Proceedings of the ASME 2009 Summer Bioengineering Conference (SBC2009)
June 17-21, Resort at Squaw Creek, Lake Tahoe, CA, USA

SBC2009-206595

FINITE ELEMENT DESIGN OF NITINOL EMBOLIC PROTECTION FILTERS BASED ON PARAMETRIC MODELLING WITH PYFORMEX: A FEASIBILITY STUDY

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INTRODUCTION

The widespread acceptance of Carotid Artery Stenting (CAS) to treat a stenosed carotid vasculature and its effectiveness compared with its surgical counterpart, carotid endarterectomy (CEA) is still a matter of debate [1]. A major concern related to CAS is embolization distal to the site of treatment potentially leading to stroke or other severe neurological complications. Embolization associated with CAS is mainly due to the plaque debris and thrombi generated during the dilatation of the stenosis and stent positioning. Consequently, embolic protection filters have been developed to capture this released debris and they appear to have a significant favorable impact on the success of CAS [2,3]. Currently, several embolic filter designs are available on a rapidly growing dedicated market. However, some drawbacks such as filtering failure, inability to cross tortuous high-grade stenoses, malpositioning and vessel injury still remain and require further design improvement.

Complementary to in vitro studies to understand the fluid dynamical impact of such devices [4], the present study uses the Finite Element Method to investigate some solid mechanical aspects of a commercially available embolic protection filter design. The Finite Element Method was chosen because of its track record in understanding and optimizing the mechanics of cardiovascular devices, such as stents [5].

MATERIALS AND METHODS

A parametric model of an embolic protection filter, based on a 4 mm diameter Angioguard embolic filter (Cordis, J&J), was created by means of the open-source pyFormex design software [6]. The geometry was obtained from a high resolution microCT scan (see Figure 1) and the most important model parameters are the number of struts, the percentage of filter coverage and the filter length and diameter. Some design variants are depicted in Figure 2.

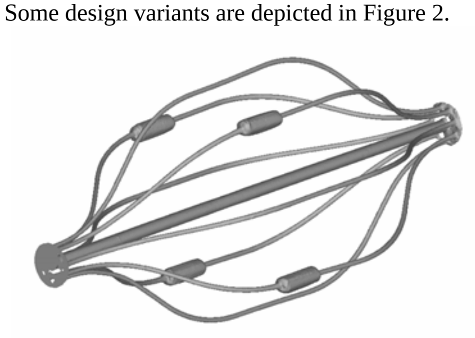

Figure 1. 3D reconstruction of microCT scan of a 4 mm Angioguard filter (membrane not visible)

Subsequently, the Finite Element Method was used to simulate the deformation of the nitinol filter being inserted into the delivery sheath. Using pyFormex as a dedicated preprocessor for ABAQUS [7], the filter was discretized with 33792 brick, the membrane with 8320 membrane and the delivery sheath with 3806 rigid elements. Both the material properties for the membrane (nylon) and the basket frame (nitinol) were taken from literature [5,8]. A progressive rigid translation along the filter axis is imposed to the delivery sheath in order to induce the necessary filter deformation to switch from the open configuration (filter out of the delivery sheath) to the closed configuration (filter within the delivery sheath). No friction was taken into account.

Validation consisted of comparing the calculated geometry of the filter for different positions relative to the sheath with microCT images of the real device exiting the delivery sheath. Consequently, we assumed that the filter frame deforms in a similar way during insertion into (simulation) and subsequent release (experiment) from the delivery sheath.

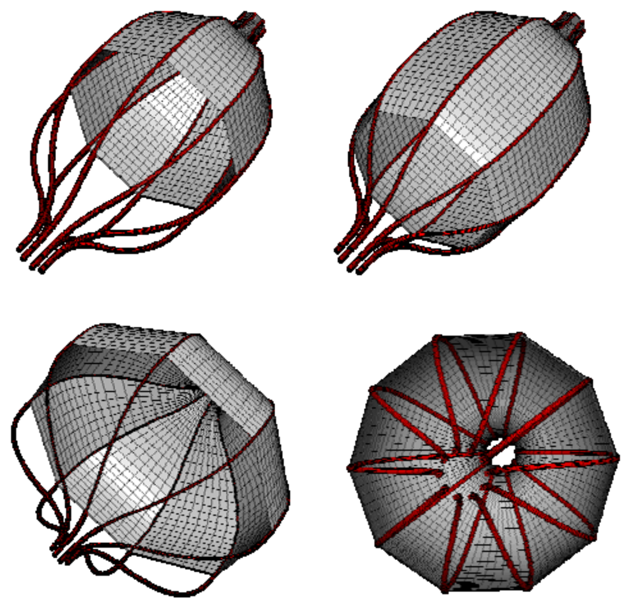

Figure 2. Design variants of the Angioguard model: original 4 mm device with 50% membrane coverage (top left), 80% membrane covered 4 mm filter (top right), 8 mm device with 50% membrane coverage (bottom left) and 10 strut variant (bottom right).

RESULTS

The simulation of the filter insertion into the delivery sheath revealed that the basket frame experiences large deformations. The radial compression of the filter frame is accomplished by an axial elongation reducing the diameter from 4 mm to 0.96 mm when the filter is completely inserted into the sheath. A good qualitative agreement is found between the numerical results and the microCT image of the partially deployed Angioguard filter (see Figure 3).

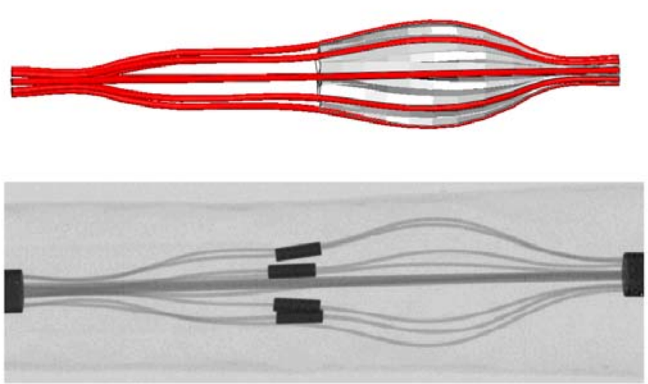

Figure 3. Finite Element simulation (top panel) and microCT image (bottom panel) of partially inserted/released filter into/from the delivery sheath

DISCUSSION AND CONCLUSIONS

We have demonstrated that it is possible to construct parametric models of complex shapes as the wire framework and filter basket of embolic filter devices such as the Angiogard device. These models can be further taken to Finite Element Software to simulate their deployment. Qualitative comparison with experimental data showed satisfactory agreement between measured and calculated shapes of the filter frame. As such, we believe that the proposed modeling methodology offers a useful tool to further investigate and to compare the mechanics of current or new designs of embolic protection filters and provides a solid base for further investigation.

Inclusion of accurate experimentally determined material properties for both the basket frame and the membrane would allow a detailed stress analysis of the complete device, but this is beyond the scope of this preliminary analysis. A thorough understanding of these stress states might reveal the potential of the device to be further miniaturized when taking of course also other important characteristics (such as the radial stiffness) into account. By performing parametric studies, altering for example number and/or size of struts, one could try to reduce the delivery sheath size in order to facilitate the crossing of tortuous high-grade stenoses. In addition, extending the model to study the interaction with a (patient specific) blood vessel might reveal clinically important information with regards to the wall apposition and possible vessel injury, as well as a further analysis of the effect of the deployed device on the blood flow and its performance in capturing debris carried by the blood flow.

ACKNOWLEDGMENTS

The authors acknowledge Lieven Maene, MD for his valuable support.

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