HEEDS™ Optimization of a Vascular Stent

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Introduction

Placing a stent into a human blood vessel presents many engineering design challenges and requires extremely high reliability and biocompatibility. From a mechanical design standpoint, the main challenges are choosing the material and the design geometry. Commonly used materials include stainless steels and shape memory alloys such as Nitinol (Nickel-Titanium).

The main difference in stents manufactured from these two materials lies in the method by which the stent gets expanded from a compact state (which facilitates its insertion) into its final configuration in the human blood vessel. Steel stents are inflated into the desired configuration using a pressurized balloon. Nitinol stents assume their final shape through material memory; the stent is stored cold then expands when it is placed into the vessel at body temperature. The stent discussed here uses the shape memory alloy Nitinol.

The manufacturer's initial design produced maximum strains that violate safety requirements. Red Cedar Technology (RCT) used its proprietary HEEDS™ Professional design optimization program to find the design geometry solution that most substantially reduced the principal strains seen in the crimping phase of Nitinol stent manufacture. This shape optimization methodology could be applied similarly for stents based on other materials.

The Shape Memory Alloy (SMA) Stent

The SMA stent's self-expanding capability, which is triggered by a temperature change, facilitates surgical insertion into the human blood vessel. The stent's final geometry is known because one of the manufacturing phases produces the stent at the exact geometry desired for the final shape inside the blood vessel. The final stent configuration is designed to keep the blood vessel expanded, allowing blood to flow freely.

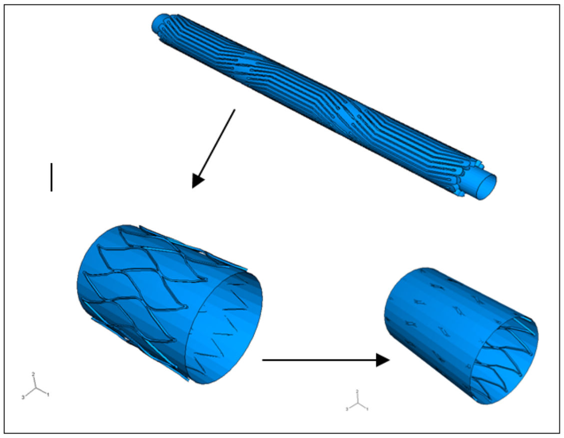

Figure 1. *Stages of stent processing.*

Fig. 1 illustrates the three steps in manufacturing a SMA stent. First, a laser cutting operation produces a regular pattern of cut-outs in a small-diameter, hollow tube. Next, the stent is expanded into a mesh-like cylinder of the desired diameter, and then annealed. Finally, the part is crimped at low temperature, reducing its diameter substantially to the configuration suitable for insertion. Once the surgeon inserts the stent into the vessel, the stent warms up to regular body temperature and expands to its original larger size due to shape memory.

Finite Element Analysis of the Stent

As part of the standard engineering design process, all of the stent manufacturing phases were analyzed with the nonlinear finite element program Abaqus by using a full model of the laser-cut stent. A complete analysis of the expansion and crimping phases took approximately four days to run on an Intel Pentium -based system. The most critical result was the principal strain in the stent after the crimping phase. The manufacturer's initial design produced maximum strains that violated safety requirements. The initial laser-cut pattern was known to critically influence these results, but the full model's long run times severely limited opportunities to explore different geometries.

The Shape Optimization of the Stent

To shorten the long run time for a design study based on the system-level model, RCT employed a novel subsystem approach called HEEDS_COMPOSE, which stands for COMPonent Optimization within a System Environment. This technology runs the majority of the finite element evaluations on a small sub-model in a matter of hours, and executes a full system level analysis only periodically during the optimization run to account for important coupling interactions between the local sub-model design and the behavior of the complete system. The model shown below in Fig. 2 represents the full stent, opened up onto a flat plane from its original cylindrical configuration. The sub-model is surrounded by a dotted outline.

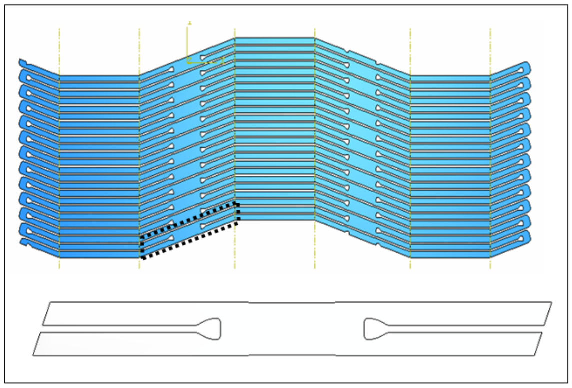

***Figure 2**. Original stent and subregion.*

RCT's objective was to use HEEDS Professional to control and vary the subsystem geometry automatically to identify the design that best satisfied the performance criterion – reducing the maximum principal strain. The full optimization sequence consisted of the following steps:

1. Analyze the baseline design by using the full Abaqus model with all load steps.
2. Automate the design generation by creating a parametric geometry model that allowed for variations in the shape of the design during optimization, remeshing the new geometry with every shape change. This model was created in Abaqus/CAE using python scripting. The script used the design variables as input to create a new geometry model and a new meshed model of the stent in each design iteration.
3. Use the HEEDS_COMPOSE technology to perform shape optimization using a small sub-model while maintaining important coupling interactions between the local sub-model design and behavior of the complete system.

Results

The HEEDS Professional optimization study reduced the maximum principal strain of the optimized solution by a factor of three. Fig. 3 illustrates the best shape found based on the design variables used in the optimization.

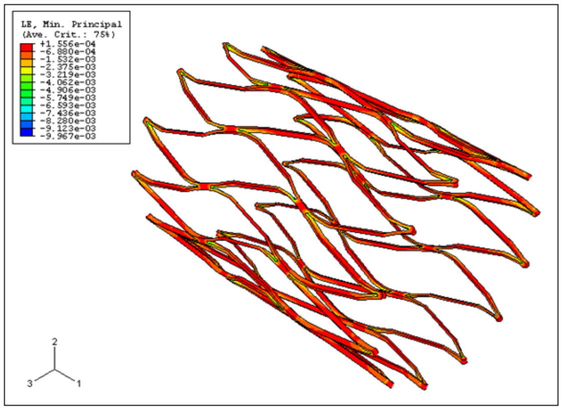

***Figure 3**. Optimized design with max strain reduced by factor of 3.*

Conclusions

The HEEDS Professional optimization performed on the vascular stent problem proved successful. The length of the design study process was reduced dramatically by using the HEEDS_COMPOSE technology. RCT was able to meet the design objective, reducing maximum principal strain by a factor of three.