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

María Sol Cabrera*, Cees W.J. Oomens, Frank P.T. Baaijens

Department of Biomedical Engineering, Group of Soft Tissue Biomechanics & Tissue Engineering, Eindhoven University of Technology, De Rondom 70. PO Box 513, 5600 MB Eindhoven, The Netherlands

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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 (Borghi 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

* Corresponding author.
E-mail address: m.s.cabrera@tue.nl (M.S. Cabrera).

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Table 1
In-vitro assessment of self-expandable stent forces in literature. COF=chronic outward force, RRF=radial resistive force, RF=radial force, AA=aortic aneurysm.

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

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.

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 σ_L is a result of the internal pressure acting on the ends of the artery, stretching its length. The circumferential (hoop) stress σ_θ 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 σ_θ according to Eq. (1):

$$\sigma_\theta = \frac{PD}{2t} = \frac{H_F}{A_{hoop}} \tag{1}$$

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

$$R_F = 2\pi H_F \tag{2}$$

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 2π, 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