Partnering with academia to foster the delivery of innovation and differentiation in the orthopaedic medical device world : The Additive Manufacturing Opportunity

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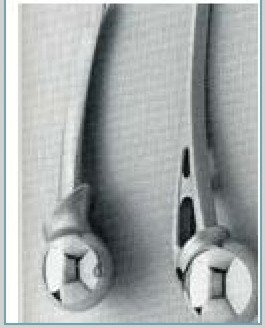
Orthopedic Product Innovations over the Years

1926

Stainless Steel Introduced as

1950

Judet Brothers Develop Stemmed



Neer Vitallium Alloy Shoulder

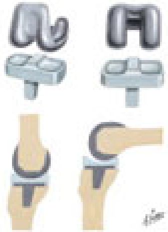
1952

First Mechanically Hinged Knee Design

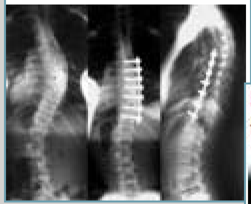
Artificial Femoral Head Developed

The Marmor Modular Knee is Introduced

Walker introduces the concept of the



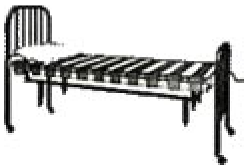
Spine Fusion Done at Rancho



Charnley Develops Prothesis for Total

1928

Fracture Bed Introduced



1969

Commercial Silicone Joint Implant

Geometric Knee Developed

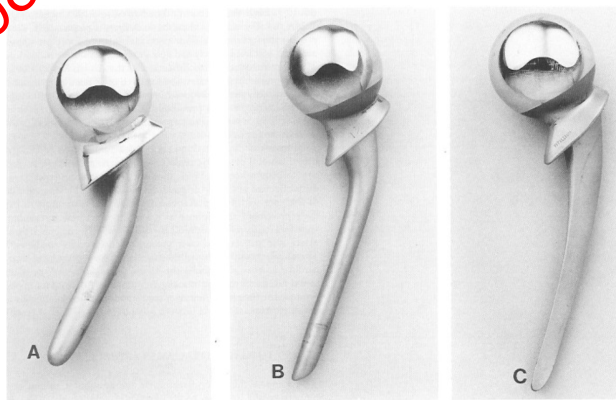
Engh introduces the first fully porous

1970

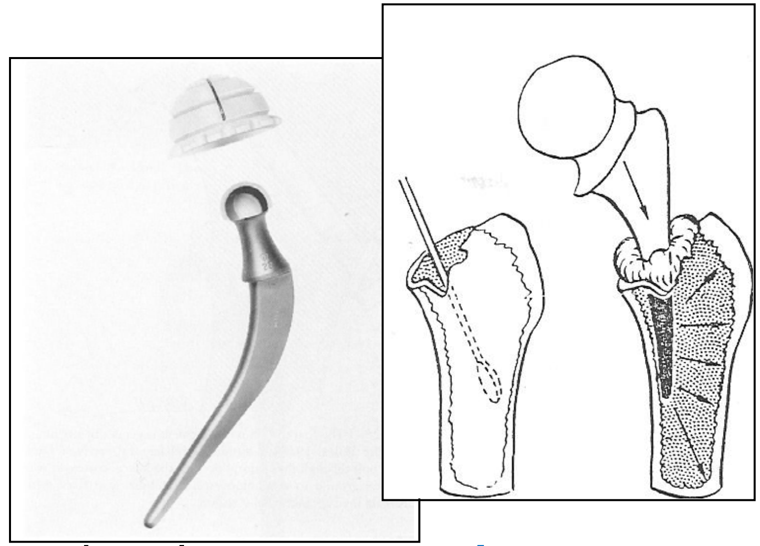
First Ceramic-On-Ceramic Hip

The Evolution of THA

Pre 1980

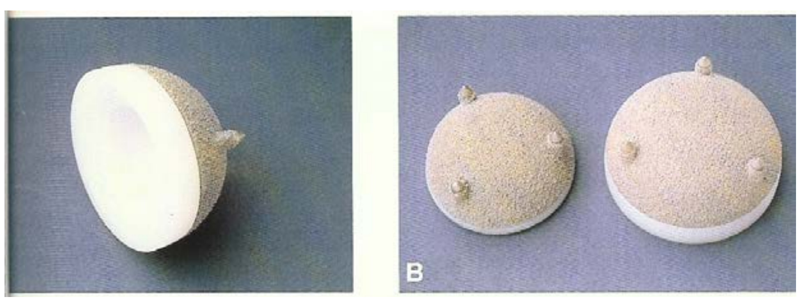


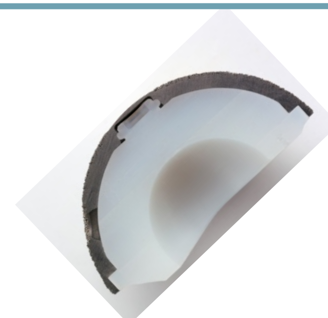
Thompson 1950



Charnley ***Cemented*** THA 1958 - 1982

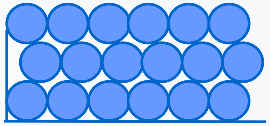
Post 1980



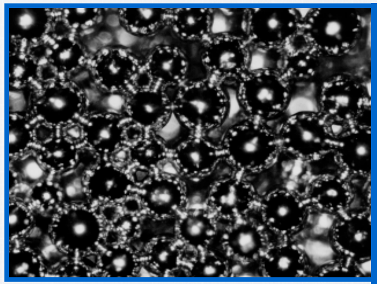


Porous Coated Biologically Fixed Modular
Press-Fit Cup and Stem 1980's

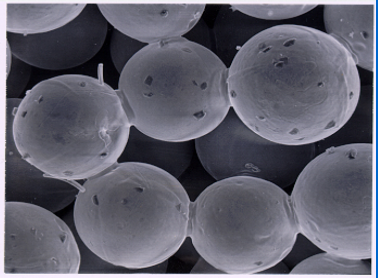
Sintered Bead Porous Coatings --
Optimized through the collaboration of universities and industry



Pocket with Uniform
3-D Interconnecting Layers
Close Packed



50X

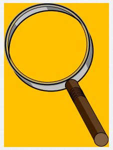


SEM

Bobyn et al. 100-400 micron effective for bone ingrowth.

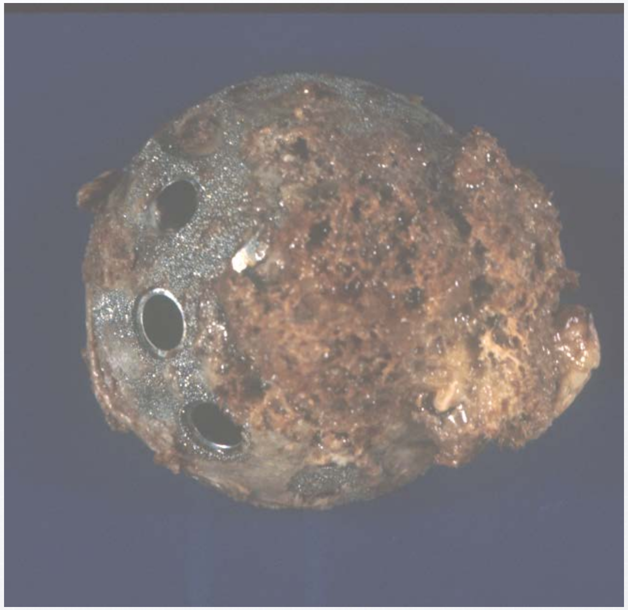
- ➔ **150+ micron mean pore size**
- ➔ **52% porosity**

Tension - 45 MPa vs. ASTM 20 MPa
Shear - Exceed ASTM
Abrasion - Exceed ASTM



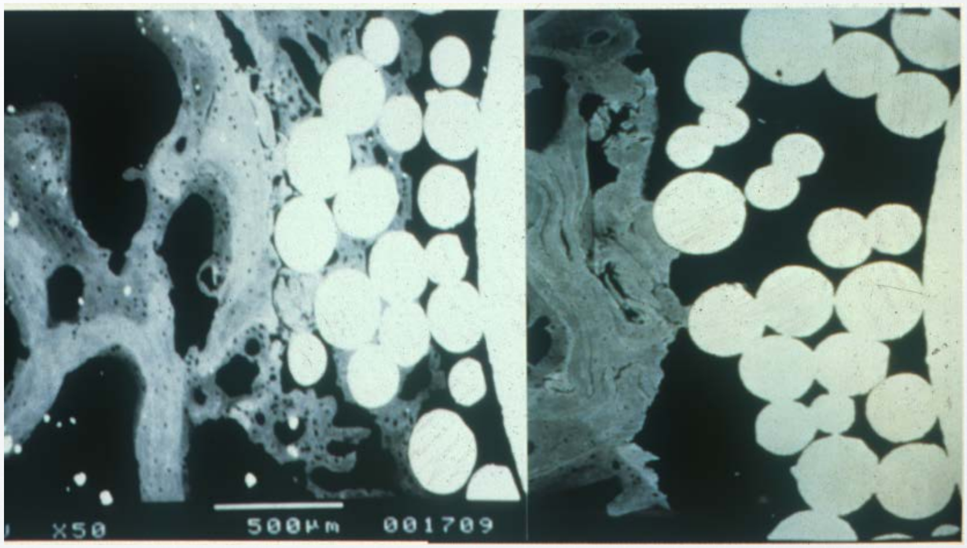
= Collaborative activities

In - vivo Response



Biomaterials development Bio - Ingrowth:

Ti vs. CoCr beads vs. plasma spray

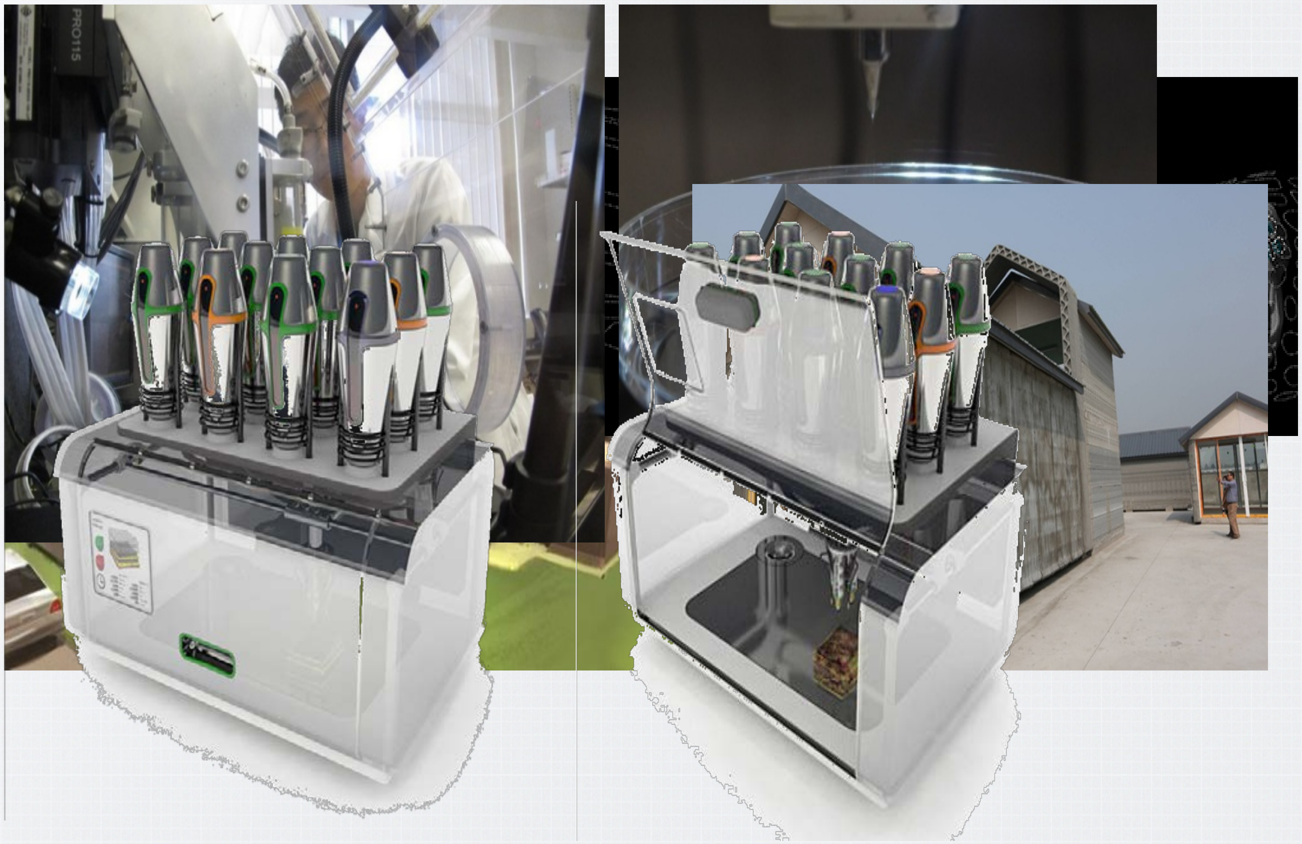


Human - 6 weeks post implantation courtesy of Bloebaum et al.

Manufacturing power – 75 years !

Additive manufacturing – The future is here

- Numerous processed materials:
  - Metal
  - Plastic
  - Tissue scaffolds
  - …
  - Concrete
  - Food

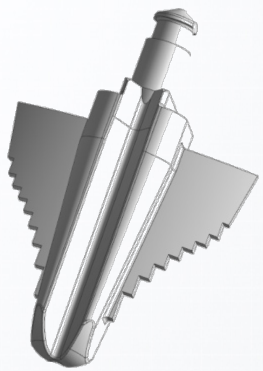


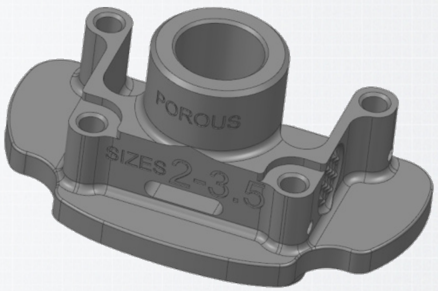
A Disruptive Manufacturing Methods is introduced ! 3-D printing = Additive Manufacturing

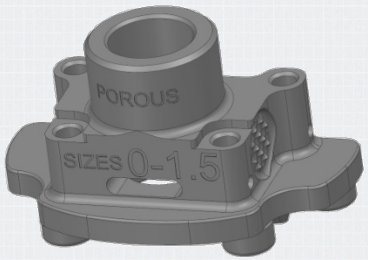
New manufacturing methods = a new “design space” for instruments and cemented and biologically fixed implants

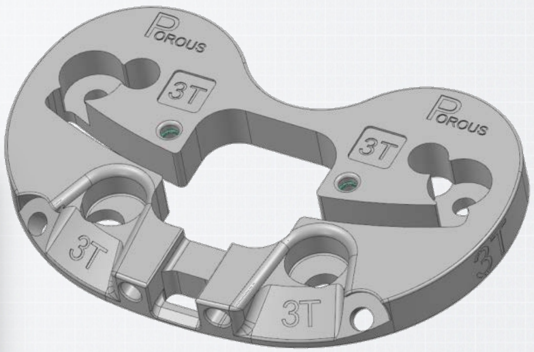
From plastic prototypes and custom components to production parts in a 5 year period

Complex solid geometries!





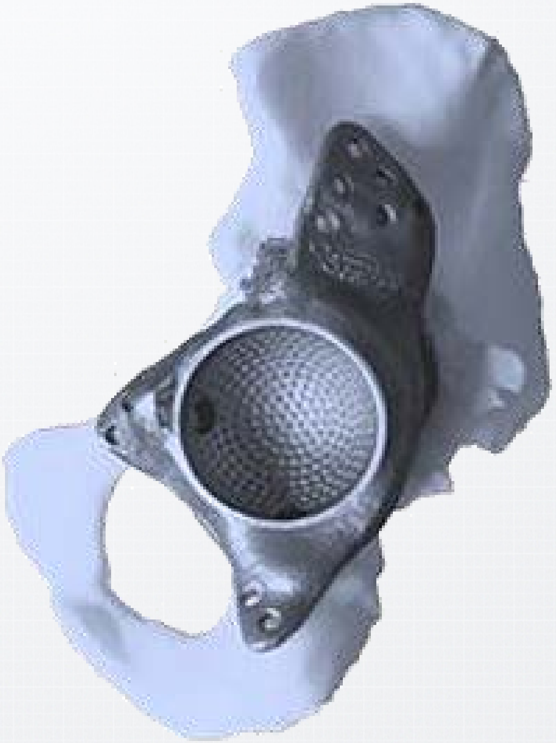




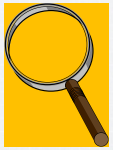
Perfect for prototyping and small unit instrument production!

Applications have expanded rapidly…………

From **custom/prototype** … to **production** (100 at a time)

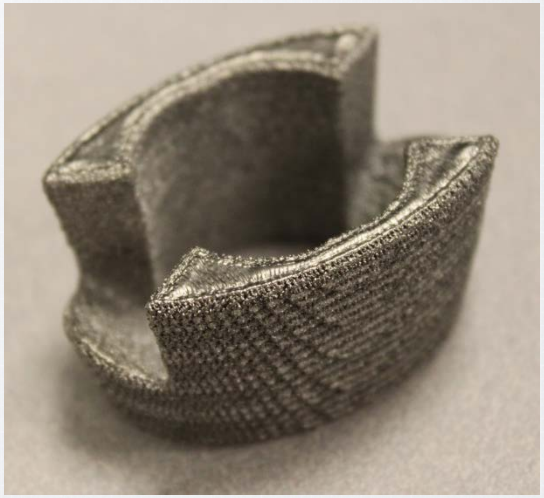


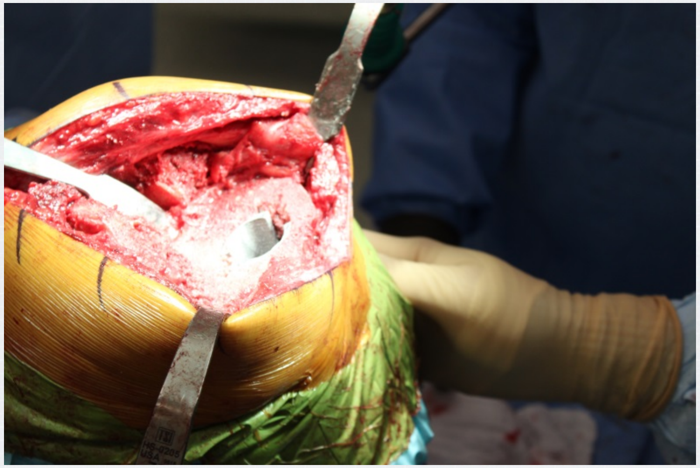
1 out of 30 hip surgeries involves components that come from an Arcam system



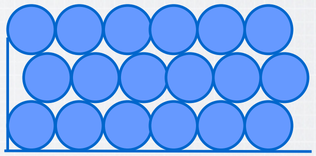
Exactech experience

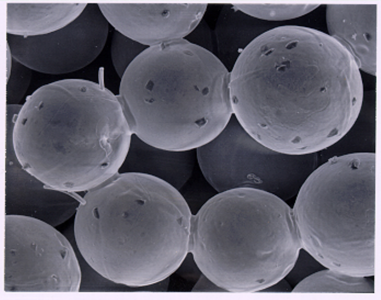
- 2010
  - First company to receive FDA clearance for a 3D printed orthopaedic implant
- 2016
  - Released 3D printed Metaphyseal Cones for knee revision





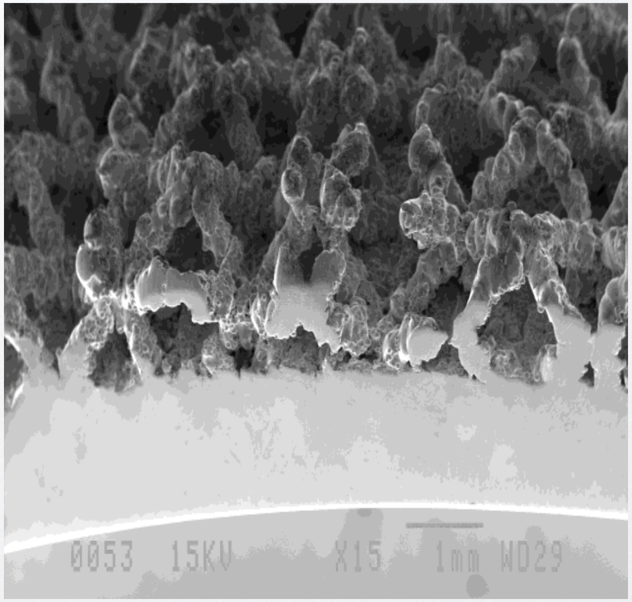
From Sintered Beads…



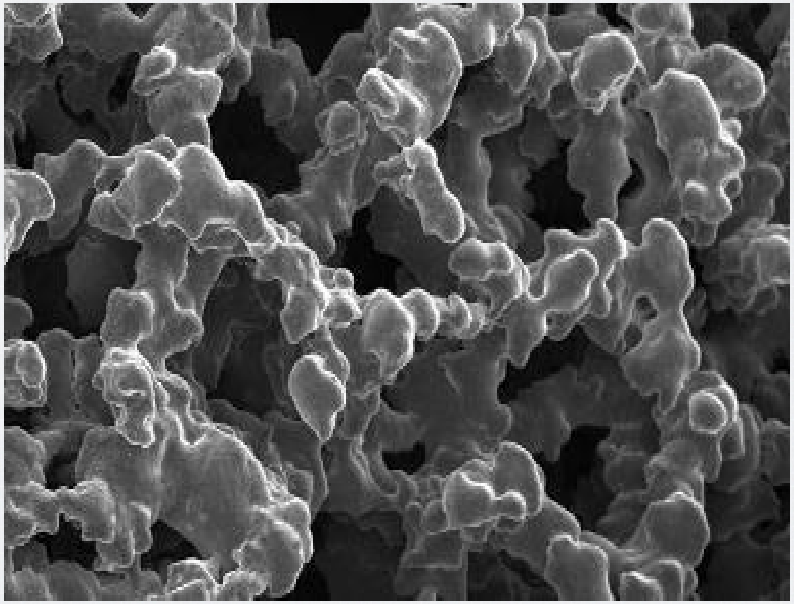


… To Variable Morphology Porous Structures

Structural continuity



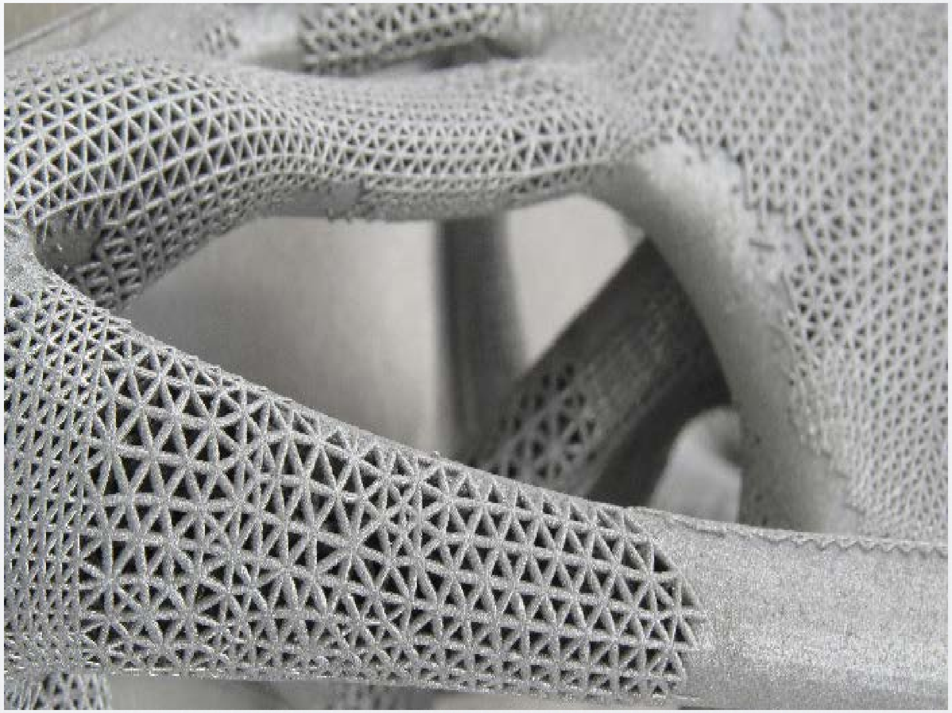
Engineered structure



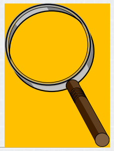
This is a truly disruptive technology where "Complexity is viewed as free"

From **Design for Manufacturing** to **Design for Function**

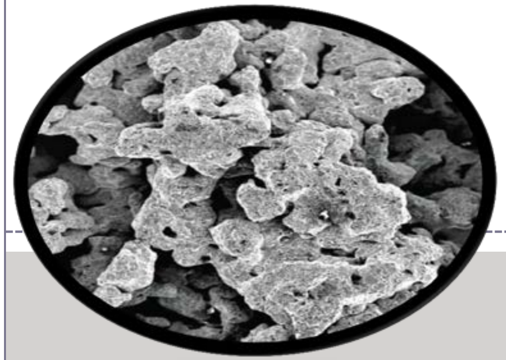
"Engineer/design your part as you envision it, without manufacturing constraints"



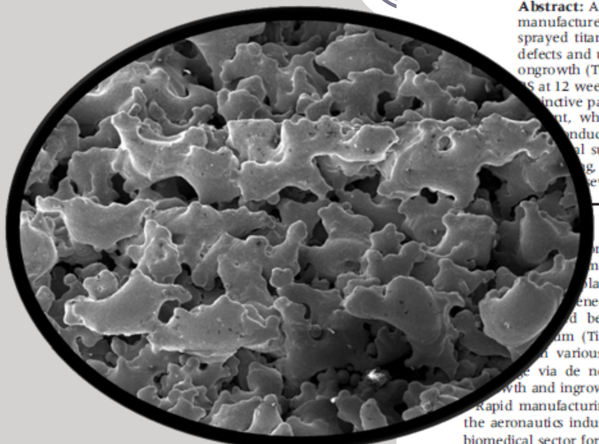
Note the overall macro, micro and nano differences in the structure



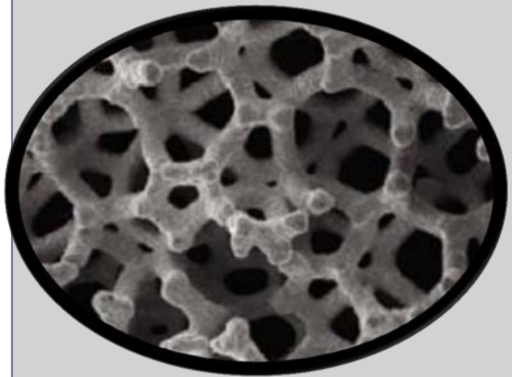
Validation Testing | Animal study



Biomet - Regenerex



Exactech - InteGrip



Zimmer – Trabecular Metal

The Journal of Arthroplasty Vol. 27 No. 8 2012

Influence of Electron Beam Melting Manufactured Implants on Ingrowth and Shear Strength in an Ovine Model

Nicky Bertollo, PhD, Ruy Da Assuncao, MD, FRCS, Nicholas J. Hancock, MD, FRCS, Abe Lau, PhD, and William R. Walsh, PhD

Abstract: Arthroplasty has evolved with the application of electron beam melting (EBM) in the manufacture of porous mediums for uncemented fixation. Osseointegration of EBM and plasma-sprayed titanium (Ti PS) implant dowels in adult sheep was assessed in graduated cancellous defects and under line-to-line fit in cortical bone. Shear strength and bony ingrowth (EBM) and ongrowth (Ti PS) were assessed after 4 and 12 weeks. Shear strength of EBM exceeded that for Ti PS at 12 weeks ($P = .030$). Ongrowth achieved by Ti PS in graduated cancellous defects followed a …inctive pattern that correlated to progressively decreasing radial distances between defect and …nt, whereas cancellous ingrowth values at 12 weeks for the EBM were not different. …nductive porous structures manufactured using EBM present a viable alternative to …al surface treatments. **Keywords:** electron beam melting, uncemented fixation, rapid …g, bone ingrowth, shear strength.

…on in joint arthroplasty is reliant …ment of a biologic and mechanical …plant-bone interface through osseoin-…ened surfaces and porous mediums, …d beads, wire meshes, and plasma-…um (Ti PS), have been applied to metal …n various forms to provide for adequate …e via de novo cortical and cancellous bone …wth and ingrowth [1].

Rapid manufacturing technologies once exclusive to the aeronautics industry are now being applied in the biomedical sector for the manufacture of osteoconductive porous mediums for tissue ingrowth in uncemented fixation [2-9]. Electron beam melting (EBM) is one such method built on the fundamental tenet of additive manufacturing. Complex meshes and macro-textured mediums/shapes can be generated in a single process from powders of pure titanium and its alloys (ie, Ti-6Al-4V) that are sintered or melted together in a layer-by-layer fashion using electron beams. One of the main advantages of EBM technology is the ability to integrate the porous structure to the solid substrate instead of traditional methods in which a coating is applied separately [2,10,11]. Porosity of these structures can be tightly engineered such that the resulting constructs mimic the elastic modulus of human cancellous bone (~0.5 GPa) and potentially ameliorate the effects of stress shielding on bone resorption [2,10]. The primary mode of fixation for uncemented tibial trays, femoral components, and acetabular cups is indeed via cancellous bone ongrowth and ingrowth.

This study evaluates the osseointegration of a macro-textured ingrowth structure manufactured using the EBM process and a control Ti PS medium after 4 and 12 weeks in situ using an established ovine implantation model in the cortex of the tibia [12-15] and cancellous bone of the distal femur and proximal tibia [16]. The Ti PS coating and EBM structure represented mediums for bone ongrowth and ingrowth, respectively. Our null hypothesis was that there would be no differences between implants with respect to interfacial shear strength in cortical bone. We also evaluated the effects of surgical interface (gap, line to line, and interference) on de novo ongrowth/ingrowth in the cancellous sites of the distal femur and proximal tibia [16]. Our additional hypothesis was that implantation configuration would have no effect on osseointegration for each of the 2 test mediums.

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The Conflict of Interest statement associated with this article can be found at doi:10.1016/j.arth.2012.02.025.
Reprint requests: William R. Walsh, PhD, Director, Surgical and Orthopaedic Research Laboratories, Prince of Wales Hospital, University of New South Wales, Sydney, Australia.

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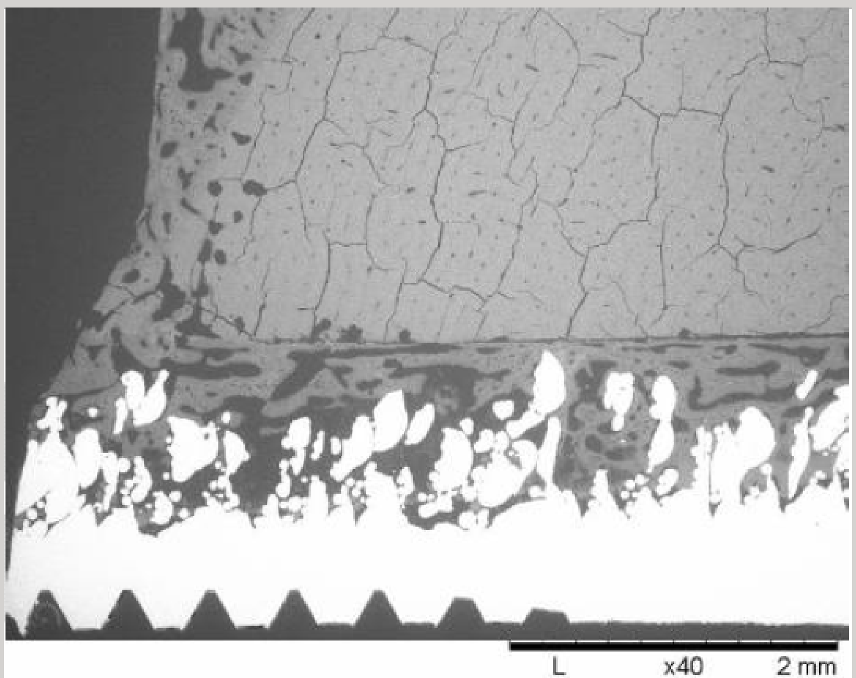
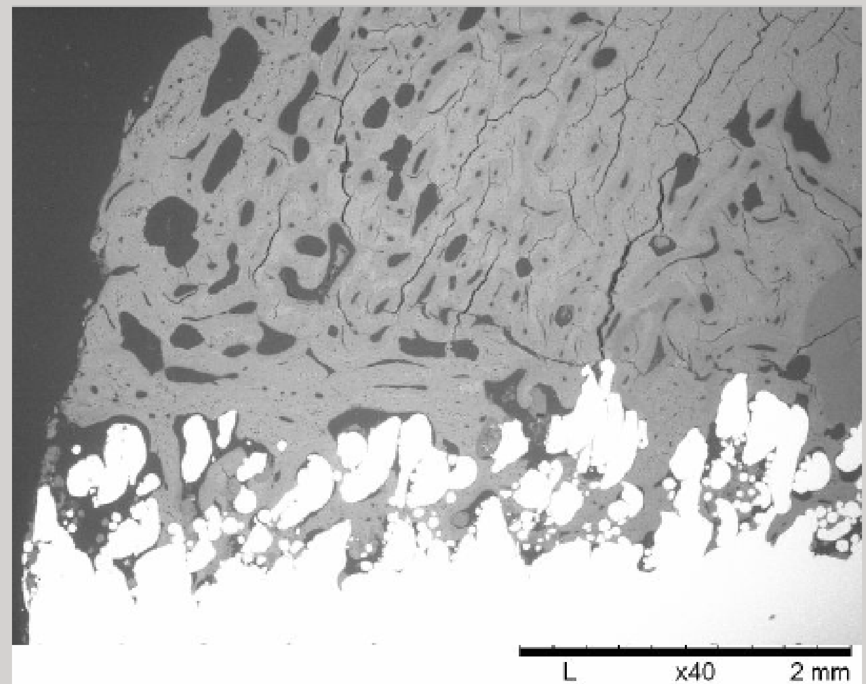
Line Fit Results

Cortical site @ 4 weeks



Cortical site @ 12 weeks



Integral fully dense material and porous surface for implants

So where is the journey taking us?

The Corporate Challenge is Somewhat Daunting and Continuing to Evolve

- Machines are evolving
  - E-beam
  - Laser
  - ………
- Quality questions emerge
  - Materials management (powders)
  - Cleaning (unfused material)
  - Reproducibility
  - Inspection methods
  - Certifications
- The Corporate Challenge Optimization of *designs* and *materials* and *fabrication*
  - Compatibility for the biological environment (bone, cartilage, muscle, tendon………)
  - Metallurgical (Co-Cr alloys, Ti alloys, other…….)
  - Morphology (shape/structure, Porosity. Interconnectivity, Frictional Behavior, Macro, Micro, Nano……….
  - Regulatory
    - ISO – ASTM – FDA Substantial equivalence
    - Accepted Protocols for testing and verification and validation

So where is the journey taking us?

Disruptive Technologies Present An Exceptional Opportunity for Collaboration

- Translational and Applied Research opportunities
- Interdepartmental and Multi-disciplinary collaborative teaching and research opportunities
  - Educational Support to prepare graduates for a career with emphasis in Additive Manufacturing
    - Additive Manufacturing processes
    - Mechanical Engineering (Machine Design)– Computer Aided Design, Finite Element Analysis and other modeling
    - Biomechanics – Host Implant Interface interactions
    - Biomaterials – Macro, Micro and Nano structural behavior and optimization
    - Biomedical Engineering - Macro, Micro and Nano structural behavior, scaffolds , engineered tissues…………….
    - …………………….
  - Research Support
    - Verification and Validation activities as an independent party
    - Test Development (ASTM, ISO etc.)
    - Laboratory and animal testing for compatibility and optimization
    - Collaboration for clinical research investigations
    - ………………………..

Deans and their chairs influence these activities through identification of opportunities, "seeding" and helping faculty "see it"

Thank you!