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Simulation of longitudinal stent deformation in a patient-specific coronary artery

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ABSTRACT

In percutaneous coronary intervention (PCI), stent malapposition is a common complication often leading to stent thrombosis (ST). More recently, it has also been associated with longitudinal stent deformation (LSD) normally occurring through contact of a post balloon catheter tip and the protruding malapposed stent struts.

The aim of this study was to assess the longitudinal integrity of first and second generation drug eluting stents in a patient specific coronary artery segment and to compare the range of variation of applied loads with those reported elsewhere. We successfully validated computational models of three drug-eluting stent designs when assessed for longitudinal deformation. We then reconstructed a patient specific stenosed right coronary artery segment by fusing angiographic and intravascular ultrasound (IVUS) images from a real case. Within this model the mechanical behaviour of the same stents along with a modified device was compared. Specifically, after the deployment of each device, a compressive point load of 0.3 N was applied on the most malapposed strut proximally to the models. Results indicate that predicted stent longitudinal strength (i) is significantly different between the stent platforms in a manner consistent with physical testing in a laboratory environment, (ii) shows a smaller range of variation for simulations of *in vivo* performance relative to models of *in vitro* experiments, and (iii) the modified stent design demonstrated considerably higher longitudinal integrity. Interestingly, stent longitudinal stability may differ drastically after a localised *in vivo* force compared to a distributed *in vitro* force.

1. Introduction

Percutaneous coronary intervention (PCI) is now the dominant method of revascularisation, with proven symptomatic and prognostic efficacy. Since the introduction of drug-eluting stents (DES) there has been a marked reduction in events associated with stent failure, in particular in-stent restenosis (ISR). However, DES have been associated with allergic reactions, stent malapposition and inflammation leading to early and late stent thrombosis (ST) [1]. Furthermore, there are on-going concerns about the attritional nature of the potential sources of failure of PCI, including ISR, ST and, more recently, longitudinal stent deformation (LSD).

Stent malapposition has been proven clinically to be connected with late stent thrombosis [2,3] and can be categorised into acute malapposition and late malapposition. Clinical studies [2,4,5] have shown that each type of malapposition is connected with several factors, such as reference diameter, balloon pressure, longer lesions, longer stents, more than one stent or stent overlap. In those studies stent malapposition was investigated by intravascular means such as intravascular ultrasound (IVUS) or optical coherence tomography (OCT). When malapposition is observed clinically, post stent deployment with non-compliant balloon dilation is used to further reshape the stent. Such post-deployment techniques, including also re-wiring or IVUS, can potentially contribute to stent distortion. Studies [6–8] indicate that those deformations are more likely to occur when the proximal struts are incompletely apposed.

There has been a well-established association between stent design and adverse events. Factors including particularly strut thickness [9], but also geometry, have been correlated with ISR, ST and LSD. It is apparent that the iterative process of design in DES has led to reduced ISR (along with anti-inflammatory stent coatings)

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Table 1
Stent length, stent alloy and the number of connectors between the circumferential rings of the four investigated devices are outlined.

BMS	Stent family	Nominal length/Un-crimped external diameter (mm)	Strut thickness/width (μm)	Alloy	Number of links
Stent A (based on Promus Element)	Offset peak-to-peak	16/1.78	81/91	Platinum chromium	2
Stent B (based on Xience)	In-phase, peak-to-valley	18/1.78	81/91	Cobalt chromium	3
Stent C (modified Promus Element)	Modified offset peak-to-peak	16/1.78	81/91	Platinum chromium	4-Proximally/2-along its length
Stent D (based on Cypher)	Out-of-phase, peak-to-peak	16/1.78	140/130	Stainless steel	6

Stent family as categorised in Prabhu et al. [12] is also referred.

with reduction in strut thickness, but that an increased reporting of LSD may be a consequence of this evolution [6–8,10]. It is therefore important that new stent designs are tested as thoroughly as possible to detect potential flaws.

To date, there have been two experimental (engineering) studies shedding light on LSD [11,12], and one computational study [13] investigating the longitudinal integrity of small stent segments (two rings) after free expansion, but no patient specific computational studies have been reported. It is likely that sophisticated computer modelling will have an increasing role in this process of validation and testing.

In this study, a patient specific artery segment was constructed from angiographic images; a computer model was developed for the deployment in this segment of different coronary stent architectures based upon one first generation and two second generation DES; post-deployment malapposition was assessed; and the effect of stent malapposition and stent architecture on the response of the devices to a compressive longitudinal force was modelled. The proposed approach allows quantification and visualisation of LSD along the entire length of the model, in contrast to the currently used LSD measurement techniques based on IVUS cross sectional images. We sought to validate this model as a potential tool for assessment of stent design behaviour and to test it using previously reported physical bench testing data.

2. Materials and methods

A patient-specific right coronary artery (RCA) reconstruction was carried out by fusing multiple IVUS frames and two bi-plane angiographic images from an actual case. The geometry segment was reconstructed in IVUS-Angio Tool, a freely available software [14], and Rhinoceros 5.0 (Robert McNeel & Associates, USA), a commercially available NURBS package. Stent designs were created in Rhinoceros 5.0. For the simulations, the commercially available finite element analysis (FEA) solver, ABAQUS/Explicit v.6-12 (Simulia Corporation, USA) was used.

2.1. Geometry, meshes and constitutive models

The vessel reconstruction procedure has been presented in detail in our previous work [15], (and is summarised in Appendix A.1).

Many constitutive models have been used to characterise arteries with the most representative being that reported by Holzapfel et al. [16]. In the current study, the wall of the vessel is modelled by using a hyperelastic, neo-Hookean strain energy function. The assumption was based on the fact that the average material of the vessel wall is plaque and the difficulty to extract the plaque composition from the IVUS images; therefore, constitutive parameters for a soft plaque were selected. The latter is proposed by Wong et al. [17] and its parameters were used within our group previously [18]. Thus, the strain energy per unit of reference volume is

$$U = C_{10}(\bar{I}_1 - 3) + \frac{1}{D_1}(J-1)^2 \tag{1}$$

where C_{10} and D_1 are material parameters related to the shear and bulk moduli ($\mu_0 = 2C_{10}$, $K_0 = 2/D_1$), $\bar{I}_1$ is the first deviatoric strain invariant defined as

$$\bar{I}_1 = \bar{\lambda}_1^2 + \bar{\lambda}_2^2 + \bar{\lambda}_3^2 \tag{2}$$

where the deviatoric stretches $\bar{\lambda}_i = J^{-1/3}\lambda_i$, J is the total volume ratio, and λ_i are the principal stretches.

The vessel was meshed using eight node linear brick reduced integration elements with hourglass control (ABAQUS element type C3D8R). The wall thickness was discretised by two elements. The total number of elements which were used to mesh the reconstructed vessel was 21,214, and 32,019 nodes, based on a mesh sensitivity study (*i.e.* accepting differences of maximum and minimum displacements between coarse and finer meshes less than 2%). The elements were checked for invalid geometry so as to avoid numerical inaccuracies.

For the stents, firstly we generated two balloon expandable stent models whose architecture is closely based upon contemporary stent designs used in the clinical arena. Stent A, which resembles the Promus Element (Boston Scientific, USA), is an ‘offset peak to peak Stent’ and stent B, which resembles Xience (Abbott Lab., USA), is an ‘in-phase, peak to valley stent design’ as categorised in Prabhu et al. [12]. Secondly, we modified Stent A by constructing two additional connectors between the first two proximal hoops (see Appendix A.2) and we model an old out-of-phase, peak-to-peak device, which resembles the Cypher (Johnson & Johnson Co., USA), used by this group previously [19]. Fig. 1A and B depicts the computer-aided design (CAD) generation of Stent B. Both current generation stents were constructed based on the unit strut creation

Table 2
Material properties of the investigated stents adopted by O'Brien et al. [20].

Stent alloy	Elastic modulus (GPa)	0.2% yield strength (MPa)	Tensile strength (MPa)	Elongation (%)	Density (g/cm^3)
Pt-Cr	203	480	834	45	9.9
Co-Cr L605	243	500	1000	50	9.1
316L SST	193	275	595	60	8.0