NUMERICAL ANALYSIS OF VASCULAR STENTS EXPLOITING SHAPE-MEMORY-ALLOY BEHAVIOR

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SOMMARIO
Si affronta uno studio computazionale del comportamento di stent coronarici in lega a memoria di forma (SMA). In particolare, utilizzando per il comportamento delle SMA un algoritmo sviluppato ad hoc, si è confrontata la risposta di stent in SMA autoespandibili (effetto superelastico) e stent in acciaio espandibili con palloncino, concentrando l’attenzione sull’interazione dello stent con l’arteria stenotica. Inoltre si è anche investigato il comportamento di uno stent in SMA espandibile con palloncino nel quale si sfrutta l’effetto memoria di forma per rimuovere il dispositivo. Scopo del lavoro è, da una parte, verificare l’efficacia del modello nel descrivere dispositivi biomedici in SMA, dall’altra evidenziare l’utilità di analisi agli elementi finiti per dare indicazioni sia ai medici che ai produttori dei dispositivi.

ABSTRACT
Shape Memory Alloys (SMA) have the unique capability to recover the original shape, once mechanically deformed, through mechanical unloading, Superelastic Effect (SE), or through thermal loading, Shape Memory Effect (SME). These peculiar behaviors, coupled with a good material biocompatibility, have stimulated a wide diffusion of SMA in the area of biomedical devices. In this work we numerically investigate the SMA performance in stent vascular applications. In particular, adopting a numerical algorithm describing the SMA thermo-mechanical behavior (Auricchio and Petrini, International Journal for Numerical Methods in Engineering, 2002), we compare the behavior of a self-expandable (SE) SMA stent during the expansion in a stenotic artery with that of a balloon-expandable stainless steel stent. Moreover, we study the response of a balloon-expandable SMA stent where SME is exploited for removing the device. The aim is to verify the model ability to describe the behavior of SMA biomedical devices as well as to show the utility of finite element analyses to give indications both to clinicians and manufactory firms.
1. INTRODUCTION

A vascular stent is a small metal tube, which is inserted into an artery at the site of a narrowing to act as an internal scaffolding or support to the blood vessel. Two types of coronary stents are available on the market, based on two different principles depending on the modality of expansion: the balloon-expandable and the self-expandable stent. The former is mounted on a catheter supporting a balloon and is positioned by inflating the balloon in the site of blockage. Under the pressure of the balloon, the stent deploys itself to mechanically support the vessel walls. When the balloon is deflated and retracted, the stent remains in place and maintains the artery open. These stents are usually made of stainless steel (SS): once plastically deformed by the balloon expansion, they assume an enlarged configuration and the high stiffness of the material allows to contrast the elastic recoil of the artery. The self-expandable stent is mounted on the catheter and is compressed by a protective sheath: when the sheath is retracted the stent expands into the artery. This behavior can be obtained realizing SS stents with suitable shape as well as exploiting shape memory alloy (SMA) intrinsic properties. Indeed, the SMA have the unique ability to recover the original shape, once mechanically deformed, through mechanical unloading, superelastic effect (SE), or through thermal loading, shape memory effect (SME). These peculiar behaviors, coupled with a good material biocompatibility (as the Nickel-Titanium alloys), have stimulated a wide diffusion of SMA in the area of biomedical devices. In particular, in the cardiovascular field, self-expandable SMA stents seem to have some advantages with respect to balloon-expandable SS stents: a more flexible delivery system, a lower risk to overstretch the artery during expansion, a lower bending stress when deployed in a tortuous vessel [1]. Moreover, the SME is used when the stent, after a short period of application, has to be removed.

The study and comparison on the performance of different type of stents, in particular in terms of stresses induced on the artery wall, are an argument of actual interest: it is commonly retained that the restenotic process in which the intra-arterial lumen is limited by the neointimal hyperplasia is strictly related to the level of injury induced in the vessel during the stent deployment. Accordingly, in the scientific literature there is a recent effort in the study of stenting procedures by means of computational structural analysis with the aim of predicting and calculating the stress state generated after a percutaneous coronary intervention [2-6].

Although SMA stents are nowadays routinely used, the literature shows a lack in computational analysis on their mechanical behavior. This situation suggests the present work. Starting from an ad hoc numerical algorithm describing the SMA thermo-mechanical behavior [7], we implement it in a commercial code and we use the finite element method (FEM) to study the performance of SMA stents. In particular, we compare the behavior of a self-expandable SMA stent during the expansion in a stenotic artery with that of a balloon-expandable SS stent. Moreover, we verify the model ability to simulate the response of a SMA stent exploiting the thermal shape recovery.

2. MATERIALS AND METHODS

In this work we perform the following analyses:
1. expansion of a balloon expandable SS stent
2. expansion of a self-expandable SMA stent
3. expansion of a balloon expandable SMA stent with thermal shape recovery
For all the analyses we consider the interaction of the stent with a stenotic coronary vessel.

The simulations are performed in large deformation regime using the FEM commercial code ABAQUS Standard (Hibbit Karlsson & Sorenses, Inc., Pawtucket, RI, USA). Since the goal is a comparative study to evaluate the effect of different materials and hence the different modality of expansion on the performance of a stent, we use in all simulations the same 3-D model (Fig. 1). It consists of three parts: the artery, the atherosclerotic plaque and the stent. The symmetries of the geometry allow us to study only one twelfth of the model in the circumferential direction and one half in the longitudinal one: the measures in the following refer to the reduced model.

The artery is modeled as a cylinder having a length of 15 mm, an internal diameter of 3 mm and a thickness of 0.5 mm. It is discretized by means of 2088 10-node tetrahedral elements with a corresponding number of nodes of 2885. To describe the mechanical behavior of the artery we adopt a hyperelastic isotropic constitutive model from the ABAQUS material library along with hybrid modified elements. In particular the constitutive equation adopted (Fig.2) is the following polynomial form:

\[
U = 0.019513 \cdot (I_1 - 3) + 0.02976 \cdot (I_2 - 3)^3
\]

where \( U \) is the strain energy and \( I_1 \) and \( I_2 \) are the invariants of the Cauchy-Green tensor. The stress-elongation curve for the artery is depicted in Figure 2 and it shows a similarity with those reported by [8-12].

The plaque is modeled as a cylinder (symmetric plaque) with a length of 8 mm, an internal diameter of 2 mm and a thickness of 0.5 mm. It corresponds to a stenosis of 56% in term of area reduction in the central cross section. The plaque is discretized using 1258 10-node hybrid modified tetrahedral element with a corresponding number of nodes of 2597 + 593 shared with the artery. Also in this case a hyperelastic isotropic constitutive model (Fig.2) is adopted with the following polynomial form:

\[
U = 0.04 \cdot (I_1 - 3) + 0.003 \cdot (I_2 - 3)^2 + 0.02976 \cdot (I_2 - 3)^3.
\]
For the stent the 3-D model adopted is the typical diamond-shaped intravascular stent (Palmaz-Schatz): it is a tube with 5 rectangular slots in the longitudinal direction and 12 slots in the circumferential one; each slot has a length of 3.2 mm, and a metal/artery surface ratio of 0.17, which is the ratio of the actual metal surface ($m$) in contact with the arterial wall surface and the overall arterial wall ($a$).

In the first analysis we consider a balloon-expandable stent made of 316L stainless steel. The undeformed (unexpanded) configuration has the following dimensions: a length of 8 mm, an outer diameter of 1.2 mm, a thickness of 0.1 mm. The stent is discretized by means of 1124 10-node hybrid modified tetrahedral elements with a corresponding number of nodes of 2760. The inelastic constitutive response of the material is described through the Von Mises-Hill plasticity model with kinematic hardening from the ABAQUS material library. The Young modulus is 193 GPa, the Poisson ratio 0.3, the yield stress 205 MPa [4].

In the last two analyses we exploit the peculiar behavior of NiTi, the most diffused SMA. Its response depends on a thermo-elastic reversible transformation between two crystallographic structures with different physical and mechanical properties: the austenite, $A$, characterized by a more ordered unit cell and stable at temperatures above $A_f$ (Martensite to Austenite transformation finish temperature), and the martensite, $M$, characterized by a less ordered unit cell and stable at temperatures below $M_f$ (Austenite to Martensite transformation finish temperature) [13].

In particular, the self-expandable stent exploits SE. The stent, in austenitic phase ($A_f <$T$_{amb}$<$T_{body}$), is compressed by a protective sheath to be mounted on the catheter: during this phase it presents a nonlinear behavior due to a stress-induced conversion of austenite into martensite. When, after the insertion of the stent into the body, the sheath is retracted, a reverse transformation from martensite to austenite occurs as a result of the instability of the martensite at zero stress for temperatures higher than $A_f$; accordingly, the stent expands into the artery trying to recover the original undeformed shape.
Because we want to avoid the influence of geometrical effects on the results, we choose the dimensions of the model in the undeformed (expanded) configuration such that, after compression, the SMA stent shows a geometry very similar to the undeformed configuration of the SS stent previously described; in particular we consider a length of 7 mm, an outer diameter of 3.5 mm and a thickness of 0.1 mm. The stent is discretized by means of 1164 10-node hybrid modified tetrahedral elements with a corresponding number of nodes of 25,777.

The balloon expandable stent with shape recovery exploits SME. The stent, in martensitic phase ($A_f > T_{body} > T_{amb}$), is mounted on a catheter supporting a balloon. When it is positioned into the body by inflating the balloon, the stent shows a non linear response with a residual deformation after the balloon retraction. This residual (apparently inelastic) strain may be recovered (shape recovery) by heating the material above $A_f$, thus inducing a conversion of martensite into austenite: accordingly, the stent recover the original unexpanded shape and can be easily removed from the body. In this case the SMA stent has the same geometry of the SS stent.

These inelastic NiTi behaviors are described by an ad hoc developed algorithm [7] implemented into the ABAQUS code through the user subroutine UMAT. In Figure 3 are depicted the characteristic stress-strain curves of the material with the main parameters to be defined in the model. Being not available the material mechanical characteristics of the stents, medium values of a common alloy was chosen. In particular, referring to Figure 3, we assumed: $E=70000$ MPa, $\sigma_0 = \beta(T-T_0)$ with $\beta=6$ MPa/K and $T_0 = M_f$, $R = 100$ MPa, $\varepsilon_{L}=0.07$ and

- $M_f = 235$ K for the self-expandable stent: during all the simulations the body temperature is assumed constant and equal to 311 K (SMA in austenitic phase)
- $M_f = 311$ K for balloon expandable stent with SME: during the simulation of expansion the body temperature is assumed equal to 311 K (SMA in martensitic phase), while during thermal shape recovery the body temperature is increased up to 323 K (SMA in austenitic phase).
The mesh of the model was automatically generated by the commercial code GAMBIT (Fluent Inc., Lebanon, NH, USA). As regard the boundary conditions, the nodes belonging to a symmetric plane are required to have zero displacement in the direction normal to the symmetry plane (Fig. 1). The contact between the stent and the coronary vessel is simulated using the CONTACT option of ABAQUS. In particular we consider a finite sliding approach with an exponential contact pressure-overclosure relationship and friction properties ($\mu = 0.05$) after basic Coulomb model.

4. RESULTS AND DISCUSSION

Simulations for the stainless coronary stent deployment are organized in the following steps: i) pretensioning up to 10% and pressurization of the vascular wall up to 100 mmHg. During this phase the internal plaque diameter increases from 2 mm to 2.28 mm; ii) application of uniform linearly increasing radial pressure ($P$) of 4 MPa at the internal surface of the stent; iii) reduction of the internal pressure on the stent till a value equal to 100 mmHg simulating the blood pressure. These steps correspond to the following phases: i) in–vivo conditions in the vessel wall; ii) expansion of the stent by inflation of the balloon; iii) deflation of the balloon and equilibrium condition between the stent and the vessel.

Figure 4 reports the Von Mises stresses distribution along the vessel in different time-steps of the analysis: indeed, the knowledge through numerical simulations of the stress variations during the stent deployment is a useful tool to understand the in-vivo coronary vessel response. In particular, we consider the configuration of maximum expansion reached at the end of the loading phase (A), the final configuration reached at the end of the unloading phase (B) and the intermediate one which shows, during the loading phase, a vessel diameter equal to the diameter reached in the final step (C). These points are depicted in Figure 5. These results underline how the steel elastic recovery during unloading requires a maximum expansion configuration with an overstretch of the vessel of 5.44% (point A with respect to point B in Fig. 5) and a loading addition of the 22% (point A with respect to point C in Fig. 5). Moreover, analyzing the deformed shape of the model, a non uniform deformation of the plaque in the radial direction during the stent expansion is detectable: in particular, at the maximum pressure the plaque reaches a diameter of 4.42 mm in the zone where it is in direct contact with the device, but a diameter of 4.13 mm in the zones between the stent strut where some prolapse takes place.

This type of response underlines a limit of the model: the lack of the balloon modeling and, consequently, the simulation of its effect through the application of a pressure concentrated on the stent surface. However, we retain that this limit does not affect the results: indeed, in the final configuration the prolapse disappears. In addition, during the loading phase the prolapse influences the vessel geometry but not significantly the stress distribution (Fig. 4 B vs. Fig. 4 C).

Simulations for the SMA superelastic coronary stent deployment are organized in the following steps: i) pretensioning up to 10% and pressurization of the vascular wall (100 mmHg). In this stage the stent maintains the undeformed original configuration with a diameter larger than the stenosis, being the contact not activated; ii) crimping of the stent. Under radial displacement control the stent internal diameter is reduced of the 67%; iii) releasing and self-expansion of the stent after removal of the
displacement constraints and activation of the contact option; \(iv\) application of the pressure on the stent till a value equal to 100 mmHg simulating the blood pressure.

Figure 4: Comparison in terms of Von Mises stresses between the following steps: A) expansion reached at the end of the loading; B) expansion reached at the end of the unloading; C) expansion reached during the loading phase when the vessel diameter is equal to the diameter at the end of the unloading. Scale A is different from B and C ones.

Figure 5: Curve pressure applied to the stent – plaque internal diameter from the SS expansion numerical simulation. We recognize the following points: A) configuration of maximum load and B) corresponding configuration after unloading; C) configuration during loading having the same diameter of B; D) configuration that has to be reached to obtain after unloading the same diameter of E; E) configuration corresponding to that reached with the SMA stent.
These steps correspond to the following phases: i) in–vivo conditions in the vessel wall ii) insertion and iii) self-expansion of the stent; iv) equilibrium between stent and artery.

At the end of the expansion, when the equilibrium between the expanding force of the stent and the reacting force of the vessel is reached, the stent enlarges the vessel up to an internal diameter of 3.2 mm. In Figure 6 (upper part) are depicted the Von Mises stresses at the maximum expansion. The stent induces an increasing state of stress uniform along the vessel, but it is not able to recover completely the original shape. On one hand, because the expansion derives from intrinsic properties of the material, superelastic stent does not require an overexpansion of the vessel as in the case of SS and hence it induces lower stress and lower damage in the vessel. It is evident if we extrapolate from the curve of Fig. 5 the configuration of maximum expansion (point D) which has to be reached by the SS stent to have on the vessel, after unloading, the same effect of the SMA stent (point E). In Figure 6 (lower part) it is depicted the deformed model when the SS stent has reached the configuration corresponding to point D: the Von Mises stresses reach values 50% higher than the one induced by SMA stent (upper part of Fig. 6).

Figure 6: Comparison in terms of Von Mises stresses between the configurations with an expanded internal vessel diameter of 3.2 mm for the self-expandable SMA stent (top) and the SS stent (bottom).

On the other hand, superelastic stent behavior and efficacy depend strictly on the material mechanical characteristics. Accordingly, as it results from the simulation, the lower stiffness of the SMA induces a lower capability to expand and to contrast the vessel elastic recoil. This is confirmed by the manufacturers who suggest to perform an angioplasty prior to the stenting: the inflation of a balloon into the stenotic vessel produces fractures into the plaque, reducing its stiffness. Our model is not able to describe this phenomenon and hence it overestimates the radial recoil of the vessel.

We also investigate the model ability to describe shape memory recovery in a complex 3D structure as a stent. In this case the simulations for the SMA martensitic coronary stent with thermal recovery are organized in the following steps: i) pretensioning up to 10% and pressurization of the vascular wall (100 mmHg); ii) application of uniform linearly increasing radial pressure (P) of 1 MPa at the internal surface of the stent (Figure 7A); iii) reduction of the internal pressure on the stent till a value equal to 100 mmHg simulating the blood pressure (Figure 7B); iv) heating of the stent up to the recovery of the original
closed shape (Figure 7C). The four steps correspond to the following phases: i) in–vivo conditions in the vessel wall; ii) expansion of the stent by inflation of the balloon; iii) deflation of the balloon; iv) removal of the stent by shape recovery and recovery of the natural body conditions.

Figure 7: SMA martensitic coronary stent with thermal recovery: A) application of uniform linearly increasing radial pressure at the internal surface of the stent till the internal plaque diameter reaches the value of 4 mm in the central region; B) reduction of the internal pressure on the stent till a value equal to 100 mmHg simulating the blood pressure; C) stent recovery of the original closed shape by heating. Grey pictures are the underformed geometries.

5. CONCLUSIONS

The results of the performed simulations allow to conclude that the developed SMA constitutive model can be fruitfully employed to study the behavior of stent as well as other biomedical devices exploiting SMA features. Moreover, the qualitative comparative analyses herein performed between stainless steel and SMA stents allow to show how finite element method may be used for better understanding some aspects of an interventional technique and eventually, when performed having accurate data and information, it could be useful both for clinicians, to choose the most appropriate prosthesis, and for manufactory firms, to improve and optimize the product design limiting the costs.

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