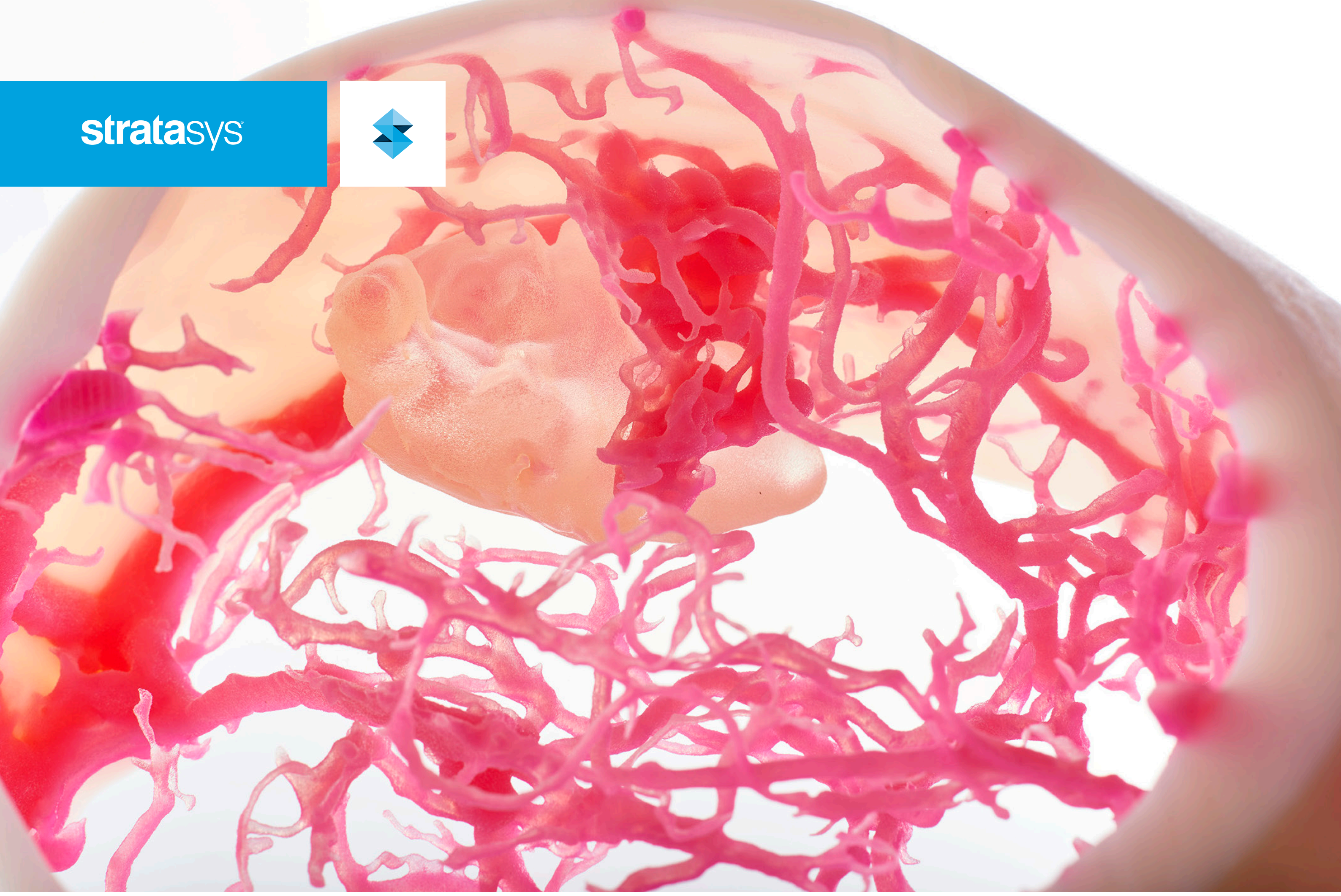

Implementing Preoperative Surgical Planning Using 3D Printing

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This white paper provides information on the elements needed to implement a surgical planning program using 3D printing in a hospital. It integrates examples of how interventionists in the neurovascular, cardiac, and peripheral specialties at Kaleida Health's Gates Vascular Institute (GVI) in Buffalo, NY, are working with engineers at the University at Buffalo's Toshiba Stroke and Vascular Research Center (TSVRC) and the Jacobs Institute (JI), a non-profit medical device innovation center non-profit institution, to use 3D printing to plan for their complex endovascular cases. It will also identify hurdles that might preclude hospitals from using 3D printing in surgical planning and suggest ways of overcoming them. Finally, the white paper identifies the ways 3D printing may improve surgical planning in the future.

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BACKGROUND

Increasingly, physicians and their partners are recognizing the value that 3D printing offers, not only for developing new medical devices, implants, and prosthetics, but also for the creation of patient-specific replicas of bones, organs, and blood vessels. These replicas are made possible through software that converts the patient's own scans such as computerized tomography (CT) and magnetic resonance imaging (MRI) 2D scans into STL files. These files essentially encode each patient's specific anatomic or pathologic features, which then can be fabricated by 3D printers.

Use of special printing materials such as photopolymers that produce both hard and soft materials allow the accurate replication of human tissue, calcification, and bone. Physicians and their teams can use these models to improve the diagnosis of illnesses, elucidate treatment decisions, plan, and, in some cases, even practice selected surgical interventions in advance of the actual treatments. The models help physicians understand patient anatomy that is difficult to visualize, especially when using minimally invasive techniques. Models also assist in accurately sizing medical devices. Finally, physicians can use the models to explain an upcoming surgery to patients and their families and to communicate the surgical steps to the clinical team.

Figure 1: Medical models are used to test the efficacy of an intended procedure before time is spent with the patient in the operating room.

Traditional preoperative surgical planning entails using patient imaging (2D scans), 3D reconstructions of patient scans on a computer, and generic physical models to imagine access routes and how particular medical devices would fit in particular anatomies. Since it is difficult to extrapolate all of the necessary information from these methods, adaptations have to be made on the fly during procedures, which adds a major element of uncertainty (Iyer Stratasys® Blog 2016). The use of 3D printed models mitigates this uncertainty and allows physicians to better anticipate problems prior to performing the procedure.

While the impact of preoperative surgical planning using 3D printed models compared to traditional planning on patient outcomes and cost has not been fully quantified, there is growing evidence that it improves measurement accuracy, reduces the number of wasted devices, decreases

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operative time, and improves understanding of the special relationships between structures (D'Urso PS et al 1999; Zein NN et al 2013; Bryant 2016). There is also evidence that it increases physician confidence using new medical devices and approaching difficult anatomies, and that it allows physicians to identify potential complications ahead of the surgery so they can plan for them (Izzo et al 2016; Kusaka M et al 2015; Iyer Stratasys Blog 2016). A recent critical review of the use of 3D printing for medical education models in transplantation medicine (O'Brien et al 2016) identified 3D printed patient-specific models for preoperative planning as one of the top three themes that emerged from a review of 68 articles. Twenty-eight of these articles highlighted the ways that 3D printing improves preoperative planning in over 15 specialties including cardiac surgery, gastroenterology, maxillofacial, orthopedic, otolaryngology, neurosurgery, urology, and vascular surgery.

Work is underway in several locations to provide quantitative evidence that surgical planning with 3D printed models adds value by saving money and improving patient outcomes compared to traditional surgical planning (Phoenix Children's Hospital in conjunction with Children's Medical Center in Washington, DC and Children's Hospital of Philadelphia; Erlanger Health System with the University of Tennessee College of Medicine Chattanooga in Chattanooga; and Stratasys, with the Jacobs Institute in Buffalo, New York).

CREATING A PREOPERATIVE SURGICAL PLANNING PROGRAM USING 3D PRINTED MODELS

About 75 hospitals in the United States and 200 around the world have access to advanced 3D printers (Storrs 2015). Not all, however, have the expertise and resources to regularly use 3D printing to plan for complex surgical cases. Several elements are important for implementing a full-scale surgical planning program using 3D printed models in a hospital setting. These include physician champions, a culture of clinical innovation, administrative champions, communication pathways, technical capabilities, and financial resources.

Physician Champions

Physician champions are critical for setting up 3D printing programs for surgical planning. They can educate their peers and identify the appropriate cases for which 3D printed models are best suited. Generally, this type of program is optimal for particularly complicated procedures and cases involving new or unfamiliar devices.

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Figure 2: Dr. Vijay Iyer uses a 3D printed heart model to test a mitral valve repair prior to treating the patient.

Physician champions must also educate hospital administrators about the advantages of 3D printing in surgical planning. They are best equipped to weigh the cost of the program versus the benefits of fewer complications, better patient outcomes, decreased OR times, and fewer wasted devices.

At the Gates Vascular Institute in Buffalo, NY, for example, neurosurgeon Adnan Siddiqui, MD, PhD, FACS, FAHA, teamed up with a University at Buffalo (UB) biomedical engineer, Ciprian Ionita, PhD. Together they created lifelike, patient-specific 3D vascular flow models known as phantoms. Dr. Siddiqui was convinced that 3D printing could create more lifelike vascular models than existing glass and silicone models. He further believed that the models could be used to plan for difficult endovascular cases.

Dr. Ionita and his team worked with software teams to simplify the segmentation (Toshiba Vital Images) and modeling (Autodesk Meshmixer) software programs needed to convert CT and MRI scans into files that could be understood by the Stratasys Objet Eden 260™ 3D Printer's program, Objet Studio™. They also developed better methods for cleaning and post-processing the delicate models. Using these tools, they were able to create a replicable process for producing patient-specific vascular flow models that are reproductions of the structure, texture, and fragility of patient vessels for use in preoperative surgical planning.

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Figure 3: Using 3D printed vascular models in a simulated catheterization lab at the Jacobs Institute.

When faced with a difficult case, Dr. Siddiqui sends the patient's CT scan to the JI/TSVRC 3D printing team who produces the model. Dr. Siddiqui is then able to connect the model to a pulsatile flow pump with water circulating in a closed loop. This arrangement allows him to deploy actual devices under fluoroscopy just as if he were in the catheterization lab. Dr. Siddiqui finds that the models allow for better visualization of the anatomy and lead to better device selection and sizing. His colleagues have seen first-hand how the models allow him to select the most appropriate devices and anticipate potential intraoperative complications, so that he is ready for them in the actual surgery (Ionita et al 2014).

"The 3D printed models are far more lifelike than silicone or glass and can capture disparities that even 3D imaging does not, such as vessels that look easy to access, but are not," reports Dr. Siddiqui.

Culture of Clinical Innovation

For a surgical planning program using 3D printing to succeed, other physicians at the hospital have to demonstrate a willingness to consider it for their own difficult cases. As more physicians use it, others will see its advantages. This type of clinical initiative is most common in hospitals that embrace clinical innovation as part of their mission to serve patients. The GVI, for example, includes medical innovation to improve patient care as part of its vision statement. Its multidisciplinary approach to the treatment of vascular disease with all of the vascular specialties working together in one location is indicative of this innovative mind-set, which tends to attract physicians who are open to new ways of doing things.

After seeing Dr. Siddiqui use the models, other vascular specialties became interested in exploring 3D printing's ability to produce more complicated models that mimic the different material properties of tissue and calcification build up. Vijay Iyer, MD, PhD, FACC, FSCAI, an interventional cardiologist specializing in structural heart disease, asked for a patient-specific, multi-material heart model that he could use to plan a difficult and relatively rare transcatheter mitral valve replacement. JI engineers collaborated with TSVRC and Stratasys engineers to create a multi-material 3D structural heart model from the patient's CTA scan and other imaging studies. After attaching the heart model to a cardiac pump, Dr. Iyer was able to deploy a demo valve under fluoroscopy just as he would in the catheterization lab. His practice allowed him to better size the replacement valve and see the effect of its placement on blood flow in the aorta.

Said Dr. Iyer, "The model helped us plan the procedure and allowed us to walk through each step of the procedure ahead of time. We were also able to identify potential risks and bail-out strategies to use, if necessary."

The vascular surgeons were the next group at the GVI to see how patient-specific models could help them practice using new fenestrated endovascular grafts for the first time to treat abdominal aortic aneurysms. They used the patient-specific models, created by the JI, the day before the actual cases. They found that the practice surgery gave them more confidence in their ability to successfully deploy the new devices and allowed them to identify challenging anatomical realities that were not indicated on the patient scans.

Dr. Siddiqui has also found the patient-specific models to be powerful tools for educating clinical staff about upcoming procedures. The staff's increased familiarity with the patient's anatomy and the devices that will be used is a critical element for procedural success. This is particularly true when new medical devices are involved. Dr. Siddiqui emphasizes the ability of the 3D printed models to mimic actual patient anatomy in a way that no other method is able to.

Administrative Champions and Communication Pathways

Given the costs involved in procuring a 3D printer and maintaining supplies, a supportive hospital administration is needed to help everyone understand the future cost savings and the positive clinical impact on patients. Savvy administrators will also recognize the public relations opportunities of 3D printed models for making complex ideas more understandable to the general public and for demonstrating the hospital's innovative nature.

Hospital administrators can also help establish the communication processes needed to alert physicians to the hospital's 3D printing capabilities and to link the different people involved in the process (surgeons, radiologists and radiation technologists, biomedical engineers)

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Figure 4: A patient-specific 3D printed vascular model.

to each other. The JI in Buffalo provides this coordination mechanism between the university and the hospital as part of its mission to foster collaboration. Some hospitals, such as Washington University Medical Center, create their own centralized biomaterials labs with 3D printing capabilities. Other hospitals, such as Children's Hospital in Omaha, have hired 3D printing coordinators who are familiar with imaging and 3D printing to oversee the entire process. The common element among these approaches, whether decentralized or centralized, was that they set up a rigorous, process-oriented approach to ensure 3D printing's value is maximized.

Hospital administrators can also work with their physicians to create criteria to guide the selection of appropriate cases in terms of clinical and economic benefits. Such criteria might include:

- Cases that involve questions about the most appropriate devices or proper device sizing. It is not possible to obtain complete information from 2D scans or even 3D computer reconstructions. The transcatheter mitral valve replacement mentioned above is a good example of this, as the patient scan gave the physician an inaccurate understanding of the dimensions of the native valve.

- Cases involving new devices or devices being used by a doctor for the first time. Even if physicians have been formally trained to use the device, if it is the first time they are using it on a complex case, practicing on a 3D printed model is an extremely useful way to reinforce what was learned.

- Cases with complicated anatomy. Physicians facing this scenario can use models to plan their best access route.

Technical Capabilities and Expertise

Good initial CT or MRI scans are imperative for creating accurate 3D printed models (Pietila AuntMinnie.com 2015). Therefore, good relationships with radiologists and radiation technologists are essential for procuring the best scans for the model application, keeping in mind the way they will be used. Will they be used to simply understand the anatomy of an organ? Or will they be used to practice a complex procedure before performing it on the patient? Different types of scans are needed depending on the intended use.

There are technical capabilities beyond clinical that are needed to use 3D printing in surgical planning. While the ideal state would be to have CT and MRI machines that could automatically convert scans into files that are understood by the 3D printer, two separate software programs are necessary: one for segmentation and one for modeling. Engineering expertise including image organization, computer modeling and image processing, coupled with anatomical knowledge, are required for this conversion process and for the 3D printing and post-processing steps.

Additional clinical expertise is needed to construct the simulation experience. For instance, in an endovascular case, the surgeon and the surgical team must include a lab tech to prepare the devices and a radiological technician to run the fluoroscopy. At the JI, the training center offers surgical teams the opportunity to practice in a simulated catheterization lab.

Resources

Using 3D printing in surgical planning is expensive from the perspective of human capital, equipment and supplies. However, there are tradeoffs that can be made depending on how the models will be used. There are a number of conversion software options available. They differ in terms of:

- Cost (free, open source to expensive proprietary options)
- User friendliness
- Regulatory status (510K FDA approval)
- Capabilities (STL-to-DICOM imaging)

There are a number of choices for 3D printers as well. These include FDM®, PolyJet™ (UV light-cured liquid resin), laser sintering (powder), stereolithography (lasered liquid resin), and binder jetting. The choice of printer is critical and needs to be determined within the context of the desired outputs. The model's final use determines the required resolution and color. Another consideration is the required material properties, including physical robustness and tactile representation. Other aspects include speed of printing, available space and cost (Pietila 2015).

While a simple desktop printer can be purchased for under $1,000, a high-quality, full-featured 3D printer ranges from $200,000 to $850,000. Software costs range from free to up to $16,000 per year, per license. Supplies cost about $1,000 per cartridge. A typical neurovascular flow model

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requires two to tent hours of engineering time for model design, eight hours for printing, and three hours for post-processing.

Any medical devices and supplies used in the practice simulation are non-reimbursable and the involvement of health care team members is an uncovered cost.

HURDLES FACED ALONG THE WAY AND WAYS OF OVERCOMING THEM

The greatest hurdle to creating a preoperative surgical planning program using 3D printed models is the lack of all prerequisites, which realistically exist only in large university teaching hospitals with access to other academic departments, including engineering. This does not mean, however, that only hospitals with 100 percent of these prerequisites can use 3D printed models for surgical planning. As mentioned previously, centers have organized their programs in a number of different ways.

The absolute minimum prerequisites include physicians who want to try this type of preoperative surgical planning, some financial resources (hospital funds, grants or industry support until CMS reimbursement becomes

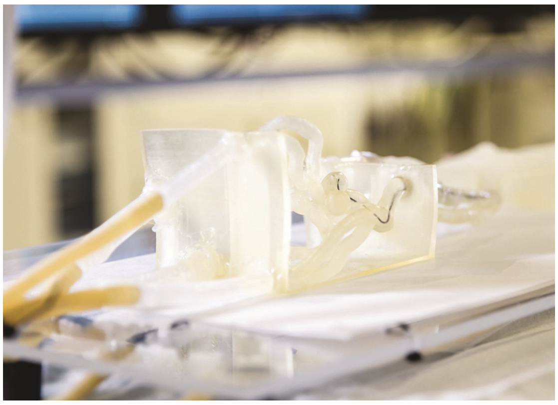

Figure 5: Testing a neurovascular procedure using a 3D printed model.

available to cover the costs) and a 3D printing partner to convert patient scans to 3D printed models. For example, when the JI first started making more complex multi-material models, it would send the STL files to Stratasys Direct Manufacturing for printing on an as-needed basis. Eventually, it was able to leverage a grant from a local foundation to secure its own multi-material 3D printer in a partnership arrangement with Stratasys.

The JI also works closely with a medical device manufacturer who makes the grafts used to treat aortic aneurysms that allow a surgeon to plan and practice a new procedure on a patient-specific model the day prior to performing the actual case. The industry partner provides a trainer and the demo devices and accessories needed for the procedure, the surgeon donates his/her time to do the preoperative planning, and the JI provides the human and capital resources to print the model

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and execute the planning session in its simulated catheterization lab.

Another hurdle is the relatively long time it takes to produce models, making them less relevant to more urgent cases. The model pictured in Figure 6 took 8 hours to print, not including the engineering time for design and post-processing. Streamlining the model request process increases efficiency, but improvements in technology are still needed.

Using 3D printing for surgical planning includes a technical learning curve, even for experienced engineers, to obtain the optimal model design. They need to learn about the best location for support structure, how the flow loop design affects blood flow patterns, and the different material choices for complex anatomical structures. While a certain amount of trial and error and self-learning is needed, it is helpful for engineers using 3D printing for the first time to receive at least a week of on-the-job training from more experienced engineers.

Figure 6: A 3D printed neurovascular flow model.

FUTURE DIRECTIONS FOR PREOPERATIVE SURGICAL PLANNING

While 3D printed models already contribute to better preoperative surgical planning, there is room for additional advances. More experience using different resins in the same print job will allow engineers to mimic disease states with more accuracy. The JI is experimenting with patient-specific vascular models that include a patient's plaque buildup. In the future, new materials will allow engineers to mimic tissue and vessel biomechanical properties, thereby making them even more lifelike.

As mentioned, there is also quite a bit of room for improvement to streamline the process of image creation and conversion into a file understood by the 3D printer, as well as print time reduction. Both improvements are necessary if 3D models are ever going to be useful in treating emergency cases.

Another pressing need is the assemblage of clinical and financial evidence that 3D printing for surgical planning reduces cost and contributes to improved patient outcomes. This evidence is needed to encourage more hospitals to use 3D printing and to convince the Centers for Medicare Services that the associated costs should be

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reimbursable. Several such studies are underway and their results will be watched closely.

CONCLUSION

There are numerous elements—clinical, technical, and administrative—that are required to create and implement a successful surgical planning program using 3D printing. Perhaps the single most important factor is a culture of innovation and collaboration. Hospital clinicians and administrators must be committed to trying unique approaches to benefit their patients. Innovation breeds collaboration among disciplines, pairing surgical expertise with engineering ingenuity. Similarly, hospital administrative support can

bolster communication about the program, both internally to gain traction among clinicians and externally with the public to understand how 3D printing impacts care.

Although there is an up-front and ongoing expense associated with a 3D printing-based surgical planning program, creative partnerships can help defray the cost. And clinicians can provide data to hospital administrators citing the patient benefit versus the cost to support the implementation and maintenance of the program.

Figure 7: Teresa Flint holds a model of her own vascular anatomy used in preparation to successfully treat her aneurysm.

Finally, more advances are still to be achieved in the application of 3D printing, the technical process of creating models, and the assemblage of additional clinical data on a hospital's bottom line impact. Surgical planning requires a commitment to innovation and is achievable by those institutions devoted to making it a success.

About The Jacobs Institute

The Jacobs Institute is a non-profit organization whose purpose is to improve treatments of vascular diseases and ultimately, improve patient outcomes using multidisciplinary approaches to community outreach, medical education, and product development. Together with its partners, the University at Buffalo's Toshiba Stroke and Vascular Research Center, and Kaleida Health's Gates Vascular Institute, the Jacobs Institute has been using 3D printing technology for the past three years to improve patient outcomes. This is achieved by:

- Enhancing pre-procedure surgical planning using 3D printed patient-specific vascular models
- Improving the skills of medical staff with hands-on simulation opportunities on the vascular models
- Helping industry engineers design better devices with hands-on simulation opportunities using their own devices and those of their competitors
- Accelerating the development of more effective tools and treatments by rapidly creating device prototypes to assess against user needs

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