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Shape optimization of coronary artery stent based on a parametric model

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ABSTRACT

The implantation of intravascular stent (IVS) is a kind of coronary angioplasty to restore the blood flow perfusion to the downstream of the heart muscle tissue. The superior mechanical properties of a stent guarantee the successful implantation. This paper intends to improve the mechanical properties of MAC STENT™ by utilizing optimization theory instead of the conventional trial-and-error approach. In order to achieve this goal, firstly, a reliable procedure of finite element analysis (FEA) is established based on a parametric geometric model. The FEA overcomes the difficulties due to nonlinearities such as elasto-plasticity, large deformation, large strains and contact. It can simulate the stent's deformations during a loading scheme of three phases without any possible failures or irregularities. Secondly, a single objective function, which includes the main mechanical properties of stents, is proposed to replace the initial multi-objective function and then an optimization model is formulated. An optimal design of MAC-J09-3.0 stent is obtained after successful execution of the optimizing process using 41 loops. Its comprehensive mechanical properties are largely improved. It is concluded that the optimization theory is very useful and efficient in the studies of coronary artery stents, although the optimization task encounters many severe difficulties and requires extensive calculation. The result also shows that the single objective function proposed in this paper is practical.

1. Introduction

Coronary artery disease has become the most common cause of death and disability. When excess fatty substance, like cholesterol, deposits on the inner walls of the coronary artery, a plaque appears and a stenosis occurs to the vessel. The stent implantation, namely stenting, is one of the coronary angioplasties to resume the vascular lumen with a minimal surgical invasion to patients.

A stent is a tiny, wire meshed, tube-like metallic structure. Under the guidance of a delivery system, the stent mounted onto a balloon is guided to the site where the plaque narrows the artery. When the balloon is inflated, it drives the stent to expand until a preconcerted deformation has been reached. After the deflation and removal of the delivery system including the balloon, the expanded stent remains in its original position, acting as a scaffold. Therefore, the blood flow perfusion to the downstream heart muscle tissue is restored.

This clinical problem also arouses great interest in the mechanics community. Many experts have a preference for using numerical techniques in their researches of IVS. In comparison with expensive experiments carried out in hospitals and laboratories, numerical simulations accomplished by computers have advantages in both flexibility and cost. A large amount of numerical work is available in recent publications. Chua et al. [2], Dumoulin and Cochelin [6], McGarry et al. [11], Migliavacca et al. [12,13] and Whitcher [17] reported their researches, respectively, into the deployment of various stents without contact effect. Furthermore, Chua et al. [3,4], Wang et al. [16] and Xia et al. [18] considered the contact between the stent and the balloon in the computation of the deformation and stress distribution of the stent. More complicated models considering multi-contacts, i.e. balloon/stent, stent/artery, stent/plaque and balloon/artery, were established to investigate both the mechanical behavior of the stents and the biomechanical response of the coronary artery wall by Chua et al. [5], Gu et al. [8], Lally et al. [9], Tan et al. [14] and Walke et al. [15]. The papers mentioned above investigated what would happen to the stent and coronary artery in a real human heart using an economical method.

By comparing the numerical results obtained from a few different design sets, Etave et al. [7] made suggestions to improve the existing design of a stent. However, the questions are whether their findings are the best design and how to establish an optimal one in a systematic way instead of it being based on a few empirical designs.

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Since the optimization theory is a powerful and practical mathematical technique for determining the most profitable or least disadvantageous choice, out of a set of alternatives in computer science, physics, engineering and other fields, this paper attempts to explore the entire process for shape optimization of a stent and improve its mechanical properties by utilizing the optimization theory.

The optimization task to improve the mechanical properties of a stent has more serious difficulties besides nonlinearities than the ordinary numerical studies which are described in the papers mentioned above.

Firstly, the ordinary numerical simulation demands only an unalterable geometric model, whereas the optimization task requires a parameterized geometric model which is represented by a set of shape design variables rather than constant values. The geometric model has to be rebuilt and re-meshed according to the updated design variables at the beginning of each optimization loop, and then the program starts to search for the solution of the present loop. Hence, information about the design variables should be shared and exchanged easily by all the associated modules including 3D modeling, meshing, FEA and optimization packages, even if they are different commercial codes.

Secondly, the ordinary numerical simulation to investigate the mechanical properties of stents may be carried out by manual operations and different technical software packages can be utilized. For example, Migliavacca et al. [13] built a 3D model by means of Rhinoceros 1.1 Evaluation (Robert McNeel & Associates, Indianapolis, IN, USA), meshed the model by GAMBIT commercial code (Fluent Inc., Lebanon, NH, USA), and then solved the problem using ABAQUS commercial code (Hibbit Karlsson & Sorensen Inc., Pawtucket, RI, USA). Gu et al. [8] developed a 3D geometry of the microstent using commercial code I-DEAS 9 (EDS, Texas, USA) and then searched for the solution by means of ABAQUS 6.3 (Hibbit Karlsson & Sorensen Inc., Pawtucket, RI, USA). These authors completed the entire research step by step by transporting their models among different software. Most of these numerical studies were carried out in Graphical User Interface (GUI) mode. However, the execution of the optimization task must be automatic, which involves both the iterations of the optimization loops and the performance of numerical simulation within each loop. Thus, the migration of the parametric model among different software carried out by manual work is excluded. The optimization task must be executed by an integrated software environment instead, which can call the associated software repeatedly and automatically. This requires that a sound parametric model should be constructed.

Thirdly, during the ordinary numerical simulation, divergence is likely to occur many times, which can be dealt with by selecting the right solving scheme using the researchers' personal experience and professional judgments and then restart the program. It is unrealistic to expect a perfect solving process which does not encounter any divergence. As long as the solution can be found eventually, several occurrences of divergence are acceptable. On the other hand, convergence failure must be avoided as much as possible in the optimization task. As the time-consuming FEA has to be performed once in every optimization loop, too many occurrences of divergence will become a big hindrance to this task. Hence, the stability and reliability of each FEA is significant to the entire optimization process. This implies that the solution control options must be chosen carefully.

Due to these difficulties besides the nonlinear problems, so far as the authors know, the successful application of optimization theory to improve the quality of stents has not been reported. In order to accomplish this ambitious goal, inevitably the authors have to make a technical compromise.

Since ANSYS (ANSYS, Inc, Canonsburg PA, USA) has already developed an optimization module, it is possible to carry out the optimization task using a batch file that contains all the necessary command lines. The whole optimization process presented in this paper is completed by using ANSYS (Implicit Scheme). Therefore, the second difficulty regarding the automatic performance has been avoided and the authors can focus on building a parametric geometric model and a reliable FEA model.

2. FEM implementation and optimization model

2.1. Model geometry

The MAC STENT™ (amg international GmbH, Germany) is of the perpendicular enforced ring design. MAC-J09-3.0, shown in Fig. 1, is the subject of this study. It has an initial length (L_0) of 9.0 mm and an outer radius (R_0) of 0.5 mm for the metallic tube. The metal wires of the stent have a width (W) of 0.095 mm. The recommended expanded diameter is equal to 3.0 mm. All these geometric data of the product are obtained from the official website and the public domain. The authors conduct this research to understand and improve the mechanical properties of stent structures and they are not sponsored or authorized by amg international GmbH. Acting as an initial design of the optimization task, the geometry model of MAC-J09-3.0 is not of the exact size of the real object, but an approximation.

The stent has periodicities in the circumferential (θ) and longitudinal (z) directions in the cylindrical coordinate system. The structure of J09-3.0 can be decomposed into repeatable unit cells, and each cell consists of two different kinds of fundamental structural components: link and wave. The wave component looks like the symbol Ω and its shape control variables are shown in Fig. 2. In this model, all the wires of the stent are filleted at corners with a constant radius of 0.06 mm.

As reported by the papers previously mentioned, the simulation of stenting will encounter serious nonlinearities including elasto-plasticity, large deformation, large strains and contact. The Newton–Raphson method is employed to solve this highly nonlinear problem, and a large number of iterations are inevitable. Furthermore, the optimization task requires further iterations at a higher level: the loops of FEA procedure. If the whole structure of the stent and the balloon is built for simulation, it is estimated that the total amount of computing time consumed by our most advanced microcomputer is a few weeks, which is a heavy workload and not cost-effective.

Most of the authors mentioned above simplified their models by considering the structure's circumferential repeatability and longitudinal symmetry if any of these is available. Xia et al. [18] elaborated on this topic specifically. Similarly in this research, only one-sixth of the stent is modeled due to the presence of circumferential periodicity, and it cannot be simplified further because of the absence of longitudinal symmetry of J09-3.0. With correct periodic boundary conditions, the reduced model with a small number of degrees of freedom (DOFs) will produce equally accurate results as the whole structure. In the following context, the asymmetric distal ends are

Fig. 1. Photograph of MAC-J09-3.0 before deployment.