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The effect of stent graft oversizing on radial forces considering nitinol wire behavior and vessel characteristics

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ABSTRACT

Stent graft fixation in the vessel affects the success of endovascular aneurysm repair. Thereby the radial forces of the stent, which are dependent on several factors, play a significant role. In the presented work, a finite element sensitivity study was performed. The radial forces are 29% lower when using the hyperelastic approach for the vessel compared with linear elastic assumptions. Without the linear elastic modeled plaque, the difference increases to 35%. Modeling plaque with linear elastic material approach results in 8% higher forces than with a hyperelastic characteristic. The significant differences resulting from the investigated simplifications of the material lead to the conclusion that it is important to apply an anisotropic nonlinear approach for the vessel. The oversizing study shows that radial forces increase by 64% (0.54 N) when raising the oversize from 10 to 22%, and no further increase in force can be observed beyond these values (vessel diameter $D = 12$ mm). Starting from an oversize of 24%, the radial force steadily decreases. The findings of the investigation show that besides the oversizing the material properties, the ring design and the vessel characteristics have an influence on radial forces.

1. Introduction

In the treatment of an abdominal aortic aneurysm with a stent graft, the choice of the oversize affects the therapeutic success. Research so far shows a link between stent graft oversizing and post-surgery complications such as prosthesis migration and endoleak type 1, which frequently occur. An endoleak type 1 exists if there is not an overall contact between stent graft rings and vessel wall components. Due to leaky areas, the blood can still flow into the aneurysm sac and therefore the therapy has failed. According to Mohan et al. [1], an increasing risk of endoleak type 1 exists for a stent graft oversize of <10%. Experiments by Schurink et al. [2] show wrinkle formation in the proximal stent graft area, which is caused by extreme oversize and thus prevents a full obturation in the landing zone. A clinical study by Sternbergh et al. [3] showed that a stent graft oversize ≥30% leads to an increased stent migration (slipping of the stent graft >5 mm). Nowadays, there exist stent grafts with and without additional proximal anchorage. Regarding the devices with hooks or bare springs, the radial force is not the most important factor. However, determination of the radial force through calculation of the stent graft vessel interaction can assist the surgeon to determine an oversizing for the stent graft. Thus, the question arises of which stent graft dimensioning is optimal for the specific patient, considering calcification, and if this task performed by the vascular surgeon can be supported by a simulation model.

A stent graft has to have a sufficient fixation in all three landing zones to provide a good long-term outcome [4,5]. The fixation in the proximal landing zone is important to prevent migration and endoleak type 1a. In the distal landing zone, the fixation force is important to reduce endoleak type 1b. The focus of the presented work is the identification of the influence of material parameters and plaque on the simulation result value radial force. Against this background, it makes no difference if the parameter study is performed for the proximal or distal part of the stent graft. The reason for focusing the distal zone in the presented work is in the easier modelling of the geometry of the distal part compared with the proximal body which can have hooks or bare springs for additional anchorage.

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The availability of material parameter for a diseased iliac artery by Holzapfel enables a good approximation of the vessel wall behavior. Usually the finite element modeling process starts with simplified approaches and later increases the level of detail. Therefore, the stent graft covering was first neglected and only one stent ring was modeled. One challenge for the surgeon in EVAR planning is to choose the right limb length and distal diameter which enables a good sealing and fixation. This can be handicapped by thrombus and plaque. Modeling the iliac limb in the distal landing zone is therefore of more interest for the surgeon than modeling the attachment point of bifurcation body and limb which boundary conditions like diameter and length of overlapping zone is usually determined by the manufacturer.

While simulation-based analysis on the interaction of the wire stent (for the treatment of stenosis) and the vessel wall had been carried out by several research teams [6–10], only two relevant papers on the numerical description of the mechanical behavior of a stent graft with Nitinol rings have been detected so far [11,12]. By means of a simplified model, Kleinstreuer et al. analyzed the effects of different material combinations of the stent graft regarding fatigue resistance, radial forces and flexibility. The main focus was on assessing various Nitinol alloys for stent rings and the comparison of PET and ePTFE for the covering of the stent graft. Thereby, only the stent graft had been modeled and vessel wall properties were not taken into consideration. For the sealing section, Kleinstreuer et al. found that the graft material has no significant influence on the mechanical response of the stent wires [8]. Consequently, the limb covering of the stent graft is not considered within this study. Within the first simulation study by Scherer et al., the support of the vascular surgeon during the planning of a stent graft intervention was discussed. Blood pressure, consistency of intima and the existence of plaque were found to be influential parameters for the representation of the interaction between stent graft and vessel. Furthermore, the choice of the respective material models was presented [12]. The fixing force of the stent graft, as well as the contact pressure of the stent ring towards vessel wall and plaque have also been detected as helpful output variables for the optimization of implant selection. In order to represent vessel wall properties as realistically as possible, Scherer et al. used the commercially available materials approach AHYPER with the input variables taken from the material model by Holzapfel [13]. A model which is relevant for planning should contain both a realistic vessel wall and plaque, and the calculation time should be acceptable. Based on these considerations, it must be assessed which simplifications in the model may be carried out without significantly influencing the results. In this context, the requirement by Viceconti et al. concerning modeling in biomedical research must be mentioned, which considers sensitivity studies for the quantification of model uncertainty (inaccuracies in the model) an important task [14]. This model uncertainty, caused by making assumptions and using highly variable input parameters, must be taken into consideration when analyzing simulation results. This article discusses modeling variants with the aim of quantifying the effects of different model approaches on the output variable radial force. Moreover, analysis of possible correlation of radial force and oversize considering superelastic material properties of the Nitinol rings used in the stent graft are presented.

2. Material and method

According to Gebert de Uhlenbrock, the fixing force of the stent graft is made up of the radial forces and the systemic compression force (blood pressure) and takes into consideration the friction couple stent graft/vessel by using a friction coefficient μ with a value of 0.4 [15]:

$$\text{Fixing force} = \mu \cdot (\text{stent force} + \text{compression force})_{\text{radial}} \tag{1}$$

The radial force between the stent and the vessel is influenced by the oversize of the stent graft (stent_o), the blood pressure (Blood_p) and the material properties of vessel, plaque and stent (Vessel_m, Plaque_m, Stent_m), which will be analyzed in the following discussion:

$$\text{Stent force} = f(\text{Stent}_\text{o}, \text{Blood}_\text{p}, \text{Vessel}_\text{m}, \text{Plaque}_\text{m}, \text{Stent}_\text{m}) \tag{2}$$

The calculated radial force depends on the input variables. In this context, a sensitivity analysis was performed to determine the sensitivity of the output variable radial force with regard to the input variables. The above-mentioned requirement towards modeling in a biomedical context by Viceconti et al. was considered, and first results in the identification of model uncertainty were achieved. Within the analysis carried out, the radial force has been calculated for several model variants in order to investigate the influence of material model and material variables.

2.1. Materials approach in the finite element model

For the description of the interaction between the stent and the vessel, the finite element method (FEM) is applied, enabling the representation of the complete nonlinear behavior. Besides the nonlinearity of the material of the stent ring and the vessel, large deformations and the difficulty of contact are considerable challenges for the calculation. The quality of the finite element model is therefore crucial [16]. Hexahedron elements with quadratic displacement behavior are applied, providing a homogenous meshing with the underlying topology. Tetrahedron elements, on the other hand, lead to increased system stiffness. Therefore, hexahedron elements should be applied as long as a representative meshing of topology can be carried out [17]. For more complex geometries (e.g. real vessel from CT scan), the use of four-sided elements may be required.

2.1.1. Stent graft

For the development of the calculation model, the company Vascutek GmbH provided construction and material data of the Anaconda stent graft (see Fig. 1).

In the simulation carried out, a model was applied in which the stent ring diameter matches the frequently used iliac limb L13 × 120 (D_{ring} = 13 mm, length l = 120 mm). The stent ring consists of multiple winding Nitinol wires, which is described by means of a stress–strain diagram. The wire windings with its diameter of d_{wire} = 0.14 mm do not go into the model separately in the form of a bundle, but they are modeled with a wire diameter resulting from the sum of the individual wires. Every wire winding experiences

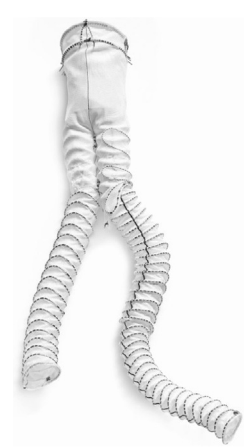

Fig. 1. Anaconda stent graft (bifurcate body with two iliac limbs), Vascutek GmbH.