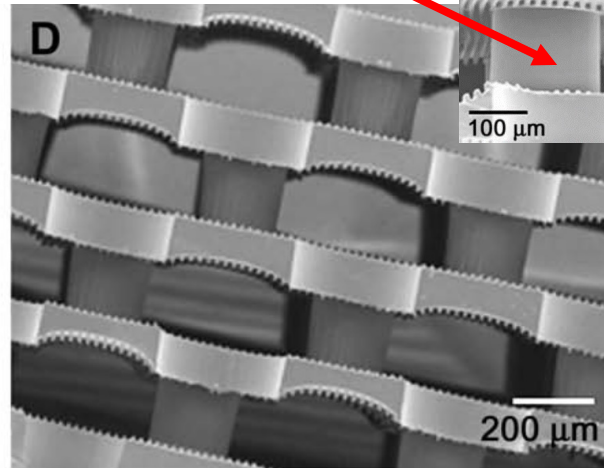
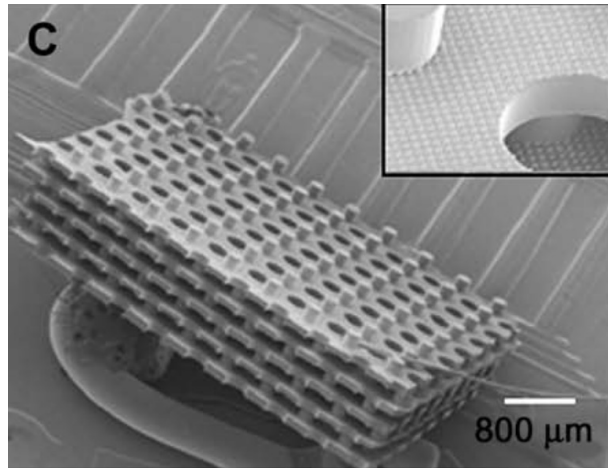
- Understand bone-implant interface for osseointegration
 - Optimize implant design, porosity, architecture
- Evaluate macro/micro/nanomechanics to better understand the tissue matrix /cellular /molecular responses
- Can lead to guided cell growth & tissue matrices

Assess Macro/Micro/Nano Mechanics

| MACRO | MICRO | NANO |
|--|--|---|
|  |  |  |
| <p>Macro load (stress vs. strain) applied results in:</p> <ul style="list-style-type: none">• Global implant strain• Multidirectional strut microstrain | <p>Individual truss loading Microstrains along each strut at the local bone interface – deep within the cage to the peripheral</p> | <p>Surface demonstrates repeating microstructure at micro and nanoscale surface features <50mm- Micro and Nanostrain</p> <ul style="list-style-type: none">• Induce mechanotransduction,• Increases Coef Friction |

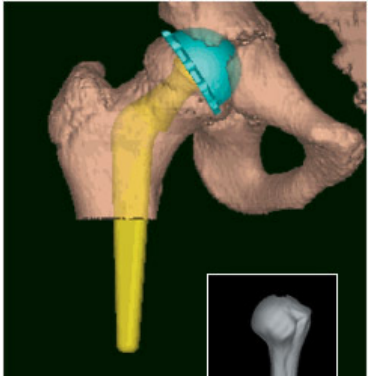
PRINT CONTROLLED STRUCTURES - GUIDE CELL GROWTH

- Bioactive surface
- Provide specific physical cues to guide cellular growth
- Efficient tissue matrix formation
- Control cellular growth & orientation

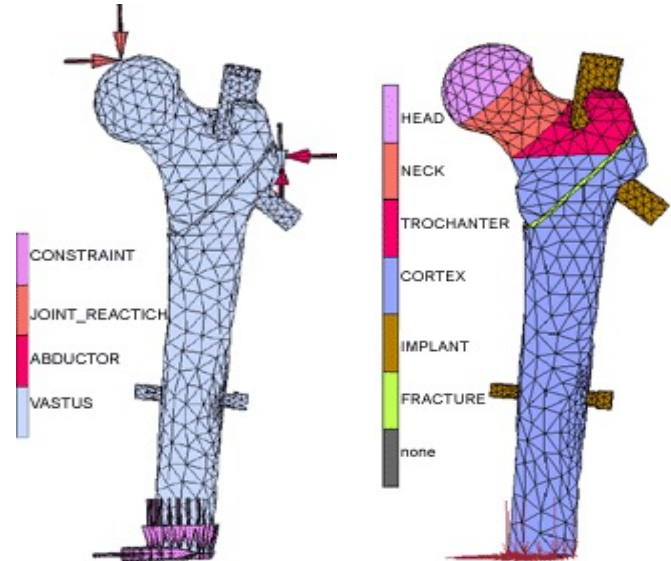
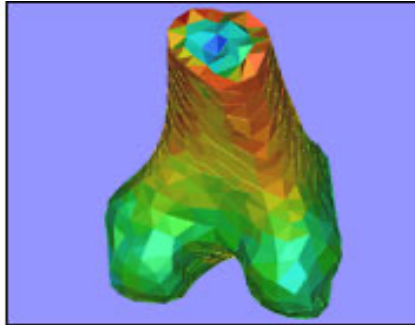
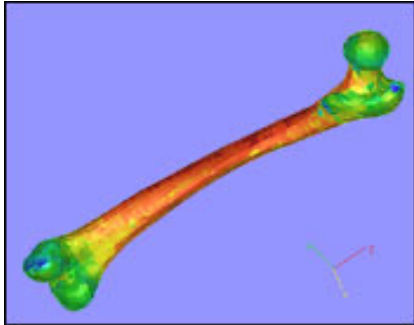


5 layer PDMS
3D porous
structure

FUTURE – PATIENT SPECIFIC PREOPERATIVE PLANNING



- Mesh design allows for computer modeling
- Patient specific stress profiles pre & post implantation
- Model blood/fluid flow patterns – heart/stent/kidneys
- Identify patient specific positioning, sizing, loading



The Future of Medical AM: Optimization

- Create repeatable surface structures – guide cell growth
- Build implantable scaffolds – cell seeding
- Control, Modulate Micromechanics & Nanomechanics
 - Cellular & Molecular levels
 - Create Macro-Micro-Nano Biomechanical Environment
- Customized patient specific implants – in Dr.'s office
- Early 'nano-detection' of diseases at curable levels through printed implantable nanostructures (Smart cantilevers)
- Bioprint tissue – optimized for organs, tissue, neural

Evolution of Technology & Medicine

- Continue to improve AM processes
- Increase resolution (nano powders)
- Improve outcomes, quality of life, longevity
- Continue to progress – good & bad



THANK YOU



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