MULTI-OBJECTIVE OPTIMIZATION OF BIORESORBABLE WIRE-BRAIDED STENTS

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Introduction

Bioresorbable stents are a promising alternative to permanent metallic devices since they naturally degrade and provide vessel support only for the required time, thus avoiding drawbacks in the long-term. Despite the promising results, several design improvements still need to be addressed due to the lower mechanical properties of polymeric bioresorbable stents in comparison to metal devices [1]. Mathematical models were investigated for characterizing the mechanical behavior of metal braided stents, however these models were inadequate to predict the properties of polymer stents due to the excessive simplification of the model assumptions [2]. In this setting, a finite element (FE) based framework is presented for the optimization of the geometry of bioresorbable braided stents in relation to their mechanical performance and associated clinical effectiveness.

Materials and Methods

The procedure applied for the stent optimization consisted of the following steps: (*i*) parametric FE modelling of the stent [3] by considering four geometric parameters (i.e., number of wires *n*, diameter of the stent *D*_s, diameter of the wire *d* and braiding angle *α*) (Fig 1a); (*ii*) FE analysis of the stent crimping with Abaqus/Explicit (Fig 1b) and evaluation of three outputs to measure the device mechanical performance: the radial force at implantation diameter, to determine the stent scaffolding capability, the foreshortening, as indicator for the precise device placement, and the peak maximum principal stress, as a measure for the risk of structural failure of the device; (*iii*) design parameter sampling simulations using the central composite design scheme; (*iv*) generation and validations of polynomial surrogate models of the three outputs; (*v*) identification of optimal stents design candidates by conducting a multi-objective optimization (non-dominated sorting genetic algorithm II) with respect to the four design parameters and three FE outputs. The optimization can be mathematically summarized as:

$$\begin{cases} \underset{\boldsymbol{x} \in D}{\max} f_{RF}(\boldsymbol{x}) \\ \underset{\boldsymbol{x} \in D}{\min} f_F(\boldsymbol{x}) \\ s.t.: \begin{cases} f_{MPS}(\boldsymbol{x}) < 150 \text{ MPa} \\ D = \left\{ \begin{array}{l} \boldsymbol{x} = [n, d, D_s, \propto]: \\ n \in [24, 48] \text{ with } n \in \mathbb{N} \\ d \in \{0.05 \text{ mm}, 0.075 \text{ mm}, 0.10 \text{ mm}\} \\ D_s \in [4.5\ mm, 5.5 \text{ mm}] \\ \propto \in [60°, 70°] \end{array} \right\} \end{cases} \end{cases} \tag{1}$$

where the radial force f_{RF} and the foreshortening f_F are the two contrasting optimization objectives; $\boldsymbol{x}$ is the vector of the design parameters; the maximum principal stress f_{MPS} is accounted as a constraint related to the material yield limit [2]; D is the design space, accounting for the manufacturing constraints.

Results

Fifteen optimal design candidates were identified, lying on the pareto-front represented in Fig.1c. Feasible stress values below the yield limit were obtained for all the optimal design candidates. Radial force values of the FE simulations showed a good agreement with experimental studies conducted on the same polymeric bioresorbable stents [2], thus proving the reliability of the numerical model and optimization approach.

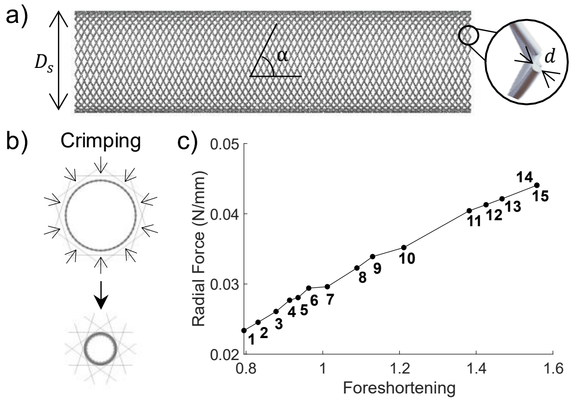

Figure 1: (a) Stent geometry parameters; (b) crimping simulation; (c) pareto-optimal design solutions.

Optimal design	*n*	*D*_s (mm)	*d* (mm)	*α* (°)
1	44	4.5	0.1	60
15	48	4.7	0.1	69

Table 1: Geometrical features of two optimal candidates

Discussion

A validated computational framework for the optimization of the mechanical performance of bioresorbable braided stents was developed within this study, contributing both to accelerate the device design phase and to increase the effectiveness of the treatment.

References

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2. Lucchetti et al., J Mech Behav Biomed Mater, 138: 105568, 2023.
3. Zaccaria et al, J Biomech,107: 109841, 2020.