The Beat Goes On

Sunshine Heart Optimizes Unique Pump Device Design with Abaqus FEA from SIMULIA

Heart failure is a debilitating, progressive disease characterized by the organ's inability to provide sufficient blood flow to the body. Some five million U.S. patients are currently suffering from heart failure (HF), with 500,000 new cases diagnosed each year. HF can result from coronary artery disease, heart attack, high blood pressure, diabetes, heart muscle infection, lung disease or valve disorders. Symptoms, which can become life-threatening, include difficulty breathing, swelling limbs, weight gain, and lack of energy and stamina.

Treatment for HF can range from drugs to defibrillators to internal heart pumps, with transplant as the final option. No single therapy works for everyone, and side effects and mechanical issues can arise for the implanted pump devices. Dr. William Peters, a cardiothoracic surgeon and research fellow at Auckland City Hospital in New Zealand, thinks there has to be a better way.

"I've always had a strong interest in devices to support the failing heart," he says (he has also invented a commercially-successful minimally-invasive bypass system). "Because of concerns about existing technologies, I was looking for a device that would not involve contact with the blood." Common implanted blood-contacting devices such as left-ventricular assist devices (LVADs), while lifesavers for people awaiting transplants, require that the patient remain on blood thinners (which themselves can be a stroke risk) to prevent clots. Reliability has also been an issue with some heart-assist device designs.

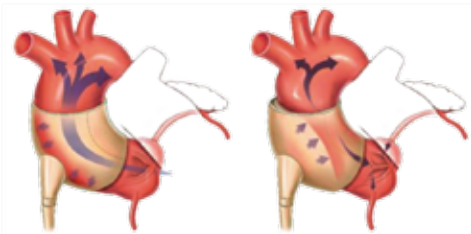

Image 1: Sunshine Heart's novel C-Pulse heart pump design consists of a cuff that encircles the aorta, inflating and deflating to enhance blood flow and decrease the heart's workload.

Novel pump works from outside the heart

Dr. Peters conceived of a novel idea for a pump system that works inside the body but outside the bloodstream, called the C-Pulse™. It consists of a cuff that wraps around the aorta (the main blood vessel that carries oxygenated blood from the heart to the rest of the body) and inflates and deflates a membrane (balloon) against the vessel's external walls (see Image 1). The positive and negative pressure of the balloon make the aorta pulsate in time with the heart, augmenting blood flow through the circulatory system, thus reducing total work and strain on the entire heart. A battery-powered pump worn outside the body powers the device (see Image 2).

Peters patented his pump idea and formed a company, Sunshine Heart, to develop and test the device, initially on the bench and in sheep. But once animal trials were successful, when the balloon was ready to be scaled up to a human model, the company decided that they needed a more sophisticated approach to the design and development process than the empirical, build-and-test approach. The goal was not only to reduce lead time, but to provide a level of confidence that long-term performance would satisfy product requirements established by physicians for an acceptable medical device.

FEA optimizes fatigue performance

"The average human heart rate of 80 beats a minute equates to 42 million inflation cycles a year," says Scott Miller, manager of mechanical engineering at Sunshine Heart. "The accumulated stress, especially on a polymer, was the design challenge—and C-Pulse is essentially a permanent implant. To ensure that our physical design solution was optimized to give us the long term fatigue performance required, we decided to look at it from a computational perspective using finite element analysis (FEA)."

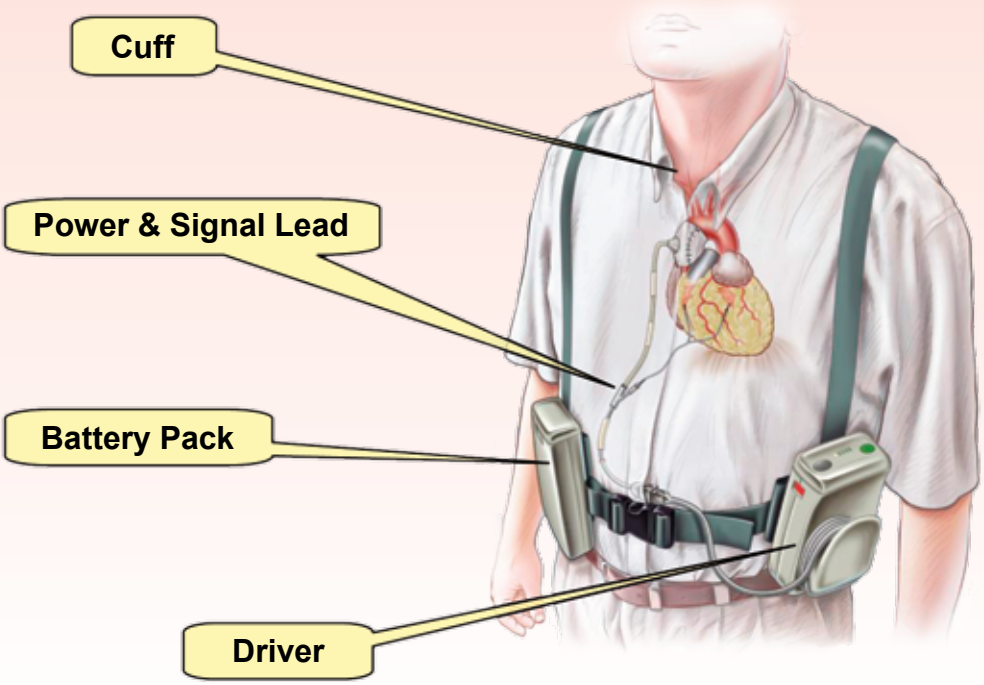

Image 2: Patient wearing the C-Pulse System. A lead from the external power source [Driver] connects to a catheter inside the body attached to the implanted device [Cuff], which is wrapped around the exterior of the heart's ascending aorta.

Miller and his product development team worked with Matrix Applied Computing Ltd for technical engineering software services. Matrix used Abaqus/Standard software from SIMULIA to model the behavior of the C-Pulse cuff and balloon interacting with the aorta.

"The FEA analysis was an iterative process that required some very unique approaches because of the way our device worked, the materials we were using, and how the device is actually assembled," says Miller. The balloon had to be easy to manipulate during implant surgery; conform to the shape of the aorta; have the strength and flexibility to "snap through" from concave to convex and back again repeatedly; compress the artery; and perform reliably from initial inflation through years of use—all within a very limited space. The goal of the FEA modeling was to accurately represent the real-world behavior of the device in order to guide design decisions and optimize the C-Pulse's performance through every stage of this process.

Element and material choices are critical

As a starting point for the FEA analysis, Sunshine heart provided Matrix with concave and convex Pro/E models of the device (see Image 3). According to Don Campbell, Principal Engineering Analyst for Matrix, "It was an interesting challenge. Our analysis involved modeling hyperelastic material; a fabric membrane; simplified biological material for the aorta; contact, large strain; and a staged assembly process."

To determine what kinds of elements (the geometric shapes mathematically representing physical units that make up an FEA mesh) to use for modeling the artery, cuff and balloon, Matrix created a series of test models. Quadrilateral shell elements turned out to be acceptable for the bulk of the parametric design studies (including determining the all-important optimum thickness of the balloon). But for modeling surface strains affecting the balloon in the fillet radius region (a critically important area where failures of the very earliest designs had occurred), hexahedron solid brick elements were chosen for more precise results using substructuring techniques with results from the shell model driving the solid element analysis (see Image 4).

The material modeling portion of the analysis was constrained by physiology and anatomy studies that had already been conducted. "We were given pre-existing data for the biocompatible material (a polymer approved for medical device applications) from which the device would be manufactured," says Campbell. "The Ogden hyperelastic material model in Abaqus provided an excellent fit with the experimental data." The Ogden model is often used to model rubberlike materials such as polymers, and biological materials.

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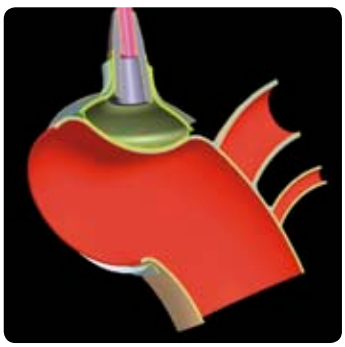

Image 3: Pro/Engineer Geometry of C-Pulse unit on which Matrix's Abaqus FEA models were based.

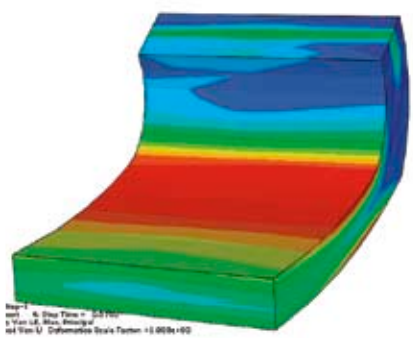

Image 4: Abaqus FEA submodel solution showing variation of strain through thickness of balloon wall.

Modeling the "snap through" function

With the FEA models of the C-Pulse set up, Matrix ran simulations to determine what shape the device's balloon should be during surgical implantation (starting with a convex configuration turned out to be most effective at minimizing strain). Next they simulated the complete balloon "snap through" motion of convex to concave and back again (see Image 5). "The complexity of the analysis was less in its geometric difficulty or problem size, but more in the simulation of the continuous, alternating process," says Campbell. "The strain on the balloon varied from the outer to the inner surface of the material as it snapped through, so the total strain we were analyzing was a combination of stretching and bending. During the simulation cycle, the location of peak strain in the fillet actually moved from the minor to the major axis of the oval-shaped balloon."

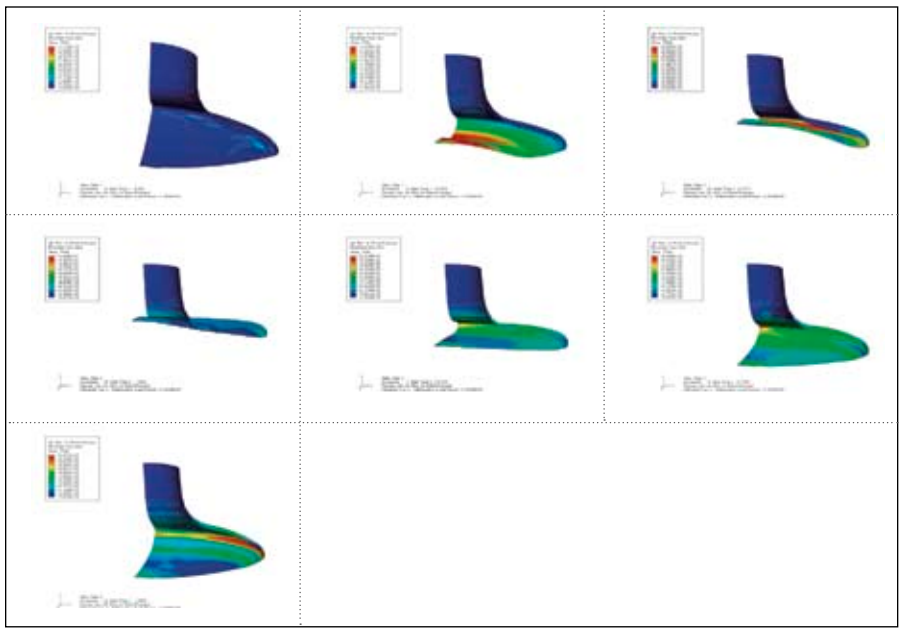

Image 5: This series of images shows an Abaqus FEA strain analysis of the "snap through" of a C-Pulse balloon membrane. Note how the area of maximum strain (red) moves from the short axis (upper right images) to the long axis of the oval balloon (final image at bottom) from start to end of the cycle.

Matrix ran its simulations as quarter, not full, models, using the assumption of symmetry to cut down on processing time and aid solution convergence (see Image 6). "There were some approximations with the quarter model since an aorta is not a straight pipe, but has some curvature," Campbell says. "However, for the purpose of optimizing the design, the lack of true quarter symmetry was thought to have a minimal effect on the ultimate design parameters. This approach also let us perform a large number of parametric runs in a reasonable amount of time."

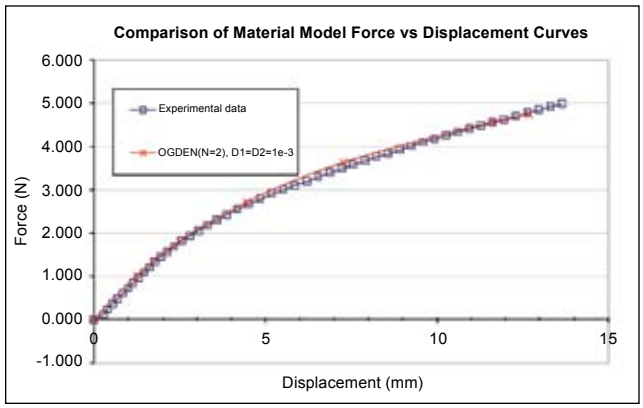

Image 7: Comparison of force deflection curves for hyperelastic material model of the C-Pulse balloon membrane (red is FEA prediction, blue is actual test results) shows how well the model performed in the test environment.

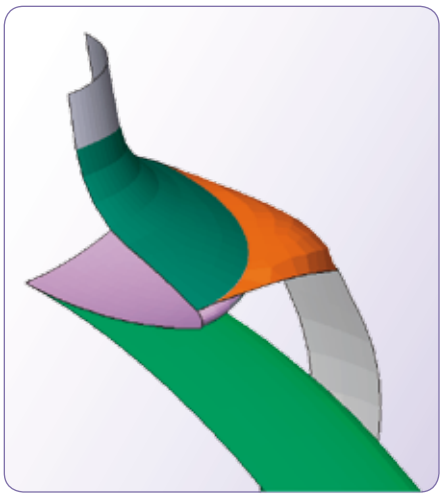

Image 6: FEA quarter model of balloon (lavender) within cuff (greys & orange) pressed up against aorta wall (green). The assumption of symmetry in the model allowed for decreased model size and shorter run times.

The ultimate goal of the FEA analysis was to arrive at a device shape which had the least variation of strain amplitude and the maximum mean compressive strain during an operational cycle. Says Campbell, "It was a project with interesting physics and the final model we came up with has performed very well in the test environment (see Image 7)."

FEA provides final design solution

The FEA models more than met Sunshine Heart's requirements. "We arrived at a design solution the first time through." says Miller. His group has subsequently proven that the solution holds true for different sizes, allowing for tailoring the device to individual patients.

And the durability of the C-Pulse design is being borne out by ongoing testing, Miller notes. "We have been running devices day and night literally for years now: the test machine requires regular maintenance because the C-Pulse keeps wearing the test unit out."

Scott Miller, M.E. is Manager of Mechanical Engineering at Sunshine Heart. U.S.-born and educated with an M.E. degree from Clarkson University, he is now an Australian citizen. He was one of the first employees of the company, which was founded in 2000.

For More Information
www.sunshineheart.com