

Innovative Methods for Aortic Aneurysm Device Testing

Case presented by Srinivasan Varahoor, Medtronic Endovascular, USA

Using patient-specific data to create benchtop models is important for accurate and realistic testing. “The Mimics Innovation Suite helped us to transform patient-specific data into physical test models. Our stent designs were tested within the physical models to define and quantify device performance,” says Srinivasan Varahoor, PhD, Principal R&D Engineer, Medtronic Endovascular. The ability to utilize geometric parameters to quantify anatomy, and show a method for developing a set of standardized, patient-based models using three-dimensional imaging and CAD tools has been a breakthrough for Medtronic Endovascular.

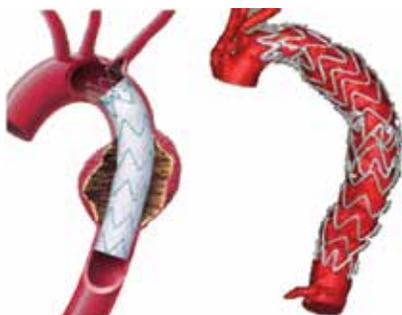


Medtronic: Advancing Treatment and Improving Lives

Medtronic is the global leader in medical technology. The Endovascular division designs and manufactures devices that treat cardiovascular disease such as Thoracic Aortic Aneurysms. Medtronic Endovascular commits unwaveringly to improving lives with patient outreach, educational programs that raise awareness of cardiovascular disease, and the continuing pursuit of new treatment options. Medtronic Endovascular is proud to have helped physicians treat over 200,000 patients worldwide.

New Ways To Design Stent Test Models

When testing grafts used to treat Thoracic Aortic Aneurysms, Medtronic’s goal is to develop models that help to accurately mimic in-vivo device performance. Due to the critical role these grafts play in a patient’s well-being, a new method of designing test models was developed. By incorporating statistical analysis with the development of benchtop test models, Medtronic is able to ensure that their devices will perform under challenging conditions.

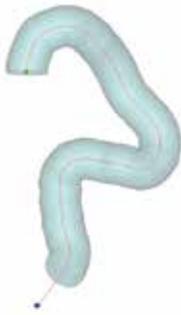


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Using the Mimics Innovation Suite, Medtronic developed a method of obtaining geometric parameters from actual patient data to define the in-vivo use conditions. Patient CT data from the field was collected and delivered to the research and development team. By means of Materialise’s Mimics software, the team segmented the 3D aortic model from the datasets. A centerline was automatically calculated in Mimics to fit the aortic model. To describe challenge-use conditions, the centerline was morphed to fit the 95th percentile value for each geometric parameter. Using this hybrid method of combining actual patient data and statistically assessed geometric parameters, the vascular models are able to be adapted to fit any requirements for testing purposes.

After forming the hybrid centerline, Materialise’s 3-matic software was used to design a thin walled patient-based aortic model. Supports and standard test-fittings were also designed into the device before using 3D Printing technology to print a physical benchtop test model.

1 Stent graft design used to treat Thoracic Aortic Aneurysms



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The model was then fitted into the benchtop test apparatus with cycling fluid to evaluate and quantify several performance metrics of the stent graft and its delivery system.

Medtronic's method for designing a patient-based benchtop test apparatus can be summarized in five steps:

- Measure geometric parameters
- Calculate centerline
- Adapt centerline to fit statistical models
- Design test apparatus
- Produce model with 3D Printing technology



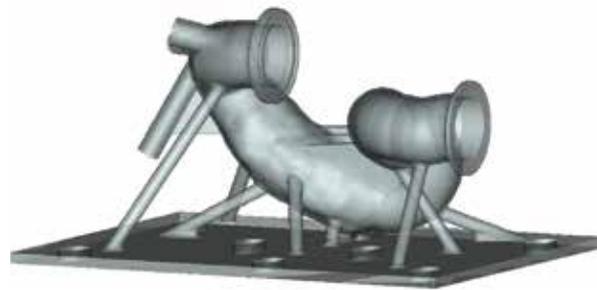
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Promising Results Achieved with the Mimics® Innovation Suite

The use of the Mimics Innovation Suite to quantify anatomical geometry and generate a set of standard patient-based models has created an unsurpassed standard for benchtop testing at Medtronic. "Mimics allows us to quantify edge of failure conditions and 3-matic can incorporate those performance limits into next generation device development test models," says Srinivasan Varahoor. These models can help systematically pin-point conditions for possible device failure during testing, and thereby, result in more robust designs. This approach is applicable to the testing and development for any vascular device system in the future.



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- 2 Aortic model generated from centerline and geometric parameters
 3 Patient-based aortic model
 4 Final benchtop design ready for manufacturing. Data courtesy of Dr. Varahoor, Medtronic Endovascular
 5 Digital representation of the manufactured test apparatus

The standard in 'Engineering on Anatomy'

The **Mimics Innovation Suite** turns 3D image data into high quality digital models in an accurate and efficient way. Starting from CT, MRI or 3D Ultrasound images, the Mimics Innovation Suite offers the most advanced image segmentation, the broadest anatomical measurement options, powerful CAD tools for Engineering on Anatomy and 3D Printing, and accurate model preparation for FEA and CFD.

In this case study, the authors used the Mimics Innovation Suite to standardize their device deployment testing using the following steps:

- Transform medical-image-based population data into virtual benchtop model designs
- Export these virtual models in the required format for 3D Printing
- Define and quantify device performance using novel population-based benchtop models

Regulatory Information:

The Medical edition of the Mimics® Innovation Suite currently consists of the following software components: Mimics® Medical version 18.0 and 3-matic® Medical version 10.0 (released 2015). Mimics® Medical is intended for use as a software interface and image segmentation system for the transfer of imaging information from a medical scanner such as a CT scanner or a Magnetic Resonance Imaging scanner. It is also used as pre-operative software for simulating/evaluating surgical treatment options. 3-matic® Medical is intended for use as software for computer assisted design and manufacturing of medical exo- and endo-prostheses, patient-specific medical and dental/orthodontic accessories and dental restorations.
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