Parameterization and Optimization of balloon expandable Stent

Karthik Shankaran, and Senthil Karrupaswamy

Detroit Engineered Products (DEP) Inc

Abstract:

Vascular stents are deployed in the blocked arteries to restore the passage of the blood flow. By acting as a mechanical scaffold, stenting is effective in preventing and treating coronary occlusion. Commercial market expect the product to have better recoil and without compromising flexibility. The current stent design analysis and optimization activity is aimed at improving recoil, flexibility and reducing foreshortening.

Conventional design analysis procedure wouldn't be able to tackle simultaneously the problems of recoil and foreshortening, and often its time consuming. Whereas the numerical simulations and optimization approach discussed in this paper can be comfortably used to optimize stent design, considering conflicting performance metrics (recoil, foreshortening).

This paper discusses the use of such advanced technique to solve the stent design problems. The paper would cover the essence of Finite Element Analysis, FE Model Parameterization and Optimization. Finite element modeling (FEM) and analysis with SIMULIA is used to estimate stress distribution in the stent. Various design parameters are identified for carrying out optimization using ISight. Different stent designs are generated using the FE model parameterization tools in MeshWorks MORPHER. Optimization based on parametric FE model is carried out to identify best design.

Keywords:

Vascular stents, Finite Element Analysis, Parameterization, Optimization.

1. Introduction

Coronary Artery Disease (CAD) results in reduced perfusion of blood through narrowed blood vessels, leading to myocardial infarction. Vascular stenting plays a major role in treating a blocked artery, to restore the perfusion to downstream heart tissue. Majority of the stents used for treatment are balloon expandable stents. Usually stents are crimped on a folded balloon, for the purpose of good deliverability into the artery. After placing the stent at the deployment location, the stent is expanded by gradually inflating the balloon. Upon reaching the target deployment diameter, the delivery catheter is deflated and extracted out. The stent undergoes plastic deformation and keeps the artery open to restore blood circulation. In recent years, lots of research has been done to improve the mechanical properties of the stents, in particular, radial recoil and flexibility. In the context of optimizing the mechanical properties of stent, numerical simulation methods provide numerous advantages, compared to physical test methods. In our present study, we optimized the stent design for improved recoil and flexibility using numerical simulation methods.

2.   Method

The stent was represented in the form of finite element model, capturing the geometric intricacies. Material behavior selected represents the elastic and plastic regime very accurately. Process of stent crimping and deployment were appropriately represented using loading and boundary conditions. All the aspects of simulation and optimization are described below.

2.1. Model geometry of stent

The stent geometry was obtained in the form of 3D CAD data. 3D CAD data was used to build the FE model using stent rolling tool MeshWorks MORPHER. The stent had length (L) of 16 mm, an outer diameter (D) of 1.55 mm, and thickness t of 0.06 mm. The FE mesh density was maintained between 20 to 30 microns. The element quality of the model was based on best practices. The crimping tool and the balloon were modeled as cylindrical structures with four node shell elements. Eight node brick elements were used to build the stent model. The entire length of the model was used for the simulation, to avoid effects due to symmetric boundary condition that was noticed in earlier simulation trials. Moreover the flexibility load case was performed with the full span of the stent.

2.2. Material model

The stent material was cobalt chromium alloy. This material has good bio-compatibility. Inflammation or foreign body reaction was not reported in vivo testing. The ideal characteristics of the stent material were good radial strength, and ability to undergo permanent deformation. The crimping tool that was for the purpose of crimping was assigned the material property of steel. The balloon was polymer material.

2.3. Simulation methods

Crimping, Deployment and Flexibility simulations were conducted using SIMULIA. Fig. 1 illustrates the crimping and deployment process. The outcome of the numerical simulation based process was correlated to data from physical testing before going ahead with optimization driven my numerical simulations.
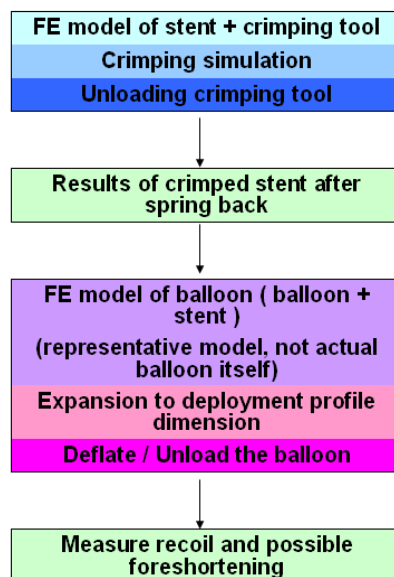
FE model of stent + crimping tool
Crimping simulation
Unloading crimping tool

↓

Results of crimped stent after spring back

↓

FE model of balloon (balloon + stent)
(representative model, not actual balloon itself)
Expansion to deployment profile dimension
Deflate / Unload the balloon

↓

Measure recoil and possible foreshortening

Fig. 1. Simulation Process through SIMULIA

2.3.1. Crimping process and simulation

During manufacturing, all the stents are crimped on the tri-folded balloon. The balloon catheter is manually inserted inside the stent, and subjected to crimping using calibrated crimping tool. The stent undergoes plastic deformation and its outer diameter was reduced to target dimension at the end of this process. There will be history stresses and strain left in the stent after crimping.
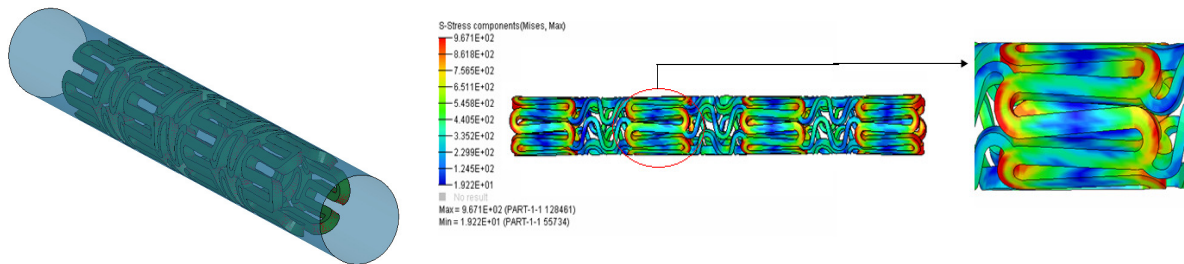

Fig. 2. Model setup for crimping (left), Stress contour of the crimped stent (right)

Crimping process was carried out in FEM by modeling the crimping tool as a cylindrical structure made out of steel. The stent was placed at the center of the crimping tool and all the nodes of the crimping tool were given inward radial displacement and the stent was mechanically crimped. The stress developed in the stent crossed beyond yield strength and underwent plastic deformation. After this, the crimping tool was brought back to its original position. The stent released its elastic strain and reached its final crimped profile of 1.1mm. The entire process was done using multiple load steps in SIMULIA. Refer Fig. 2

2.3.2. Deployment process and simulation

The stent is mounted over a deflated balloon attached to the device called stent delivery catheter. Stent delivery catheter is inserted into the blocked blood vessel. Post balloon angioplasty the stent delivery catheter is inflated causing the stent to expand to the size and contour of the vessel. The stent acts as a mechanical scaffold and keeps the vessel open. The balloon on the stent delivery catheter is deflated and the delivery catheter without the stent is removed from the patient.

The crimped stent from the previous simulation along with the history stress and strain due to crimping is the start process for deployment simulation. The balloon was modeled as cylinder of 20 microns thickness, and was placed at the center of the stent. All the nodes of the balloon were given outward radial displacement, so that all the struts of the stent get deformed to the deployed shape. The displacement was applied to balloon in such a way that the diameter of stent reached the size and contour of the vessel. The stent underwent plastic deformation for the second time during deployment. Later the balloon was deflated by bringing the nodes of the balloon to its original co-ordinates. While doing so the stent slightly sprang back due to elastic strain. This phenomenon is called as radial recoil. Refer Fig. 3
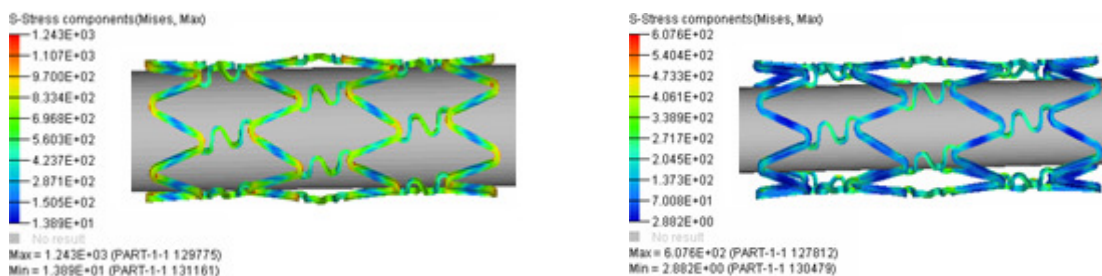
Fig. 3. Stress contour of the stress during inflation of balloon (left), deflation of balloon (right).

The output quantities measured from the simulation were the radial recoil and foreshortening.

$$\text{Radial recoil} = \frac{R \text{ (load)} - R \text{ (unload)}}{R \text{ (load)}} \qquad \text{Foreshortening} = \frac{L - L \text{ (load)}}{L}$$

The post processed results from numerical simulation revealed that the baseline stent design had radial recoil of 8.35% and foreshortening was 2.36%. Stent radius (R).

2.3.3. Flexibility process and simulation

Bending flexibility of stent is a significant factor in its ability to track through the vascular anatomy. Bending flexibility of a deployed stent may be one measure of its ability to flex with vessel, or conform to the natural curvature of a vessel. This parameter can be investigated using SIMULIA with accurate results. The stent can be subjected to either two points loading or four points loading.
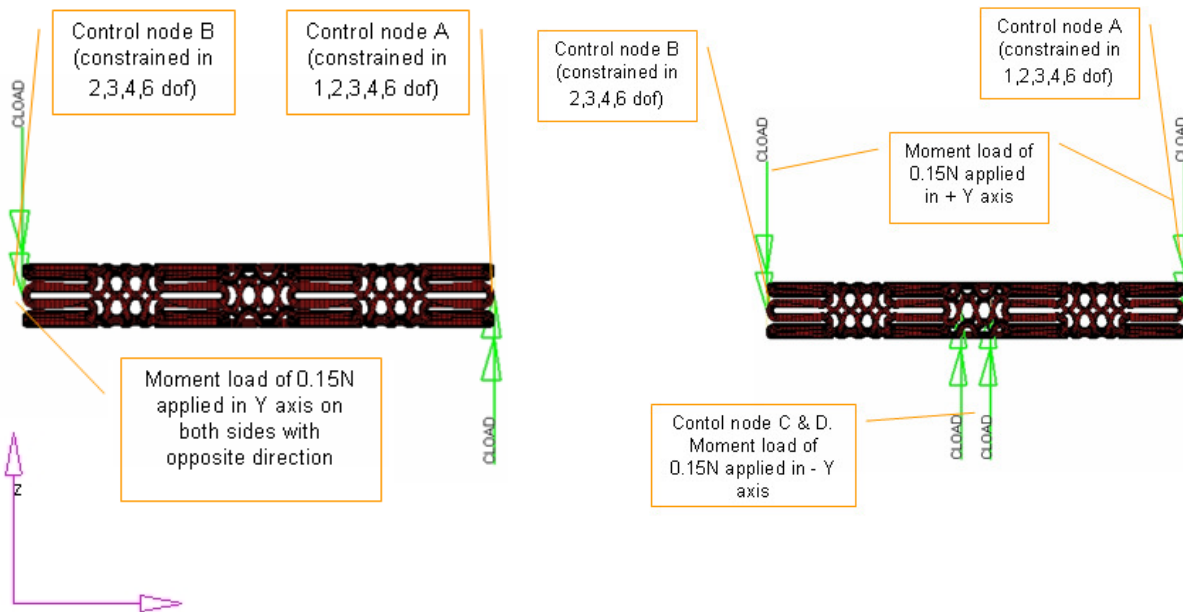

Fig. 4: Model setup for two point bending load case (left), four point bending load case (right)

Moment load of 0.15N was applied to the stent to bend it uniformly. To transform the moment load to the model uniformly, kinematic coupling elements were created on the control nodes A, B, C and D. For each kinematic coupling element, the independent node was the control node and the dependent nodes were part of stent model. The model set up is as indicated in (Fig. 4).
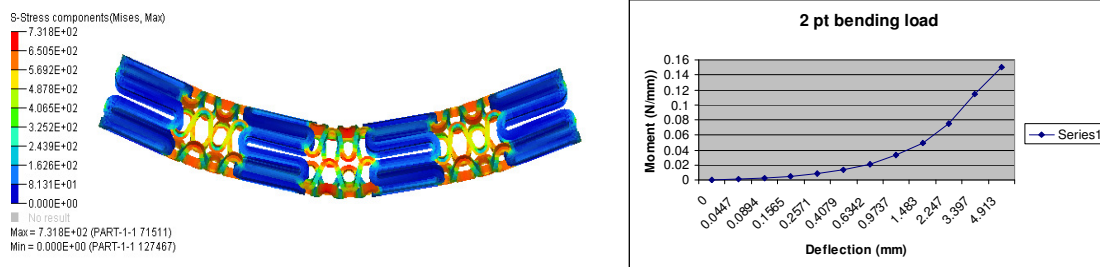

Fig 5a. Stress contour (left), Moment – deflection curve (right) for two point bending load.
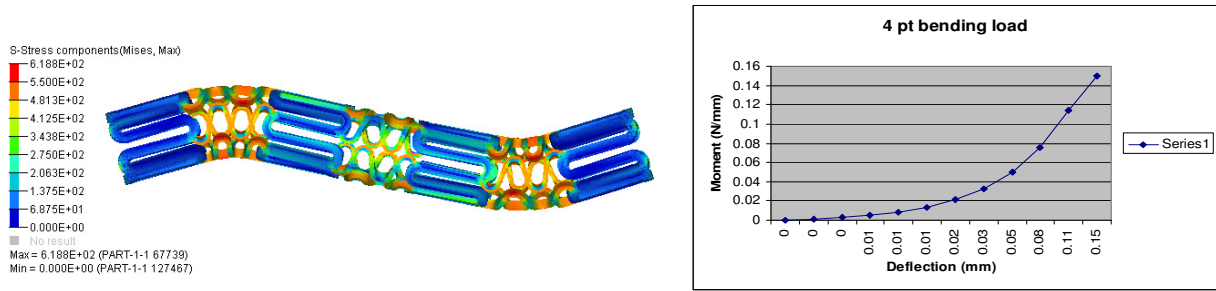
Fig 5b. Stress contour (left), Moment – deflection curve (right) for four point bending load.

Fig. 5a and Fig. 5b shows the deformation and the moment deflection curve of the stent. This simulation enabled measurement of stent flexibility.

2.3.4 Wall stress simulation

This simulation deals with study into the inner wall stresses induced due to stent deployment. The stress might lead to vascular injury and induce the formation of occlusive intimal hyperplasia. Vascular injury caused in vessel by the implantation of the stent may be due to the depth of penetration of the stent wires. The coronary artery was modeled as a cylinder with a diameter far lesser than the diameter of the expanded stent representing artery with plaque. Appropriate material model was picked for the coronary artery. For this simulation the stent profile as outcome of deployment process was the start point. At the end of this simulation the vessel contracted around the stent with the stent behaving as the scaffold within the vessel. Refer fig. 6.
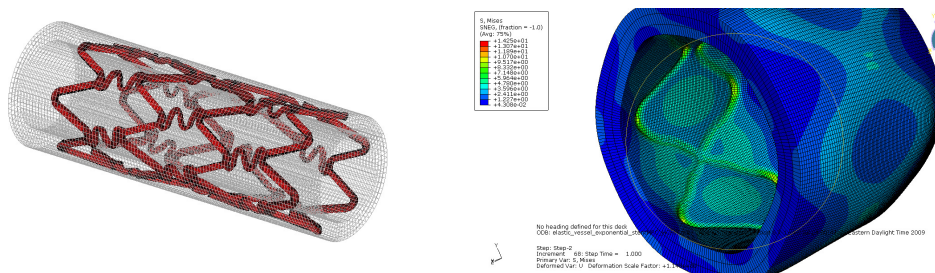

Fig. 6. Wall stress FE model, stress results of the simulation.

3. Optimization Process for stent design

Optimizing different parameters of the stent simultaneously was dealt using Parametric FEA model and DoE driven optimization approach. The optimization process driven by parametric FEA model lends itself very well for optimization of stent design which is multi objective with multiple design parameters. Refer Fig. 7

Objective: Reducing recoil and improving flexibility.
Constraint: Foreshortening shouldn't exceed 3% and wall stress shouldn't exceed 10MPa.
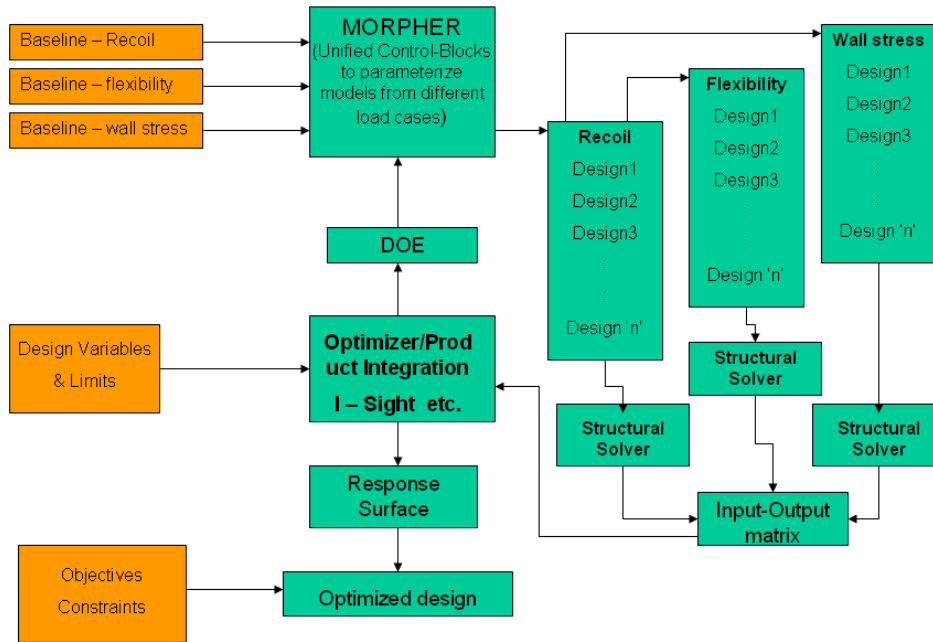

Fig. 7. MOO process flow chart and Morpher's role

The objective and constraints of the optimization were decided as the initial step. Various design variables had to be identified to achieve the target objective. The design variable options were shape changes, thickness changes or material changes. Limits had to be decided for each design variable, depending upon the implementation constraints. Design of Experiments (DOE) was generated using Latin Hypercube algorithm.

MeshWorks Morpher was used to parameterize the FE model. This parameterization meant way for creation of design variables for optimization. MeshWorks Morpher read in the DoE matrix from ISight to generate various designs (FEA models) that were essentially combinations of design variables. The designs(FEA models) generated from MeshWorks Morpher were submitted to SIMULIA for analysis/simulation. All the results from simulations were fed into the Input-Output matrix before setting them up for optimization using Isight. From the Input-Output table, optimization tool generated response surface depending upon the results from the simulation of various designs. Outcome from the optimizer helps judge, the optimized design and its performance. The optimized design has optimum flexibility and radial recoil.

3.1 Design Variables (DV)

Totally five design variables (DV) were picked for this optimization study based on their sensitivity to the performance metrics. All the DVs and their ranges were carefully chosen, considering engineering and manufacturing constraints. The sensitivity analyses studies can be carried out check the effect of DV has any effect on the model. Table 1shows the DVs and their ranges applied for the stent model.

Table 1. DV table with its range.

Parameter	min	max
Slot length	0	1.28
Thickness	-0.01	0.01
Width increase	-0.005	0
H bridge height	-0.015	0.03
H bridge width	-0.01	0.01

3.2 DOE matrix

The DOE matrix was generated according to Latin Hypercube algorithm, with 15 points. Therefore there were fifteen designs generated for this optimization study. All the designs had the DV values within the range specified as shown in Table 2. The designs were checked whether they have good element quality, before analysis. Automatic quality correction tools available in Morpher, were used to correct the quality of the hexa elements.

Table 2. DOE matrix.

Deign no	Design variables				
	Slot length	Thickness	Width	H bridge height	H bridge width
1	0.0000	-0.0071	-0.0039	0.0300	-0.0029
2	0.0914	0.0014	-0.0018	0.0236	0.0043
3	0.1829	0.0086	-0.0043	0.0171	-0.0057
4	0.2743	-0.0029	-0.0021	-0.0118	-0.0086
5	0.3657	-0.0057	0.0004	0.0268	-0.0071
6	0.4571	0.0100	-0.0029	0.0011	0.0057
7	0.5486	-0.0100	0.0007	0.0043	0.0014
8	0.6400	-0.0014	-0.0050	-0.0021	-0.0014
9	0.7314	0.0071	0.0000	0.0139	0.0029
10	0.8229	0.0029	-0.0014	-0.0150	0.0000
11	0.9143	-0.0086	-0.0036	-0.0054	0.0071
12	1.0057	0.0000	-0.0025	0.0204	-0.0043
13	1.0971	0.0043	-0.0046	0.0075	0.0086
14	1.1886	0.0057	-0.0032	-0.0086	-0.0100
15	1.2800	-0.0043	-0.0011	0.0107	0.0100

3.3 Input-Output (IO) table

Each design that was generated by MeshWorks Morpher, went through crimping, deployment, flexibility and wall stress simulations. Results were post processed and interpreted. The results were tabulated in the form of IO table. All the designs were not successful in the DOE runs. Some of the simulations didn't go through due to analytical issues. Hence few points were rationalized to form the IO table. The points in the IO table were considered for building the response surface. (Refer Table 3)

Table 3. Input-Output table.

Deign no	Input					Output				
	Design variables					radial recoil %	foreshortening %	stiffness 2 pt flex N/m	stiffness 4 pt flex N/m	wall stress Mpa (wom)
	Slot length	Thickness	Width	H bridge height	H bridge width					
Baseline	0	0	0	0	0	8.35	0.6	2.035	22.69	8.309
3 - 95%	0.18285714	0.008571429	-0.004285714	0.017142857	-0.00571429	8.1	0.96	2.294	22.23	10.57
4 - 95%	0.27428571	-0.002857143	-0.002142857	-0.011785714	-0.00857143	7.08	0.68	3.271	29.54	11.3
5 - 94%	0.36571429	-0.005714286	-0.000357143	0.026785714	-0.00714286	7.08	1.12	2.603	23.3	10.86
6 - 94%	0.45714286	0.01	-0.002857143	0.001071429	0.005714286	8.22	0.911	1.876	17.59	8.479
8 - 95%	0.64	-0.001428571	-0.005	-0.002142857	-0.00142857	6.66	0.64	3.905	32.53	12.02
10 - 94%	0.82285714	0.002857143	-0.001428571	-0.015	0	7.91	0.87	2.289	19.33	8.848
12 - 95%	1.0057143	0	-0.0025	0.020357143	-0.00428571	8.01	1	2.558	20.53	8.876
13 - 95%	1.0971429	0.004285714	-0.004642857	0.0075	0.008571429	7.34	0.88	2.893	22.59	10.5
14 - 95%	1.1885714	0.005714286	-0.003214286	-0.008571429	-0.01	7.06	0.729	2.671	20.67	9.839
max design	1.28	-0.1	-0.005	-0.015	-0.01	6.51	0.58	4.775	35.09	10.89
min design	0	0.01	0	0.03	0.01					

3.4 Response surface

A response surface is essentially a simplified multi dimensional surface fit to what is usually a more complex function. Often the function is highly nonlinear and computationally expensive to evaluate. To compute the fit, the function is evaluated at several non planar sample points, the number of which is determined by the nature of the response surface and number of DVs. To estimate the function optimum, the optimal point on the quadratic surface fit is identified by a simple and efficient process. (Refer Fig. 8)
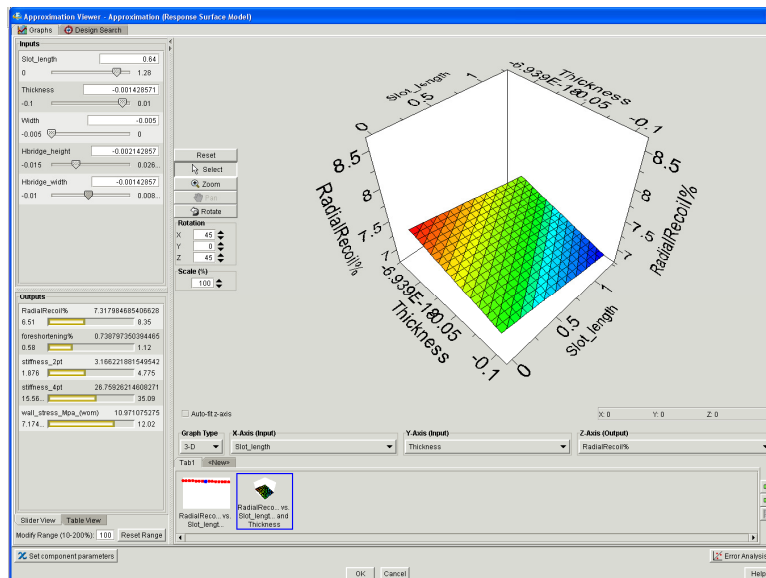
Fig. 8. Response surface for the Optimization of stent

4. Engineered best stent design

The best design was arrived from the Isight using the response surface. The optimization goal was reduction of radial recoil and improving flexibility, the constraints being the foreshortening and the wall stress. Different methods were tried in this process. NLPQL optimization technique was used for this optimization project. The optimization process could improve the radial recoil parameter by 14.37% and foreshortening by 6.35% over the baseline, satisfying the constraint values. The optimum design has the following design variable values. Refer Table 4.

Table 4. Optimized design variable values.

Hbridge_height	-0.015
Hbridge_width	-0.01
Slot_length	1.28
Thickness	-0.01
Width	-0.001223655

Table 5. Result comparison table.

	Objectives		Constraints	
Scenario	**Radial recoil**	**4pt stiffness**	**Wall stress (MPa)**	**Foreshortening (%)**
Baseline	8.35	22.69	8.309	0.6
Optimal design - Isight	7.15	21.25	9.165	0.77
% improvement	14.37	6.35	< 10	< 3

5. Conclusion

The outcome of simulation process (Fig 1) presented in this paper had good correlation with the physical test results. Upon validation, the numerical process was found suitable for DoE based optimization to meet the stent performance metrics. The parametric CAE model based approach was followed for optimization. The design variables were identified based on sensitivity study on the performance metrics. The parameterization of stent CAE model to represent design variables was created using MeshWorks Morpher. MeshWorks Morpher had right set of parameterization tools that were powerful and yet easy to use. The minimum design and maximum design limits from the DoE were used to check the quality levels of models generated out of MeshWorks Morpher. The quality of models were found acceptable. ISight was used for the creation of DoE matrix. MeshWorks Morpher compatibility with ISight to read in DoE matrix helped create stent CAE models for simulations. SIMULIA was used to evaluate stent performance metrics. ISight was used to drive MeshWorks Morpher and SIMULIA. The optimization was carried out in Isight. The optimization process led to identify stent design that met the performance metrics within manufacturing constraints. This process of DoE based parametric CAE model driven optimization for stent was very effective to quickly identify the possible optimized design and the trade offs.

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