Step Change in Design: Exploring Sixty Stent Design Variations Overnight

Frank Harewood, Ronan Thornton
Medtronic Ireland (Galway)
Parkmore Business Park West, Ballybrit, Galway, Ireland
frank.harewood@medtronic.com

Paul Sharp
Altair ProductDesign
Imperial House, Holly Walk, Leamington Spa, CV32 4JG
paul.sharp@uk.altair.com

Abstract

Traditionally, computer analysis has been used to verify the structural performance of a proposed stent design. The stent deployment process consists of multiple stages (e.g. crimping, springback, expansion etc.) which is highly non-linear inducing material plasticity and load transfer via component contact. A single structural verification assessment would require a couple of days to compute on a PC. This paper investigates how recent developments in Computer Aided Engineering (CAE) and computer hardware combine to facilitate the rapid exploration of many stent design variations. It is demonstrated that by utilising these technologies, over sixty stent design variables can be assessed overnight provides valuable design sensitivity information and an optimum stent geometry configuration. On an example baseline geometry considered the radial stiffness was significantly enhanced with an improvement in structural performance. This represents a step change in the CAE assessment of a stent design.

Keywords: Non-linear Optimization, Stent Design, LS-DYNA, HyperStudy, OptiBox

1.0 Introduction

Due to the complex nature of a coronary stent deployment **(Figure 1)**, CAE has been utilised as a design verification tool to assess the structural performance of the process. This activity was extremely time consuming requiring a couple of day's computer time to simulate a stent deployment process which consisted of a number of stages (e.g. crimp down, deployment, fatigue cases etc.). These stages induce both non-linear material and geometric behaviour into the stent structure.

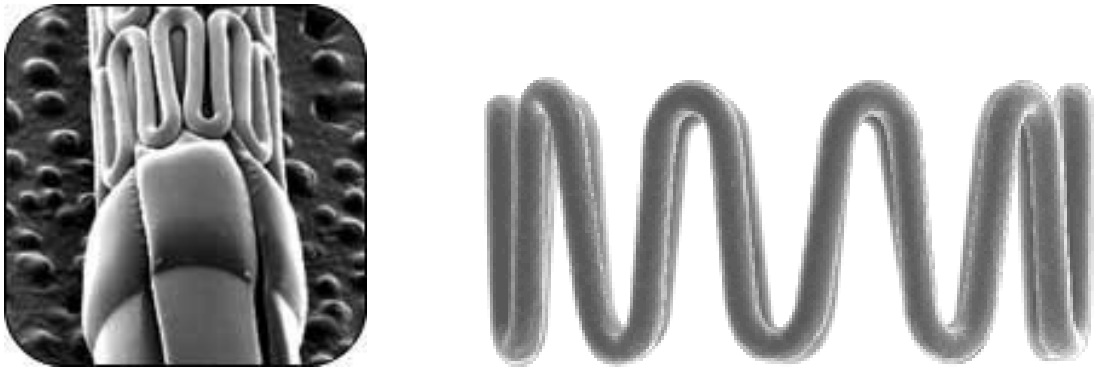

Figure 1: Typical Stent Structure

It was decided to investigate how recent enhancements to CAE software and computer hardware could impact stent design. For a baseline stent configuration, a number of design variables and their corresponding upper and lower bound limits can be defined (e.g. number of crowns in a circumference, strut height, strut width etc.). Typically for this complex non-linear system, five design variables will require around sixty individual finite element analyses to adequately explore the design space.

Once the design space has been explored an optimization study can be performed to automatically determine the maximum radial stiffness of the design and minimise fatigue

stresses resulting from in-vito pulsatile loads. This optimization will be performed automatically using Altair HyperStudy **[1]**.

2.0 Base Simulation

Before optimization technology is applied, it is important to obtain a comprehensive understanding of the baseline stent design subjected to crimp, expansion and in service loading (pressure and bending cases). The non-linear implicit solver, LS-DYNA **[2]** is used to simulate the deployment.

The model is of one half of a single stent section with symmetry boundary conditions applied at the cut planes. The complete model consists of 14,232 ten noded tetrahedral elements, 10,368 eight noded solid elements and 27,158 nodal points **(Figure 2)**.

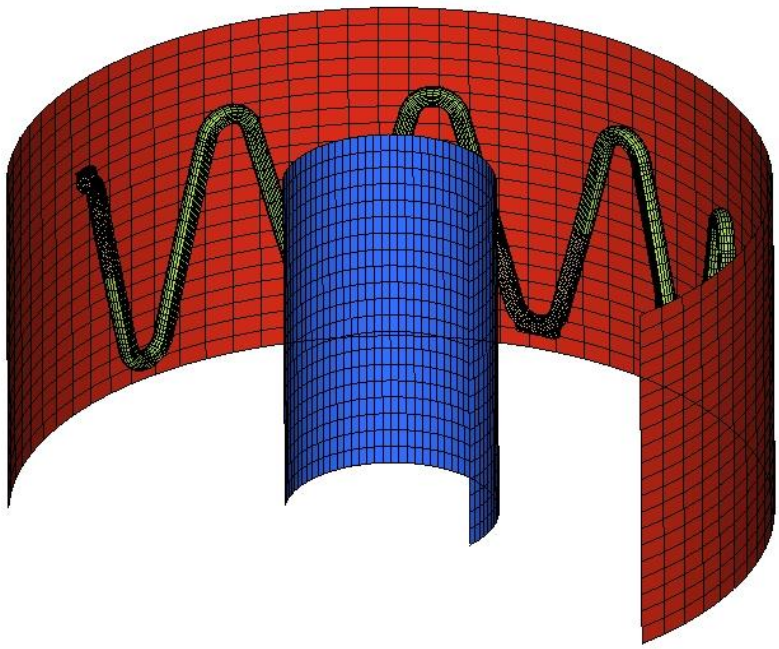

Figure 2: Three Dimensional Stent Model with Crimp and Expand Contact Surfaces

Figure 3 shows the seven loading steps modelled for the stent. The required CPU time for the baseline run using LS-DYNA Implicit was 2 hours. The material model used a specialised non-linear elastic shape memory response. Cylindrical shell element surfaces were used to perform the stent crimping and expansion processes.

The maximum tensile principal stresses are monitored in the area surrounding the weld region of the stent since this is where the peak stresses occur during both the in service load cases. The levels of these stresses and the difference between them are used to assess the fatigue performance of the stent design. A radial stiffness measurement is also taken during the Pressure phase defined as ‘applied radial force/radial deflection’ at the symmetry plane.

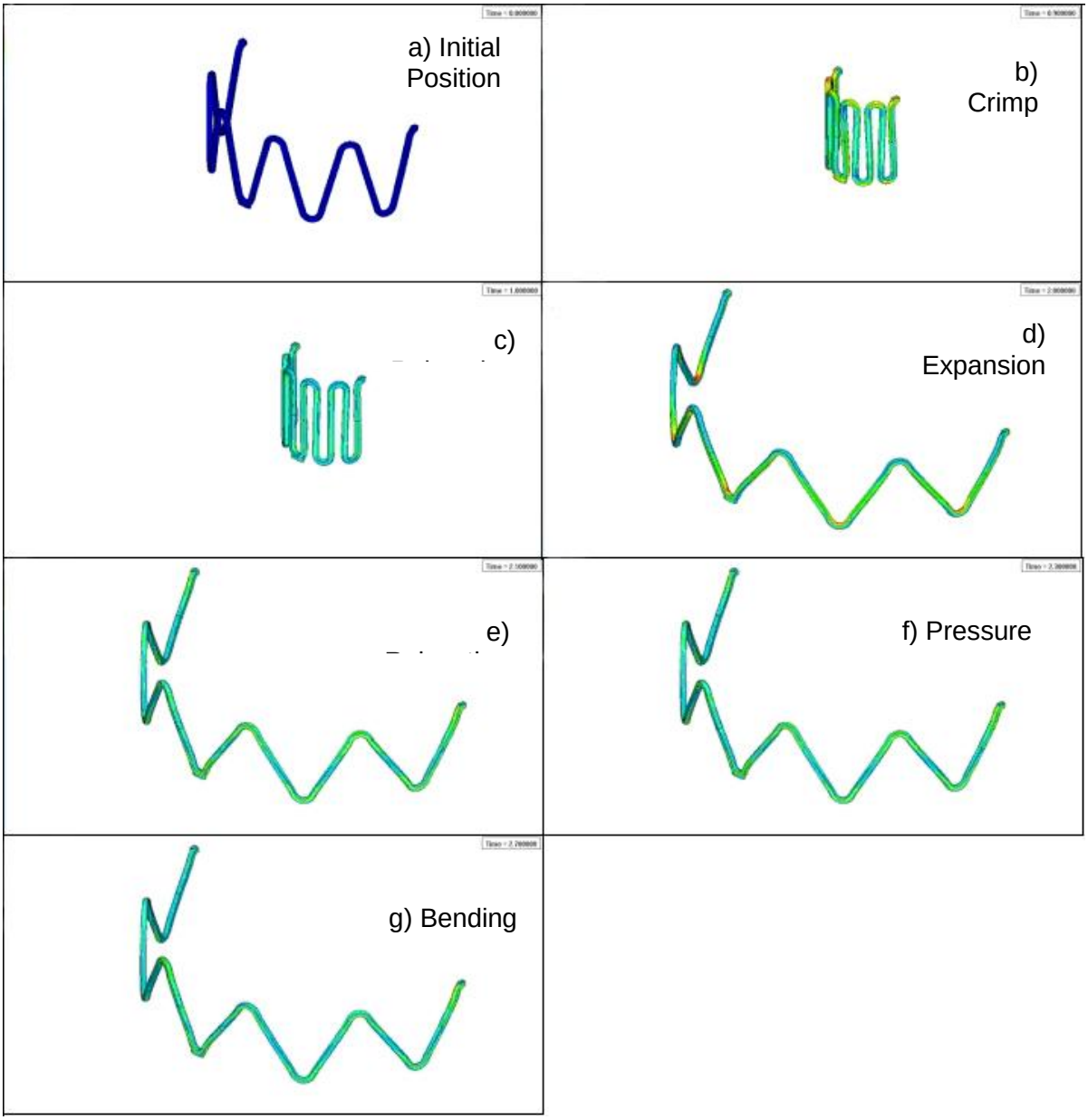

Figure 3: Baseline Stent Model Tensile Principal Stress Contours at Key Analysis Stages

3.0 Optimization

3.1 Optimization Problem Set-Up

Any optimization study requires the specification of a design objective (e.g. minimize weight, maximize strength etc.), design constraints (e.g. required limits on displacements, forces,

stresses, strains etc.) and design variables (e.g. adjust structural shape, thickness etc.). The design parameters selected for the stent optimization process are presented.

Design Objective

The design objective is to maximise the radial stiffness which is measured at the completion of the pressure phase defined as 'applied radial force/radial deflection' at the model symmetry plane.

Design Constraint

The design constraints consist of structural constraints imposed on the stent to ensure that the structural characteristics exhibited by the baseline design are maintained by the optimum. These constraints consist of the magnitude of the principal tensile stresses during the pressure and bending phases and the difference in stress level between them.

Design Variables

The design variables consist of five geometric shape variables which are used to vary the geometry of the stent **(Table 1)**. Each design variable can be varied independently within defined bounds in order to generate a different stent design. The nominal shape for each variable corresponds to the baseline stent design while the extremes of each variable correspond to a pre-defined percentage increase or decrease in shape.

The shape change given by the design variables is approximately ±25% for all the design variables except for the strut length at ±20%. Some of the design variables could not be changed independently whilst maintaining a feasible design. For this reason the radius variable also encompasses a small change in length and the length variable causes a slight change in angle. Also it is possible that combinations of the design variables (for example radius and length) can lead to the individual upper or lower limit value being exceeded for one of those variables.

Design Variable Description	DV Label	Variation (%)
Inner Crown Radius **(Figure 4)**	DV1	±25
Strut Length **(Figure 4)**	DV2	±20
Strut Width **(Figure 4)**	DV3	±25
Strut Thickness **(Figure 5)**	DV4	±25
Weld Radius **(Figure 6)**	DV5	±25

Table 1: Design Variables with Associated Variation

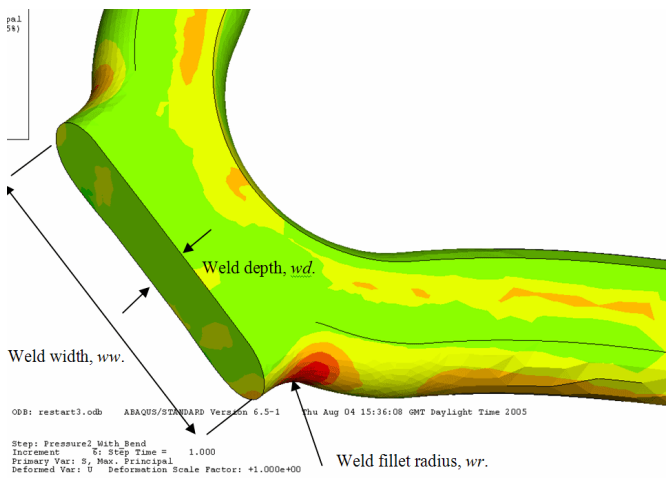

Figure 4: Design Variables Defining Weld Fillet Radius

The shape variables were created using Altair HyperMorph, a tool for setting up shape optimisation studies. This provided a method of stretching the stent model into new shapes whilst retaining the mesh quality and also saving the new shape as a shape variable for use in HyperStudy.

In addition, the shape variables (perturbations) can be combined to generate a unique stent geometry. This approach has been adopted in order to allow the optimization technology to develop a large variation of shapes. The upper and lower bounds of the shape variables are shown in **Figures 7-11**.

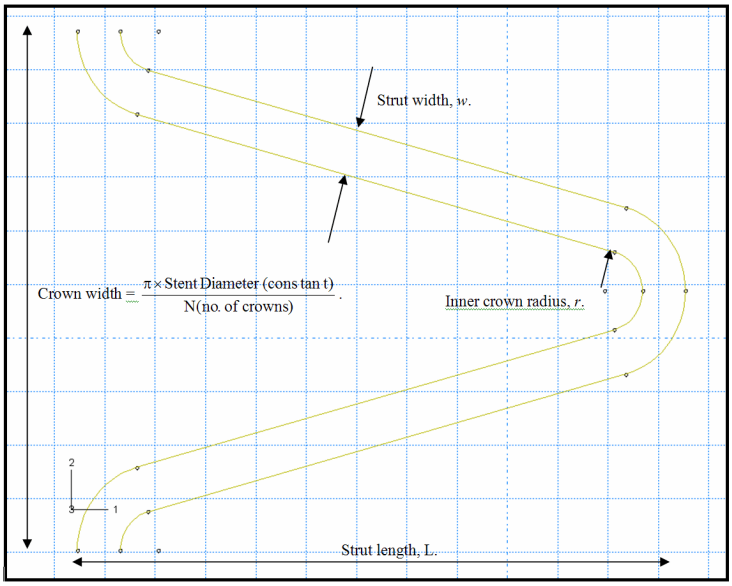

Figure 5: Design Variables Defining Inner Crown Radius, Strut Length and Width

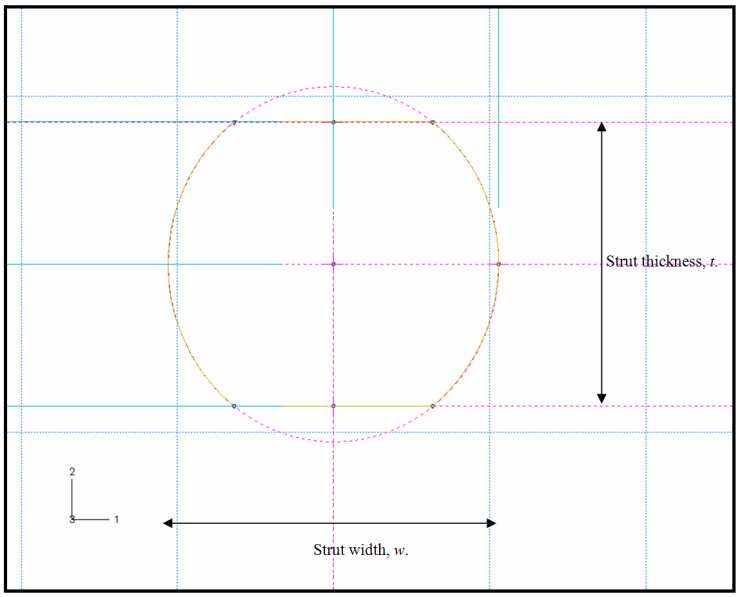

Figure 6: Design Variables Defining Strut Width and Thickness

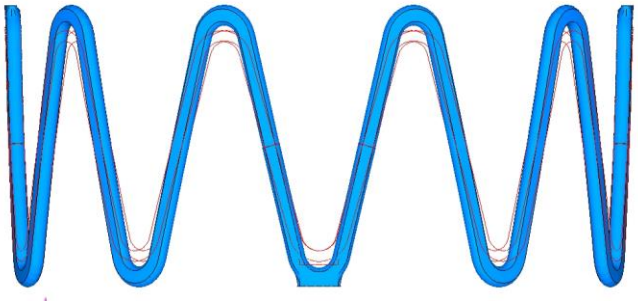

Figure 7: Upper Bound of Length Variable: Length Variable=1; Stent Length +20%

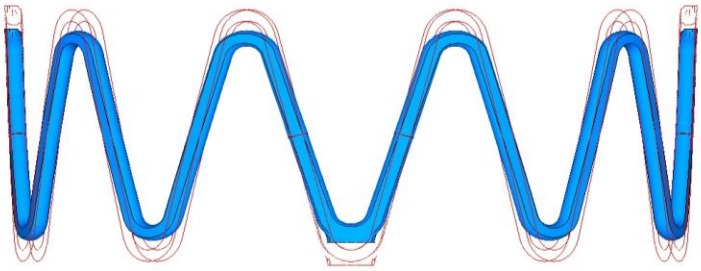

Figure 8: Lower Bound of Length Variable: Length Variable=-1; Stent Length -20%

Figure 9: Upper Bound of Weld Radius Variable: Weld Radius Variable=1; Weld Radius +25%

Figure 10: Lower Bound Weld of Radius Variable: Weld Radius Variable=-1; Weld Radius -25%

3.2 Non-linear Optimization

Each design variable has lower and upper bounds specified **(Table 1)**, this defines a multi-dimensional design space. A typical point in this space is defined by specific values for all five design variables which corresponds to a unique stent geometry. The first stage in the non-linear optimization process is to sample the system's response (i.e. design objective and design constraints) at pre-defined locations within this multi-dimensional design space. The pre-defined locations are selected by HyperStudy to ensure a uniform sampling within the design space. A Hammersley Sampling Method is used.

The optimization considers sixty discrete locations within the design space. This was considered adequate for a concept assessment. Each of these sixty combinations of design variables is output from HyperStudy as an analysis input deck. LS-DYNA simulations are performed to determine the radial stiffness and the maximum tensile principal stresses in the weld region of the stent during the in service loading conditions. The total CPU time to run the sixty case was 130 hours which on a sixteen CPU cluster was completed in eight hours. The improvement of the optimum solution over the baseline design is presented in **Table 2.**

Analysis Type	**DV1 Length (mm)**	**DV2 Radius (mm)**	**DV3 Width (mm)**	**DV4 Thick (mm)**	**DV5 Weld CSA (mm²)**	**Stiffness (N/mm)**	**Principal Stress Difference (N/mm²)**	**Principal Stress Mean (N/mm²)**
% Increase of Optimum Relative to Baseline	-19	+24	-22	+4	+3	+125	-71	-18

% Increase of Optimum Relative to Baseline = (Optimum Result – Baseline Result) / Baseline Result *100

Table 2: Comparison Between Baseline and Optimum

The second stage of the non-linear optimization process is to fit a curve through the sixty discrete locations to obtain a numerical approximation (i.e. response surface) which defines the complete design space. HyperStudy is used to perform this advanced curve fitting operation and provide this relationship between the design variables and the system responses. Once this analytical representation has been obtained HyperStudy can be used to determine the optimum solution **(Table 2)**.

Within HyperStudy **[1]** a further 20 run "validation" DoE is completed in order to assess the quality of the response surface approximation created on the original 60 Run DoE data set. HyperStudy utilizes this validation DoE to automatically alter the closeness of fit parameter in the Moving Least Squares Method approximation to give the best fit to the responses.

Once the response surface approximation has been completed, an optimization search is conducted on the surface to find the optimum combination of design variables for the given constraints and objective. In this case the Stress difference and mean were constrained to 50 and 600 respectively and the target was to maximize Stiffness. In order to reduce the likelihood that the optimization on the response surface was finding local minima the variable values from each of the best 3 DoE runs were used as the initial start point.

Once a suggested optimum was obtained from the optimization process an LS-DYNA analysis check run was conducted using the suggested input variables to test the optimum suggestion.

3.3 Design Verification Analysis

A three dimensional model of the suggested optimum Stent geometry has been generated to verify the optimum design. The responses from this simulation are recorded in **Table 2.**

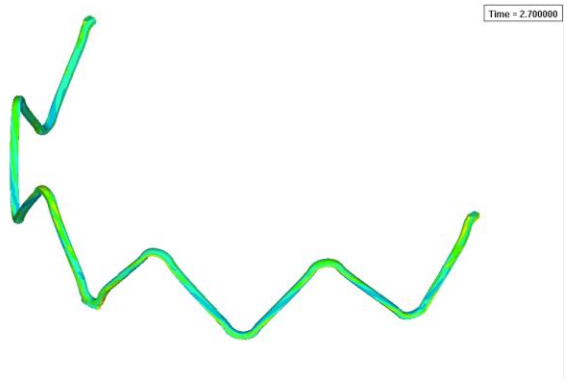

Figure 11: Three Dimensional Stent Model Using Suggested Optimum Variables

While the responses did not exactly replicate the approximated values (perhaps because three of the variables were at extremes of the variable range) the responses from the simulation gave a set of responses that were a significant improvement on the baseline simulation and a better compromise of stiffness versus stress than any of the sixty simulations. The shape of the stent produced by the optimization study is shown in **Figures 12-13**.

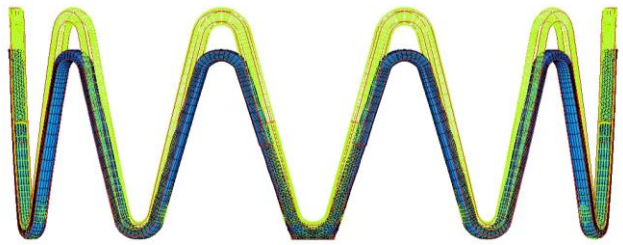

Figure 12: Optimized Stent shown against Baseline (wireframe)

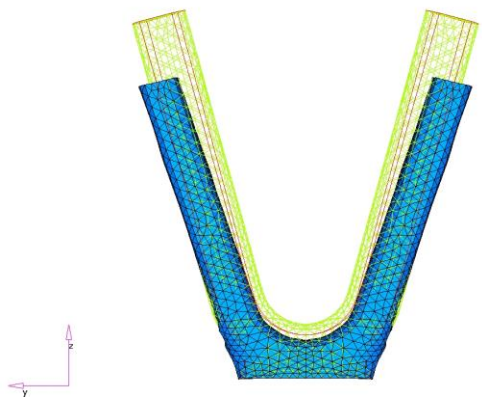

Figure 13: Optimized Stent Weld Area

4.0 Conclusions

It has been successfully demonstrated that stent designs may be optimized efficiently, through use of cluster computing technology and the efficiency of LS-DYNA. A three dimensional LS-DYNA (Implicit) model has been developed that allows the reliable simulation of the crimp, expansion, pressure and bending steps within a single analysis. This model has enabled the use of design optimization. Altair HyperStudy has been used to create run matrices utilizing a parameterized form of the LS-DYNA input deck. Key to the ability to do this was the utilization of three dimensional stent shape variables developed in HyperMorph.

The computational time required for sixty runs using LS-DYNA was 130 hours; in real terms this meant that the optimization could be completed overnight using a multi-node Linux cluster, Altair OptiBox. Consequently, the optimization was able to efficiently assess a large range of combinations of Stent geometry.

When checked by running using a further simulation, the suggested optimum combination of design variables exhibited a radial stiffness improvement of 124% over the baseline simulation. The Difference in Stress **(Table 2)** had been reduced by 71% reduction compared to the baseline, and the mean stress had been reduced by 18% compared to the baseline.

The optimization suggested a best compromise shape for the stent, equated back from the optimized shape variables; these can be found in **Table 2.** It should be noted that three of the

variables are on the bounds of their allowable limits suggesting that it may be possible to further improve the design if the allowable maximum weld size was bigger and the allowable minimum stent width and thickness were smaller.

5.0 References

[1] **'HyperStudy User's Manual'**, Version 7.0**,** SP1, Altair Engineering Limited, 2005.

[2] **'LS-Dyna Version 970'**, LSTC, 2006.

