FINITE ELEMENT STENT DESIGN OPTIMIZATION - TOWARDS A UNIFORM EXPANDING FIRST GENERATION PALMAZ-SCHATZ STENT

M. De Beule*, R. Van Impe*, B. Verhegghe**, P. Segers*** and P.R. Verdonck***

* Laboratory for Research on Structural Models, Ghent University, Gent, Belgium
** Laboratory for Mechanical Construction and Production, Ghent University, Gent, Belgium
*** Cardiovascular Mechanics and Biofluid Dynamics, Ghent University, Gent, Belgium

Matthieu.DeBeule@UGent.be

Abstract: Stents are supporting - mostly metal - tubular mesh structures which are deployed in an obstructed artery in order to reopen it, and to offer radial stiffness to prevent elastic recoil of the dilated vessel. At present, advanced numerical models (e.g. Finite Element models) - in addition to a variety of experimental tests - offer interesting insights in the mechanical behavior of stents and will undoubtedly influence the design of future generation stents. A brief literature review on numerical studies dealing with the mechanical behavior of stents is presented. Subsequently, the Finite Element Method is exploited to investigate and compare different designs of a 'first generation' Palmaz Schatz stent in order to increase the uniformity of the complete stent expansion. Our computational models are described in terms of geometry, constitutive material model, numerical aspects and criteria to evaluate stent expansion. Altering the original symmetric stent design by taking into account asymmetry of the stent strut geometry appears a promising way to enhance uniform stent expansion. Although the model is suitable to study basic aspects of stent deployment, further research is necessary, especially accounting for newer generation stent geometries and more realistic balloon-stent interaction.

Introduction

Cardiovascular disease, which is often related to atherosclerosis, is the most common cause of death in Western countries . According to the European cardiovascular disease statistics, 49% of all deaths in Europe are related to this disease. Atherosclerosis is an inflammatory disease [1] and is the process in which deposits of fatty substances from the blood (e.g. cholesterol, lipids, ...) build-up between the inner (tunica intima) and middle (tunica media) layer of an artery. This build-up may lead to progressive formation of plaque and eventually cause an obstruction (stenosis) for blood flow through the artery. To restore the perfusion of downstream tissues, an intravascular stent (i.e. small tube-like structure) can be deployed in the obstructed vessel offering radial stiffness and preventing abrupt artery closure. The major limitation associated with this procedure is restenosis (re-closure). In order to reduce restenosis rates, recent stents are being coated with specific drugs (e.g. paclitaxel, sirolimus, ...) [2]. Nevertheless, as the mechanical injury to the stenotic arteries due to the stenting procedure is not relieved by the pharmacological coatings themselves, it is very important to investigate the stent's mechanical behavior in order to reduce those mechanical injuries to a minimum. These mechanical injuries [3] are due to stent insertion, expansion and its chronic nature - stents (except bioabsorbable implants [4]) remain inserted in the vascular system. A frequently observed example of mechanical injury during the stent expansion is caused by the so-called dogboning effect. The stent ends are the first to come into contact with the artery, they may pinch the tissue, damage it, activate local restenotic mechanisms and possibly produce dissections [5].

At present, advanced numerical models (e.g. Finite Element models) - in addition to a variety of experimental tests [6]- offer interesting insights in the mechanical behavior of existing and new stent designs. As the physical reality is always approximated by numerical models, it is the important task of the scientist to decide where the results are reasonable and correct and in which contexts to use the developed mathematical models. With regards to numerical studies concerning uniform expansion, literature is very scarce. Some authors have altered the design in order to reduce the dogboning (i.e. stent ends open first) [5, 7, 8, 9, 10, 11], but as the dogboning index only takes into account the radii at the central and distal part of the stent, nothing can be concluded concerning the uniformity of the complete stent expansion [11].

As the expansion behaviour is strongly related to the stent geometry, this study exploits the finite element method (FEM) [12] to investigate and compare different asymmetric variations of a 'first generation' Palmaz Schatz stent in order to enhance uniform stent expansion. This approach can be easily applied to most recent (coronary) stent designs, since - to the best of our knowledge - the vast majority has a symmetric geometry.

Materials and Methods

Symmetric stent

Model geometry: In the unexpanded state, the investigated stent has a tubular shape with rectangular slots along its length. Its initial length, inner diameter and thickness are equal to 16 mm, 1 mm and 0.1 mm, re-

 ISSN: 1727-1983

spectively. The number of slots in the circumferential direction is 12 and in the longitudinal direction this number is 5, each slot length measuring 2.88 mm. The corners of the slots are modelled with inclusion of a curvature to avoid unrealistic stress concentrations, making the model more realistic. The width of the slots is taken equal to the width of the metal (in between two slots) in the circumferential direction; the metal/artery index is 1 [8]. This index is defined as α_P/α_V, where α_P is the angle described by the metal and α_V is the angle described by the slot in the cross section of the unexpanded configuration.

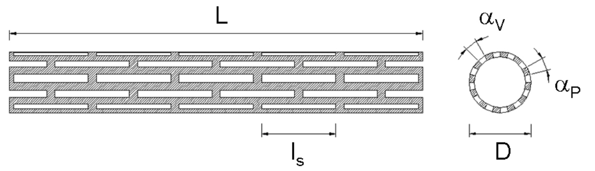

Figure 1: Geometry of the symmetric stent; L: length of the stent, D: outer diameter, l_s: length of the slot; α_V: angle described by the slot, α_P: angle described by the metallic surface

In view of the circumferential and longitudinal symmetry of the model, only a 60 degree sector of half of the model is considered. Of course symmetric boundary conditions are applied.

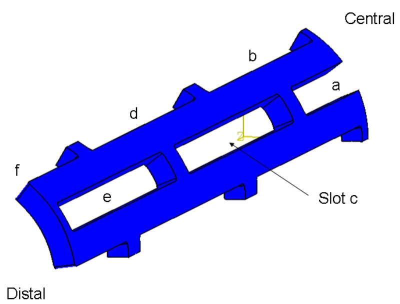

Figure 2: Unexpanded symmetric stent sector

Constitutive material model: The balloon expandable stent is made of 316LN stainless steel. The isotropic inelastic constitutive response of SS 316LN is implemented by a von Mises model with isotropic hardening. The Young Modulus is 196000 N/mm^2, the Poisson ratio 0.3 and the yield stress 205 N/mm^2. The Cauchy stress vs. nominal strain curve is obtained from Auricchio et al. [5].

Numerical aspects: Neglecting the balloon's stiffness compared to the stiffness of the stent, the presence of the balloon itself is discarded in the analysis. Consequently, the action of an internal balloon is simulated by a uniformly distributed internal pressure (P) applied to the inner surface of the stent. The validity of this hypothesis is a subject for further research [9]. Similar to a balloon inflation up to 7 atm, the internal pressure is assumed to increase from 0 to 0.7 N/mm^2, while the deflation of the balloon is modeled by decreasing the pressure back to zero. The complex geometry of the stent is approximated by a finite element mesh using tetrahedral elements with quadratic interpolation. The total number of elements (#) is 11440. In order to understand the convergence of the numerical results, simulations were performed for different mesh densities (# = 5466 and # = 35949). For these meshes the maximal radial displacements at the end of the loading phase were compared to those of the retained mesh: the percent differences resulting from the chosen and the other meshes were 2.1% and 0.3%, respectivily. For this reason no further mesh refinement was considered.

Criteria to evaluate stent expansion: A currently used index to evaluate stent expansion is dogboning, defined as

$$Dogboning = \frac{R_{distal}^{load} - R_{central}^{load}}{R_{distal}^{load}} \quad (1)$$

where R_{distal}^{load} and $R_{central}^{load}$ are the radii at the distal and central part of the stent at the end of the loading phase (P = 0.7 N/mm^2). As this index takes into account only these radii, nothing can be concluded concerning the uniformity of the complete stent expansion. In order to quantify this 'uniformity' we propose to calculate the ratio of the minimal and maximal values of the radii of the stent at the end of the loading phase. These values define the internal (R_{ivc}) and external (R_{evc}) virtual enveloping cylinders of the expanded stent. A high value of the R_{ivc}/R_{evc} ratio is a good indication for the uniformity of the stent expansion. A complete uniformly expanding stent would have a ratio value of one.

Asymmetric stents

As the expansion behavior is strongly related to the stent geometry, several simulations with varying geometry have been performed in an attempt to enhance uniform stent expansion. The symmetric stent's geometry was adapted by varying the slot width in the longitudinal direction of the stent in such a way that the radial stiffness increased at the distal and decreased at the central part of the stent. Since the pressure is applied uniformly over the stent's inner surface, the surface area determines the net force on the stent. Therefore the slot width variations are chosen in such a way that the area of the internal surface is kept constant, enabling exactly similar loading conditions for all stents. A straightforward way to express the slot width variations, for the 6 slots (slots a-f shown in Figure 2) present in the 60 degree-segment model, is half the angle α_V. Varying these angles leads to 6 asymmetric stent configurations (Asc_1-6; see Table 1)

Results

The results of the simulations in terms of the R_{ivc}/R_{evc} ratio and the dogboning index are summarized in Table 2.

The contour plots of the radial displacements below show the expanded stent shape at 0.7 N/mm^2 for the symmetric stent and the asymmetric stents Asc_1 and Asc_6.

ISSN: 1727-1983 © 2005 IFMBE

Table 1: Values of half the slot angle α_V [degrees] in the cross section of the unexpanded configurations; a-f: slot indication

Model	**a**	**b**	**c**	**d**	**e**	**f**
Ssc	7.50	7.50	7.50	7.50	7.50	7.50
Asc_1	8.75	8.25	7.50	7.75	6.50	6.25
Asc_2	8.00	7.75	7.50	8.50	6.75	6.00
Asc_3	7.75	7.75	7.50	8.75	6.75	5.75
Asc_4	7.75	7.75	7.50	9.00	6.75	5.25
Asc_5	7.25	7.75	7.50	9.00	7.25	4.75
Asc_6	7.50	7.75	7.25	9.00	7.50	4.50

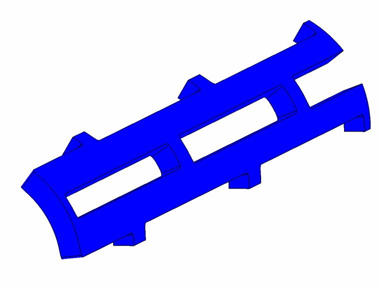

Figure 3: Unexpanded asymmetric stent_1 sector

These plots, the values of the R_{ivc}/R_{evc} ratio and the dogboning index show clearly the limitations of the dogboning index as an indication for the uniformity of the complete stent expansion. The first asymmetric stent configuration (Asc_1) results in a similar expansion behaviour of the central and distal part of the stent, i.e. 4.16% dogboning, but the expansion is not at all uniform, i.e. R_{ivc}/R_{evc} is 0.60 and thus by far equal to 1.

The simulations indicate the strong increase in the uniformity of expansion - and reduced dogboning compared to the symmetric set-up - by the use of asymmetric stent geometries. There is an increase from 0.49 for the symmetric stent to 0.80 for the asymmetric stent Asc_6 for the R_{ivc}/R_{evc} ratio. Consequently, further research could result in a complete uniformly expanding stent.

Discussion

In this study we varied the radial stiffness of the stent longitudinally by changing the slot width. The radial stiffness can also be altered via a variable thickness, but this approach would be unacceptable from a manufacturing point of view. Production of the stents with varying thickness would increase the costs, and the laser-cut process of the stent would be more complicated as the laser energy would (continuously) have to alter.

Besides the effect on the dilatation behaviour, taking asymmetry in the stents geometry into account may also influence other factors (e.g. radiopacity, drug elution for coated stents, ...).

It is acknowledged that no experimental validation of

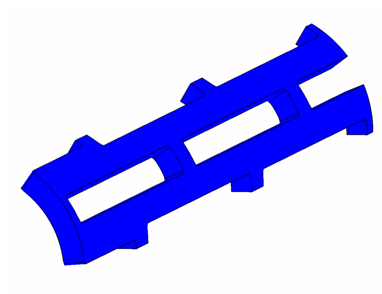

Figure 4: Unexpanded asymmetric stent_6 sector

Table 2: Numerical results for different stent geometries

Model	R_{ivc}/R_{evc} [-]	**Dogboning** [%]
Ssc	0.49	33.38
Asc_1	0.60	4.16
Asc_2	0.68	17.13
Asc_3	0.71	18.41
Asc_4	0.76	15.15
Asc_5	0.79	20.22
Asc_6	0.80	18.07

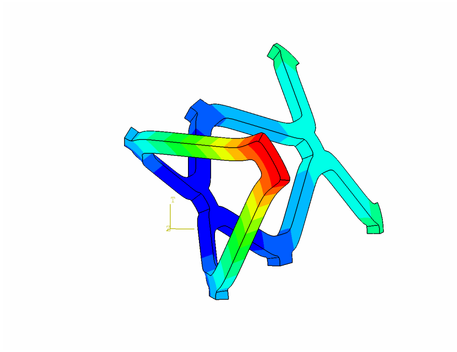

Figure 5: Expanded symmetric stent (P = 0.7 N/mm^2)

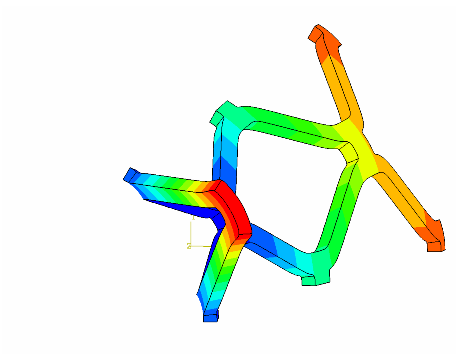

Figure 6: Expanded asymmetric stent_1 (P = 0.7 N/mm^2)

the numerical results has been performed, and that newer generation stent geometries and more realistic balloon-stent interaction are topics that should be investigated in future studies. A logic continuation would be to study the

ISSN: 1727-1983

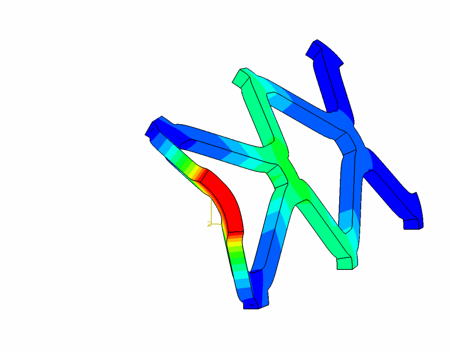

Figure 7: Expanded asymmetric stent_2 (P = 0.7 N/mm^2)

mechanical response of the vessel to these asymmetric configurations.

Conclusions

The finite element method has proven to be a useful tool in simulating different asymmetric stent geometries, increasing the R_{ivc}/R_{evc} ratio from 0.49 for a symmetric stent to 0.80 for an asymmetric stent. For this reason, taking asymmetry into account in the design of stents appears a promising way to enhance uniform stent expansion.

As the dogboning - a currently used index for stent expansion - only takes into account the radii at the central and distal part of the stent, nothing can be concluded concerning the uniformity of the complete stent expansion. The ratio of the radii of the virtual enveloping cylinders is a much better parameter to give a clear indication of the uniformity of the expanded stents shape.

This approach can be easily applied to most recent (coronary) stent designs, since - to the best of our knowledge - the vast majority has a symmetric geometry.

References

[1] Ross, R. Atherosclerosis - an inflammatory disease. *The New England Journal of Medicine*, 340-2:115–126, 1999.

[2] van der Hoeven, B.L., Pires, N.M.M., and Warda, H.M. Drug-eluting stents: results, promises and problems. *International journal of Cardiology*, 99:9–17, 2005.

[3] Squire, J.C. Dynamics of endovascular stent expansion. *PhD, Massachusetts Institute of Technology*, pages 19–22, 2000.

[4] Müller, H. Development of metallic bioabsorbable intravascular implants. *Proc. of ESVB - New technologies in vascular biomaterials. Strasbourg, France*, pages 23–32, 2005.

[5] Auricchio, F., Di Loreto, M., and Sacco, E. Finite element analysis of a stenotic artery revascularisation through a stent insertion. *Computer Methods in Biomedical Engineering*, 00:1–15, 2000.

[6] Rieu, R., Garitey, V., and Barragan, P. In vitro comparative mechanical characterization of stents. *Proc. of ESVB - New technologies in vascular biomaterials. Strasbourg, France*, pages 33–46, 2005.

[7] Chua, D.S.N., MacDonald, B.J., and Hashmi, M.S.J. Finite element analysis of a stenotic artery revascularisation through a stent insertion. *Computer Methods in Biomedical Engineering*, 00:1–15, 2000.

[8] Migliavacca, F., Petrini, L., Colombo, M., Auricchio, F., and Pitrabissa, R. Mechanical behaviour of coronary stents investigated through the finite element method. *Journal of Biomechanics*, 35-6:803–811, 2002.

[9] Wang, W.Q., Liang, D.K., Yang, D.Z., and Qi, M. Analysis of the transient expansion behavior and design optimization of coronary stents by the finite element method. *Journal of Biomechanics*, in press:1–12, 2004.

[10] Holzapfel, G.A., Stadler, M., and Gasser, T.C. Changes in the mechanical environment of stenotic arteries during interaction with stents: computational assessment of parametric stent designs. *Journal of Biomechanical Engineering*, 127-1:166–180, 2005.

[11] De Beule, M., Van Impe, R., Verhegghe, B., Segers, P., and Verdonck, P.R. Finite element analysis and stent design: Reduction of dogboning. *Proc. of BioMech 2005 - Applied Biomechanics. Regensburg, Germany*, page in press, 2005.

[12] Abaqus Inc. Standard user's manual - version 6.5, 2004.

ISSN: 1727-1983 © 2005 IFMBE