

Multi-objective optimization approach for bio-medical stent using parametric optimization.

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Abstract

Stent deployment process and its long-term usage requires to meet multiple objectives like final stent diameters for cardiovascular disease treatments, and minimalistic plastic strain during the deployment to meet the fatigue life. Achieving an exact dilation diameter and maintaining minimal plastic strain values are mainly based on stent geometric design, cross section, material, amount of crimping and expansion diameter.

This paper presents an effective stent finite element (FE) modelling and parametric optimization method using DEP MeshWorks stent rolling and parametric tools, LS-DYNA and LS-OPT optimization tools. Controllable design and deployment process parameters are considered for optimum random sampling using a Design of Experiments (DOE) approach, and using a parametric tool, designs are generated, on which analysis and optimization is performed using LS-DYNA explicit solver. The result is an optimum design solution which meets the required diameter criteria, without exceeding the minimal plastic strain limit, and within the foreshortening and flexibility limits.

Key words: Stent rolling, parametric optimization approach, stent deployment process, sensitivity study

1. Introduction

The main cause for coronary artery disease is an excessive buildup of plaque which obstructs regular blood flow in the artery. It can be treated by implanting a tiny wire mesh tube called stent at the obstruction location. Stent implantation is a non-surgical method to treat coronary artery disease. Balloon expandable vascular stenting is commonly used to support the artery walls and ease the blood flow in areas blocked by plaque.

Balloon expandable stents ensure safe and smooth deployment of the stent to the right location of the artery. The balloon expandable stents deployment process involves multiple stages that starts from crimping the stents into the delivery catheter, placing it at the right location, dilating the stent gradually to the exact diameter and extraction of the deliver catheter.

During the deployment process, the stent undergoes plastic loading conditions at the crimping stage while it crimps into a small catheter diameter, as well as at the dilation stage, while it keeps the artery open to restore normal blood circulation. Crimping and dilation diameters are affected by spring back and recoiling caused by this plastic deformation. Spring back and recoiling effects also need to be calculated to keep the target crimping and dilation diameters respectively. In recent years, a lot of CAE numerical studies have been done to simulate the mechanical behavior of stents to foresee any physical conditions, particularly in predicting spring back, recoil and flexibility. CAE simulation results gives numerous advantages in the prediction and optimization process for stent designs, without the accrued effort and time of individually testing various stent work pieces.

An effective method for stent deployment simulations to check the mechanical behavior of the stent design is the CAE finite element method using nonlinear analysis with LS-DYNA. The multi objective optimization process is a very helpful tool to achieve design performance targets such as final crimping and dilation diameters, von-misses stress, effective plastic strain, maximum principal stresses, and bending flexibility. In our present study, we optimized the stent design improving bending flexibility, reducing the recoil radial diameter and design constraints, where the foreshortening should not exceed 3%.

2. Method

The full span of the stent model is considered for CAE simulations to predict the foreshortening and to avoid symmetric boundary condition effects, which also provides better accuracy.

The stent was modeled with 8 node hex elements with 4 layers, capturing the geometry details using DEP MeshWorks 2D meshing and stent rolling tool. Since the crimping and dilations simulations undergo both plastic and elastic behavior during the deployment process, MAT24 Elastic-plastic material was chosen with stress versus strain curve.

The stent geometry was designed and developed based on the normal artery diameter at the plaque location, shape of the plaque and strength of the artery, in the form of 2D line segments. The stent design is obtained as a 2D line sketch with dependable wire cross section. Quad dominated shell elements are then generated capturing all 2D geometry sketch including weld profiles.

The stent rolling tool converts the 2D plane mesh into cylindrical 3D hex elements with minimalistic inputs like, radius of the stent, axis of rotation, thickness of the stent and number of layers required. Material and section properties including the specified element form and self-contact between the stent hex elements are automatically updated as well.



Fig.1: DEP MeshWorks stents modelling tool

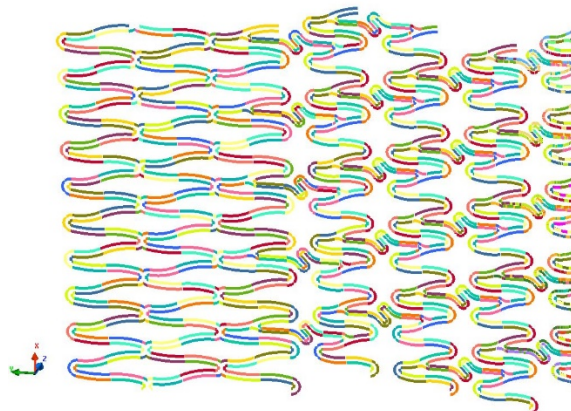


Fig.2a: 2D Mesh Data

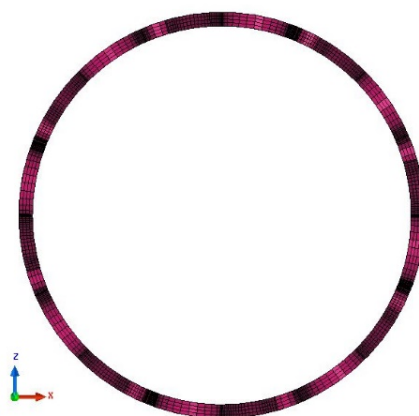
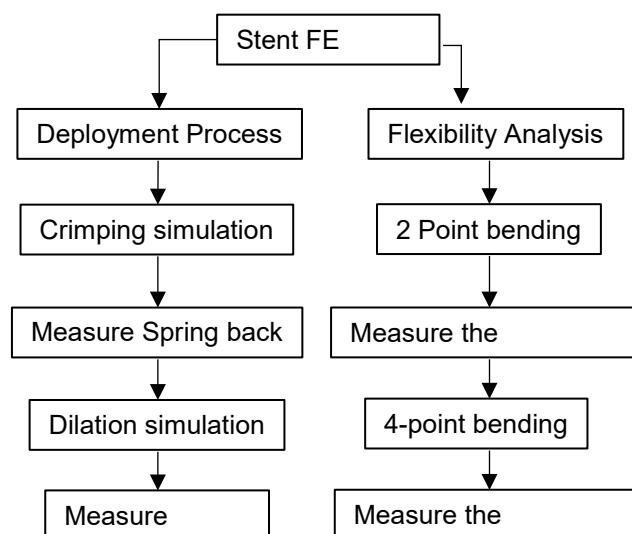


Fig.2b: Output form stent rolling tool

3. CAE Simulations

Stent deployment process and flexibility analysis simulations are major load cases considered for the CAE simulation. All these simulations were conducted using LS-DYNA as shown in following process chart.



3.1 Stent crimping and dilation process simulation

During the assembly process, the balloon catheter is manually inserted inside the stent and subjected to crimping using a calibrated crimping tool. The crimping tool reduces the diameter of the stent and undergoes plastic deformation. Certain amount of residual stress is always stored in the stent because of the plastic deformation.

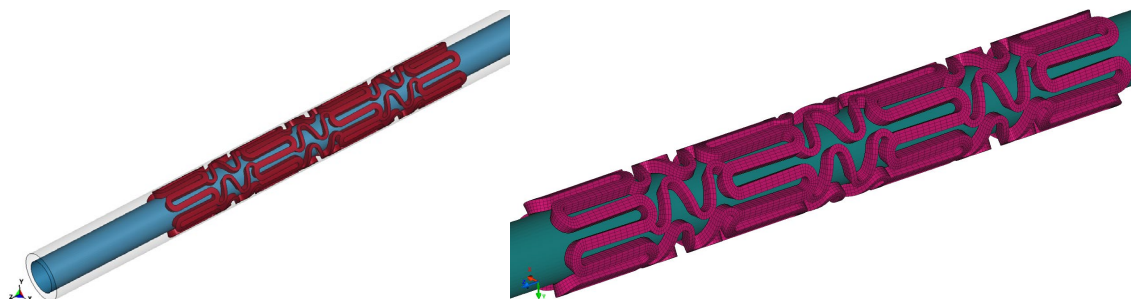


Fig.3: Stent with Crimping & dilation tools

The stent delivery catheter is inserted into the blocked artery and inflated till the stent expands to the required artery size. The stent acts like a mechanical scaffold and keeps the artery open at the required size. This is the second time the stent undergoes plastic deformation during the deployment process. Residual stress generated from the crimping and dilation process has been considered for analysis.

The stent deployment process was conducted using LS-DYNA explicit solver to use its robust contact functionality that solves the complex 3D elements contact problems without an iterative approach. The increment time was carefully calculated to stabilize the explicit solvers and function like an implicit solver. The internal and kinetic energies were monitored during the analysis, and the kinetic energy was maintained to be less than 5% to guarantee numerical stability similar to the linear-static condition.

Stent deployment tool automatically generates the crimping tool and dilation balloon with material properties, surface to surface contacts and self-contacts and prescribed boundary motions.

Change in diameter and length of the stent was tracked at multiple locations to study the spring back, recoiling and foreshortening. Max von-mises stress, max principal stress and effective plastic strain were also tracked and plotted.

3.1.1. Crimping

The Crimping process was carried out by applying radially inward boundary prescribed motion using the displacement option on every node of the crimping tool. This develops a contact pressure on the outer surface of the stent, thus crimping it to the target diameter.

The induced stress exceeds the yield strength resulting in permanent plastic deformation. During the crimping process, the maximum stress and effective plastic strain values were monitored to stay within the desired plastic limit without reaching the braking failure point. The crimping displacement is applied slightly more than the required final crimping diameter in order to consider the spring back effect. The figures from 4a to 4f illustrate the crimping process with its corresponding analysis results.

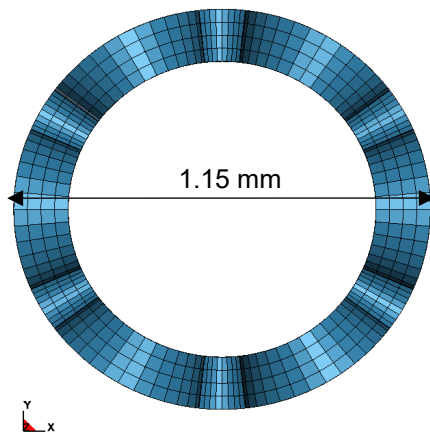


Fig.4a: Initial Condition

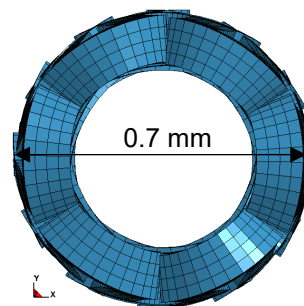


Fig.4b: Crimped state

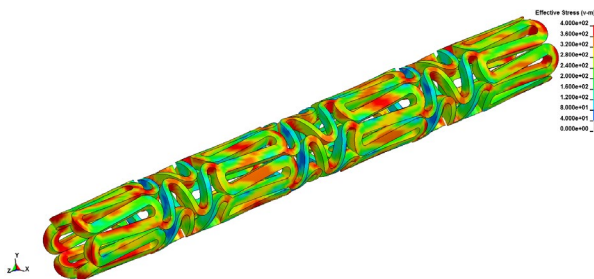


Fig.4c: Von Misses Stress at Crimped

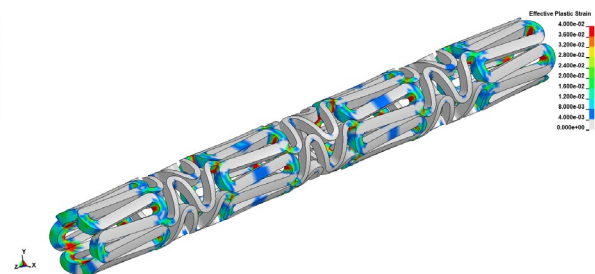


Fig.4d: Effective Plastic strain at crimped state

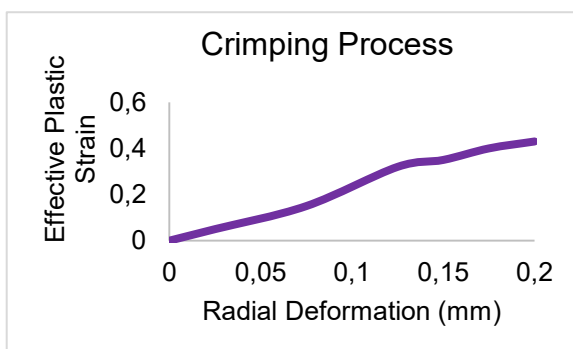
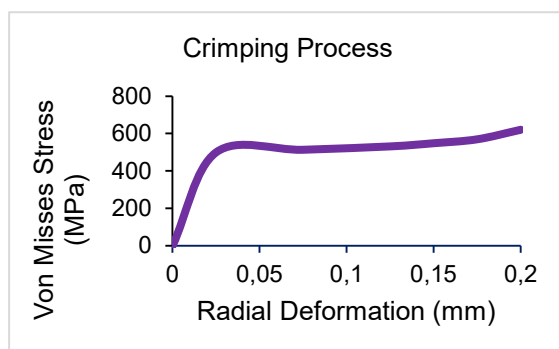


Fig.4e: Stress Vs. Radial deformation

Fig.4f: Eff. Strain Vs. Radial deformation

3.1.2. Spring back

Followed by the crimping process, the stent was kept at crimped condition for a while. Later, as the contact between crimping tool and stent was removed, it started to deform freely to recover elastic strain as there was no constraints applied in the absence of the crimping tool contact. The final crimping diameter matches the dilation tool diameter and the contacts were thus recognized. The figures from 5a to 5f illustrates the spring effect with its corresponding analysis results.

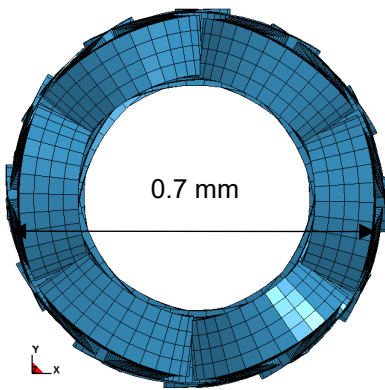


Fig.5a: crimped state

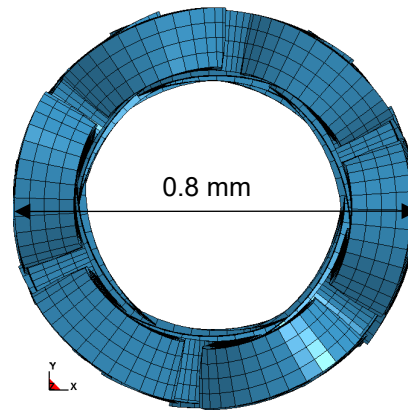


Fig.5b: After spring back

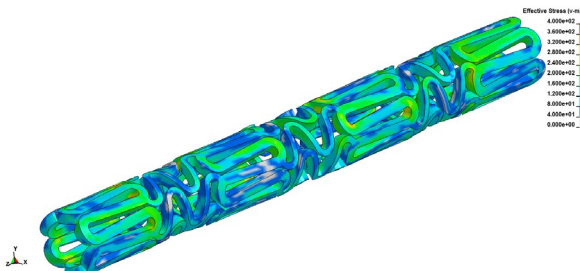


Fig.5c: Von Misses Stress after spring

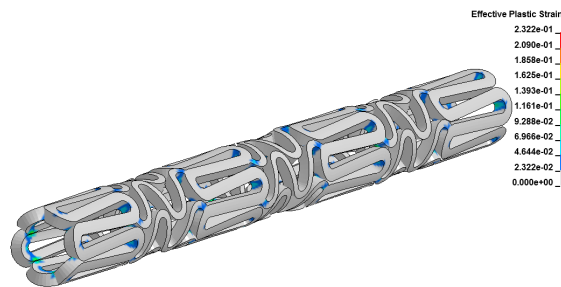


Fig.5d: Effective Plastic strain after spring

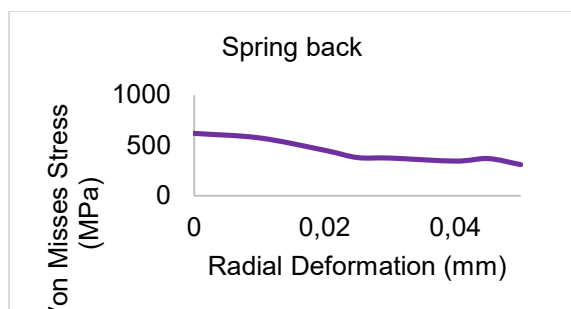


Fig.5e: Stress Vs. Radial deformation

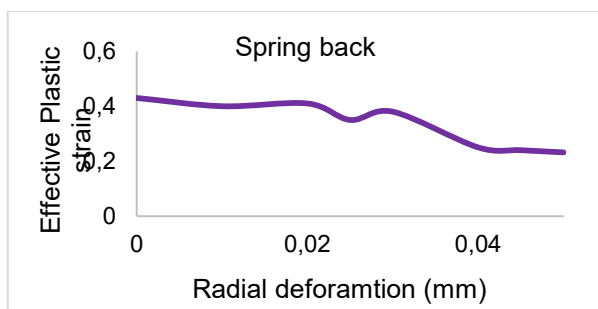


Fig.5f: Eff. Plastic strain Vs. Radial deformation

3.1.3. Dilation

The dilation process was carried out by applying radially outward boundary prescribed motion using displacement option on every node of the dilation tool. This develops a contact pressure on the inner surface of the stent, thus dilating it to the target diameter.

The induced stress exceeds the yield strength causing permanent plastic deformation. During the dilation process, the maximum stress and effective plastic strain values were monitored to retain values within the plastic limits and not to exceed the breaking point.

The dilation displacement applied, was slightly more than the required final dilation diameter in order to take the recoiling effect into consideration. The figures from 6a to 6f illustrate the dilation process with its corresponding analysis results.

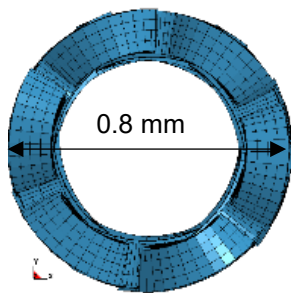


Fig. 6a: After spring back

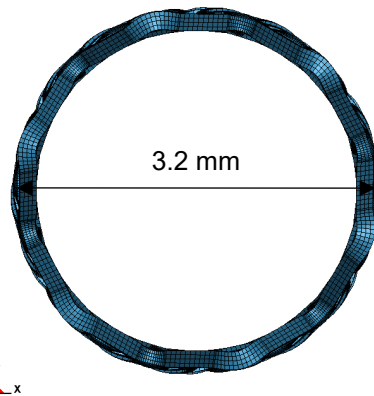


Fig. 6b: Dilation state

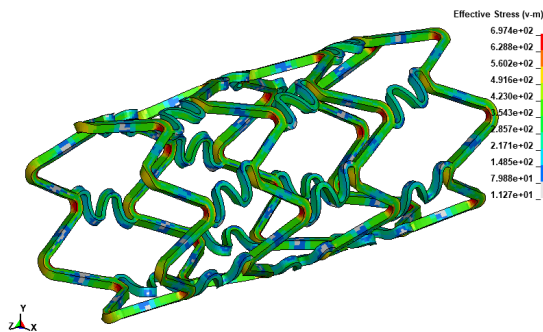


Fig. 6c: Von Mises Stress at dilation state

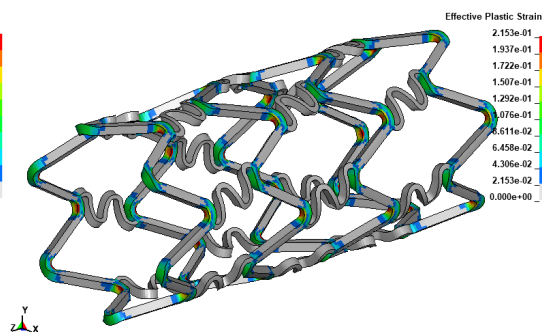


Fig. 6d: Effective Plastic strain at dilation state

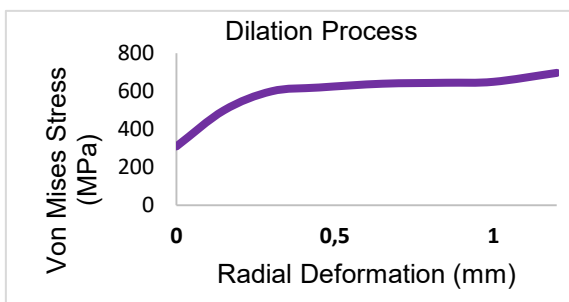


Fig. 6e: Stress Vs. Radial deformation

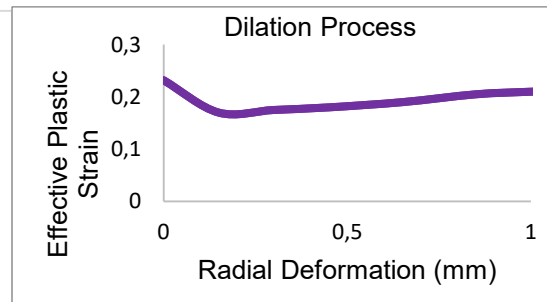


Fig. 6f: Eff. Plastic strain Vs. Radial deformation

3.1.4. Recoil

Following the dilation process, the stent was kept at an idle condition for a while. Later, as the contact between the dilation tool and stent was removed, it started to deform freely to recover elastic strain as there were no constraints. The final dilation diameter thus matches the artery wall diameter. This process is known as radial recoiling. The figures from 7a to 7f illustrate the recoiling effect with its corresponding analysis results.

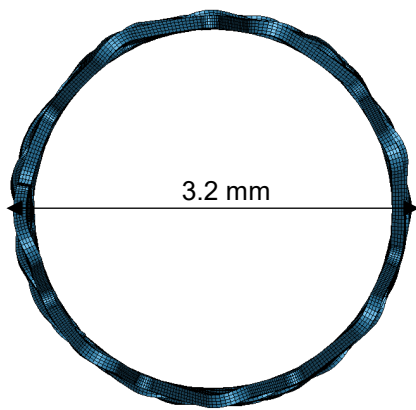


Fig.7a: Dilation state

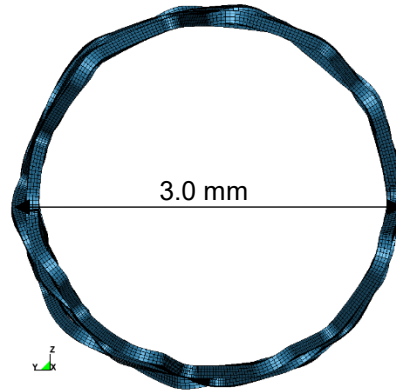


Fig.7b: After Recoil

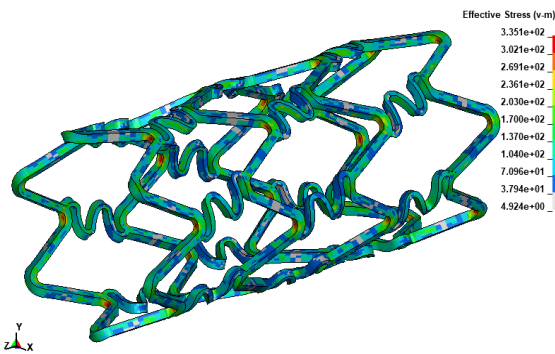


Fig.7c: Von Misses Stress after recoil

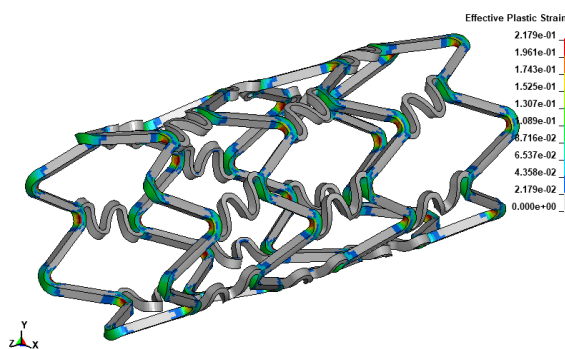


Fig.7d: Effective plastic strain after recoil

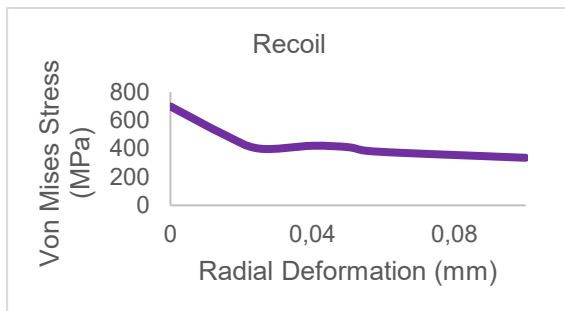


Fig.7e: Stress Vs Radial deformation

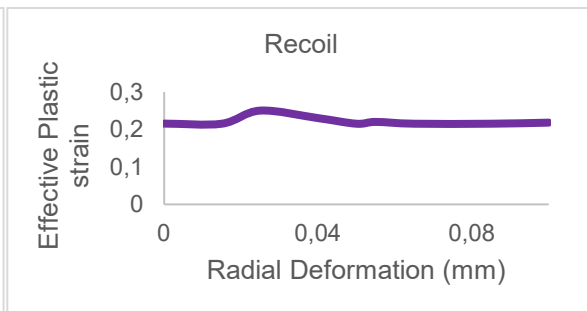


Fig.7f: Eff. Plastic strain Vs Radial deformation

3.1.5. Stent crimping and dilation process results summary

As mentioned in Table 1, after the crimping process, the outer diameter of the stent was reduced to 0.7 mm at fully crimped state. While crimping, the localized maximum Von Mises stress and maximum principal stress were observed at 620 MPa and 680 MPa respectively. Due to spring back, the diameter of the stent increased to 0.8 mm. Residual stress observed after the crimping process was 310MPa.

Following the dilation process, the stent was radially expanded to 3.2 mm outer diameter. The localized maximum von Mises stress and maximum principal stress during the dilation process were observed to be 697 MPa and 715 MPa respectively. The radial recoil effect is observed after dilation reducing the outer diameter to 3 mm. The Residual stress observed after the dilation process was 335 MPa

Stage	Outer diameter	Localized, Max stress	Max strain
Initial Condition	1.15mm		
Crimping state	0.7mm	620MPa	0.521
Spring back	0.8mm	310MPa	0.232
Dilation state	3.2mm	697MPa	0.2153
Radially recoil state	3.0mm	335MPa	0.2179

Table 1: Stent crimping and dilation process results

Percentage of radial recoil and foreshortening effects are calculated using the following formulae:

$$\% \text{ of Radial recoil} = \frac{\text{Stent Radius at loaded state} - \text{Stent Radius at unloaded state}}{\text{Stent Stent Radius at Loaded state}}$$

$$\% \text{ of Foreshortning} = \frac{\text{Stent Length at initial state} - \text{Stent Length at final state}}{\text{Stent Length at initial state}}$$

For the baseline model the numerical CAE results shows that Radial recoil is 6.2% and foreshortening was 7%.

3.2 Flexibility analysis simulation

Bending flexibility is one of the characteristic features required for the stent to navigate to the predetermined location without any damage to the artery.

Bending flexibly load cases are decided based on the vascular anatomy shape. The bending load was applied along the length of the stent. The deformations were measured and the bending stiffness was calculated for various load case scenarios. This analysis has been conducted using LS DYNA implicit analysis. The deformations were measured at the load application points and the results are represented as bending stiffness.

3.2.1 2- point bending stiffness

Constrained nodal rigid body (CNRB) has been created at both ends of the stent. Equal and opposite forces of 1N were exerted on these CNRB elements center node. Boundary and loading conditions and their corresponding analysis results are illustrated in fig 8a to 8d.

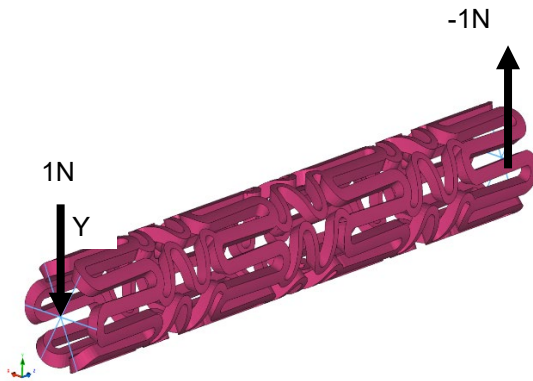


Fig.8a: Load and boundary conditions

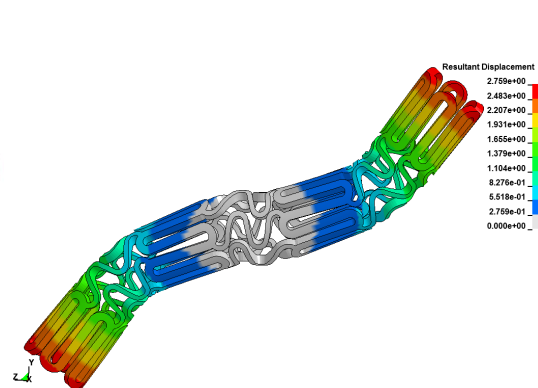


Fig.8b: displacement contour 2-point bending

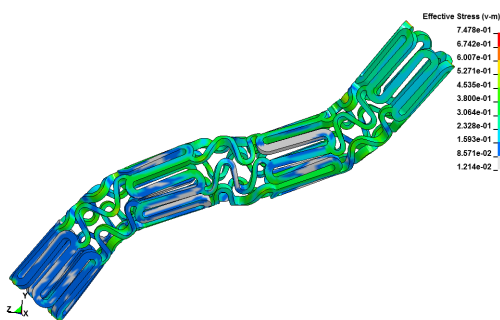


Fig.8c: Von-mises stress for 2-point bending

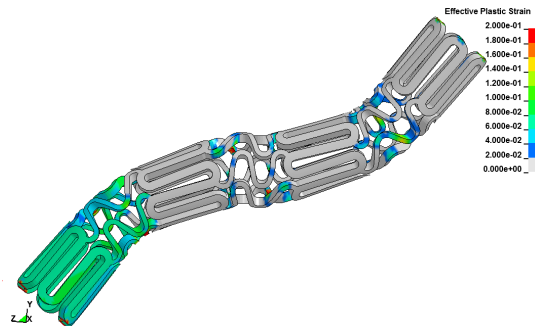


Fig.8d: Eff. Plastic strain contour 2-point bending

An equal and opposite Force of 1 N is applied at both ends of the stent and the displacement was measured at both these ends. From this load applied, bending stiffness of 0.4 N/mm and 75 MPa stress was observed.

3.2.2 4-point bending stiffness

Four Constrained nodal rigid body elements have been created on both ends of the stent and two on the middle. Boundary conditions have been applied on both ends CNRB element center node and 1N force was applied on middle CNRB center nodes in the same direction. Boundary and loading conditions and their corresponding analysis results are illustrated in fig 9a to 9d.

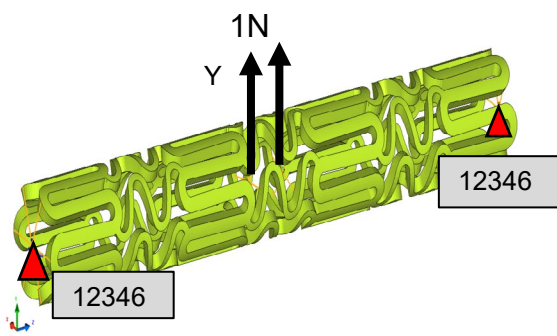


Fig.9a: Load and boundary conditions

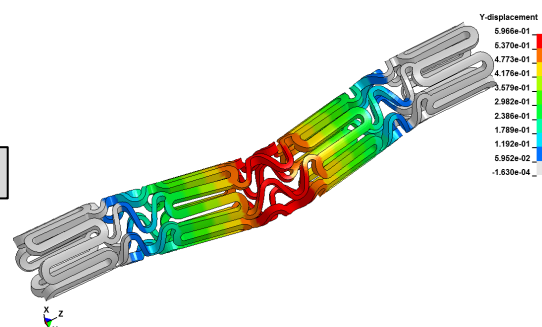


Fig.9b: displacement contour 4-point bending

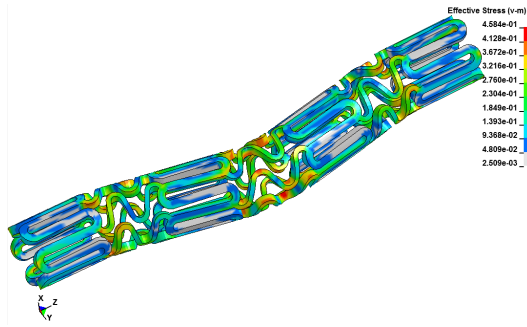


Fig.9c: Von Mises Stress 4-point bending

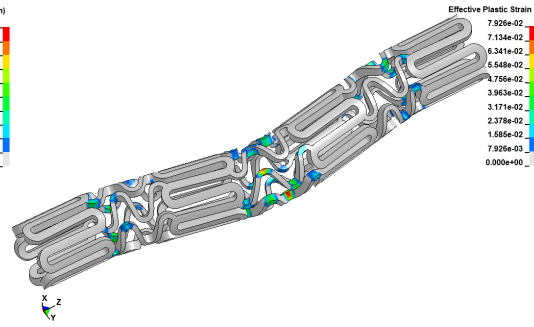


Fig.9d: Effective Plastic strain 4-point bending

Force of 1N was applied on the two CNRB nodes at the center and the displacement was measured at both these nodes. From this load applied, bending stiffness of 1.6 N/mm and 75 MPa stress was observed.

4. Optimization

Design objective function, design variables, latin hypercube sampling method and design constrains, have been defined in LS-OPT meta model (Fig 10), and the DEP MeshWorks parametric model was coupled in the optimization loop.

DEP MeshWorks morphing approach was used to create the designs as per the latin hypercube random sampling values, using parametric model. DEP MeshWorks parametric model changes the existing mesh to a new geometric shape using offset and translate functions, along with freeform and control block morphing techniques. To ensure the quality standards of this process the maximum and minimum material condition designs have been generated and verified for the required element quality with intersection and penetrations check.

4.1 Parameterization

4.1.1 Design Variable-01: Thickness parameter

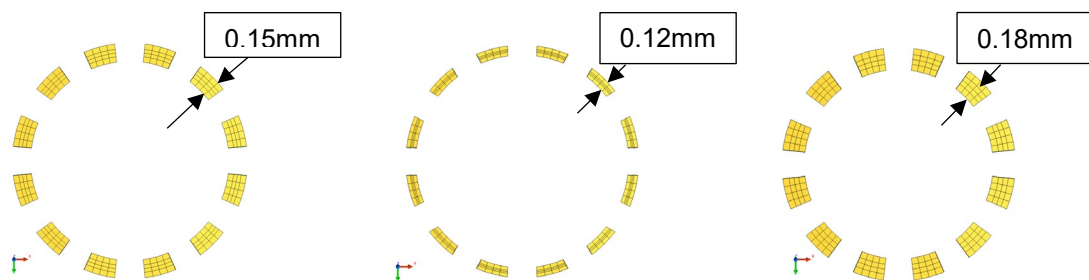


Fig. 10a: Baseline stent c/s

Fig. 10b: Min design radial c/s

Fig. 10c: Max design radial c/s

Thickness of the stent along the entire length has been parametrized using offset function radially with ± 0.03 mm range

4.1.2 Design Variable-02: Width parameter

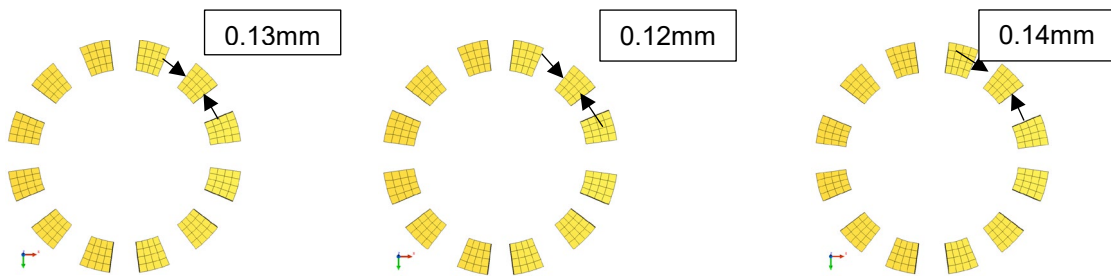


Fig. 11a: Baseline stent c/s

Fig. 11b: Min design radial c/s

Fig. 11c: Max design radial c/s

Width of the stent along the entire length has been parametrized using offset function circumferentially with ± 0.01 mm range except the W-bridge strands.

4.1.3 Design Variable-03: Stent slot length parameter

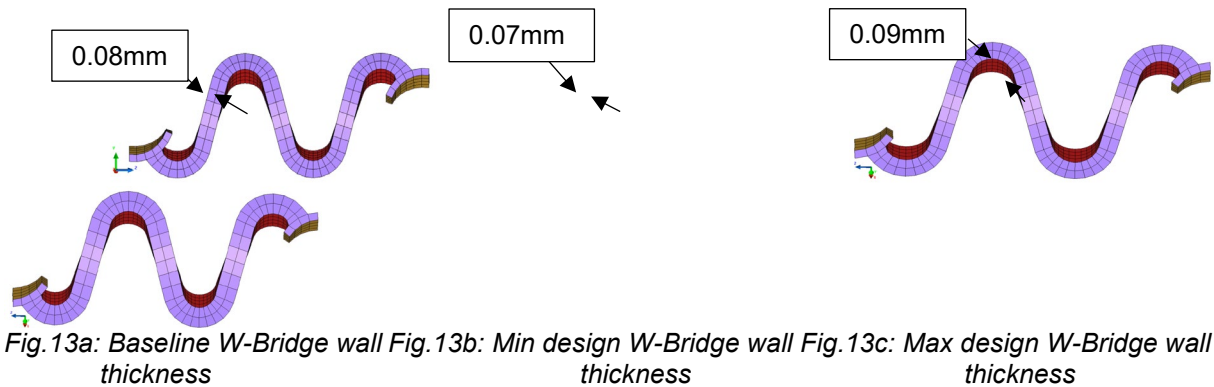


Fig. 12a: Baseline longitudinal view

Fig. 12b: Max design longitudinal view

Every slot length has been individually parametrized with 0.25 mm. These parameters are combined as a single "General Transform Parameter", so that, the length of the stent is parameterized with 1 mm.

4.1.4 Design Variable-04: W-bridge width parameter



Width of the W-bridge strands has been parametrized using offset function along with side walls with ± 0.01 mm range.

Design variable	Baseline	Lower Limit	Upper limit
Thickness parameter	0.15mm	0.12mm	0.18mm
Width Parameter	0.13mm	0.12mm	0.14mm
Slot Length parameter	8.50mm		9.50mm
W-Bridge Parameter	0.08mm	0.07mm	0.09mm

Table 2: Design variable with its ranges

4.2 Sampling

A total of four design variables, as mentioned in the table 2, were picked with the upper and lower limits set as per the design feasibility and manufacturing constraints as shown in the Table 2. Since 4 design variables were selected, a total of 20 sample designs ($5 \times$ number of design variables) were generated using latin hypercube methods

4.3 Simulations

LS-DYNA explicit simulations were executed to obtain the FE responses such as, displacement, strain and max stress values of for every design and for corresponding load cases. These responses are then supplied to LS-OPT to define the objective functions and constraints.

4.4 Meta Models and Optimization

Linear approximation method was used to define the meta model for the given sample designs. Genetic algorithm method was used to perform multi objective design optimization with the following design constraints percentage of radial recoil, percentage of spring back, maximum principal stress, and minimal plastic strain. The following objective functions were selected, namely, maximize the flexibility and minimize the foreshortening.

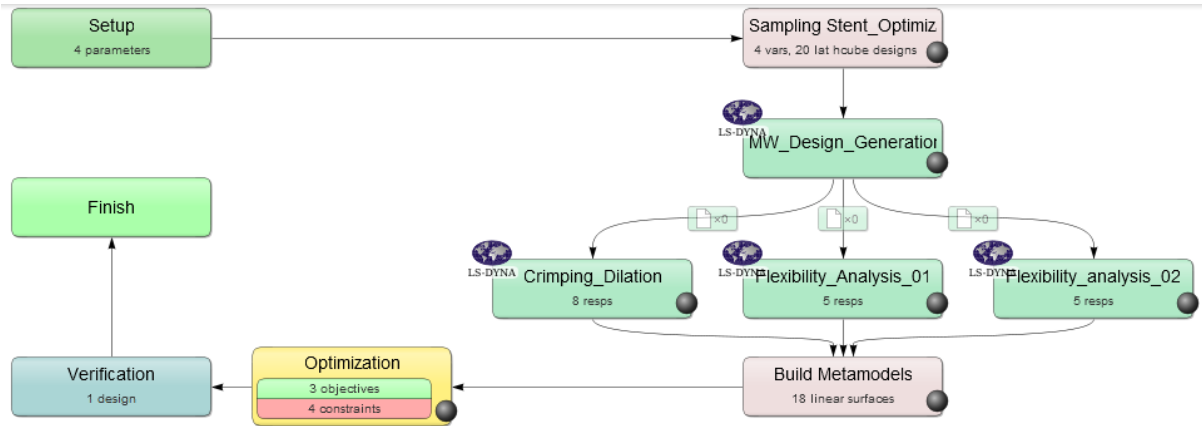


Fig.14:LS-OPT Meta model

5. Optimized design validation

Optimization design was obtained using genetic algorithm multi objective function. From the optimization process, the best design variables values are mentioned in the table 3, satisfying both the design constraints and objective functions.

Design variable	Baseline Design	Optimized Design values
Thickness parameter	0.15mm	0.17mm
Width Parameter	0.13mm	0.12mm
Slot Length parameter	8.50mm	7.90mm
W-Bridge Parameter	0.08mm	0.073mm

Table 3: Results comparison between baseline design and optimized design

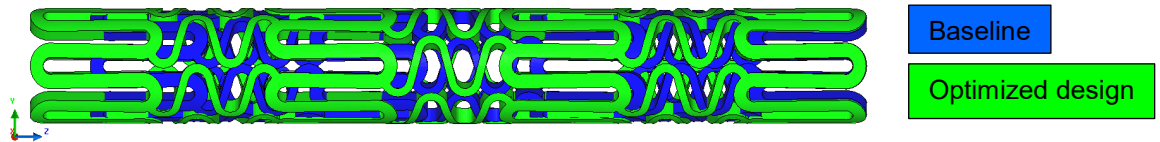


Fig.15a: overlay between baseline and optimized design

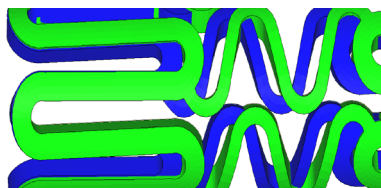


Fig.15b: slot length comparison

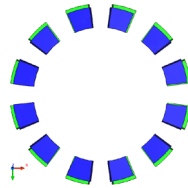


Fig.15c: stent c/s comparison

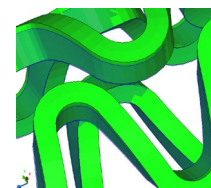


Fig.15d: W-bridge profile comparison

The analysis results are summarized and compared with baseline results in the following table.

Design variable	Final Recoil diameter	Final Stent length	Max plastic strain	%Recoiling	% foreshortening	2 point stiffness	4 Point stiffness
Baseline	3mm	7.4mm	0.53	6.12%	7%	0.4N/mm	1.6N/mm
Optimized design	3mm	8mm	0.47	4%	3%	0.35N/mm	1.45N/mm

Table 4: results summary

6. Summary

Coupled between LS-OPT & DEP MeshWorks, the parametric model generation for stent Design of Experiments (DOE) based optimization study was successfully demonstrated within limits for the desired target conditions. The optimized design is validated and the results are in accordance with the sensitivity of each parameter. The optimum design variables are within the predetermined upper and lower bound without violating the design feasibility and manufacturing constraints. DEP Meshworks morphing tool helps to modify the stent geometry by morphing the existing mesh with ease and precision. The robustness of LS DYNA explicit contacts makes it an ideal option for realistic representation of both, “self-contacts” -between stent strands and “surface to surfaces contact” - between stent and crimping & dilation tool. Analysis parameters such as mass scaling effect, percent of kinetic energy and percent of Hourglass energy are confined within the acceptable limits. The DOE based, parametric CAE driven multi objective optimization study proved to be an effective method to obtain the best optimum design with the least involvement of CAD tools.

7. Literature

LS-DYNA user's manual 971, LSTC
DEP Meshworks Help manual 8.0 DEP
LS-OPT Help Manual, 2015