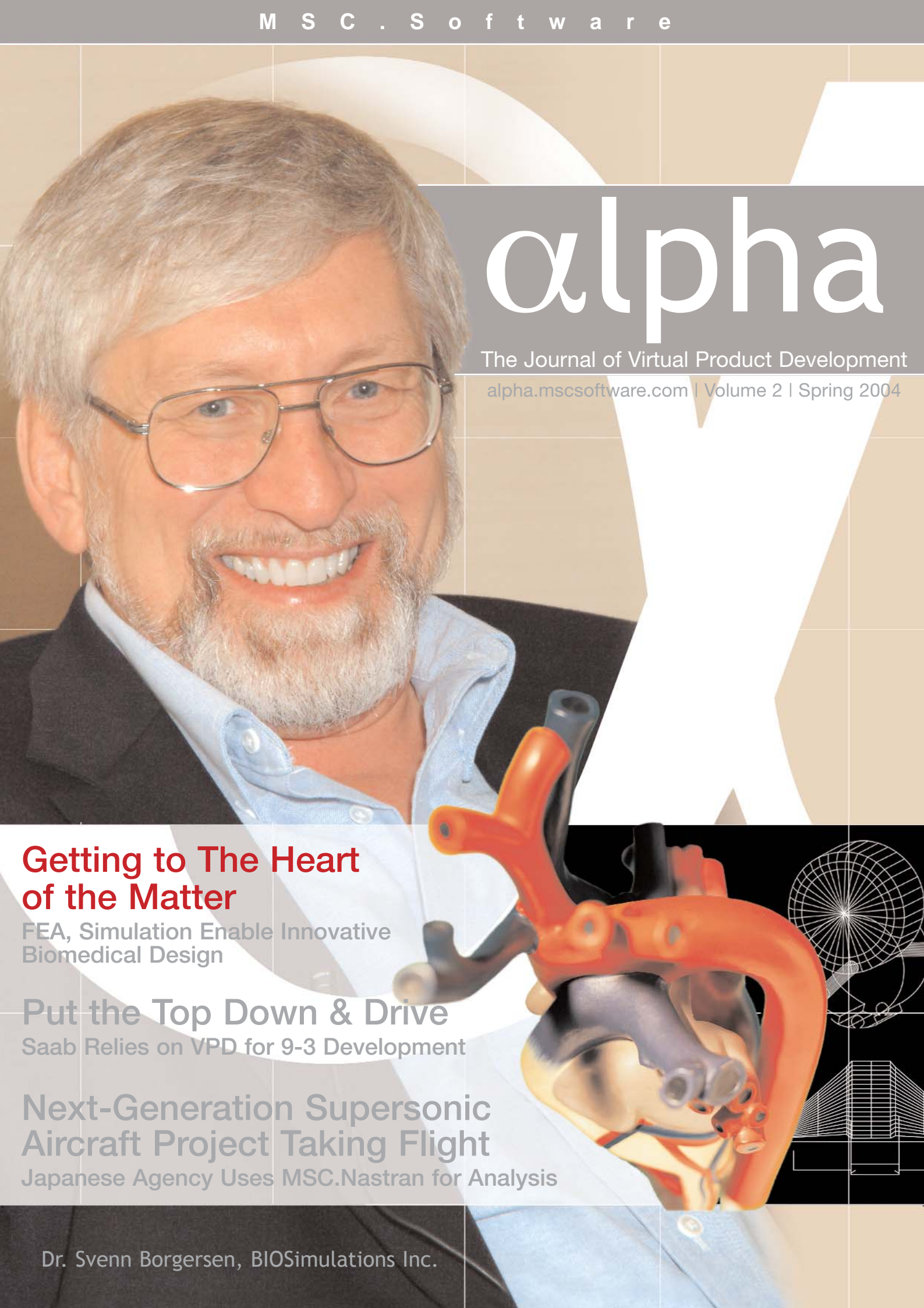


# alpha

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## Getting to The Heart of the Matter

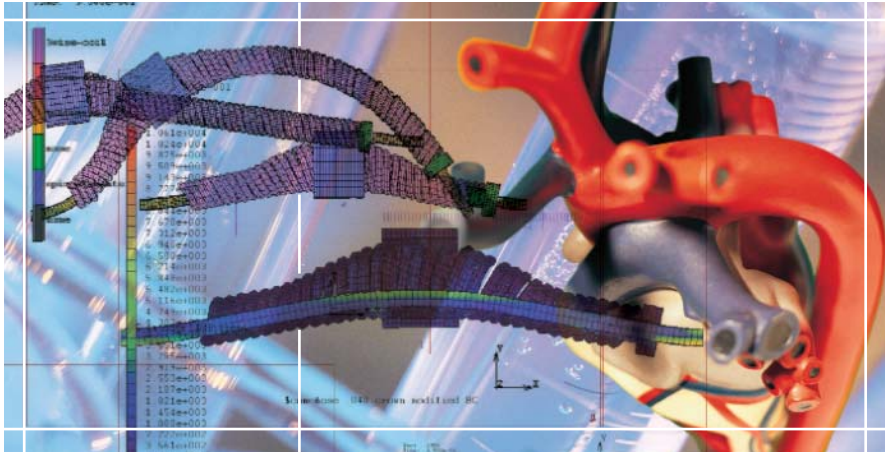
FEA, Simulation Enable Innovative Biomedical Design

## Put the Top Down & Drive

Saab Relies on VPD for 9-3 Development

## Next-Generation Supersonic Aircraft Project Taking Flight

Japanese Agency Uses MSC.Nastran for Analysis



## Safety and Innovation in Biomedical Device Design: The Increasing Role of Simulation

*As the baby boomer generation ages, the demand for faster release of innovative biomedical devices increases. The medical device industry consists of thousands of companies ranging in size and medical specialty, and recent estimates place the worldwide 2003 medical device market valuation at more than \$180 billion.<sup>1</sup> These devices, such as implantable surgical devices, prostheses, and artificial limbs and organs, are critical for procedures that improve quality of life and, in many cases, save lives. Cardiovascular applications are one of the fastest growing segments of the industry. Stents and artery-clearing devices are crucial tools in the ongoing effort to prevent or minimize the effects of strokes, heart attacks, and other circulatory problems.*

*Because these are high-risk, invasive devices that are implanted in the human body, biomedical device manufacturing is, not surprisingly, a heavily regulated industry. Rigorous physical testing is required before products can be certified and released for clinical trials and ultimately to doctors and patients. Adequate physical testing of new devices is at best lengthy and expensive and, at worst, completely cost-prohibitive and often incapable of providing a complete understanding of how a device works and responds in a wide variety of real-world applications. At the same time, introducing innovative new products faster than the competition is*

*key to winning and capturing market share. Balancing the absolute requirement for safety with the desire for speed puts medical device manufacturers in a difficult position.*

*Today, Virtual Product Development (VPD) is changing the way these manufacturers are moving products through development, manufacture, and regulatory approvals. Simulation with virtual prototypes is playing a significant role in design verification and validation, and reducing the risk of product failure. One example of this shift in biomedical device design is an orbital atherectomy device being developed with the assistance of Dr. Svenn Borgersen, who heads his own consulting firm, BIOSimulations Inc., in Eagan, Minnesota. There are currently three primary methods for performing atherectomy, the removal of plaque from arteries, but each has certain disadvantages. In this interview conducted by Alpha editor Carrie G. Bachman, Dr. Borgersen describes how simulation is making the ongoing development of this innovative device for the removal of vascular occlusions possible.*

**Alpha:** Let's start with a description of the device you are helping develop.

**Svenn Borgersen:** The orbital atherectomy device we're developing consists of a helically wound, three-wire driveshaft, an eccentric cutting head, and a safety tip. The cardiologist, guided by imaging

technology, can see where the blockage is, and positions a catheter and guide-wire at the required location. The guide-wires have a tip that is highly reflective to help the doctor see where it is. The cardiologist then deploys the device over the guide-wire and the cutting head is rotated at speeds from 80,000 to 200,000 rpm to remove the blockage. It has been tested successfully in animals and shown to remove stenotic tissue very quickly.

It's a really unique product with several advantages over other devices. First, it doesn't completely block blood flow in the artery during the procedure. Therefore, it's much more comfortable for the patient, unlike balloon angioplasty, which may temporarily block blood flow. Second, the surgeon can control the diameter of the tissue to be removed by varying rotational velocity, unlike other devices that have fixed cutter diameters that have to be removed so a larger device can be reinserted during the procedure.

Third, the device pulverizes the blockage and appears to work equally well on either soft or hard stenotic tissue. Some other devices cut the blockage into large particles that are then siphoned out or captured for removal. With this device, the particle sizes are smaller than those normally found in the blood stream. Because of this, the particles do not require capture and removal. This capability could make the device suitable for unblocking carotid arteries, peripheral arteries, and veins in addition to its cardiovascular applications.

**Alpha:** What advantage is simulation bringing to this product's development?

**SB:** Simulation is shortcutting our time to market. It's also doing something that's otherwise been almost impossible to do on these small devices – allowing us to design for safety. The one thing that we want to make sure of is that we have a device that's safe. You're rotating a mechanical device inside the human body at 200,000 rpm – if anything goes wrong, there could be a problem. We are very safety-conscious, following the premier caveat of "do no harm." Our second concern is making sure that the device functions properly and does what it's supposed to do. But above all, we want to make sure we have a safe product.

<sup>1</sup> Data for 2003 is a projection based on 2002 AdvaMed worldwide market valuation.

I've been using MSC.Software's MSC.Marc for biomedical applications for approximately 15 years. MSC.Marc has allowed us to simulate coil wire stresses during production of the device's driveshaft, as well as examine the contact stresses in critical design areas. The software enables us to actually examine the structural stresses in the bonds, components, sub-assemblies and assemblies that go into making this device, to be sure it can handle the kind of loads anticipated during the cardiology procedure. We've been able to simulate the driveshaft, cutter head and safety tip actually rotating at a variety of design speeds, enabling us to evaluate contact stresses between components, and stresses within the components to ensure product safety.

One of the problems with some current atherectomy devices is that guide-wires tend to fracture. That's a difficult situation, because once the guide-wire breaks, you have to retract the atherectomy device, and the cardiologist has to go in and remove the guide-wire. While they are highly flexible and made of high-strength materials, guide-wires can be broken. There are now some special tools that will remove the broken guide-wire, but it's a nasty procedure because it's time-consuming and may be hazardous to the patient. These guide-wires are nine-thousandths of an inch in diameter, not very large. The guide-wire tip region, which is positioned within the occlusion to be removed, and which is the highest load contact region between the guide-wire and the rotational atherectomy device, is only five-to-seven thousandths of an inch in diameter.

We have been simulating what it takes to break a guide-wire, not only with bench-top testing, but using MSC.Marc to model this. One of the advantages of MSC.Marc is that it can actually perform the rotational sliding contact, which is a very complicated problem to simulate. MSC.Marc has been an excel-

lent product for that. It can also handle all the non-linear material properties, so when we are working with a material stressed into the high end of its plasticity range, the software is able to handle that very nicely.

**Alpha:** What would you say is the greatest value of simulation?

**SB:** It has the potential to enhance product performance and safety, and it saves lives. It allows us to generate a product design that's much safer than it would be otherwise. A design engineer can evaluate what could happen if he makes a design change. Let's say that you make an assumption and redesign your part – simulation lets you do a 'what-if' analysis. If you know how the baseline product design works, and then you change a part or component, you can examine the effect and evaluate the results.

**Alpha:** Would these types of devices would be possible without simulation and analysis software tools?

**SB:** Oh, you could probably come up with the same kind of thing, but it would take much longer, and you would have no way of evaluating product safety except through exhaustive testing to prove whether your design assumptions were correct or not. That's a primary advantage of finite element analysis – it's a tool that can give you information you can't get any other way.

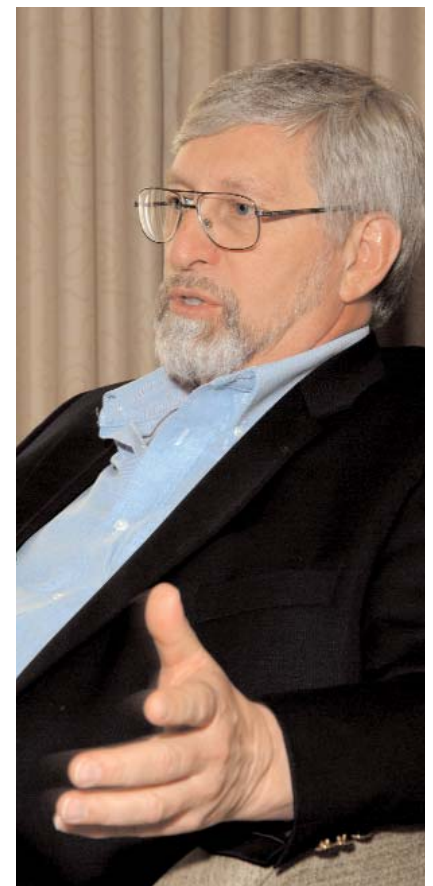
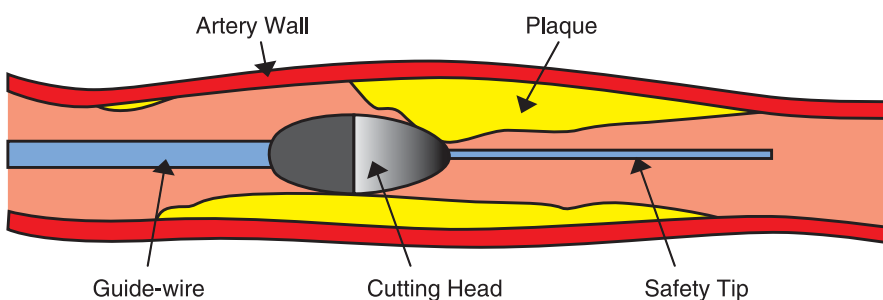
We face several challenges in product development. For example, the part of our device that grinds away tissue has a diameter between 1.0 and 1.9 millimeters. That's smaller than the tip of a pencil. The driveshaft consists of three wires that are approximately 0.15 millimeters in diameter, helically wound into a driveshaft with a diameter of approximately 1.73 millimeters and a length of approximately 1300 millimeters.

For cardiovascular procedures, our method inserts the driveshaft into the human body through the femoral artery and follows the arterial canal up to the

heart. There are a number of small arteries that lie on the outside surface of the heart, and we have to come up through the main aortic arch and out into these arteries. Our device has to be flexible enough and small enough to fit into these arteries, while still having sufficient strength to cut away the blockage. Once we can open up that blockage, blood can flow in to feed the heart muscle, which prevents any further damage, assuming there has been damage.

It's a real challenge to design a device flexible enough to go in through that vascular canal and into the coronary arteries, yet strong enough to spin at 150,000-200,000 rpm and remove the blockage. We have to design a cutter that is not going to damage the artery wall, but will remove the plaque deposits, both soft and calcified plaque, with a particle size small enough to remain in the bloodstream and not cause complications for the patient. And, we have to do this in such a manner that we allow blood to continue flowing during the process to reduce patient discomfort.

The device components are very, very small and you can't effectively strain-



gauge something that size. At best, you can do some load testing on the wires used to wind the driveshaft and the bonds used to assemble components. With the MSC.Marc finite element program, we can simulate these tests on the computer to evaluate tensile, compression, torque, and bending effects. The software allows us to evaluate the various stress components as the load changes, and lets the design engineer actually evaluate how the driveshaft coil wires interact with each other. It makes a big difference in predicting fatigue life and associated loading effects. FEA is a great tool when properly applied.

**Alpha:** Do you still build a physical prototype to test against? Do you find that you need fewer of these because of the upfront work you're able to do with simulation?

**SB:** The answer to that is yes and no. Yes, we can build fewer physical prototypes because of simulation capabilities. We analyze the proposed design and build a minimum number of prototype test devices to check to make sure that the analysis and test results correlate well. This provides a very high degree of confidence in the design. But the Federal Drug Administration (FDA) still requires physical tests to be performed, so we have to do those also. However, FEA simulation certainly allows us to enter the test program with a much higher degree of confidence that the product is going to function as designed.

**Alpha:** Do you think the FDA is ever going to say that simulation is all you need?

**SB:** No, I don't think they will. I heard a presentation by Boeing Company about their new aircraft that's going to be completely designed on a computer system. I think that's marvelous. But what people forget is that the reason they're able to do that is that they have spent 50 to 60 years doing all kinds of testing – structural testing, wind tunnel testing. They've built up the database necessary to validate the analysis approaches that they're using. We're basically doing the same thing, only we don't have those years of experience in biomedical applications. The materials and performance parameters of the human body have not been as well-defined as aircraft materials and the

environment in which aircraft perform. Finite element analysis in the biomedical field is relatively new, and the knowledge base for human tissue material properties is very limited.

**Alpha:** What is the FDA's familiarity level with simulation? Are they recognizing the benefit that it brings?

**SB:** They have experts of their own, and those experts ask questions. When you submit documentation to the FDA, they not only look at the test results, but any analysis information you submit. They look at that very carefully, searching for anomalies, and will come back with questions. It's an ongoing process. If you're very fortunate and you do everything correctly the first time through – you provide the information that they're looking for and everything correlates properly – then you may get that Investigative Design Exemption (IDE) approved right away. Otherwise it may take several rounds. I've been in situations where we've submitted our results to the FDA and 30 to 45 days later we get a list of questions back that require another 30 to 45 days to answer. Then you send back the results, and you go round and round. These kinds of things do happen; it's not a slam-dunk by any means. My experience has been that having good solid analysis, verifiable through testing, and submitting it all as a package makes life a lot easier, both for the FDA and for the company.

**Alpha:** What are your top three goals as



a company? Faster time-to-market, a superior concept, more collaboration with surgeons...?

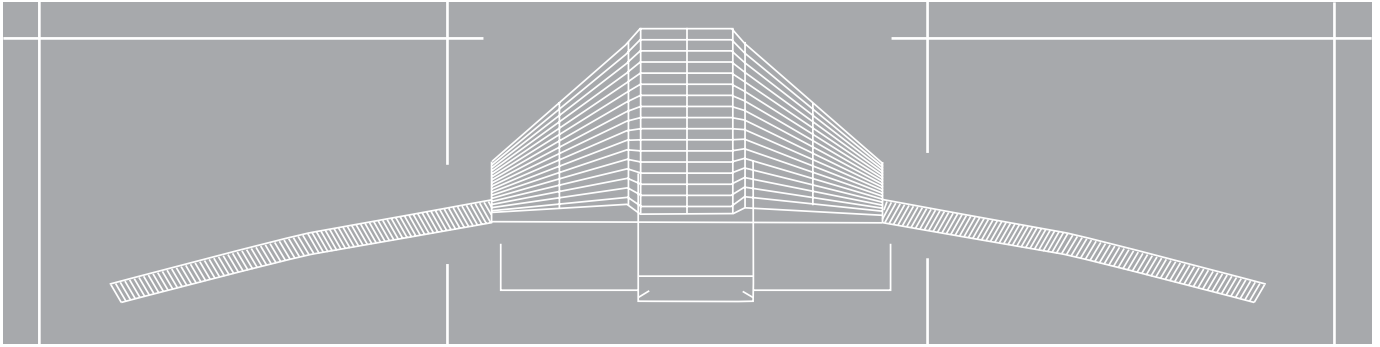
**SB:** Yes, but ahead of all that is safety, product safety. After that, time-to-market; good, efficient product design; low cost. Analysis in the long run can help in all of those areas. Analysis itself isn't a be-all and end-all, but it certainly is a very important part of the equation for bringing a good, sound, safe product to market as quickly as you possibly can.

**Alpha:** Is this the first in a series of planned products?

**SB:** Yes, we have other products we're researching. And of course there will be improvements to this particular product line, along with variations for other applications.

**Alpha:** In many industries, there's often a disconnect simply because of the jargon the different groups speak. Here you have engineers, such as yourself, using these engineering tools to create the devices. On the other hand you're working with surgeons and doctors who, one would assume, don't have an engineering background. Does having virtual prototypes, simulations, analysis results help in describing and marketing the product?

**SB:** Oh, certainly. With the information that we're generating right now, we can perform numerical simulations with MSC.Marc and animate some of the results. Those animations can be very, very interesting. We are able to perform demos with the animations, using the FEA results to show how the device moves, how it behaves at different rotational speeds. The animations can form the basis for educational and training tools to show the medical community how our device works. We have these analysis results, we have these animations, and, by the way, here's a picture of how the device is running in our test fixture so you can see what's going on. There's nothing like a good finite element analysis picture with all those colors to impress people. Cardiologists and surgeons are very innovative themselves and they can see the value. We've already demonstrated our product for a number of cardiologists who are currently using other devices. After seeing our product and what it does, they're very interested and very much want to be part of our investigative programs.



It's helped quite a bit to be able to show them demos and simulations.

**Alpha:** So there is a partnership between your company and the surgeons...

**SB:** Absolutely. They're already a part of the process. A cardiologist who is very experienced in atherectomy procedures conducted our animal tests. The client company has an established Scientific Advisory Board composed of highly qualified members of the medical community, and its board of directors includes very experienced people from the biomedical industry, as does the company's top management. Having access to these highly qualified medical experts and receiving their input is a real advantage.

**Alpha:** Can you quantify in general terms the product development cost for a biomedical device?

**SB:** Not really, because it differs from company to company. Depending on what kind of biomedical device you're working on, company size and overhead structure, R&D funding methods, software and computer systems required, the cost varies tremendously. The bottom line is that development costs are very high, in the millions of dollars. Our device has probably been less costly, has required a shorter development time and lower staffing than a pacemaker, an angioplasty balloon, or a stent. I've worked on angioplasty balloons, stents, pacemakers, and pacing leads, so I know what's involved as far as R&D goes.

But, consider the potential that for every stent that's been put in, there's a stent that may need to be cleaned out sooner or later. Even the new drug-coated stents that are currently being introduced still may have problems with restenosis, although the process may be slowed considerably. Our device appears to have the potential to open occluded

stents, cardiovascular arteries, carotid arteries, peripheral arteries, and veins. There's a potential of penetrating a half-billion dollar market, and that makes the development effort well worthwhile.

**Alpha:** What makes those devices different? Is it that you're using simulation so heavily with your device, or is it just the nature of those particular devices?

**SB:** Actually, stents are probably one of the most heavily analyzed biomedical devices in the market today. The companies that produce stents generally use MSC.Marc and other products to analyze the stents, both on a preliminary design basis and on the final design and analysis. FEA analysis has become an integral part of the product development cycle.

Our device, from a functionality and analysis point of view, is probably much more complex than a stent. A stent is basically a static analysis, structural stability problem, with some consideration for long-term cyclical fatigue life. Stent loads are quite modest, with the exception of crimping onto the balloon catheter or deploying within the artery. On the other hand, our rotational atherectomy device is a very complex analytical challenge – initially the device driveshaft is formed by winding three stainless steel wires around a mandrel, which plastically deforms the wires at stress levels well past the yield point; then it is heat-treated to its final geometric shape, which alters the material properties; then high-temperature brazing processes are used to attach the cutting crown and tip. The final product represents a highly complex 3-D contact problem, combined with the physics of

an eccentric mass rotation up to 200,000 rpm that produces large displacements and centrifugal forces. Removal of stenotic tissue at these rotational speeds means that high-speed impact forces also need to be considered.

**Alpha:** When implementing virtual product development tools, companies need to understand that this is not just plug in, sit down and everything works. There's a cultural change and an education curve that goes along with it. What has been your experience with this?

**SB:** It does change the entire organization and the design environment, and it's very important that management develops some rudimentary understanding of what these tools are capable of being used for. You also need to know some of the things that can get you into trouble if you don't understand the limitations of the tools. There are correct ways to use FEA to simulate a physical event, and achieve good, accurate answers. Unfortunately, it's also possible to create FEA models that solve properly, and yet develop completely misleading results. It takes good insight, an engineering background, and knowledge to perform modeling and analysis safely.

Advancements in analysis and numerical simulation have grown by leaps and bounds in the last seven years. The more we look at it, the more use we have for it in almost every single industry. In my opinion, if you're going to develop any kind of biomedical device, simulation is one of the most powerful tools you can use. **α**

