

Multiobjective robust optimization of coronary stents

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ABSTRACT

Coronary stents are used extensively as a minimally invasive device for unblocking occluded coronary arteries stably. Restenosis is the re-occlusion of the artery post-stent implantation, which can be caused by an injury to the artery during stent deployment with neointimal growth on the metallic stent. The design of stent structure for minimizing the risk of arterial injury and maintaining stent stability involves several competing objectives. These objectives include reduction in dog-boning, foreshortening, elastic radial recoil, and stresses developed in the arterial wall during stent deployment. Another aspect is that the stent insertion and deployment process is subject to variabilities (uncertainties) such as slight movement of the stent on balloon catheter, and changes in stent material properties during manufacturing. Following the nonlinear finite element analyses of a parameterized stent model, in this study, the surrogate models are constructed to formulate the mathematical relationships between the stent geometrical parameters (control parameters) and biomechanical responses. With presence of uncertainties, the surrogate models include both mean and standard deviation components. To address the issue of stent design involving uncertainties, a multiobjective robust optimization is proposed here such that the effects of uncertainties on optimal objectives can be minimized. The Multiobjective Particle Swarm Optimization (MOPSO) algorithm is adopted to generate robust Pareto fronts for an optimal set of trade-offs between the objective functions while ensuring that the effects of the noise parameters are minimal.

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1. Introduction

Coronary stents signify interventional devices with metallic, tubular, mesh-like structures. They are mounted on a balloon catheter, and deployed in the coronary artery by expanding itself to unblock a sclerosed segment. Arteries affected by atherosclerosis will become narrower (sclerosed) due to the build-up of lipids in the vessel wall [29]. This narrowing leads to a reduction in blood flow through the vessel and may cause angina (chest pain) or with more severe sclerosis, lead to heart attacks and strokes [3,5,28].

The stent deployment involves the inflation of the folded balloon which deforms the stent elasto-plastically. Once the stent has been expanded to its desired diameter, the balloon is deflated and the catheter is withdrawn from the body. The stent will recover its elastic deformation and slightly reduce the diameter; this is known as elastic radial recoil. The stent thereafter acts as a scaffold to support the arterial walls to keep the lumen open thereby allowing normal blood flow.

The studies by Rogers et al. [27] and Kastrati et al. [17] through finite element analysis (FEA) and clinical experimentation have shown that stent structure plays an important role in restenosis. To reduce the risk of restenosis, several past studies have attempted to optimize the structure of the stent. For example Migliavacca et al. [23] characterized

the mechanical behaviours of stents and used various metrics such as dog-boning and fore-shortening to measure the adverse effects of stent deployment on damage to arterial and restenosis. The dog-boning refers to a typical final shape of the stent after the deployment, where the end portions of the stent expand more than the central portion, giving the stent a shape that resembles a dog bone. Severe dog-boning could to some extent damage the arterial wall. Fore-shortening refers to the longitudinal shrinkage of the stent when it expands radially; which happens due to Poisson's effect in its traditional mesh-like structure. Significant fore-shortening would affect the area of support and potentially lead to stress concentration [20]. It is generally accepted that these metrics are correlated with the level of arterial injury and stress during balloon and stent expansion in vivo; and together with neo-intimal proliferation due to the presence of the metallic stent, they could potentially cause restenosis [24,34]. As a result, they should be considered in the design optimization of stent.

An article by Li et al. [21] sought to optimize the balloon expandable stent structure by attempting to minimize the dog-boning (DB), fore-shortening (FS) and elastic radial recoil (ERR), where several objective functions were combined into a single cost function. Each of the objectives in this cost function was given a weight chosen subjectively from the author's experience. In the articles by Azaouzi et al. [1] and Azaouzi et al. [2], a self-expandable stent deployment model was created and used to optimize the fatigue endurance of these self-expandable stents. Self-expandable stents differ from balloon expandable stents, since they use a shape memory alloy such as Nitinol [16] and therefore no need to

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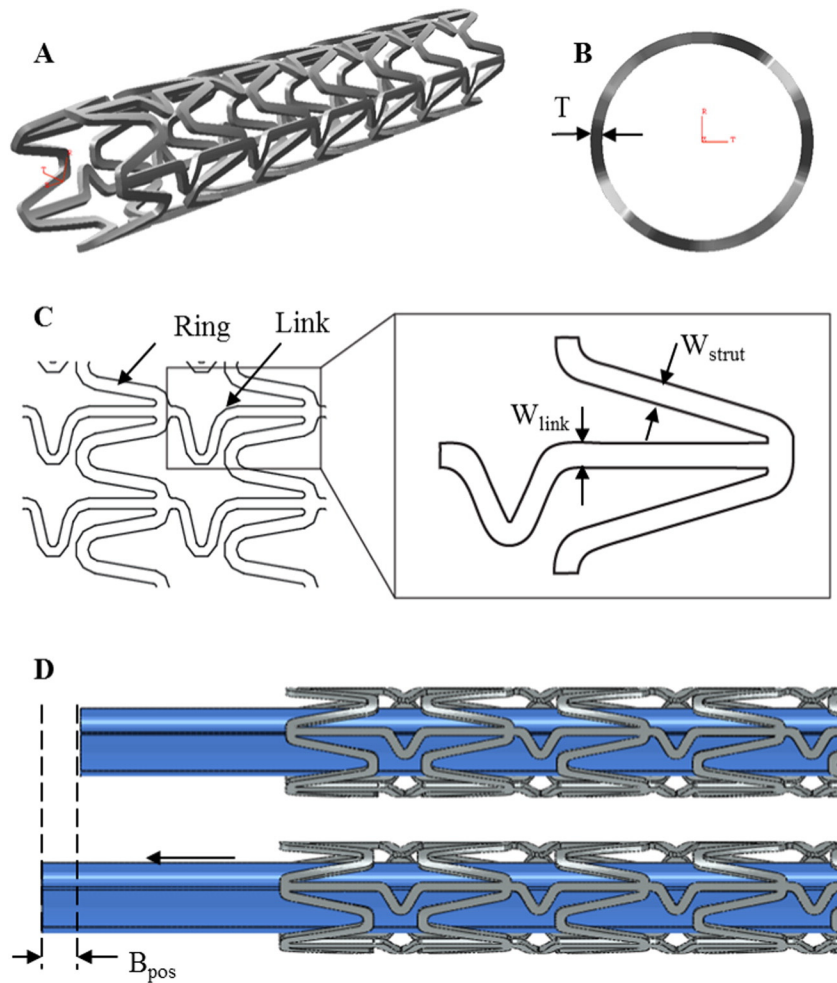


Fig. 1. MAC-Plus stent and parameters used in simulations; (A) Oblique view of MAC-Plus, (B) view along z-axis (axial direction) is used to show the stent thickness, a control variable (T), (C) planar view of the MAC-Plus stent structure and a unit cell showing strut and link widths, (D) noise variable B_{pos} refers to the shift in balloon position.

use a balloon for deploying the stent, though the basic structure and stent objectives are similar for both self-expandable and balloon expandable stents. In their studies also, single objective function, multiple constraint model was used to minimize the stent strut volume, while retaining the fatigue resistance of the stent to pulsatile loading from the artery over time. A surrogate model for the strain distribution was built based on the Kriging interpolation method; and the sequential quadratic programming algorithm was used to obtain the optimal stent strut. In the further work by Pant et al. [26] and Pant et al. [25], a multiobjective optimization of the balloon expandable stent was performed where the structure was optimized for several objective functions simultaneously; and they obtained the Pareto optimum, clearly showing the trade-offs between the competing objective functions in a multi-disciplinary context.

The Pareto plots obtained from the existing deterministic multiobjective optimization provide an optimal set of solutions, assuming that there is no any uncertainty. In reality, there exists a level of uncertainties, such as variation in stent material properties or movement of the stent relative to the balloon during the deployment process causing lopsided expansion of the stent. It is noted that single objective or multiobjective optimization with constraints, typically push the optimum to the boundary of design domain [13]. Presence of such uncertainties can easily violate the design constraints and sometimes significantly degrade the optimization outcomes [32,33]. For this reason, taking these uncertainties and noise factors into account is critically important in design optimization, in which their effects are expected to be minimized, thus assuring the robustness of design optimization. This

study aims to address this issue by developing multiobjective robust optimization for coronary stents.

2. Materials and methods

2.1. Stent modelling

The geometry of the stent considered herein is based upon the MAC-Plus stent (amg-International GmbH, Germany). It is a new generation stent with ring-and-link structure as shown in Fig. 1. The ring architecture allows for not only large radial deformation, but also shortening of the ring along its longitudinal axis. The links extend longitudinally when expanding to counteract the ring foreshortening, thereby improving the flexibility of the stent when manoeuvring the stent to the site of the lesion through tortuous vessels.

The dimensions of the baseline design of MAC-Plus were from the manufacturer, where the stent has a length of $L = 10.990$ mm, a baseline thickness of $T = 0.095$ mm, with a baseline inner diameter of

Table 1
Coefficients for the constitutive model for each layer of the artery [15].

Layer	C10	C20	C30	C40	C50	C60
Intima	6.79E-03	0.54	-1.11	10.65	-7.27	1.63
Media	6.52E-03	4.89E-02	9.26E-03	0.76	-0.43	8.69E-02
Adventitia	8.27E-03	1.20E-02	0.52	-5.63	21.44	0.00

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