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Multi-objective optimization of nitinol stent design

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ABSTRACT

Nitinol stents continuously experience loadings due to pulsatile pressure, thus a given stent design should possess an adequate fatigue strength and, at the same time, it should guarantee a sufficient vessel scaffolding. The present study proposes an optimization framework aiming at increasing the fatigue life reducing the maximum strut strain along the structure through a local modification of the strut profile.

The adopted computational framework relies on nonlinear structural finite element analysis combined with a Multi Objective Genetic Algorithm, based on Kriging response surfaces. In particular, such an approach is used to investigate the design optimization of planar stent cell.

The results of the strut profile optimization confirm the key role of a tapered strut design to enhance the stent fatigue strength, suggesting that it is possible to achieve a marked improvement of both the fatigue safety factor and the scaffolding capability simultaneously. The present study underlines the value of advanced engineering tools to optimize the design of medical devices.

1. Introduction

Nowadays, self-expanding nitinol stents are widely used as part of percutaneous minimally-invasive techniques aimed at treating occluded vessels. Unfortunately, several mechanical failures of such a class of devices have been observed [1]; this drawback often results in loss of scaffolding capabilities of the stent, thrombus formation, and restenosis [2,3]. In particular, partial or total stent fractures have been found in aortic [4], renal [5], and pulmonary [6] implants, as well as in lower limb arteries, i.e., superficial femoral artery (SFA) and popliteal artery [7–10]. Therefore, the long-term structural integrity of a given stent model should be one of the principal design parameter to be taken into account.

Given such considerations, it is necessary to optimize stent design performing a thorough engineering analysis, able to assess the relation between the stent geometry and its structural performance. Such an optimization should increase the fatigue strength without penalizing other biomechanical design requirements, such as the vessel scaffolding.

Despite several studies already addressed the analysis of nitinol stents [11–13] and the literature provides some example of stent design optimization analysis [14–19], to the best of our knowledge, only two studies deal with fatigue strength enhancement of nitinol stents [20,21]. Abad et al. [20] proposed a planar lattice for the realization of a stent with smooth cell shapes in order to reduce peaks of strain induced by abrupt changes in the stent geometry. The study proposes a single-objective optimization process to minimize the curvature of the elementary unit defining the stent design, i.e., stent cell. Azaouzi et al. [21] presented a single-objective optimization approach based on Kriging response surfaces; such an approach has been used to improve the fatigue strength of the stent by minimizing the strut volume without decreasing the stiffness of the stent. The algorithm considers the strut geometry (width, length, and thickness) as the design variables to be optimized. Both studies combine *single-objective* optimization methods with structural finite element analysis (FEA).

Moreover, a further literature analysis suggests that: (i) it is possible to enhance fatigue strength acting on the stent cell design but such an improvement has its counterpart in a loss of stiffness [22,23]; (ii) a tapered strut profile enhances the stent fatigue strength, being thus an ideal starting point for the stent design optimization [24,25].

Relying on the previous observations, in the present study we propose a *multi-objective* optimization procedure acting on both stent cell geometry and strut shape to enhance the fatigue strength of a nitinol stent and its scaffolding capabilities. In particular, the optimization framework accounts for non-linear structural

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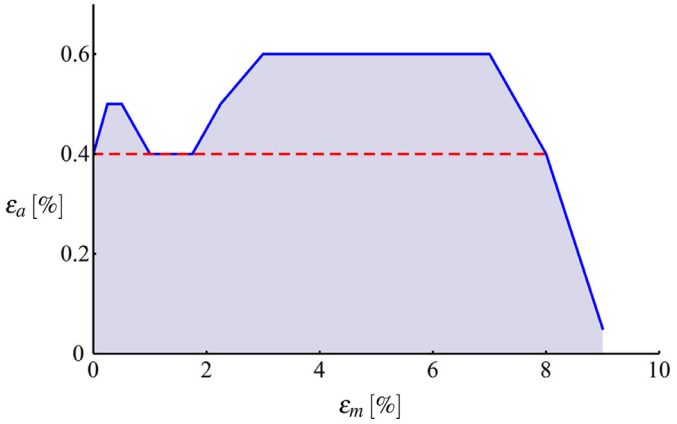

Fig. 1. Constant fatigue life diagram [23,28]: shaded area represents specimens conditions that survived 10^7 cycles while the dashed line represents the value of ε_a, i.e., 0.4%, that we adopt in the present paper as conservative threshold.

FEA combined with a Multi Objective Genetic Algorithm (MOGA) [26] based on Kriging response surfaces.

2. Materials and methods

2.1. Fatigue strength analysis

For the purposes of our study we adopt a strain-based approach, which is the most suitable method to deal with fatigue of nitinol stent, as suggested by Robertson et al. [27]. In particular, in case of time-varying cyclic loads, it is possible to define the mean and the alternating value of the first principal strain, respectively ε_m and ε_a, as:

$$\varepsilon_m = \frac{\varepsilon_{\max} + \varepsilon_{\min}}{2} \tag{1a}$$

$$\varepsilon_a = \frac{|\varepsilon_{\max} - \varepsilon_{\min}|}{2} \tag{1b}$$

where $\varepsilon_{\max}$ and $\varepsilon_{\min}$ are respectively the maximum and the minimum principal strain values in a loading cycle.

As demonstrated by Pelton et al. [23,28], who tested to failure planar diamond-shape specimens under various combinations of ε_m and ε_a, the fatigue strength mainly depends on the alternating value of the first principal strain ε_a. As shown by the diagram depicted in Fig. 1, it is possible to define a conservative threshold of 0.4% for the alternating value of the first principal strain ε_a for any value of mean strain ε_m.

It is worth noting that the damage tolerance analysis (DTA) is the alternative method commonly used for the study of fatigue. Such an approach essentially relies on fracture mechanics and Paris–Erdogan law [29]. As concerns nitinol stents, very few studies have been conducted in order to evaluate the fracture strength and other parameters typical of DTA. One reason is that it holds for values of the flaw size larger than a threshold value below which there is no propagation of the fracture: as reported in Robertson and Ritchie [30] this critical flaw size is about 15–50 μm. Medical devices such as stents have geometric dimensions that are comparable with this threshold value, making DTA useless: it is therefore more useful to focus on prevention rather than on control of the growth of flaws.

For these reasons it can be assumed that the DTA is more appropriate when the typical dimensions of the device are large enough to support the flaw growth or when, for example, the production-process is not sufficiently established to ensure the absence of flaws of critical dimensions [27].

2.2. Stent geometry

In order to define the link between the overall size of a typical "v-shaped" stent and the size of the single cell, it is appropriate to refer to the planar projection of the stent obtained from a virtual unrolling, as illustrated in Fig. 2. In this way, the whole stent design can be thought as a repetition of N cells along the circumference (y axis) and M cells in the axial direction (x axis). For the optimization procedure, we adopt such a simplified planar model. Accordingly, it is possible to define the following geometrical relation:

$$l_c = \frac{\pi D}{N} \tag{2}$$

where D is the outer diameter of the stent and l_c is the length of the unrolled cell in the circumferential direction. Similarly, we have:

$$l_z = \frac{L}{M} \tag{3}$$

where L and l_z are the lengths of the whole stent and of the cell in the axial direction, respectively.

A change, ΔD, of the stent diameter D leads to a variation of the cell height, Δl_c, (see Figs. 2 and 3) that, according to Eq. (2), reads:

$$\Delta l_c = \frac{\pi \Delta D}{N} = 2\delta \tag{4}$$

being δ the displacement, along y-direction, experienced by the single strut and due to a given variation of the stent diameter ΔD. Each cell is made up of three basic elements: strut, link, and crown. Two struts and the crown that connects them constitute the v-shape portion of the planar stent cell [31] as shown in Fig. 2. Fatigue strength and scaffolding do not depend only on the cell geometry but also on strut dimensions (width w, length l, and thickness t) and on its shape (constant cross-sectional profile versus variable one). Thus, we restrict our attention in relating fatigue strength and scaffolding capabilities to such geometrical quantities: lower will be the alternating value of the first principal strain, higher would be the fatigue strength, while higher will be in-plane cell stiffness (ratio F/δ as shown in Fig. 3), higher would be stent scaffolding capability.

To this end, let us consider a v-shape portion of the planar stent cell as shown in Fig. 3, subjected to a total displacement $\delta_{\text{tot}} = 2\delta$ in y-direction resulting from the application of a load F. We consider the strut as a cantilever beam having rectangular cross-section: from simple beam mechanics, under the assumptions of small strain approximation and linear elastic constitutive behavior [22,23], the maximum elongation in the strut is experienced at the outer curvature. The corresponding first principal strain is:

$$\varepsilon = Z \frac{w\, \delta_{\text{tot}}}{l^2} \tag{5}$$

having the value of $Z = 3/2$ for rectangular cross-section. Eq. (5) shows that the principal strain ε is proportional to the strut width w and inversely proportional to the strut length l.

We also consider the opening radial force that a nitinol stent applies to the vessel wall after the deployment, namely the chronic outward force (COF) which, in case of "v-shaped" stents, can be evaluated considering the geometry and the mechanics of the single "v-shape" portion [22,23]. Stent and vessel interact with radial forces, acting along the z-axis in Fig 2, through the external surface of the stent and the internal wall of the vessel. However, forces applied on the vessel wall by a nitinol stent originates from its circumferential stiffness [22,23] and, in the same way, vessel recoil is contrasted by stent internal circumferential forces (y-axis in Fig 2).

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