Study of Stent Deformation and Stress Developed at Different Stent Deployment Pressures

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Abstract According to clinical reports, cardiovascular disease has become a major global healthcare problem of the present decade. The deposition of fats, cholesterol etc. at the arterials walls causes thrombus formation leading to arterial blockage and narrows the lumen of vessels (stenosis). To tackle this problem along with arterial- bypass surgery, the use of the Cardiovascular Stent is considered promising and effective (in single vessel and bi vessel diseases). While initial results were satisfactory, yet the risk of Stent Failure remains high. In this study, we aim to find the effectiveness of stent deployments and their possible causes of failure. For the study we have used the Structural Mechanics module of COMSOL Multiphysics® V4.2a. We have considered one particular design of stent and four different materials (Stainless Steel, Nitinol, Tantalum and Elgiloy) for their Finite Element Analysis. We assess their mechanical performance under different realistic deployment pressures.

Keywords Stents, Angioplasty, Stenosis, Finite Element Analysis, Stress Strain Analysis, Stent Fracture

1. Introduction

To treat stenosis of cardiac vessels, Percutaneous transluminal coronary angioplasty (PTCA) is a common method of treatment employing stent interventions. A stent is an artificial 'tube' inserted into a natural passage/conduit in the body to provide a mechanical support to the diseased vessel and prevent, or counteract, a disease-induced, localized flow constriction. Usually it is a small, meshed metal tube placed into an artery to compress the plaque and widen the vessel wall and provide a mechanical support to the vessels. The principal advantage is that they do not require open heart surgery

Stents possess deformation regions that behave differently according to the type of load applied. High stress concentration occurs at the links, better known as struts. While the link regions are more expandable regions, the cell regions are responsible for bearing the stresses and maintaining the shape of the structure as described in Fig 1.

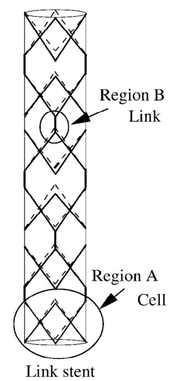

Fig 1: A general stent design (Koji Mori et.al)

Many studies show high correlations between restenosis (narrowing of vessels after interventions) and the stresses that develop within a stent after deployment [1, 5]. Physiological conditions of the subject like evidence of diabetes, an unhealthy lipid profile, smoking and alcohol habits etc also highly attribute to performance of stents [9]. Several studies were conducted to assess the mechanical properties of the various materials used for the manufacture of these stents [2, 4, 6, 7]. The properties were studied by mathematical modeling with determination of stent deployment pressure, intrinsic elastic recoil etc. in order to compare the performance of different stent designs [1, 3, 5]. Also, interactions of these stent structures with the arterial tissue have been simulated and analyzed [2]. For the fabrication of stents, mechanical properties like radial strength, elastic modulus have been studied [10].

In this present try we try to focus on the deformation of the stents that is caused at different deployment pressures. Also the Von Mises Stress that develops due to different deployment pressures is analyzed. We employ three pressures- 2 atmospheres (as prescribed by COMSOL Multiphysics® Structural Mechanics documentation, V 3.5a), 7 atmospheres, 12 atmospheres (clinically relevant deployment pressure for Stainless Steel and Tantalum) and 17 atmospheres (clinically relevant deployment pressure for Nitinol and Elgiloy). The stent geometry (slotted tube) has been kept constant in all the cases.

2. **Materials**

In this study four different stent materials are considered. They were selected from a detailed survey of academic literature and industrial data base. The materials are:

- 316L Stainless Steel
- Tantalum
- Nitinol (Ni-Ti alloy)
- Elgiloy (Co-Cr alloy)

Their different properties like Modulas of Elasticity, Tensile Strength, Ultimate Tensile Strength, Poisson's Ratio and Yield Strength were taken into account. The different properties are tabulated in Table 1.

Table 1: physical properties of different materials

Material	Elastic Modulas (GPa) msi	Tensile Strength (MPa) ksi	Ultimate Tensile Strength (MPa) ksi	Poisson's Ratio	Yield Strength (MPa)
316L-SS	193	260	550	0.300	300
Tantalum	185	165	205	0.350	170
Nitinol	83	195 to 690	1160	0.300	560
Elgiloy	190	690	1020	0.226	520

While SS-316L and Tantalum are balloon expandable stents, Nitinol and Elgiloy are Self Expanding stents.

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.

3. **Modelling**

The modelling of a single cell of a rectangular slotted coronary stent was developed using Comsol Multiphysics® v4.2a. The Structural Mechanics module has been used. The stent design has a hollow slotted tubular structure; the tube is made up of six identical units, each unit of two solid metal struts and two openwork struts. Here we use a section of the slotted tube geometry of the Palmaz- Schatz Stent (Cordis, USA) for the analysis. Only a single element of the full stent has been used in the model for ease of analysis and symmetry has been assigned so that it is replicated in the entire geometry (Fig 2).

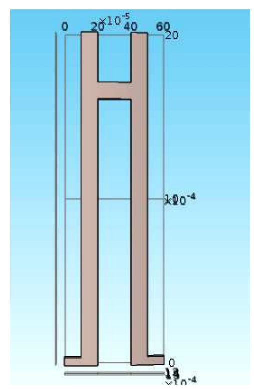

Fig 2: A single element of Stent in XY Plane

3.1 Boundary Load

Clinical data suggests that pressure in the range of 10-17 atmospheres is usually recommended as in-situ deployment pressures of stent. Three different loads have been used in the present study to assess the stress and deformation of stent geometry. A load of 2 atm. was chosen as per the documentation of Structural Mechanics Module of Comsol 3.5a and another load of 7 atm was considered. The third load was selected from clinically relevant data. They were 12 atm (for SS-316L and Tantalum) and 17 atm (for Nitinol and

Elgiloy) respectively. These pressures were deployed as boundary loads at the whole inner surface of the stent.

3.2 Boundary conditions

Symmetry boundary planes have been used to prevent rigid body translation in Y and Z directions and rotation around all axes.

3.3 Point Setting

A fixed point constraint in X direction has been used to fix the rigid body translation in this direction.

3.4 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)).

3.5 Mesh Generation

A physics controlled mesh has been generated with triangular elements. The grid sensitivity with finer grains has been tested for all materials and loading conditions.

3.6 Solver

Parametric solver has been used. In solver output, three dimensional deformations and Von Mises Stress developed in the stents have been chosen.

3.7 Parameters

The parameters describe the stent loading with balloon inflation from the crimped position and the unloading. Appropriate load parameters have been used.

4. Results and Discussion

Using the above specifications, the simulation was created using COMSOL Multiphysics® V4.2a. The Von Mises Stress (N/m^2) and Deformations (mm) were obtained using three different pressures. The values obtained are tabulated in Table 2.

Table 2: Von Mises Stress and Radial Displacement of Materials at different Deployment pressures

Deployment Pressure →	2 atm	7 atm	12 atm
Material: 316L-Stainless Steel			
Von Mises Stress (N/m^2)	221.92	776.80	1331.70
Displacement (mm)	0.192	0.672	1.153
Material: Tantalum			
Von Mises Stress (N/m^2)	211.77	741.23	1270.70
Displacement (mm)	0.2412	0.844	1.447
Deployment Pressure →	2 atm	7 atm	17 atm
Material: Nitinol			
Von Mises Stress (N/m^2)	208.26	728.90	1770.20
Displacement (mm)	0.597	2.008	5.071
Material: Elgiloy			
Von Mises Stress (N/m^2)	214.53	747.54	1815.40
Displacement (mm)	0.2474	0.866	2.104

From Table 2, we observe that at different deployment pressures, the Von Mises Stress experienced by the stents varies almost linearly. At deployment pressure of 12 atm., the Stress obtained is almost 6 times to the Stress caused at 2 atm. and 1.7times to that caused at 7 atm in cases of 316L Stainless Steel and Tantalum. And the Von Mises Stress observed in case of Nitinol and Elgiloy at 17 atm. was 8.4 times than that found in 2 atm and 2.4 times than that found in 7 atm.

Figure 3 shows the stress built up in an element of Stainless Steel-316L stent at a deployment pressure of 2 atm. at the XY plane. As expected the Von Mises Stress was more concentrated at the strut regions.

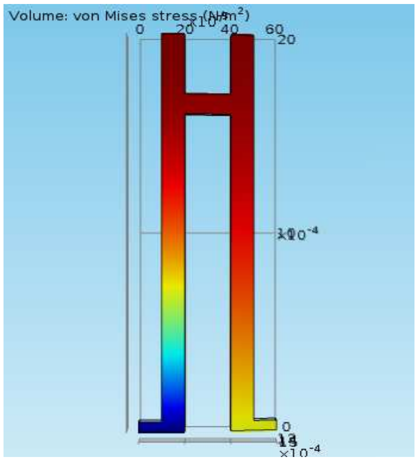

Fig 3: Von Mises Stress in SS-316L in a single element at a pressure of 12 atm.

If we compare the Von Mises Stress that develop in the stents, we find that in case of SS-316L at 7atm and 12 atm., the stress developed is much greater than the UTS of a material. But in Tantalum, even a minimum pressure of 2 atm. builds a Von Mises Stress higher than its Ultimate Tensile Strength (UTS). The stress developed in case of Nitinol is optimum at 2 atm and 7 atm, but the stress developed at 17 atm (clinical deployment pressure) is slightly higher than its UTS. Same is the condition in case of Elgiloy stents where the Von Mises Stress becomes higher than its UTS only at 17 atm.

Here we have only simulated the free expansion of the geometry. But in reality, when a stent is placed, it is subjected to a combination of stresses (bi- axial and tri- axial). Here the force applied on the stent by the flowing blood and by the arterial wall is not taken into account. To assess the real life stress contour (particularly the shear stress) developed on stents, the effect of these two aspects should not be over ruled.
In case of metals and alloys (ductile materials) , the shear failure is largely responsible for stent fractures. Figure 4 shows a typical fracture occurred in a SS-316L stent.

Fig 4: A Typical 316L SS Stent breakage (Courtesy: Adrian James Ling et. al., [13])

It has also been observed that cellular proliferation accelerates around the stent grafts if the stress experienced is high. It leads to callous formation and resulting to stent fracture. It has been also known that stent deployment pressure causes endothelial cell denudation (a pre-curser to stent fracture), suggesting balloon related injury. Keeping the inter-strut distance and balloon compliance constant, studies suggest that surface stress increases with deployment pressures. Increasing the geometric complexity of stent designs and/ increasing the number of struts reduces the surface contact area of stent. This reduces the chances of stent failures (Farnoush et.al)

In the figure 5, a particular junction of the stent is highlighted so as to understand whether there is major strain incompatibility in the domain surrounding the struts/ connection. We have found that in different portions of the stent around the strut the value of deformation varies through a great extent (Table 2). So it may be noted that there is a marked non-uniformity in the deformation pattern. From stability point of view it seems to be detrimental. The variation of deformation with deployment pressure is also found to be almost linear. It is observed that Nitinol stent shows more displacement than other stents. This raises a concern of the over expansion. This may trigger more Neo-Intimal Hyperplasia (cell proliferation) and further cause endothelial cell denudation over the arterial system.

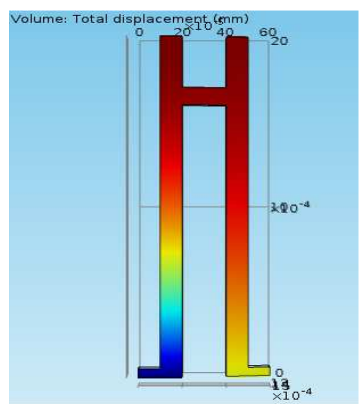

Fig 5: Deformation of an element of 316L-SS stent at a pressure of 12 atm.

A quarter of a fully deformed stent of Palmaz- Schatz (Cordis, USA) having the similar Slotted Geometry design and made up of Nitinol is shown in XY plane in Fig 6. The deformation causes the slotted tube geometry to change into a diamond shaped formation. This is commonly referred to as DS Geometry. One finds a non uniform strain developed across the entire dimension of the stent. As the geometry approaches towards the open ends, the extent of radial expansion increases (Fig 6). This may be attributed to less constraint at the end than at the middle.

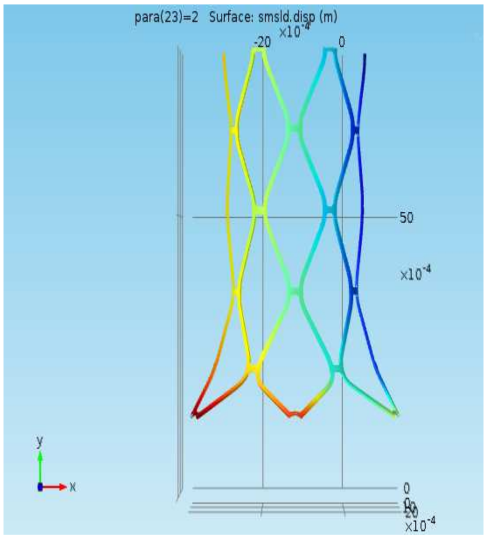

Fig 6: A section of DS Nitinol Stent at a deployment pressure of 17 atm.

In the human arterial system, the diameter of the coronary arteries ranges from 1.1 (±0.4) mm to 4.6(± 0.5) mm. So, according to the lumen diameter of the arterial vessel, the material should be chosen. If the arteries have a very narrow lumen, then the deformation may cause severe localized injury. When these stents are placed in situ, the strain experienced by the materials is not just because of deployment pressure, but also because of the compressive force given by the arteries. In this respect, we should remember that arteries are highly visco-elastic in nature and the force exerted by the arteries will be dependent on various factors like patient's age, his physiological condition, the size and shape of atherosclerosis and the rigidity of the artery itself. Hence, whenever stress analysis studies are done over cardiac stents, all such patient parameters should be taken into account.

5. Conclusion

From the study reported here the following major observations are to be noted.

a. It is a preliminary study to make a realistic assessment on the effect of deployment pressure on the mechanical performance of cardiac stents.
b. The study has been done on four mostly used commercial stent materials: stainless steel, Tantalum, Elgiloy and Nitinol. Performance of these stents under varied deployment pressures was asessed.
c. It was found that deployment pressure in the range of 12- 17 atm. generates higher stress and deformation in SS 316L and Tantalum in Comparison with Nitinol and Elgiloy.
d. From the available deformation and stress data, it was evident that SS 316L and Tantalum were likely to be more prone to fracture under In Situ condition.
e. Higher deformation and stress associated with these stents can cause endothelial cell denudation of the arterial wall. However, its still a conjecture and require detailed experimental study to confirm.

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