SPACECLAIM CORPORATION

Advancing New Non-Invasive Surgical Therapies through Technology

CASE STUDY

Devices and Analyses Developed without Human or Animal Testing

Dr. Gary Long, a Research Engineer with Ethicon Endo-Surgery, a Johnson & Johnson company, shares the important work being conducted to develop new medical devices and therapies that attack non-operable, malignant tumors through heat and electric pulses and how he has leveraged 3D Direct Modeling with SpaceClaim and COMSOL Multiphysics to advance his research.

> *Dr. Long had been designing probe concepts in 2D and determined he could perform more thorough analyses if he moved to designing in 3D. He chose the SpaceClaim 3D direct modeler and was pleasantly surprised by his ability to design probes easily and intuitively, and to draw detailed sections of the anatomy, including the lobes of the liver. By moving from 2D to 3D, he was able to quickly create different concepts and optimize them with finite element analysis using COMSOL's Multiphysics solutions.*

ABOUT ETHICON

ETHICON, a global medical device company, has been a leader in surgical sutures (stitches) for more than 100 years. Today, we have expanded our expertise into wound management, women's health, and cardiovascular surgery. We have four business units that operate separately under the ETHICON umbrella, yet share the synergy of being not only part of ETHICON, but of Johnson & Johnson, the world's most comprehensive and broadly based manufacturer of healthcare products.

ETHICON enjoys a reputation for developing quality products to enhance the lives of patients and for providing outstanding service to customers.

ETHICON ENDO-SURGERY, INC.
a Johnson & Johnson company

Ethicon Endo-Surgery, Inc. (EES), a Johnson & Johnson company, develops and markets advanced medical devices for minimally invasive and open surgical procedures. The company focuses on procedure-enabling devices for the interventional diagnosis and treatment of conditions in general and bariatric surgery, as well as gastrointestinal health, gynecology and surgical oncology.

Minimally invasive surgery, which refers to surgery performed in ways other than through large "open" incisions in the body, are fast becoming the treatment of choice for patients around the world. And for some, such as cancer patients who are not candidates for surgery based on where the tumor is located, new therapies are critical to extending life.

The company's IdeaCenter fosters new innovative surgical product ideas developed by surgeons, nurses, health care workers, engineers and researchers. Gary Long, PhD, is an electrical engineer with 20 years experience developing medical devices. His area of specialty is developing energy and molecular-based devices for procedures such as thermal ablation of malignant tumors.

This highly important work requires very precise design and intensive testing of the application of electric pulses or heat to a diseased organ. An example would be Dr. Long's design of probes to test low energy DC pulses that can cause the death of malignant cells but can have potential serious side effects, such as over stimulation of skeletal muscle causing a sustained contraction of tetanus. Finding the right duration and height of the pulse to avoid the side effects is key to Dr. Long's research and new tools have enabled him to pursue these potential life-sustaining solutions through technology and without testing on humans or animals.

The liver plays a vital role in digesting, absorbing and processing food. The liver must filter the blood coming from the digestive track, as well as detoxify chemicals and create proteins for blood clotting. Because the liver is heavily involved in the body's functions, it often becomes the landing place for malignant cells. When the liver is infected with malignant tumors, surgery can be difficult

or impossible to remove all the cancer. Dr. Long's research has been focused on testing the lobes of the liver for non-invasive techniques to eliminate malignant cells.

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In the illustrations shown, Dr. Long designed the probe using SpaceClaim (figure 1) to use during his testing and then started by creating a small section of the liver with SpaceClaim (figure 2). He then imported the model into COMSOL Multiphysics to mesh of the liver lobules (figure 3). Through COMSOL, he added tissue properties to the mesh and simulated the resultant electric field, current flow, and heat generated in the tissue (figure 4). By varying the frequency and current of electrical pulses, Dr. Long could optimize the design to ensure that the tumor tissue would be destroyed but the healthy tissue would be unharmed

Dr. Long was able to model the anatomy of the liver lobe in under an hour. More importantly, he was able to perform the study without testing on humans or animals: a major initiative of Johnson & Johnson. The only technology tools he uses for the process of design and analysis are SpaceClaim and COMSOL Multiphysics.

Dr. Long uses stereolithography (SLA) when he wants a rapid prototype made. He draws the part in SpaceClaim, saves it to a format that will be accepted by the rapid prototyping company he works with, Morris Technologies. He saves the files easily in SpaceClaim and uploads the part to Morris, usually receiving the prototype within the next day. SpaceClaim also works with Ethicon's in-house CNC machining, making the delivery of prototypes fast and easy.

Because SpaceClaim is easy to learn and use, Dr. Long provided other members of his team, including medical staff, with SpaceClaim to enable them to create their thoughts in 3D and send them to him – saving time and avoiding the necessity to "interpret" someone else's ideas.

SpaceClaim provides the world's fastest and most innovative direct modeler, empowering users to create 3D solid models more easily than ever before. SpaceClaim is optimized for design and conceptual engineering, conceptual analysis, and computer-aided-engineering (CAE) model preparation. Unlike feature-based indirect modelers, direct modelers enable casual users to quickly and easily create new concepts and edit existing CAD models.

As evidenced by Dr. Long's application of SpaceClaim, the software enhances the design and analysis process, extends collaboration and provides intuitive and flexible tools for detailed, precise design of 3D solids. Dr. Long envisions great opportunities to continue to leverage SpaceClaim's functionality and enable him to draw detailed anatomies and extend his important and ongoing research.

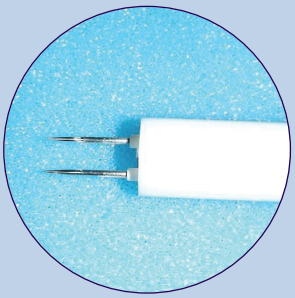

Figure 1 Stainless steel electrodes used to apply the electrical pulses to the tissue

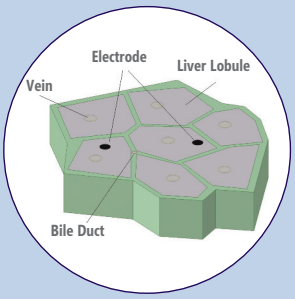

Figure 2 Real lobes

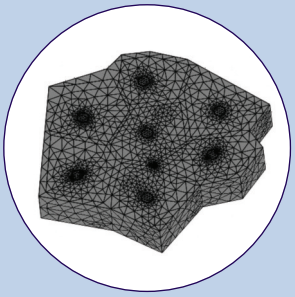

Figure 3 Tetrahedral mesh of the liver lobules

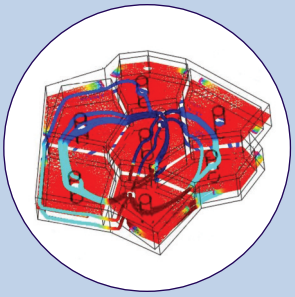

Figure 4 Electric field (color pattern) and current flow (tubes)

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