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

1926
Stainless Steel Introduced as

1950
Jude Brothers Develop Stemmed
Neer Vitallium Alloy Shoulder

1952
First Mechanically Hinged Knee Design
Artificial Femoral Head Developed
The Marmor Modular Knee is Introduced

1959
Spine Fusion Done at Rancho

1969
Commercial Silicone Joint Implant
Geometric Knee Developed

1970
Engh introduces the first fully porous
First Ceramic-On-Ceramic Hip
The Evolution of THA

**Pre 1980**

- Thompson 1950

**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

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

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

Nicky Bertollo, PhD, Ruy De 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 uncremented fixation. Osteointegration 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 cemented (TIPS) were assessed after 4 and 12 weeks. Shear strength of EBM exceeded that for Ti PS by 12 weeks (P < 0.05). Osteointegration achieved by Ti PS in graduated cancellous defects followed a pattem that correlated to progressively decreasing radial distances between defect and, whereas cancellous ingrowth values at 12 weeks for the EBM were not different, inductive porous structures manufactured using EBM present a viable alternative to surfacetreatment. Keywords: electron beam melting, uncremented fixation, rapid prototyping technology

In joint arthroplasty is reliant upon the development of a biological and mechanical interface region between the bone and implant. This bone-implant interface is maintained through osteointegration, a process by which bone is in close contact with the implant surface. Various forms of osteointegration have been described, including: (1) direct or primary osteointegration, where bone directly contacts and inlets with the implant surface; (2) secondary osteointegration, where bone forms a layer between the implant and primary osteointegration layer; and (3) tertiary osteointegration, where bone forms a layer around the implant that is in direct contact with the primary osteointegration layer. In this study, electron beam melting (EBM) is one such method to fabricate this type of osteointegration. EBM is a technique that uses a focused electron beam to melt titanium and other metallic materials on a solid or semi-solid substrate. The resulting material is then cooled and solidified, forming a porous structure that is similar to cancellous bone. This allows for the formation of a biological interface region between the bone and implant.

Biomet - Regenerex

Exactech - InteGrip

Zimmer – Trabecular Metal
Line Fit Results

Cortical site @ 4 weeks

Cortical site @ 12 weeks

Exactech, 2015
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!