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NUMERICAL STUDY ON MECHANICAL PROPERTIES OF STENTS WITH DIFFERENT MATERIALS DURING STENT DEPLOYMENT WITH BALLOON EXPANSION

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Abstract: Remediation of the diseases like stenosis, aneurysm with percutaneous transluminal stent angioplasty is an important field of study in medical and bioengineering research. The main reason for stent implantation is to provide mechanical support to the arterial wall. So it is important to consider the different mechanical properties of different stent materials while studying the stent's efficacy. Inappropriate mechanical properties might cause damage to the vessel wall. The present study gives a comparative overview of mechanical behaviors of different stent materials most commonly used. Deformation process has been studied numerically for different stents with finite element analysis model. COMSOL Multiphysics version 3.5 (Structural Mechanics Module) has been used for computational modeling. Different materials of stents are used like 316L Stainless steel, Nitinol (nickel, titanium), Elgiloy (Cobalt-Chromium). With the parametric loading of stent with a specific radial pressure, the deformation of stent diameter has been continuously monitored. With the stress-strain analysis, it has been detected whether there is a chance of fracture of the stent of a particular material.

Key words: stent, coronary artery, finite element analysis, angioplasty, stress strain analysis, stent fracture

Introduction

Percutaneous transluminal coronary angioplasty (PTCA) is a largely used method for treatment of cardiovascular disorders like stenosis and anurysm where small metallic stents are deployed in the coronary arteries with balloon expander catheter. Coronary stents are smooth metallic mesh structures (tubular or coil) which provide mechanical support to the artery wall. The principal advantage is that they do not require open heart surgery. During the procedure, a stent is deployed in the blood vessel using a catheter with balloon expander. Once placed, the balloon is inflated to expand the stent. Then the balloon is removed, and the expanded stent continues to act as a scaffold to keep the artery open.

Stent design as well as the study of mechanical behavior of stent material is significant in the procedure. Fracture can be initiated in stent when initial deployment pressure is applied. The study of stress developed inside stent and deformation of stent boundary is important.

There are several studies made in the last decade on mechanical behaviors of stent materials. Mechanical properties for appropriate stent fabrication, the properties like radial strength, elastic modulus have studied [1]. Mechanical properties were studied by mathematical modeling with determination of stent deployment pressure, intrinsic elastic recoil etc. in order to compare the performance of tubular stent and coil stent [2]. The deformation pattern and the stress distribution of the entire stent have been studied with a repeated unit cell approach of finite element analysis [10].

In the present study, focus has been given to the stress and deformation characteristics of four different stents made of different materials. The stent geometry and deployment pressure value have been kept constant for each stents. Comparison has been made for the obtained von mies stress and integrated deformation. Results also help in to decide the best material to choose in order to obtain the desired performance.

Method

Medical Stent Data Study

Various kinds of stent data have been studied which are widely used in the cardiovascular treatment. The mechanical properties of different stent materials are shown in the below table (Table 1). In this study, four stent materials have been chosen. The stent geometry and deployment pressure value have been kept constant for each stent. In general, the geometry of Palmaz-Schatz Balloon Expandable Stent (J&J, Warren) has been chosen for the study. It has a hollow slotted tubular structure; the tube is made up of 6 identical units, each unit of 2 solid metal struts and 2 openwork struts (Figure 1 a, b).

We will briefly discuss here the materials selected in this study. The material used in stainless steel stent is 316 L annealed stainless steel with 17% chromium, 12% nickel, and less than 0.03% Carbon. The second selection, nitinol, is an alloy of 55% nickel and 45% titanium. This alloy is also known as shape memory alloy. Shape Memory Alloys or SMAs are materials which have the ability to return to a predetermined shape when it is heated. When it is cold, it has low yield strength. So, it can be deformed into any new shape. It will then retain that shape. Nitnol can be austenite or martensite. Here we have chosen austenite nitinol. It has lower value of ultimate tensile strength. So, it will help in benchmarking when we will study the stent fractures and stress analysis in this review. The third selection, Elgiloy, is an alloy of cobalt(40%) and Chromium (20%). It has high ultimate tensile strength, so it can withstand high stress and large deformation. Our forth selection of material is pure tantalum metal.

Computational Modeling

We have selected four models of stent made of four different materials which are discussed above. The geometry of four stents are similar (also discussed in the above section). The stents are with same length (8 mm) and same initial diameter (1.37mm). For computational simulation of geometry, we have used here the predefined model of biomedical stent provided in the COMSOL Multiphysics structural mechanics model library (Courtesy: COMSOL® v3.5 Multiphysics Structural Mechanics Module) (Figure 1 (c)). Only one quarter of full stent geometry has been used in the model.

Physical Model Specifications

The physical properties of four different stent materials have been given in the table below (Table 2). The values of different materials' young modulus, poisson's ratio, yield strength, isentropic hardening modulus, and density have been specified in the computational model. The model has used the physics mode of structural mechanics module solid stress-strain setting.

Boundary Conditions

Symmetry boundary conditions have been applied to prevent rigid body translation in the y and z direction and rotation around all coordinate axes.

Point Setting

A point constraint has been applied in the x direction to prevent rigid body translation in this direction. .

Loads

Clinical data shows that a radial outward pressure with standard value of 2 atmospheres is required to inflate the balloon to deploy the stent in the coronary artery. So, in the present study, a same value of radial outward pressure has been applied to the inner surface of the stent. During loading, the pressure has been increased with the parametric solver to a maximum value of 0.3 MPa. It is followed by decreasing the pressure load to zero. At this time, the final shape of the deformed stent has been obtained.

Equation

A normal load has been applied here which acts radially outward on the stent wall. Following is the equation for load:

Load_max*((para<=1)*para+(para>1)*(2-para)).

Mesh generation

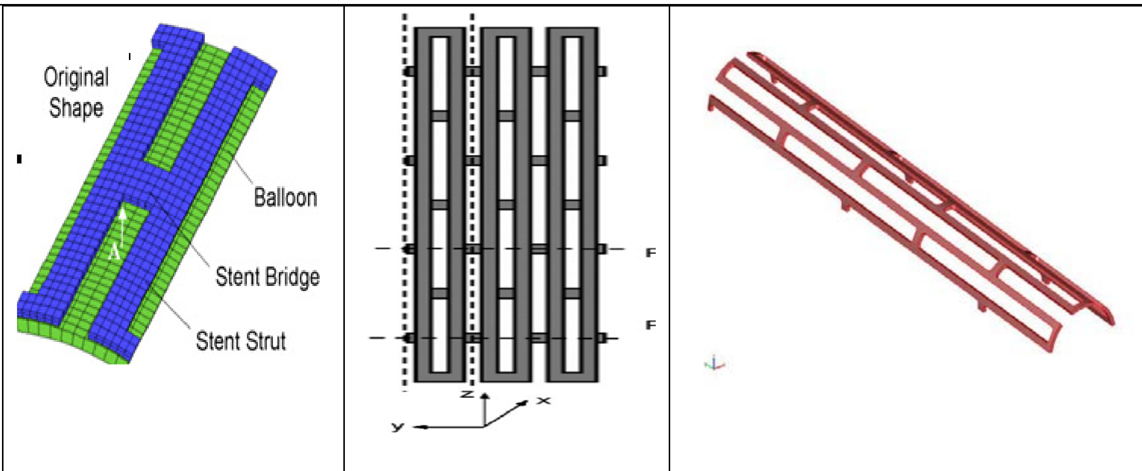
The predefined fine mesh size has been used to mesh the geometry with the free mesher. Total number of generated tetrahedral elements is approximately 7300.

Solver

Parametric solver has been used. The details of solver parameters have been mentioned below. In solver output, three dimensional deformations and von Mies stress developed in the stents have been chosen.

Table 1

Metal	Composition, wt%	Elastic modulus, GPa (Msi)	Tensile strength σ_ε, MPa (ksi)	Ultimate tensile strength $\sigma_{u\lambda\tau}$, MPa (ksi)	Elongation, %	Poisson's ratio	Yield Strength (Mpa)	Isentropic hardness modulus (GPA)	Dens (kg/m
316 L Stainless Steel, Annealed	17Cr, 12Ni, 2.5 Mo, <0.03C, balance Fe	193 (28)	260 (38)	550 (80)	50	0.3	300	2	7
Nitinol (Austenite)	55 Ni - 45 Ti	83 (12),	195 to 690 (28 to 100)	960	25 to 50	0.3	560	1	6
Tantalum	Pure	185 (27)	165 (24)	205 (30)	40	0.35	170		1
Co-Cr-Mo Alloy (Elgiloy) Heat treated at 525 c for 5 hours	40Co, 20 Cr, 7Mo, 15.5Ni, 2Mn, 1Be, 0.15C, balance Fe	190 (28)	690 (100)	1020 (148)	38	0.226	520		8



(a)	(b)	(c)

Figure 1: (a) A single unit for the Palmaz-Schatz stent before expansion (Courtesy: Zihui Xia et. Al [10]), (b) the roll-out geometry of stent in rectangular coordinates in 2D plane (ZY) (Courtesy: Zihui Xia et. Al [10]), (c) One quarter of stent geometry (Courtesy: COMSOL® v3.5 Multiphysics Structural Mechanics Module)

Table 2

Stent Type	Young modulus	Poisson's Ratio	Ultimate Tensile Strength	Yield Strength	Density	Length	Diameter (Mounted)
Stainless Steel	193	0.3	550	300	7850	8	3.681
Nitinol	83	0.3	960	560	6478	8	1.568
Elgiloy	190	0.226	1020	520	8300	8	1.483
Tantalum	185	0.35	205	170	1669	8	3.681

Parameters:

Following 23 load parameters have been used. These parameters describe the stent loading with balloon inflation from the crimped position and the unloading (Parameters - 0.0, 0.3, 0.35, 0.4, 0.45, 0.5, 0.54, 0.58, 0.6, 0.62, 0.64, 0.68, 0.72, 0.76, 0.8, 0.84, 0.88, 0.92, 0.96, 1.0, 1.05, 1.5, 2.0).

Results

The results obtained for each stents in terms of von Mies stress and maximum radial displacement are shown in the below table (Table 3). It is observed that the stress developed is of the lowest value in case of nitinol. Also, the maximum displacement values are less in case of nitnol and elgiloy. For stainless steel and tantalum materials, the maximum displacements

Table 3: Maximum von Mies Stress and Maximum Displacement

Sl. No.	Materials	Max. Von Mies Stress (Mpa)	Maximum Displacement (mm)
1	Stainless steel	939.1	3.681
2	Nitinol	762	1.568
3	Elgiloy	847.3	1.483
4	Tantalum	939.1	3.681

are of higher values, which may pose a risk that coronary artery wall might be damaged due to large value of deformation.

Deformation comparison

The integrated deformation value is the lowest in case of elgiloy; the deformation value of nitinol is also acceptable. The values in case of stainless steel and tantalum are too large for an coronary artery stent deployment.

Table 4: Comparative values of deformations

Stent	Stainless Steel	Nitinol	Elgiloy	Tantalum
Deformation (m3e-8)	2.64	0.9	0.67	2.64

Detailed Results of each Stents

Diameter deformation plot: The integral deformation of stent boundary has been plotted in the graph against load parameters (Figure 3). It can be noted that the pattern of nitnol and elgiloy stent deformations are similar though deformation values are different in both cases. Similarly the deformation patterns of stainless steel and tantalum stents are similar.

Study of stress developed and fractures

The values of stress experienced by each stent have been shown in table 4. In comparison with the material's ultimate tensile strength, it can be concluded whether fracture will be initiated in the stent or not. The comparison in the table shows that in case of nitinol and elgiloy stents, no fracture will be initiated. But in case of stainless steel and tantalum, fracture will be initiated.

The below figures (Figure 4) show the locations in the stent where high stress concentration will occur and thus stent fractures (marked in red circle). Figure 4 (a) shows that, in stainless steel stent, fracture will be initiated at the edge of stent and near the joint of stent strut and bridge. Figure 4 (b) shows that the high stress concentration has occurred at the edge of stent length. Here no fracture will occur as the value of stress developed is less that the ultimate tensile stress. Figure 4 (c) shows a full deformation overview of a nitinol stent. The maximum deformation occurred at the stent edge.

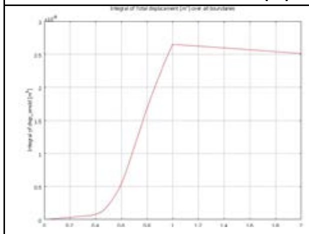
Comparison with real life stent fracture – in vivo

Following images shows sample stent fracture occurred in arteries (CT images in vivo). (Courtesy: Adrian James Ling et. al., [11])

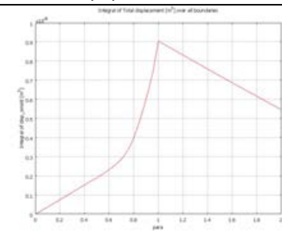
Conclusion

The above results show that, among the four different stents, the chances of developing fractures are evident in case of stainless steel and tantalum stents during the deployment process. On the other hand, in case of nitinol and elgiloy stents, there are no risks of fractures initiation as the maximum stress experienced by stent is lower than the material's ultimate tensile strength. The deformations during the balloon expansion (loading) of nitinol and elgiloy stents are also acceptable in the deployment process. The deformed shapes after the unloading are also giving desired outcomes in supporting the vessel inner wall. But, in case of the other materials, the stress developed have exceeded the corresponding materials' ultimate tensile stress. In the site of high stress concentration in the stent, fractures will be initiated. Once a fracture will appear, over the time, it will propagate and ultimately it will cause the stent failure and will damage the artery wall. From this perspective, conclusion can be drawn that, for a given shape and geometry of stent and for a standard stent deployment procedure, a nitinol shape memory alloy stent and a elgiloy stent will give the desired outcomes. The other materials will pose

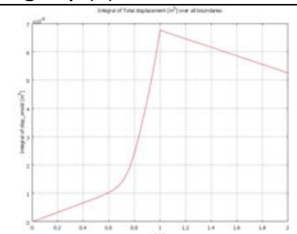
Stainless steel stent (a)



Nitinol (b)



Elgiloy (c)



Tantalum (d)

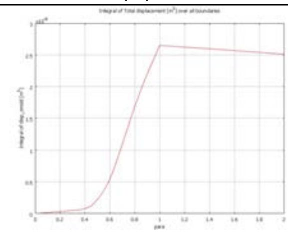


Figure 3: Plot of integrated deformation of stents against parameters – (a) stainless steel, (b) nitinol, (c) elgiloy, (d) tantalum.

Table 5

Stent Materials	Ultimate Tensile Strength (MPa)	Max. Von Mies stress (MPa)	Will fracture occur?
Stainless steel	550	939.1	Yes
Nitinol	960	762	No
Elgiloy	1020	847.3	No
Tantalum	205	939.1	Yes

a risk of fracture initiation in stent during the deployment process. For other stent materials, it will be suggested to modify the design accordingly to get the optimized result.

Further scope of study

The modified design for stent required for the optimized result is not in scope of the present study. Further study can be made in order to find out the design change required for the desired results in case of materials other than nitinol.

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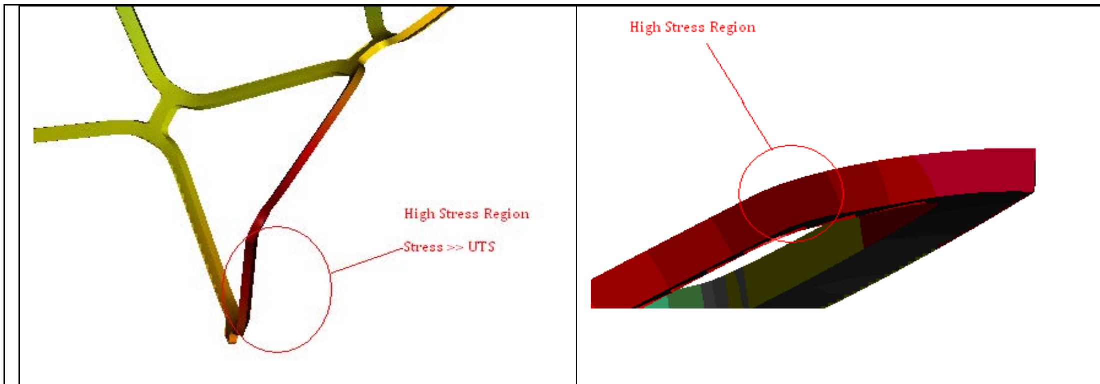
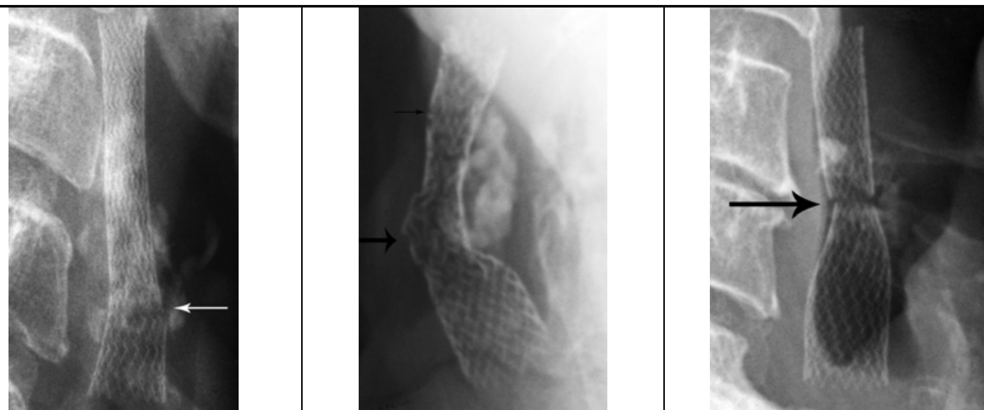


(a) Stainless Steel	(b) Nitinol

Figure 4: The deformation of stents and stress analysis: (a) Stainless steel deformation, (b) Nitinol stent deformation,



(a)	(b)	(c)

Figure 5: (a) Type I fracture (arrow) in a sample stent. Note the presence of adjacent calcification.

(b) Type II fracture - The presence of two or more fractures, with obvious discontinuity of the stent margin (arrows).

(c) Type III fracture. Transverse linear fracture without stent displacement (arrow)

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