Additive Manufacturing is Changing Surgery

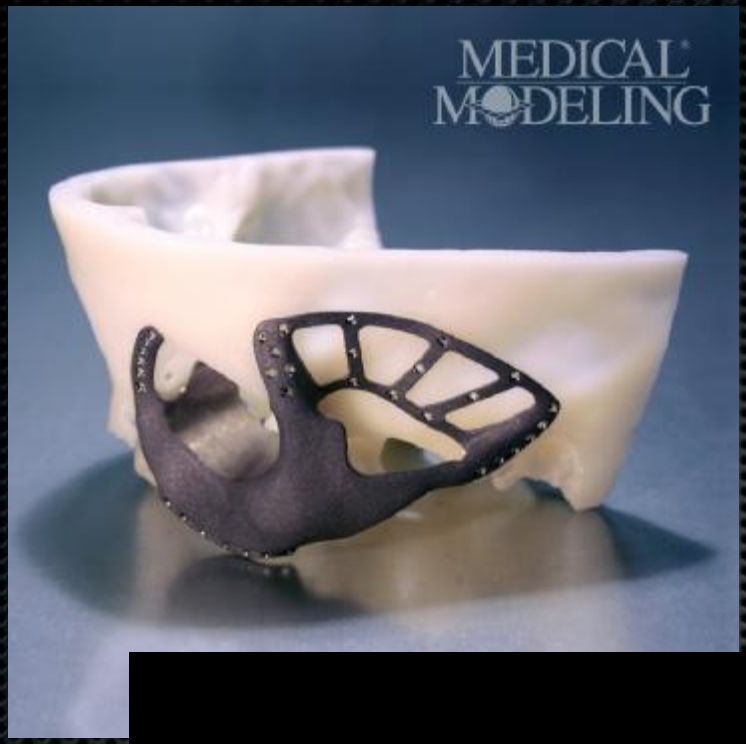
Andy Christensen

Medical Modeling Inc. (Golden, CO)

September 19, 2011
Mountain View, California

MEDICAL MODELING

Proven Uses of AM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Training & Education

Complex Surgeries

Written in Bone:

Forensic Files of the 17th-Century Chesapeake

February 7, 2009 – February 6, 2013

Smithsonian Institution

Smithsonian National Museum of Natural History, Washington, DC


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SKELETONS
SPEAK
EXAMINING
THE EVIDENCE

Needed Tools

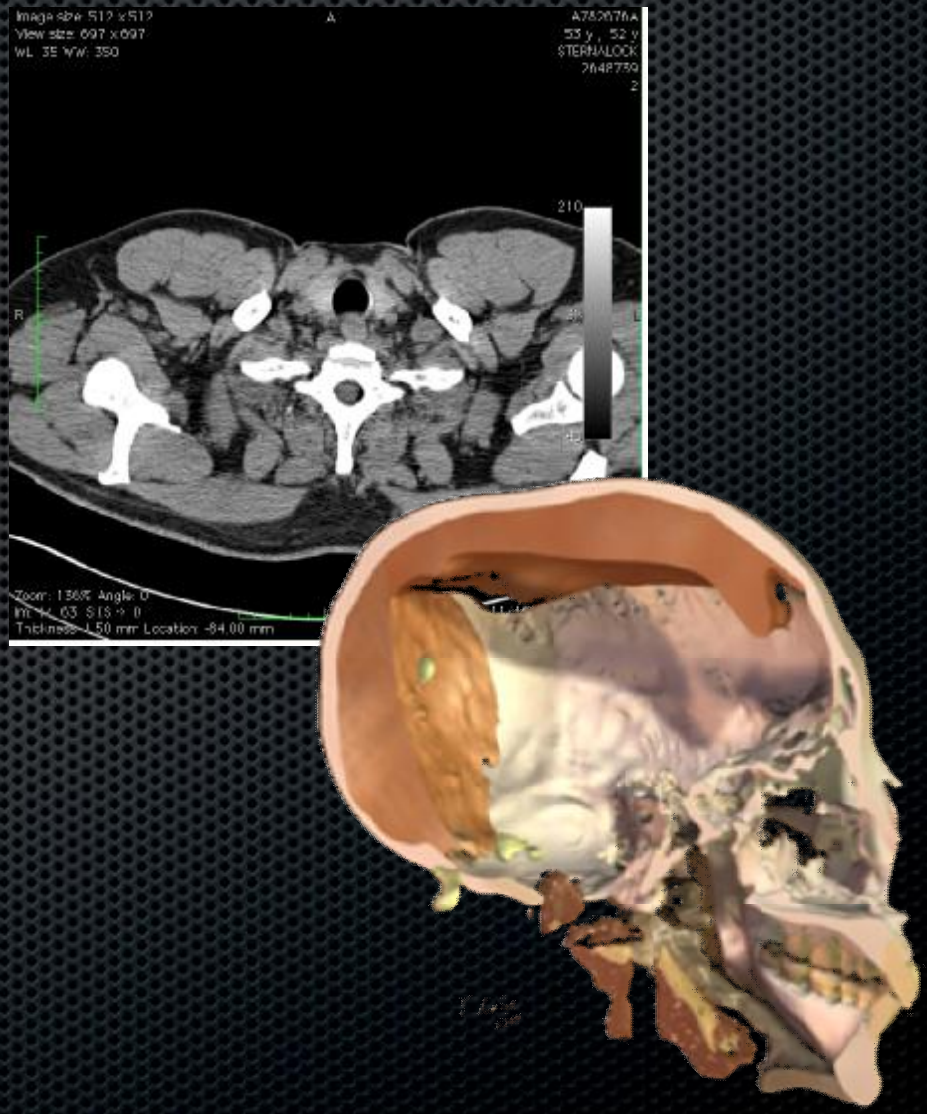
- Medical Imaging
- Data Manipulation/Surgical Planning
- Design of “Clinical Transfer” Implements
  - These are the tools that transfer the surgical plan from the computer to the operating room
- Additive Manufacturing: Metals & Plastics
- We still need a skilled surgeon in case of unforeseen events but in general the skill level needed is much less

Medical Imaging

- Higher quality, more resolution, faster, less radiation - all evolving very fast now
- In-office volumetric imaging is exploding in dental specialties, sub $100k machines

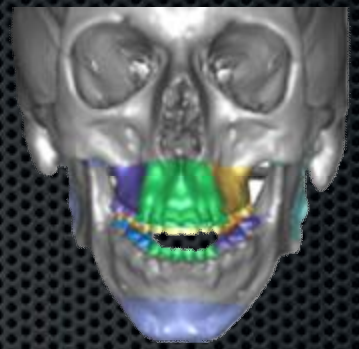
Data Manipulation

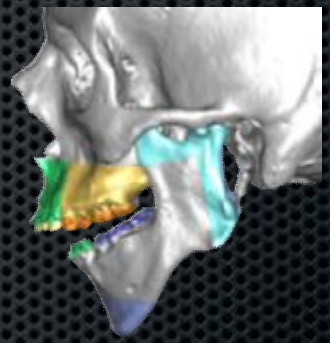
- Data cleanup remains one of the most laborious tasks in a digital workflow
- A backward step in image quality with in-office systems
- Automation is coming

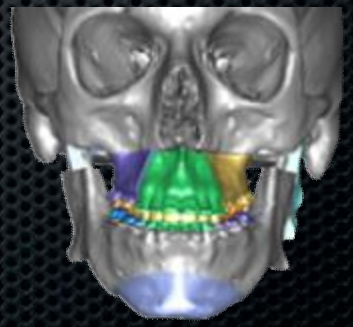


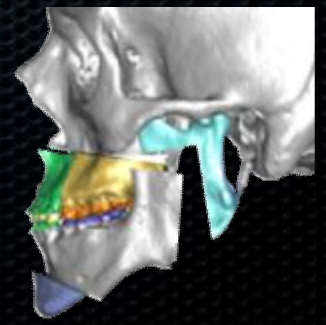
Surgical Planning

- Done either real-time with collaborative webmeetings involving the surgeon or off-line with case report communication



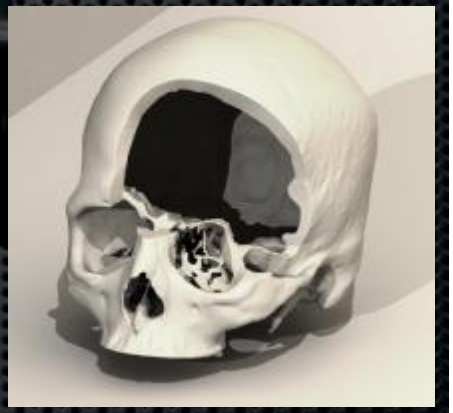


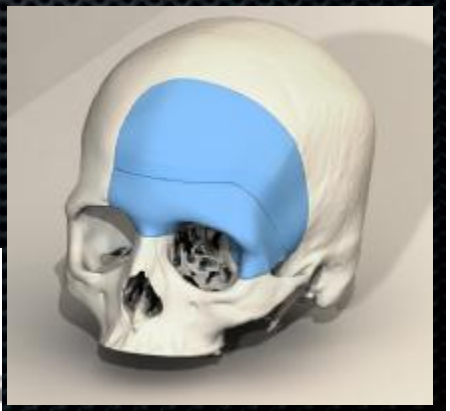


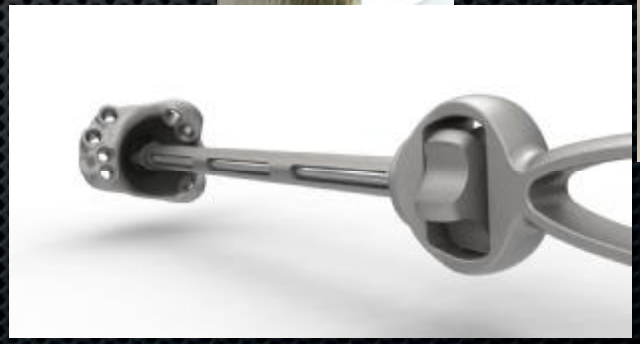


Design & Production of Clinical Transfer Tools

- These tools or implants transfer the digital plan to the patient in surgery
- Tools mostly plastic, implants all metallic







Additive Manufacturing: Plastics

- Perfect fit for “instruments”, guides, templates, etc. which are all custom, complex shapes
- Lot size of 1 works well, no problems with throughput, time, etc.
- Many materials with proven biocompatibility are being used daily to facilitate surgeries around the world.

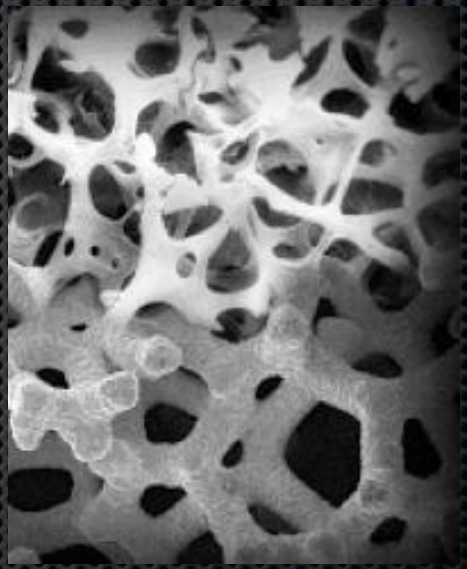
AM Materials: Plastics/Plaster

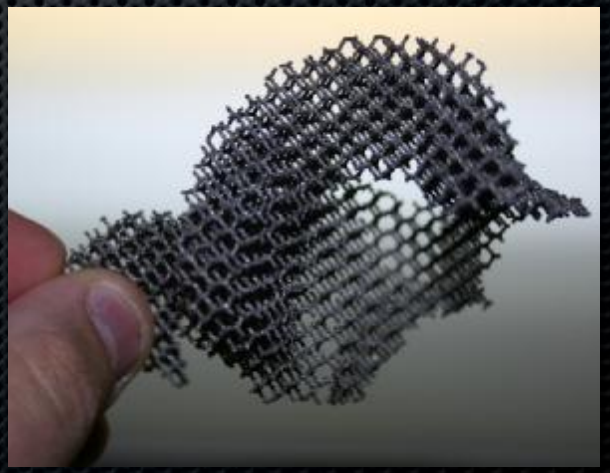
	Rigid	Flexible	Opaque	Translucent	Full Color	Biocompatible
SLA	X		X	X		X*
SLS	X	X	X			X*
FDM	X		X			X*
3DP	X		X		X	
PolyJet	X	X	X	X		X*

*Certain materials available for AM processes have been tested to at least some elements of ISO-10993 biocompatibility standards

Additive Manufacturing: Metals

- Primarily two technologies driving the market, EBM (Electron Beam Melting) and DMLS (Direct Metal Laser Sintering)
- Titanium and Titanium Alloys are the metals of choice using these AM technologies
- Used for both custom and off-the-shelf implants for fracture repair, reconstruction and total joint reconstruction





How is AM changing surgery?

- Review of total joint market, surgical planning methodologies and guidance with AM
- Assessing surgical outcomes
- Customized implants
- What’s next?

Total Joint Replacements

- Worldwide 2010 Data (Courtesy OrthoWorld, Inc.)
  - Hip Replacements = 1,400,000
  - Knee Replacements = 1,100,000
  - AM-Guided Knees = 40,000+ (3%, my estimate)
- U.S.-Only 2015 Estimates (Courtesy OrthoWorld, Inc.)
  - Hip Replacements = 600,000
  - Knee Replacements = 1,400,000

Traditional Total Joint "thinking"

- One size fits all
- Decisions on surgical procedure made in-vivo, during surgery
  - Highly dependent on "fairly normal" patient population
  - Highly dependent on skill level of surgeon
  - Takes time in surgery to make these decisions, thus lengthening the ideal, shortest surgical time possible

What if...

- Your surgery could be personalized to you...
  - To your unique anatomy
  - To your unique functional needs
  - To your unique aesthetic needs
- Why wouldn’t any and all patients want this?
- What’s in it for the surgeon?

Personalization of Surgery

CUSTOM IMPLANTS	CUSTOM FIT OFF-THE-SHELF IMPLANTS
1. CT Scan	1. CT/MRI Scan
2. Implant Design	2. Implant Sizing/Positioning
3. Design Approval	3. Guide Design
4. Implant Production	4. Guide Production
5. Implants Shipped	5. Guide & Standard Implants Shipped

Step 1: Incision and exposure

Step 2: Distal femoral resection

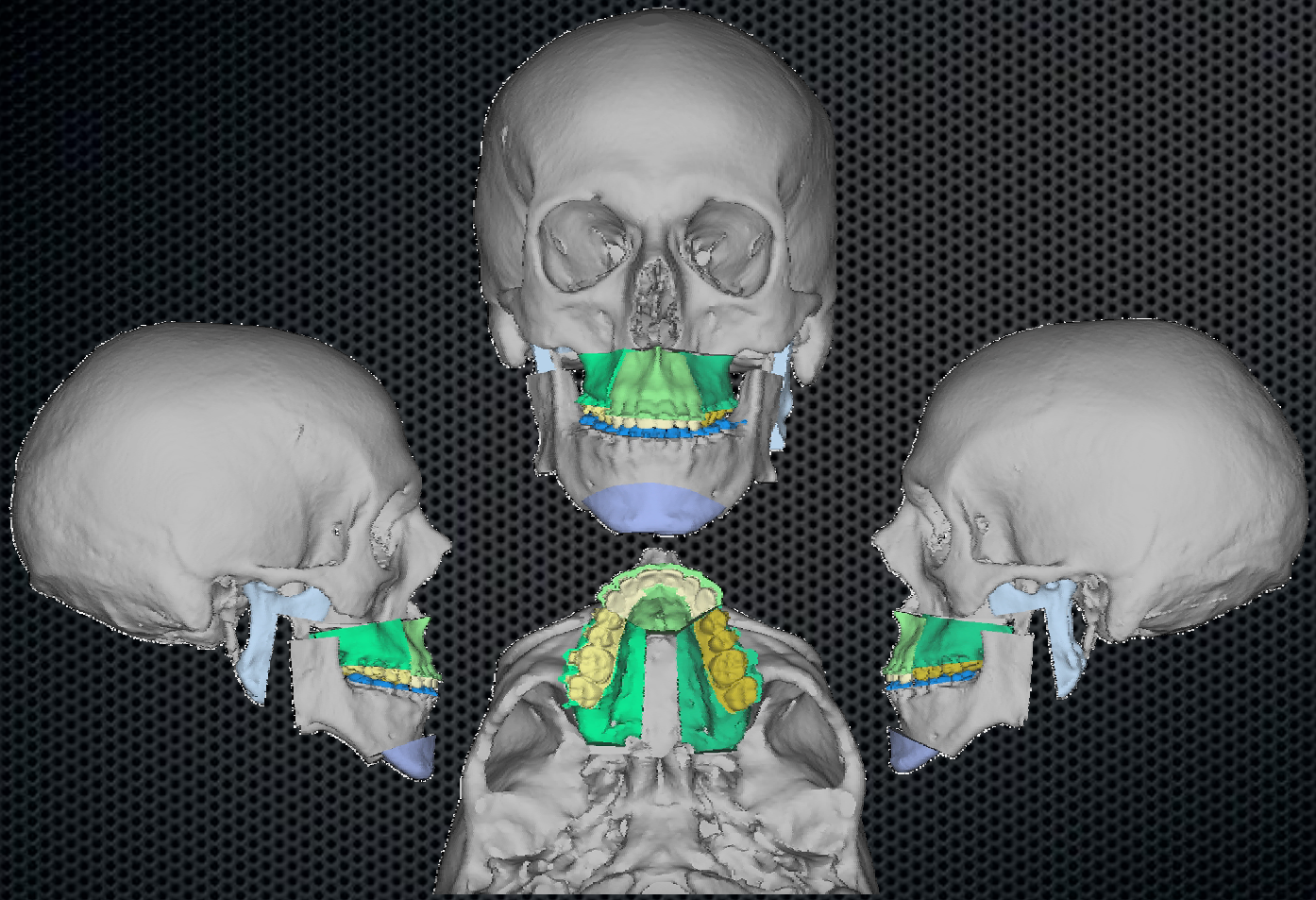
Step 3: Proximal tibial resection

Step 7: Tibial plateau preparation

Step 8: Tibial keel preparation

Step 9: Femoral lug preparation

Typical Maxillofacial Patient



Clinical Transfer Via Templates

Before Surgery

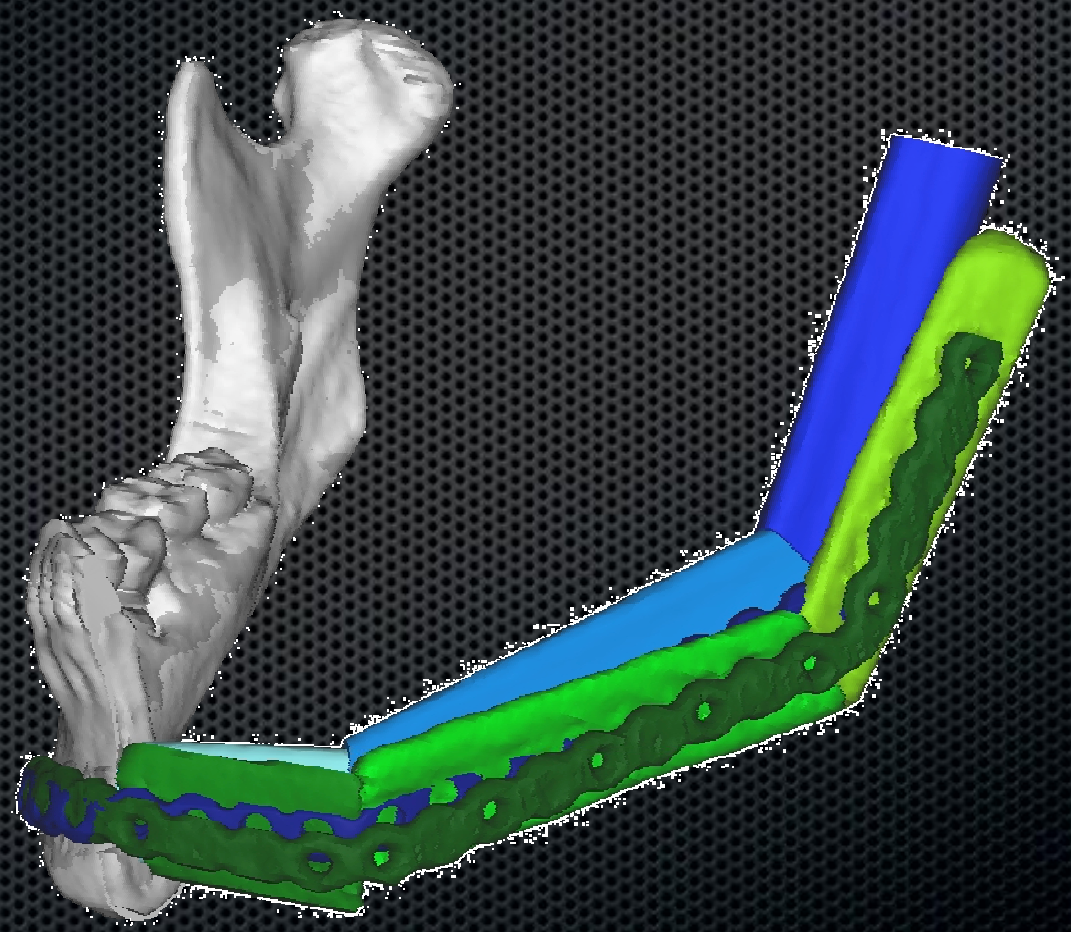
After Surgery

Courtesy of R. Bryan Bell, MD, DDS, FACS
Legacy Emanuel Hospital and Health Center,
Portland, Oregon

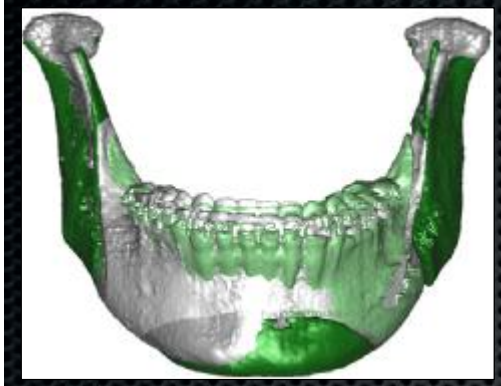
Assessing Surgical Outcomes

- Comparing a surgical outcome to another outcome for a similar group of patients is possible today
- What is not possible is comparing your outcome for a single patient to what was planned for that patient
- Until now… With a precise plan as the baseline for 3D comparison we can now review, refine and assess surgical outcomes like never before

Overall Shape Comparison: 3D Surface Overlays



Point-to-Point Measurements

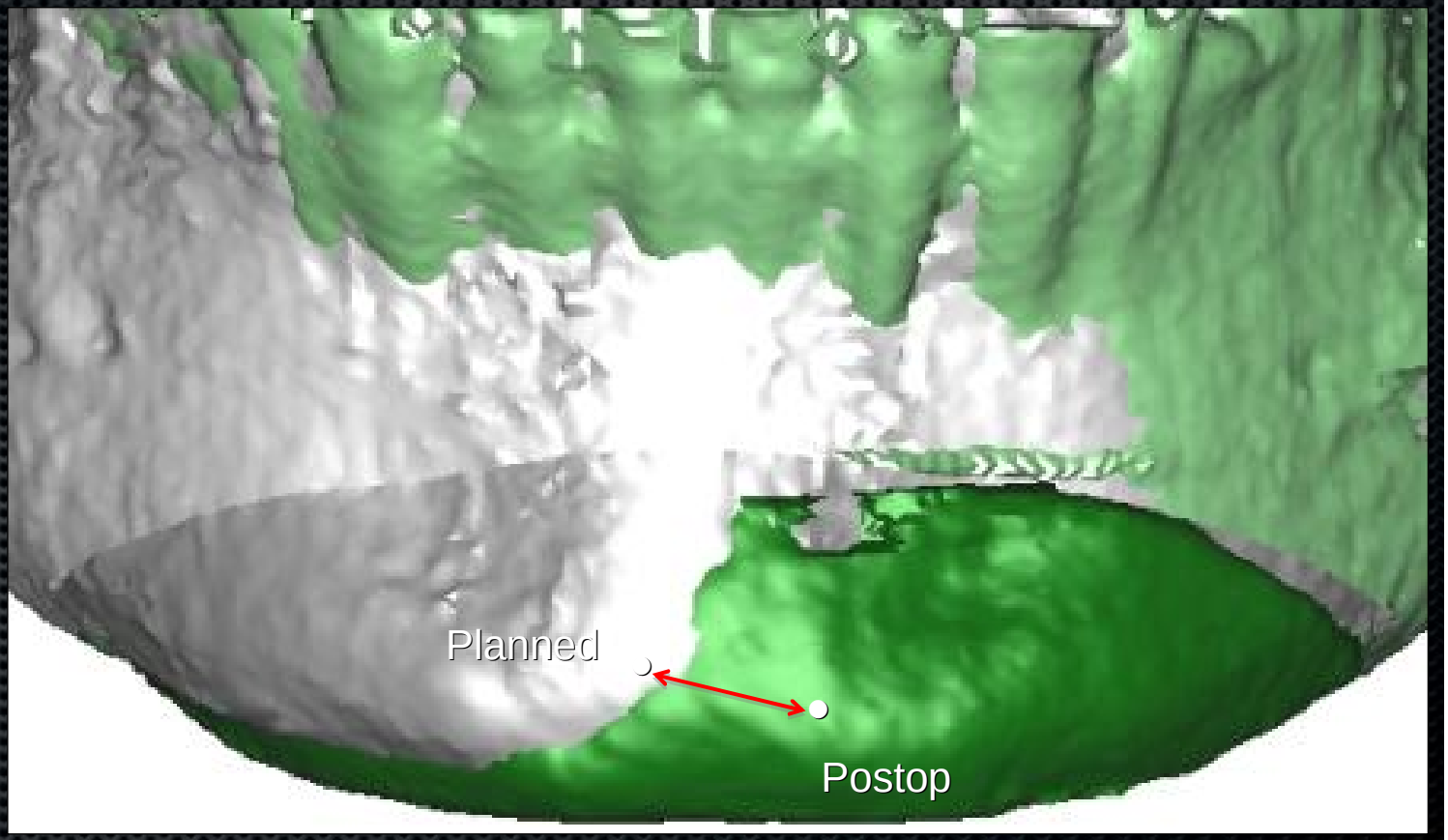


Distal Mandible

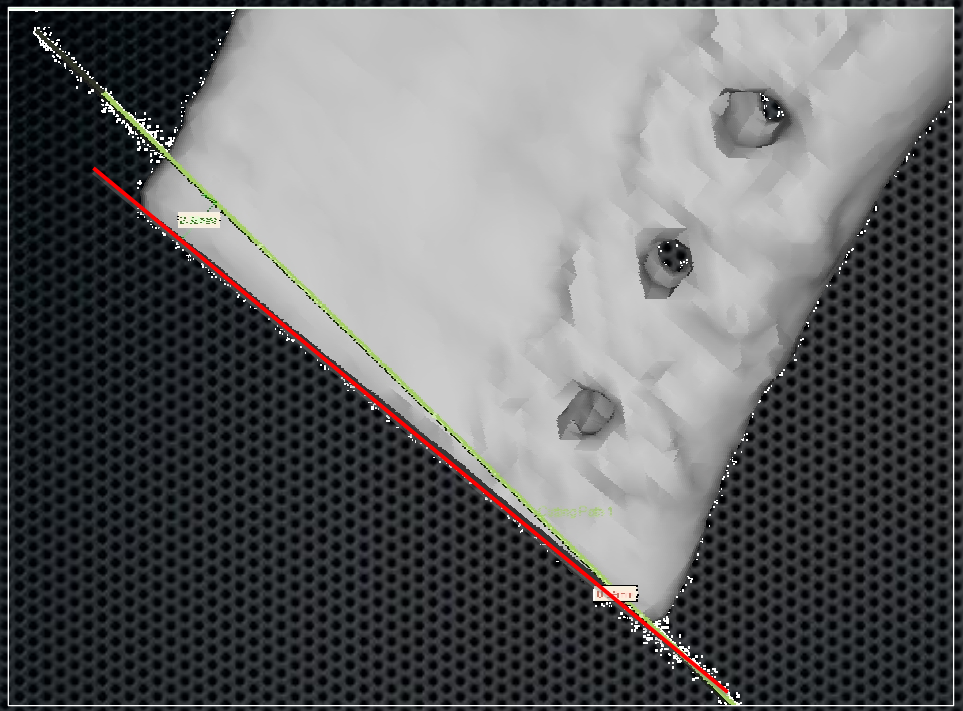
Postop Chin

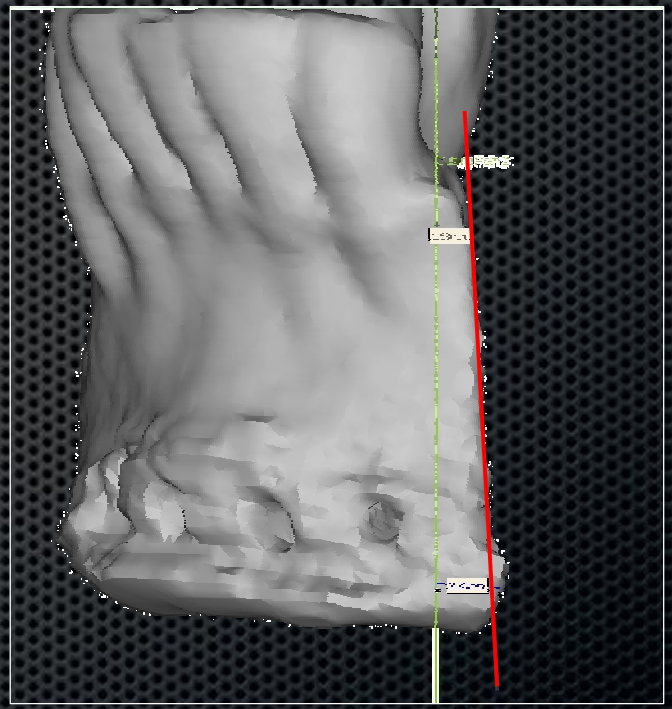
Virtual Plan: Chin

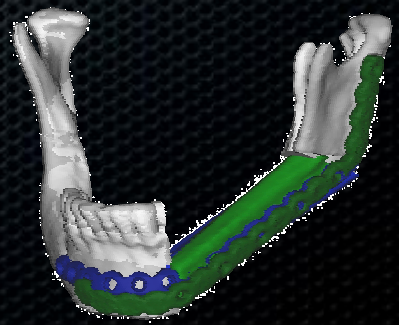
Virtual Plan: Distal Mandible



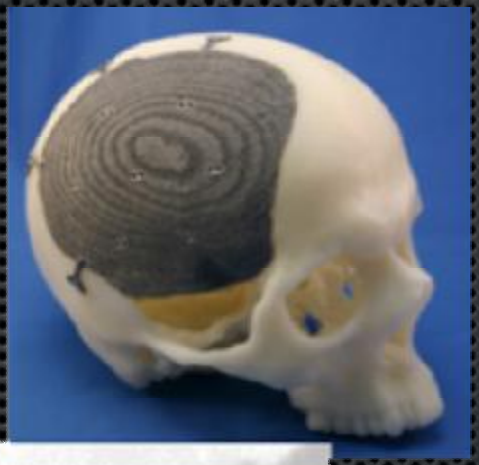
Plane-to-Plane Measurements

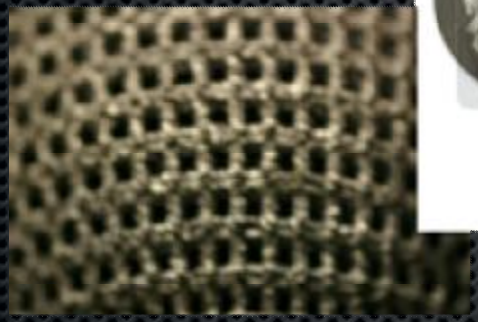




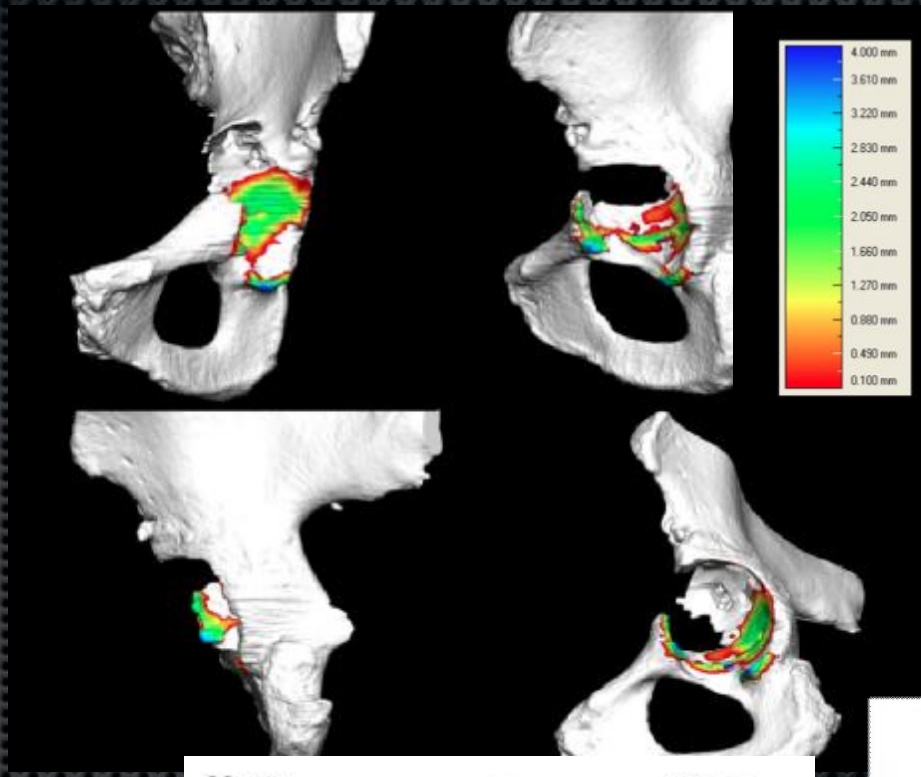


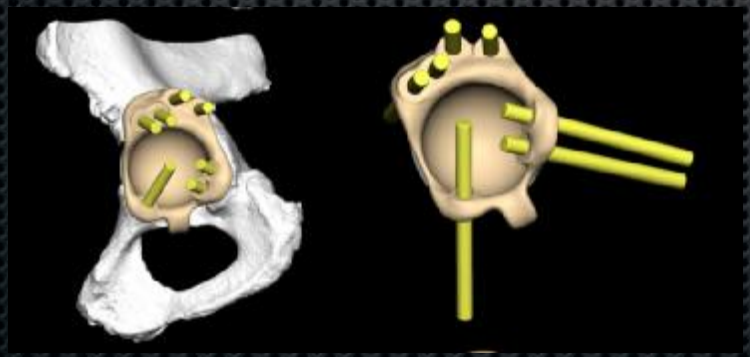
Additive Manufacturing: Metals, Custom & Off-the-Shelf

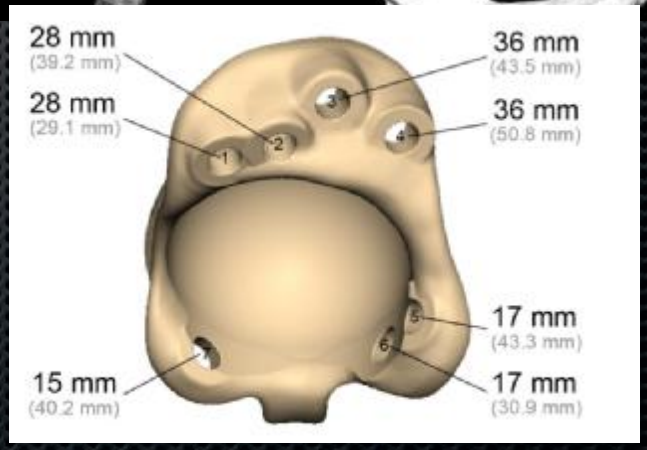




Custom Implants







AM & the Future

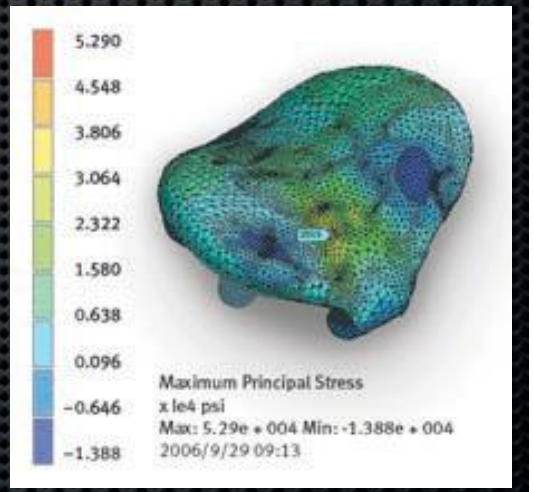
- Automation of:
  - Imaging, Diagnosis, Surgical Planning, Design
- Robotic Assistance
- “Easy”, Real-Time Guidance
- Design for function
- Biomaterials that mimic human tissue

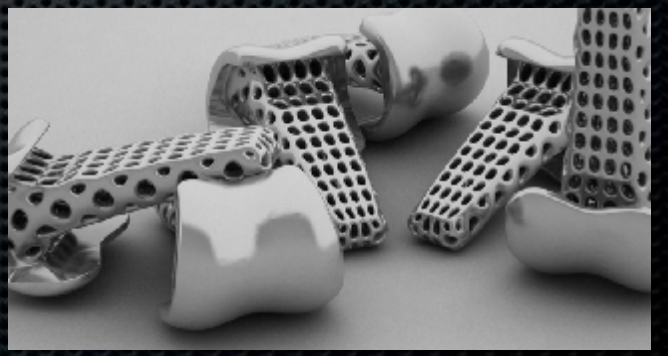
Design to Match Function

- Today's total joint replacements use proven designs that are typically over-engineered for strength to prevent fracture and premature failure
- Problems exist with proper loading of the bone which is crucial to keeping bone healthy and intact and preventing bone loss
- The number one source of failure today is implant loosening, much of which could be attributed to osteolysis (bone loss)

Designs to Match Function

- Tomorrow's designs will be custom-fit, not only to the shape of the patient but, more importantly, to the functional requirements of that patient
- Implants will increase in complexity with structural "solid" elements combined with lattice structures (think aircraft wings)
- Additive manufacturing is a perfect fit for this task, allowing much great flexibility for producing complicated structures





Materials

- Today's implantable metals and plastics either remain intact or dissolve completely over time
- Tomorrow's materials of choice will be those which restore normal human tissues with normal human tissues coming from;
  - Materials that are cultured prior to implantation, or
  - Materials that gradually morph into the tissues they are replacing

Final Thoughts

- Additive manufacturing in medicine is already impacting many tens of thousands of patients a year at this point
- The trend toward personalization of medicine and surgical treatment goes hand-in-hand with AM's core competencies of flexibility, complexity for "free" and relative speed
- Future efforts will push guidance and materials farther
- Automation will make it more cost-effective, opening new markets

Thank you! Questions?

andy@medicalmodeling.com

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