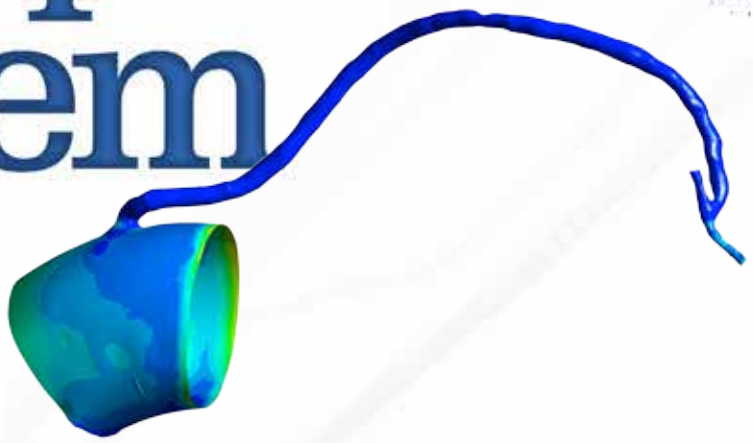
Support System



Each year, more than 2 million patients worldwide undergo a procedure called coronary artery bypass grafting (CABG). Used to treat blocked arteries and restore normal blood flow to the heart, CABG involves grafting a blood vessel — typically taken from the leg — around the diseased area, re-establishing blood flow to the heart tissue.

Veins used for CABG offer an inadequately durable solution to coronary artery disease, with a long-term outlook that is not promising. Within 18 months, 25 percent of the implanted veins fail — and, after five years, that failure rate increases to 40 percent.

"The blood vessels in the leg are relatively large and easy to harvest and implant, but unfortunately they are not built for the high flow rates and pressures near the heart," explains Mohammed El-Kurdi, co-founder and director of research at Neograft, a startup headquartered in Taunton, U.S.A. "Over time, these grafted veins begin to dilate and eventually become blocked, necessitating another surgery."

A mechanical engineer by training, El-Kurdi focused his doctoral work at the University of Pittsburgh on designing a structural support system that would improve the durability of arterial vein grafts. In 2009, he co-founded Neograft, and Jon McGrath, a seasoned health care entrepreneur, became the company's chief executive officer. Neograft markets a patented product called Angioshield that is designed to increase success rates for CABG procedures.

"Through a novel process called electrospinning, our Angioshield technology creates a 'scaffold' of polymer material around the vein prior to implant. This scaffold improves both the vein's strength and its geometric uniformity," says El-Kurdi.

According to El-Kurdi, Neograft's proprietary advanced material is key to the success of Angioshield. "Our polymer sheath shapes itself to the vein without deforming it," he notes. "And, because the material is porous, it allows nutrients and new cells to migrate to the tissue. Over time, this results in the growth of stronger and healthier graft tissue."

Because of the difficulty associated with visualizing and manipulating structures inside the human body, El-Kurdi began relying on the power of engineering simulation while still in the Ph.D. program at Pitt. Today, Neograft engineers use simulation to model different blood flows inside implanted veins, as well as to understand diverse mechanical forces that act on vein grafts, such as the motion associated with a beating heart. Product developers can then change the physical properties of the polymer scaffold as they increase their understanding of vein graft mechanics.

An external stent for the grafted vein, Angioshield is deposited directly onto the outer surface of the vein via a novel electrospinning process. Neograft's product development team has used ANSYS finite element analysis (FEA) software to ensure the structural strength of the stent, and has leveraged ANSYS computational fluid dynamics (CFD) software to study and optimize blood flows inside the grafted vein. Fluid–structure interaction analysis is planned for the future, as Neograft expands its use of ANSYS solutions.

"Perfecting the Angioshield material is an iterative process, during which we apply different material configurations, then test the treated vein's resulting strength and durability," states El-Kurdi. "It would be impossible to move so quickly, and conduct so many studies, without working in a risk-free virtual design environment. By the time we moved to animal and clinical trials, we had a deep foundation of knowledge that allowed us to predict outcomes very accurately. And we continue to add to that knowledge base every day."

Today, as Angioshield is tested in patients, computerized tomography angiography (CTA) generates images of the implanted vein. These images are fed back into ANSYS software to generate 3-D models of Angioshield inside an actual human body. "We're currently using simulation as an investigative tool to understand patient-specific behaviors of treated veins," says El-Kurdi. "Our studies will enable the Neograft engineering team to build better predictive models and continually improve the product."

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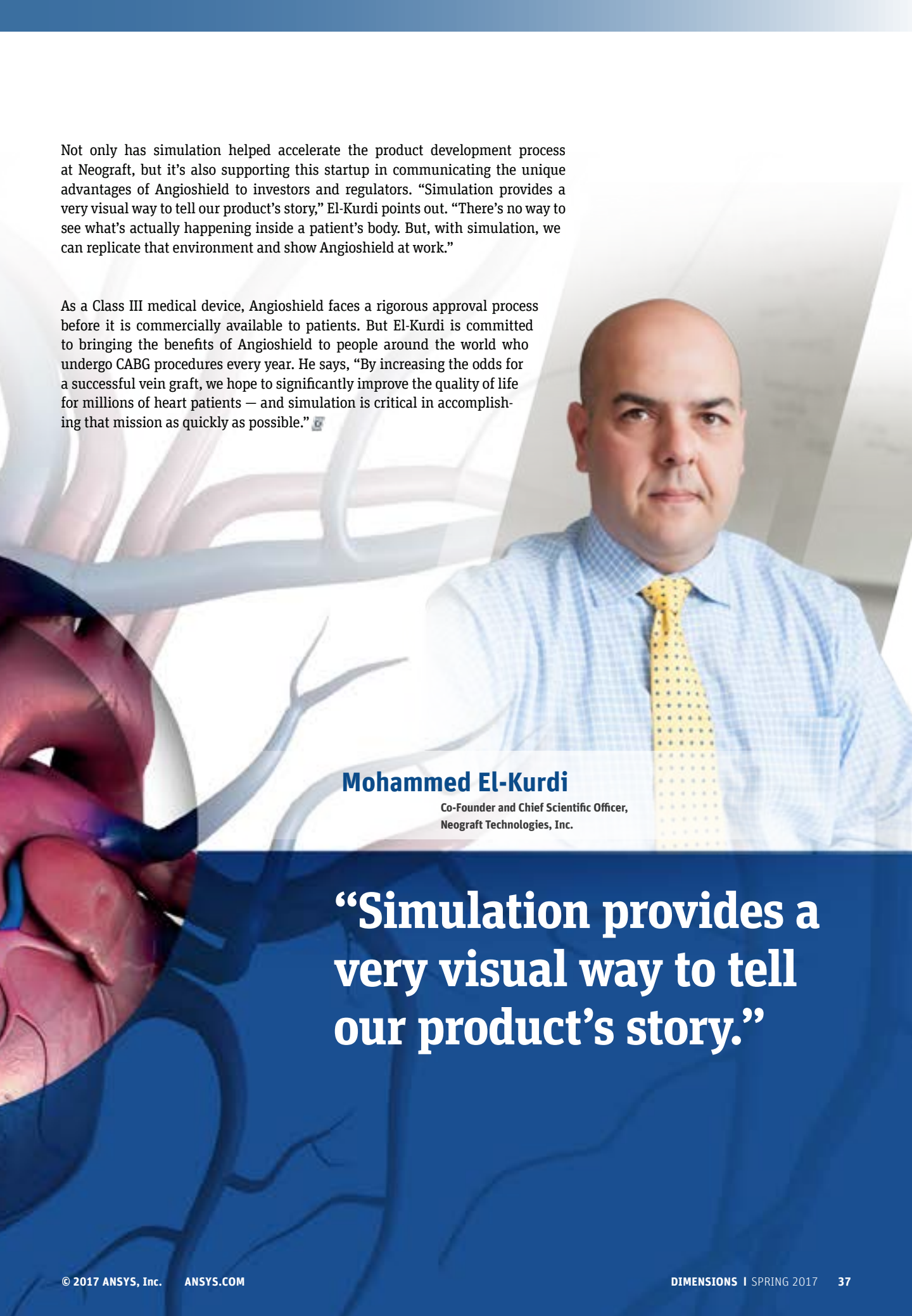
Not only has simulation helped accelerate the product development process at Neograft, but it's also supporting this startup in communicating the unique advantages of Angioshield to investors and regulators. "Simulation provides a very visual way to tell our product's story," El-Kurdi points out. "There's no way to see what's actually happening inside a patient's body. But, with simulation, we can replicate that environment and show Angioshield at work."

As a Class III medical device, Angioshield faces a rigorous approval process before it is commercially available to patients. But El-Kurdi is committed to bringing the benefits of Angioshield to people around the world who undergo CABG procedures every year. He says, "By increasing the odds for a successful vein graft, we hope to significantly improve the quality of life for millions of heart patients — and simulation is critical in accomplishing that mission as quickly as possible."



Mohammed El-Kurdi

Co-Founder and Chief Scientific Officer, Neograft Technologies, Inc.

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