InSilicoCARDIO

Self-Expandable Valve (SEV) Radial Force Test

Degenerative heart disease, calcification, congenital abnormalities, and infections are some of the causes of heart valve disease. Aortic and mitral valves may become stenotic (narrowed and consequently restricting the blood flow to the body) or regurgitant, requiring replacement or repair.

Heart valve disease is prevalent throughout the world, and the number of heart valve replacements is expected to increase rapidly in the coming years. Transcatheter heart valve replacement provides a safe and minimally invasive means for heart valve replacement in high-risk patients. The latest clinical data demonstrates that transcatheter heart valve replacement is a practical solution for low-risk patients (1).

Transcatheter valve replacement or repair has been gaining traction replacing some surgical procedures with implants typically delivered percutaneously through a catheter. Transcatheter valves are designed to be crimped into a catheter, delivered during the implantation procedure through a vessel and placed on the patient's diseased valve to restore its native functionality.

Transcatheter valves are generally composed by a bioprosthetic valve sutured on a metal frame (or stent) and can be grouped into balloon-expandable and self-expandable valves. The latter are featured by a frame made of Nitinol, a special alloy that has the property of self-expanding when released from the catheter exerting a superelastic material property.

Transcatheter Aortic Valve Replacement - TAVR

For the first time in August 2019, FDA approved an expanded indication for several TAVs to include not only high-risk patients but also patients at low risk for death or major complications associated with open-heart surgery to replace the damaged valves (6).

Currently, there are approximately 180,000 potential candidates for TAVR in Europe and US annually, expecting an increase in the next years (2). Due to its minimally invasive approach and ongoing success, TAVR could become the standard treatment (3), leading to a fast expansion of new TAV designs (4).

Transcatheter Mitral Valve Replacement - TMVR

After the success and worldwide adoption of TAVR, the percutaneous replacement of a diseased mitral valve rapidly became a target for investigators and industry.

Mitral valve disease is more common than aortic stenosis, and the surgical approach remains the gold standard treatment for degenerative mitral regurgitation. For patients at high surgical risk, TMVR may mature as a promising therapeutic option. (5)

Standard tests

Standard tests in medical devices represent a consensus on testing procedures that foster innovation while protecting public health. Harmonized compliance with the regulations, a key element of timely market introduction of advance technology, is facilitated by the appropriate use of relevant medical device standards.

Standards developed by organizations like ISO (International Organization for Standardization) outline the essential principles of safety and performance of medical devices. The ISO 5840-3 Standard Test Method (7) establishes a test method that is used by the medical device industry to evaluate the design and manufacture of transcatheter heart valve substitutes.

While setting up their transcatheter valve development and regulatory submission programs, medical device companies encounter the following challenges:

- High costs for the testing of multiple device prototypes before manufacturing
- Collection of scientific evidence about the safety and performance of the device to provide to the regulatory bodies

What is SEV Radial Force Test?

Self-Expandable Valve Radial Force Test is the result of a collaboration between Politecnico di Torino and InSilicoTrials Technologies.

Self-Expandable Valve Radial Force Test is based on a computational finite element model which describes the compression and expansion of a self-expandable heart valve prosthesis, following ISO 5840-3 standard.

The test aims to characterize Radial Resistive Force and Chronic Outward Force in self-expandable heart valves. The product also provides maps of mechanical strain within the valve geometry.

Self-Expandable Valve Radial Force Test enables simulations of Radial resistive force and Chronic outward force test in various types of self-expandable heart valves made in Nitinol, such as transcatheter aortic valve and transcatheter mitral valve.

The tool can be used to test different prototype designs before manufacturing, or to test the final device design for regulatory submission, as a report following FDA guidelines is provided to the user.

Advantages

Securely test a proprietary valve design

Simulate radial compression and expansion in various types of self-expandable heart valves, in order to characterize Radial Resistive Force and Chronic Outward Force

Inspect strain values within the valve geometry

Customize material parameters or use literature params

Generate a report for regulatory submission based on FDA guidelines (8)

How it works

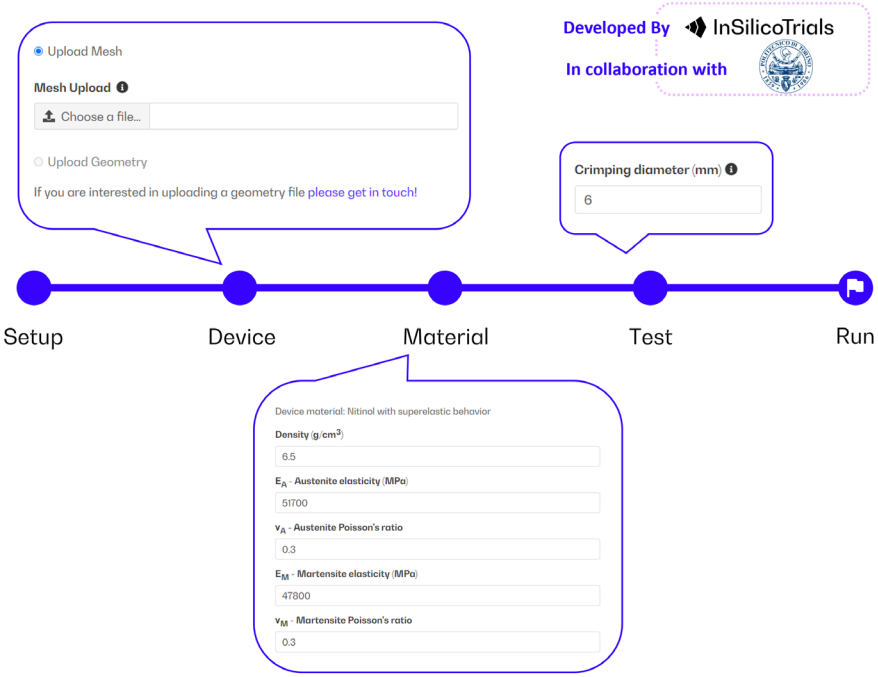
Self-Expandable Valve Radial Force Test enables to setup and run computational simulations in a user-friendly way by using a step-by-step integrated workflow that can be applied to any self-expandable valve uploaded by the user:

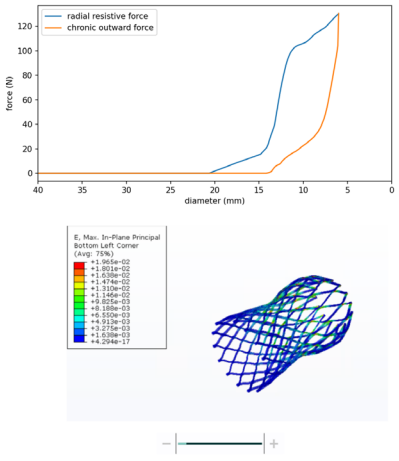
- Set the simulation name
- Upload the device mesh in the admissible format or submit a request to upload a geometry file.
- Insert Nitinol material properties or use the default values from suggested by the user as default values
- Insert the crimping diameter value (the minimum diameter reached at the end of the radial compression)

After running the simulation, results will be displayed as:

- Radial Resistive Force and Chronic Outward Force in function of the diameter
- Color maps of the strain values of the valve frame

Radial Resistive Force and Chronic Outward Force values can be downloaded in .csv format. Simulation details, settings and results can be reported and exported in .pdf format following FDA guidelines (8).





- Resistive Force and Chronic Outward Force
- Colored maps of device strain

Download PDF report for regulatory submission

In silico methods can innovate medical device research and development

Today, the costs and duration of the development and regulatory assessment of new medicines and medical devices are becoming a burden to innovation in healthcare.

Regulatory agencies have been encouraging the use of in silico methods in research and development for years (9), since the use of these methods can significantly reduce costs and greatly accelerate the go-to-market of new products while maintaining or improving the level of safety.

However, specialize expertise and dedicated computing infrastructures require a continuous investment from companies, hence representing a barrier to a rapid uptake of computational solutions.

To help solve these challenges, InSilicoTrials Technologies has developed a game-changing-solution. Our experts:

Select computational models from research centers of excellence around the world
Integrate them in our cloud-based platform
Make them available through user-friendly online products

This solution enables companies to leverage cutting-edge in silico methods at low costs without specific computational expertise, IT infrastructure and solvers investments requirements. On our cloud-based platform, users can select the online computational product of their choice in pay-per-use, or ask us to build the digital product they need.

Why working with InSilicoTrials

SaaS

Buy tokens and use the online products of your choice among those available on the platform

VIRTUAL PATIENTS

Design and accelerate your clinical trials with the virtual patient populations you need

ON DEMAND & CUSTOM

Ask us for the models and simulations you need, or ask us to evaluate where modeling and simulation can support you

TECHNOLOGY-ENABLED SERVICES

Ask us for support on technology integration, in silico trials planning, execution and reporting, in line with regulatory requirements

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