OPTIMIZING MEDICAL STENTS WITH MACHINE LEARNING

Medical stents are a lifeline for patients with cardiovascular illness and disease. These carefully designed small tubes are inserted into a blocked passageway to keep it open, restoring the flow of blood or other fluids and ultimately saving a patient's life.

Intravascular stents made of shape memory alloy materials like Nitinol are becoming more widespread. Nitinol is corrosion resistant, but most importantly, is highly elastic and can be compressed to easily insert into the body before returning to its original shape. This makes it easy to insert stents that conform perfectly to the vessel anatomy.

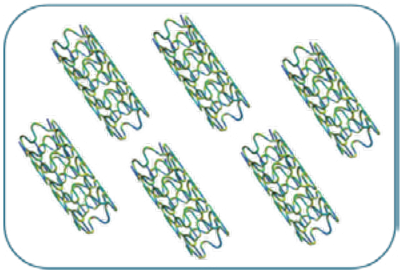
Traditionally, device manufacturers are required to dedicate large amounts of time and expense for clinical tests of these stents to validate safety and performance claims. Additionally, if the design process lacks computer aided engineering tools (CAE) it is difficult to validate components, some of which are often microscopic, resulting in a slow development time.

Altair's solutions can speed up the development time by satisfying the testing of variables virtually, allowing engineers to truly optimize the design and performance of medical stents.

Design Process

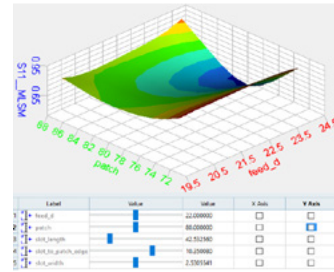
One way to achieve an optimized design is to set up the design parameters so they can be adjusted within certain conditions. The response of the design such as stress, strain, and displacement are factored in, with constraints on those responses considered to avoid exceeding a specific level of stress of strain. Additionally, objectives such as minimized mass and maximized stiffness are defined. While this approach provides basic answers about the design of a product, it fails to deliver more detailed information that can be used to achieve the most optimal design.

Alternatively, a Design of Experiment approach (DoE) can be used to help fill in the blanks and provide engineers with clearer answers. A DoE approach allows the user to gain a greater understanding of how different design changes affect the performance of the design overall and gives insight into how design characteristics are related. This is achieved by running a series of designs, each with minor modifications, making it possible to explore the design space. This approach creates a lot of data that needs to be filtered, sorted, and analyzed, making it a perfect application for machine learning (ML), utilizing algorithms that can analyze data, show patterns, and provide meaningful results.



Simulation data with multiple variables
(Supervised Data needed for ML)

Machine learning with regression



Mathematical model

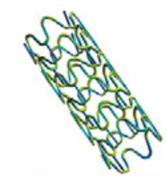
DOE

Final Design

Design Specifications ▶ Initial Design ▶ Trained Math Model ▶

Optimized Model

ML Optimization



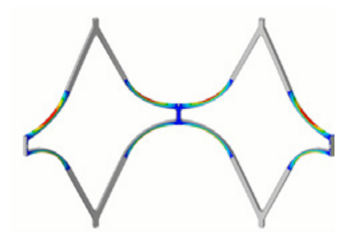
Optimization through Machine Learning

In its simplest organization, the two main categories of ML are supervised and unsupervised, each with its own objectives and uses. Under the umbrella of these methods, a range of applications can be explored and optimized to provide faster workflow, optimized design, and more accurate predictions. When designing a stent, a regression ML model is ideally suited due to the numerical and simulation data produced, providing a general mathematical function to characterize the data. This allows the engineer to accurately predict results. For example, f (x1, x2, x3, x4, x5, ...) = Y.

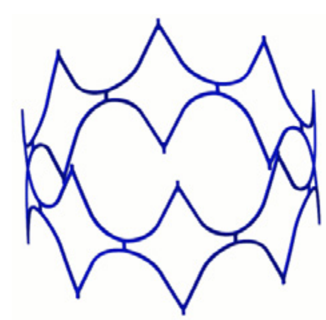
Altair Solutions for Design Optimization using Machine Learning

With Altair's solutions, users can perform in-depth simulations and analyses of a stent design, capitalizing on ML and optimization techniques built right into the software. Below is an overview of the process for designing and optimizing a medical stent using Altair's solutions:

Pre-Processing – Setup and Shape Definition - Firstly, a symmetrical portion of the stent is meshed, and design features are modified via mesh morphing and saved. This is then utilized as a design variable and set up for the analysis. Altair HyperMesh™ is a high-fidelity element modelling software ideally suited for stent modelling. The ability to handle very large finite element models and a broad range of CAD formats supported natively makes it easier for the engineer to achieve the best possible design.

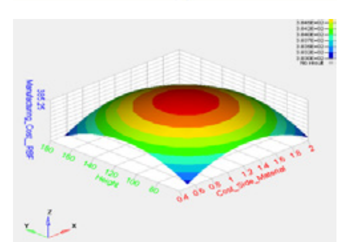


Powerful tools such as visualization mapping and semi-automatic mesh generation make mesh generation easier, leading to a faster design process. Additionally, open architecture allows users to generate their own scripts to customize the environment and automate tasks.



Nonlinear Simulation - Secondly, the model is submitted for nonlinear analysis using a high-performance computer. This provides scalable and repeatable results thanks to the computational power of Altair's HPC solutions. Specific to stent simulation is the support of shape-memory material such as Nitinol. Using structural analysis software such as Altair Radioss™ it's possible to accurately predict the behavior of the stent material when under different loads.

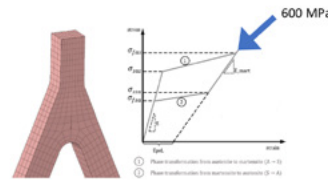
DoE Machine Learning and Optimization - Lastly, the DoE regression modelling via ML and optimization is performed. Altair HyperStudy™ is a multidisciplinary design study software that enables engineers to explore and optimize their product performance and robustness. Exploring the design of medical devices can be performed via DoE to investigate relationship, effects, and correlations. The data produced from this can be used to teach a ML model to make predictions and review trade-offs and "what-if" scenarios.



To learn more about the stent model setup and simulation, watch the webinar.

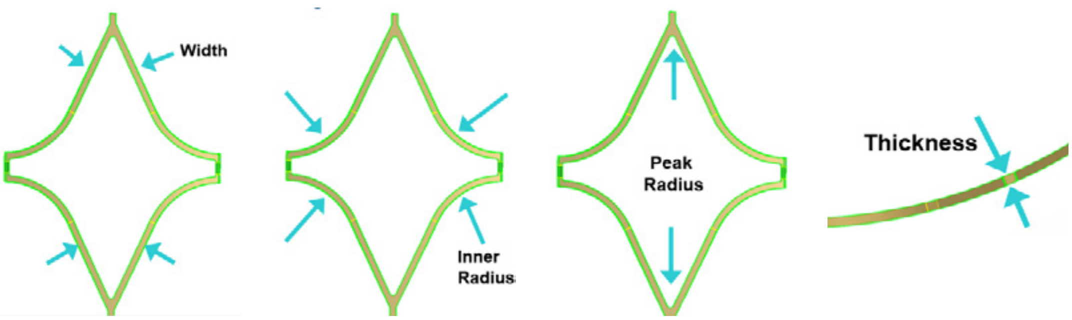
Model Setup

When setting up the finite element model, a 1/8th symmetrical model was utilized to reduce simulation time. A total of 9400 hexahedral elements were also used to ensure reduced simulation time and high-quality results. As mentioned previously, Nitinol was the material chosen for this medical stent due to its biocompatibility, super-elasticity, fatigue, and kink resistance.



1/8th symmetrical model.

The 600MPa notation is important to note in the stress-strain plot as it will be a constraint considered for the optimization – exceeding this could permanently deform the stent. The loading of the stent is a simplified representation of a stent application comprised of a crimping phase which reduces the radius by 50%, then a relaxation phase, and ending with a radial pressure-pulse of 150mmHg.



Mesh morphing is used to generate four different shapes which will be used as variables in the DoE.

Design of Experiment and Optimization Setup

Using a modified DoE method called "modified extensible lattice sequence" (MELS), multiple design variables for a stent design can be randomly modified within their bounds, populating the design space. An advantage of using this approach is that DoE's are extensible, making it possible to add further DoE's to the initial experiment without repetition.

This example DoE contains 25 runs, with a further 25, making 50 runs in total. Two additional DoE's were added to explore the design space in more detail and provide more data for the ML model. During these runs the stress, strain and radial displacement were monitored. For the optimization, the radial displacement was constrained to a minimum, with the objective of minimizing the maximum stress. The objective here is to not exceed the super elastic region whilst minimizing stress and constraining radial displacement i.e., stiffness.

When designing medical stents, a typical optimization problem is the minimum stress and constrain displacement, as the responses conflict with one another. A stent needs to maintain stiffness to support the artery but also limit the stress to ensure fatigue life. As a result, this DoE could have also been defined by maximum stiffness and minimum stress as objectives.

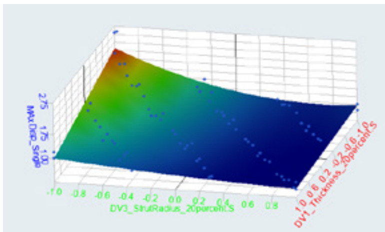
Trained Mathematical Model using Machine Learning

Once the design space is explored and a working model has been set up, a trained model can be generated using a propriety ML algorithm called FAST (Fit Automatically Selected by Training). This analyzes the data and selects the best regression approach. Rules and boundaries such as Least Squares Regression and Moving Least Squares can all be specified.

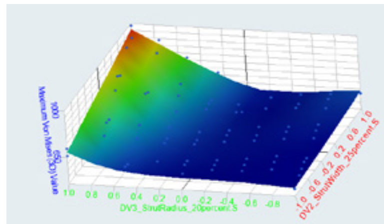
Using Altair HyperStudy™, it is also possible to analyze the radial displacement of the stent model and compare the DoE results with the trained ML model. The plot below shows both results align well, indicating that the trained model is accurate. For reference, a perfect match would be a straight line with an R-square value of 1. An R-square value of 0.85 was achieved for the radial displacement after the given number of runs - a good value, as the goal is to achieve 0.8 or above. Additional runs may help this but may not be necessary as enough data has been collected to improve the design.

Comparing the Trained Model and DoE

To understand this data, a surface plot of the trained model response surface can be compared to the DoE data points, seen in blue. From this, we can see the strut width and radius design variables showed the highest change at the corners of the design space, resulting in the lowing of the R-Square value. These areas can be more difficult to fit due to their relative change to other data points as their values are well outside of the design constraints utilized in the optimization. As a result, a comparison between the verification model and baseline model is needed to determine if the design performance has improved.



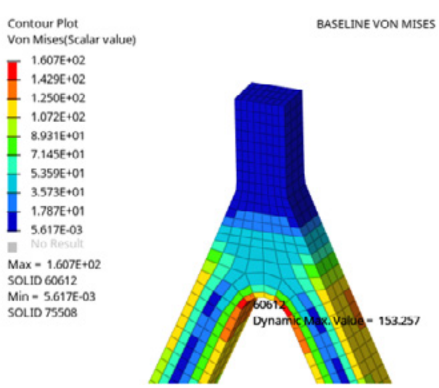
Von Mises — Width-Radius

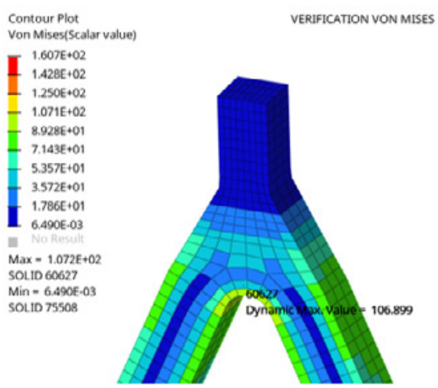


Displacement — Thickness-Radius

Results

A total of 50 runs were performed to ensure adequate design space exploration and to determine if the R-square value could be improved, each iteration taking 1.5 hours on a 16 core HPC. When comparing the baseline and optimized models, the radial displacement decreased from 0.8mm to 0.54mm, or an increase of 32% stiffness, a considerable improvement. Additionally, the maximum stress during the crimping phase does not exceed the 600MPa limit, with the stress during the pressure pulse phase decreasing by 30%, having beneficial implications on fatigue life. As a result, we can deduce that additional DoE runs and improvements to the mathematical model were not necessary.

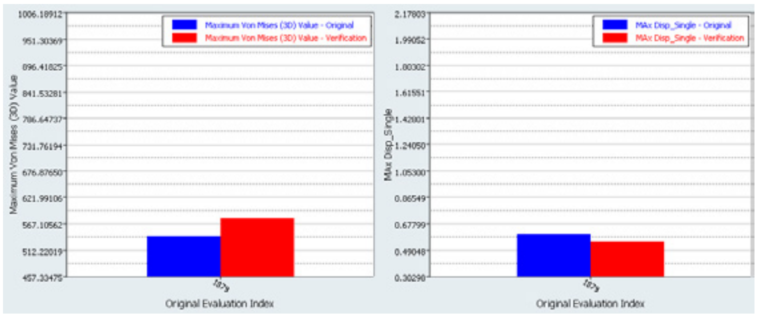




Using the mathematical model mentioned earlier, an optimization can be run in seconds providing the optimal design variables. A verification simulation can then be submitted and compared to these results:

Thickness(DV1)	Width (DV2)	Strut Radius (DV3)	Peak Radius (DV4)
0.999	0.999	-0.277	0.114

The results of this comparison show a difference between the mathematical model and the original design. The verification run shows that the design properties of the medical stent produced by the machine learning model can withstand 6% more stress and has 6% lower displacement. Based on the R-square values this was to be expected. From these results, it is possible to compare a surface plot of the model to the DoE data points to determine why this may be and to give direction if additional runs should be performed or if outliers are producing the difference.



Evaluation index comparison

Working with Altair

Simulation can be the key to understanding complex issues, unlocking medical breakthroughs, and getting the latest advancements to the public faster, safer, and making them more broadly accessible. Altair helps medical companies across the world design better products, improve patient care, and reduce costs with simulation-driven design. Our simulation and optimization tools enable device designers and manufacturers to deliver quality and reliability while meeting regulatory standards, and our data analytics technologies empower healthcare providers to make faster, more informed decisions.

Learn more at altair.com/healthcare