



Case Series: The Use of 3D Printed Models to Plan Complex Endovascular AAA Repair Procedures

The Jacobs Institute

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The model provides me with additional anatomical information that imaging studies alone do not and allows me to identify potential complications, so I can plan and be ready for them in the actual case. Finally, it allows me to test the feasibility of an endovascular versus a surgical approach in a patient with arterial stenosis and/or vessel tortuosity.”

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Summary

Abdominal aortic aneurysm (AAA) is a common clinical condition that poses a considerable threat to patients’ lives (1, 2). As recently as 2001, over two-thirds of AAA repairs were performed using open repair, whereby patients’ abdomens were surgically opened, increasing risk (3). However, over the last two decades, catheter-based minimally invasive interventions, such as endovascular aortic aneurysm repair (EVAR), have rapidly become a mainstay of treatment for AAAs requiring operative intervention (4, 5, 6). EVAR demands a high-level of technical-competency requiring a shift in approach for training vascular surgeons (7, 8). Supervised training with progressive exposure to the

procedure has traditionally been the norm (7). As in aviation and in virtually all other professions that are based on technical skills, “learning by doing” training philosophy that leaves the learning curve on the patient’s side alone is no longer acceptable. We recently instituted procedural training involving 3D patient-specific models and X-ray guided vascular simulation surgery (SS) to shorten the learning curve and avoid patient exposure to unnecessary procedural risks. Here, we share the Jacobs Institute’s experience using 3D printed models to help surgeons plan for five challenging AAA cases at Kaleida Health’s Gates Vascular Institute. The models helped increase their self-confidence in performing the actual surgery.

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All five patients presented with a juxtarenal abdominal aortic aneurysm (JAAA), an anatomical complexity characterized by a short proximal neck - less than 10 mm of normal aorta between the renal artery takeoff and aneurysm sac. This anomaly makes it impossible to secure a series of modular synthetic tubes with metal mesh supports to the vessel proximal and distal to the aneurysm sac to create a new “pipe” as is done in the standard EVAR procedure, preventing further growth and subsequent aneurysm rupture.

Therefore, a more technically challenging fenestrated endovascular aortic repair (FEVAR) procedure was required. A graft with small cut outs for the renal arteries and the superior mesenteric artery (SMA) allow graft-vessel apposition at the proximal aneurysm neck, a type of placement not possible with standard EVAR grafts. As the takeoff angle and offset height of the renal arteries and SMA vary from patient to patient, the grafts were custom-designed and manufactured for each case based on diagnostic computed tomography angiogram (CTA) imaging. Small stents were placed from the graft through the fenestrations into each visceral artery to keep it open.

FEVAR cases are challenging because both CT scans and CT three-dimensional reconstruction are difficult to interpret and may not present the precise anatomical geometry of the aorta. This makes exact fit and positioning of the graft to allow cannulation of the aortic branches, which is critical to the success of the procedure, difficult to achieve (7,8). In addition, fenestrated stent grafts have a complex deployment process including: 1) critical image guided placement and deployment to ensure the fenestrations open to three major branching arteries of the abdominal aorta, 2) concurrent control of multiple catheter systems from up to three arterial access points, and 3) coordinating overlap of five or six modular stent grafts to achieve a leak-proof

system and to avoid the possibility of endoleak, a major complication, requiring further surgical intervention.

To overcome these challenges, patient-specific 3D printed models were used to enable greater direct visibility of the aneurysm and to understand the spatial relations between the aorta, its branches and visceral arteries. In addition, the patient-specific models allowed: 1) visualization and acclimation to the unique FEVAR graft orientation techniques via radiopaque markers, 2) practice of modular endograft placement under fluoroscopy guided intervention, 3) rehearsal and refinement of concurrent handling of the modular grafts and accessory devices, and 4) identification of potential failure modes in a risk-free clinical simulation. In summary, the patient-specific models were successfully used to make and refine patient-specific grafts, to identify patient-specific challenges, to make optimal surgical plans for challenge cases, and to practice and refine the surgical approach in a risk-free environment.

Future studies are planned to quantify the benefits of training with the vascular simulation model utilizing patient-specific models, namely operating room time savings along with reductions in fluoroscopy time and volume of contrast used.

This case series will explain how physicians at the Gates Vascular Institute (GVI), a vascular hospital in Buffalo, New York, are using patient-specific 3D printed models as part of an EVAR simulation system produced by the Jacobs Institute (JI), a medical device innovation center associated with the hospital, to improve patient care through adjunctive procedure training and pre-surgical planning.

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Natural History and Treatment of Juxtarenal Abdominal Aortic Aneurysms

AAAs are areas on the walls of the aortic artery, the main artery carrying oxygenated blood from the heart to vital organs in the body, which have become weakened and bulge out. In some cases, AAAs are at risk of rupture, which leads to bleeding and often death. About 10,000 people die per year from aortic aneurysm rupture.

When an aneurysm is growing rapidly or is causing symptoms, open or endovascular surgery may be performed electively to repair it before rupture can occur. Open surgical repair of aortic aneurysms involves the replacement of a portion of the weak and bulging vessel with a graft made of a synthetic material. More recently, a minimally invasive endovascular approach that uses patients' vessels as conduits to the area of interest has become available. In an EVAR procedure (Figure 1), the physician deploys catheters and guidewires under X-ray guidance through the patient's femoral and iliac arteries to the aortic aneurysm. Once there, the physician is able to send up a collapsed graft through the catheters and expand it against the offending vessel wall causing blood to bypass the aneurysm.

When an abdominal aneurysm is near the visceral vessels, it is called a juxtarenal abdominal aortic aneurysm (JAAA). With JAAs, the placement of an aortic graft may cut off the flow of blood to these vessels, so fenestrated endovascular aortic repair (FEVAR) is used. In this procedure (Figure 2), a patient-specific aortic graft is produced that has small fenestrations (windows) where the patient's superior mesenteric artery (SMA) and renal arteries branch off from the aorta. Small stents are placed from the graft through the fenestrations into each visceral artery to keep them open.

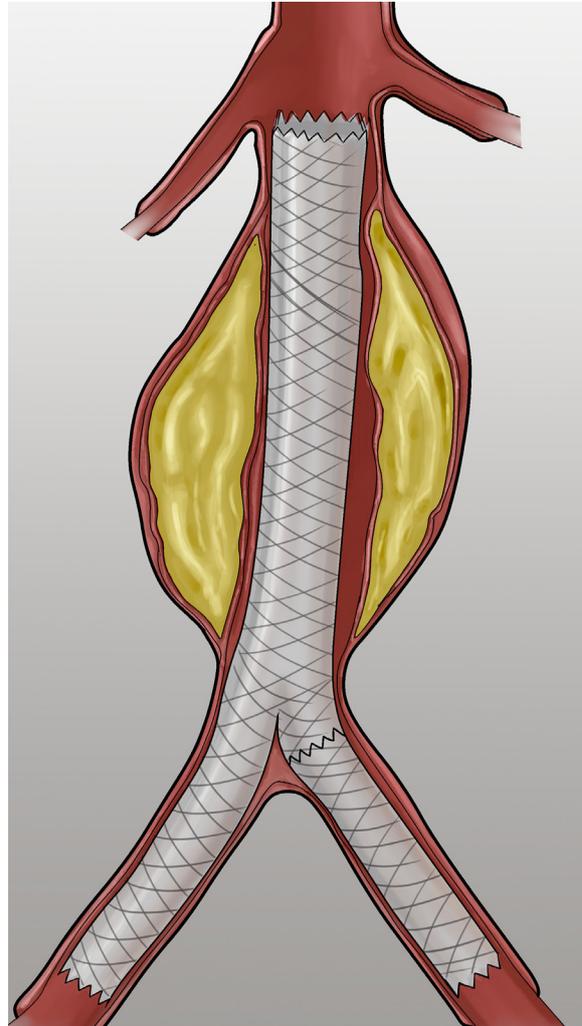


Figure 1. Endovascular Aortic Repair (EVAR).

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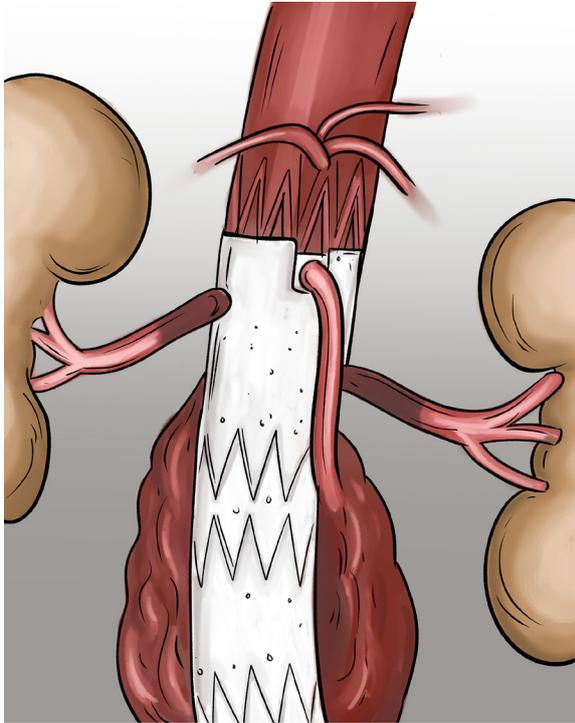


Figure 2. Example of fenestrated graft placement.

In cases where it is not possible to perform a FEVAR because of anatomical challenges such as stenosis in the visceral arteries, a snorkeling technique is sometimes used. This technique involves the off-label use of an aortic graft and smaller branch stents. The distal ends of the stents are placed within the vessel and the proximal ends extend into the aorta alongside the aortic graft (Figure 3) allowing the kidneys and intestines to receive blood.

Patient-Specific 3D Printed Models for Hands-On Training and Surgical Planning

These AAA cases are challenging because both CT scans and CT three-dimensional reconstruction are difficult to interpret and may not present the precise anatomical geometry of the aorta, making exact fit and positioning of the graft, critical to the success of the procedure,

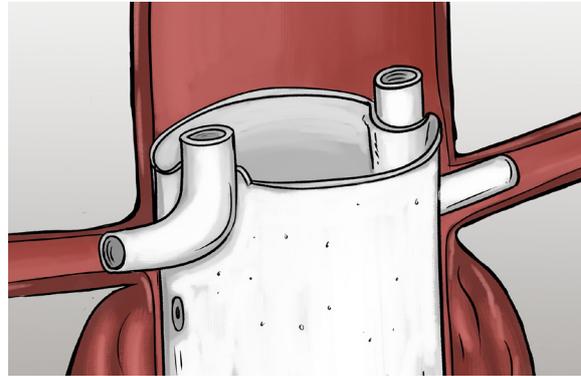


Figure 3. Example of two-vessel (left and right renal arteries) snorkeling procedure.

difficult to achieve. Moreover, there are a large number of devices employed concurrently in AAA repair procedures and surgeons must become familiar with unique graft orientation techniques for optimal surgical outcome.

To overcome these challenges, patient-specific 3D printed models have been utilized in a number of centers to enable greater direct visibility of the aneurysm and to understand the spatial relations between the aorta, its branches and visceral arteries. The models have successfully been used for additional hands-on training for physicians as an adjunct to traditional training delivered by medical device manufacturers (MDMs).

This use of 3D models may result in avoiding peri-procedural complications and extra time spent on device learning during the actual procedure. Shorter procedures reduce radiation exposure to the patient and staff, decrease anesthesia and contrast agent exposure to the patient, and reduce procedure time by avoiding “on the fly treatment changes.” Carrying out the procedure on a 3D printed patient-specific model prior to the actual surgery allows the surgeon to identify potential failure modes in a risk-free clinical environment, develop strategies for dealing with the failure modes should they

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occur during the actual procedure, and test the feasibility of endovascular solutions for patients with complicating factors such as stenosis and vessel tortuosity prior to the actual surgery (7, 8).

Four recent publications highlight the benefits of the use of 3D printed patient-specific models in AAA. [Click here](#) to read a summary of these articles.

Five Simulated AAA Repair Cases at the Jacobs Institute

Between March 2016 and October 2017, three vascular surgeons at the GVI used patient-specific 3D printed vascular models produced

by the Jacobs Institute for five cases to gain additional hands-on training and to plan for complex AAA repair procedures (Table 1). For the first three cases, the physicians had both training and surgical planning objectives, as it was the first time each of them was going to do a FEVAR case following their training by the MDM. The last two cases were focused on determining the feasibility of the planned procedure, as the cases involved complicating factors that made it unclear if endovascular repair of the aneurysms would be possible.

| Case Descriptions & Simulation Summary | | | | | |
|---|---|---|---|---|---|
| | Case One March 2016 | Case Two June 2016 | Case Three August 2016 | Case Four August 2017 | Case Five October 2017 |
| Patient | 65-year-old male diagnosed with a juxtarenal abdominal aortic aneurysm (JAAA) | 54-year-old male JAAA | 79-year-old male JAAA | 73-year-old female diagnosed with a JAAA and severe stenosis in her visceral arteries | 79-year-old female JAAA |
| Objectives of 3D printed model sessions | Hands-on practice and procedure planning | Hands-on practice and procedure planning | Hands-on practice and procedure planning | Procedure planning (Feasibility of endovascular snorkeling technique) | Procedure planning (Feasibility of endovascular repair) |
| Scan Identification | Jl Biomedical Engineer | Jl Biomedical Engineer | Jl Biomedical Engineer | Jl Biomedical Engineer | Jl Biomedical Engineer |
| Segmentation Software | Vitrea & VMTK | VMTK | VMTK | VMTK Lab | Materialise Mimics |
| Clean Up Software | AutoDesk Mesh Mixer | AutoDesk Mesh Mixer | AutoDesk Mesh Mixer | AutoDesk Mesh Mixer | AutoDesk Mesh Mixer |
| Model Verification Software | CloudCompare | NA | NA | CloudCompare | CloudCompare |
| Printer | Eden260V™ | Objet500 Connex3™ | Objet500 Connex3 | Objet500 Connex3 | Objet500 Connex3 |
| Material | TangoPlus | TangoPlus™ | TangoPlus | Agilus30™ Clear | Agilus30 Clear |
| Post Processing | Waterjet & internal lumen flushing with catheters | Waterjet & internal lumen flushing with catheters | Waterjet & internal lumen flushing with catheters | Waterjet & internal lumen flushing with catheters | Waterjet & internal lumen flushing with catheters |

Table 1. Case Descriptions & Simulation Summary

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The training and planning objectives of the individual sessions can be categorized further into the following sub-objectives (9):

- Training Objectives
 - To visualize and acclimate the physician to the unique FEVAR graft orientation techniques
 - To practice endograft placement under fluoroscopy-guided intervention
 - To rehearse and refine concurrent handling of the modular grafts and accessory devices
- Planning Objectives
 - To identify potential failure modes in a risk-free clinical simulation
 - To test the feasibility of endovascular solutions on a patient with complicating factors such as stenosis and vessel tortuosity
 - To identify the actual instruments to be used in the case and to select optimal graft size

Cases One Through Three

The three vascular surgeons used patient-specific 3D printed AAA models to practice for their first FEVAR procedures. They performed the procedures on the models one to two days prior to the actual procedures after having received traditional training within the previous several months. The patients were all diagnosed with JAAs and deemed to be suitable candidates for FEVAR treatment.

Diagnostic CTA imaging, originally ordered for design of the patient-specific FEVAR grafts by Cook Medical, was used by the Jacobs Institute's biomedical engineers to design and fabricate patient-specific 3D printed models. Using segmentation software, the vessels,

calcifications, and thrombus were extracted from the patient's CT scans and turned into stereolithographic files. With a program called AutoDesk MeshMixer, image artifacts were removed and the anatomies of interest were cleaned up. Inflows and outflows were built into the models for functionality. These modifications allow the models to be hooked up to pulsatile pumps simulating blood flow. This is an important feature because it results in physiologic pressure and natural device behavior. The STL files were then exported to the Stratasys Eden260V 3D printer for the first case and to the Objet500 Connex3 printer for the second and third cases, where they were printed in TangoPlus photopolymer, an elastic material similar in feel to human arteries. For a detailed description of the segmentation and smoothing processes refer to reference 10.

Due to the print tray size of the Eden260V, the AAA model for the first case was printed in pieces and then glued together to create the closed loop system. The much larger print tray of the Objet500 Connex3 printer allowed the subsequent models to be printed in one piece with bases for anatomical orientation.

Post-processing of the models involved using a waterjet and catheters to flush support materials out of the lumens of the vessels. An ultrasound gel was used to fill the thrombus chambers to mimic the grainy material found inside aortic aneurysms.

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The mock procedures were performed under fluoroscopic guidance in a clinical training lab. To simulate blood flow, the models were connected to a Harvard Apparatus cardiac pulsatile pump which drew from a water bath heated to body temperature. The clinical setup is shown in Figure 4.

All devices were inserted and deployed the same way they would be in actual surgical procedures (Figure 5). Wires and catheters were used to

gain access to the visceral arteries. The FEVAR endograft was oriented and deployed in the AAA followed by stents through the endograft into the visceral arteries. To complete the new “tubing,” a bifurcated graft connected the FEVAR endograft to two iliac endografts for a complete re-build of the abdominal aorta, bypassing flow to the AAA.

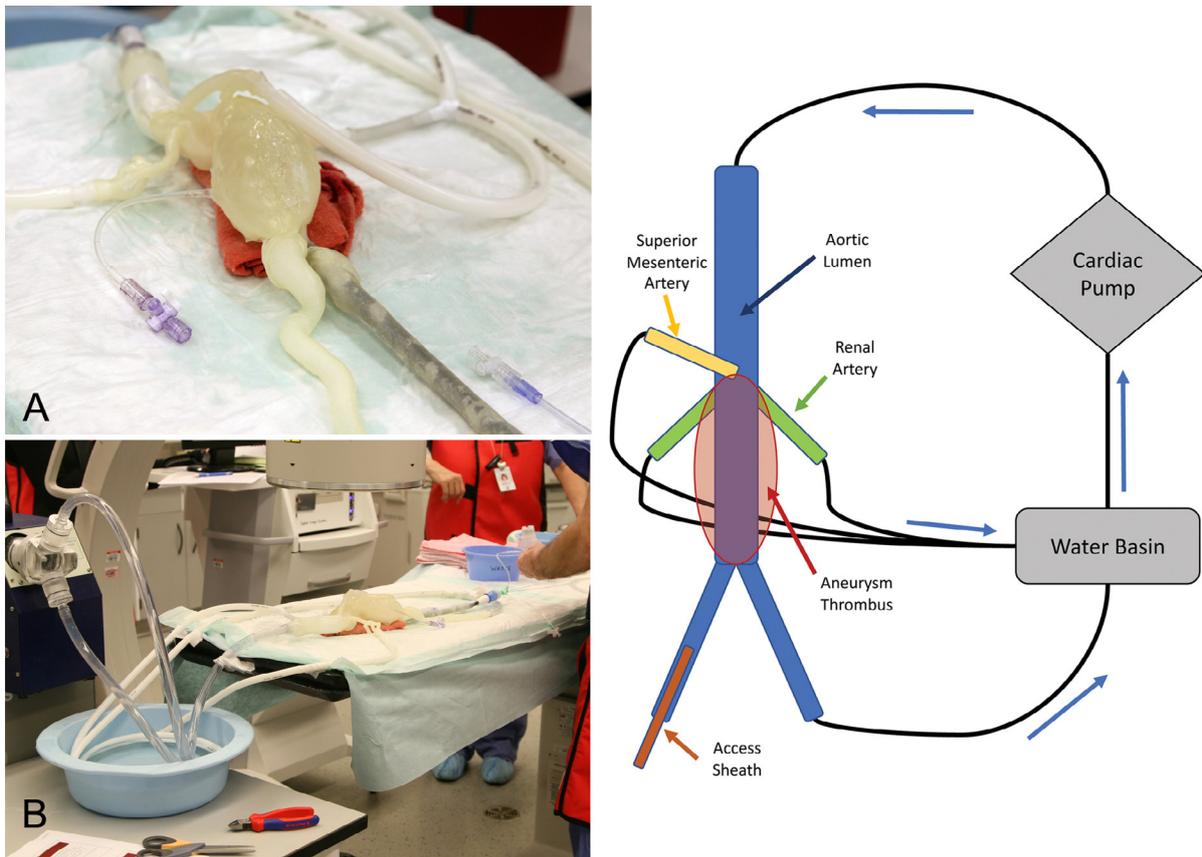


Figure 4. Experimental 3D printed flow model set up: Clinical simulation system design including: (a) assembled AAA phantom within the flow loop system, (b) simulation catheterization laboratory setup including cardiac pump, fluoroscopic imaging system, and clinical staff manipulating devices through the introducer sheath entry to the AAA phantom. System diagram, on right, depicts the fluid recirculation system into the abdominal aorta with outflows from the renal arteries, SMA, and iliac artery (9).

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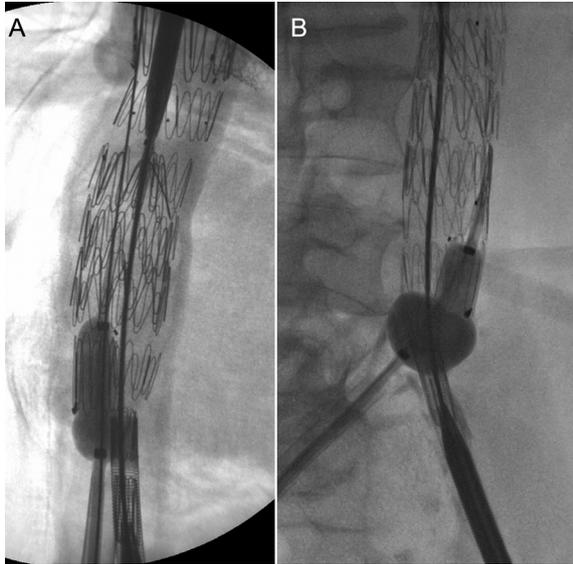


Figure 5. Coda balloons in model and in patient.

The simulation allowed for better sizing of the catheters and stents selected for use. The models were transparent, but not optically clear. Color was used in the second case to show areas of calcification. In terms of accuracy vis-à-vis the actual patient's anatomy, CloudCompare was used in the first case to compare the actual patient scans to those obtained from the model under fluoroscopy.

The physician feedback indicated that they felt more confident going into their first FEVAR cases and more prepared for potential complications after having performed the procedural simulations in the patient-specific models. They also reported that the 3D models revealed anatomical anomalies that were not apparent in the 2D imaging. As CTA scans had only coronal and axial views, there were vessel curves and distances that could not be appreciated. The models also helped them determine the optimal surgical devices for each given anatomy and to better understand how the devices were going to work during surgery.

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Traditional 3D imaging is presented in a series of 2D images that requires the user to scroll through each image in various planes to understand the anatomy of interest. This is often time consuming and is inherently challenging for a user to reconstruct and visualize the 3D object in his or her mind. The 3D anatomical structures including size, angulation, and pathways of vessels can be challenging to visualize. The physical model allows for a 3D replica of the anatomy of interest combining the data from all the individual 2D images into one model for interpretation and understanding of the anatomy. Holding the anatomy in one's hands provides infinite perspective views and a more natural understanding of shape and morphology (Figure 6).

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Figure 6. Side by side visualization comparison of a patient's AAA via traditional 2D CTA imaging slice and a 3D printed model. The model allows the visualization of every CTA imaging slice in one instance, and is better able to capture vessel curves and distances compared to a CTA.

The physical 3D printed model is often used during the actual surgery as an additional tool to visualize the anatomy of interest. Fluoroscopy images of the patient during the case are often compared to the 3D printed model to confirm arteries and infer a 3D understanding from the 2D images. As such, the surgeons were better prepared for the actual cases. All three cases had excellent patient outcomes.

Cases Four and Five

Cases four and five differed from the previous three discussed in that the prime objective was to determine the surgical feasibility of the procedure due to the anatomical complexity. In addition, the material used to print the models was different. The previous three case models used TangoPlus, an earlier generation material, which can be fragile and prone to leaking and tearing.

Jacobs Institute's role as a Stratasys 3D Printing Center of Excellence in Healthcare enabled it to have advance access to a new material, Agilus30 that was launched publicly in November 2017 as

part of the Stratasys Digital Anatomy™ realism platform. The JI found that models printed in Agilus30 retained their compliant realism and were significantly more robust than the TangoPlus models and subsequently easier to clean and use for simulation.

The latter two case models were also produced with different segmentation software than previous models. The model used in case four was segmented with VMTK Lab and the model for case five was produced using Materialise Mimics software. Both software programs significantly reduced segmentation time.

The models in cases one, four, and five used CloudCompare to verify that the geometry in the model was still accurate in the simulated environment. A 3D spin x-ray of the model was compared to the original patient scan and found to be accurate.

Case Four

Physicians used the patient-specific 3D printed vascular model to test the feasibility of the endovascular approach on a 73-year-old patient with an AAA in a location that would typically call for FEVAR. After attempting the procedure in the simulation model, it was determined that a FEVAR was not possible due to the presence of severe stenosis in the left and right renal arteries and the SMA, making it nearly impossible to cannulate the visceral arteries through the fenestrated graft.

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A surgical debranching procedure was considered, which would involve sewing a graft into the aortic artery, occluding the visceral arteries at their takeoffs on the aorta, and reattaching them directly to the iliac arteries via synthetic vessels. Although it was determined it could be performed, in an effort to avoid the risk of complications and longer recovery times associated with an open procedure, the feasibility of using an endovascular snorkeling technique was tested in the simulator using the patient-specific 3D printed vasculature model. The goal was to assess if cannulation of the visceral arteries was even possible and find out if the selected sizing of the grafts would form a proximal seal that would prevent endoleak, which is persistent blood flow outside the lumen of the synthetic graft and into the aneurysm sac.

Two models were made for this case. Because it was unclear whether the sheaths would be able to track up the iliac pathway, a scan of the patient's iliacs was turned into an STL file and printed first to assess the feasibility. Once it was established that the sheaths could pass, a second model of the patient's aortic artery was printed.

Using the same techniques explained above, the patient's scans were turned into two STL files that were exported to the Jacobs Institute's new multi-material Objet500 Connex3 printer. The use of multi-material allows for the replication of both the elasticity of vessels and the hardness of the calcification. Unfortunately, only the elasticity of the vessels were replicated limiting our ability to predict in vivo performance. A support structure was also created for the purpose of collecting the circulating water from the outflows and holding the vessels in their correct anatomical position.

The mock procedure was performed under fluoroscopic guidance in the same set up as described above. After multiple attempts with a variety of different products, the physician was successful in cannulating the SMA and

both renal arteries. When a contrast injection was performed, there was no visible endoleak. Relative flow measurements were taken before and after the placement of the stent. There was improved flow to both the left and right renal arteries and the SMA, suggesting that the procedure would allow more blood flow to the patient's kidneys and intestines.

As a result of this simulation, the physician decided to bring the patient in and attempt to cannulate the right renal and superior mesenteric arteries, as these were the most challenging. The guidewire/catheter combination that allowed access in the simulation model would be used in the actual surgical procedure, avoiding the need to experiment with other access devices, saving time and money. Appropriate catheter size, length and tip shape along with stent diameter and length were determined during the simulation as well as the general order of device use.

Given that the vessels were successfully cannulated, they would then undergo balloon dilation and a snorkeling procedure would be scheduled. If the cannulation was not possible, the patient would then undergo a debranching procedure.

Ultimately, the vessels could not be cannulated, and a successful surgical debranching procedure was performed.

The experience provided valuable feedback and underlined the need to replicate the calcification in the patient's vessels in the patient-specific model.

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Case Five

A patient-specific model was used to test the feasibility of a FEVAR in a patient whose aneurysm neck had a very small diameter and two severe angles. The goal was to determine if the graft could track around the angles of the neck and whether it could be expanded once in the area of the aneurysm.

The mock procedure used the same set up as the previous cases with a patient-specific model that was produced as described above. In the course of the simulated case, the physician accidentally twisted the graft too far during orientation simulating a candy wrapper. The physician was able to successfully troubleshoot and resolve the failure after trying multiple techniques in the risk-free simulation model and now had a strategy to overcome this event should it occur during an actual procedure in this or future cases.

To date, the actual procedure has not been performed due to scheduling issues.

Conclusion

The use of patient-specific 3D printed models for training and surgical planning purposes is becoming more common at the GVI and JI as physicians become aware of the ways it can contribute to better patient care. Similarly, the 3D printing technology and the models themselves are constantly being improved by the engineering teams at Stratasys and the JI. The larger print bed of the Objet500 Connex3 printer and introduction of more robust materials allowed the JI to use clinically relevant pressures in the simulations.

The JI/GVI experience has also shown how institutions evolve from using patient-specific 3D printed models for training purposes to planning purposes as the models become more realistic and able to capture the mechanical properties of real vessels.

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