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Parametrical optimization of stent design; a numerical-based approach

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ABSTRACT

Developing an efficient stent for treating atherosclerotic related diseases requires effective and appropriate methodology for the optimization of its design factors. Present work reports the use of a multi-parameter computer-aided-design (CAD) model for optimization of stent design. A defined aggregate objective function including mechanobiological and haemodynamical objectives which affect stent response in human blood vessel was minimized using the proposed model. FEM results indicate that the stents made of Nitinol can increase the risk of stent restenosis (ISR) and allergic contact dermatitis due to Ni^{2+} ions releasing. Moreover, a drug delivery simulation of Heparin and Paclitaxel, two commonly used drugs in drug-eluting stents, indicated that a conjugated Heparin–Paclitaxel drug is more favorable.

1. Introduction

Coronary stent, a cardiovascular implant used to compress the build-up intravascular cholesterol plaque, improves the blood flow. Stent therapy is more effective method for treating atherosclerotic related diseases compared to classic cardiological practices (i.e. Bypass, Angioplasty, Atherectomy, etc.) especially in complex situations. Identification of the effective optimum design in developing of a stent is a prerequisite for its successful commercial exploitation. This is especially true when this stent have to compete with over than 100 different designs of stents [1].

The geometrical complexity of the stent, limits the use of all standard tests required for a medical device. For instance, strain measurement is a problematic issue for the structures such as stent [2]. In this regards, finite element method (FEM) is a powerful tool for facile evaluation and improving of design prior to clinical trials [3]. Etave et al. [4] used FEM for comparing the performance of two different commonly used stents for quantification the main mechanical characteristics. Berry et al. [5] studied the haemodynamics and wall mechanics of compliance matching stents in a stent–artery hybrid structure both in vivo and in vitro. Migliavacca et al. [6,7] and Petrini et al. [8] studied the mechanical properties and behavior of balloon-expandable stents by the use of FEM. Li et al. [9] estimated mechanical properties of stent by FEM and optimized the design of MAC STENT™ (amg International GmbH, Germany). Azaouzi et al. studied the effect of different geometrical characteristic on the structural and fatigue life of balloon expandable stents by the use of FEM [10,11].

A survey of previous literature on optimal design of stent indicates that a parametric stent design is the main goal and the geometrical parameters have been studied very limited [12–18]. Since the first approval of the drug-eluting stent (DES), the treatment of coronary artery blockage has been dominated by such stents; these include hydrophilic polymers such as heparin and hydrophobic heparin [19]. On the other hand, hydrophobic and hydrophilic drugs require expensive and difficult tests, and consequently computational techniques can be employed as a very cost-effective approach. Zhu et al. [20] introduced a finite volume method for simulating stent drug delivery system and derived an analytical expression which can be used to determine regions in the arterial with higher free-drug concentration than bound-drug concentration. Feenstra and Taylor [21] used a reaction–advection–diffusion (RAD) transport analysis to calculating spatial and temporal drug distribution and concluded that for a period of one week, the drug distributes longitudinally but will remain in the proximity of the stented area.

The aim of current work was to evaluate the geometrical parameters – namely as W_{apex}, W_{bridge} and W_{kerf} – affecting mechanobiological stent characteristics such as von Mises stress over the stent and artery structure, stent recoil and wall shear stress on inner arterial wall tissue. A multi-objective optimization

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methodology was used to optimize the stent based on von Mises criterion regarding the recoil and wall shear stress. Also a drug delivery simulation was developed for the comparison of two commonly used drugs (Paclitaxel and Heparin) for coating on DES in order to reducing the stenting injuries although this drug delivery simulation was not taken into account for optimization process.

2. Materials and methods

2.1. Geometry

For simplification purposes, stent was placed in a straight single-wall cylindrical tube similar to an artery with the inner diameter of 4 mm, thickness of 1 mm and length of 20 mm. The choice of a particular design of stent strongly depends on its service conditions. For instance, for treatment of coronary heart disease stainless steel stents are an appropriate option; while Nitinol stents are more suitable for the treatment of peripheral vascular disease [22].

Generally, in the design of a stent two parts can be recognized as: expandable ring elements in a zigzag pattern and connecting elements called "bridges". In the present work, the geometry of stent were parameterized by SolidWorks 2010 (Dassault Systems, Waltham, Massachusetts, USA) with an inner diameter of 1.693 mm, thickness of 0.111 mm and length of 15.23 mm (Fig. 1).

A multi-parameter geometry is considered for analyzing the stent design. The independent parameters are listed in Table 1 and other parameters are considered as functions of independent parameters.

2.2. Mesh generation

A tetrahedral 20 node element with mean size of 80 μm is employed to mesh the stent geometry. Also, a hexagonal 20 node element with mean size of 70 μm is used to mesh the artery geometry (Fig. 2).

2.3. Mechanobiological simulations

Stent biomechanical response is conducted using a commercially FEM solver, ANSYS 13.0 (ANSYS, Inc. Canonsburg,

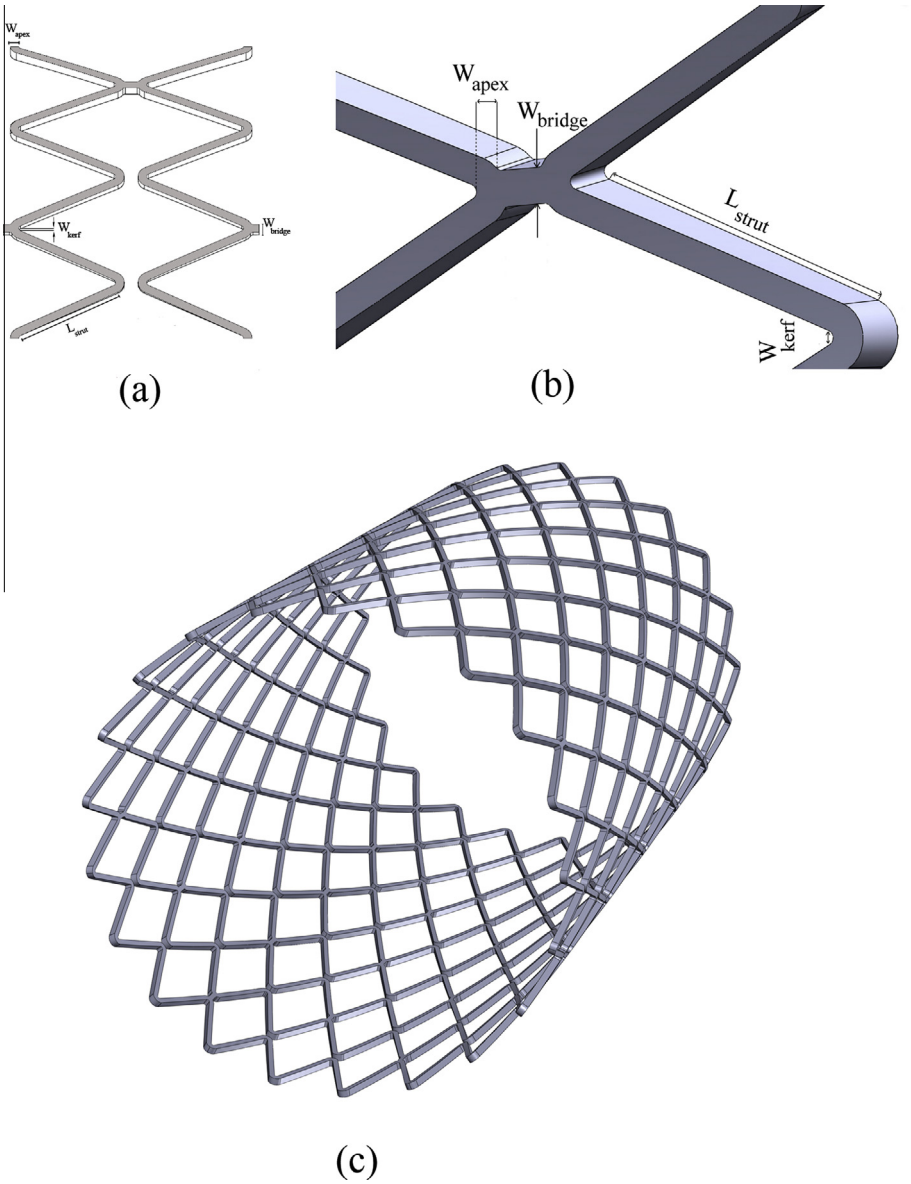

Fig. 1. Typical stent design. (a and b) represent stent's ring and individual parameters and (c) final geometry of stent design.