



### Clinical Efficacy and Outcomes

The promise of 3D printing for pre-surgical planning



Personalized medicine is the preeminent focus for providers and hospitals to deliver patient-centered case planning and treatment, and 3D printing has emerged as a functional tool to improve training, enhance presurgical planning, and improve patient putcomes.

3D printing has found its way to multiple applications in various fields of medicine, with each field having come a long way over the recent decades. Overall, the chief advantage of 3D printing is the ability to transform two-dimensional imaging of a patient, once merely viewable on a flat screen, into a tactile 3D visual model that can be handled or a functional model that can be physically manipulated. Clinical applications, which deal with complex anatomical relationships and rely on advanced imaging modalities to make judgments and plan possible interventions, are poised to derive the greatest benefit from advances in 3D printing.

3D medical modeling is being implemented across a variety of specialties and applications, including vascular surgery, cardiovascular surgery, orthopedics, neurosurgery, pediatrics, and many others, because of the technology's ability to provide a safe, accurate environment for pre-surgical planning and training<sup>1</sup>. In fact, a 2021 study found that use of a 3D model improved students' ability to retain learned information.<sup>2</sup>

<sup>1</sup> Meyer-Szary, J. *et al.* The role of 3D printing in planning complex medical procedures and training of medical professionals—cross-sectional multispecialty review <sup>2</sup> 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.

### The Benefits of 3D Printing Across Specialties

#### Impacts on quality outcomes

#### Enable clinically-significant preparation.

• Positive results from research on the use of 3D printing for critical care supported the hypothesis that uses of 3D printing are clinically significant.<sup>3</sup>

#### Reduce operation room and imaging time.

- Patient-specific 3D printed instruments can drastically reduce OR and intraoperative imaging time, according to a 2020 literature review.<sup>4</sup>
- An analysis of 63 cases indicated an average time saving of ~24 minutes in the OR and ~2.8 minutes in intraoperative imaging per patient.

#### 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.<sup>5</sup>
  - 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).
- Use of 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.6



<sup>4</sup> 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.
<sup>5</sup> 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.
<sup>6</sup> Abstracts from the 3dMed Australia Conference 2018.

<sup>&</sup>lt;sup>3</sup> Boshra, M., Godbout, J., Perry, J.J. et al. 3D printing in critical care: a narrative review.

# **Indication-Specific Applications**

Evidence-based effectiveness data

#### Orthopedics

In orthopedics, 3D printing can be used to create bone models and guides for surgical preparation, and provide an opportunity to increase awareness in young residents and medical students about trauma and fractures.<sup>7</sup> 3D printing is ideal for prototyping bones because the calcium in the human skeleton makes scanned images extremely clear, so surgeons can use

the 3D printed bone models for better consultation and assessment ahead of surgeries.8

These anatomical models can provide essential information such as initial condition, sizes, directions, positions, and angulations of the bones and surrounding soft tissues.<sup>9</sup> By preparing for orthopedic operations with 3D models, clinicians can shorten the surgical process and increase operation accuracy and success rate.<sup>10</sup>

Recent advances in orthopedic 3D printing include:

#### Knee joint and ACL (anterior cruciate ligament) repair<sup>11</sup>

The success of ACL repair depends on several surgical parameters, including: graft stiffness, dimensions and pre-tensioning, tunnel placement and orientation, and donor-site morbidity (non-modifiable).

- The study: A 2021 study looked at the potential for creating mechanically accurate knee joints for ACL reconstruction. Researchers created multi-color, multi-material realistic knee joint anatomical models with PolyJet<sup>™</sup> 3D printing technology with a fibers matrix that mimics soft tissue anatomy. This enabled the combination of hard and elastic materials in a single project that reproduced the behavior of strain-stress curves.
- The results: The research found that soft tissue anatomy-mimicking materials are strong enough to withstand stretching during the flexo-extension. 3D models printed with PolyJet technology can be used as an alternative to replacing cadaver specimens for medical training, pre-operative planning, research and education purposes, and predictive models validation.



<sup>&</sup>lt;sup>7</sup> Bizzotto, N., Tami, I., Santucci, A. et al. 3D Printed replica of articular fractures for surgical planning and patient consent: a two years multi-centric experience.

<sup>&</sup>lt;sup>8</sup> Stratasys case study: Cutting costs to the bone: 3D models improve hospital's orthopedic surgeries.

<sup>&</sup>lt;sup>9</sup> Ruiz, O.G., Dhaher, Y. Multi-color and Multi-Material 3D Printing of Knee Joint models.

<sup>&</sup>lt;sup>10</sup> Stratasys case study: Cutting costs to the bone: 3D models improve hospital's orthopedic surgeries.

<sup>11</sup> Ruiz, O.G., Dhaher, Y. Multi-color and Multi-Material 3D Printing of Knee Joint models

# **Indication-Specific Applications**

Evidence-based effectiveness data

#### Hip joint and SCFE (Slipped capital femoral epiphysis) in children<sup>12</sup>

A preliminary study suggests potential direct benefits to SCFE patients, including reduced time under anesthesia, less intraoperative radiation exposure, and increased surgical accuracy.

- **The study:** 3D printed drill guides were designed specific to each surgical plan, with one side shaped to fit the patient's bone and the other side containing holes to guide the surgical drill.
- The results: Researchers concluded that CT-based preoperative planning and intraoperative navigation using individualized drill guides allow for improved accuracy of wires, reduced operative time, and reduced radiation exposure in simulated hips.

#### **Pediatric orthopedics**<sup>13</sup>

The pediatric patient population has considerable variation in anatomy. Compared to conventional methods of performing femoral or pelvic osteotomy, the use of patient-specific instrumentation (PSI) for pediatric orthopedics has led to improved accuracy and precision, decreased procedure times, and decreased intraoperative imaging requirements. Additionally, the technology has become more cost-effective and accessible since its initial inception and use.

<sup>12</sup> Zakani, S., Chapman, C., Saule, A. *et al.* Computer-assisted subcapital correction osteotomy in slipped capital femoral epiphysis using individualized drill templates. <sup>13</sup> 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.

# **Indication-Specific Applications**

Evidence-based effectiveness data

#### **Distal radius** <u>fractures</u><sup>14</sup>

Distal radius fractures are common skeletal injuries that occur at all ages of the general population. These types of fractures are reported as having one of the highest incidences, accounting for over 15% of bone fractures.<sup>15</sup>

- **Study 1:** A 2020 study explored the use of 3D printed braces for fracture treatment.
  - **The results:** The study found that it is possible to treat a dislocated DRF (Distal radius fractures) in the acute setting on day one with a custom-made 3D printed brace, anatomically modeled from a 3D scan of the contralateral wrist.
- Study 2: Traditional casts are described as having poor ventilation and an improper fit. These symptoms associated with conventional casts may cause additional complications, including cutaneous disease, bone and joint injuries, or malunion. A patient-specific, 3D printed cast offers a proper fit to immobilize the injured arm and hold the fracture reduction appropriately.
- The results: Patients express a strong preference for using a 3D-printed cast instead of a plaster cast. A custom-fitted structure reduces the risk of pressure-related complications due to the high and concentrated local stress, and the ventilated and lightweight design minimizes interference with a patient's daily activities and reduces the risk of cutaneous complications.



#### Lower arm osteotomy<sup>16</sup>

3D preoperative planning and 3D-printed patient-specific implants and saw guides are increasingly used during orthopedic procedures. In addition to increasing understanding of complex anatomies, 3D printing for surgical procedures can improve surgical results, and decrease operating time and radiological exposure.

A lower arm osteotomy is one of the orthopedic applications where 3D planning tools and patient-specific saw guides show a significant clinical improvement.

#### Bone defects<sup>17</sup>

- The study: 2019 research looked at the mechanical behavior of 3D printed anisotropic scaffolds as bone analogs by fused deposition modeling (FDM).
- The results: 3D printing technology can easily fabricate complex shapes to match patients' unique defects.<sup>18</sup> Results showed no intra- or postoperative complications, shortened surgery time, and less intraoperative blood loss than historical cases.<sup>19</sup>

- <sup>15</sup> Chen, YJ., Lin, H., Zhang, X. et al. Application of 3D-printed and patient-specific cast for the treatment of distal radius fractures: initial experience.
- <sup>16</sup> Willemsen, K., Ketel, M.H.M., Zijlstra, F. et al. 3D-printed saw guides for lower arm osteotomy, a comparison between a synthetic CT and CT-based workflow.
- <sup>17</sup> Hu, J., Wang, J.H., Wang, R. et al. Analysis of biomechanical behavior of 3D printed mandibular graft with porous scaffold structure

designed by topological optimization.

<sup>&</sup>lt;sup>14</sup> Janzing, H.M.J., Bessems, S.A.M., Ligthart, M.A.P. et al. Treatment of dorsally dislocated distal radius fractures with individualized 3D printed bracing: an exploratory study.

<sup>&</sup>lt;sup>18</sup> Hu, J., Wang, J.H., Wang, R. et al. Analysis of biomechanical behavior of 3D printed mandibular graft with porous scaffold structure designed by topological optimization.

<sup>&</sup>lt;sup>19</sup> Gigi, R., Gorrtzak Y., Golden, E. et al. 3D-printing cutting guides for lower limb deformity correction in the young population.



E-Book

# Indication-Specific Applications

Evidence-based effectiveness data

#### Spine<sup>20</sup>

Competence in spinal procedures is acquired through experience and training, and training using a realistic lumbosacral spine model helps novices acquire the skills and confidence to perform CT-guided spine procedures. New trainees usually learn to perform these procedures through real-time interaction with patients, but this may subject patients to a longer procedure, higher radiation dose, and unnecessary risk.

- **The study:** This study examined the efficacy of using a 3D printed lumbosacral spine phantom to improve trainee proficiency and confidence in CT-guided spine procedures.
  - The results: Training with a realistic 3D printed lumbosacral spine model could help novice trainees acquire the technical proficiency and confidence to perform CT-guided minimally-invasive spine procedures.

#### Orthoses<sup>21</sup>

Creating an orthosis model is a time-consuming process that requires significant CAD experience. This skill gap limits clinicians from applying this technology in fracture treatment.

- The study: A recent study highlighted the feasibility of using a parametric model for the design of 3D printed orthoses, and whether this would be easier for medical personnel to use than the CAD technique.
- The results: Results from this design exercise accurately reflected real-world situations in which an inexperienced user utilizes a generator, and demonstrated the utility of the parametric model approach and strategy for training and interfac

<sup>20</sup> Li, Y., Li, Z., Ammanuel, S. *et al.* Efficacy of using a 3D printed lumbosacral spine phantom in improving trainee proficiency and confidence in CT-guided spine procedures. <sup>21</sup> Li, J., Tanaka, H. Feasibility study applying a parametric model as the design generator for 3D–printed orthosis for fracture immobilization.

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### **Neurosurgery**

Neurosurgery revolves around minute anatomical structures, and when it comes to performing operations on such vital, complex parts of the human anatomy, preparedness and accuracy are critical. Technology that allows clinicians to practice procedures and understand neurovascular structures can make the difference between a successful or unsuccessful surgery.<sup>22</sup>

Given the delicacy of neurovascular operations, clinicians have found the use of custom, patient-specific 3D models "invaluable" in preoperative planning.<sup>23</sup> 3D printed models give neurovascular surgeons a three-dimensional understanding of their patient's anatomical structure, and the high degree of accuracy of 3D printers allows extremely detailed modeling.<sup>24</sup>

#### Recent advances in neurological 3D printing include:

#### Cerebral aneurysms:25

The treatment of cerebral aneurysms requires specialized skill development and proficient use of micro-instruments, and neurosurgical residents are finding it more difficult to obtain experience as the primary operator in aneurysm surgery.

- The study: Researchers successfully created an accurate simulation of a human head with a middle cerebral artery (MCA) aneurysm.
- **The results:** As these models were constructed based on patient medical imaging or cadaver-derived computational 3D models they provided a realistic representation of surgically relevant anatomically accurate features.



<sup>&</sup>lt;sup>22</sup> Stratasys case study: Current and future perspectives in neurosurgical applications.

<sup>&</sup>lt;sup>23</sup> Pacione D. et al. The utility of a multi-material 3D printed model for surgical planning of complex deformity of the skull base and craniovertebral junction.

<sup>&</sup>lt;sup>24</sup> Frölich AM et al. 3D printing of intracranial aneurysms using fused deposition modeling offers highly accurate replications.

<sup>&</sup>lt;sup>25</sup> Nagassa, R.G., McMenamin, P.G., Adams, J.W. *et al.* Advanced 3D printed model of middle cerebral artery aneurysms for neurosurgery simulation.

### **Neurosurgery**

#### **Biocompatible cranioplasty implants:**<sup>26</sup>

Cranioplasty is still one of the most commonly performed neurosurgical procedures worldwide. Extensive cranial defects can occur owing to traumatic injuries, infections, congenital or neoplastic diseases, and decompressive craniectomy (DC). Cranioplasty restores the cosmetic form of the cranium to avoid post-craniectomy complications such as seizures, syndrome of the trephined, and brain herniation through the defect.

- The study: Patient-specific 3D printed custom surgical templates were created.
- **The results:** Systematization of the entire manufacturing process leads to a fast and cost-effective process (approximately \$6,300 dollars per implant vs significantly inflated costs for a high-quality custom template).

#### Alzheimer's disease<sup>27</sup>

Alzheimer's disease prevalence will reach epidemic proportions in coming decades. Currently, in the United States, 5.5 million people are afflicted with Alzheimer's disease, with this number estimated to rise to 15 million by 2050. There is a need for impactful educational materials to help patients, families, medical practitioners, and policy makers understand the nature and impact of the disease.

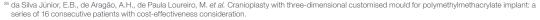
• The study and results: Researchers created effective models of

Alzheimer's brains that can be used in patient education, medical

education, and policy forums.

#### Patient-specific tooling<sup>28</sup>

• The study and results: Clinicians produced custom helmets for a specific and diverse range of applications including scalp radiation therapy, external fixation of facial fractures, orthosis for acrani, and improved aesthetics for cranial defects.



<sup>27</sup> Marks, M., Alexander, A., Matsumoto, J. et al. Creating three dimensional models of Alzheimer's disease.

<sup>28</sup> Pang, S.SY., Fang, E., Chen, K.W. et al. Patient-specific 3D-printed helmet for post-craniectomy defect – a case report.





# Vascular Surgery

To give surgeons the most realistic training, vascular models must replicate how native tissue expands and contracts as pressure is applied. 3D printing has been shown to help understand vascular anatomy and has been used for medical education and procedural training.<sup>29</sup>

3D printing can be used to plan surgeries for patients with planned vascular intervention, including complex and enlarged dissections. 3D printed models have also been shown to aid understanding of complex anatomy, making them useful for planning procedures and increasing operator confidence.<sup>30</sup>

#### Recent advances in vascular 3D printing include:

#### **Carotid Artery Stenting**<sup>31</sup>

Carotid Artery Stenting (CAS) is increasingly being used in selected patients as a minimally-invasive approach to carotid endarterectomy. Outcomes in CAS are heavily dependent on operator training and skill, and attempts by inexperienced surgeons lead to higher complication rates, higher fluoroscopy, increased nephrotoxic contrast volume usage, and longer procedural durations.

- The study: Patient-specific 3D printed anatomies were used to deploy stents in order to improve training and mitigate increased stroke risk in CAS.
- The result: Low-cost 3D modeling provides visual insights in stent deployment and positioning, and can allow for patient-specific procedure planning and enable training on difficult anatomical variations which cannot be observed in animal models.

#### Intracranial vasculature<sup>32</sup>

• The study and results: A 2020 study demonstrated that complex intracranial vasculature 3D modeling is possible.

#### Aortic aneurysms<sup>33</sup>

• The study and results: A 2018 study concluded that a AAA model would be of use in endovascular aneurysm repair planning and education, particularly for practicing placement of hooked or barbed stents, due to the model's balance of flexibility, transparency, robustness and cost-effectiveness.

<sup>&</sup>lt;sup>20</sup> 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.

<sup>30</sup> Ibid.

<sup>&</sup>lt;sup>31</sup> De Backer, P., Allaeys, C., Debbaut, C. et al. Point-of-care 3D printing: a low-cost approach to teaching carotid artery stenting.

<sup>&</sup>lt;sup>22</sup> Cogswell, P.M., Rischall, M.A., Alexander, A.E. et al. Intracranial vasculature 3D printing: review of techniques and manufacturing processes to inform clinical practice.

<sup>33</sup> Chung, M., Radacsi, N., Robert, C. et al. On the optimization of low-cost FDM 3D printers for accurate replication of patient-specific abdominal aortic aneurysm geometry.

# **Cardiovascular Surgery**

3D printed models can also be used to improve surgical planning efficiency and operative outcomes for cardiothoracic surgery. Cardiovascular surgeons have reported increased patient safety and clinician confidence when they practice and plan both routine and relatively novel procedures on 3D printed models.<sup>34</sup>

3D printed models can aid surgeons who are treating adult cardiovascular patients and those who are working on pediatric cases. Reports reflect the advantages of planning with 3D printed models for pediatric patients, who often have attendant fine vasculatures and rare congenital defects.<sup>35, 36</sup>

#### Recent advances in cardiac 3D printing include:

#### Accurate, validated heart models<sup>37</sup>

- The study: Researchers created patient-specific models to determine the utility of 3D printed heart models for pre-procedural planning. Heart models underwent quality assurance testing to establish a standard operating procedure for model verification.
- The results: CT scanning of the 3D printed model allowed end-to-end verification of the entire 3D printing workflow by comparing the final 3D printed model directly to the patient's anatomy in the original DICOM images.

#### Pediatric heart models <sup>38</sup>

- The study: A 2021 study sought to create 3D printed pediatric heart models to limit scanning/radiation exposure in pediatric patients.
- The results: Researchers were able to successfully apply 3D modeling for education and training to pediatric cardiology.

#### Hemodynamically-accurate coronary arteries <sup>39</sup>

- The study: A 2020 study sought to simulate the hemodynamics of coronary disease.
- The results: Through the use of 3DP, researchers were able to create patient specific coronary benchtop models with geometrically accurate coronary arteries with the addition of a compliance chamber and distal coronary artery resistance components simulating the capillary beds.



<sup>&</sup>lt;sup>34</sup> Stratasys white paper: The clinical and economic promise of 3D printing for surgical planning.

<sup>&</sup>lt;sup>35</sup> Valverde I et al. Three-dimensional patient-specific cardiac model for surgical planning in Nikaidoh procedure.

<sup>&</sup>lt;sup>38</sup> Olivieri L.J. et al. Three-dimensional printing of intracardiac defects from three-dimensional echocardiographic images: Feasibility and relative accuracy.

<sup>&</sup>lt;sup>37</sup> Odeh, M., Levin, D., Inziello, J. et al. Methods for verification of 3D printed anatomic model accuracy using cardiac models as an example.

<sup>&</sup>lt;sup>38</sup> Hopfner, C., Jakob, A., Tengler, A. et al. Design and 3D printing of variant pediatric heart models for training based on a single patient scan.

<sup>&</sup>lt;sup>39</sup> Sommer, K.N., Iyer, V., Kumamaru, K.K. et al. Method to simulate distal flow resistance in coronary arteries in 3D printed patient specific coronary models.

# **Surgical Oncology**

Similar to other complex diseases, disease state and treatments can vary drastically between patients with cancer. Surgical management may be necessary for symptom relief or in cases where cosmesis is altered.

In surgical oncology, 3D printing can be used to create replicas of tumors and to depict the extent of disease and relationships of sensitive anatomy. Understanding a patient's unique anatomy and disease progression can reduce operating time, enhance utilization of new treatment techniques, and improve patient outcomes.<sup>40</sup>

#### Recent advances in oncological 3D printing include:

#### Pituitary tumors<sup>41</sup>

- The study: 3D anatomical models of pituitary tumors were successfully created from PET/CT and MRI using four different 3D printing techniques.
  - The results: 3D printing methods can be adopted into routine clinical practice with only a modest investment.

#### Pelvic tumors 42

• The study and results: A 3D-printed model created an accurate reconstruction of the pelvic tumor and traversing nerves for preoperative planning and allowed for efficient and safe surgery.

#### Breast tumors 43

Breast cancer is the most common form of non-cutaneous cancer and the second most common cause of cancer-related deaths. A personalized approach to breast cancer is important as breast cancer is a heterogeneous disease where management is dependent on multiple patient-specific factors.

The goal is to safely remove the tumor with adequate surgical margins and provide good cosmetic outcome without compromising survival. In patients undergoing BCS, negative margin status greatly reduces risk of local recurrence and increases relapse-free survival.

- The study and results: Tumor localization can be optimized as finite information can be provided regarding tumor morphology, shape, and location. This aids with achievement of negative surgical margins.
  - Patient-specific 3D printed breast molds can be used intraoperatively to facilitate the surgeon in shaping the contour and positioning of the autologous tissue by placing the free flap inside the mold in a manner that adapts to the shape of the template.
- 3D printing is poised to revolutionize breast cancer surgery by allowing patient-specific pre-surgical planning and customized intraoperative surgical guides for breast conservation and reconstruction.



41 Orecchia, L., Manfrin, D., Germani, S. et al. Introducing 3D printed models of the upper urinary tract for high-fidelity simulation of retrograde intrarenal surgery.

<sup>42</sup> Fox, Olivia. 3D printed composite model of pelvic osteochondroma and nerve roots.

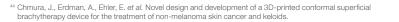
<sup>43</sup> Galstyan, A., Bunker, M.J., Lobo, F. et al. Applications of 3D printing in breast cancer management.

# **Surgical Oncology**

#### Skin tumors<sup>44</sup>

Skin tumors are the most predominant form of cancer in the United States. The treatment of superficial skin cancers on irregular surfaces, such as the nose, lips or ears, present challenges for treatment.

- The study: Researchers created a treatment prototype along with 3D printed models to improve patient-specific treatment for complex sites.
- **The results:** 3D printed models may significantly lower the overall cost of treatment compared to conventional electron therapy.





# **General Anatomy**

3D printed models can be used to create patient-specific models for surgical planning across medical areas. To give surgeons the best preparation for treating patients, 3D replicas must accurately and realistically present anatomical structures. Research reports that 3D printed models meet these criteria.<sup>45</sup>

As the demand for more accurate custom models increases, clinicians are finding that 3D printing offers differentiated, anatomically precise colors and varied textures within a single model, closely approximating individual patients and surgical cases.<sup>46</sup>

#### Recent advances in 3D printing include:

#### ENT (Ear Nose Throat): 47

• The study and results: Researchers successfully created a viable custom 3D printed ossicular prosthesis for conductive hearing loss due to ossicular chain defects.

#### Tissue 48

• The study and results: Researchers demonstrated a successful design, use of 3D printing for component fabrication, integration, characterization, and analysis of initial in vivo collected measurements with excellent performance for a miniature force sensor for the assessment of tissue viscoelastic properties.

#### Prosthetics 49, 50

- The study and results: The use of 3D printing exhibited great potential for the fabrication of functional partial finger prostheses that improve function in amputees.
- The study and results: Numerous custom prostheses and attachments were successfully translated from the research domain to clinical reality, in particular, those that feature the use of computed tomography (CT) reconstructions.



<sup>&</sup>lt;sup>45</sup> Stratasys white paper: 3D printing applications for medical education and training

<sup>&</sup>lt;sup>46</sup> Stratasys white paper: The clinical and economic promise of 3D printing for surgical planning.

<sup>47</sup> Hirsch, J.D., Vincent, R.L. & Eisenman, D.J. Surgical reconstruction of the ossicular chain with custom 3D printed ossicular prosthesis.

<sup>&</sup>lt;sup>48</sup> Kumat, S.S., Shiakolas, P.S. Design, inverted vat photopolymerization 3D printing, and initial characterization of a miniature force sensor for localized in vivo tissue measurements.

<sup>49</sup> Young, K.J., Pierce, J.E. & Zuniga, J.M. Assessment of body-powered 3D printed partial finger prostheses: a case study.

<sup>&</sup>lt;sup>50</sup> Liacouras, P.C., Sahajwalla, D., Beachler, M.D. et al. Using computed tomography and 3D printing to construct custom prosthetics attachments and devices.

### **General Anatomy**

#### Urology 51

• The study and results: 3D printing had a significant impact in urology thanks to the incredible anatomical accuracy of the printed models and the low costs associated. It has been successfully used to improve patient education, pre-operative planning and simulation-based training.

#### Gynecology 52

To minimize the risk of surgical complications and offer the best health outcomes to patients, successful gynecologic surgery requires a thorough understanding of the patient's anatomy and burden of disease.

• The study and results: Clinicians successfully created 3D printed uterine fibroids and endometriosis models.

### **Economic Efficacy and Outcomes**

The promise of 3D printing for surgical planning

In a healthcare environment shifting towards valueand outcome-based care, 3D printed models for surgical planning – with their ability to facilitate procedural efficiency, improve treatment outcomes, and reduce downstream re-intervention costs – offer high potential value.<sup>53</sup>

#### Costs savings per case

A 2020 cost-savings analysis demonstrated a 60 minute mean decrease in surgical time when intraoperative surgical guides or 3D printed models were used for pre-operative planning in maxillofacial surgery. This decrease in operating time translated to a mean savings of \$3,720 USD per case.<sup>54</sup>

### Cost savings for pre-surgical planning compared to other methods

3D printed models can enable training on difficult anatomical variations which cannot be observed in animal models. Procedure-specific-simulation can shorten the learning curve and lead to better patient outcomes. In-hospital 3D-printing services can facilitate the introduction of these training models and give more residents access to training with limited costs.<sup>55</sup>

<sup>55</sup> De Backer, P., Allaeys, C., Debbaut, C. et al. Point-of-care 3D printing: a low-cost approach to teaching carotid artery stenting.



<sup>&</sup>lt;sup>51</sup> Orecchia, L., Manfrin, D., Germani, S. et al. Introducing 3D printed models of the upper urinary tract for high-fidelity simulation of retrograde intrarenal surgery.

<sup>&</sup>lt;sup>62</sup> Flaxman, T.E., Cooke, C.M., Miguel, O.X. et al. A review and guide to creating patient specific 3D printed anatomical models from MRI for benign gynecologic surgery.

<sup>&</sup>lt;sup>53</sup> Stratasys white paper: The clinical and economic promise of 3D printing for surgical planning.

<sup>&</sup>lt;sup>54</sup> De Backer, P., Allaeys, C., Debbaut, C. et al. Point-of-care 3D printing: a low-cost approach to teaching carotid artery stenting.

### References

Abstracts from the 3dMed Australia Conference 2018. 3D Print Med 4, 14 (2018). https://doi.org/10.1186/s41205-018-0036-5.

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. 3D Print Med 6, 34 (2020). <u>https://doi.org/10.1186/s41205-020-00087-0</u>

Boshra, M., Godbout, J., Perry, J.J. et al. 3D printing in critical care: a narrative review. 3D Print Med 6, 28 (2020). <u>https://doi.org/10.1186/s41205-020-00081-6</u>.

Bizzotto, N., Tami, I., Santucci, A. et al. 3D Printed replica of articular fractures for surgical planning and patient consent: a two years multi-centric experience. 3D Print Med 2, 2 (2016). <u>https://doi.org/10.1186/s41205-016-0006-8</u>.

Calvo-Haro, J.A., Pascau, J., Asencio-Pascual, J.M. et al. Point-of-care manufacturing: a single university hospital's initial experience. 3D Print Med 7, 11 (2021). <u>https://doi.org/10.1186/s41205-021-00101-z.</u>

Chen, YJ., Lin, H., Zhang, X. et al. Application of 3D–printed and patient-specific cast for the treatment of distal radius fractures: initial experience. 3D Print Med 3, 11 (2017). <u>https://doi.org/10.1186/s41205-017-0019-y.</u>

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. 3D Print Med 4, 11 (2018). <u>https://doi.org/10.1186/s41205-018-0030-y</u>.

Chmura, J., Erdman, A., Ehler, E. et al. Novel design and development of a 3D-printed conformal superficial brachytherapy device for the treatment of non-melanoma skin cancer and keloids. 3D Print Med 5, 10 (2019). <u>https://doi.org/10.1186/s41205-019-0045-z</u>.

Christensen, A., Rybicki, F.J. Maintaining safety and efficacy for 3D printing in medicine. 3D Print Med 3, 1 (2017). <u>https://doi.org/10.1186/s41205-016-0009-5</u>.

Chung, M., Radacsi, N., Robert, C. et al. On the optimization of low-cost FDM 3D printers for accurate replication of patient-specific abdominal aortic aneurysm geometry. 3D Print Med 4, 2 (2018). <u>https://doi.org/10.1186/s41205-017-0023-2</u>

Cogswell, P.M., Rischall, M.A., Alexander, A.E. et al. Intracranial vasculature 3D printing: review of techniques and manufacturing processes to inform clinical practice. 3D Print Med 6, 18 (2020). https://doi.org/10.1186/s41205-020-00071-8.

da Silva Júnior, E.B., de Aragão, A.H., de Paula Loureiro, M. et al. Cranioplasty with threedimensional customised mould for polymethylmethacrylate implant: a series of 16 consecutive patients with cost-effectiveness consideration. 3D Print Med 7, 4 (2021). <u>https://doi.org/10.1186/</u> <u>s41205-021-00096-7</u>.

De Backer, P., Allaeys, C., Debbaut, C. et al. Point-of-Care 3D Printing: A low-cost approach to teaching carotid artery stenting. 3D Print Med 7, 27 (2021). <u>https://doi.org/10.1186/s41205-021-00119-3</u>.

Dahan, Gal et al., Screw Pull-Out and Driving Torque Experiments. Computational Mechanics and Experimental Biomechanics Lab, Final Report (2020).

Fox, O., Kanawati, A. 3D printed composite model of pelvic osteochondroma and nerve roots. 3D Print Med 7, 31 (2021). <u>https://doi.org/10.1186/s41205-021-00121-9</u>.

Frölich A.M. et al. 3D printing of intracranial aneurysms using fused deposition modeling offers highly accurate replications. AJNR Am J Neuroradiol. 37, 1 (2016). <u>https://doi.org/10.3174/ajnr. A4486</u>.

Galstyan, A., Bunker, M.J., Lobo, F. et al. Applications of 3D printing in breast cancer management. 3D Print Med 7, 6 (2021). https://doi.org/10.1186/s41205-021-00095-8.

Gillett, D., Bashari, W., Senanayake, R. et al. Methods of 3D printing models of pituitary tumors. 3D Print Med 7, 24 (2021). <u>https://doi.org/10.1186/s41205-021-00118-4</u>.

Gigi, R., Gorrtzak Y., Golden, E. et al. 3D-printing cutting guides for lower limb deformity correction in the young population. Ortho Proceedings 103-B, 6 (2021). <u>https://online.boneandjoint.org.uk/doi/abs/10.1302/1358-992X.2021.6.047</u>.

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 Med 4, 3 (2018). <u>https://doi.org/10.1186/s41205-018-0025-8</u>.

Hirsch, J.D., Vincent, R.L. & Eisenman, D.J. Surgical reconstruction of the ossicular chain with custom 3D printed ossicular prosthesis. 3D Print Med 3, 7 (2017). <u>https://doi.org/10.1186/s41205-</u>

### References

#### <u>017-0015-2</u>.

Hopfner, C., Jakob, A., Tengler, A. et al. Design and 3D printing of variant pediatric heart models for training based on a single patient scan. 3D Print Med 7, 25 (2021). <u>https://doi.org/10.1186/s41205-021-00116-6</u>.

Hu, J., Wang, J.H., Wang, R. et al. Analysis of biomechanical behavior of 3D printed mandibular graft with porous scaffold structure designed by topological optimization. 3D Print Med 5, 5 (2019). https://doi.org/10.1186/s41205-019-0042-2.

Janzing, H.M.J., Bessems, S.A.M., Ligthart, M.A.P. et al. Treatment of dorsally dislocated distal radius fractures with individualized 3D printed bracing: an exploratory study. 3D Print Med 6, 22 (2020). <u>https://doi.org/10.1186/s41205-020-00075-4</u>.

Kumat, S.S., Shiakolas, P.S. Design, inverted vat photopolymerization 3D printing, and initial characterization of a miniature force sensor for localized in vivo tissue measurements. 3D Print Med 8, 1 (2022). <u>https://doi.org/10.1186/s41205-021-00128-2</u>.

Li, J., Tanaka, H. Feasibility study applying a parametric model as the design generator for 3D– printed orthosis for fracture immobilization. 3D Print Med 4, 1 (2018). <u>https://doi.org/10.1186/</u> <u>s41205-017-0024-1</u>.

Li, Y., Li, Z., Ammanuel, S. et al. Efficacy of using a 3D printed lumbosacral spine phantom in improving trainee proficiency and confidence in CT-guided spine procedures. 3D Print Med 4, 7 (2018). <u>https://doi.org/10.1186/s41205-018-0031-x</u>

Marks, M., Alexander, A., Matsumoto, J. et al. Creating three dimensional models of Alzheimer's disease. 3D Print Med 3, 13 (2017). <u>https://doi.org/10.1186/s41205-017-0020-5</u>.

Meyer-Szary, Jaroslaw et al. The role of 3D printing in complex medical procedures and training of medical professionals—cross-sectional multispecialty review. Int J. Environ Res 19 (2022). <u>https://doi.org/10.3390/ijerph19063331</u>.

Nagassa, R.G., McMenamin, P.G., Adams, J.W. et al. Advanced 3D printed model of middle cerebral artery aneurysms for neurosurgery simulation. 3D Print Med 5, 11 (2019). <u>https://doi.org/10.1186/s41205-019-0048-9</u>.

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. 3D Print Med 7, 2 (2021). <u>https://doi.org/10.1186/s41205-020-00092-3</u>.

Odeh, M., Levin, D., Inziello, J. et al. Methods for verification of 3D printed anatomic model accuracy using cardiac models as an example. 3D Print Med 5, 6 (2019). <u>https://doi.org/10.1186/s41205-019-0043-1</u>.

Olivieri L. J. et al. Three-dimensional printing of intracardiac defects from three-dimensional echocardiographic images: Feasibility and relative accuracy. J Am Soc Echocardiogr 28, 4 (2015). https://doi.org/10.1016/j.echo.2014.12.016.

Orecchia, L., Manfrin, D., Germani, S. et al. Introducing 3D printed models of the upper urinary tract for high-fidelity simulation of retrograde intrarenal surgery. 3D Print Med 7, 15 (2021). <u>https://doi.org/10.1186/s41205-021-00105-9</u>.

Pang, S.SY., Fang, E., Chen, K.W. et al. Patient-specific 3D-printed helmet for post-craniectomy defect – A case report. 3D Print Med 8, 4 (2022). <u>https://doi.org/10.1186/s41205-022-00131-1</u>.

Pacione D. et al. The utility of a multi-material 3D printed model for surgical planning of complex deformity of the skull base and craniovertebral junction. J Neurosurg 4, 1-4 (2016). <u>https://doi.org/10.3171/2015.12.JNS151936</u>.

Ryan, J., Plasencia, J., Richardson, R. et al. 3D printing for congenital heart disease: a single site's initial three-year experience. 3D Print Med 4, 10 (2018). <u>https://doi.org/10.1186/s41205-018-0033-8</u>.

Rybicki, F.J. The impact of regulation, reimbursement, and research on the value of 3D printing and other 3D procedures in medicine. 3D Print Med 8, 6 (2022). <u>https://doi.org/10.1186/s41205-022-00132-0</u>.

Ruiz, O.G., Dhaher, Y. Multi-color and multi-material 3D printing of knee joint models. 3D Print Med 7, 12 (2021). <u>https://doi.org/10.1186/s41205-021-00100-0</u>.

Severseike, Leah et al. Polyjet 3D printing of tissue-mimicking materials: How well can 3D printed synthetic myocardium replicate mechanical properties of organic myocardium? bioRxiv (2019). https://doi.org/10.1101/825794.

Sommer, K.N., Bhurwani, M.M.S., Tutino, V. et al. Use of patient specific 3D printed neurovascular phantoms to simulate mechanical thrombectomy. 3D Print Med 7, 32 (2021). <u>https://doi.org/10.1186/s41205-021-00122-8</u>.

### References

Sommer, K.N., Iyer, V., Kumamaru, K.K. et al. Method to simulate distal flow resistance in coronary arteries in 3D printed patient specific coronary models. 3D Print Med 6, 19 (2020). <u>https://doi.org/10.1186/s41205-020-00072-7</u>.

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. 3D Print Med 7, 28 (2021). <u>https://doi.org/10.1186/s41205-021-00114-8</u>.

Stratasys case study: Current and future perspectives in neurosurgical applications. (2020) <u>https://</u><u>www.stratasys.com/en/resources/whitepapers/jacobs-institute-neurosurgery</u>.

Stratasys case study: Cutting costs to the bone: 3D models improve hospital's orthopedic surgeries. (2022) <u>https://www.stratasys.com/en/resources/case-studies/prince-of-wales-hospital</u>.

Stratasys white paper: The clinical and economic promise of 3D printing for surgical planning. (2020) <u>https://www.stratasys.com/en/resources/whitepapers/3d-printing-surgical-planning</u>.

Stratasys white paper: 3D printing applications for medical education and training. (2020) <u>https://</u><u>www.stratasys.com/en/resources/whitepapers/3d-printing-clinical-simulation</u>.

Valverde I et al. Three-dimensional patient-specific cardiac model for surgical planning in Nikaidoh procedure. Cardiol Young, 25, 4 (2015). <u>https://doi.org/10.1017/S1047951114000742</u>.

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. 3D Print Med 5, 4 (2019). <u>https://doi.org/10.1186/s41205-019-0041-3</u>.

Willemsen, K., Ketel, M.H.M., Zijlstra, F. et al. 3D-printed saw guides for lower arm osteotomy, a comparison between a synthetic CT and CT-based workflow. 3D Print Med 7, 13 (2021). <u>https://doi.org/10.1186/s41205-021-00103-x</u>.

Young, K.J., Pierce, J.E. & Zuniga, J.M. Assessment of body-powered 3D printed partial finger prostheses: a case study. 3D Print Med 5, 7 (2019). <u>https://doi.org/10.1186/s41205-019-0044-0</u>.

Yoo, SJ., Thabit, O., Kim, E.K. et al. 3D printing in medicine of congenital heart diseases. 3D Print Med 2, 3 (2016). <u>https://doi.org/10.1186/s41205-016-0004-x</u>.

Zakani, S., Chapman, C., Saule, A. et al. Computer-assisted subcapital correction osteotomy in slipped capital femoral epiphysis using individualized drill templates. 3D Print Med 7, 18 (2021). https://doi.org/10.1186/s41205-021-00108-6.

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