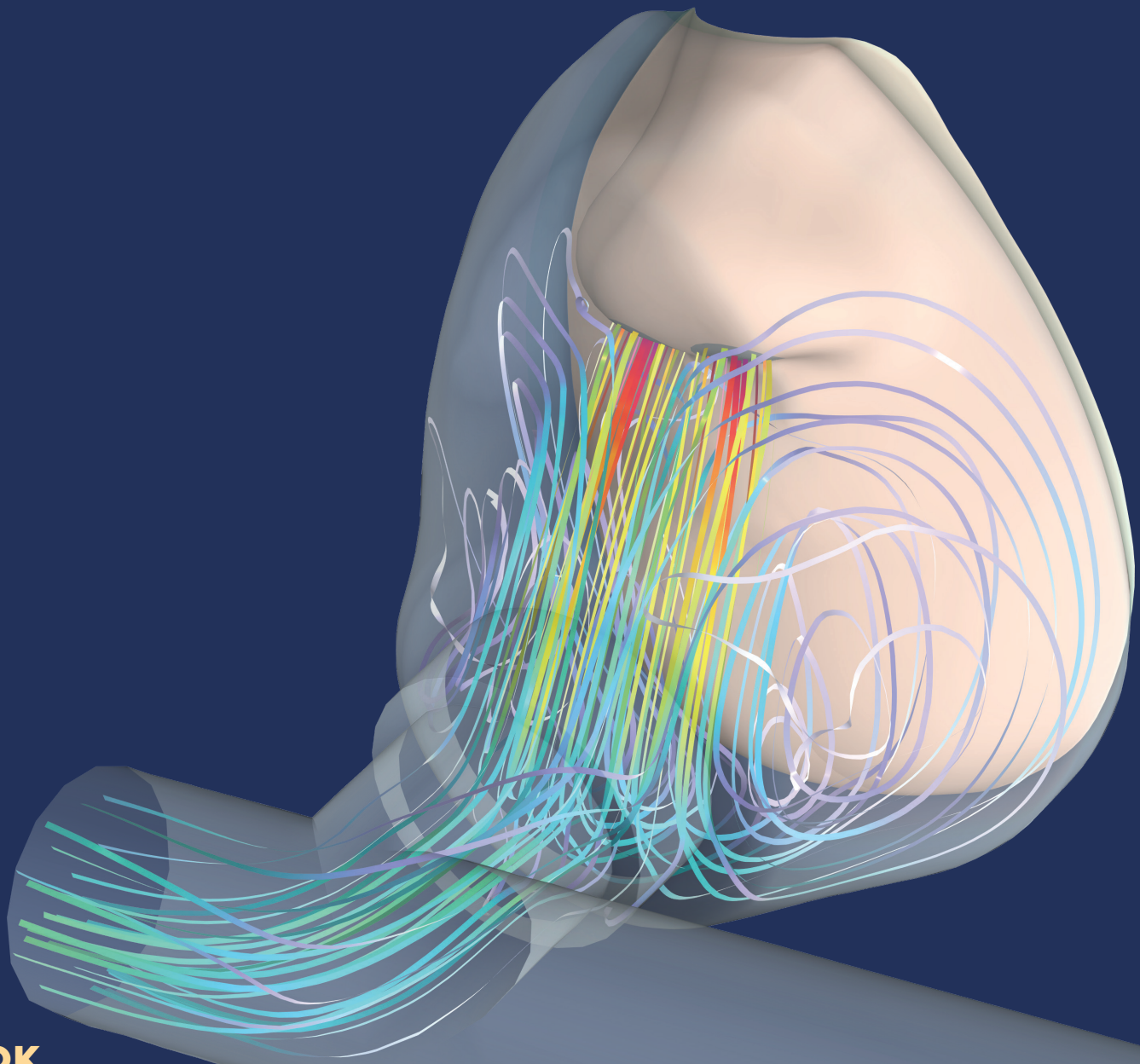


EBOOK

Medical Device R&D

simulation success stories

COMSOL

Medical Device R&D

Computational modeling and simulation (CM&S) is gaining in use in the healthcare industry for understanding, designing, and optimizing devices and processes, allowing for efficiently tackling key questions related to patient safety, product quality, and regulatory compliance. In this ebook, you will learn how four teams from around the world are using CM&S to create safe and effective medical devices while reducing costs and the need for *in vitro* and *in vivo* testing.

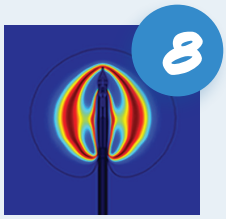
In one story, you will learn about implanted medical devices and how MED Institute, a full-service contract research organization (CRO) for the medical device industry, is using computational modeling to analyze the RF heating of these devices when exposed to MRI systems. On page 8, you will learn how Medtronic, one of the world's premier medical technology and services companies, studied ablation technology using multiphysics simulation to enhance physicians' abilities to plan and implement ablation procedures.

In addition, you will see how Abbott Laboratories has been using numerical simulations to engineer left ventricular assist devices (LVADs) to improve the outlook and quality of life for patients with heart failure. There is also an article on how engineers at STMicroelectronics are using simulation to optimize their semiconductor solutions for a wide range of use cases, such as ensuring the accuracy of a bioimpedance meter.

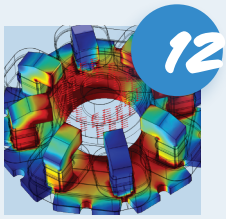
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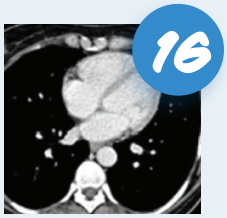
Radiofrequency-Induced Heating of Medical Devices in MRI Systems
MED Institute, Indiana, USA



Medtronic Advances Ablation Technology with Multiphysics Simulation
Medtronic, Colorado, USA



Enhancing Performance and Safety of Medical Implantable Devices with Multiphysics Simulation
Abbott, California, USA



Reliable Structures and Wearable Systems Call for Multiphysics Simulation
STMicroelectronics, Italy

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MED INSTITUTE, INDIANA, USA

RADIOFREQUENCY-INDUCED HEATING OF MEDICAL DEVICES IN MRI SYSTEMS

Implanted medical devices in patients should be designed to be safe in and compatible with a magnetic resonance imaging (MRI) environment. MED Institute, a medical device development research organization, is using computational modeling and simulation to analyze RF heating of devices in MRI systems.

by **DIXITA PATEL**



FIGURE 1 *Engineers at MED Institute Inc. performing physical MRI testing to evaluate the safety of medical devices in the MRI environment.*

Over 80 million magnetic resonance imaging (MRI) scans are conducted worldwide every year. MRI systems come in many different shapes and sizes, and are identified by their magnetic field strength. These scanners can range from below 0.55 tesla (T) to 3 T and beyond, where tesla is the unit for the static magnetic field strength. For patients with implanted metallic medical devices, the strong magnetic fields generated by MRI systems can pose several safety concerns.

For instance, high-powered magnets generate forces and torques that can cause the implant to migrate and potentially harm the patient. In addition, the gradient coils in MRI systems, used for spatial localization, can cause gradient-induced heating, vibrations, stimulation of the tissue, and device malfunction. Lastly, the large radiofrequency (RF) coil in MRI systems can cause the electrically conductive implant to electromagnetically resonate (called the "antenna effect"), resulting in RF-induced heating that can potentially burn the patient.

MED Institute, a full-service contract research organization (CRO) for the medical device industry, is using multiphysics simulation to better understand the effects of RF-induced heating of medically implanted devices for patients that need MRI scans.

STANDARDIZED TEST METHODS FOR MEDICAL DEVICES

MED Institute provides support throughout the entire product development cycle. Its MRI Safety team helps manufacturers evaluate and perform physical testing of their medical devices for safety and compliance in the MRI environment (Figure 1). The team works closely with the Food and Drug Administration (FDA), which oversees the development of medical products to ensure safe and effective use. Furthermore, the team complies with the standards of the American Society for Testing and Materials (ASTM) and International Organization for Standardization (ISO). Specifically, it follows the ASTM F2182 standard to measure RF-induced heating of a medical implant within a gel phantom (Figure 2) and follows ISO/TS 10974 to evaluate electrically active implantable medical devices (AIMD) during MRI.



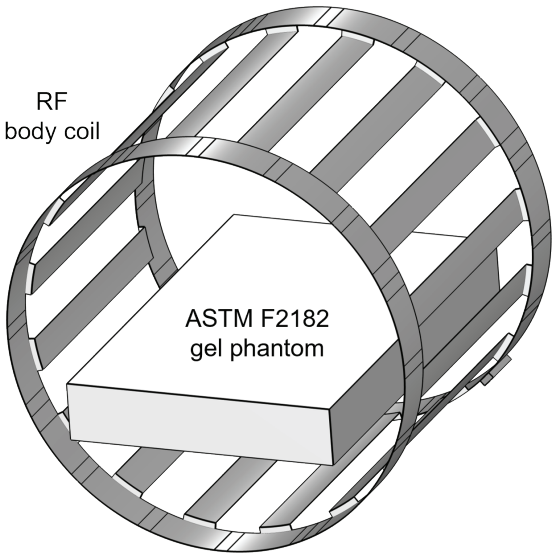


FIGURE 2 *The ASTM F2182 standard used during physical testing under an MRI (top) and under virtual testing (bottom).*

The gel phantom used for testing is a rectangular acrylic container filled with a conductive gel that approximates the thermal and electrical properties of average human tissue. The phantom is placed on the patient table inside the RF coil of an MRI scanner and fiber optic temperature probes (1 mm in diameter) are attached to the device before submerging it into the gel. The probes measure the temperature changes experienced by the device during the MRI scan. This type of physical experiment is used often, but it poses some potential problems. For instance, movement within the phantom can introduce uncertainty into the experiment, and inaccurate probe placement can lead to invalid results. In addition, depending on the materials of construction and their magnetic susceptibility, magnetic force could also be an issue.

To help address these issues, the team at MED Institute uses computational modeling and simulation as an alternative to physical testing. David Gross, PhD, PE, Director of MRI Safety Evaluations and Engineering Simulations, leads a team of analysts that use simulation to gain a better understanding of physics-based problems. He says, "The simulation provides us with 3D temperature contours anywhere within a volume of interest; we are not limited to discrete point-probe measurements, and we do not have to worry about the inaccuracies of the equipment or uncertainty of probe placement from the experiment."

The team has experience conducting these simulations for closed-bore MRI systems, in which a patient is contained in a compact tube. The team is now using simulation to perform these same analyses for open-bore systems (Figure 3), which have wider physical access, making them beneficial for "imaging pediatric, bariatric, geriatric and claustrophobic patients", as is explained on the MED Institute website.

MULTIPHYSICS SIMULATION FOR RF-INDUCED HEATING

With COMSOL Multiphysics®, MED Institute is able to evaluate the RF-induced temperature rise of implants and compare the results of various sizes and constructs of a device within a product family to determine a worst-case configuration. The analysts at MED Institute can import a CAD file of a client's device using the CAD Import Module, an add-on to COMSOL Multiphysics®. In terms of RF-induced heating, the team uses the RF Module and Heat Transfer Module add-on products to combine the physics of electromagnetics with transient heat transfer. For analyzing electromagnetics, the RF Module enables the use of Maxwell's equations to solve for the wave equation at every

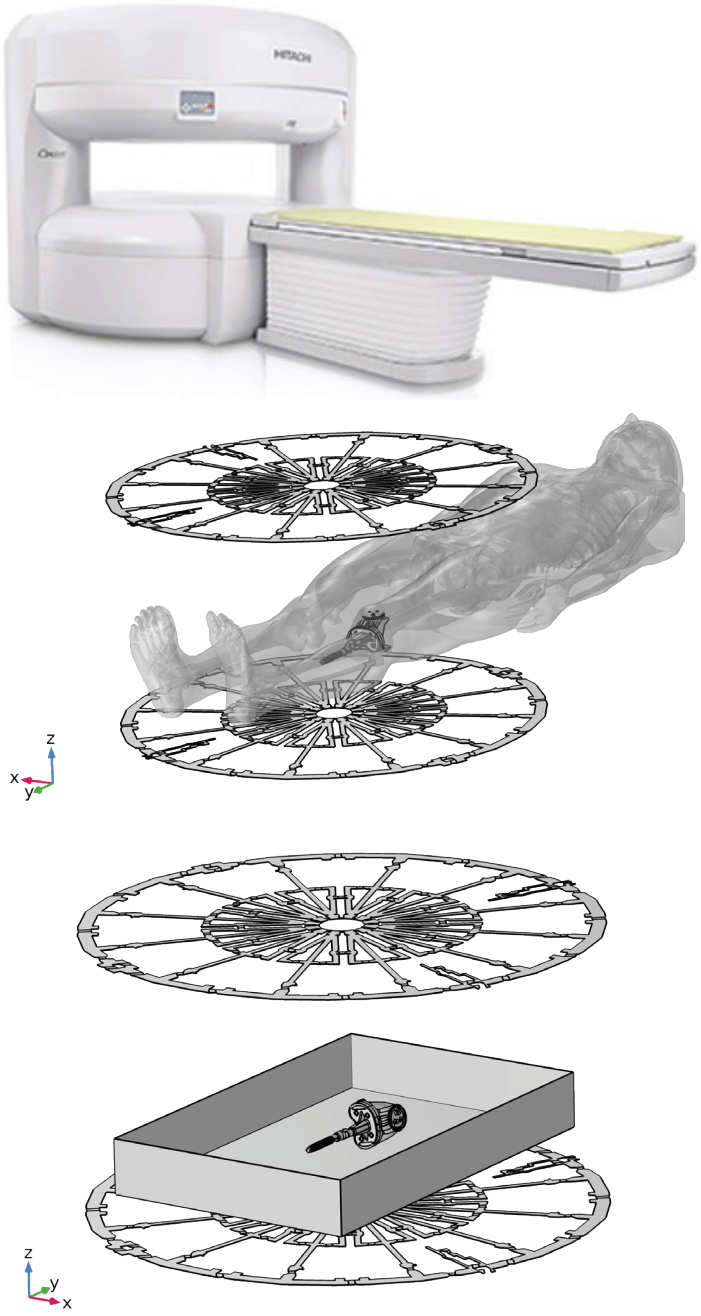


FIGURE 3 *An open-bore MRI system (top), RF body coil with the IT'IS Foundation's Duke virtual human model (center), and an RF body coil of a knee implant in an ASTM gel phantom (bottom).*

point within the model that is impacted by electromagnetic fields. This is done in a steady-state frequency domain, which is then sequentially coupled to the transient heat transfer. With the Heat Transfer Module, the team is also able to solve heat conduction equations.

In the example below, MED Institute imported a CAD file of a knee implant into the COMSOL Multiphysics® software. The geometry of the implant included a stem extension, tibial tray, femoral tray, and other components. All of these components can have various sizes and can be assembled in various ways, and patients with the implant can be scanned in various MRI systems that create different electromagnetic fields. With the overwhelming amount of permutations that these variables can produce, it is often not clear which configuration would result in the worst-case RF-induced heating.

"This is where the use of simulation comes in; you focus your efforts on the primary factors that can change the resonance of a particular implant," Gross says. By using the COMSOL® software, the organization is able to better understand the relative bounds of where it would expect to see resonance and how the device behaves under different electromagnetic fields. This helps with performing sensitivity analyses, where the team can test what causes the change in resonance, such as modifying the diameter of the stem or other components of the implant. For this particular case, the team ran hundreds of simulations to determine the worst-case device size and worst-case RF frequency.

Using worst-case analysis is crucial in the verification process because it allows manufacturers to test different factors for a wide range of devices — such as determining which size brings the most complications — rather than conducting physical testing for every variant of one product. "Performing multiple physical experiments becomes very expensive and time-consuming, especially when you account for the hourly cost of using a physical MRI scanner," says Gross.

As shown in Figure 4, the electric field in the gel phantom of a 1.2 T open-bore system (upper left) is very different from a 1.5 T closed-bore system (upper right). The knee implant was simulated in both systems, where the results show a different resonance and maximum temperature rise at the end of the stem (lower images).

Using COMSOL® allowed the team to better understand how a device behaves under electromagnetic fields. With these results, the team was then able to determine where they should place temperature probes while physically testing the device in an actual MRI system to obtain temperature rise results.

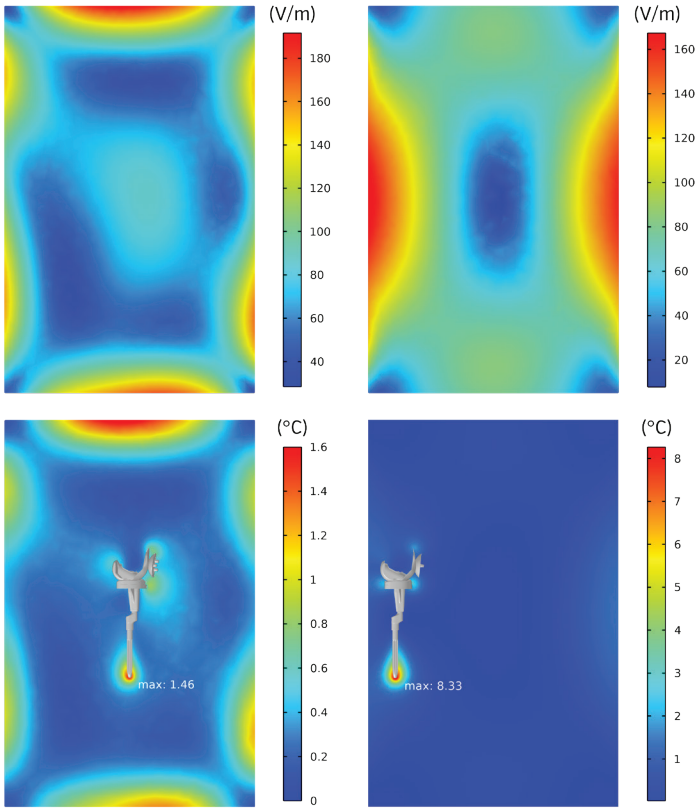


FIGURE 4 *A knee implant in a gel phantom comparing the simulation results of an open-bore (left) and closed-bore (right) system.*

FDA QUALIFICATION OF MED INSTITUTE'S VIRTUAL MRI SAFETY EVALUATIONS

MED Institute's experience with using simulation to test RF-induced heating of medical devices has inspired development of a promising new simulation tool that accelerates the product development cycle. The MED Institute team submitted this simulation tool to the FDA's Medical Device Development Tool (MDDT) program, which allows the FDA to evaluate new tools with the purpose of furthering medical products and studies. As stated on the FDA website, "The MDDT program is a way for the FDA to qualify tools that medical device sponsors can choose to use in the development and evaluation of medical devices." Once qualified, the FDA recognizes the tool as an official MDDT.

In November 2021, MED Institute was granted FDA qualification of its MDDT, "Virtual MRI Safety Evaluations of Medical Devices". This is an evaluation process that involves using multiphysics modeling and simulation to test the interactions of medical devices in an MRI environment. The tool is used for modeling an RF coil of an MRI system, ASTM gel phantom, and a medical device placed within the gel. Simulation is then used to analyze the electromagnetics and the heat that generates around the device.

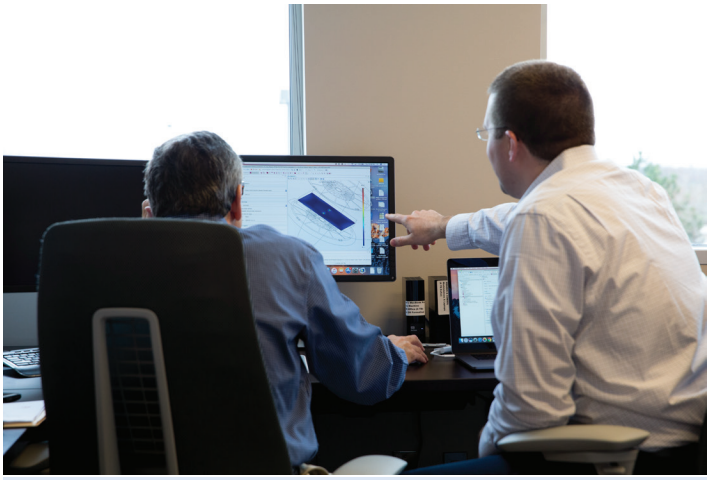
After testing is complete, the labeling of the device is described by ASTM 2503 or, if it is an electrically active implant, by the ISO 10974 test. The labeling is placed on the device packaging and inside the instructions for use (IFU) so that an MRI technologist or radiologist can see the relevant information for a patient with an implanted device.

"With our MDDT, we can not only augment physical testing but even replace it with simulation in some cases," says Gross.

MODELING AND SIMULATION SUPPORT FROM THE FDA

Over the years, MED Institute has evaluated many medical devices for MRI safety with COMSOL Multiphysics® simulations. It has found that COMSOL® is a powerful and efficient platform for solving complex multiphysics problems. "The immediate, positive results are that our clients are able to have their products evaluated quicker and at less cost because we are able to rely on the simulation. It does not require them to send us the actual product to test for RF-induced heating," says Gross.

The FDA has been supportive of computational modeling and is willing to evaluate and accept data from simulation in lieu of physical testing. "It is important for medical device sponsors to know that they have the encouragement and support of the Agency," Gross says. MED Institute has had the privilege of working alongside the FDA for many years for the benefit of patients.



MED Institute uses the COMSOL Multiphysics® software to accelerate the product development cycle for its clients.

MEDTRONIC, COLORADO, USA

MEDTRONIC ADVANCES ABLATION TECHNOLOGY WITH MULTIPHYSICS SIMULATION

The new technology will enhance physicians' abilities to plan and implement ablation procedures, potentially leading to better patient outcomes.

by **GARY DAGASTINE**

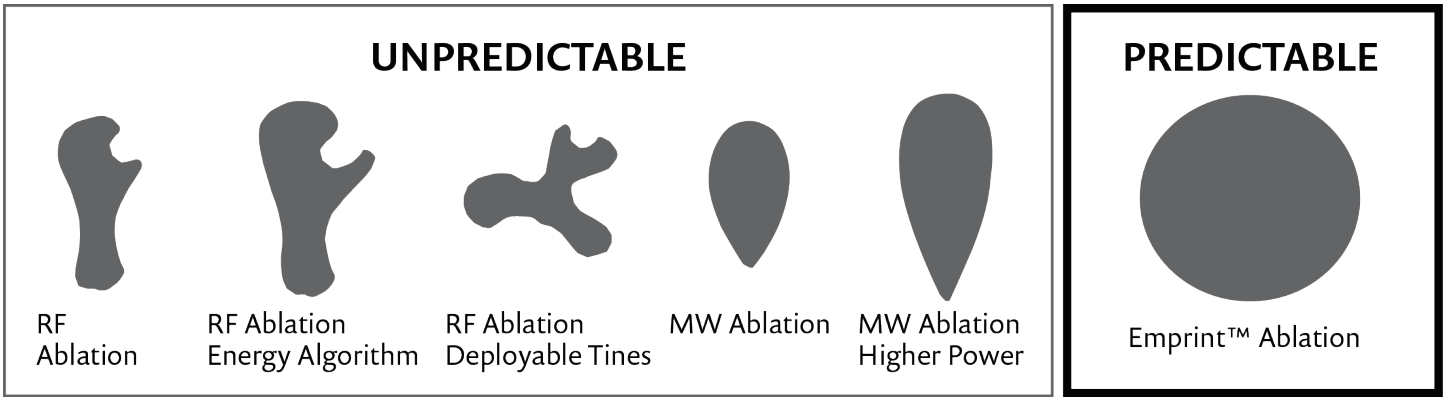


FIGURE 1 *At left, shapes of tissue ablation zones that can result unpredictably from the use of various ablation technologies. At right, Medtronic's Emprint™ ablation system with Thermosphere™ technology yields predictable spherical ablations regardless of target location or tissue type.*

Ablation, or the use of high-frequency electromagnetic (EM) energy to destroy soft-tissue tumors, has been in existence for a few decades, but in recent years its underlying technology has evolved.

The benchmark of minimally invasive tissue treatment has long been the application of electrical current to kill abnormal tissues. This is done by heating tissues until they break down, a process called thermal ablation. Energy is delivered at 500 kHz, within the radio frequency (RF) range of the EM spectrum, hence these systems are called RF ablation systems.

In recent years, microwave (MW) ablation technology has also become commercially available and increasingly pop-ular. At MW frequencies, oscillating EM fields are utilized to perform thermal ablation. Medtronic, one of the world's premier medical technology and services companies, is a leader in both RF and microwave ablation technologies. With both RF and MW systems, the energy for ablation is applied using one or more needle-like probes.

Medtronic's latest innovation, the Emprint™ ablation system with Thermosphere™ technology, offers more predict-able and repeatable results than other techniques and devices (Figure 1). These advantages come from the fact that Thermosphere™ technology enables precise control of an EM field independent of the surrounding tissue environment.

STRIVING FOR BETTER PREDICTABILITY

According to research, physicians rate predictability as their number one concern with ablation performance. The higher the level of predictability, the easier it is for a physician to plan a treatment procedure that will be safer, more effective, and less time-consuming.

Because of its nature, it's challenging to be certain that RF ablation procedures will achieve the desired results. Given their different electrical conductivities, some tissues are less amenable to effective RF heating than others. Moreover, as the temperature in targeted tissue approaches 100˚C, water in the tissue begins to vaporize and electrical conduc-tivity rapidly decreases. This can make it difficult to generate temperatures high enough to cause cell breakdown.

MW ablation technology attempts to overcome these limitations by using an EM field radiated into the tissue (Figure 2). However, in practical application, tissue type and the vaporization of water during ablation cause the size and shape of the EM field to vary.

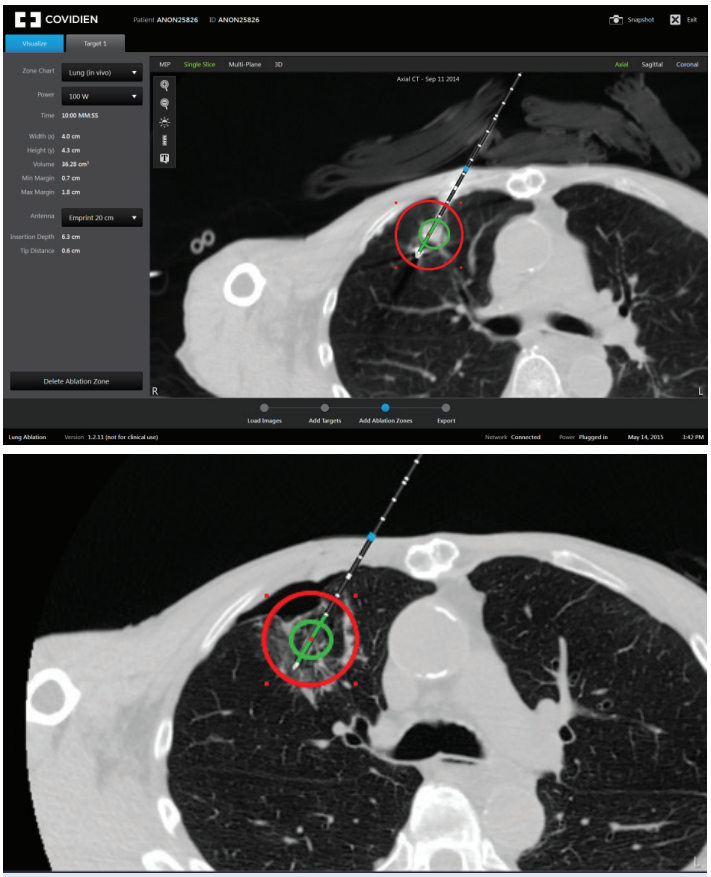


FIGURE 2 *The photo on top illustrates placement of an ablation probe. The green circle delineates the target (where the lesion is located) and the red circle delineates the margin the ablation is meant to achieve. The bottom image shows the site after ablation has taken place.*

The Emprint™ ablation system with Thermosphere™ technology realizes the promise of predictability. It gives physicians the ability to easily control the thermal energy delivered by allowing precise control of the EM field across tissues and temperatures. This allows clinicians to accurately predict the boundaries and characteristics of the ablation zone.

REAL-TIME MONITORING OF ABLATIONS

"The challenge now is to monitor the ablation performance in real-time," said Casey Ladtkow, principal engineer in the Early Technologies unit of Medtronic's Minimally Invasive Therapies Group (MITG). "At present, when performing ablations, physicians don't have continuous real-time feedback on the effectiveness of their procedure. If they could know exactly what is happening in real-time from start to finish, the effectiveness of ablation treatment would increase," he said.

With some 40 staff members focused on interventional oncology, the mission of his unit is to deliver procedural solutions that alleviate pain, restore health, and extend life. He and his team are using COMSOL Multiphysics® software to develop new ablation probes in order to achieve even higher levels of predictable performance and effectiveness.

One development-stage project is to optimize the design of these probes so they can both create a more precise ablation zone and also provide real-time feedback using radiometers.

Radiometers measure EM radiation and enable the characterization of the spatial distribution of an EM field. Ladtkow's team is incorporating radiometers into Medtronic probes in order to give clinicians real-time feedback about the ablation zone. This will enable a clinician to fine-tune the zone as needed during the procedure, and to make sure the radiation destroys the targeted tissues while minimizing effects on the surrounding healthy tissue.

The team uses COMSOL Multiphysics and its RF Module to help them model the probes and better understand and optimize their emitting/radiating and receiving/monitoring properties. "The performance and accuracy of MW ablation systems are affected by a number of dynamic factors that arise simultaneously in multiple physics domains. COMSOL® software gives us the ability to perform the relevant complex modeling quickly and easily, to help us understand these coupled effects and improve our design," Ladtkow said.

SIMULATION ENABLES FAST AND SAFE DESIGN, OPTIMIZATION, AND PROTOTYPING

For such a complex device, the traditional approach of building and evaluating a series of physical prototypes is all but out of the question because of the complexity and relationships among the many physics-based factors that impact device performance.

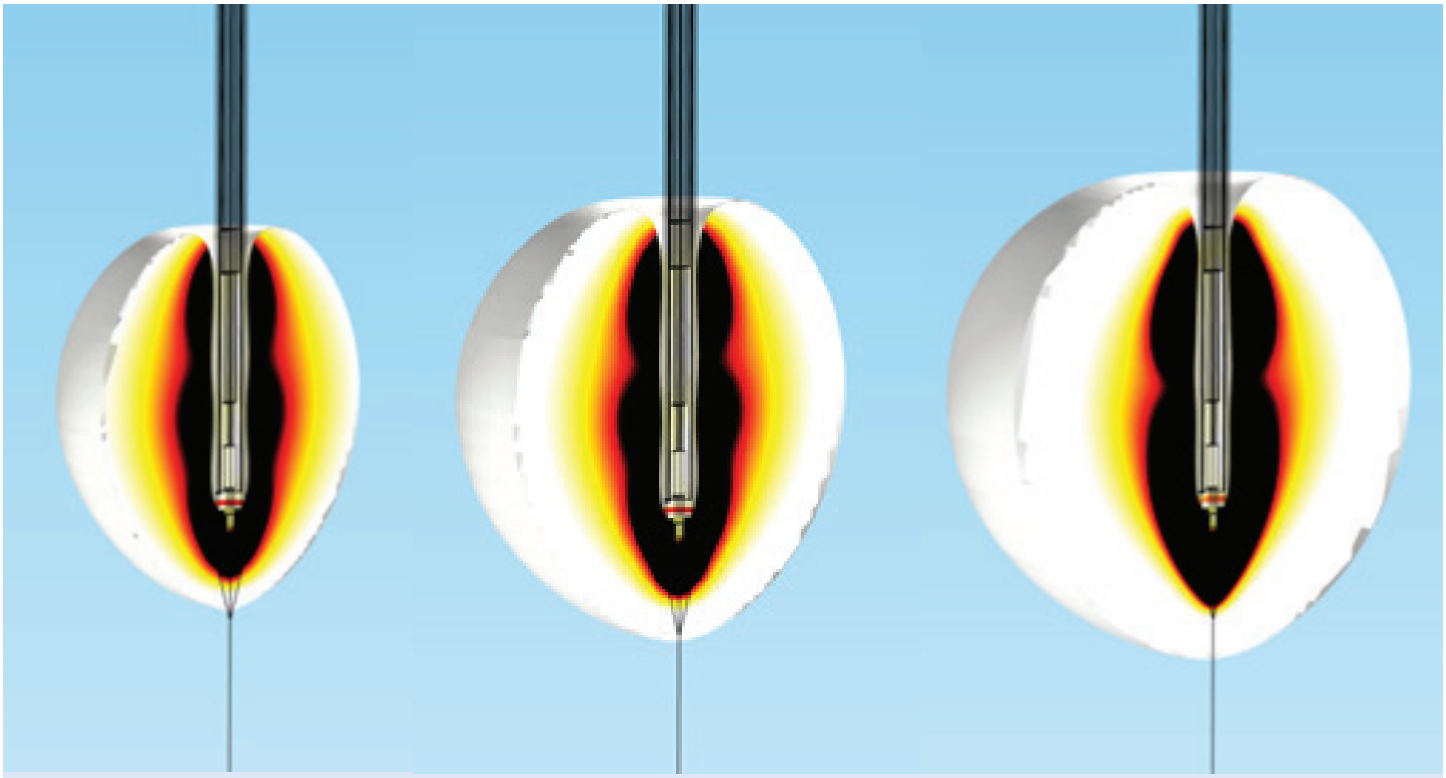


FIGURE 3 *These results from a COMSOL® software simulation show the power dissipation density, or the extent of the ablation, as determined by the thermal damage calculation. The antenna and the surrounding tissue are initially well-matched, and the match (i.e., the antenna pattern) changes over time as tissue temperature increases during the procedure (left to right).*

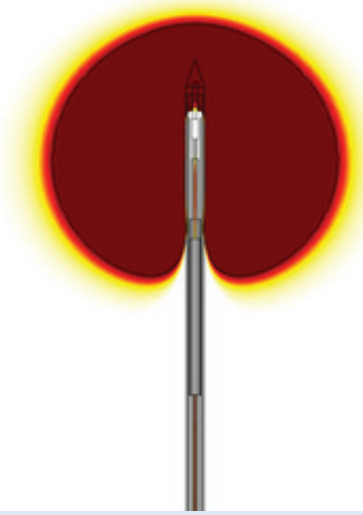


FIGURE 4 *A COMSOL plot showing a cross section of the predicted ablation volume, or predicted tissue damage. This information is used to modify the bioheat equation and thereby to modify perfusion conditions in the tissue. Red areas represent coagulated tissue where no perfusion is present, and white areas represent areas of normal perfusion. This makes the model more accurate by creating a realistic on/off condition for the perfusion term in the bioheat equation.*

The team used COMSOL to model the energy radiator and test designs that incorporated radiometric sensing in the same device. They simulated coupled thermal and electromagnetic effects around the radiative probe hardware to determine radiometric performance under different conditions (Figure 3).

Ladtkow analyzed heat transfer in living tissue using a bioheat equation, which included a perfusion term, to account for blood flow cessation once the tissue coagulated (Figure 4). This helped his team understand heat transport to cells around the tumor and predict the temperature distribution to ensure efficient and predictable energy delivery.

He performed other studies as well: investigations of temperature dependence of reaction rates (to understand the size of the ablation zone); radiometry modeling to determine how much energy enters the tissue and how much is reflected back into the radiator; and liquid-to-gas phase-change dynamics (Figure 5). “The latter is critical to knowing what the wave pattern will look like, because knowing how much water is in the tissue is critical to knowing how a radiometer will behave, because of the change in wavelength,” he said. “Implementing this model in COMSOL is straightforward.”

Simulation showed that lengthening the proximal radiating section (PRS) and shortening the distal radiating section (DRS) of an antenna would produce an efficient ablation radiator and an efficient receiver. These studies (Figure 6) resulted in versions of a prototype ablation radiator with an integrated radiometer, along with results showing the performance of the integrated probe.

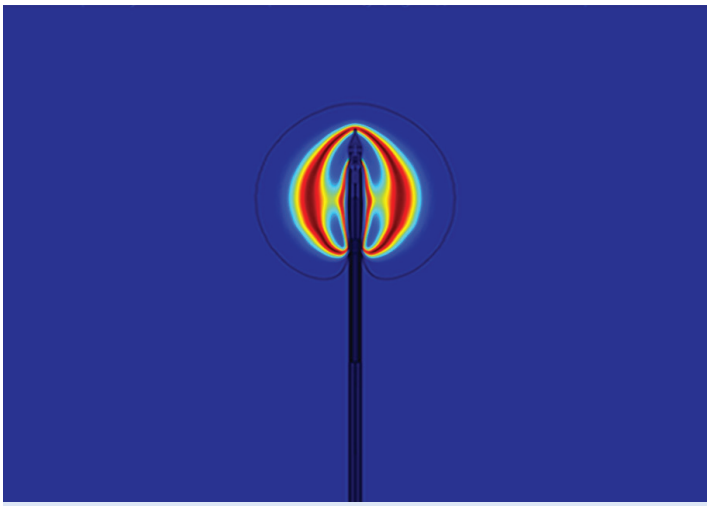


FIGURE 5 *COMSOL results show the change in heat capacity in the tissue surrounding the probe, dominated by phase change of water in that tissue. Knowing where water is boiling is important because the MW radiation wavelength is dramatically different for liquid water than for vaporized water.*

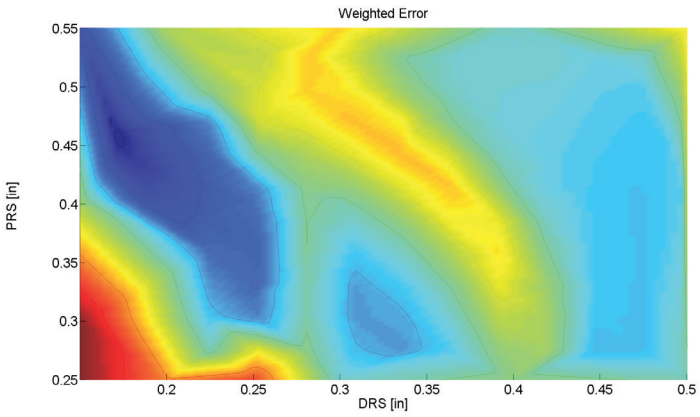


FIGURE 6 *A COMSOL weighted error plot. Blue areas indicate regions where reflected power is low for delivered ablation energy and also where the receiver quality is good. They represent antenna configurations that are both good ablation devices and good radiometers.*

FROM IMPOSSIBLE TO POSSIBLE

"Without COMSOL to help us perform these analyses, it simply would be impossible to do enough experiments to find an optimum solution that integrates an emitter and a receiver. COMSOL helps us see that certain architectures — which we'd never have investigated otherwise—might make an integrated device possible," Ladtkow continued.

His team uses COMSOL® software in conjunction with MATLAB® software, and he said that the combination gives him a powerful ability to optimize complex models with highly sophisticated algorithms quickly and easily. He also hopes to integrate the Application Builder available in COMSOL Multiphysics into their modeling workflow. This would enable the team to create simulation apps allowing partners to test and verify different designs, while protecting their proprietary models.

"Based on our simulations, we are now realizing the potential to introduce ablation devices that will allow clinicians to not only deliver a precise energy dose, but also monitor ablations in real time," Ladtkow said. "Multiphysics simulation enabled the rapid development, evaluation, and optimization of our design, which would not have been possible otherwise."

ABBOTT, CALIFORNIA, USA

ENHANCING PERFORMANCE AND SAFETY OF MEDICAL IMPLANTABLE DEVICES WITH MULTIPHYSICS SIMULATION

At Abbott Laboratories, ventricle assist devices are developed to improve the lives of patients with heart failure. Numerical simulation is used throughout the design process to characterize diverse concurrent aspects of the design, from thermal effects and fluid dynamics to power transfer.

by **SARAH FIELDS**

The development of a device meant to assist or completely replace functioning of the heart is undeniably complex. This design process involves immense challenges, from supplying power to the device to ensuring it does not interfere with normal biological functioning. Researchers at Abbott Laboratories use multiphysics simulation to engineer left ventricular assist devices (LVADs) in an ongoing effort to improve the outlook and quality of life for patients with heart failure.

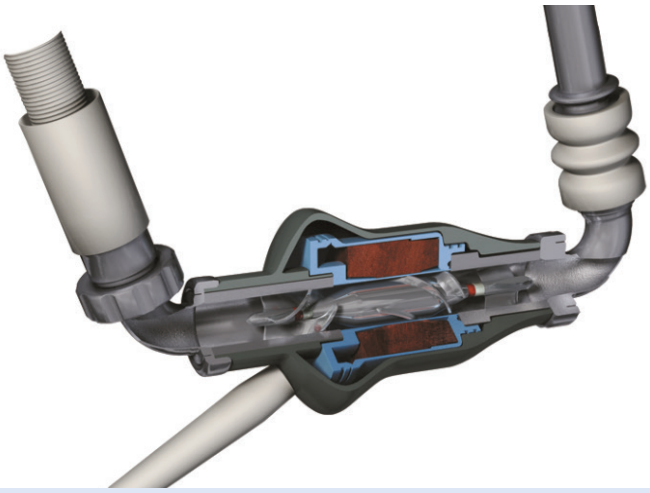


FIGURE 1 *An LVAD pump is responsible for circulating oxygen-rich blood throughout the body. Image courtesy of Abbott Laboratories.*

The condition typically begins with the left side of the heart, as the left ventricle is responsible for pumping oxygen-rich blood throughout the body a greater distance than the right ventricle, which pumps blood through the lungs. Often, in patients with a poorly functioning left ventricle, an LVAD (see Figure 1) can provide mechanical circulatory support.

The ventricle assist device is one of the most complex machines ever implanted in a human being. An LVAD must circulate the entire human blood stream and support life, as well as be compatible with the internal environment of the human body. Thoratec, now part of Abbott, brought LVADs to a wide market in 2010, after years of clinical trials.

DESIGNING A POWERFUL, EFFICIENT, AND HEMOCOMPATIBLE PUMP

The design of an LVAD must take many factors into consideration. The device must be small enough to connect to the heart and be made of compatible materials and geometry that permit the device to reside in the body without being rejected. Fluid dynamics, power supply, and thermal management must also be considered. As multiple interacting physical effects must be accounted for at each area of development, multiphysics simulation is vital to the design process.

Freddy Hansen, Staff Research Physicist at Abbott, uses his expertise in physics and mathematical modeling to characterize complex implantable medical devices like LVADs before experimental studies.

Hansen has been using the COMSOL Multiphysics® software since 2011 and has since created more than 230 models that address a wide range of design challenges pertaining to the unique physics of artificial pumping devices.

"I use COMSOL Multiphysics every day, from proof-of-concept models to quite sophisticated simulations featuring detailed CAD geometries and coupled physics. I work with some complex models for months before I have taken all of the information I want from them."

With each generation of LVADs introduced to market, improvements are made that contribute to enhanced safety and quality of life for the patient. Research and development efforts at Abbott are centered on improving biocompatibility, hemocompatibility, and immunocompatibility, such that the device does not illicit an adverse immune response or interfere with other bodily systems.

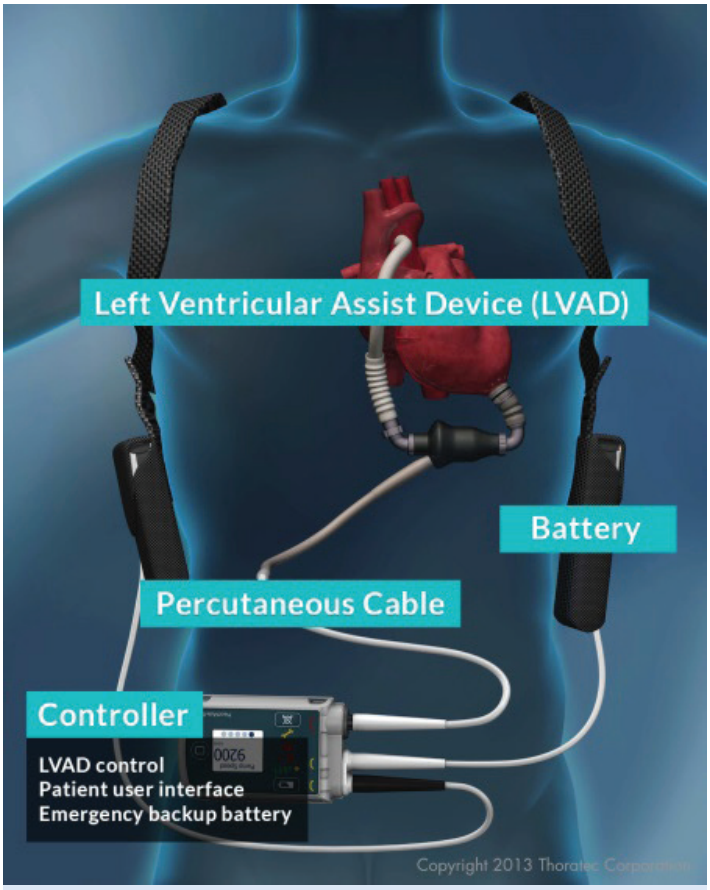


FIGURE 2 *External Equipment of an LVAD. Image courtesy of Abbott Laboratories.*

Geometry and size of the device play an important role in its overall effectiveness. To implant the LVAD, the surgeon connects one end of the LVAD to the left ventricle and the other end to the ascending aorta (see Figure 2). If the device is smaller, it is less cumbersome and less likely to interfere with neighboring organs or tissue. Simulation allows for the evaluation of changes in size or geometry of the LVAD design before implementation in a physical prototype.

OPTIMIZING LVAD DESIGN FOR BIOCOMPATIBILITY

Many simulations were used in the development of the centrifugal pump of the LVAD. One challenge associated with engineering these devices is the prevention of blood clotting in any space in or around the pump. To address this, a magnetically levitated rotor was developed, which eliminated the need for ball bearings and other components with geometries that might promote clotting. Hansen used the rotating machinery modeling technology available in the software to model both the magnetically levitated rotor and turbulent fluid flow.

A permanent magnet in the pump rotor is driven by coils in the stator, which exert a torque on the rotor and provide active control of the position of the rotor axis. The vertical position — or levitation — of the rotor is accomplished by magnetic field line tension and does not need active control. The rotor receives blood axially and redirects it radially, into the volute, or fluid collector (see Figure 3). Some of the blood flows back and around the outer edge of the rotor and flows back into the rotor inlet, resulting in a constant washing of the blood, which serves to eliminate places where the blood can stagnate and clot.

Another significant advance was the development of a pump system with pulsatile flow, rather than continuous flow, which more closely mimics a functioning heart. The pulsatile flow aids in the washing of the blood, preventing blood clots, and is also believed to have a positive physiological effect on blood vessels throughout the body.

WIRELESSLY POWERING A FULLY IMPLANTABLE LVAD

Current LVADs require power transfer from external batteries in a controller outside the body to the pump by way of a cable, made with materials engineered to be biocompatible. But what if the cable could be eliminated?

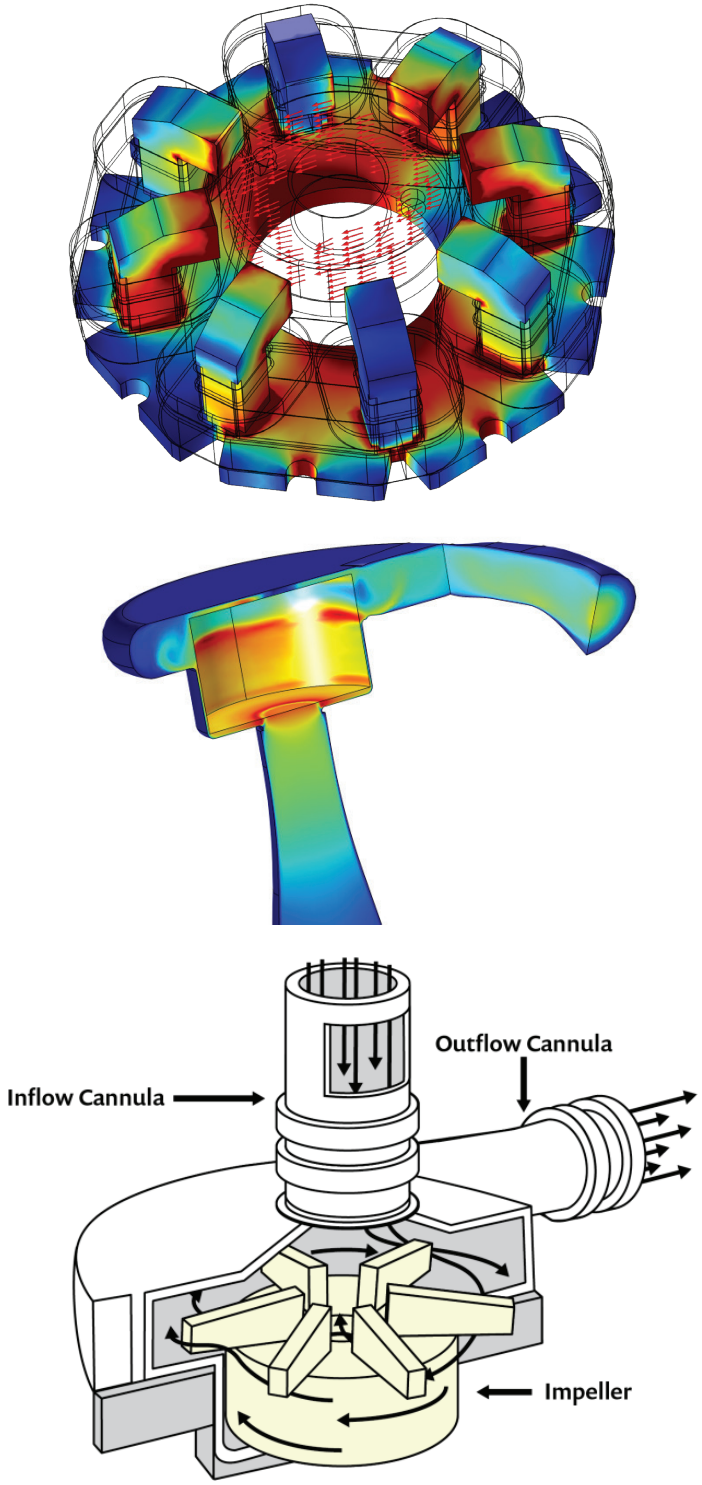


FIGURE 3 *Visualization of the magnetically levitated rotor, which eliminates the need for ball bearings and other components with geometries that might promote clotting. Here, the magnitude and direction of the magnetic field in the rotor, as well as the magnitude of the magnetic field in the stator are shown (top). 3D CFD simulation depicting fluid velocity within the pump chamber (middle). Diagram of the centrifugal pump of an LVAD (bottom).*

Hansen explored transferring power by way of magnetic resonance coupling. Magnetic resonance coupling occurs when two objects with almost the same resonance frequency transfer energy to each other through their oscillating magnetic fields. In this way, power can be transferred from a power source to another device, even through a biological medium such as tissue.

A fully implantable LVAD system (FILVAS) would decrease infection risk and improve patient quality of life, as the patient would not need to be concerned with cable management. With this concept, the patient could shower or swim without concern for the cable.

To assess the feasibility of wireless power transfer to an LVAD and determine how much power could be delivered between reasonably sized coils, Hansen coupled a 3D magnetic field model with an electrical circuit model to determine operating efficiency and power loss, as well as optimal circuit design and component values.

He evaluated different materials for important components, such as the wires of the transformer coils. He also studied the misalignment of a coil due to patient walking, running, and other activities, and together with the effect of the presence of nearby magnetic or metallic objects.

Engineers also had to ensure that body temperature and biological systems will not be affected by the implant. The wireless transfer of energy induces small currents in the body tissue near the coils. Hansen modeled the heat generated in the tissue as a result of the induced currents; combined this with models of heat generated inside the implant (in magnetic wires, electronics, and batteries), and then used the thermal conductivity coefficient determined from a famous Cleveland Clinic experiment, to determine the temperature increase in body tissue near the implant (see Figure 4).

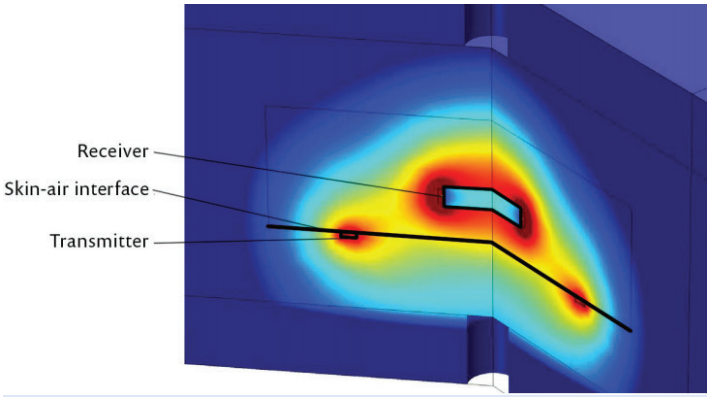


FIGURE 4 *Model of heating induced in the body through magnetic power transfer. Results show power density distribution in the tissue and the surrounding air.*

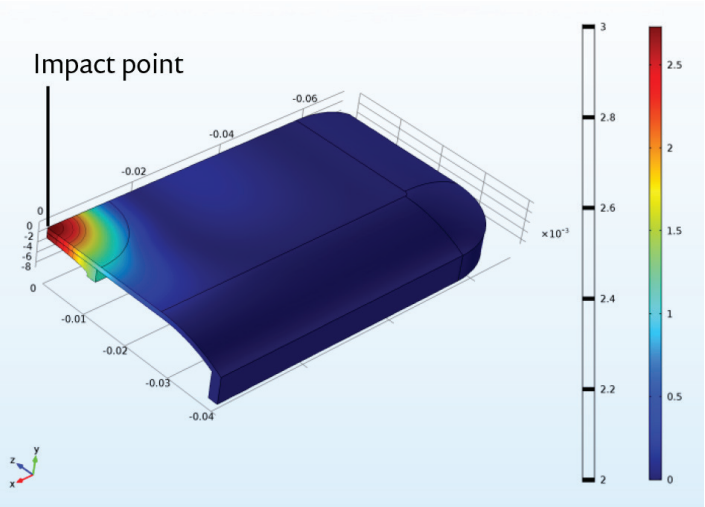


FIGURE 5 *Simulation of a steel ball impacting an LVAD controller to evaluate resiliency of the controller. Visualization of displacement along the vertical axis.*

PROTECTING LIFE-SUSTAINING BATTERIES

Patients must live with their LVADs every single day, which inevitably means that the external LVAD controller must be able to withstand the wear and tear of life, as well as the occasional dropping of the controller to the floor. To ensure that the controller (which contains crucial life-saving batteries) will continue to function even if the patient tosses it around, Hansen developed a mechanical impact analysis of the controller in order to assess its resilience (see Figure 5).

He also analyzed the edges and surfaces of the deformed structural shell and the frame for twisting, to verify the integrity of the controller. The analysis proved that the controller would continue to provide life-sustaining power to the LVAD even after a substantial impact.

NEW TECHNOLOGY SHOWS IMPROVED OPTIONS FOR PATIENTS IN THE FUTURE

In designing devices to assist and replace the function of the heart, multiphysics analysis has proven to be essential. Hansen combines experimental characterization and mathematical modeling to understand the physics pertaining to ventricle assist devices, and improve the biocompatibility of the device as well as the overall patient experience.

The latest innovations to mechanical pumping systems — including a smaller device size, a more hemocompatible pump, the introduction of pulsatile flow, and now the possibility of wireless power transfer — hold much promise for better treatment in the future.

STMICROELECTRONICS, ITALY

RELIABLE STRUCTURES AND WEARABLE SYSTEMS CALL FOR MULTIPHYSICS SIMULATION

Engineers at STMicroelectronics use numerical simulation to optimize their semiconductor solutions for a wide range of applications.

by **VALERIO MARRA**

The increasing demand for miniaturized electronics and internet of things (IoT) devices has created new challenges for the specialists who design microdevices such as actuators, controllers, drivers, sensors, and transmitters. From responsive equipment and wearable monitors to energy efficient lighting in the office and automation in the factory, engineers need to bridge the microscopic components of semiconductors and our macroscopic world with reliable and innovative products. This shift has inspired engineers to find new solutions by exploring their ideas in the virtual world of numerical simulation.

STMicroelectronics, a world leader in designing and manufacturing semiconductor solutions, employs 7500 individuals in the area of research and development (R&D). Lucia Zullino, technology R&D engineer at STMicroelectronics explains their efforts, "In our field we need to analyze very small structures and understand their interaction with large packages in different configurations over a wide range of environments and applications."

For semiconductor manufacturers, the choice of material and design is critical. This is where simulation plays an important role in the evaluation of materials and performance parameters. "Much of our work is done through the COMSOL Multiphysics® software, which we use to validate hypotheses and to optimize products," explains Zullino. "There are about 30 users within STMicroelectronics, and although we belong to different departments and work in various locations, we are continually building and sharing knowledge about mathematical modeling techniques used in several projects."

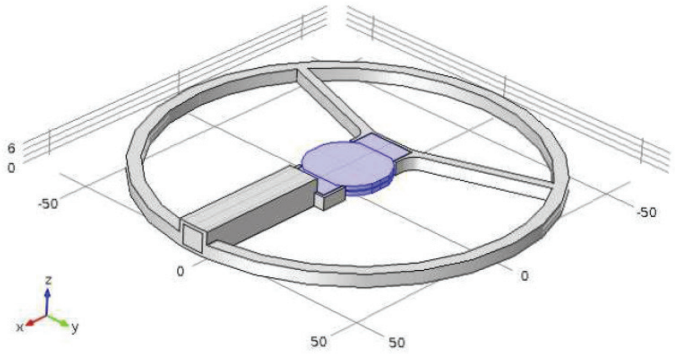


FIGURE 1 *Geometry of the embedded structural health monitoring sensor. The sensing part is highlighted in blue.*

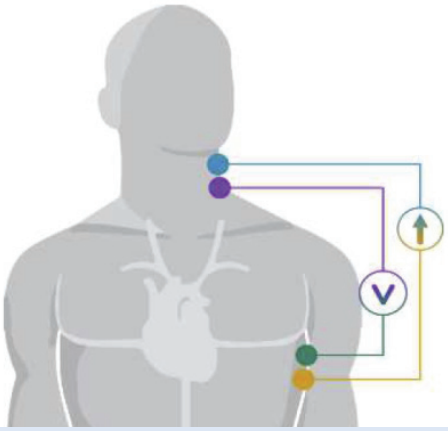


FIGURE 2 *Technique used to measure the bioimpedance of an organ.*

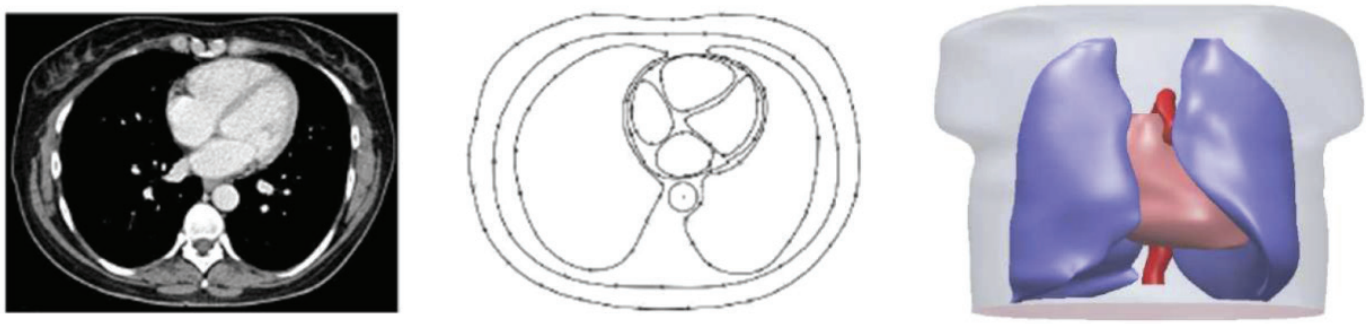


FIGURE 3 *3D model created from computed tomography (CT) images (left), postprocessed with CAD tools (middle), and then interpolated to generate the volumes (right) needed for the analysis.*

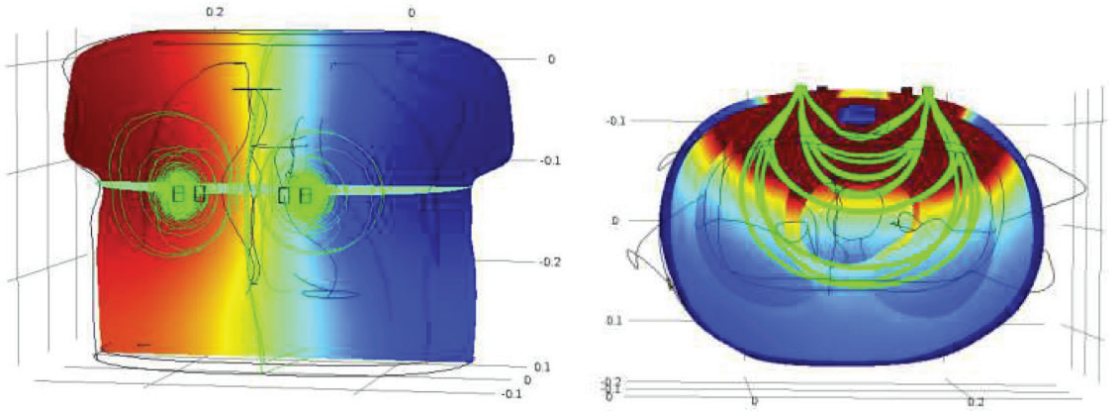


FIGURE 4 *Simulation results showing the electric voltage and current distribution in a human torso.*

MULTIPHYSICS SIMULATION FOR RESEARCH AND PRODUCT DESIGN

Simulation is used to understand multiphysics interactions at every stage of the development process for several products. A few examples include: optimizing an epitaxial reactor for faster wafer production, controlling reactant flow distortion in the wet etching process, and investigating the interaction between die and package at the microscopic level. In addition to design and manufacturing of microchips,engineers at STMicroelectronics work on the design of miniaturized actuators such as micromirrors used in recognition technologies that require optics and cameras. Simulation was also used in another actuator-related project to investigate printheads and compare the effectiveness of two different working principles: displacement of ink through pressure-generated bubbles or using a membrane actuated by a PZT a ceramic material made of lead zirconate titanate. Through this work the researchers were able to determine that the thin-film piezo printhead offers better compatibility with a wide variety of inks, higher printing speed, superior print output quality, and extended printhead lifetime.

SENSING CONCRETE HEALTH

Governments and businesses have been implementing various sensor technologies to monitor the performance of concrete for years. In one development project simulation was used to analyze the properties of concrete and predict the capacity of an embedded sensor (Figure 1) to monitor age-related changes and relay a signal to the surface. This structural health monitoring (SHM) system has already been deployed in Italy. It is being used on various structures to assess the health of concrete and log damage following any unexpected stress that may impact the structural integrity and reliability of the system.

WEARABLE MEDICAL MONITORING

Over the years, STMicroelectronics has developed many healthcare applications. In one prototype project, a patch was designed to measure the bioimpedance of an organ, such as the heart, inside the human body (Figure 2). Working from medical imaging of human organs, researchers created a 3D model (Figure 3) to run an AC/DC simulation in the frequency domain (Figure 4) and

assess the effect of the electrode shape and position on the measured physiological parameters. The simulation results they obtained (Figure 5) correlated closely with real-life measurements and enabled the development of a wearable configurable patch capable of indicating physiological changes. These sensors will enable doctors monitoring various heart conditions to get real-time data to provide patients with the best care using the latest technology.

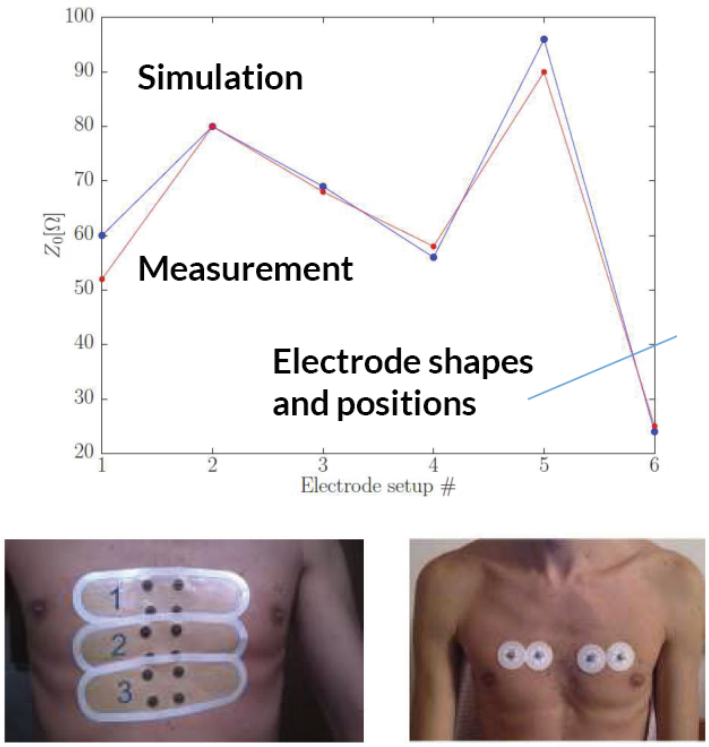


FIGURE 5 *Comparison between measured and simulated bioimpedance values (top) for different electrode shapes and positions (bottom).*

TACKLING MORE AND MORE COMPLEXITY THANKS TO SIMULATION

"Through simulation we have learned a lot about potential problems and we have gotten better at optimizing semiconductors for the outside world. Simulation now drives product design, both for internal and external customers," comments Zullino. She and her colleagues see opportunities to continue using multiphysics simulation in all aspects of development. She shared that studies on humidity inside packaging and the potential for corrosion are already in progress.

"We can assess materials and structures more quickly and screen for the best ones, which means less time spent on trials, better technical decisions and quicker business decisions," concludes Zullino. "Compared to physical testing, we can implement new solutions and verify them at zero cost. Simulation is one of the key tools that drives innovation."