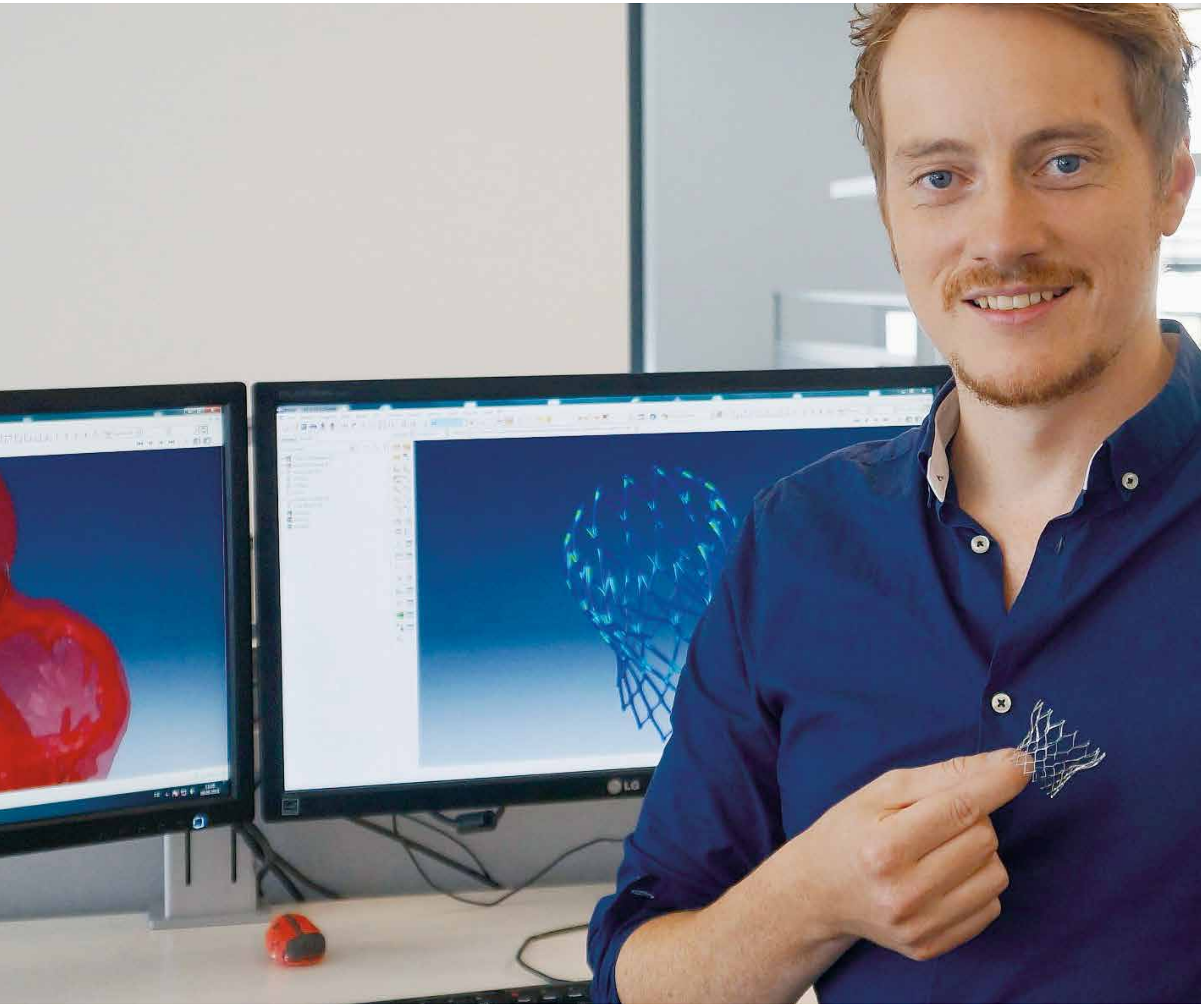
ADMEDES
LIFE SCIENCES



Challenge:
Leading manufacturer Admedes was looking for ways to extend the lifespan of their implantable Nitinol stents, heart valve frames, and similar cardiovascular repair components.

Solution:
Simulating the implantation of devices within Dassault Systèmes' Living Heart model, engineers used Abaqus FEA to identify stress areas and potential failure points of Nitinol structures, then optimized the topology of the components using Tosca Structure.

Benefits:
Admedes can now deliver more accurate designs to their customers and contribute to the improvement of patient health and lifespans.

Make a fist. Now give it a good squeeze. This is the approximate size and function of an average human heart—a muscle that weighs little more than a double cheeseburger but pumps enough blood in a lifetime to fill several crude oil supertankers. The network of blood vessels connected to it is over 60,000 miles long. The largest of these—the aorta—is as big around as a garden hose, while the capillaries that feed individual cells are far smaller than the hairs on our heads. To say the human heart and the cardiovascular system that services it are complex is a gross understatement; they are intricate, indefatigable, and indeed wondrous.

For an average human, the heart beats more than 100,000 times each day—do the math and that means billions of heartbeats per lifetime, assuming you're fortunate enough to have good health. Yet sometimes that wonderful muscle fails prematurely. Cardiovascular disease is the number one killer of men and women alike, leading to heart attack, arrhythmia, congestive heart failure, and stroke. Millions of people are treated with stents each year to open clogged arteries. Millions more receive heart valve replacements, vascular filters, and occlusion devices.

Memory metal

This is the work of Admedes Schuessler GmbH, a global manufacturer of stents and other lifesaving devices. Since 1996 Admedes has specialized in laser micromachining, assembly, and finishing of self-expanding Nitinol components for the medical industry. The teams in Germany and the United States consult with customers on product design and material selection, and offer services such as laboratory testing, prototype development, and full scale production of Nitinol-based medical products. They use Abaqus FEA software from Dassault Systèmes' SIMULIA both internally and for their customers.

Known throughout the medical community as a shape-memory alloy, Nitinol is a unique, highly biocompatible metal composed of roughly equal parts nickel and titanium. Metallurgists will tell you that Nitinol undergoes a "thermoelastic martensitic phase transformation" during its manufacture, and that this is what's responsible for its super-elasticity, excellent damping characteristics, and uncanny ability to "remember" its original form.

Whatever you call it, it's cool stuff. Bend a bit of Nitinol wire into a pretzel, apply a small amount of heat, and the wire will immediately pop back to its original shape. This characteristic is both tunable and predictable, allowing manufacturers such as Admedes to create virtually any desired part geometry, then teach it to retain that geometry via a process known as "shape setting."

The end result of all this metallurgical legerdemain is that Nitinol is an ideal material for orthodontic guide wires, laparoscopes, endoscopic guide tubes, blood filters, and especially stents and frames for aortic and mitral heart valves—which support valve "leaflets" that repeatedly open and close, thousands of times each hour, tens of millions of times each year.

An engineer discovers The Living Heart

Philipp Hempel is an FEA engineer with a PhD in Computational Materials Mechanics. He came to Admedes in 2014 after graduating from the nearby Karlsruhe Institute of Technology. He and two others comprise the manufacturer's FEA group, which works with customers to improve their product designs. "Performing FEA before manufacturing is very important, and is a service we frequently do for our customers, especially the ones that may not have the engineering capabilities or analytical tools we have available here at Admedes," he says.

Hempel has used Abaqus for the past ten years. Shortly after joining Admedes, he was browsing the Dassault Systèmes' website when he discovered the Living Heart Project (LHP). He immediately recognized its potential. Having a 3D model of the human heart would give him and the team far greater visibility to its inner workings, allowing them to virtually implant their Nitinol devices directly into the heart model and rapidly analyze various product designs. It would also mean far less need for in-vivo testing—a huge cost benefit to their customers, and something that would greatly speed the design cycle. The company applied for membership to the LHP and was accepted soon after.

The Living Heart Project is a collaborative effort between Dassault Systèmes and dozens of medical researchers, device manufacturers, clinicians, and regulatory agencies. These include the United States Food and Drug Administration, Stanford University, The Mayo Clinic, the universities of Texas, Southampton, Cape Town, and others, as well as leading pharmaceutical and device suppliers. Hempel looked forward to working as part of this prodigious group.

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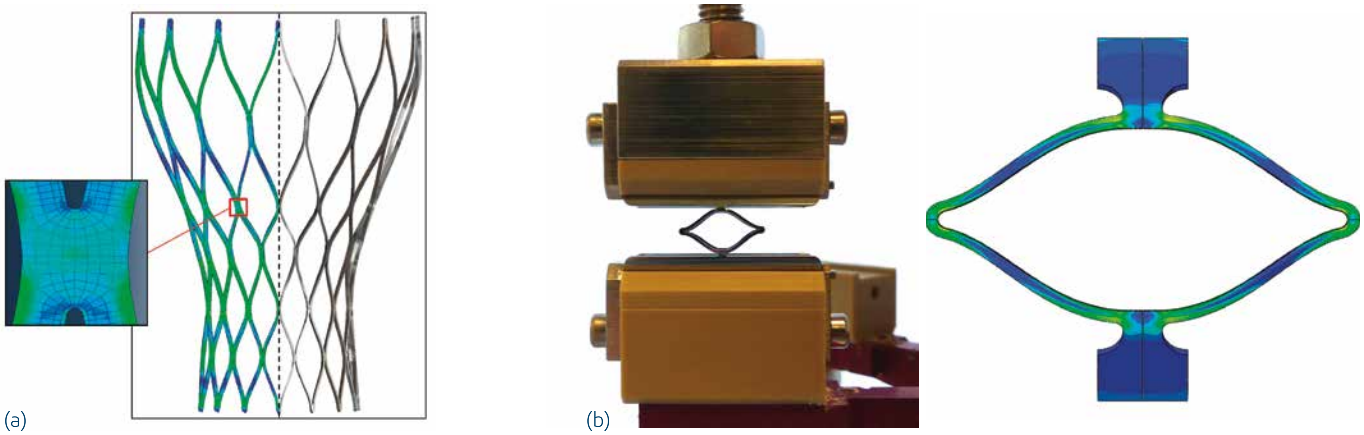
>
> —Philipp Hempel, Admedes FEA engineer



(a) Finite element analysis of a heart valve frame with a close-up view of a strut intersection. (b) Mechanical fatigue testing (left) helps correlate the results of FEA strain sampling (right).

Pushing boundaries

Hempel started by evaluating the 3D heart model on its own, but quickly moved to "implant" a generic heart valve frame made of Nitinol. He created a cylindrical surface in which to mount the frame, "crimped" it to 10 mm (0.394 in.), and actuated contact between the outer surface of the cylinder and the tissue of the 3D heart, "almost like a real implantation," he says.

"Determining accurate boundary conditions and the amount of load acting on the frame body is very important to the development of these types of devices," Hempel explains. "Without that information, there's no way to identify the fatigue strains during the actual application in the body. However, it is very difficult to obtain this data from animal studies, which suffer from large uncertainties."

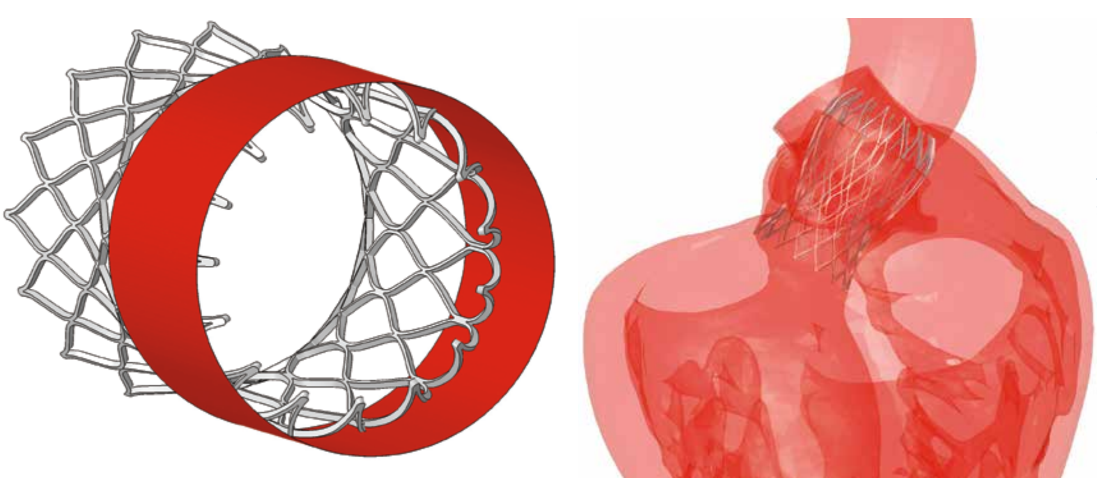
This is where the LHP model comes into play. Hempel was able to visualize the strains produced during valve implantation, as well as the strains generated during the heartbeat. He then took the simulation a step further by optimizing the design using Tosca Structure. Rather than using the Living Heart model itself for optimization, he mimicked the loading seen in the model by extracting boundary conditions and applying them for optimization.

"We received the Extended Token for our Abaqus suite last year, so we had the option to try out additional tools," he says. "Tosca was fairly new to me at the time, but after six iterations I was able to reduce the maximum strain by 35%, the alternating strain amplitude in a fatigue life evaluation by almost 50%, and better distribute strains overall. The design changes were quite small actually, so I was both surprised and quite pleased that they would have such an impact on product strength."

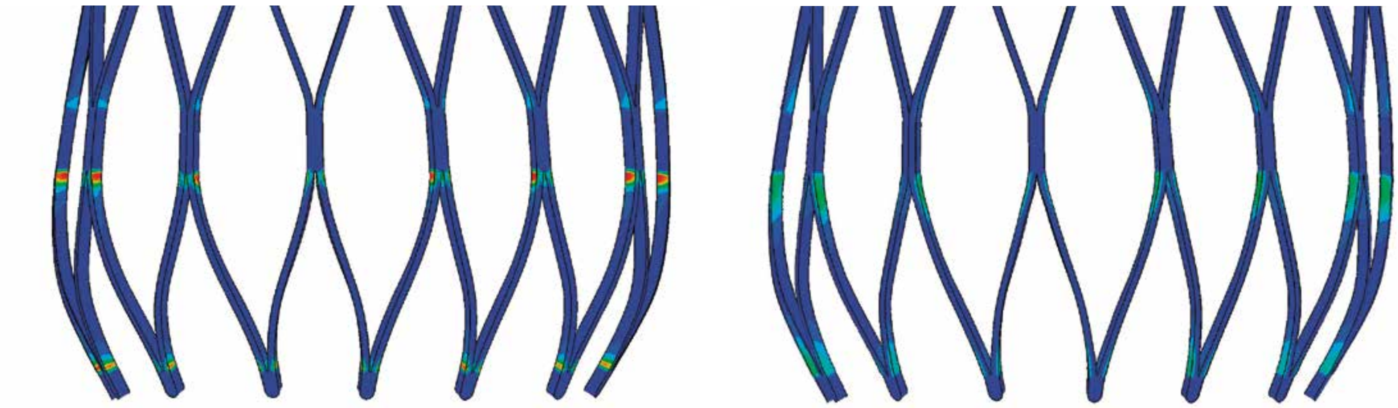
"Prior to Tosca, we could analyze customer designs, offering advice based on our extensive experience with Nitinol products, but there was no chance to actually compute an optimized design," says Hempel. "That's all changed now."

Pushing ahead

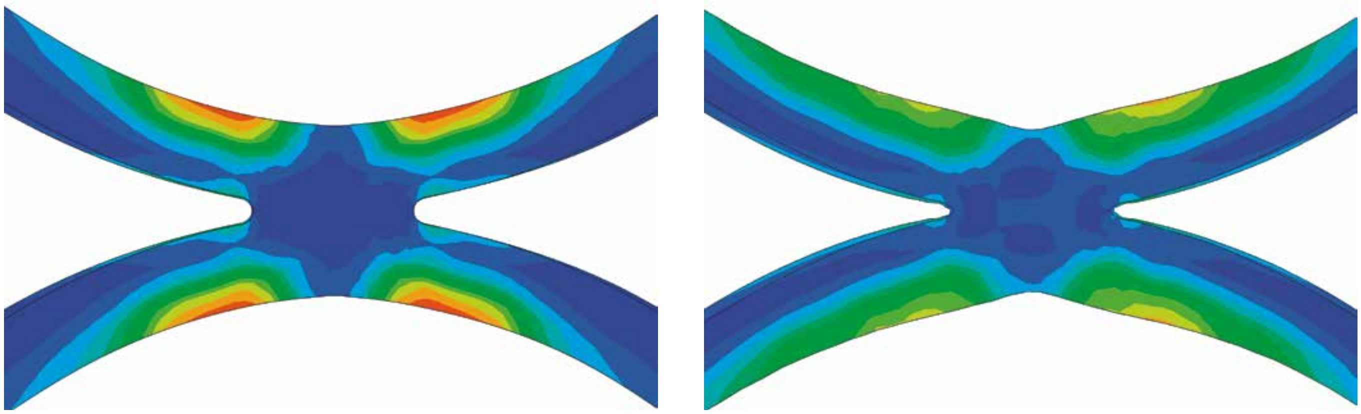
There's more work to be done. Hempel says he postponed simulation of the "leaflets"—sections of the valve body that actually contain the blood during the closure cycle—for future testing. "I didn't have the requisite computational time needed to perform such an analysis during this initial study, so I could only extract the compression of the device that occurs with contraction of the heart," he says. "I did, however, apply additional radial displacement—which we can gain from experiments or analytical approximations to simulate leaflet closure—in order to make the simulation as accurate as possible."



(Left) A "crimped" stent cylinder (grey), used as an attachment point within the Living Heart (red), providing metal to tissue contact simulation. (Right) Living Heart simulation of a heart valve frame implanted in the aortic section of a human patient.



Before and after: on the left, the red sections at the strut intersections illustrate areas of metal fatigue, while the Tosca-optimized version to the right shows a 35% improvement.



Tosca topology optimization results. The cross-section to the right clearly shows stress reduction at the top and bottom portions of the strut joint.

Hempel looks forward to simulating the entire heart valve including the leaflets using fluid structure interaction, and to gain greater understanding of the impact of disease and age on valve design. He also anticipates using Isight (for parametric optimization), fe-safe (for fatigue analysis), and other modules within the Abaqus product suite.

His vision is that methodology such as this will be standard in the future. "Perhaps one day we will have commercially available patient-specific cardiovascular devices," he says. "Until then, the Living Heart project provides many possibilities not only for design optimization, but also for playing a strong role in academic teaching and training of anyone involved in cardiology work."

"Our goal was to reduce crimp and fatigue strains in a generic heart valve design," he concludes. "We accomplished this goal and have used what we learned to assist our customers. We also provided feedback to Dassault Systèmes on ways to improve the Living Heart model—something they were very receptive to. It's been a lot of fun to work with cutting-edge technology such as this. I've learned a lot from it."

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