Closed-Loop Geometry Optimization of a Coronary Stent Using Three-Dimensional Structural Analysis

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Abstract: A numerical procedure for optimization of a coronary stent geometry using three dimensional analysis techniques is presented. The objective of the optimization analyses is to maximize the long term durability (fatigue-safety), while keeping acute structural safety (plastic strains) below a given threshold. The expanded and crimped radial stiffness, as well as diametrical expansion recoil output quantities of each optimization simulation are also monitored. The software used during the optimization process consists of HEEDS, an optimization software package developed by Red Cedar Technology, coupled to Abaqus/Explicit. Inherent asymmetry in elements of the stent geometry required a large model to be representative of the entire stent's geometrical pattern. Utilization of a three dimensional (solid) description for such a model is unique in that each evaluation has the potential of taking a long time to complete, thus making this modeling approach less attractive during an optimization analysis typically requiring hundreds of evaluations to determine a 'best' solution. A combination of running the evaluations in parallel and model simplifications provide for a tractable solution to be completed in a reasonable amount of time. A representative example will be presented to exhibit the key features of the optimization process and results.

Keywords: Design Optimization, Fatigue, Coronary Stent, Implantable Medical Device, Scripting.

1. Introduction

Coronary stent design has evolved across the last decade to provide increased performance during delivery of the stent/catheter system to the target lesion site, while additionally making substantial strides in enhancing the implant attributes in the deployed state within the human arterial vasculature. The stent designs have not only included newer materials, but also resulted in more "intricate" geometry to enhance acute and chronic safety and performance. Traditional stent geometries include reasonable symmetry such that representative "unit-cells" can be defined both across the stent circumferential direction as well as the axial direction. This definition of a "unit-cell" greatly simplifies the resulting structural analysis during concept development and through subsequent stages of product development. However to maximize device performance, certain elements of asymmetry may need to be introduced while maintaining overall (macroscopic) symmetry across the device geometry. Another aspect to highlight is that contemporary open-cell stent designs truly exhibit some degree of out-of-cylindrical-plane deformation at the deployed state – therefore assumption of "perfectly cylindrical" geometrical state of the stent and subsequent two-dimensional simplification could lead to erroneous trends in stent stress and fatigue life predictions.

The below work discusses one such geometrical concept where elements of geometric asymmetry have been introduced to enhance the implant's performance, thus requiring a substantially larger three-dimensional finite-element model from a degree-of-freedom perspective. The "starting stent concept" was generated through a series of earlier optimizations from a general topological perspective. Once the general stent geometrical topology was defined, the starting concept was then thoroughly characterized both using finite-element simulations as well as through bench-top experiments to understand the initial performance (baseline) characteristics of the concept. Subsequently, the starting concept was optimized from a parametric perspective to further improve the implant's performance. This parametric optimization process is described in the following work using an automated closed-loop optimization system. The software utilized for this purpose consists of HEEDS, an optimization software package developed by Red Cedar Technology, and Abaqus/Explicit.

In the presented optimization process, maximizing the long-term structural durability (fatigue safety) of the implant was chosen as the objective. In addition to manufacturing geometrical constraints, constraints were placed to ensure the acute structural safety, i.e., plastic strains at deployed state did not exceed the intrinsic materials plastic strain threshold. Keeping in perspective the optimization intent, it was determined that a three-dimensional model was necessary to accurately predict performance trends of the starting concept. This introduced significant computational cost, limiting the number of design iterations that could be completed within a given time-span. Therefore, numerical studies were conducted *apriori* to understand possible model simplifications (such as mesh density) which could potentially cut-back on the "precision" of the model while not compromising the design directionally offered by the optimization.

Due to company proprietary reasons, the actual stent geometry used for the optimization is not shown in this article. Instead, an illustrative stent example is used to convey the methodology described.

2. Automated Geometric Optimization

Automated geometry optimization techniques in conjunction with finite element analysis (FEA) models were utilized to parametrically optimize the structural performance of the coronary stent concept. The commercial software packages HEEDS v5.3 (optimization software developed by Red Cedar Technology) and Abaqus/Explicit 6.9-EF2 were coupled together in a closed-loop form to automatically generate stent concepts that maximized the design objective while meeting the defined design constraints. The following figure provides an overview of the automated design optimization process.

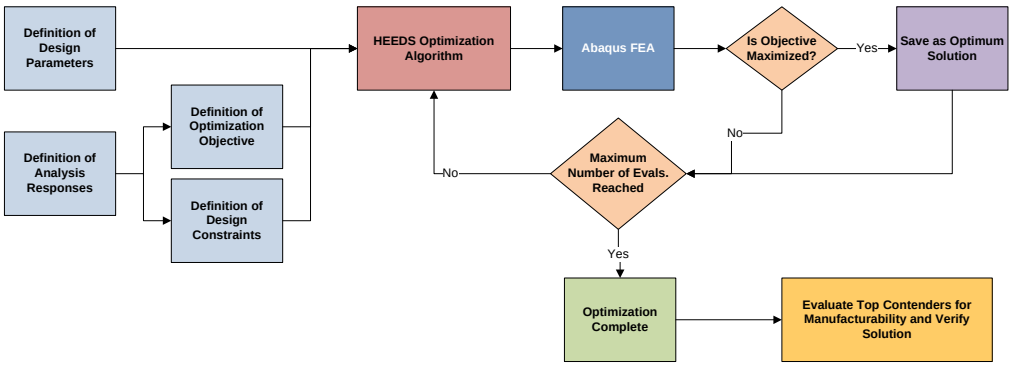

Figure 1. Overview of the Automated Optimization Procedure.

2.1 Optimization Model Setup

The HEEDS based optimization algorithm utilized was SHERPA, which employs numerous search strategies that dynamically adapt for the specific problem based upon what is learned about the design space (Red Cedar Technology, 2009). An efficient and robust optimization algorithm was considered imperative for the case described, due to large FEA simulation time per iteration prohibiting a substantial number (e.g. thousands) of design iterations to fully understand the design space.

The main aspects of the optimization model setup can be described as follows:

1. **Definition of Design Parameters:** The intrinsic aspects of the design concept the optimization algorithm alters in order to determine the optimum concept. The design parameters could be geometry or material related – in the study described later, only geometry design parameters were used.
2. **Definition of Analysis Responses:** This implies identification of intermediate or final analysis outputs (responses) that in turn could be use to constrain the optimization or alternately chosen as the objective.
3. **Definition of Objective Function:** Identification of the response that the optimization algorithm would need to maximize (or minimize) through successive design iterations.
4. **Definition of Design Constraints:** Identification of responses that the optimization algorithm would need to constrain to bound the acceptable design space. For instance, the constraints can be defined such that certain performance related responses are not compromised, while the objective response is being maximized.

There are many stent structural performance related responses which can be the utilized as the objective function (e.g. maximum plastic strain, expanded radial stiffness, expansion recoil, fatigue safety, etc.). In the current study, improvement to acute and long-term structural durability will be the focus of the effort.

The acute structural durability was assessed by examining the maximum equivalent plastic strain (PEEQ response) after the stent deployment. To ensure that the plastic strain for the various

design iterations did not exceed the stent material's plastic strain threshold, an appropriate design constraint was defined while setting up the optimization.

The concept's long-term structural durability was estimated for radial fatigue loading (pulsatile blood-pressure loading) when deployed within a mock artery. The long-term structural durability was quantified by calculation of a Fatigue Safety Factor (FSF) as described in section 2.3. and was chosen as the objective function of the optimization.

Three other analysis responses as listed below were chosen for output purposes only, with the intention of monitoring and providing additional feedback regarding the various design iterations.

1. Crimped stent radial stiffness
2. Expanded stent radial stiffness
3. Expansion recoil

2.2 Parametric Model Details

The automated nature of the optimization scheme presented in this study required a technique to update the geometric features of the stent without user intervention. This was accomplished by creating a fully parametric model of the starting concept geometry in Abaqus/CAE. An illustrative example of the asymmetric nature of the stent concept utilized during the current optimization study is shown in Figure 2.

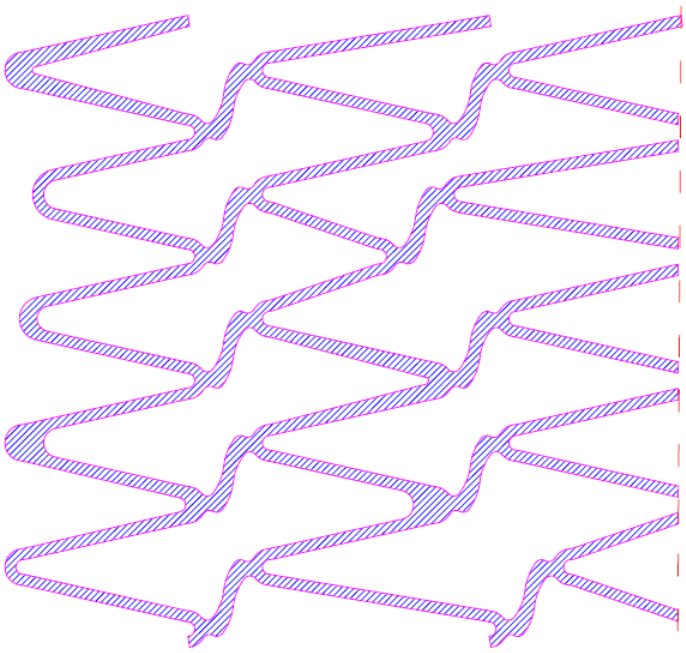

Figure 2. An Illustrative Example of the Stent Concept Geometry Utilized During Optimization.[1]

The asymmetric nature of the stent design both in the axial and circumferential direction can be observed in the figure with no clear repeating pattern. The lack of symmetry introduces a two-fold complexity into the optimization process in that (a) a substantially larger numerical model is required to represent the stent as well as (b) results in a several-fold increase in independent design parameters across the stent geometry. The consequence of the above two aspects is larger computational cycle time per design iteration as well as increased number of design iterations to converge on potentially optimized geometrical solutions. In the current study, twenty-seven (27) design parameters were utilized, with the parameters representing geometrical variables distributed across the entire stent.

In order for HEEDS to update the geometry of the stent, a mechanism was required to automatically, i.e., without user intervention, make changes to the stent design. This update procedure consisted of executing a Python script within Abaqus/CAE. The following flow chart details the actions performed by the script, including parametric re-generation of geometry, subsequent meshing and creation of resulting input deck for finite element analysis.

[1] The stent concept geometry shown in Figure 2 is solely for illustrative purposes, and to the authors knowledge does not represent a currently marketed stent design.

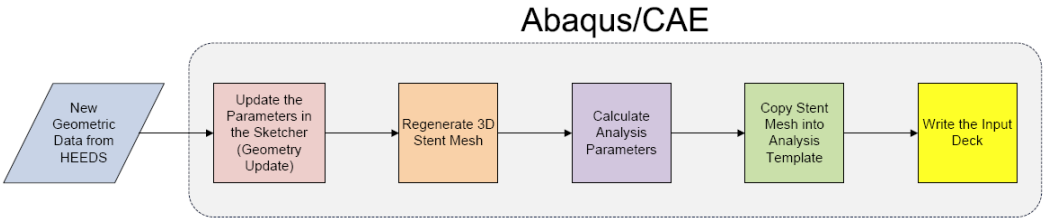

Figure 3. The Process Flow to Automatically Update the Stent Geometry and Create Input Deck in Abaqus/CAE.

2.3 Finite Element Model Details

The structural performance of the stent was assessed through a quasi-static Abaqus/Explicit analysis. Analyzing the structure in Abaqus/Standard was assessed and found to be just as efficient as using Abaqus/Explicit for this specific case. The main advantage of using Abaqus/Explicit was ensuring that simulation failures due to solution non-convergence did not occur, thereby preventing inadvertent termination of the optimization after several days of optimization progress.

The components within the finite element model included the coronary stent, mock artery, crimp cylinder, and expansion cylinder, as depicted in Figure 4.

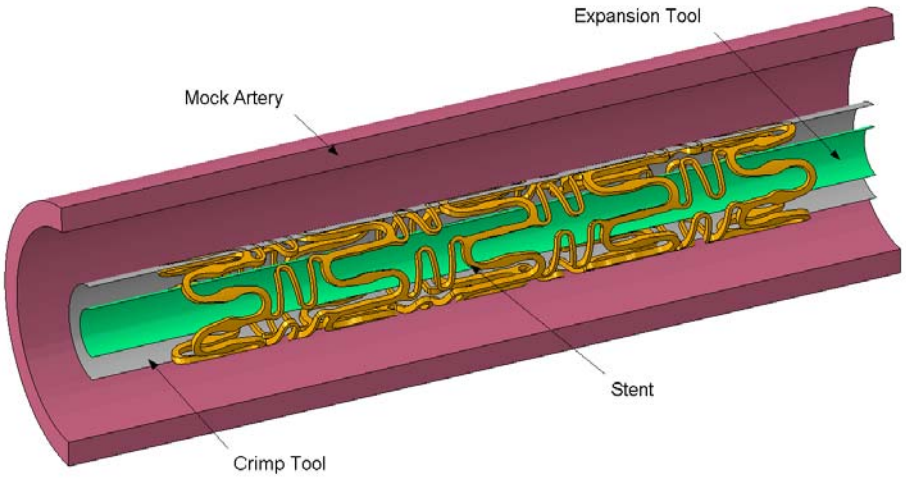

Figure 4. The Geometric Details of the Finite Element Model.[2]

The following table details the element types and material models utilized for each component in the simulation:

Table 1. The Element Types and Material Models used in Finite Element Model.

Component	Element Types	Material Model
Stent	C3D8R, M3D4R	Elastic-Plastic (Mises)
Mock Artery	C3D8R	Neo-Hookean
Crimp Tool	M3D4R	Semi-rigid
Expansion Tool	M3D4R	Semi-rigid

As can be seen from Table 1, a three-dimensional (solid) representation was utilized to model the stent. Although a solid model represented more computational cost than other element types (e.g. shells, beams or two-dimensional plane stress), the higher fidelity solution was considered a requirement to ensure that that the stress/strain predictions were accurate and led to a "truly" optimized solution.

The analysis history consisted of the following steps:

1. **Crimp:** Simulate the mounting of the stent onto the delivery system.
2. **Expansion:** Expand the stent into an idealized mock artery
3. **Expansion Recoil:** Allow the stent to recoil after deployment.

[2] Coronary stent geometry shown in Figures 4 and 5 solely to illustrate the analysis technique and not representative of actual stent model used for optimization.

4. **Systolic Pressure:** Apply the systolic pressure to the mock artery inner diameter.
5. **Diastolic Pressure:** Apply the diastolic pressure to the mock artery inner diameter.

The analysis steps can be further described as follows. In the first step of the finite element simulation, the stent was crimped to simulate the assembly of the stent onto the balloon catheter (Figure 5). This was accomplished by modeling contact between the stent outer surface and a semi-rigid crimp cylinder. The nodes on the "semi-rigid" crimp cylinder were constrained axially as well as circumferentially on a cylindrical coordinate system oriented along the stent longitudinal axis. Boundary conditions were imposed to radially contract the crimp cylinder, thereby crimping the stent to the desired profile.

At the end of the crimp step, a semi-rigid expansion cylinder was used to expand the stent to the intended deployed diameter (Figure 5). This step simulated the controlled inflation of the balloon (underlying the stent), driving the stent to expand to the desired expansion diameter. This expansion was performed into a simulated hyper-elastic tube representative of a coronary artery. The stent expansion step was accomplished by modeling contact between the expansion cylinder and the stent as well as between the stent and the internal surface of the tube. For this specific treatment, the material constants of the hyper-elastic tube were numerically calibrated at the onset of the analysis to exhibit a physiologically relevant coronary arterial distension for a conservative blood pressure range on the order of 100 mmHg.

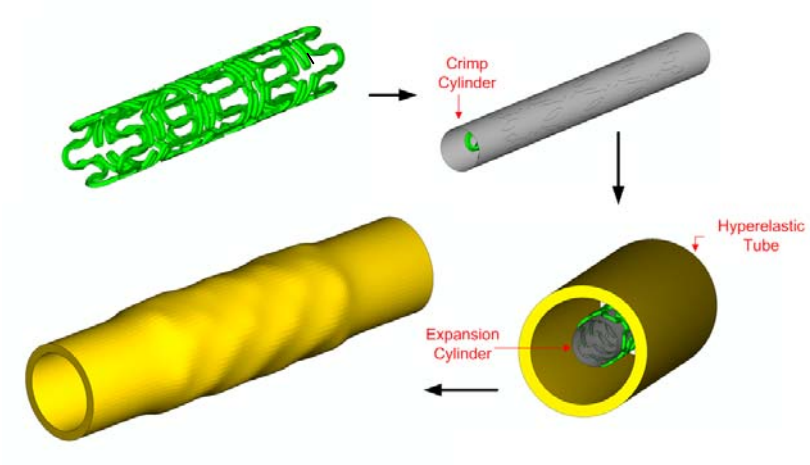

Figure 5. Schematic of the sequence used to assemble and deploy the stent involving the crimp and expansion steps in the finite element model.

After the expansion step, the stent/tube system was allowed to recoil by retracting the expansion cylinder. This step simulated the balloon deflation and retraction of the balloon catheter. Maximal and minimal pressure loads bounded by the 100 mm Hg pressure range, were then sequentially applied to the internal faces of the tube to conservatively represent physiological systolic and diastolic blood-pressure loads within the artery. The stent material response was found to be linear-elastic during the fatigue cycle. The stress distribution across the stent for the two pressure load steps was used to predict a Fatigue Safety Factor (FSF). The FSF was estimated by using the modified Goodman relationship (Shigley, 2001), which can be expressed mathematically as follows when a structure is subjected to repetitive cyclic loading:

$$\frac{1}{FSF} = \frac{S_a}{S_e} + \frac{S_m}{S_{uts}} \qquad (1)$$

Where:

- FSF ≡ Fatigue Safety Factor response
- S_a ≡ Alternating Stress response
- S_m ≡ Mean Stress response
- S_e ≡ Stent Material's Endurance Limit (10 year fatigue life equivalent of blood pressure loading)
- S_{uts} ≡ Stent Material's Ultimate Tensile Stress (defined in terms of true stress)

2.4 Computational Hardware Setup

In order to further improve the efficiency of the optimization process, the FEA simulations were run on a high-performance computer cluster. In addition to running the Abaqus analyses on multiple CPUs, HEEDS can also run multiple jobs in parallel. The following diagram explains the hardware and software configuration utilized during the optimization:

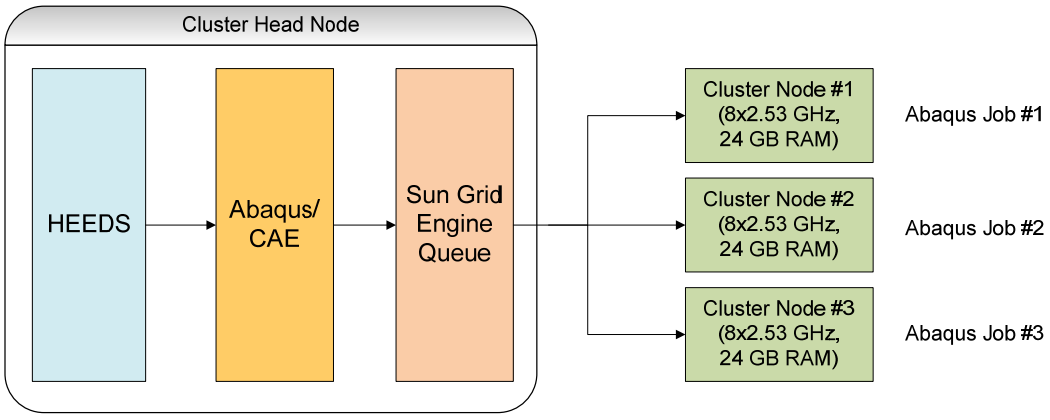

Figure 5. Optimization Hardware and Software Configuration.

The simulations that were created for the design iterations by HEEDS and Abaqus/CAE were submitted to the cluster by the Sun Grid Engine queue. As shown in Figure 5, the FEA simulation pertaining to a design iteration was run across one node (eight computational cores per node). Three nodes were used to allow for three design iterations to be evaluated in parallel. Since each FEA simulation took approximately four hours to complete, eighteen evaluations could be completed across a 24 hour period. The optimization was allowed to run for one hundred and fifty evaluations, taking a little over eight calendar days for the entire optimization process to complete.

3. Results

The "optimized" geometrical option as determined from the optimization process was first assessed for manufacturability, and then re-analyzed while excluding the model simplifications to confirm that it indeed increase the objective function (FSF) while maintaining the design constraints. The results of this confirmatory FEA simulation can be found in the table below. The percentages indicate difference in performance relative to the starting geometrical concept as input to the optimization process.

Table 2. Summary of the "Optimized Stent Geometry"

Performance/Safety Metric	Percentage Relative to Initial State
Minimum FSF	**+13.6%**
Maximum PEEQ	**-3.9%**
Crimped Radial Stiffness	**-0.1%**
Expanded Radial Stiffness	**-0.5%**
Expansion Recoil	**+3.0%**

Note: It should be emphasized that the percentages shown in Table 2 are not absolute values, but indicative of percentage difference relative to starting stent concept.

As can be seen from Table 2, the optimization resulted in an increase of the objective function by approximately 14%. For a given stent topology, this increase in Fatigue Safety Factor is considered appreciable from a device structural durability perspective. It should be noted that a conventional "manual" optimization approach involving an iterative sequence of FEA simulation and manual stent geometry modifications would take order of months for completion as opposed to roughly a week with the presented closed-loop automated optimization process. Additionally the described optimization process presents two additional benefits – firstly, the optimization requires minimal or no user intervention saving man-hours of the design engineer or computational analyst and secondly, it is highly improbable that a manual optimization based on engineering intuition could realize an equivalent increase in the design objective function. Table 2 indicates that the design constraint for plastic strains was met during the optimization – in fact, the optimization resulted in an approximately 4% decrease in plastic strains at the deployed state of the design.

As indicated earlier, responses related to the crimped radial stiffness, expanded radial stiffness and expansion recoil were solely monitored during the optimization. The "optimized" geometry demonstrated negligible trade-offs with respect to the crimped and expanded radial stiffness while resulting in 3% (relative) increase in recoil compared to the starting concept.

4. Conclusions

A technique to parametrically optimize the performance of a coronary stent through a closed-loop system was presented. The software utilized during the optimization process was HEEDS in conjunction with Abaqus/Explicit. The method was shown through an illustrative example of a coronary stent. A novel aspect of the optimization was that a three-dimensional model and discretization was utilized during the FEA simulation, while circumventing challenges related to simulation cycle-time per design iteration as well a large number of design parameters. The results of the optimization as applied to an "actual" coronary stent geometry was presented, proving the viability of the proposed technique.

5. References

1. Red Cedar Techonolgies, *HEEDS Professional User's Manual v5.3*, 2009.
2. Shigley, J. E., and Mischke, C. R., *Mechanical Engineering Design Sixth Edition*, pp. 389-408, McGraw Hill, 2001.