



INNOVATIVE AT HEART

With its groundbreaking stent design, Cardiatis is poised to change the lives of cardiac patients worldwide. But this Belgian company is also changing the way employees at all levels of the organization use specialized technology that is traditionally associated with product-development engineering.

By Nouredine Frid, Chief Executive Officer, Cardiatis, Isnes, Belgium

Cardiatis is accustomed to doing things differently. Even though the medical community has been using the same basic stent design to treat aneurysms for decades, traditional devices have obvious drawbacks — including a lack of permeability that interferes with normal blood flows and tissue regeneration in the area of the aneurysm. Since 2002, Cardiatis has focused on developing a better solution.

The company's product, the Multilayer Flow Modulator (MFM®), represents a paradigm shift in the treatment of aortic aneurysms. Composed of layers of a braided cobalt alloy that form a mesh, the MFM is porous. It enables the turbulent blood flow that characterizes traditional stents to become more uniform, reducing shear wall stress and supporting healing of damaged tissue.

Cardiatis focuses on making this technology available to patients around the world as quickly as possible, because time is critical after an aneurysm is detected. Without timely surgical intervention, aortic aneurysms can rupture — and they kill approximately 15,000 people each year in the United States alone. Because Cardiatis is confident that the MFM represents the best possible treatment for aortic aneurysms, company employees are dedicated to getting this product launched into the global marketplace in a rapid manner.

However, as with any groundbreaking technology, there are significant barriers to bringing the MFM to market. Since Cardiatis is a small startup company, it needs to attract investors to support continued optimization of the MFM. To win customers, the product's actual users — in this case, cardiovascular surgeons — must be convinced of the benefits of the MFM over traditional stent designs.

Because the MFM is a medical product, exhaustive product testing must be conducted to ensure that the device is safe and effective. Government agencies around the world must grant regulatory approvals, and insurance companies need to formally certify the effectiveness of the MFM before they offer patients financial coverage.

In keeping with its focus on innovation, Cardiatis has identified a reliable solution for addressing every one of these needs: engineering simulation.



*Healthcare is one of the fastest-growing industries in the world. This rapid growth is fueling the development of **breakthrough technologies.***

Simulation has been an indispensable design tool for the product development engineering team at Cardiatis for years. Because the organization is competing with larger companies that have greater engineering resources, the strategic use of simulation helps Cardiatis to keep pace by amplifying the efforts of its product development team. Obviously, it is unfeasible to perform early-stage product testing on human patients, so simulation has been a foundational solution in modeling the MFM's performance inside a virtual human body.

At Cardiatis, a team of Ph.D. engineers is currently simulating the performance of the MFM inside a range of human anatomies that represent actual cardiac patients. Working with a database of 4,000 two-dimensional CT scans — which are transformed into three-dimensional geometries — this team is ensuring that the MFM will deliver consistent results for all patients. This ongoing effort is an essential part of the company's product development efforts.

Of course, physical testing is also required — and simulation is helping to drive significant costs out of prototyping at Cardiatis. Engineers leverage simulation to pre-select the best product configuration as well as to optimize the physical testing to focus on key areas. This intelligent approach to prototyping minimizes the use of expensive cobalt alloy material. By minimizing material waste, Cardiatis estimates that simulation reduces the cost of physical testing by about 10 percent.

However, engineers are not the only people at Cardiatis who rely on simulation — or who use powerful simulation images

of the MFM at work inside virtual human bodies. At Cardiatis, simulation is a critical tool for demonstrating and validating the MFM to a wide range of audiences.

From the Operating Room to the Boardroom

Whatever the product or industry, resistance to change will always be an issue when introducing a revolutionary new technology. Customers like to maintain the way they have always done things — and they are naturally resistant to change. For Cardiatis, the key challenge is convincing cardiac surgeons to switch to an entirely new stent technology. In the medical industry, making even a small change can affect patient outcomes, so physicians need to be extremely confident in choosing a new solution.

To provide visual proof of MFM's superiority, every member of the sales and marketing team at Cardiatis has simulations loaded onto their laptops. When meeting with surgeons, they can show — not merely describe — the real advantages of Cardiatis's approach. This has been a powerful tool in helping a group of early adopters begin using the MFM in actual patients.

Another challenge for Cardiatis lies in attracting financial investors who will fund its intensive research and development efforts. Engineering simulation has been equally effective in demonstrating the MFM technology to venture capital firms. Simulation takes a theoretical idea and makes it visual and easy to understand. Even people who don't have a medical background respond enthusiastically when they see Cardiatis's unique stent design in action.



Because the MFM is composed of a permeable metal mesh, it supports robust blood flows.

It is essential that the healthcare industry begins to adopt new tools and processes.

Because the MFM could represent the best-possible treatment for aortic aneurysms, Cardiatis employees are dedicated to getting this product launched into the global marketplace in a rapid manner.

Securing Critical Approvals

The Cardiatis MFM is in use today in Europe and South America to treat high-risk patients who are unable to benefit from traditional stents. Before providing coverage for these patients, insurance companies request proof of the likely results from the MFM — and this proof is submitted in the form of patient-specific simulations.

The engineering team at Cardiatis generates simulations that are based on the actual patient's scans and images, then provides these simulations to the medical team and health insurer. In these high-risk cases, the patient's physical geometry is often very complex, with multiple aneurysms or severely compromised blood flows.

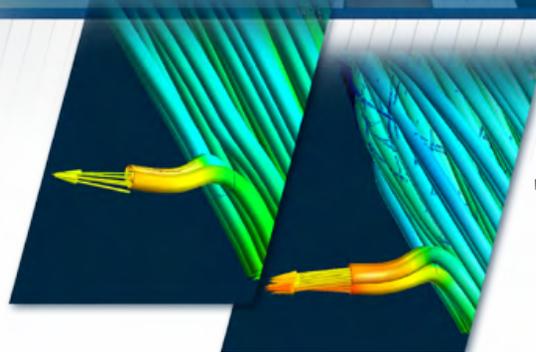
Cardiatis has been pleased with the ability of simulation to represent these complex geometries quickly and accurately. And, for those patients relying on the MFM for a year or two, simulation has proven remarkably accurate in predicting how the MFM would perform.

Insurance companies have also been impressed with the results achieved from simulation. In some markets, including Brazil, insurance claims are not covered unless a simulation has been submitted in advance of the surgical procedure.

In other parts of the world, including the United States, Cardiatis is still securing regulatory approvals for the MFM. This is a complicated process that is supported by simulation. For example, in the U.S.,

the MFM is considered a Class 3 device, which means it has no “predicate,” or pre-existing competitor. The approval process for Class 3 devices is long and complicated — typically around 50 months.

Engineering simulation is proving to be very helpful in submitting proof of concept. While clinical trials are still a prerequisite to regulatory approval, simulation is helping to get to that stage faster by providing early-stage validation that the technology actually works.



Blood flow simulation without MFM (left) and with MFM (right)



Cardiatis at a Glance

- Number of employees: 41
- Headquarters: Isnes, Belgium
- Industry: Healthcare

Taking the Pulse of the Future

More than most companies, Cardiatis has democratized engineering simulation by placing it in the hands of virtually every professional — from top-level executives to sales reps. Demonstrating the real-world benefits of MFM technology via fluid-flow simulations has become a way of life within the company.

But Cardiatis is just getting started in re-imagining how simulation might be used outside the engineering function. Cardiatis envisions a day when surgeons will have tablet computers loaded with a consumer-level version of simulation software. In assessing an aneurysm patient, a doctor could input two-dimensional scans such as CTs or MRIs, then see immediately how that specific patient might benefit from the MFM. The physician could then submit the simulation images electronically to both the surgical team and the patient's insurance provider.

As the global population ages and life expectancy increases, healthcare is one of the fastest-growing industries in the world. This rapid growth is fueling the development of breakthrough technologies, like the MFM, that propose new solutions to common health issues.

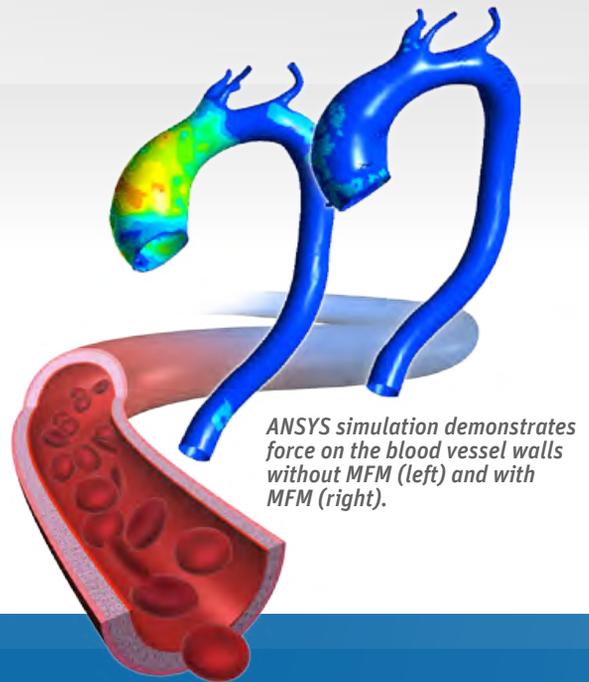
To get these innovations to market quickly so patients can begin benefiting from them, it is essential that the healthcare industry begins to adopt new tools and processes. Cardiatis believes that simulation — once the domain of engineers — offers a number of advantages, especially as other healthcare businesses seek to validate their products to doctors, investors, regulators, insurers and other key audiences. Beyond its use in the medical field, simulation is a powerful tool for any company looking for an innovative, flexible means to demonstrate its products.



About the Author

Trained as an engineer in industrial chemistry, Nouredine Frid started his career at Corvita, focusing on developing vascular prostheses for surgery. He also worked on first-generation covered

aortic stents — aneurysmal excluders with no need for open surgery. This innovative technique was designed for patients who could not undergo classic open surgery to treat their aneurysms. While working at Medicorp R&D Benelux S.A., he successfully developed a new stent design for the treatment of carotid stenosis, composed of a shape-memory material that would become rigid at human body temperature. This device, Expander®, is now implanted in thousands of patients worldwide. In 2002, he founded Cardiatis to develop a new concept: 3-D stents composed of several interconnected layers. Frid is the owner of 20 patents for his technology innovations.



ANSYS simulation demonstrates force on the blood vessel walls without MFM (left) and with MFM (right).

5 DIMENSIONS OF SIMULATION

- Reduce Cost:** Reduce cost of physical testing by about 10%
- Enable Sales:** Show, not tell, product benefits
- Attract Investors:** Demonstrate product technology to venture capitalists
- Provide Insurance Evidence:** Provide proof of treatment effectiveness to obtain patient funding
- Secure Regulatory Approval:** Deliver early-stage validation of product technology to streamline approval process