Analysis and Selection of Bio-Stents Using Finite Element Method

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Abstract: A lot of research has contributed towards the design, optimization, and development of bio-stents for the last few decades. This paper reviews about many existent stents, and suggests an optimized structure of stent that satisfies all constrain functions including stress generation in artery since the arterial cells also have some limitation in enduring stresses both in the longitudinal and circumferential directions. The Finite Element method is employed to determine mechanical properties of stents at various load conditions during its deployment. In addition, the best stent structure among the seven optimized stents reported in the literature is suggested in this work based on the combined behavior of artery and stent, like foreshortening and elastic radial recoil. The selected stent is then modelled and analyzed with stainless steel and Nitinol materials. A unit cell of the stent is considered along with a cylindrical artery to reduce computational time, and the results are reported.

***Keywords*:** Bio-stent, Artery, Finite element method, Structural analysis

1. Introduction

The annual world data of the number of people who died as a result of specific diseases in 2016 shows that cardiovascular disease had taken first place. It reports that 17.65 million people died that year. Stent research has become a recent trend due to its high requirement all over the world. From the bibliometric analysis, 7790 journals and articles have been published from 1986 to 2013. In the Web of Science databases, USA ranks first for contributing 24% of the publications whereas Germany 11% and others 65% [1].

To analyze the best stent structure we collected seven optimized stents structure reported in different pieces of literature and compared their mechanical performance. This analysis is on a single blocked artery.

Stent dimensions depend on individual's artery and plaque sizes but the structure can be of similar shapes, which performs the best. Selection of the best stent is based on defined necessitate functions. There are three important parts in the stent analysis, namely, the stent, the balloon, and a cylindrically shaped artery. One-eighth part of the whole model has been taken for the simulation to reduce computational time.

The Percutaneous Coronary Intervention (PCI) has been well-documented as a lifesaving therapy for patients who are suffering from heart problems and also as a pain-reducing treatment for individuals with multiple blocked arteries who are suffering from angina. In this process, we insert a thin flexible guide wire into the narrowed or blocked part of the coronary artery, after that we push a thin tube called a balloon catheter over the guide wire. Its function is to expand which assists in pushing plaque against the artery wall to reopen the artery and restore the blood flow. A tiny wire mesh made up of superelastic material is placed permanently keeping an artery open, called a stent, and is guided by the balloon catheter. After placing the stent, the catheter is withdrawn from the body.

2. Method

2.1. Stent Model

There are seven models that are considered from the literature and they are named in our work as Model A, Model B, Model C, Model D, Model E, Model F and Model G. The Model A and Model B are parametric optimized design as suggested by Amirjani et al. [2], Model C and Model D have tapered strut profile to reduce strain field along the strut as suggested by Alaimo et al. [3]. The Model E and Model F are based on the reduction of diameter of stent that is necessary when the artery diameter is set but the thickness of plaque is more. To deal such cases, we need lesser diameter of a stent with greater expansion or uncoiling capacity. Thus, the parameters of Model E and Model F are the same as model A and B respectively, however with a difference in the link angle α. The structure of these two models is slightly similar to the ones suggested by Pauck et al. [4]. Model G is based on multi-objective robust optimization [5]. The data available for coronary artery dimensions in an Indian population varies from 2.6 mm to 4.52 mm [6,7]. Therefore, an established artery dimension has taken for appropriate comparison among seven stents. The inner and outer diameter of the artery is 2.8mm and 3.5mm respectively and the thickness of intima, media and adventitia are 0.3, 0.25 and 0.15mm respectively. All the models are shown in Fig.1 and the meshing of parts are shown in Fig. 2. The parameters of the stent are given in Table 1.

Table 1: Input parameters of the strut in mm

Stent	**Outer Dia D_o**	**Thickness t**	**Length l_s**	**Strut width W_s**	**Centerline space C_s**	**Link width W_l**	**Link angle α**
Model A	2.03718	0.22	1.4	0.21	0.4	0.125	11.4°
Model B	2.03718	0.22	1.4	0.13	0.4	0.125	11.4°
Model C	2.03718	0.22	2.0	0.21	0.4	0.18	9.43°
Model D	1.32417	0.18	2.0	0.21	0.26	0.21	0°
Model E	2.03718	0.22	1.4	0.21	0.4	0.125	11.4°
Model F	1.33769	0.18	1.4	0.163	0.26	0.125	0°
Model G	1.32420	0.2	1.7	0.19	0.26	0.125	0°

Table 2: Coefficients of the constitutive model for each layer of the artery

Artery 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	1.2e-02	0.52	-5.63	21.44	0.00

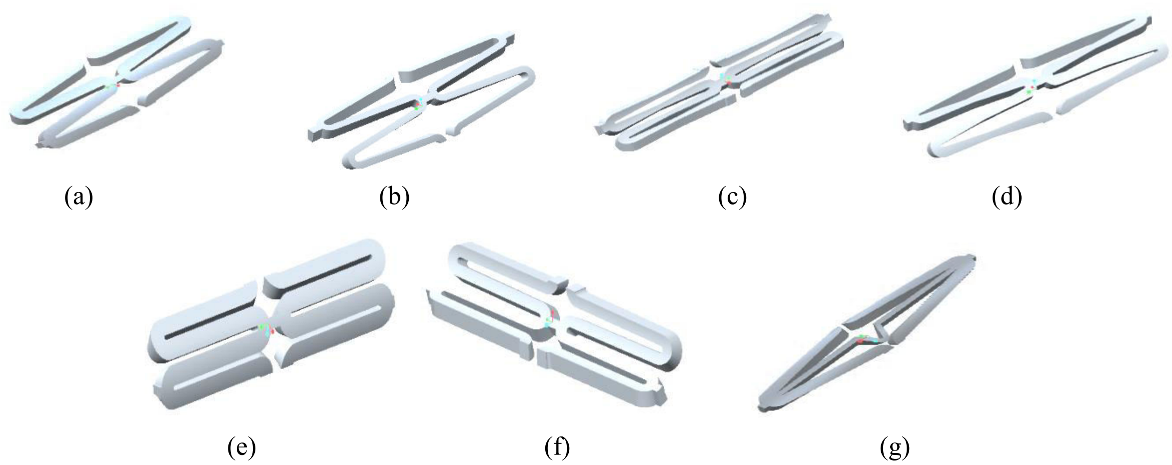
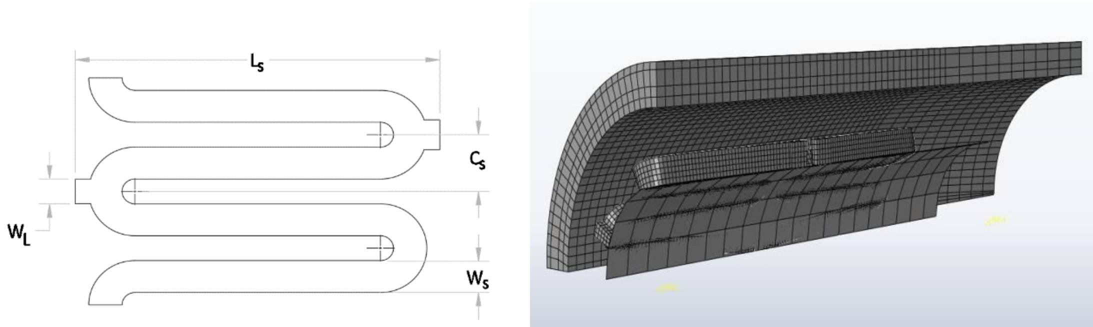


Fig 1: Stent models (a) Model A (b) Model B (c) Model C (d) Model D (e) Model E (f) Model F (g) Model G



(a) (b)

Figure 2: (a) Dimensioning parameters (b) Meshing and Assembly of the artery, stent, and balloon.

2.2. Material

Three layers of an artery called adventitia, media and intima are suitable for incompressible isotropic hyperelastic material behavior. For each layer, the coefficients of reduced polynomial strain energy potential are listed in Table 2 [5]. The six order constitutive equation is described as,

$$U = \sum_{i+j=1}^{N} C_{ij}\left(\overline{I_1} - 3\right)^i\left(\overline{I_2} - 3\right)^j + \sum_{i=1}^{N} \frac{(J_{el}-1)^{2i}}{D} \quad (1)$$

where, I_1 and I_2 are the strain invariants and D_i refers the compressibility. The material will become incompressible if the second term becomes zero in Eq. (1)

An elastic-plastic material such as the stainless steel 316L (SST) [5] and the most biocompatible material Nitinol [8,9] are used to model the stent. Their material properties are compiled in Table 3.

Table 3: Material properties of stainless steel and Nitinol

Youngs Modulus (GPa)	**Density (Kg/m^3)**	**Poisson ratio**	**Yield strength (MPa)**	**Plastic Strain**
		Stainless steel 316l		
196	8000	0.3	205	0
			515	0.6
		Nitinol		
41	6450	0.33	140	0
			895	0.45

2.3. Boundary conditions

The boundary conditions are implemented according to one-eighth part of the model. The radial displacement is specified to the balloon for its expansion instead of using pressure boundary conditions, as per reverse engineering by Jiao *et al*. [10].

2.4. The meshing of The Model

The following elements are used for various parts in the assembly; for stent C3D8R eight node linear brick elements, for balloon SFM3D4 four-node quadrilateral surface element and for artery C3D8H eight node linear brick hybrid element.

2.5. Objective and Constraints

Our objective is to minimize the stress on the stent, arterial stress, foreshortening Khosravi *et al*. [11], elastic radial recoil. The constraint functions are subjected to, maximum circumferential arterial stress ≤ 1.43 MPa [4], maximum longitudinal arterial stress≤ 1.3 MPa [4], recoil ≤ 30% and foreshortened length of stent ≥ length of plaque.

3. Results

After the completion of all simulations, the mechanical parameters such as stress generation on stent's curve part, PEEQ, foreshortening, recoil, arterial stress, and longitudinal stretch or say foreshortening of the artery is extracted from FEA output database (ODB field output). The maximum stress on the stent and artery at each stage are determined.

3.1. Model Comparison

Initially to compare all the models in order to choose the optimized one, the stainless steel is used in all the stents. The model satisfying all constrain functions is considered as the best stent structure among all of them. All obtained results are shown in Table 4 whereas the corresponding contour plots are displayed in Fig. 3.

Table 4: Maximum stress on the stent, arterial stress, PEEQ, foreshortening, recoil for each model of SST

Design Name	Stent Stress (MPa)	Artery Stress (MPa)	PEEQ	Recoil (mm)	Foreshortening stent (mm)	Longitudinal stretch artery (mm)
Model A	307.04	6.49	0.198	0.06	0.101	0.767
Model B	247.27	7.62	0.082	0.1	0.084	0.661
Model C	250.27	8.06	0.088	0.09	0.065	0.901
Model D	241.91	0.33	0.071	0.69	0.028	0.211
Model E	299.85	0.09	0.183	0.30	0.060	0.111
Model F	228.75	0.25	0.046	0.289	0.050	0.164
Model G	275.169	0.435	0.165	0.255	-40E-03	0.167

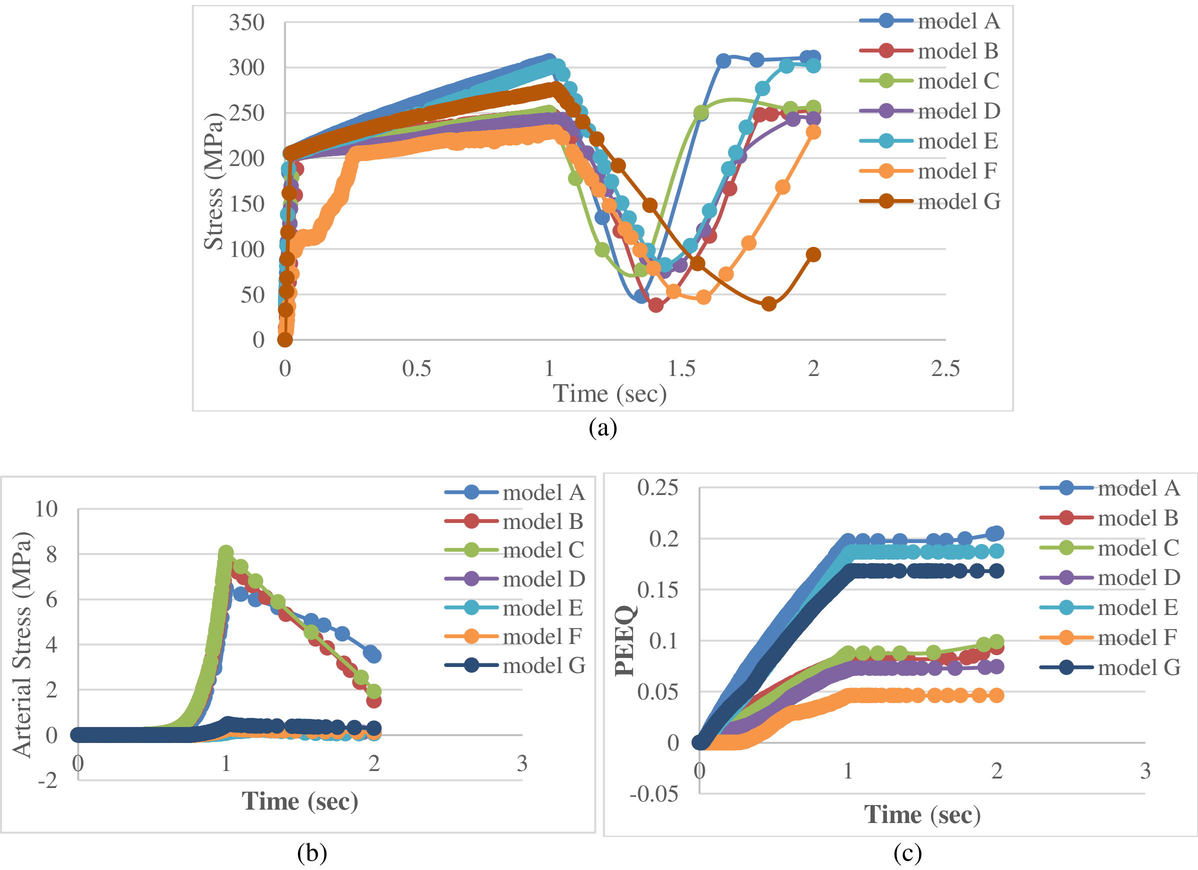


Figure 3: (a) Stress on the stent (b) Arterial stress and (c) PEEQ for all models with respect to time

The negative value of stent foreshortening of Model G indicates that the stent length is increasing. According to our objective, the maximum stent stress should be minimum and hence, the models B, C, D, F, and G are better qualified over the other two models. Similarly, for arterial stress, the models D, E, F and G are better than the other models. As far as PEEQ is concerned, the models A, E and G can dominate the other models. From the stent foreshortening point of view, the models D, E, F and G outshines the other models. For recoil, the models A, B, C, E, F, and G are better than the model D. Finally, for longitudinal stretch of an artery, the models E, F and G outperform the other models. From the above comparison, it is clear that the Model G is the best fit for the stent structure as it has satisfied all constraint functions and objectives.

Now, the Model G of stainless steel is compared with the Model G of Nitinol material restoring the same objective and constraint functions. The comparison result is shown in Fig. 4 and the mechanical properties are listed in Table 5.

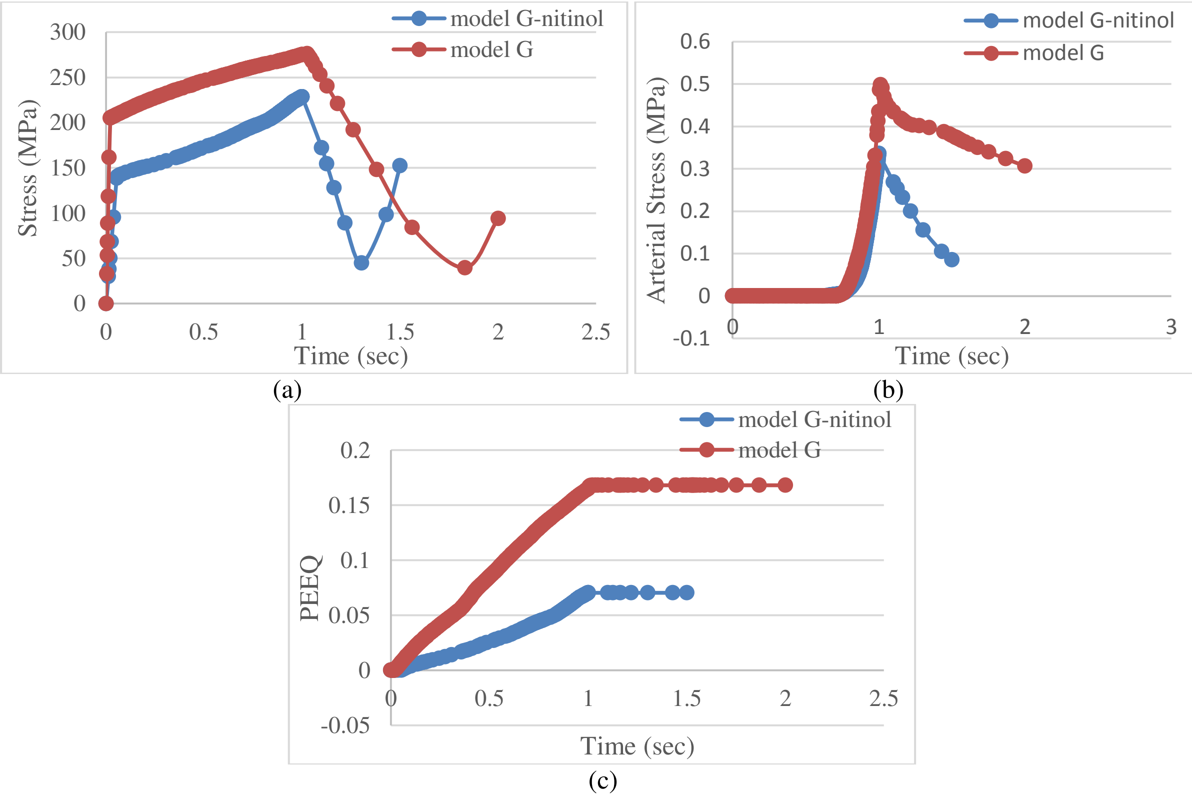


Figure 4: Comparison of Model G between stainless steel and Nitinol materials

(a) stress on the stent (b) arterial stress and (c) PEEQ

Table 5: Nitinol material results

Design Name	Stent Stress (MPa)	Artery Stress (MPa)	PEEQ	Recoil (mm)	Foreshortening stent (mm)	Longitudinal stretch artery (mm)
Model G-Nitinol	228.5	0.336	0.07	0.105	-4.70E-03	0.143

4. Conclusions

In this study, seven stents with varying structures are chosen from literature for comparison to select the best one based on various characteristics of stent. From the analysis, it is suggested that Model G with Nitinol material seems a better choice as compared with other stent models chosen for comparison.

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