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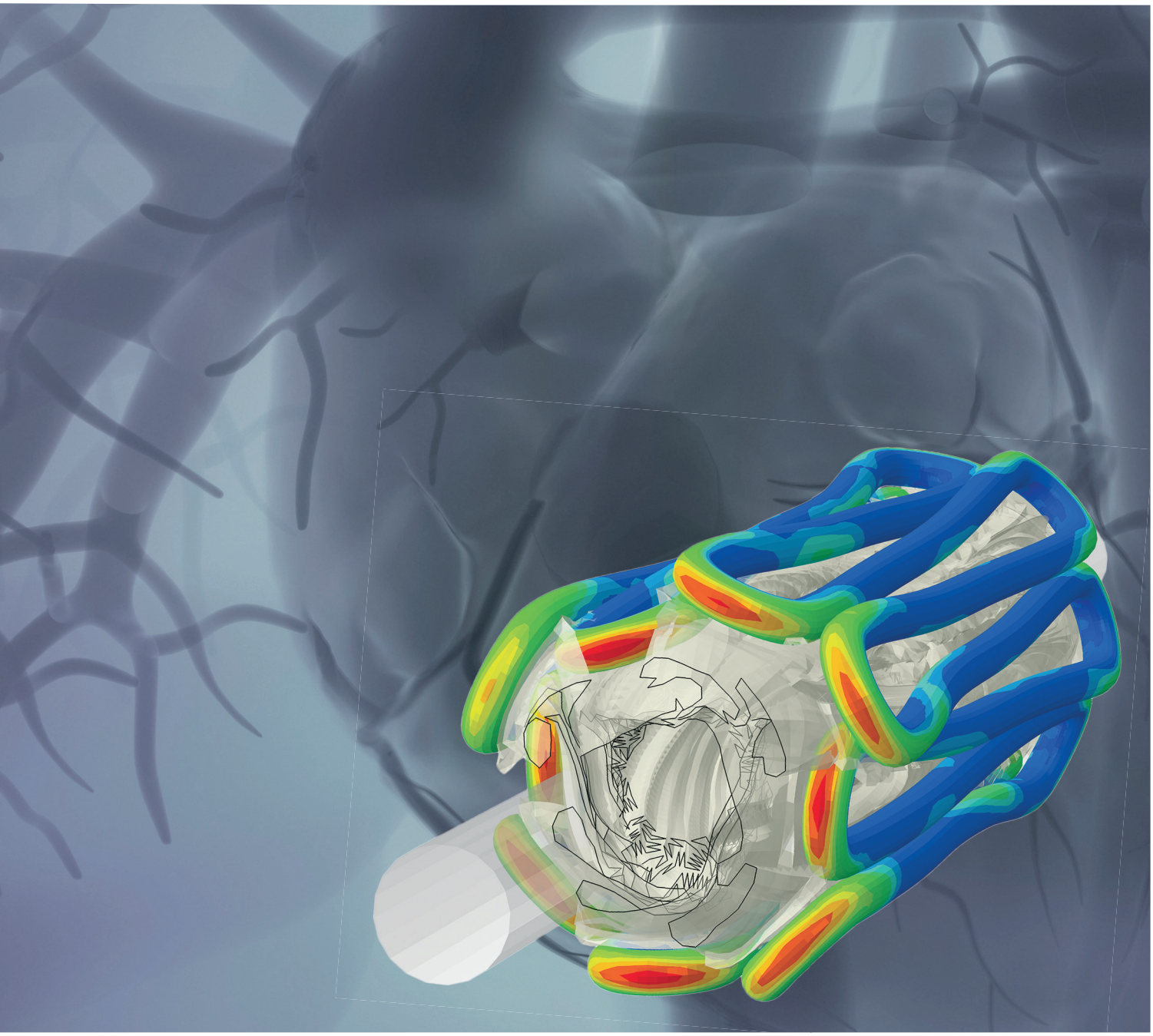
Life Sciences Case Study



Challenge

The Medtronic Endovascular Therapies R&D group was looking to understand the *in-vivo* performance and surgical delivery of stent grafts to further optimize device behavior for better patient outcomes.

Solution

Using Abaqus FEA and advanced probabilistic computational tools in Isight, engineers were able to identify key parameters, input manufacturing tolerances and variability, and improve stent component performance, which was then verified to be in good agreement with physical test results simulating a regulated 10-year-life product performance requirement.

Benefits

Realistic simulation in conjunction with automated workflows enabled the Medtronic team to identify the stent graft device's most important parameters and reduce stent design cycle time to a minimum while increasing design reliability to further benefit patients.

The heart pumps blood through the 60,000-mile-long human circulatory system 60 to 80 times each minute. The body's core blood vessel, the aorta, must carry oxygenated blood from the left ventricle of the heart all the way down to the abdomen. As a result, aortic walls are under pressure from the blood's constant pulsing. Over time, age stiffens the vessel's walls and disease can create additional stress. Apply these cumulative loads over the years and it's no surprise that the body's major artery can be prone to problems.

Damage to the aorta can result from atherosclerosis (clogged vessels), smoking, diet, or heredity. When vessel walls weaken, an aneurysm (or bulge) can form that allows the blood to pool, impairing normal circulation. If left untreated, the aneurysm can eventually rupture with potentially life-threatening consequences. Originally, the only way to repair an aortic aneurysm was through open surgery. But with the first successful implant of a stent graft in the early 1990s, doctors and patients had an effective and less invasive treatment option available.

Stent grafts are tubular wire-mesh structures with a membrane-like fabric covering. They function like an alternative piece of piping, channeling blood flow so that it bypasses the weakened section of the artery. (Stents, on the other hand, are wire mesh tubes without a covering that are used to physically expand a constricted vessel.) Stent grafts are now frequently used in both thoracic (above the diaphragm) and abdominal aortas in a procedure called an endovascular aneurysm repair (EVAR). It's reported that as many as 45,000 abdominal aortic aneurysm surgeries are performed each year (see Figure 1).

Striving to improve stent grafts with simulation

"While EVAR surgeries are now seen as somewhat commonplace, an expanded understanding of in-situ stent graft performance and delivery is still critically important for improving patient outcomes," says Atul Gupta, senior principal engineer on Medtronic Endovascular Therapies' R&D team.

According to Gupta, as a surgeon inserts the stent graft in its catheter, they can encounter difficult anatomy, calcified vessels, or an aneurysm site that's angulated. Once the device is in place, it must provide a good seal with no endo-leaks, and it can't migrate away from the site as a result of the constant sheer stress due to blood flow. It also needs to withstand the structural fatigue originating from pulsatile loading for a minimum of ten years—or about 400 million cycles total—to satisfy regulatory and ISO standards requirements.

To fully understand these complex structural behaviors and fine-tune stent grafts to accommodate them, Gupta's California-based group employs computational modeling with Abaqus finite element

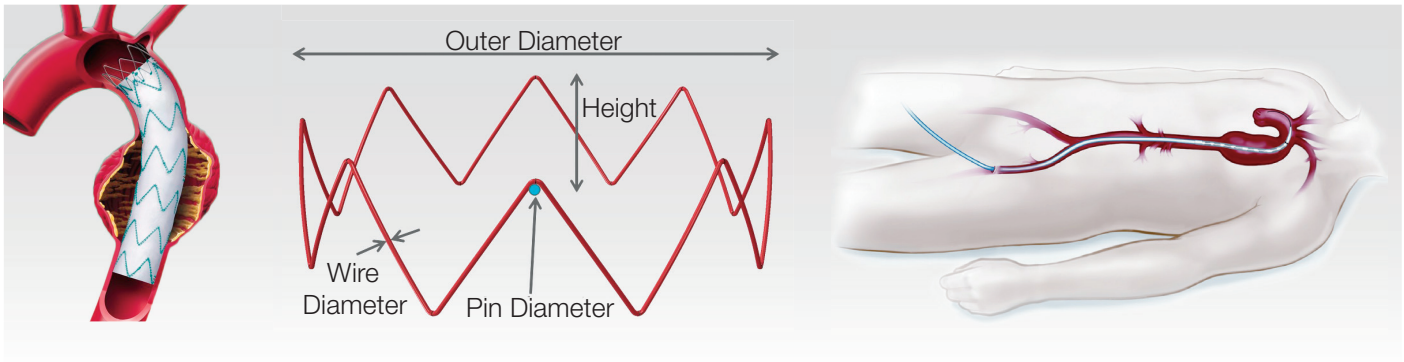


Figure 1. This cutaway view of a thoracic aorta (left) shows a stent graft that has been deployed at an aneurysm site so that blood can bypass the bulge in the vessel walls. The detail view of the stent rings (center) identifies the key stent graft design parameters. The device is inserted using a minimally invasive catheter-based procedure called an Endovascular Aneurysm Repair (EVAR) (right). Medtronic utilizes Abaqus FEA and Isight workflow automation to simulate stent graft and surgical delivery-system behaviors.

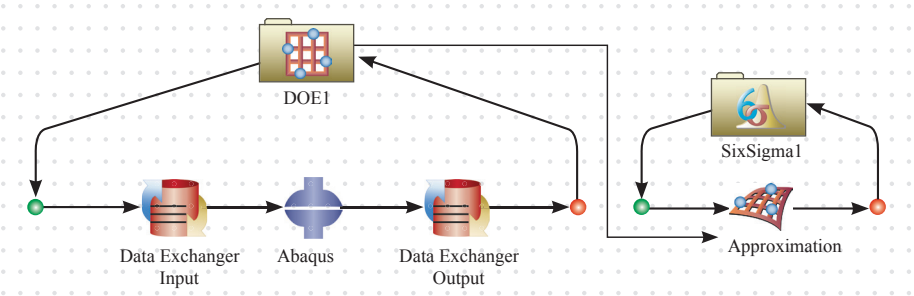


Figure 2. This simulation process-automation workflow in Isight shows (on the left) the iterative loop for a Design of Experiment (DOE) that included an Abaqus FEA analysis and (on the right) the probabilistic evaluation that helped in evaluating the reliability of the stent design when parameters were varied within tolerances. The workflows are created in Isight using a simple drag-and-drop process.

analysis (FEA). "The Endovascular Therapies group at Medtronic has been using Abaqus in-house for more than six years now," says Gupta. Of particular importance to his team are its advanced contact capabilities, scripting interface for customizations and the fact that it's an excellent modeling tool for Nitinol, the metallic alloy from which these stents are made.

"The medical space is highly regulated, so the quality assurance and ISO certification of the software is also very important," says Gupta. Verified and validated simulation models can provide medical device designers, as well as regulatory agencies, with highly accurate assessments of performance, reliability, and durability. When modeling stent grafts, for example, FEA has allowed Gupta's team to look closely at radial strength, peak stresses and strains, and fatigue safety factors of the metallic stent rings.

Earlier exercises in stent modeling typically included some necessary simplifications to keep the analyses manageable. "In the past, we created models with nominal dimensions and material properties to save computational time and analyst effort," says Gupta.

Manufacturing variances were often not included in analyses, though fabrication relies on considerable hand labor, and both material and dimensions could vary within tolerances. Additional variability—resulting from the often dramatically different in vivo boundary conditions seen in actual patient-specific anatomy—was also not part of standard methods. "In order to fully understand the variation of all factors and their influence on device performance, we knew that further investigation was required," says Gupta.

A single FEA model can provide a snapshot of one set of stent graft variables for one specific design at a time. An entire series of FEA results provides the researcher with a kind of 'animation' in which each subsequent image captures the behavior of a slightly different design with a slightly different set of design variables. Viewing the results as a sequence of snapshots allows engineers to more completely understand and explore the vast range of design-space options and solutions, and leads to a more robust design.

With this goal in mind, the R&D group decided to examine their Abaqus results through statistical analysis techniques that could be linked into an automatic workflow to save time. They chose Isight simulation process automation and design optimization software. "Isight is well integrated with Abaqus," says Gupta. "Its easy-to-use, drag-and-drop graphical interface provides access to a number of advanced probabilistic modeling routines. It also accommodates our internal tools."

"Now the product development cycle is much more efficient because we run numerous simulations first and then choose the design that is optimal—before we make anything."

Atul Gupta, Senior Principal Engineer, Medtronic Endovascular Therapies' R&D Team

Testing new automated workflows

To put their new methodology to the test, the R&D team started with a thoracic aortic stent ring and created a model for it in Abaqus/CAE. They used a rigid representation of the vessel and assigned superelastic material properties to Nitinol, determined from experimental data. To encompass as much design variability as possible, they then added real-world manufacturing tolerances for key stent parameters, including stent height (±10%), wire diameter (±10%), crown radius/pin diameter (±25%), outer diameter (-1% to +2%), diameter of the vessel (±2.5%), and material plateaus (±10%).

The analysis incorporated an automated Design of Experiment (DOE), which ran 200 iterations in Isight with Abaqus serving as the FEA solver (see Figure 2). For the FEA analysis, the engineering team subjected the model to a sequence of quasi-static loading steps. The outputs of most interest, according to Gupta, were crimp strains inside the delivery catheter during loading (important for avoiding permanent plastic deformation), the radial forces at deployment (which ensure proper contact of the stent graft to the vessel wall), and the safety factor of the stent under pulsatile fatigue loading due to vessel dilation. The team created a response surface approximation from these outputs (with errors less than one percent for all results), which were then combined with the expected manufacturing variability added earlier.

"Next we ran probabilistic sampling analyses that included thousands of simulations and allowed us to change variables for all the key parameters to assess design reliability," says Gupta. The result was a statistical distribution of crimp strains, radial force, and fatigue safety factors. Tools in Isight, like Pareto charts and scatter plots, helped the team identify wire diameter and stent height as the most critical design parameters when trying to achieve target crimp strains (see Figures 3 and 4).

Isight includes a variety of Six Sigma probabilistic techniques—such as Monte Carlo, importance, and mean value sampling methods, among others. As part of the analysis, the engineering team was able to compare these methods to determine which could most accurately predict the probability of success and the tightest confidence interval.

To validate the various findings, the R&D team compared analysis calculations with bench test results derived from radial force testing. The fatigue performance of the stent was also confirmed using an acoustic-fluid testing protocol, which applied radial pulsatile loading on the stent graft. The experimental data, collected over three to six months, mirrored the ISO and regulatory requirement of bench testing for 10-year load cycle. "We found that our simulations and probabilistic methods accurately captured the inherent variability in stent performance and helped in coming up with a design that could survive in the in vivo loading environment," says Gupta.

"Ultimately, what we do is all about patient safety. Simulation helps us be much more certain of our designs."

Atul Gupta, Senior Principal Engineer, Medtronic Endovascular Therapies' R&D Team

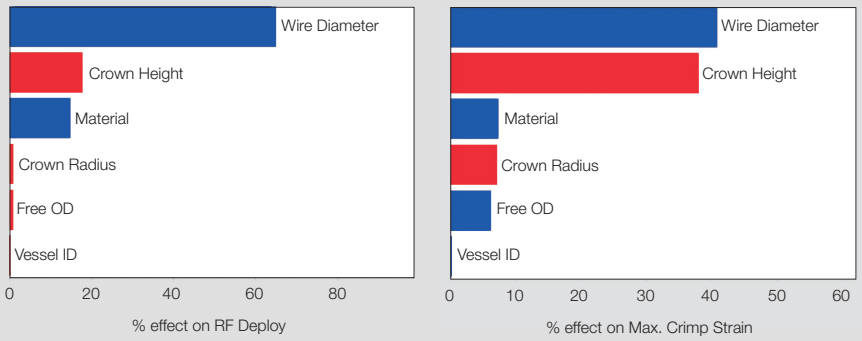


Figure 3. Computational modeling techniques in Isight software calculate sensitivity plots (Pareto distributions) for stent graft radial force (top) and crimp strains (bottom). In both outputs, the key parameters were determined to be wire diameter and crown height. Blue bars indicate a positive correlation and red bars indicate a negative correlation.

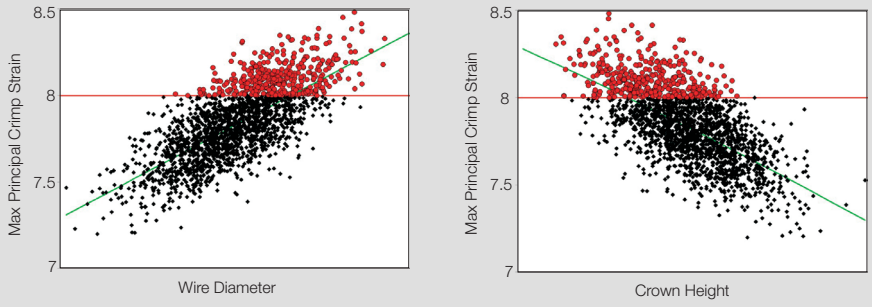


Figure 4. These scatter plots, produced as part of an Isight workflow, resulted from a probabilistic technique used in this case to show how crimp strain on the stent is affected by changes in wire diameter (top) and crown height (bottom). The green trend line indicates a positive correlation between crimp strain and wire diameter and a negative correlation of strain with crown height. Red data points indicate the values for which crimp strain surpassed the predetermined limit indicated by the red line.

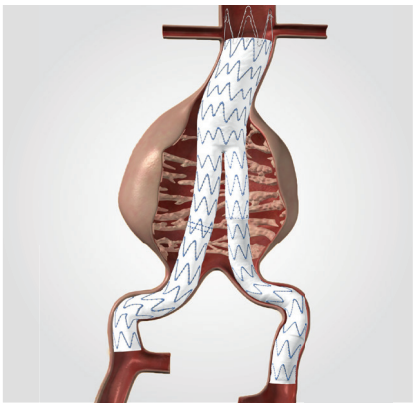


Figure 5. This cutaway view shows a bifurcated abdominal stent graft used in abdominal EVAR interventions. Computational modeling is being used to predict the performance and delivery of these devices and has been instrumental in significantly shortening the design cycle.

The future of stent graft improvement

"Before we had these computational modeling tools, we practiced a make-and-break type of approach: We would fabricate some stent prototypes, do some quick testing, and then repeat the process," says Gupta. "Now the product development cycle is much more efficient because we run numerous simulations first and then choose the design that is optimal—before we make anything." The efficiencies of new workflow routines have allowed the team to cut the stent design cycle by an order of magnitude, Gupta adds.

Acceleration of time to market and identification of key design parameters are both major improvements in the Medtronic team's product development cycle. But Gupta feels there is much more that simulation has to offer. "So far we have only looked at the stent rings and some parts of the delivery system. All of the device's components and its delivery system can be independently optimized," says Gupta. "And the assembly, which is very complex, can also be analyzed as a whole. So we'll take it one step at a time."

For next-gen devices, first steps already include using simulation to explore improved abdominal stent graft designs (see Figure 5). The R&D team is also conducting a study that examines multiple materials used to make a catheter and is looking at lowering its profile so surgical delivery is even less invasive. Future steps include exploring how best to model the unstable behavior of the polyester fabric membrane and stent-graft interactions with blood flow inside the vessel. For this, engineers are developing models that can capture instabilities in the material and a fluid-structure interaction (FSI) framework.

Currently the FDA accepts FEA results as a way to present the 'worst-case' model in a device design application. Results are always validated with physical testing prior to reporting. But the regulatory emphasis is evolving to include improved definitions about the in vivo loading environment and applicability of computational models to capture device behavior throughout their life cycle in-situ. And Medtronic is collaborating with the federal agency on refining these regulations.

"Ultimately, what we do is all about patient safety. Simulation helps us be much more certain of our designs," says Gupta. "Given the predictive power of available software tools and techniques, computational modeling is sure to become increasingly important for our industry in the future."

Stent graft manufacturing and materials

"The human aorta comes in all sizes," says Atul Gupta of Medtronic Endovascular Therapies. As a result, stent grafts, which are used to repair damage to the vessel, do too.

To match individual anatomy, both diameter and length of stent grafts can vary. The gold standard is to use patient CT scan data for sizing. For the thoracic aortic region, the Medtronic device is a simple tubular structure, ranging in diameter from 22mm to 46mm. For the abdominal region, where the aorta splits into the two femoral arteries, it is shaped like a y-joint and varies from 23mm to 36mm for the main stent graft. "It's all sort of like pipework," says Gupta.

The 'skeleton' of a stent graft is a series of circular metallic springs, or stents. This component is made by wrapping wire around protruding pins on a mandrel, creating the stent's characteristic sinusoidal shape. The wire is then crimped to connect the two ends. As a final step, a woven polyester membrane is sewn to the cylindrical metal frame.

Because of the complex process involved throughout, there is inherent variability. Stent graft wire also has a large tolerance: Nitinol, an alloy of nickel and titanium, is heat-treatment sensitive and, as a result, material properties can vary by as much as plus or minus 10 percent.

"In an ideal world, designers would like everything to be perfectly dimensioned," says Gupta. That would include the stent graft's material properties, as well as its outer and inner diameter, wire specifications, and manufacturing tolerances. "But one rule of thumb is that the tighter the tolerance, the higher the cost of manufacturing," he adds.

So to keep costs controlled, design engineers have to decide which parameters are most critical. Thicker wire and smaller stent peak height, for example, result in larger radial force and a better seal. But thicker wire also produces higher strains when crimped inside the catheter. When that happens, the material may deform permanently during loading into the catheter, and fatigue strain may increase, affecting the device's fatigue life.

"Probabilistic modeling techniques, like those in Isight, help us determine what features are most important to performance," adds Gupta. "Then we are able to focus on those key parameters. It's a tricky balancing act."

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