Agilus30[™] Improves Performance of Vascular Models

"Agilus30 allows us to simulate a range of patient disease states, such as plaque buildup, that were not possible with past materials. Its increased robustness also allows us to print smaller vessels so we can simulate procedures in the more distal cerebral anatomy. Finally, devices behave more realistically in the Agilus models than in models made of other materials."

- Dr. Adnan Siddiqui, The Jacobs Institute

SITUATION

The mission of the Jacobs Institute (JI), located on the Buffalo Niagara Medical Campus in Buffalo, New York, is to accelerate the development of next-generation technologies in vascular medicine. Physicians, engineers, entrepreneurs and industry have partnered in this one-of-a-kind medical innovation center to speed the development of next-generation technologies in vascular medicine for preoperative surgical planning, training and education, and medical device testing.

The JI has pioneered the development of 3D printed neurovascular models to guide the development of new devices and improve physicians' ability to treat cerebrovascular diseases such as strokes and aneurysms. 3D printed models with compliant polymer materials provide physicians, engineers and students

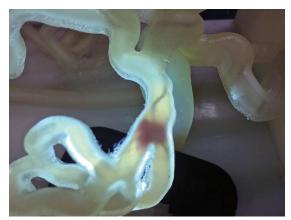




A vascular model 3D printed in Agilus30.

with anatomically accurate and clinically relevant models of the vasculature within a patient's brain. The use of 3D printing in medical models has been instrumental in enabling the JI to print patientspecific pathologies for planning, educating and testing.

Prior to 3D printing, the only medical models available for this application were rigid models or assembled silicone tubing, neither of which are customizable or accurately mimic a patient case. Pathology-specific 3D printed models aid in testing prototype medical devices, planning for the treatment of complex diseases, training students and physicians in a realistic vascular environment, and visualizing a patient's anatomy prior to treatment.



An example of a clot in a 3D printed intracranial model.

When testing a prototype medical device, 3D printed models need to both simulate human vasculature and be robust enough to withstand 30-50 device tests prior to degrading in order to facilitate a comparative analysis of medical device tools. This enables lifelike environments for testing devices such as stentrievers, which are newly developed clot retrieval devices credited with revolutionizing stroke treatment.

Additionally, endovascular procedures require the use of introducer sheaths that serve as portals for physicians to transport medical devices into patients' vascular systems. Medium to large sheaths pose a challenge for flexible photopolymer 3D printing, resulting in frequent tears as the sheaths translate and rotate with very little clearance between the product and the vessel wall.

These medical models function as more than just visual representations of complex vasculature. One of the common use cases involves training a physician to retrieve a blood clot from a blood vessel deep within the brain in order to treat a stroke. This is challenging because once the location of the clot is identified, it must then be captured by a device and removed from the body against the direction of blood flow. So, during training, it is critical that the blood flows represent



This tear in an early version of a 3D printed model guided new material development.

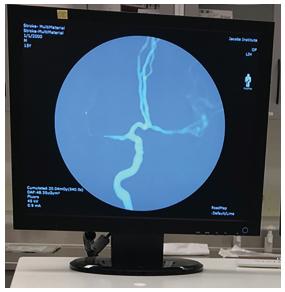
physiological conditions. In a 3D printed model, this can be achieved by designing the vasculature compliance of the 3D printed model and attaching a pulsatile pump to the system.

In its early 3D printed models, the JI used TangoPlus[™] photopolymer for device testing on the Stratasys Connex3[™] 3D Printer. The Connex3 is able to print 15um layers, and overall tolerances between the target geometry and printed geometry within 200um. TangoPlus models provide lifelike haptic feedback, affording physicians a realistic maneuverability within the vasculature, especially as compared to the previous standard – glass models – which provided no compliance. Though successful overall, TangoPlus has been prone to tearing, ripping and leaking during post-processing and use. Attempts to increase the wall thickness, by adding shell-based reinforcements in higher stress locations, and using higher durometer materials, maintained the models' clinical realism, but still left a few challenges.

SOLUTION

Stratasys, working closely with the JI, developed the next generation of rubber-like PolyJet[™] materials to enable more testing, easier cleaning and greater tear resistance. Agilus30 improves performance and realism of these complex models. "Agilus30 allows us to simulate a range of patient disease states, such as plaque buildup, that were not possible with past materials. Its increased robustness also allows us to print smaller vessels so we can simulate procedures in the more distal cerebral anatomy. Finally, devices behave more realistically in the Agilus models than in models made of other materials," said Dr. Adnan Siddiqui, chief medical officer at the JI.

3D printing complex vasculature with Agilus30 enables physicians to perform the entire procedure under fluoroscopic image guidance just as if it were a real endovascular intervention using various medical devices including sheaths, catheters, guidewires, stentrievers, flow diverters



X-ray road map of a model showing occluded right carotid artery (left side of image).

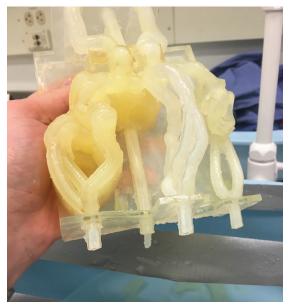
and embolic products. Contrast agents can be injected through devices to image the phantom vasculature using clinical techniques such as digital subtraction angiography (DSA), roadmap overlays for guidance and CT for 3D analysis.

In extensive testing, the JI has found Agilus30 offers superior results for the resolution for complex shapes, intricate details and smooth surfaces. More durable, rubber-like, tear-resistant prototypes and models can stand up to repeated flexing and bending. This makes the JI's vascular models more effective for surgical planning, more lifelike for training and education, and more durable for medical device testing.

RESULTS

As part of the development of this new material, a thorough evaluation was performed to understand how vascular models printed in the new Agilus30 compared to those printed in TangoPlus with a specific focus on anatomical accuracy, tear resistance, durability, haptic feedback and ease of post-processing.

Agilus30 showed a similar anatomical accuracy compared to TangoPlus. When comparing Agilus intracranial models to TangoPlus models with the same vessel thicknesses during cleaning, models printed in Agilus30 consistently perform at a higher level with respect to tear resistance and



A technician with a 3D printed intracranial model mid-cleaning.

overall durability than the TangoPlus models. The Agilus30 models can withstand the methods needed to clean out tortuous anatomies with smaller, more angled vessels to a greater extent than the TangoPlus model.

Post-processing cleaning time is reduced by about one-quarter to one-half using Agilus30, which avoids the ruptures that result in significant repair time and possible leakages during use. Also, because it is easier and more efficient to clean the models, there is less room for variation between technicians, which improves the reproducibility of the models. Finally, the additional robustness of Agilus30 allows for the design and cleaning of more complex anatomies that would otherwise be difficult.

Agilus30's higher tear resistance and durability have enabled the JI to create more life-like simulations of arterial access, more tortuous anatomies and the incorporation of atherosclerotic vasculature, not before possible. By experimenting with different vessel thicknesses, the JI has been able to develop Agilus30 models that are more robust than TangoPlus models, but that also provide the desired compliance.



A 3D printed intracranial vasculature model printed with Agilus30.

The innovation potential of the Agilus30 models is considerable. These include anatomies with high angulation, small vessels, many branches and large blood pool models. This allows physicians to train with larger and more complex anatomies for presurgical planning, allows for the manufacturing and prolonged use of anatomically accurate in vitro models for product testing, and extends the lifetime of models for use in physician training and education. The 3D printing of vascular models using Agilus30 enhances the JI's ability to accelerate next-generation technologies in vascular medicine.



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