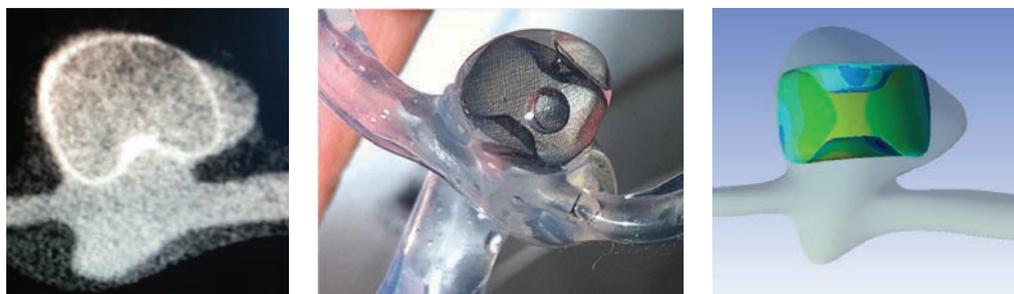


Brain Trust for Aneurysm Treatment

By **Mathieu Sanchez**, Chief Executive Officer, Sim&Cure, Montpellier, France



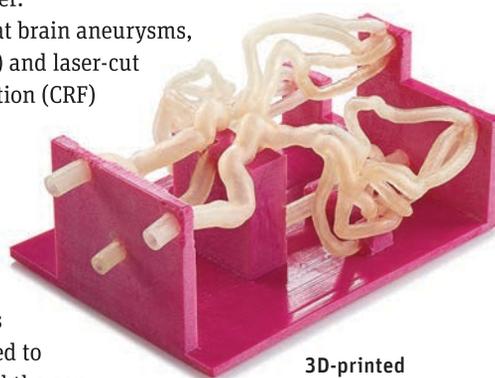
TO PROVIDE EFFECTIVE TREATMENT FOR BRAIN ANEURYSMS, a pioneering healthcare company has developed a digital twin to help physicians place implant devices during surgery. Incorporating ANSYS structural mechanics solutions, the surgeon can simulate the deployment of the implant and determine its optimal sizing and positioning to decrease the risk of failure and reduce operating times.



Medical devices can be tested using three methods – within the body (in vivo, left), outside the body (in vitro, center) and within a computer (in silico, right).

Approximately 2 percent of the population has a brain aneurysm, an enlarged section of an artery caused by a weakening of the arterial wall. Although most show no symptoms or have no health problems, about 1 percent of these aneurysms rupture every year, and about 30 percent of ruptures result in death. Small aneurysms with a low probability of causing damage are often managed simply by tracking their size. One way to treat larger aneurysms is to surgically open the brain, remove the diseased section of artery and clip the remaining ends together. Retrospective analyses have found that surgical options are associated with a higher risk of bad outcomes, longer hospital stays and longer recovery times compared with endovascular procedures. In an endovascular procedure, a catheter is inserted into an artery of the leg near the groin. Aided by medical imaging, the surgeon guides the catheter, which carries the implant, to the aneurysm. Once the device is in position, the surgeon expands the implant and removes the catheter.

Several types of endovascular implants are used to treat brain aneurysms, including flow diverters (FDs), intrasaccular devices (IDs) and laser-cut stents. According to the Cardiovascular Research Foundation (CRF) and the National Center for Biotechnology Information (NCBI), selecting an implant with the right diameter, length and expansion to closely fit the cross section and length of the aneurysm is of paramount importance in achieving the best outcome for the patient. Papers published by the NCBI indicate that up to 65 percent of endoscopic procedures are characterized by various types of geographic miss. For example, if an ID implant designed to deploy inside the aneurysm sac is too small, blood can fill the gap and apply pressure on the aneurysm. Oversizing of the implant could lead to the creation of a clot and an ischemic stroke.



3D-printed model of arterial network in brain

Sim&Cure's solution to this involves the generation of a digital twin. While the patient is under anesthesia, the surgeon runs software that incorporates a model of the structure and behavior of the patient's damaged blood vessel. The software quickly and accurately helps physicians to define the optimal size of the implant and where it should be positioned to give the best results.

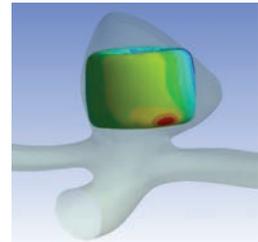
Current Methods for Implant Sizing

Physicians have traditionally used one of two methods to size and position the implant. One approach is to perform measurements on 2D scans captured as part of 3D rotational angiography, or measurements of the 3D scans themselves, just before surgery. This takes at least 10 minutes, so it lengthens the time the patient must be under anesthesia, increasing the risk of complications. These measurements do not account for the deformation and movement of the implant during the procedure, so effective deployment depends upon the skill, experience and intuition of the individual physician.

Another approach is to employ 3D rotational angiography to produce a computer-aided design (CAD) of the blood vessels. Then a 3D printer slowly builds a physical model of the blood vessels, which is used to test different device sizes and deployment factors. But the drugs used during the procedure significantly alter the size and shape of the artery, so the model builders must try to estimate these effects. Actual conditions may vary from the physical model that was used to size the implant.

Simulation Software Provides a More Accurate Solution

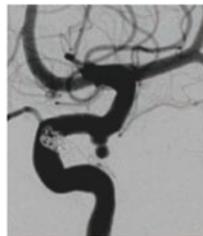
In Sim&Cure's new method, 3D rotational angiography is used to produce a 3D model of the aneurysm and surrounding blood vessels after the patient is prepped for surgery. Sim&Cure's software imports the model of the artery and presents it to the surgeon, who selects points on the artery that define the ideal final position and deployed size of the implant.



“Sim&Cure is the first company to be cleared to market a patient-based digital twin incorporating simulation for aneurysm treatment that includes expansion and deployment of implants based on the patient’s unique arterial geometry.”



Arterial system with aneurysm viewed with 3D rotational angiography



Arterial system with aneurysm (circular protrusion from artery) viewed with 2D axial angiography

Sim&Cure's IDsize® software simulates intrasaccular device implants incorporating models of a wide range of sizes of the available implant devices so the surgeon can select the specific implant that he or she wishes to simulate. Sim&Cure combines the model of the patient's arteries with a model of the selected device and produces an ANSYS Mechanical input file. ANSYS Mechanical analyzes the deformation of the device and arteries, along with their interaction with each other, and provides a 3D model of the device deployed in the patient's artery that shows the implant and the aneurysm superimposed on each other.

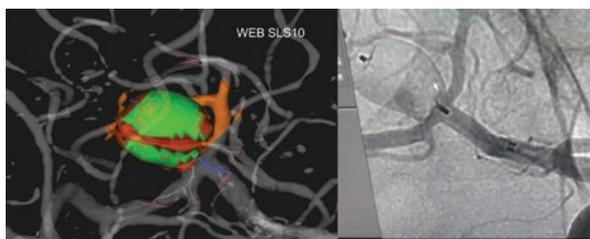
The physician can translate, rotate and zoom the image to fully understand the relationship between the implant and the aneurysm. Color coding can be used to show the exact area where the implant touches the embolism (blockage). A cross-sectional profile indicates any gaps between the implant and the artery. Each simulation takes only 10 to 25 seconds, depending on the device that is selected. The surgeon can easily select and simulate additional devices and sizes for analysis in order to determine which one will provide the best results. In less than five minutes, the surgeon can complete the simulation process, select the optimal device and begin the operation.

Clinical Trial Results are Positive

Normally, about 10 percent of endovascular treatments require follow-up surgery, usually because of issues with the sizing or positioning of the implant. But in more than 500 surgeries conducted in three clinical trials with Sim&Cure’s software, follow-up surgery has never been required for a single patient.

In many aneurysm surgeries, a second or even a third implant may be required, usually because the one that was originally selected turns out to be the wrong size when inserted into the patient. This results in a longer surgery and increases the risk of complications to the patient. Doctors who used Sim&Cure software have reduced the number of devices used per surgery from 1.35 in the past to only 1.05 now. Besides reducing the risk to the patient, this saves 3,000 euros (approximately US\$3,600) per operation. The trials also show that Sim&Cure reduces the time required to perform surgery by about 30 minutes, which further reduces the risk of complications and provides additional cost savings.

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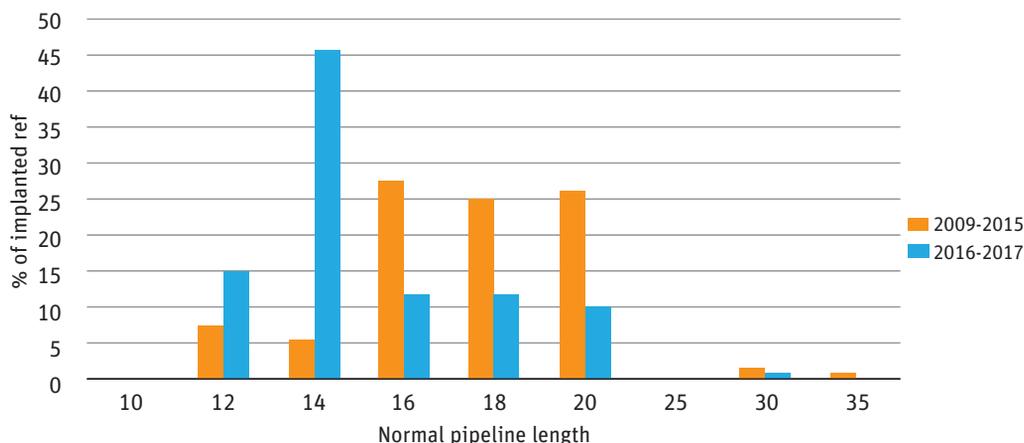


ANSYS Mechanical simulation of implant deployed in aneurysm (left). The surface of aneurysm that abuts the implant is shown in green. Simulation results accurately predicted implant deployment, resulting in successful intervention.

Sim&Cure engineers selected ANSYS Mechanical for this application for several reasons. They wanted to avoid the time and resources that would be required to develop their own finite element analysis software, and they wanted the package with the highest level of accuracy and the strongest reputation in the medical field. ANSYS Mechanical filled both requirements. The ANSYS customer excellence team in Europe worked closely with Sim&Cure engineers to help ensure a fast and seamless integration.

Sim&Cure is the first company to be cleared to market a patient-based digital twin incorporating simulation for aneurysm treatment that includes expansion and deployment of implants based on the patient’s unique arterial geometry. Clinical trials conducted in three European hospitals have shown a significant reduction in follow-up surgeries and in surgery duration. Sim&Cure’s solution is now being used in 17 different countries with expectations that it will be used in more than 2,000 surgeries by the end of this year. ¹

Histogram of Implanted Nominal Length



Histogram shows how use of Sim&Cure software in 2016–2017 made it possible to use smaller implants than were employed previously, reducing risk of complications.