EVALUATION OF INTRAVASCULAR STENT FLEXIBILITY BY MEANS OF NUMERICAL ANALYSIS

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INTRODUCTION

Nowadays stent therapy is widely adopted to treat atherosclerotic vessel diseases. The high commercial value of these devices and the high prototypation costs suggest to use finite element analyses, on behalf of classical trial and error technique, to design and verify new models [1-5].

In this paper a methodology based on the finite element method (FEM) is proposed to study new generation stent performance in terms of flexibility. Indeed, the stent ability to bend in order to accommodate vessel turns or angles during delivery is one of the most significant prerequisite for a good stent behavior. Herein, two different FEM models realized resembling two new generation intravascular stents were developed; the main model dimensions were obtained by means of a stereo microscope.

Bending tests under displacement control in the unexpanded and expanded configuration were carried out. A curvature index defined as the ratio between the rotation angles at the extremes and the length of the stent yielded comparative information about the device capability to be delivered into tortuous vessels and to conform to their contours.

MATERIALS AND METHODS

Two three-dimensional models resembling two new generation intravascular stents (Cordis BX-Velocity, Johnson & Johnson, Interventional System, Warren, NJ, USA and Sirius Carbostent, Sorin Biomedica, Saluggia, VC, Italy; in the following CV and SC), both in the unexpanded and in the expanded configuration, are considered. Both structures can be seen as a sequence of tubular-like rings and bridging members (links). On the basis of these geometrical considerations it is reasonable and computationally convenient to study the flexibility adopting only a stent sub-model or unit, composed by two rings and the links between them. The units of the two intravascular stents herein studied are depicted in Fig. 1. In the CV model the external diameter is 0.104 mm in the unexpanded configuration and 2.5 mm in the expanded one, the thickness is 0.14 mm. In the SC model the external diameter is 1.1 mm in the unexpanded configuration and 2.5 mm in the expanded configuration, the thickness is 0.1 mm.

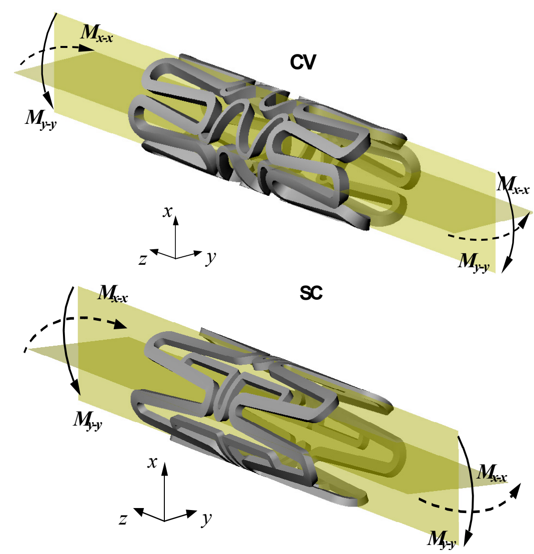

Figure 1. Geometry of the two stent units studied and planes of application of the bending moment.

The stents are assumed to be made of 316LN stainless steel. The inelastic constitutive response is described through a Von Mises-Hill plasticity model with isotropic hardening. Young modulus is 196 GPa, the Poisson ratio 0.3, the yield stress 205 MPa [6]. A large deformation analysis is performed using the commercial code ABAQUS (Hibbit Karlsson & Sorenses, Inc., Pawtucket, RI, USA) based on the FEM. The models were meshed with 10-node tetrahedral elements. The number of nodes and elements were in the range 31871÷77228 and 14704÷39398, respectively. The analyses were performed under displacement control both on the unexpanded and expanded configuration: the extremes of the models were rotated of a fixed angle φ around two axes x and y as sketched in Fig. 1. Results were expressed in terms of bending moment (M) at the extremes as function of a curvature index, defined as: $\chi = \Delta\varphi / L$ where $\Delta\varphi$ is equal to $2\cdot\varphi$ and L is the length of the unit. The flexibility was measured as the inverse of the slope of the M-χ curve.

RESULTS

Figure 2 shows the curves M-χ for the CV and the SC models in the unexpanded configuration for a bending around the x and y axes. From the obtained results it is possible to evince that the CV model showed a behavior independent from the axis of rotation. On the contrary, the SC model showed a different behavior according to the selected rotation axis. This can be explained considering the different stent geometries. The six links of the CV have two crests and are connected with the top of the rings, while the five links of the SC model have only one crest and are connected with the center of the rings. As a consequence, the CV links exhibit a high capability to deform independently from the rings and, consequently, from the rotation axis: the rings remain unstressed (Fig. 3a). On the contrary, the SC rings and links deform together and hence the stiffness of the structure depends on the rotation axis: accordingly, stresses interest also the rings (Fig. 3b). Moreover, in both the rotation cases a self-contact of a single link takes place at small rotations (about 8°, χ = 0.05 rad·mm^{-1}), which causes a discontinuity in the M-χ curves and a strong increment in the slopes. The flexibility in the plastic range was calculated before the self-contact. Increasing φ, the curves show a softening behavior: it is connected to an instability phenomenon due to the rings which, during their rotation, push inwards the link in contact.

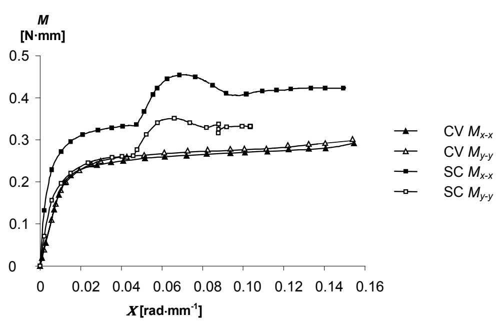

Figure 2. Moment-curvature index curves for the unexpanded configurations of CV and SC models.

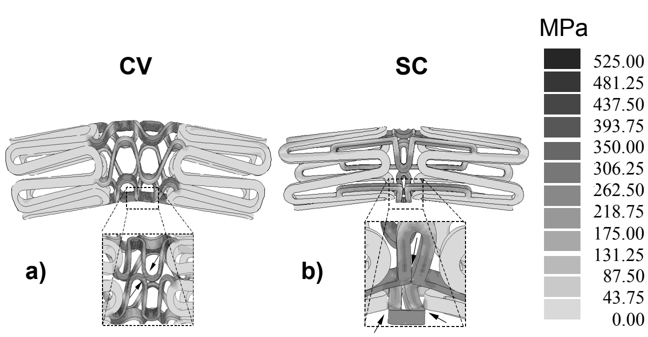

Figure 3. Von Mises stresses (χ = 0.06 rad·mm^{-1}) for the CV (a) and SC (b) models in the unexpanded configuration during the bending around the x axis. Arrows in the enlargements reverse view indicate the areas of contact.

The M-χ curves relative to the expanded configurations showed a tendency similar to the unexpanded ones, but with a lower flexibility. The numerical results in terms of flexibility for both the configuration are reported in Table 1.

Table 1 Flexibility values of the unexpanded and expanded configuration of the models in the elastic and plastic fields.

Model	Rotation Axis	Elastic field flexibility [rad·N^{-1}·mm^{-2}]		Plastic field flexibility [rad·N^{-1}·mm^{-2}]	
		Unexp.	Expan.	Unexp.	Expan.
CV	x	0.052	3.87	0.0138	0.383
CV	y	0.052	4.45	0.0138	0.383
SC	x	0.015	0.75	0.0042	0.161
SC	y	0.029	2.74	0.0041	0.154

CONCLUSIONS

It has been shown that the balloon influences the stent flexibility in the unexpanded configuration [7]: the absence of any modeling of the balloon during the analysis is the main limitation of this work and further works are in progress. Nevertheless, the proposed methodology allows to evaluate a comparative index of flexibility both when the material is elastically deformed (smaller rotation) or plastically deformed (larger rotation). This index could be used as design parameter for new generation stents

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