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NON-LINEAR FINITE ELEMENTS APPLICATION REMOVAL OF SOFT TISSUE STENOSIS

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The non-linear finite element method has been used for the analysis of a variety of non-traditional materials involving large deformations such as rubber, plastics, and soft tissues. In these types of nonlinear analysis, strain energy density functions are usually postulated that may incorporate dissipative internal variables to indicate micro-tearing and/or damage. One particular challenging area is plaque accumulation in cardiovascular and other arterial lumens that may partially or completely occlude blood flow, leading to coronary events such as stroke, myocardial infarction, or death. This paper describes the efficacy of a proposed high speed rotational atherectomy device for the removal of arterial plaque. The prototype design is based on the use of Finite Element Methods to evaluate the efficacy of a proposed high speed rotational atherectomy device for the removal of arterial plaque. Correlation between the numerical FEA model results and real world test results was achieved using a prototype device, a simulated arterial lumen with and without a fully deployed stent in the vascular lumen. The test results obtained by using the prototype high speed rotational atherectomy device to remove plaque in an arterial lumen with fully expanded stent are also presented in this paper.

Keywords: Rotational, Atherectomy, Numerical, von Mises.

1 INTRODUCTION

Nonlinear finite elements analysis has been used to model large deformation of soft tissues. Such simulation tools provide engineers an ability to help design medical devices necessary to promote patients' health. The approach usually involves postulating the existence of a strain energy density function that would then serve as a potential function to obtain stresses using Lagrangian formulation (Fung 1993, Liu *et al*. 2004). To incorporate dissipative mechanisms in soft tissue behavior, internal variables are used within the general theory of continuum thermodynamics (Hokanson and Yazdani 1997).

Medical device companies face continuous pressure to accelerate innovation while maintaining quality and efficacy in the product design. Devices need to be smaller and smarter to support less invasive procedures. Evaluating new biomedical material and design behavior is complex, time consuming and expensive. These factors lead companies to seek methods for improving the way they select, develop, and test new materials and products. Virtual simulation by finite element method has become a powerful tool to reduce development cost and required prototyping time.

This study describes the proposed removal of arterial stenosis through the development and use of an atherectomy device, rotating at very high speeds about a central guide wire passing through the vascular channel. The atherectomy prototype is unusual in that it consists of a multi-strand, helically wound structure formed by mechanically deforming around an internal mandrel, the leading and trailing sections being reduced in diameter, and the central section having an expanded "waist" surrounded by a solid metal collar coated by abrasive material on its outer surface.

2 REMOVAL OF PLAQUE

A comparison of a normal artery with that of a partially occluded artery is provided in Figure 1. Plaque modification may be accomplished by any of several methods, depending on the type of plaque deposit, location of the accumulation and other factors. If the plaque deposit is sufficiently soft, the vascular blockage may be opened through the use of an angioplasty balloon and guide wire. The guide wire is passed through the blockage, and an angioplasty balloon is advanced along the guide wire to the preferred location along the blockage. The angioplasty balloon is then expanded, usually using a saline solution under pressure, until the desired lumen diameter is achieved.

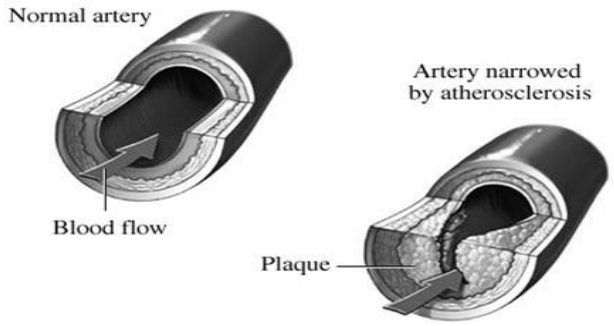

Figure 1. Comparison of clear and plagued artery.

In order to maintain the desired lumen, and prevent collapse of the vascular wall, a compressed stent is advanced along the guide wire and similarly expanded to maintain the arterial lumen. Angioplasty stents are available from a number of biomedical companies, have individual designs and are fabricated from a variety of materials, including stainless steel alloys, shape-memory alloys such as Nitinol, and non-metallic materials, including bio-absorbable materials.

A typical stent scaffold design is shown in Figure 2. The stent geometry shown is a typical cylindrical scaffold design, with member connections and material properties which allow the stent to be compressed onto an angioplasty balloon, and deployed along a central guide wire to the desired location. Once in position, the angioplasty balloon is then inflated, expanding the stent to a design diameter and using the expanded stent as a cylindrical scaffold to maintain the vascular lumen. Metallic stents are generally inserted as a permanent structure, but some bio-absorbable stent materials and designs allow the stent structure to be dissolved within the vascular lumen.

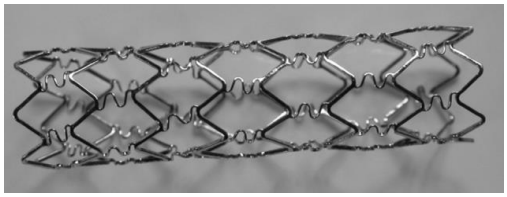

Figure 2. A typical stent scaffold design used in angioplasty.

Re-stenosis of the vascular lumen may occur after balloon angioplasty, with or without stent emplacement. Removal of the new plaque deposit may sometimes be accomplished by repeating the above procedure and installing additional stents.

A novel approach for the removal of arterial stenosis (plaque) is proposed in this paper by development and use of a rotational atherectomy device, rotating at very high speeds, about a central guide wire passing through the vascular channel. The proposed prototype is unusual in that it consists of a multi-strand, helically wound structure formed by mechanically deforming around a mandrel, the leading and trailing sections being reduced in diameter, and the central section having an expanded "waist", surrounded by a solid metal collar or spin-element, coated by abrasive material on its outer surface (Figure 3). The abrasive material on the outer surface of the cylindrical "waist" is intended to remove the plaque deposit through high speed abrasion of the plaque material.

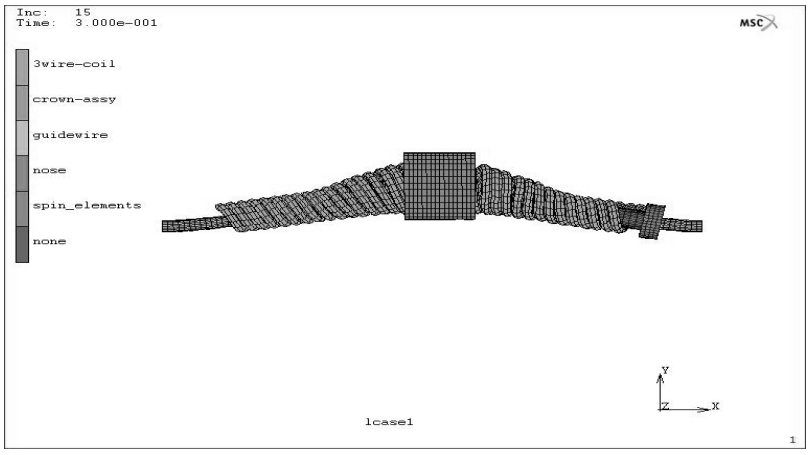

Figure 3. Finite element presentation of the rotational atherectomy device.

There are many advantages of the high speed rotational atherectomy device as designed. These include: a) removal of fatty and calcified deposits in arteries; b) with the rotation of 150,000 to 200,000 rpm very small particles are created that are smaller than red blood cells so that there would be no need to capture the particles; c) occluded vessels may be opened as long as guide-wire can pass through; and d) with very quick procedure in 1-2 minutes, greater patient comfort is provided.

The cutting path diameter depends on Rotational speed, stiffness of coil geometry and guide-wire, system center of rotational mass eccentricity, and fluid drag effects.

These all have been included in the finite element analysis presented in the next section. Fatigue life factors include parameters such as operational cycles, stress corrosion of guide-wire surface, fatigue of guide-wire, and safety factors.

3 FINITE ELEMENT ANALYSIS AND RESULTS

FEA Models of Three Filar Coil Shaft with Crown, Guide-wire and Tip were developed and contact normal forces between the coils and the guide-wire were evaluated (Figures 4, and 5).

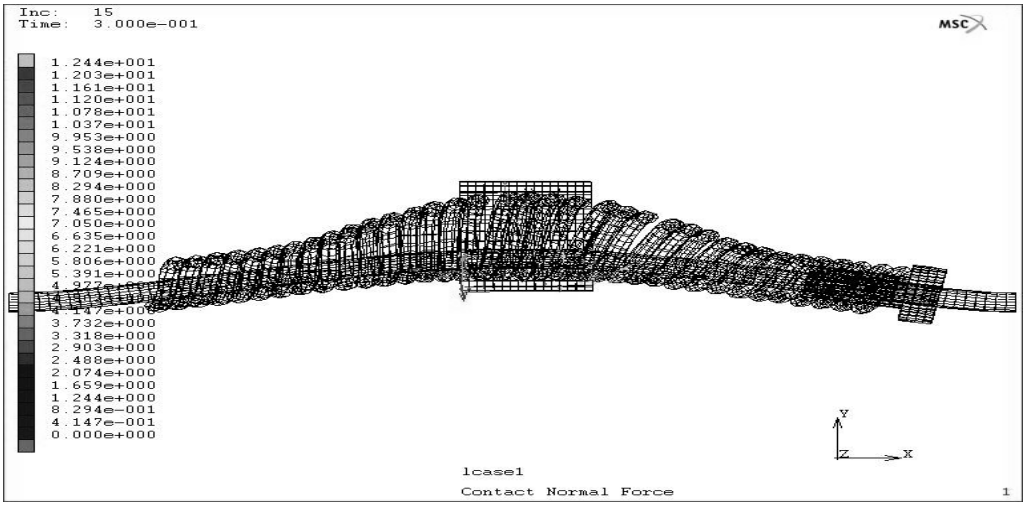

Figure 4. Contact normal force variation and intensity.

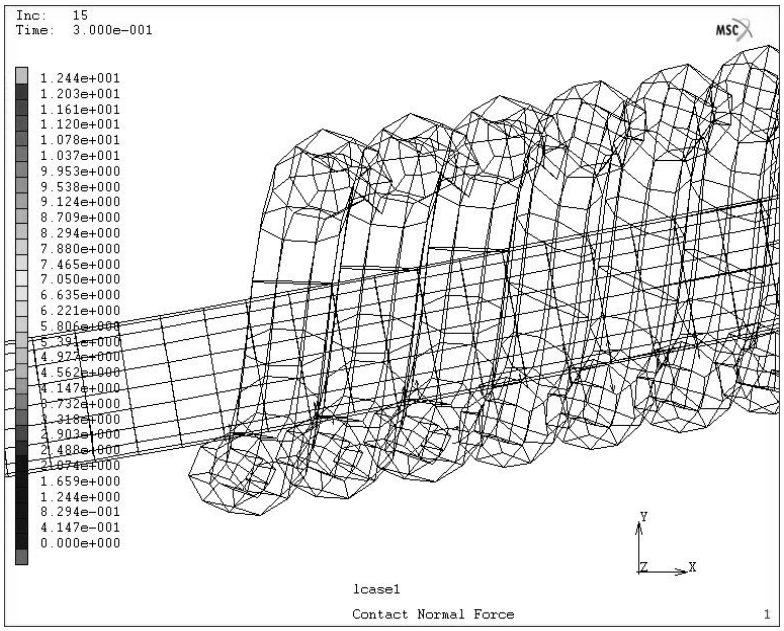

Figure 5. Guide wire and tail end.

Modified FEA models (Figure 6) were also used to evaluate the effect of variances in tip length and rotational speeds with respect to Crown diameter, cutting diameter (dynamic shift in center of gravity), contact stresses at the interface between the guide-wire/atherectomy device coil wires, and internal stresses in the design. These were used to predict fatigue life, factors of safety, and evaluate joint stress levels. Stress distribution within the proposed design was determined using the FEA model, equivalent von Mises stress distributions (Figure 7) was used as an evaluation factor.

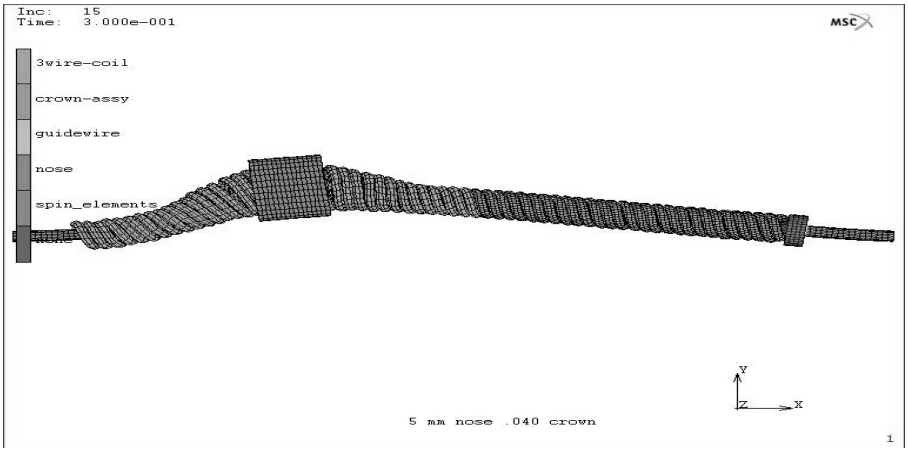

Figure 6. Extended nose length simulation in FEM model.

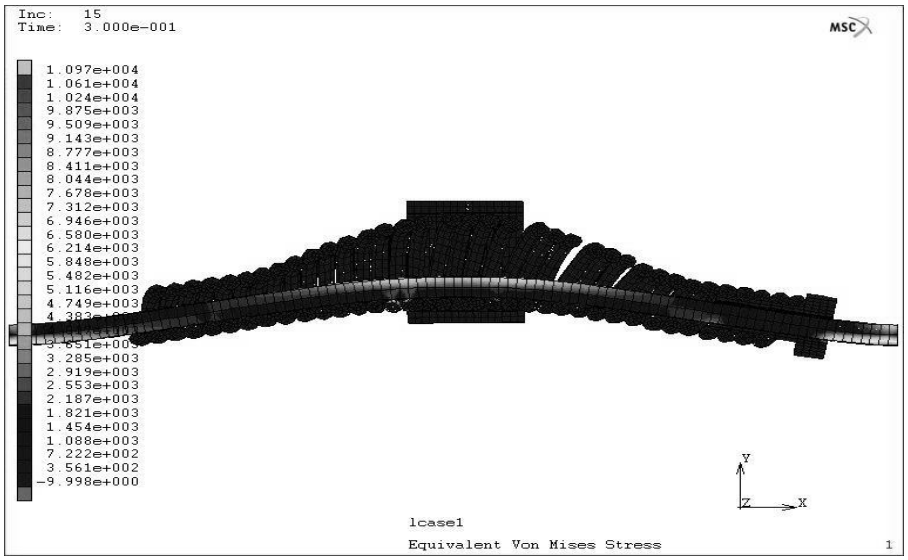

Figure 7. Equivalent von Mises stress distribution.

4 PLAQUE REMOVAL – BENCH TESTS

Preliminary rotational atherectomy design, analysis and testing results were highly successful. Therefore a determination was made to perform a series of final proof of

concept tests using a Tygon tube to replicate a vascular artery/stent configuration. Initial testing was performed using a bare stent and a rotational speed which would simulate "cleaning" plaque from the interior surfaces of the stent. Examination of the interior stent surface after several such cleanings revealed that the stent member surfaces were gouged by the abrasive materials on the atherectomy crown's surface.

This type of gouging would possibly lead to weakening of the stent members, resulting in the possible collapse of the stent and the arterial lumen it was designed to support. A test guideline was then established to maintain an operational rotational speed which would not allow the atherectomy device crown to contact the stent members, but safely allow the maximum removal of plaque.

As a final bench test, the stent was expanded within the Tygon tubing (Figure 8) simulation an arterial lumen. The intent of the test was to insert the guide-wire along the arterial lumen, through the expanded stent and pass the rotational atherectomy device through the stent at various rotational speeds. During the test, it was found that at specific rotational speeds or frequencies, the guide-wire began to oscillate in conjunction with the rotating atherectomy device. This dynamic coupling unexpectedly causing the rotational diameter of the atherectomy/guide-wire assembly to contact the stent members. Stent members became entangled with the rotating atherectomy device, resulting in a dramatic failure.

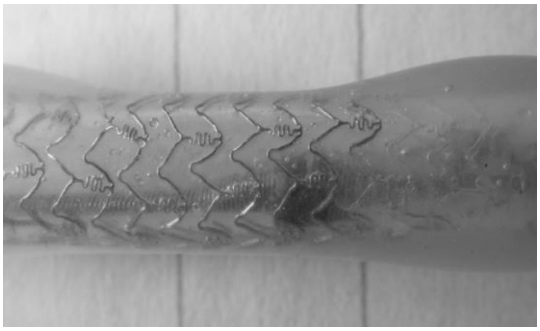

Figure 8. Stent/atherectomy device in the simulated arterial lumen.

5 CONCLUSION

Detailed FEA simulations are a very useful technique to evaluate a proposed prototype device design, there is no substitute for real life bench testing. A failure of this type in a cardiovascular artery during plaque removal from a stent using a rotational atherectomy device of this design, would most probably result in the death of a patient.

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