Design evaluation of a balloon expandable coronary stent

About the Client

The client is a leading manufacturer and exporter of cardio-vascular products including stents.

The client approached DEP with the primary goal of evaluating a unique prototype stent design for structural behavior during crimping, expansion and implant of the stent.

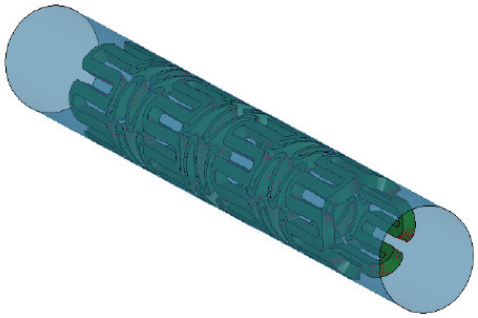


Figure 1: Model setup for crimping

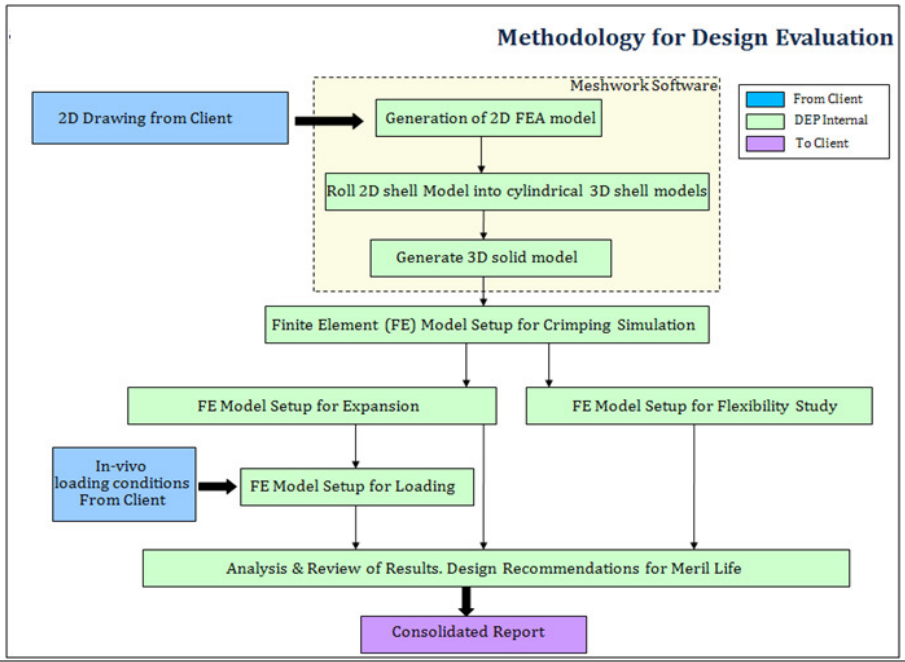
The Challenge

With advances in stent design and material technology, the goal of any medical device company is for rapid design evaluation of the stent to reduce the time to deliver the product the market. FEA is a valuable tool to accurately analyze and predict the structural behavior of the stent. The challenge in this project was to evaluate the stent implant in accordance with regulatory standards and also considering scenarios during the production of the stent and implanting of the stent in the body.

The Solution

Using latest techniques and methods in DEP MeshWorks, DEP was successfully able to develop 3D Hex Mesh finite element model from 2D line data to simulate realistic stent deployment for balloon expandable stents. The Stent Rolling tool in DEP MeshWorks quickly rolled the 2D line data of stent profile into a 3D Hex Mesh model.

Hex mesh Quality improvement tool was used to smooth the elements. Displayed adjacent is a schematic of the DEP's benchmarked CAE development / simulation methodology through ABAQUS Standard CAE software.



The Result

Following crimping and expansion analysis, areas exhibiting anomalous behavior and unacceptable deformations were identified and presented to client for re-design. DEP also carried out simulations to measure stent's flexibility as per ASTM standard. In addition, design recommendations were provided to the client for generating design with higher inherent radial strength.

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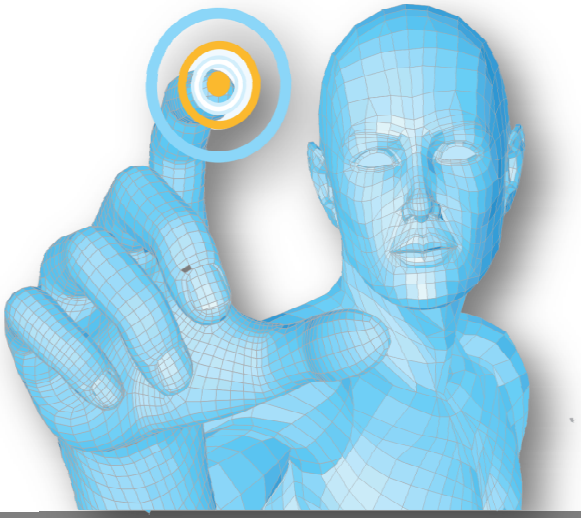

The DEP Advantage

- Reduction in design time compared to traditional method of device design.
- Reduced cost due to benchmarked/validated CAE derived design process for the client.
- Reduced cost of product development by about 40% & time by about 50%.
- Access to in-house tools and proprietary DEP MeshWorks software, allowed for rapidgeneration of multiple designs based on client's requirements.
- Implementing design recommendations, the client was able to achieve approximately 50% increase in the radial strength of the stent, without affecting other critical parameters of the design.

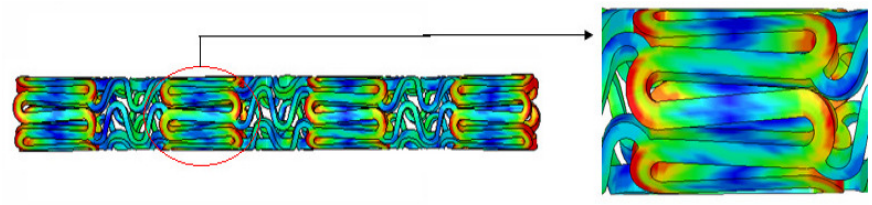

Figure 2 :Stress contour of the crimped stent

Figure 3: Stress contour of the stress during inflation of balloon (left), deflation of balloon (right)

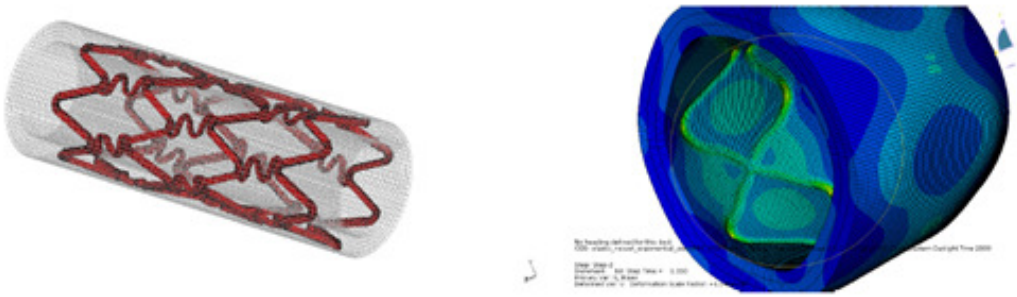

Figure 4: Wall stress FE model, stress results of the simulation