Additive Manufacturing is Changing Surgery

Andy Christensen
Medical Modeling Inc. (Golden, CO)

September 19, 2011
Mountain View, California
Proven Uses of AM
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
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

<table>
<thead>
<tr>
<th>AM Process</th>
<th>Rigid</th>
<th>Flexible</th>
<th>Opaque</th>
<th>Translucent</th>
<th>Full Color</th>
<th>Biocompatible</th>
</tr>
</thead>
<tbody>
<tr>
<td>SLA</td>
<td>X</td>
<td></td>
<td>X</td>
<td>X</td>
<td>X</td>
<td>X*</td>
</tr>
<tr>
<td>SLS</td>
<td>X</td>
<td>X</td>
<td>X</td>
<td>X</td>
<td></td>
<td>X*</td>
</tr>
<tr>
<td>FDM</td>
<td>X</td>
<td></td>
<td></td>
<td>X</td>
<td></td>
<td>X*</td>
</tr>
<tr>
<td>3DP</td>
<td>X</td>
<td></td>
<td></td>
<td></td>
<td>X</td>
<td></td>
</tr>
<tr>
<td>PolyJet</td>
<td>X</td>
<td>X</td>
<td>X</td>
<td>X</td>
<td>X</td>
<td>X*</td>
</tr>
</tbody>
</table>

*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

1. CT Scan
2. Implant Design
3. Design Approval
4. Implant Production
5. Implants Shipped

## CUSTOM FIT OFF-THE-SHELF IMPLANTS

1. CT/MRI Scan
2. Implant Sizing/Positioning
3. Guide Design
4. Guide Production
5. Guide & Standard Implants Shipped

**Personalization of Surgery**
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

Planned
Postop
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 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