The Beat Goes On

The Project: Develop a more sophisticated approach to the design and development process beyond the build-and-test method for a novel cardiac pump device.

The Solution: Use FEA software to test a variety of different variables that need to be examined for a successful design of the device.

By Lynn Manning

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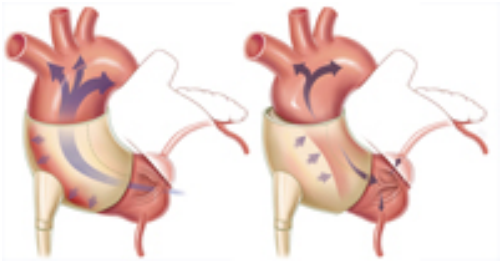


Heart failure is a debilitating, progressive disease characterized by the organ's inability to provide sufficient blood flow to the body. Some five million U.S. patients are currently suffering from heart failure (HF), with 500,000 new cases diagnosed each year. HF can result from coronary artery disease, 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.

Pump Works From Outside 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 (Figure 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 (Figure 2).

Peters patented his pump idea and formed a company, Sunshine Heart, to develop and test the device—initially on the bench and then 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 they'd been using. 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

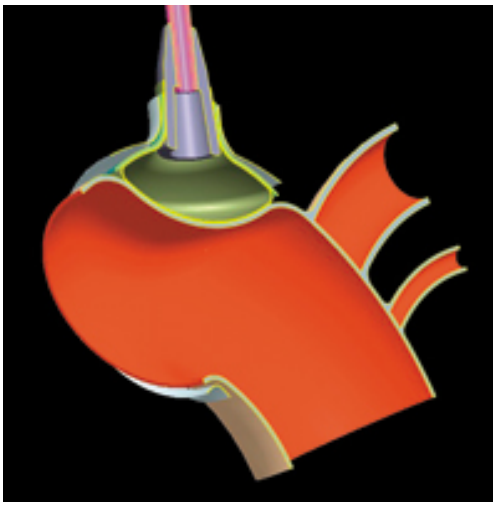
"The average human heart rate of 80 beats a minute equates to 42 million inflation cycles a year," says Scott Miller, manager of mechanical engineering at Sunshine Heart. "The accumulated stress, especially on a polymer, was the design challenge—and C-Pulse is essentially a permanent implant. To ensure 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)."

Miller and his product development team worked with Matrix Applied Computing Ltd. for technical engineering software services. Matrix used Abaqus/Standard software from SIMULIA, the Dassault Systèmes brand for realistic simulation, 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 Materials Choices Are Critical



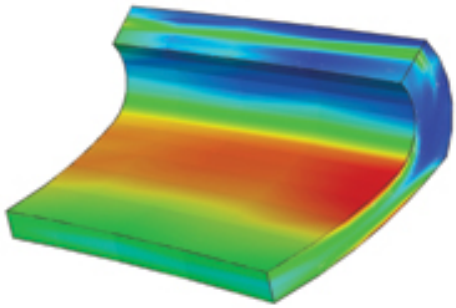
As a starting point for the FEA analysis, Sunshine heart provided Matrix with concave and convex Pro/E models of the device (Figure 3). According to Don Campbell, principal engineering analyst for Matrix, "It was an interesting challenge. Our analysis involved modeling hyperelastic material; a fabric 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 (Figure 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 rubber-like materials, such as polymers, and biological materials.

Modeling the ‘Snap Through’ Function

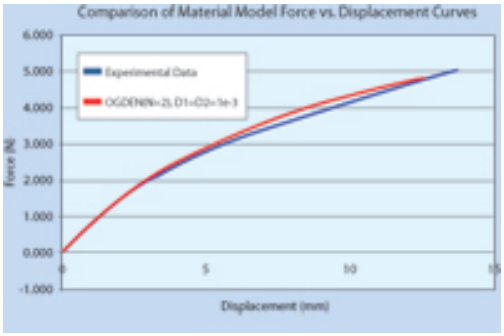


With the FEA models of the C-Pulse set up, Matrix ran simulations to determine what shape the device’s balloon should be during surgical implantation (a convex configuration turned out to be most effective at minimizing strain). Next, they simulated the complete balloon “snap through” motion of convex to concave and back again. “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.”

Matrix ran its simulations as quarter, not full, models, using the assumption of symmetry to cut down on processing time and aid solution convergence. “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.”

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 (Figure 5).”

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 and haven't needed any additional FEA since then," 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."

Online

For additional information on the technologies and products discussed in this article, see *MDT* online at www.mdtmag.com [2] and the following websites:

- www.3ds.com [3]
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- www.sunshineheart.com [5]

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