Safe Clinical Use of Anatomical Models

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Potential Conflict of Interest

FTE of Materialise NV
Topics of Discussion

- What is the current state of the market?
- Is there risk in using anatomical models?
- What are the operational considerations?
Since 1990

- Developing segmentation and digital CAD software for 3D printing
- 3D printing anatomical models
- PHIDIAS project 1993
How did preoperative planning change the decision?

<table>
<thead>
<tr>
<th>Planning of skin incision</th>
<th>34</th>
</tr>
</thead>
<tbody>
<tr>
<td>To operate or not</td>
<td>66</td>
</tr>
<tr>
<td>General surgical concept</td>
<td>131</td>
</tr>
<tr>
<td>Detail of the surgical concept</td>
<td>167</td>
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<tr>
<td>Composition of the surgical team</td>
<td>77</td>
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<td>Positioning of patient on operating table</td>
<td>22</td>
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<tr>
<td>Selection of osteosynthetic material</td>
<td>94</td>
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<td>Selection of instruments and devices</td>
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<td>Implantation site of osteosynthetic material</td>
<td>108</td>
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<td>Sequence of steps of intervention</td>
<td>121</td>
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</tbody>
</table>

Fig. 3  

Compared to other imaging modalities, the planning model had influence on

<table>
<thead>
<tr>
<th>Little</th>
<th>Average</th>
<th>Heavy</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>4</td>
<td>35</td>
</tr>
<tr>
<td>3</td>
<td>2</td>
<td>94</td>
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<td>8</td>
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<td>17</td>
<td>19</td>
<td>156</td>
</tr>
</tbody>
</table>

Fig. 4  

Phidias Report, 1996
Market perspective

- Trend towards POC 3D printing facilities
- Implementation strategies fragmented
- Funding uncertainty

Hospitals in the U.S. with a centralized 3D printing facility
Using Materialise Mimics technology

Top 5 Medical Disciplines Leveraging 3D Printing Technology
Publications on planning, education and visualization

Is there risk when using anatomical models?
Purpose: We describe state-of-the-art software and hardware requirements for the manufacture of high quality medical models manufactured using medical rapid prototyping. The limitations of medical models, the source of artefacts, and their physical appearance are illustrated along with remedies for their removal.

Materials and Methods: Medical models were built using predominantly stereolithography and fused deposition modeling at both institutions over a period of 6 years. A combined total of 350 models have been produced for a range of maxillofacial, neurosurgical, and orthopedic applications. Stereolithography, fused deposition modeling, computerized numerical milling, and other technologies are described along with computer software requirements.

Results: A range of unwanted artefacts that create distortions on medical models have been identified. These include data import, computed tomography gantry distortion, metal, motion, surface roughness due to support structure removal or surface modeling, and image data thresholding. The source of the artefact has been related to the patient, imaging modality performance, or the modeling technology. Discussion as to the significance of the artefacts on clinical use is provided.

Conclusions: It is recommended that models of human anatomy generated by medical rapid prototyping are subject to rigorous quality assurance at all stages of the manufacturing process. Clinicians should be aware of potential areas for inaccuracies within models and review the source images in cases where model integrity is in doubt.

Operational Considerations

- Image quality and protocol designed for intended use.
- Design for 3D printing. Integrity compromised?
- Equipment risks. Material risks.
- Clear instructions for use.

**Image Acquisition**
- Human factors, variability. Include relevant anatomy?

**Segmentation**
- Case is managed properly.

**Design considerations**
- File prepared appropriately for printer.

**File labeling and fixing**
- 3D Printing

**Cleaning and Inspection**
- Functional deliverable
- Cleaned & Inspected.
Summary

- Anatomical models are useful
- Intended use should drive requirements
- Don’t look at system in isolation
Final thoughts…

- Anatomical models are very low risk when….

- For higher risk devices, use certified manufacturer or implement robust QMS
Thank You!

: 3D Printing in Hospitals
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