Understanding the requirements of self-expandable stents for heart valve replacement: Radial force, hoop force and equilibrium

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**ARTICLE INFO**

**Keywords:** radial force self-expandable nitinol stent ovine pulmonary artery human pulmonary artery finite element modeling

**ABSTRACT**

A proper interpretation of the forces developed during stent crimping and deployment is of paramount importance for a better understanding of the requirements for successful heart valve replacement. The present study combines experimental and computational methods to assess the performance of a nitinol stent for tissue-engineered heart valve implantation. To validate the stent model, the mechanical response to parallel plate compression and radial crimping was evaluated experimentally. Finite element simulations showed good agreement with the experimental findings. The computational models were further used to determine the hoop force on the stent and radial force on a rigid tool during crimping and self-expansion. In addition, stent deployment against ovine and human pulmonary arteries was simulated to determine the hoop force on the stent-artery system and the equilibrium diameter for different degrees of oversizing.

**1. Introduction**

The evolution of minimally-invasive methods has led to the development of percutaneous implantation techniques as emerging alternatives to conventional surgery for a subgroup of cardiac patients at very high risk of morbidity and mortality. These procedures will likely become the predominant means of treating critical valve disease in the upcoming years (Rosengart et al., 2008). Percutaneous pulmonary valve implantation can be performed safely (Haas et al., 2013; Vezmar et al., 2010), especially in patients who have undergone surgery on the right ventricular outflow tract during repair of congenital heart disease. Nitinol stents are commonly used for minimally-invasive delivery and anchoring of heart valve prostheses. The large elastic strains that nitinol allows, reduces the risk of stent damage during insertion in the delivery system, while enabling the large diameter reductions required for minimally-invasive delivery.

Accurate sizing of the stent with respect to the host vessel is critical for fixation. Insufficient forces could result in loose fit, migration (Pang et al., 2012) and paravalvular leakage (Padala et al., 2010). On the other hand, excessive forces are associated with the risk of wall degeneration and damage. Matching the stent size to the size of the vessel is hindered by the continuous and radially outward directed expanding force that self-expandable stents exert after deployment, leading to negative chronic recoil and a larger vessel after follow-up (Duerig and Wholey, 2002). To ensure safe anchoring, self-expanding stents are typically oversized with respect to the artery. However, one of the most concerning effects related to stent oversizing and increasing radial force is tissue remodeling. The presence of a permanent stent, and the amount of force it exerts, has an undisputed influence on the host tissue with a risk of triggering adverse biological processes such as thrombosis (Thierry et al., 2002), in-stent restenosis and neo intimal proliferation (Kornowski et al., 1998).

For in-vivo functionality assessment of minimally-invasive stented pulmonary valves, sheep is the most used animal model (Driessen-Mol et al., 2012; Metzner et al., 2010; Schmidt et al., 2010; Zhang et al., 2014). On the other hand, the current standard to evaluate self-expanding stents consists on in-vitro measurement of the radial outward force (FDA Guidance documents, 2010). Radial force on its own, may be insufficient to assess the suitability of stents for different purposes, as it does not capture the artery-stent interaction (Rorghi et al., 2014). Such interaction depends on the elastic properties of the host tissue and these might differ within species (Cabrera et al., 2013) and age (Jani and Rajkumar, 2006). For this purpose, finite element (FE) methods that account for interspecies variation, enable the prediction of stress distribution on the arterial lumen, providing a tool to compare the performance of different stents for the implantation scenario in question.

Several groups have pursued different ways to perform in-vitro assessments on self-expanding nitinol stents. A comparison with prior art in the literature shows that a variety of tests have been performed to...
characterize stent forces and results are reported in dissimilar manners, making it difficult to use the outcomes to compare the performance of different stent designs (Table 1). In addition, a number of groups have performed numerical studies regarding the expanding forces of nitinol stents and some of them have accounted for the interaction with the host tissue (Table 2). Once again, it becomes difficult to make a direct comparison of the radial force of different stent designs when dissimilar loading conditions are applied, forces in different directions are reported and reduced geometries are considered.

To assess the stent-artery interaction by FE methods, the hysteretic behavior of nitinol and the non-linear behavior of the host tissue cannot be ignored. Therefore, the aim of this study is to capture the distinctive behavior of the constitutive materials that define the stent-artery interaction by FE methods and assess the forces arising from minimally-invasive implantation. Our main goals are: i) to clarify the basic definitions and terms surrounding the concept of stent radial force and the methods to determine it (addressed in Sections 2.1 and 3.1); ii) illustrate the influence of computational parameters on the stent force (Sections 3.2 and 3.3); iii) assess the effect of stent deployment on the stress pattern of arteries with different mechanical properties (Section 3.4.1); iv) simulate implantation of stents with different degrees of oversizing, evaluating the influence on the host tissue (Section 3.4.2). For this purpose, a laser-cut nitinol stent used for animal trials of tissue-engineered heart valve (TEHV) implantation in sheep models was reconstructed from its crimped state and expanded until its nominal diameter using FE models. Radial crimping and parallel plate compression experimental tests were used to fit the parameters of the nitinol material model. Computational models resembling crimping and free expansion were used to quantify and compare the hoop and radial forces produced by the stent. Subsequently, the implantation of the stent was simulated with an anisotropic, hyperelastic arterial model fitted with biaxial tensile tests of pulmonary arteries of human and ovine origin (Cabrera et al., 2013). The equilibrium diameter and hoop force were determined for different arterial sizes.

### Table 1

<table>
<thead>
<tr>
<th>Author</th>
<th>Stent type</th>
<th>Test</th>
<th>Force term</th>
<th>Outcome</th>
</tr>
</thead>
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<tr>
<td>Duda et al., 2000</td>
<td>Endovascular</td>
<td>Mylar film (force registered on a load cell placed at one end of a film looped around the stent as vertical displacement is applied)</td>
<td>COF (unloading force, at nominal diameter minus 1 mm) RRF (force when crimping back the stent to its nominal diameter, minus 2 mm)</td>
<td>Single values of COF and RRF tabulated</td>
</tr>
<tr>
<td>Takahata and Gianchandani, 2004</td>
<td>Coronary</td>
<td>Crush tests (force registered on a force gauge connected to a plate that applies vertical compression)</td>
<td>Radial stiffness</td>
<td>RF per unit length vs. displacement curve</td>
</tr>
<tr>
<td>Okamoto et al., 2009</td>
<td>Carotid</td>
<td>U-shaped measuring system (force applied by the stents to a tubular holder linked to an electronic balance)</td>
<td>RF</td>
<td>RF for tube diameters of 8,6,5 and 4 mm</td>
</tr>
<tr>
<td>Isayama et al., 2009</td>
<td>Biliary</td>
<td>RF measurement (force recorded by a force gauge deployed inside a contracting cylinder)</td>
<td>RF</td>
<td>RF vs. diameter curve. RF at 4 mm diameter</td>
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<tr>
<td>Johnston et al., 2010</td>
<td>Gianturco</td>
<td>Mylar film</td>
<td>RF</td>
<td>RF vs. area reduction plot</td>
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<tr>
<td>Hirdes et al., 2013</td>
<td>Esophageal</td>
<td>RF measurement</td>
<td>COF</td>
<td>RF vs. diameter curve</td>
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2. Materials and methods

2.1. Preliminary considerations

Taking into account the circumstances above described, we consider it relevant to clarify some terminology regarding forces and stresses before going deeper into the analysis. When internal pressure is applied on an artery, stresses are developed in the longitudinal and circumferential direction. The longitudinal stress $\sigma_l$ is a result of the internal pressure acting on the ends of the artery, stretching its length. The circumferential (hoop) stress $\sigma_\theta$ is the result of the radial action of the internal pressure acting on the walls of the artery, increasing its diameter. The effect of stent deployment on the artery or a crimping tool on the stent is comparable to the influence of internal pressure on the artery or external pressure on the stent respectively. In this way, the stent applies a radial force (RF) on the artery as it expands, generating a hoop stress that is associated with an expansive hoop force (HF) on the artery wall. Similarly, the RF imposed by the crimping tool generates a hoop stress on the stent from which a HF can be derived.

The terms chronic outward force (COF) and radial resistive force (RRF) have been coined by Duerig to describe the specific characteristics of nitinol stents (Duerig et al., 2000). COF makes reference to the opening force of the stent acting on the artery as it tries to go back to its nominal diameter. For being conceived as an expanding force acting on the artery, this force is circumferential and it matches the term “hoop force” for generating hoop stress. RRF refers to the force generated by the stent to resist compression. For being conceived as a compressive force acting on the stent, this force is circumferential and also coincident with the term “hoop force” despite the fact that it is referred to as a radial force.

Regardless of the terminology, RF and HF differ in magnitude and direction and hence cannot be directly compared. Based on the theory of thin-walled tubes, a hollow cylinder of diameter $D$ (mean value of inner and outer diameter), thickness $t$ and length $l$ (Fig. 1) subjected to an internal pressure $P$ develops a $\sigma_\theta$ according to Eq. (1):

$$\sigma_\theta = \frac{PD}{2t} - \frac{HF}{A_{hoop}}$$

(1)

where $P = \frac{\sigma_\theta}{Apexial}$, $A_{hoop} = lt$ and $A_{radial} = \pi Dt$. Hence, the relationship between RF and HF can be expressed by Eq. (2):

$$RF = 2\pi HF$$

(2)

Taking the previous remarks into consideration to interpret the outcomes of in-vitro tests, the only method for direct measurement of RF is a radial force machine which registers the force inside a cylinder that allows for crimping and self-expansion. The Mylar film test compresses the stent circumferentially and provides a direct measurement of the HF. This force could be expressed in terms of RRF when reporting values of stent compression and COF with values on stent expansion. If these results are multiplied by $2\pi$, then the RF would be approximated. A crush test does not provide a measurement of the RF or HF since the applied load is vertical. In pinching loads, the struts are not bent around the circumference as in radial compression. On the
other hand, it is easier to measure than hoop loads and this loading mode is important in situations where stents are exposed to external crushing such as the carotid artery (Duerig et al., 2003). Crush tests have also been used to fit the parameters of nitinol models for FE use (Tzamtzis et al., 2013).

2.2. Experimental mechanical tests

In the present study, experimental set-ups were used to derive the mechanical response to parallel plate compression and radial crimping of self-expanding laser-cut nitinol stents used for animal trials of TEHV implantation (pfm medical, Germany). The stents are composed of a repeating design with four rings of 40 struts, connected by tilted bridges (Fig. A1A, Appendix A). The internal diameter (ID) is 30 mm and the stent struts have a cross section of 0.3 mm×0.4 mm.

2.2.1. Parallel plate compression (crush test)

Four stents were tested under parallel plate compression at room temperature in a universal testing machine (Zwicki-Line, Zwick/Roell, Germany) with a 2.50 kN load cell. The stents were compressed at room temperature from their nominal diameter until a 5 mm clearance between plates. The displacement of the head was later reversed, allowing self-expansion of the stent. RF and diameter were recorded.

2.2.2. Radial compression

A radial compression test was performed in a radial force machine (RX 650, Machine Solutions Inc., Flagstaff, Arizona) on three homologous stents at 37 °C. A crimping head composed of 12 movable wedges disposed about a rotational axis, crimped the stents from their nominal diameter until 15 mm. The displacement of the head was later reversed, allowing self-expansion of the stent. RF and diameter were recorded.

2.3. Computational simulations

Stent crimping and deployment involves complex contact conditions and large deformations of non-linear material structures that require to reconstruct the stent geometry in its laser-cut configuration and subsequently expand it until its nominal diameter (Fig. A1 B, Appendix A). FE calculations were performed using Abaqus/Standard 6.13 (SIMULIA, Dassault Systèmes). Mesh sensitivity studies were carried out to ensure that all results are independent of further mesh refinements. As the stiffness of the TEHV is orders of magnitude lower than that of the stent, it was assumed that the force exerted by the valve is negligible and only the stent was modeled.

2.3.1. Stent forming

The geometry of an undeformed laser-cut stent was reconstructed according to the manufacturer's specifications regarding tube dimensions, geometry and width of the laser beam. From a planar scheme, a 3D mesh was created. The geometry was wrapped to an initial internal diameter of 3.5 mm and discretized with C8D3R hexahedral elements with hourglass stiffness control. Due to angular symmetry, only 1/20 of
the stent was modeled (Fig. 2A). The super-elastic behavior of nitinol was modeled using a material subroutine, based on the model described by Auricchio and Taylor (1997) (Fig. A2, Appendix A). Local cylindrical coordinates were created and a single node was fixed in the axial and circumferential direction to prevent rigid body motion. Cyclic boundary conditions with 20 repetitions were imposed. The thermo-mechanical forming of the stent was simulated by means of a deformable rigid cylinder, acting as an expanding mandrel. A surface to surface contact algorithm was applied between the inner surface of the stent (slave) and the outer surface of the tool (master). A penalty interaction property and frictionless contact was used. The tool was modeled with SFM3D4R membrane elements. Expansion from the crimped to the nominal diameter was carried out with intermediate annealing steps, imposing a zero stress condition on the stent to erase the loading history. At this first stage, nitinol material properties were assigned according to data provided by the manufacturer.

2.3.2. Stent crushing

A model of half stent geometry covering 360° (due to axial symmetry) was used (Fig. 2B), fixing two nodes in the horizontal direction to avoid rotation. A predefined temperature field of 22 °C was assigned to the stent. Compression plates were modeled as 3D discrete rigid surfaces initially separated by 31.2 mm and discretized with R3D4 elements. Surface to surface, finite sliding frictionless contact enforced by the penalty algorithm was imposed between the compressing plates (master) and the outer surface of the stent (slave). Only vertical displacement of the upper plate was allowed, compressing the stent until a clearance of 5 mm with respect to the lower plate. The distance between the plates vs. the reaction force on the reference point of the upper surface was obtained. Due to the symmetry condition, the force was multiplied by 2 to obtain the final results. The material parameters for the nitinol formulation were initially fitted with experimental crush and crimp tests independently and subsequently adjusted considering simultaneous fitting.

2.3.3. Stent crimping and self-expansion

To minimize computational time cost, the stent geometry was simplified replacing the tilted bridges that linked the struts, by straight bridges (Fig. A3, Appendix A). The rationale to suppress the tilted bridges is to ease the task of reducing the stent geometry to the smallest representative unit. The presence of tilted bridges, that further rotate as the stent expands, induced complicated boundary conditions. The decision to straighten the bridges has shown to have a negligible influence on the outcomes but eases the task of reducing the geometry towards lowering computational time. A deformable rigid cylinder was modeled by membrane elements to simulate a crimping tool. Frictionless contact was assumed between the external surface of the stent and the internal surface of the tool. After crimping, displacement was applied in the opposite direction to allow self-expansion. The stent was crimped to 15 mm to simulate in-vitro RF measurements. In addition, in order to simulate crimping into a delivery system of 18 F, the stent was further compressed to a diameter of 6 mm. A predefined temperature field of 37 °C was assigned to the stent. The material parameters for the nitinol formulation were initially fitted with experimental crush tests and subsequently adjusted considering simultaneous fitting with crush and crimping experimental tests.

Two consecutive stent struts were isolated, imposing axial and circumferential symmetry boundary conditions. When crimping diameters lower than 8 mm are considered, the presence of adjacent struts needs to be considered. For this purpose, by adding two analytical surfaces, one horizontal and another one at 9°, we were able to capture the contact force between struts (Fig. 2C). A frictionless contact between the stent lateral free surfaces and the contact planes was prescribed. The RF of the two-strut model was determined by summing the radial reaction forces (RFsum) of all the nodes of the rigid cylinder (Fig. 3A). To obtain the total RF of the stent, the results of the two-strut model were multiplied by 80 (due to axial and circumferential symmetry). The HF of the isolated stent portion was determined by summing the circumferential forces (HFsum1 and HFsum2) of the nodes on the lateral free surface of the stent portion (Fig. 3B). When the use of analytical surfaces was required, the contribution of the contact force (CF) was included in the HF. To obtain the total HF of the stent, the results of the two-strut model were multiplied by 2 (due to axial symmetry). RF and HF versus diameter curves were obtained varying the number of struts modeled (Section 3.1), crimping diameter and tool discretization (Section 3.2).

2.3.4. Stent deployment

The artery was modeled with C3D8H elements and considered as an incompressible anisotropic hyperelastic material, defined by a strain energy density function proposed by Gasser et al. (2006) (Eq. A1–3, Appendix A) with two families of fibers oriented in a helicoidal manner; fitted with biaxial tensile tests (Cabrera et al., 2013). The material parameters used for the ovine and human pulmonary arteries are included in Table 3. Symmetry boundary conditions were applied in the circumferential direction. The contact algorithm provided master priority to the internal surface of the artery while the external stent surface was the slave. The extremes of the artery were fixed in the longitudinal direction to achieve inflation without length variation. The two-strut stent model was considered and the stent was crimped while a uniform pressure was applied to the inner diameter of the arterial wall. The material parameters for the nitinol formulation were simultaneously fitted with crush and crimping experimental tests. To simulate stent deployment, the contact between the stent and the crimping tool was deactivated on the next step while the contact between the stent and the artery was enabled. To create different
degrees of oversizing, the diameter of the host tissue was adjusted. The initial size of the arteries was defined in such a way that after applying a pressure of 2.18 kPa, in agreement with the mean arterial pressure in ovine pulmonary arteries (Cabrera et al., 2013), the final diameter was 23, 25 and 27 mm respectively. The HF on the artery was determined by summing the circumferential reaction force along all the nodes of the tangential free surface (HFsum) and multiplying the results by 2 (Fig. 3C). The increase in HF due to stenting was calculated by subtracting from the HF of the artery, the HF value after pressurization. During stent deployment, the vessel wall will experience a tensile HF with the stent in compression. Despite the fact that the HF on the artery and the stent differ in direction, they have been plotted with the same sign to depict the equilibrium point. When the stent and the artery become in contact, the increase of HF on the artery is considered null (as only the physiological pressure is generating HF) while the HF of the stent has its maximum value during contact. From this moment on, artery and stent have the same diameter as they expand together, the HF on the artery increases and the HF on the stent decreases. The intersection of the curves determines the equilibrium state.

3. Results

3.1. Effect of geometry reduction

To illustrate the effects that geometry reduction and the adopted terminology may have in the reported RF, a simple exercise was carried out. Crimping simulations were performed, considering different reduced portions of stent (two consecutive struts, four consecutive struts and four consecutive struts mirrored). The RF on the crimping tool and the HF computed on the stent for each stent portion are presented in Figs. 3.3A and 3.3B respectively.

The typical nitinol hysteresis crimp curves can be appreciated in all cases (Fig. A4 A, Appendix A), with forces during loading being higher than during unloading at the same diameter. Since the RF depends both on the axial and circumferential symmetry, an increase in RF is achieved when more struts are added (Fig. 4A). The HF, on the other hand, depends only on the axial symmetry which is evidenced by an increase in HF only when consecutive struts are added and remaining constant when struts are mirrored (Fig. 4B). A comparison between Figs. 4.3A & B shows that the RF is considerably lower than the HF. However, as the full geometry is considered (Fig. 4C), the RF soon becomes higher than the HF verifying Eq. (3.1).

3.2. Effect of crimping diameter and tool discretization

To assess the effects of crimping diameter in the reported RF and HF, crimping simulations were carried out varying the radial displacement of the crimping tool. Additionally, to evaluate the influence of tool discretization, a circumferential seeding defining 56 elements was compared against a 12 element seeding. The nitinol material parameters adopted for this purpose were fitted with experimental crimping tests (Appendix A, Table A1).

Both the RF on the crimping tool (Fig. 5A) and HF on the stent (Fig. 5B) presented a change of slope in the loading curve below 8 mm and the force increased drastically when the stent was further crimped to a size equivalent to 18 F. This characteristic is consistent with experimental results of radial crimping reported by Isayama (2009) and Hirdes (2013). The source of this sudden force increase is self-contact within the struts (the additional increase is not evidenced in the reaction force registered on the stent itself but in a sudden increase of the contact force on the analytical surfaces). It is due to self-contact force increase that the maximum crimping force is not a good indicator of the radial force of the stent. In addition, contact with the artery may occur far from this peak value.

By varying the number of elements along the diameter of the crimping tool, a right-shift of the RF curve was observed when the mesh was coarsened (Fig. 5C). However, the HF on the stent does not seem to be affected by the number of elements of the tool (Fig. 5D). In further sections, the 12 element tool discretization will be used, which is consistent with the number of segments of the iris of the experimental crimping head.

### Table 3

<table>
<thead>
<tr>
<th>Material parameters of hyperelastic anisotropic fiber reinforced arterial model.</th>
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<td></td>
<td>κ [-]</td>
<td>c [kPa]</td>
<td>k₁ [kPa]</td>
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<td>Ovine pulmonary artery</td>
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<td>4.2</td>
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<td>Human pulmonary artery</td>
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</table>

Fig. 3. Computed forces in two-strut model and determination of total forces accounting for full geometry: A) rigid tool; B) stent and C) artery.
3.3. Nitinol constitutive model

Having discussed in depth the implications regarding forces, geometries and boundary conditions of our models, we will focus on obtaining a good resemblance with in-vitro tests. For this purpose, crimping and crush simulations were simultaneously compared with experimental findings and the parameters of the nitinol constitutive model were modified accordingly to reproduce both tests with the best possible level of accuracy. Figs. 3.6A-C show the results of the crush and radial crimping experimental test overlapped with the corresponding simulations for different material parameters.

In Fig. 6A the nitinol model was fitted to the crush test obtaining a remarkable correspondence of numerical and experimental RF results. The typical nitinol hysteresis crush curves can be observed (Fig. A4B, Appendix A). The resulting parameters were used for the crimping simulation, where the resemblance between simulation and experiment was not satisfactory. Conversely Fig. 6B shows the results of fitting the nitinol model with crimping results and applying the resulting parameters to the flat plate compression simulation. Once again, a low quality matching was obtained in the second case. Consequently, the influence of the variation of individual stress and elasticity related parameters was assessed. Since $E_A$ (Young’s modulus of the austenitic phase) is the only parameter that has a significant influence in the crush test, this quantity was fitted first until a good compromise between both experimental tests was obtained. The remaining parameters were modified until a good crimping response was obtained for being this test the most sensitive to stress related parameter variations. Finally, the material parameters were adjusted until the FE simulations reproduced both in-vitro tests simultaneously (Fig. 6C). For a follow-up of the influence of the individual nitinol parameters on the crimping behavior, see Fig. A5, Appendix A.
3.4. Stent-artery interaction

3.4.1. Stent deployment in ovine and human arteries

In these final models, the influence of the artery was included. To illustrate the relevant forces that characterize stent performance, the mechanical properties of ovine and human pulmonary arteries were assigned to idealized cylinders with an internal diameter of 27 mm and thickness of 2.85 and 1.06 respectively (Cabrera et al., 2013), prescribing a low degree of stent oversizing (11%) which falls in the rage of values used in regular practice (García et al., 2012). The evolution of the HF of the stent during crimping and self-expansion, and the artery during stent deployment, were assessed to determine the distinctive features of the stent-artery interaction.

In the HF vs. diameter curve of the stent and the ovine artery (Fig. 7A), the maximum crimping force (CF=7.3 N), the deployment force (DF=2.2 N) and the equilibrium force (EFo=0.5 N) are indicated. When the material properties and thickness of the human artery were considered (Fig. 7B) CF and DF remained coincident, as these forces are inherent of the self-expansion of the stent in absence of any restriction. Nevertheless, due to the higher stiffness of the human artery, the equilibrium force in the human case (EFp=1.1 N) doubles the value of the ovine artery, leading to a lower diameter at equilibrium. Note that for this stent design, EF falls in the zone of austenitic unloading (linear portion of the force vs. diameter curve). Nevertheless, higher oversizing (smaller arteries), results in a displacement of DF towards the zone of low force variation in the nitinol curve (Fig. 7C), following a more gradual HF decrease subsequent to stent deployment.

To anticipate possible clinical outcomes related to the stent-artery interactions previously described, the results of biaxial tensile tests performed in ovine and human pulmonary arteries (Cabrera et al.,

Fig. 6. Crush and radial crimping experimental and computational tests for different nitinol material parameters (absolute values). A) Crush test fitting; B) radial crimping fitting and C) crush and radial test simultaneous fitting.

Fig. 7. Hoop force vs. diameter curve: nitinol stent and 27 mm A) ovine; B) human artery and C) different sizes of ovine arteries.
were further assessed. The stress at failure during biaxial tensile testing, quantified as the maximum circumferential stress before tearing of the sample was evidenced, was compared with the von Mises stress profiles obtained from the simulation of stent deployment in the ovine and human arteries.

In the ovine case, the majority of the samples failed right after reaching values between 50–70 kPa (Fig. 8A, left). A peak von Mises stress of 61 kPa was obtained from the simulation (Fig. 8A, right), which falls within this range. We could speculate that in many cases the stent would damage and puncture the lumen with 11% of stent oversizing. In the human artery, the majority of the samples failed right after reaching values between 260–290 kPa (Fig. 8B, left) which is higher than the von Mises peak stress of 210 kPa obtained from the simulation (Fig. 8B, right). Hence, only in a few cases the stent would damage the luminal side of human arteries of these dimensions, despite the fact that the hoop force exerted by the stent at the moment

Fig. 8. Maximum stress and stent deployment in human and ovine artery. A) Right: experimental circumferential stress when ovine sample tearing was evidenced (percentage of sample failure per stress range), left: von Mises stress in 27 mm ovine artery (distal and proximal) after stent deployment; B) idem with human artery.

Fig. 9. Hoop stress on arteries of different sizes: A) pressurized ovine and B) stented.
of equilibrium is higher than the force when ovine properties were considered.

3.4.2. Oversizing in ovine artery

To evaluate the effect of stent oversizing, we have used the ovine artery. In Fig. 9 the hoop stress of ovine pressurized arteries before and after stenting is visualized for different degrees of stent oversizing. For all cases, blue and red represent the minimum and maximum hoop stress at physiological pressure respectively whereas grey indicates the zones where the hoop stress exceeded the maximum hoop stress at physiological pressure.

The values of HF and RF at deployment and equilibrium for the different degrees of oversizing are displayed in Table 4. With 11% oversizing, the maximum physiological stress is exceeded only at the luminal side and the hoop stress of the stented artery doubles the value of the physiological condition. With 20% oversizing, (RF=16 N) the maximum physiological stress is tripled not only at the luminal side but also across the thickness. Finally, with oversizing values higher than 30%, (RF=17.5 N) the maximum physiological stress is greatly exceeded along all the stented area, reaching the outer surface of the artery.

4. Discussion

4.1. Stent radial force and the methods to determine it

Different in-vitro tests have been performed during the years to characterize stent forces, applying loads in different directions, using diverse terms to define these forces and choosing dissimilar ways to report the results. A similar scenario is found in computational studies where different approaches have been considered to fit nitinol behavior, model the host tissue and report radial forces. As explained in Section 2.1, it is important to distinguish that the values are not directly comparable if the tests used to determine them require the use of forces in different directions.

FE studies usually involve the use of reduced geometries to minimize computational cost. In addition, in many cases, RF is reported as HF or vice versa (Borghi, 2014; Kleinreuter, 2008). As shown in Section 3.1, the use of reduced models can result in an understimation of the RF if the outcomes are not properly modified to account for the complete geometry. Similarly, an overestimation of the RF will occur if the complete geometry has been accounted for but the term RF represents the HF. It is for these reasons that the comparison of stent designs from different studies and correlation of their forces during deployment becomes confusing. It should be possible to clearly distinguish when and how to convert the reported outcomes to obtain the overall force in the desired direction. Hence, for a comprehensive interpretation of the reported outcomes of stent FE models, not only stating the boundary conditions is required but it becomes important to clarify if the reported outcomes correspond to the reduced geometry or indicate how they were extrapolated to account for the adequate force symmetry. This is particularly important for studies that do not include experimental validation or where the validation was carried out on reduced geometries as well. In this way, regardless of the terminology adopted, it will always be clear how the results should be interpreted.

In the present study, to evaluate the performance of the selected stent and its influence in the host artery, two different loading modes were reproduced. Crush loading, reporting full force vs. displacement curves; and radial crimping, reporting full force vs. diameter curves and computing RF and HF of the stent. These computational results could be correlated with crush tests between parallel plates, in-vitro experimental Mylar film tests and radial crimping tests.

4.2. Influence of computational parameters on stent force

The scope of the present study is the computational evaluation of stent designs for TEHV applications, where the force that the stent exerts on the artery is determinate of its capacity to successfully deliver the heart valve prosthesis. Providing a value for the minimum force that a stent should achieve upon implantation to guarantee successful delivery and functionality of the implant, is therefore highly desired. Nevertheless, the evolution of stent force during crimping and deployment is described by a force-diameter curve and therefore reporting one single value to define stent performance should be taken with extreme care.

The influence of tool discretization and crimping diameter in the radial and hoop force curve was discussed in Section 3.2. Even though tool discretization does not have a significant influence on the force outcome, the choice of crimping diameter has a considerable effect on the shape of the RF/HF vs. diameter curve. This study highlights that the maximum crimping force (CF) can significantly increase due to strut self-contact, reaching values that could be several times higher than the stent-artery equilibrium force (EF). Hence, the report of the maximum RF during crimping is not indicative of the interaction that the stent will have with the artery. It is for this reason that CF should not be considered as an indicator of stent performance. On the other hand, CF can give an idea of the force required to push the stent out of the catheter.

In Section 3.3 the effect of fitting modes of the nitinol constitutive model was assessed. As nitinol models fitted with crush tests do not necessarily reproduce radial crimping, a simultaneous calibration such as the work performed by De Bock (2013) is highly recommended. Furthermore, we propose that at least the full unloading force versus diameter curve after crimping is reported to ease future comparison with other stent sizes and designs.

4.3. Effect of stent deployment on the stress pattern of arteries with different mechanical properties

One must be careful to consider that the force of the stent at the estimated size of the host tissue (DF) is representative of the force that it exerts on the artery. Due to the continuous radial outward force of self-expandable stents, this situation only represents the first instant of deployment (when the stent external diameter and the internal diameter of the artery are coincident). Our simulations have shown that this scenario can rapidly change, depending on the stiffness of the artery, leading to a rapid decrease in the force of the stent until equilibrium is reached. A relevant force that can describe stent performance is therefore EF, which is not influenced by the degree of crimping and accounts for the capacity of the artery to restrict the self-expansion of the stent.

Since the material properties of the artery have an undisputed influence on the forces computed with FE models, only accounting for a suitable representation of the host tissue can determine the equilibrium condition that defines the performance of the stent in-vivo. The direct consequences of an inadequate representation of the host tissue

<table>
<thead>
<tr>
<th>Oversizing [%]</th>
<th>Deployment HF/RF [N]</th>
<th>Equilibrium HF/RF [N]</th>
</tr>
</thead>
<tbody>
<tr>
<td>11</td>
<td>2.2 /13.9</td>
<td>0.5 /3.3</td>
</tr>
<tr>
<td>20</td>
<td>2.6 /16</td>
<td>0.9 /5.7</td>
</tr>
<tr>
<td>30</td>
<td>2.8 /17.5</td>
<td>1.3 /8.3</td>
</tr>
<tr>
<td>43</td>
<td>2.9 /18</td>
<td>1.8 /11.2</td>
</tr>
</tbody>
</table>

Table 4 HF and RF at deployment and equilibrium for different degrees of oversizing.
during the optimization phase of the design, could be high forces in the vascular wall, excessive remodeling response/damage and unexpected post-implantation diameters.

Sheep is the preferred model for heart valve research and therefore, accounting for the mechanical properties of ovine tissue, is of paramount importance to design stents that can perform adequately in pre-clinical studies. In addition, computational models provide the possibility to anticipate how the stent may interact with the host tissue in clinical studies. For the use of computational platforms to test stent designs and materials that will be evaluated in animal models prior to human implantation, it is crucial to account for both scenarios in the design phase of the implant.

4.4. Stents with different degrees of oversizing

To finalize, DF can help to understand the adaptive response of arteries to prolonged exposure to supra physiological conditions. A comparison between the force trends identified in our computational study of oversized stent implantation in the ovine model suggests that stent radial forces that exceed 16 N may induce medial damage and that forces of approximately 17.5 N can damage the adventitial layer. Even though these claims remain to be investigated, we could hypothesize that 16 N could be indicative of stent-induced vascular growth and remodeling, since the medial layer of the artery is mainly composed by smooth muscle cells and in response to vascular injury, SMC exhibit loss of contractility and show abnormal proliferation, migration, and matrix synthesis (Kawai-Kowase and Owens, 2007; Lagna et al., 2007). Similarly, we could hypothesize that forces of approximately 17.5 N lead to perforation of the artery.

5. Conclusions

A computational study was carried out to analyze the stent-artery interaction arising from self-expanding stent deployment in heart valve replacement with particular focus on the properties of each component.

This study highlights that vascular adaptation in response to self-expandable stent implantation could vary in pre-clinical (ovine) and clinical studies (human) due to the discrepancy in dimensions and mechanical properties of the host tissue. Furthermore, the deployment and equilibrium forces identified in this study offer relevant information for stent design purposes. The force ranges provided can be considered in future studies to avoid damage due to stent oversizing and hypothesize possible links between stent forces and the adaptive response of the artery.

Acknowledgements

We would like to thank Marco Bartosch from the Deutsches Herzzentrum Berlin for the radial compression tests and pfm medical for providing the planar stent design and information about the material. The research leading to these results has received funding from the [European Community’s] [European Atomic Energy Community’s] Seventh Framework Programme ([FP7/2007–2013] [FP7/2007–2011]) under grant agreement no 242008.

Appendix A1

Pulmonary arteries

See Figs. A1–A5 here.

A)
Nitinol stent

B)
Finite element model.

Fig. A1. A) Nitinol stent and B) Finite element model.

Fig. A2. Stress-strain and stress-temperature curves of nitinol material (ABAQUS documentation).
The strain energy density function for the pulmonary arteries (Eq. (A1)) is represented by
\[ \psi = \frac{1}{2} c (l_1 - 3) + \frac{k}{2k_2} \{ \exp(k_2 E_2^2) - 1 + \exp(k_2 E_2^2) - 1 \} \]

where \( c > 0 \) and \( k > 0 \) are stress-like material parameters, \( I_1 = tr C \) represents the first invariant of the symmetric right Cauchy-Green deformation tensor \( C \), \( k_2 > 0 \) is a dimensionless material parameter and \( \kappa (0 \leq \kappa \leq 1/3) \) describes the level of dispersion in the fiber direction. \( I_{\alpha\alpha} \) are pseudo-invariants of \( C \) and the mean preferred directions of the fiber families (\( \overrightarrow{A}_s \) and \( \overrightarrow{A}_b \)) and \( \phi \) is the angle of the fiber families with respect to the circumferential direction.

\[ E_{\alpha\beta} = \kappa (l_1 - 3) + (1 - 3\kappa)(I_{\alpha\alpha} - 1) \]  

\[ I_{\alpha\alpha} = \overrightarrow{A}_s \cdot \overrightarrow{C} \cdot \overrightarrow{A}_s = f (\phi) \]
Table A1
Nitinol material parameters that fit both tests.

<table>
<thead>
<tr>
<th>Parameter</th>
<th>Crush fit (σC)</th>
<th>Crimp fit (σS)</th>
<th>Both (σB)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Austenite elasticity (E_A)</td>
<td>58000</td>
<td>88000</td>
<td>78000</td>
</tr>
<tr>
<td>Austenite Poisson’s ratio (ν_A)</td>
<td>0.33</td>
<td>0.33</td>
<td>0.33</td>
</tr>
<tr>
<td>Martensite elasticity (E_M)</td>
<td>22000</td>
<td>22000</td>
<td>22000</td>
</tr>
<tr>
<td>Martensite Poisson’s ratio (ν_M)</td>
<td>0.33</td>
<td>0.33</td>
<td>0.33</td>
</tr>
<tr>
<td>Transformation strain (ε_T)</td>
<td>0.0405</td>
<td>0.0405</td>
<td>0.0405</td>
</tr>
</tbody>
</table>

Loading (σ / Tₘₐₓ):
- Start of transformation loading (σ_Lₘₐₓ) = 680
- End of transformation loading (σ_Lₘᵢₜ) = 550
- Reference temperature (Tₘₐₓ) = 22
- Unloading (σ / Tₘᵢₜ):
  - Start of transformation unloading (σ_Lₘᵢₜ) = 320
  - End of transformation unloading (σ_Lₘᵢₜ) = 170

Volumetric transformation strain (ε_Vₘₐₓ): 0.0405

References


Pang, P.Y.K., Chiam, P.T.L., Chua, Y.L., Sin, Y.K., 2012. A survivor of late prosthesi...


