



Modelling and stress analysis of cardiovascular stent using finite element method

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Abstract

Cardiovascular stents are commonly applied in angioplasty to mitigate coronary heart disease. A stent is a small spongy tube that's used to treat narrow or weak arteries. They are expanded in the cardiac artery to remove the plaque in order to allow for a smooth blood flow. The high variability of stent failure incidence suggests that it is due to several correlated aspects, such as loading conditions, material properties, component design, surgical procedure, and patient functional anatomy. This can be solved by using suitable biomaterial and models. Using the finite element method (FEM) this study aimed to investigate different stent models and materials such structural steel, titanium alloy as well as other metals or alloys to find suitable biomaterials. A total of four (4) cardiovascular stents model materials of various densities, poisson ratios and Young's Moduli of elasticity were subjected to the testing and investigated using the finite element method. Stainless steel and A-36 Steel seem to be the most suitable in the materials tested followed by titanium and aluminum alloys. PMMA seem to be the list favourable in this investigation.

Keywords: stent, finite element method, biomaterials, model

Introduction

Coronary stents have revolutionized the treatment of coronary artery disease. Improvement in clinical outcomes requires detailed evaluation of the performance of stent biomechanics and the effectiveness as well as safety of biomaterials aiming at optimization of endovascular devices. Stents need to harmonize the hemodynamic environment and promote beneficial vessel healing processes with decreased thrombogenicity. Stent design variables and expansion properties are critical for vessel scaffolding. Biodegradable and bioabsorbable stents go one step further providing complete absorption over time governed by corrosion and erosion mechanisms. The advances in computing power and computational methods have enabled the application of numerical simulations and the evaluation of the performance of stent devices made up of complex alloys and biomaterials in a range of dimensions and designs and with the capacity to retain and elute bioactive agents. This research presents stent biomechanics, from computational modeling approaches. Numerical and experimental non-clinical assessments will be included in the recommendations and thus will be exploited in the analysis of stent performance. Optimization-based simulation methodologies will be developed as well, to improve the fatigue endurance of novel designs. Future developments in stent modeling will most likely include further integration of innovative stent designs and materials in realistic patient-specific models. Such integrated models may even further raise its share in the stent design phase and eventually enter the clinical practice to optimize the coronary revascularization procedure for a specific patient (e.g., as a presurgical planning tool). In the "hunt" for the ideal stent, new stent materials [e.g., cobalt-chromium, superelastic shape-memory alloys, (biodegradable) polymers, magnesium.] are emerging. Each of these materials has a specific constitutive behavior and consequently requires a specific innovative stent design.

These inventive stent designs and materials can and will further be tested and evaluated "in numero" (Matthieu, 2009) [8].

Future developments in stent modeling will most likely include further integration of innovative (braided and tubular) stent designs and materials in realistic patient-specific stenosis models. Such integrated models may even further raise its share in the stent design phase and eventually enter the clinical practice to optimize the coronary revascularization procedure for a specific patient (e.g., as a presurgical planning tool).

Surface characteristics of a stent material, which influence thrombosis and neointimal hyperplasia, include surface energy, surface texture, surface potential, and the stability of the surface oxide layer. In many circumstances a combination of one or more of these listed factors predicts the outcome. The surface properties of stent largely depend on the surface treatment. Structure of stent also influences the surface area and level of trauma that the blood encounters. Surface tension, the residual binding capability of the exposed surface, can affect the hemocompatibility of a material. Blood cells and vessels are negatively charged an isoelectric point between pH 4.8 and 5. The vessel wall being negatively charged causes platelets to be repelled and helps reduce thrombogenic potential. Distribution of charged sites and surface polarity will affect plasma protein absorption to the material. Modification of stent materials in one area may not solve all issues with regard to hemocompatibility. For example, hydrophilic substituents have a stimulatory effect on the complement cascade, but simultaneously have negligible effect on platelet activation. However, hydrophobic substituents show a reduced complement activation, but stimulate platelet adhesion. Generally, blending or mosaics are used to balance hydrophilic/hydrophobic properties to improve hemocompatibility (Liu, 2018) [4].

Stent material is divided into two groups: metal and polymer. The term metallic material encompasses nitinol, stainless steels and other metallic alloys. The term polymer material includes nylon, polyurethane and other polymers. The category of metallic stent is also divided into two types of expansion methods: a self-expandable type and a balloon expandable type. Nitinol stent is a self-expandable type due to its SE characteristics (Ohkata, 2011) [5].

The pursuit of discovering a material with ideal surface properties and essential mechanical properties is a continued work in progress, particularly in the case of cardiovascular stent materials. The current generation of stent materials tends to trigger various adverse reactions such as inflammation, fibrosis, thrombosis, and infection. Most of these issues arise due to interface problems between the stent surface and its immediate environment. The main focus of most research groups therefore lies on modifying the surface of materials without altering the bulk properties. Most polymeric materials already possess the proper bulk properties, for instance, light weight-to-volume ratio, exceptional corrosion resistance, easy processing and molding, and excellent mechanical properties. Altering the surface properties of the already available polymers is therefore the most followed approach. Various surface modification methods have been studied extensively, resulting in enhancement of the hemocompatibility by decreasing either late-stage restenosis or acute thrombogenicity (Rankumar, 2018).

Titanium alloys have found application in a range of biomedical materials because of their favourable corrosion resistance, biocompatibility and mechanical properties, although they have not been widely accepted as stent materials (O'Brien *et al.*, 2008). However, studies of coatings of titanium-nitride oxide produced on stainless steel stents using physical vapour deposition in a mix of oxygen-nitrogen gas have been demonstrated to reduce neointimal hyperplasia compared to bare stainless steel stents in a porcine restenosis model (Windecker *et al.*, 2001). The efficacy of the coating in attenuating the neointimal proliferation was mainly attributed by the authors to its electrochemical properties. The 'TiNOX' stents have subsequently undergone clinical trials. In 2005

Windecker and colleagues revealed 2005). In 2006, Karjalainen and colleagues compared stainless steel stents coated with titanium-nitride oxide with a paclitaxel eluting stent and demonstrated that both stent types produced favourable outcomes with infrequent need for repeat interventions in high risk patients (Karjalainen *et al.*, 2006). In 2008 the same group reported a 12 month follow-up to the TITAX AMI trial which concluded that the titanium-nitride oxide stents resulted in comparable clinical outcomes when compared with paclitaxel eluting stents in patients treated for acute myocardial infarction (Karjalainen *et al.*, 2008) and more recently report on the two and three year follow-up study on patients treated for acute MI have indicated an improved clinical outcome following implantation of the TITANOX stent compared with paclitaxel eluting stents (Karjalainen *et al.*, 2009a) and reduced the need for target vessel revascularisation (Karjalainen *et al.*, 2009b).the results of the TiNOX trial which concluded that re-vascularisation with the titanium-nitride oxide coated stents was safe and effective in patients with de novo native artery lesions and that the coatings reduced restenosis and major adverse cardiac events when compared with stainless steel counterparts (Windecker *et al.*,

Materials and methodos

This chapter describes the materials and methods used for the investigation to achieve the stated objective for this research.

1. Materials

1. A computer Aided Design (CAD) model of a stent was created using SolidWorks CAD designer.
2. ANSYS, finite element analysis software is used for simulation of the stent biomechanics.
3. The materials and their properties are presented in Tab. 3.1

| Number | Materials | Young's modulus | Poisson ration | Density |
|--------|------------------|-----------------|----------------|---------|
| 1. | Structural Steel | 2E +11 | 0.3 | 7850 |
| 2. | A-36 Steel | 2E +11 | 0.26 | 7800 |
| 3. | Aluminum | 7.05E +10 | 0.342 | 2300 |
| 4. | Ti-6Al-4V | 1.16E +11 | 0.342 | 4430 |
| 5. | PMMA | 2.60E +10 | 0.4 | 1100 |



Fig 3.1: Imported stent model

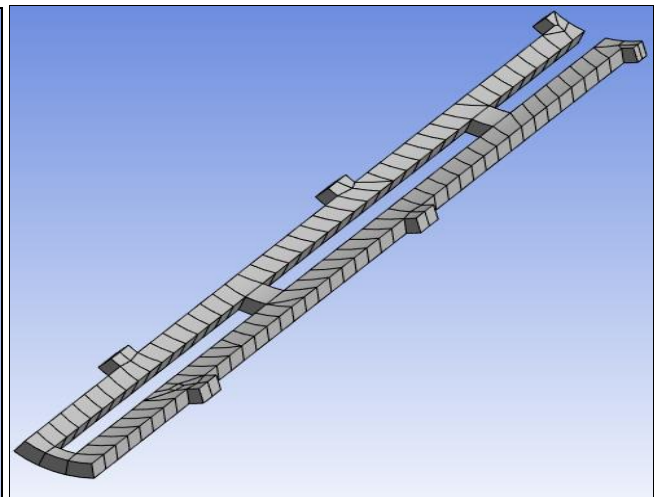


Fig 3.2: Hexahedral mesh of model

Methods

The stent model is developed in SolidWorks thereafter it is sliced into piece such that just a fraction of the model is used to reduce simulation time. The model is then imported into the ANSYS workbench. Meshing is done with a simple hexahedral of 1249 nodes and 111 elements to discretize model.

Specification of material properties are the material properties supplied to the software from Tab. 3.1. Stress-Strain value for each material is included in the simulation to generate yield point as well as strain hardening. A balloon-pressure of 100Pa is applied to the surface of the stent to cause plastic deformation.

Expected results

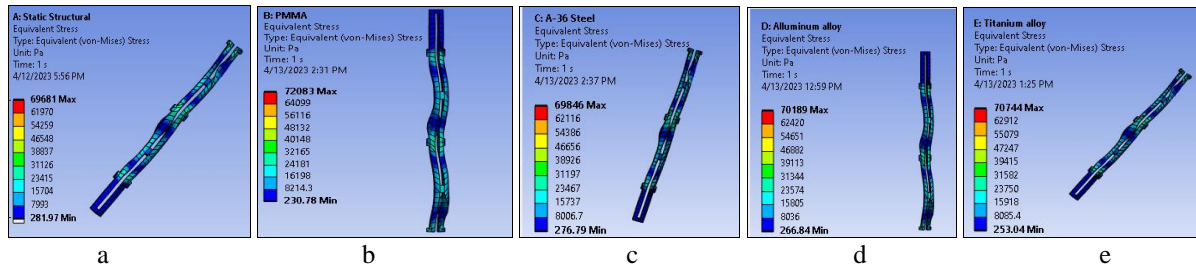


Fig 4.1: Equivalent Stresses: (a) Structural Steel (b) PMMA (c) A-36 Steel (d) Alluminum Alloy (e) Titanium Alloy

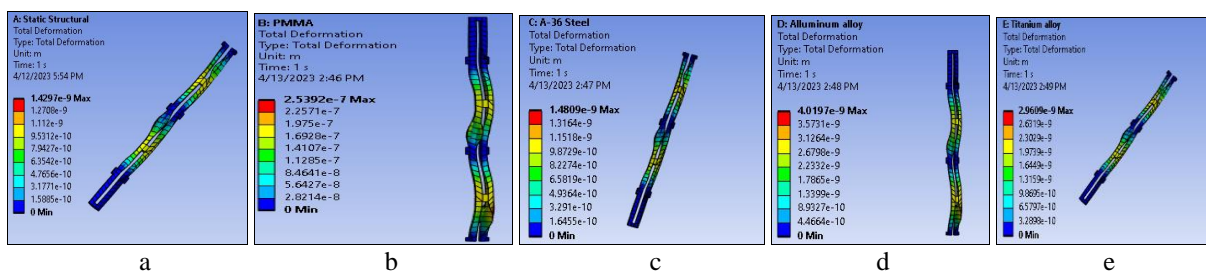


Fig 4.2: Total Deformation: (a) Structural Steel (b) PMMA (c) A-36 Steel (d) Alluminum Alloy (e) Titanium Alloy

Table 4.1

| Materials | Average von-Mises Stress | Average Directional Deformations | Total Deformations |
|------------------|--------------------------|----------------------------------|--------------------------|
| PMMA | 10903Pa | -3.26x10 ⁻⁸ m | 6.96x10 ⁻⁸ m |
| Aluminum Alloy | 10978Pa | -5.09x10 ⁻¹⁰ m | 1.08x10 ⁻⁹ m |
| Titanium Alloy | 10952Pa | -3.36x10 ⁻¹⁰ m | 8.00x10 ⁻¹⁰ m |
| A-36 Steel | 10995Pa | -1.88x10 ⁻¹⁰ m | 3.99x10 ⁻¹⁰ m |
| Structural Steel | 11004Pa | -1.81 x 10 ⁻¹⁰ m | 3.85x10 ⁻¹⁰ m |

Discussion

Stent biomaterials research is of vital importance in development of stent due to reaction between materials of stent and the internal environment of the body. Biodegradable, bioabsorbable as well as safe materials must be considered. Also requiring consideration is the plastic properties of materials. Material hardening is an important scaffolding property to ensures that the stent does not collapse after the balloon has been introduced in the affected area. Also important is the need for the material not to fracture due to overstretching. Thus, the need for material with suitable plastic properties. Although the four main materials used for stent currently are Tantalum, Stainless Steel, Nitinol and Cobalt Chromium this-articles investigates some more materials such as Aluminum alloy, A-36 Steel, Structural Steel, Titanium alloy and PMMA. Table 4.1 show us that all materials tested were within their yield point with same pressure applied (von-Mises stress). Structural Steel has the highest amount of average directional deformation and equivalent stress as well as lowest total deformation followed by A-36 Steel. These two materials seem to be of more suitable physical properties for

stent design amongst the materials tested in this research. These are followed by Titanium and Aluminum alloys and lastly by PMMA.

Recommendations

The research in stent biomaterials is ongoing and development is being made at rapid pace. More material properties, bio-properties, cheap properties as well as locally sourced properties should be investigated in future researches to enable patients get the best treatment as doctors make better decisions based on available data.

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