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The Clinical and Economic Value of 3D Print Technology for Pre-Surgical Planning

E-Book

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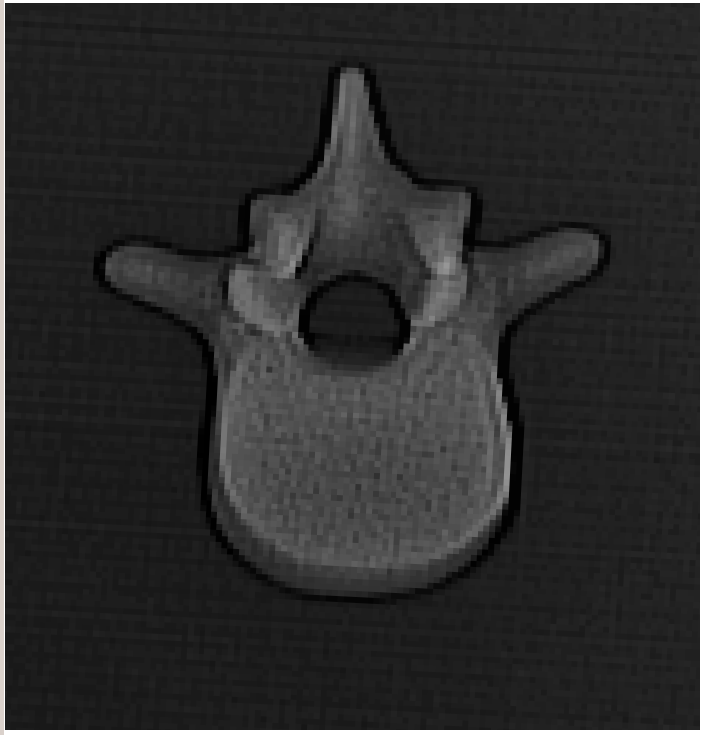


The Need for Advances in Surgical Preparation

Why hospitals are looking to new planning technologies

Medical error has the potential to harm patients and drive up healthcare costs. Technical errors, such as problems in equipment use or in the performance of a procedure, cause many of these reported events.[1]

Experiencing the behavior of native tissue is a crucial part of preparing surgeons to treat patients safely and confidently.

2D images are limited.

- Historically, procedural planning has been mainly performed using two-dimensional models based on CT or MRI data.
    - Advances have allowed for 3D renderings on 2D screens.
- Traditional models are useful for pre-operative visualization, but limited in their ability to depict all aspects of the procedure, including prospective complicating factors.
- 2D models cannot offer tactile interaction with internal structures.

Every patient is unique.

- Advances in technology and the move toward precision health have created greater opportunities for patient-specific care.

Healthcare is shifting to value- and outcome-based measures.

- Relative Value Units (RVUs) are used to determine reimbursement rates for a given service. As patient-specific care becomes increasingly common, reimbursement rates are shifting to reflect value- and outcome-based care.

[1] Grillo, F.W., Souza, V.H., Matsuda, R.H. et al. Patient-specific neurosurgical phantom: assessment of visual quality, accuracy, and scaling effects.

3D Print Technology for Pre-Surgical Planning

Why on-premise 3D anatomical modeling

3D printing has emerged as a revolutionary paradigm shift for helping surgeons and interventionalists perform procedures in a more informed way.[2]

Increasing adoption of medical 3D printing has been driven by a number of factors including lower cost, faster printing with multicolor, multi-material capabilities, interoperability standards, cloud-based workflow management tools, and an increasing commitment from medical societies and regulators who see the positive impact 3D modeling can have on patient care.

Provide comprehensive preparation for surgical procedures.

- With highly the most realistic anatomical models available, you can standardize surgical skills and practice complex procedures before operating to create consistency across the continuum of care.
- The tactile, physical nature of 3D printed models enables clinicians to conduct thorough preoperative preparation.

Standardize delivery of care.

- 3D printing adds a new dimension to understanding patient anatomy.
    - 3D printing, which uses imaging technology to generate a 3D solid object from a digital file, can be used to create highly-detailed, patient-specific models for surgical planning.
    - With 3D printed models, clinicians planning for surgeries are able to engage with fully-realized models capable of displaying complex articulation.
        - Stratasys Digital Anatomy 3D printed models replicate the same biomechanical properties as human tissue to minimize variability in device testing and surgical training, which leads to **more consistent outcomes for patients.**

Add an invaluable tool to your precision medicine arsenal.[3]

- 3D printing will play an increasingly important role in enabling precision medicine.
- In situations where complex pathologies necessitate transforming clinical imaging data into a physical model, 3D printed models are able to follow common clinical standards.
- 3D printing offers differentiated, anatomically precise colors and varied textures within a single model, closely approximating individual patients and surgical cases.

[2] Christensen, A., Rybicki, F.J. Maintaining safety and efficacy for 3D printing in medicine.
[3] Chepelev, L., Wake, N., Ryan, J. et al. Radiological Society of North America (RSNA) 3D printing Special Interest Group (SIG): guidelines for medical 3D printing and appropriateness for clinical scenarios.

Clinical Efficacy and Outcomes

The promise of 3D printing for surgical planning

Across a systematic review of peer-reviewed literature, 3D printing for surgical planning has shown expanding utility for surgical planning applications in a wide range of specialties including cardiothoracic, vascular, orthopedic, cardiac, neuro, surgical oncology, and others.

Enable clinically-significant preparation.

- Hands On Surgical Training (HOST) is the future of medical training.
- A 2021 prospective, andomized study of 31 medical students found that use of a 3D model improved students' ability to retain learned information.[4]
- Positive results from research on the use of 3D printing for critical care supported the hypothesis that the uses of 3D printing are clinically significant in a 2020 narrative literature review.[5]

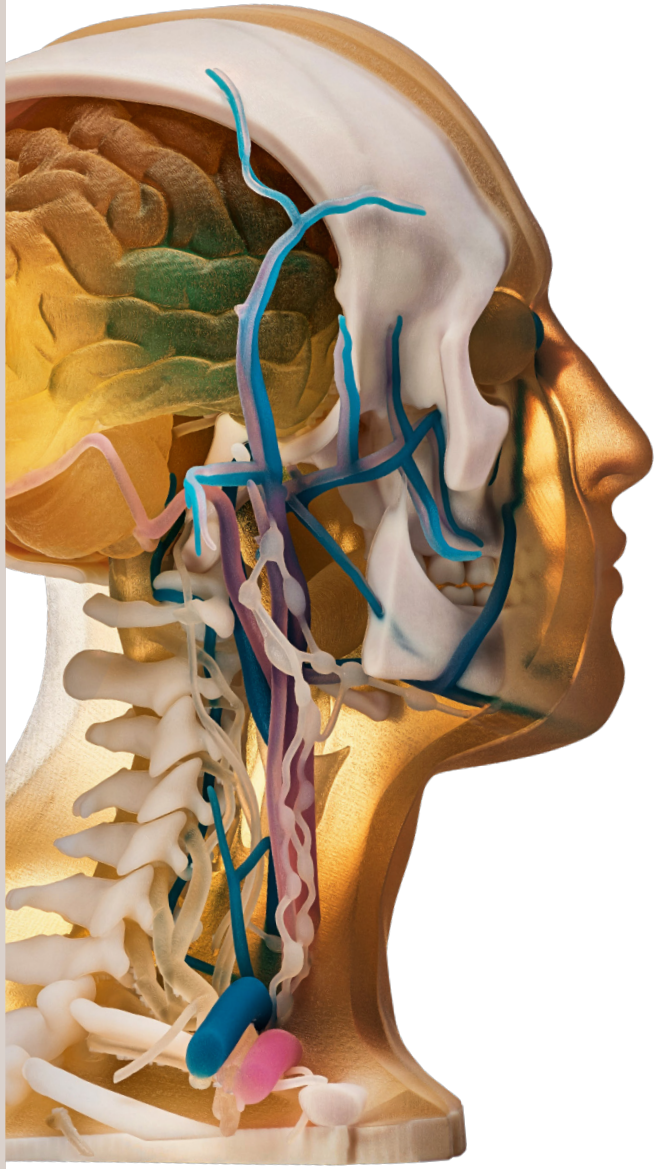
Reduce OR and imaging time.

- Patient-specific 3D printed instruments can reduce OR and intraoperative imaging time, according to a 2020 literature review.[6]

Improve patient education and outcomes.

- A 2019 study surveyed 200 patients on their level of understanding of their disease and surgical plan to treat kidney and prostate cancer.[7]
    - Patients had a greater understanding using 3D printed models versus imaging for all measures including comprehension of disease, cancer size, cancer location, treatment plan, and the comfort level regarding the treatment plan (range 4.60–4.78/5 vs. 4.06–4.49/5, $p < 0.05$).
- A 2023 literature review of 392 articles found that using patient-specific models for case preparation has been shown to:
    - Improve patient safety with reduced time under anesthesia
    - Reduce operating time
    - Decrease recovery time
    - Reduce intraoperative blood loss[8]

[4] O'Brien, C., Souza, C.A., Sheikh, A. et al. Use of tracheobronchial tree 3-dimensional printed model: does it improve trainees' understanding of segmentation anatomy? A prospective study.
[5] Boshra, M., Godbout, J., Perry, J.J. et al. 3D printing in critical care: a narrative review.
[6] Baraza, N., Chapman, C., Zakani, S. et al. 3D - Printed Patient Specific Instrumentation in Corrective Osteotomy of the Femur and Pelvis: A Review of the Literature.
[7] Wake, N., Rosenkrantz, A.B., Huang, R. et al. Patient-specific 3D printed and augmented reality kidney and prostate cancer models: impact on patient education.
[8] Abstracts from the 3dMed Australia Conference 2018.



Make It With Stratasys

3D printing solutions for medical innovation
Visual, Functional and Diagnostic[9] Medical Models

Digital Anatomy™ Printer
Better preparation. Better outcomes.

Digital Anatomy Printer technology creates models that replicate the same biomechanical properties as human tissue to provide the most realistic testing and training.

With highly repeatable, realistic surgical preparation, hospitals can create consistency across the continuum of care—all at a cost reduction of up to 70% compared with fabricated simulators, animals and cadavers.

- 100+ physician-tested, clinically-validated anatomical presets.
- Unique material combinations to create realistic models that vary in softness, flexibility, and density, mimicking native tissue behavior.
- Advanced design tools when you need them to choose from 500,000+ colors, define transparencies, and determine textures and finishes.

Minimize variation in a clinical setting with highly-realistic, lower-risk training. Digital Anatomy 3D printed models give physicians the opportunity to standardize surgical skills and delivery of care by practicing on the most accurate representation of the targeted pathology:

Musculoskeletal: Experience the density properties of human bone.

- A 2020 benchtop study found that Digital Anatomy Printer 3D printed models **accurately mimic bone density characteristics and behave like native bone** when force is applied such as drilling, reaming, or sawing.
- The driving torque and pull out force of screw fixation in the 3D printed bone models demonstrated similar haptic response to human bone.[10]

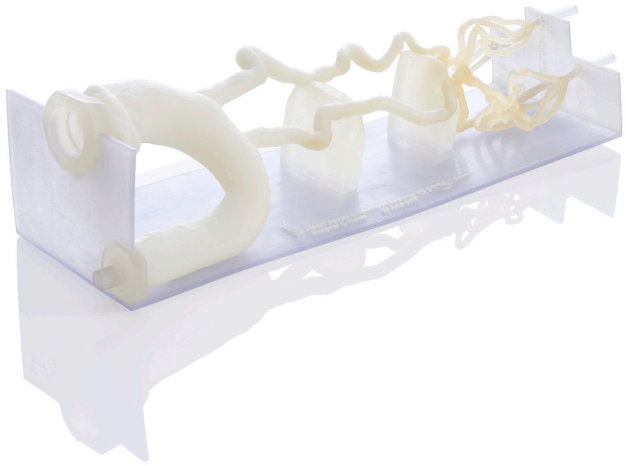
[9] Certified solutions offered with Axial3D, Materialise Mimics and Simple ware Scan IP segmentation software for selected printers and materials.
[10] Dahan, Gal et al. Screw pull-out and driving torque experiments.

Structural heart: Experience the physiological response of native cardiac tissue.

- A study comparing the biomechanical properties of porcine tissue to 3D printed myocardium found that **Digital Anatomy printed models mimic real tissue better than any other material.**[11]
- The 3D printed model demonstrated similar compliance and failure modes as real tissue.

General anatomy: Experience the response of native organ tissue.

- See the accurate biomechanical behavior associated with organ structures and disease states.
- Feel realistic feedback while suturing, cutting, inserting, and deploying devices.
- A 2020 mechanical testing compared the stiffness of synthetic 3D printed liver, epicardium, and aorta models created on using the Digital Anatomy Printer and compared them to porcine tissue. Researchers determined that the Digital Anatomy Printer provides the versatility to mimic the mechanical properties of biological tissue and qualitative haptics.[12]



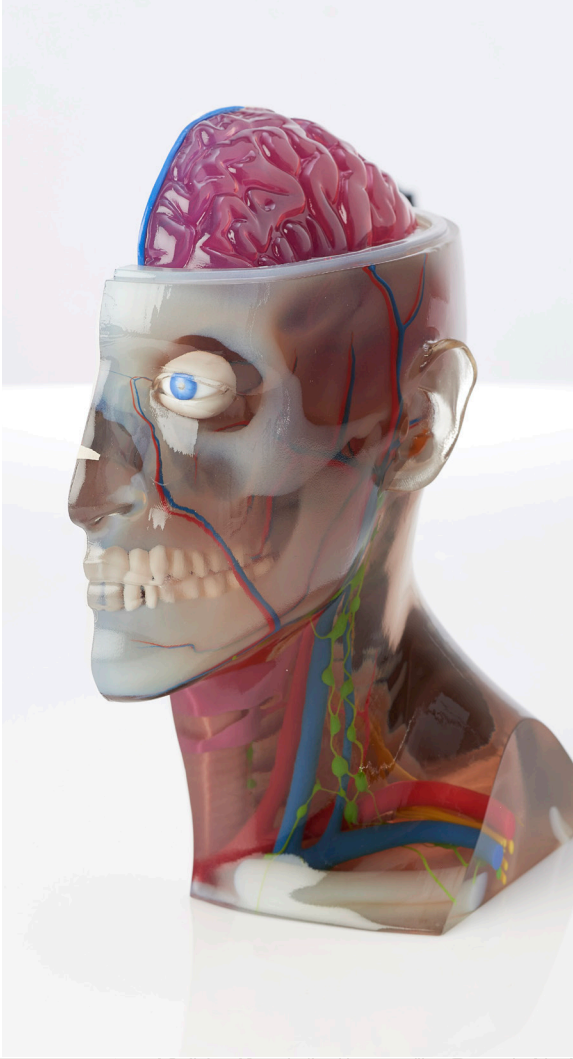
Blood vessel: Experience the arterial elasticity caused by changes in blood pressure and disease.

- 2021 mechanical testing comparing 3D printed aortic, carotid, and coronary artery models to native vessel behavior found that t**he Digital Anatomy Printer can create accurate arterial models.**[13]
  - Aortic, carotid, and coronary arteries were simulated to mimic blood pressure changes at body temperature and measured using IVUS.
  - The study demonstrated that the 3D printed vessels mimicked
    the same biomechanical properties as native vessels.
- In 2021, researchers at the University of Pavia in Pavia, Italy evaluated the performance of blood vessel models printed on the Digital Anatomy Printer, comparing different material combinations to porcine tissue samples. Their research resulted in a new printing preset for suturable vascular models that mimics vessels' mechanical response during suturing.[14]
  - Suturable vessel wall 3D models printed with the Stratasys Digital Anatomy Printer can provide surgeons and researchers biomechanically accurate blood vessel models for realistic treatment planning and training.

[11] Severseike, Leah et al. Polyjet 3D printing of tissue-mimicking materials: How well can 3D printed synthetic myocardium replicate mechanical properties of organic myocardium?
[12] Severseike, L. et al. **PolyJet 3D printing of tissue mimicking materials: An investigation of characteristic properties of 3D printed synthetic tissue.**
[13] Sparks, A.J., Smith, C.M., Allman, A.B. et al. Compliant vascular models 3D printed with the Stratasys J750: a direct characterization of model distensibility using intravascular ultrasound
[14] Marconi, S. et al. **Quantitative assessment of 3D printed blood vessels produced with J750™ Digital Anatomy™ for suture simulation.**

J5 MediJet™

The all-in-one medical printer.



The full color, multi-material medical printer that creates ultra-realistic, biocompatible and sterilizable models. Produce brilliantly vivid anatomy for better planning, education, and testing—all in less time with less handling.

With lower total cost of ownership, MediJet is designed to maximize your investment in 3D printing.

Maximize your investment in 3D printing: With less upfront investment and a lower total cost of ownership, MediJet offers multi-material, full color printing in a single tray to accommodate more 3D printing requests at the same time, with less handling.

Improve treatment decision-making and patient education: Give physicians an invaluable tool to visualize complex anatomy and work with the team on the best approach. Educate patients for more informed consent.

Improve clinical outcomes: Save time and cost, and minimize risks associated with lengthy OR time with patient-specific pre-case planning including 3D printed biocompatible and sterilizable surgical guides*. Print materials are biocompatible and meet sterilization requirements so providers can reference the model during a procedure.

*With approved 3rd party 510k cleared segmentation software.

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