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Computational Assessment of Stress Development during Deployment of Commercially Available Stents

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Abstract*— Cardiac disease accounts for maximum number of untimely deaths in today's time. Stent angioplasty is a very popular technique to treat atherosclerotic diseases. Yet the rate of restenosis (renarrowing of arterial lumen) remains high. Several studies have been performed to analyze the efficacy of these stents. This study considers three commercially available stent designs (PS Stents, S 670 Stents and ION Stents) of three different companies and aims to analyze the mechanical factors that contribute to stent performance using computational simulation. The material aspects of stent design as well the design factors were taken into consideration to analyze the Von Mises Stress that develop post stent deployment procedure. Five different materials (SS 316L, Co- Cr Alloy, Pt- Cr Alloy, Nitinol and Tantalum) were considered for the simulation using three different clinically used deployment pressures (14 atm, 15 atm and 16 atm). Best performance was found in the design of S 670 Stents followed by ION Stents. PS Stents were found to develop maximum Von Mises Stress.

***Index Terms*- Atherosclerosis, Finite Element Analysis, Stents, Von Mises Stress, Restenosis.**

I. INTRODUCTION

For single vessel and bi-vessel diseases of atherosclerosis (plaque deposition in the arterial lumen) *Coronary Stents* are becoming increasingly popular owing to its minimally invasive method and lesser trauma caused to the patient. A stent is an artificial 'tube' inserted into a natural passage/conduit in the body to prevent, or counteract, a disease-induced, localized flow constriction. The term may also refer to a tube used to temporarily hold such a natural conduit open to allow access for surgery.

Several studies were conducted in the last decade on fluid dynamics of the arterial wall. 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 [1]. Fry first postulated that high wall shear stresses could do mechanical damage to the arterial wall [2]. Analysis of mechanical behaviors of stents was found to be an important aspect of the study [3 & 4]. Mechanical properties for appropriate stent fabrication, the properties like radial strength, elastic modulus have been studied. The 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 [5]. The deformation pattern and the stress distribution of the entire stent have been studied with a repeated unit cell approach of finite element analysis. Many studies have shown high correlations between restenosis and the stresses that develop within a stent after deployment [6]. Petrinia et. al showed that stent behavior also depended on the geometry of the design [7]. Holzapfel et al proposed to vary stent parameters using FEM and concluded that unwanted dog boning of stents might be avoided by using appropriate stent balloons, varying the stent geometries and thickness of stent struts [8].

Commercially one finds various types of stents in the market with varying materials and design modifications. While satisfactory results are being obtained with stent interventions, yet the risk of restenosis (stenosis in the vessel post stent interventions) remains high [9]. Rogers et.al observed that higher inflation pressures, wider strut openings and more compliant balloon materials caused appreciably larger surface- contact areas and contact stresses between struts [10]. Evidences of stent fracture have been related with deployment pressure of stent, stent design as well as fluid structure interaction [11]. Gay et.al considered analyzing fluid- structure interaction of stents using computational technique. It was found that stress distribution is a function of applied pressure, balloon and stent material properties, fluid properties and stent geometry [12].

Hence one finds the dire need of simulating the various factors that might contribute to the failure of stents so that new and innovative materials are designs can be brought out for developing stents with maximum efficacy and minimum complications. Through this study we try to analyze the stresses that develop in different commercially available stent designs and thereby make a preliminary observation on the performance of these stents.

II. METHODOLOGY AND MODELING

To analyze the effects of stent deployment a computational study is designed. Three stents that are used commercially have been considered for the analysis: PS Stent (Cordis- JnJ, USA), S 670 Stent (Medtronic, USA) and ION Stent (Boston Scientific, USA). A three dimensional stationary analysis of stent expansion is done on a unit cell of each stent design employing Finite Element Method using COMSOL Multiphysics® V4.3A. In this study planar designs of stents have been considered. The stents were drawn computationally in the COMSOL platform in a two dimensional plane followed by extrusion of the design to form a three dimensional object. The geometries have been recreated considering the designs of commercially available PS Stent (Fig. 1a), S 670 Stent (Fig. 1b) and ION Stent (Fig. 1c). Only a single unit of the stent geometry was developed for analysis.

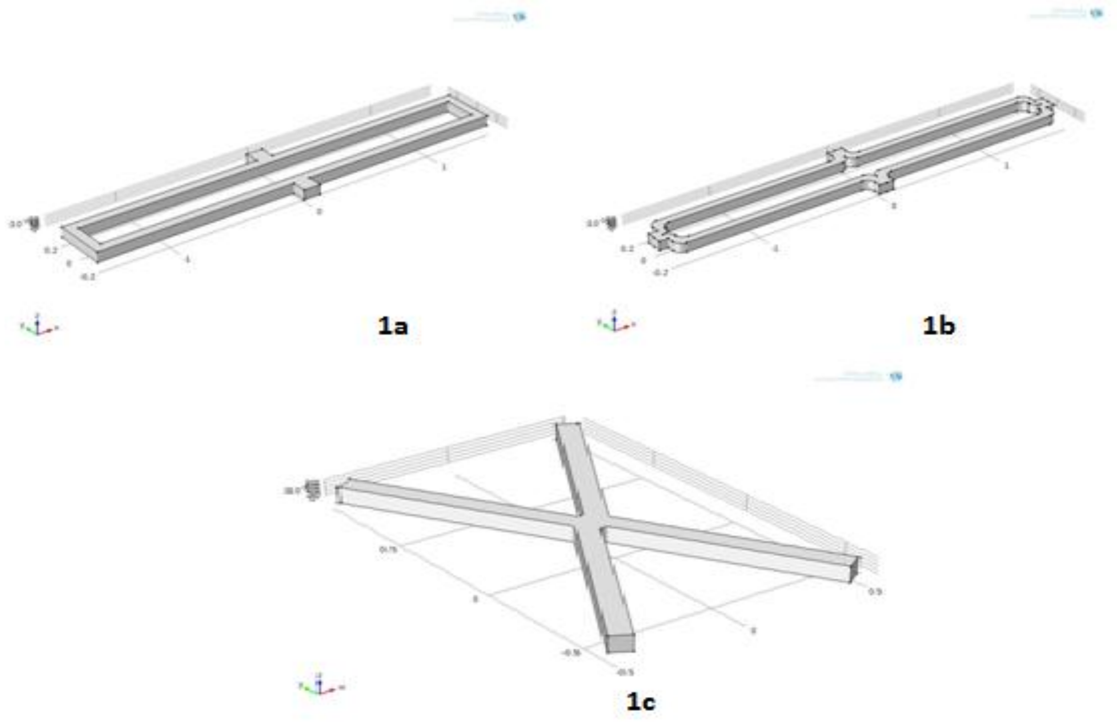
1a
1b
1c

Fig. 1: Modeling of different stent designs.

For the stationary analysis the clinically used stent deployment pressures of 14atm, 15 atm and 16 atm respectively were considered at the inner wall of the stent. The pressure given by the atherosclerotic plaque at the outer wall of the stent was chosen to be 780 KPa. The different materials that are commercially used for manufacture of stents were chosen for the study. The materials chosen were Stainless Steel (SS 316L), Cobalt Chromium Alloy (Co-Cr), Platinum Chromium Alloy (Pt- Cr), Nitinol (Ni- Ti) and Tantalum (pure metal). The various material properties were provided as input to the Finite Element Analysis software platform; the properties are tabulated in Table 1.

Table 1: Material properties of stents

S. No.	Material	Density (kg/m^3)	Modulus of Elasticity (GPa)	Poisson's Ratio	UTS of material (MPa)
1.	316L SS	7850	193	0.226	595
2.	L 605 Co-Cr	9100	243	0.3	1020
3.	Pt- Cr	9900	203	0.3	834
4.	Ni- Ti	6478	83	0.3	1100-1200

5.	Tantalum	1669	185	0.35	285

The meshing was done for the simulation of resultant domain (Fig. 2). A physics controlled fine mesh was constructed in the unit cell geometries using triangular and tetrahedral elements. Grid sensitivity was done for each case and was found that at mesh generated by COMSOL Multiphysics, the results didn't show any appreciable deformation after refining the mesh to a finer state. Hence the physics controlled fine mesh was chosen. Each design had more than thirty vertex elements and more than five hundred and fifty boundary elements. The degree of freedom was more than four thousand for all cases of stent design.

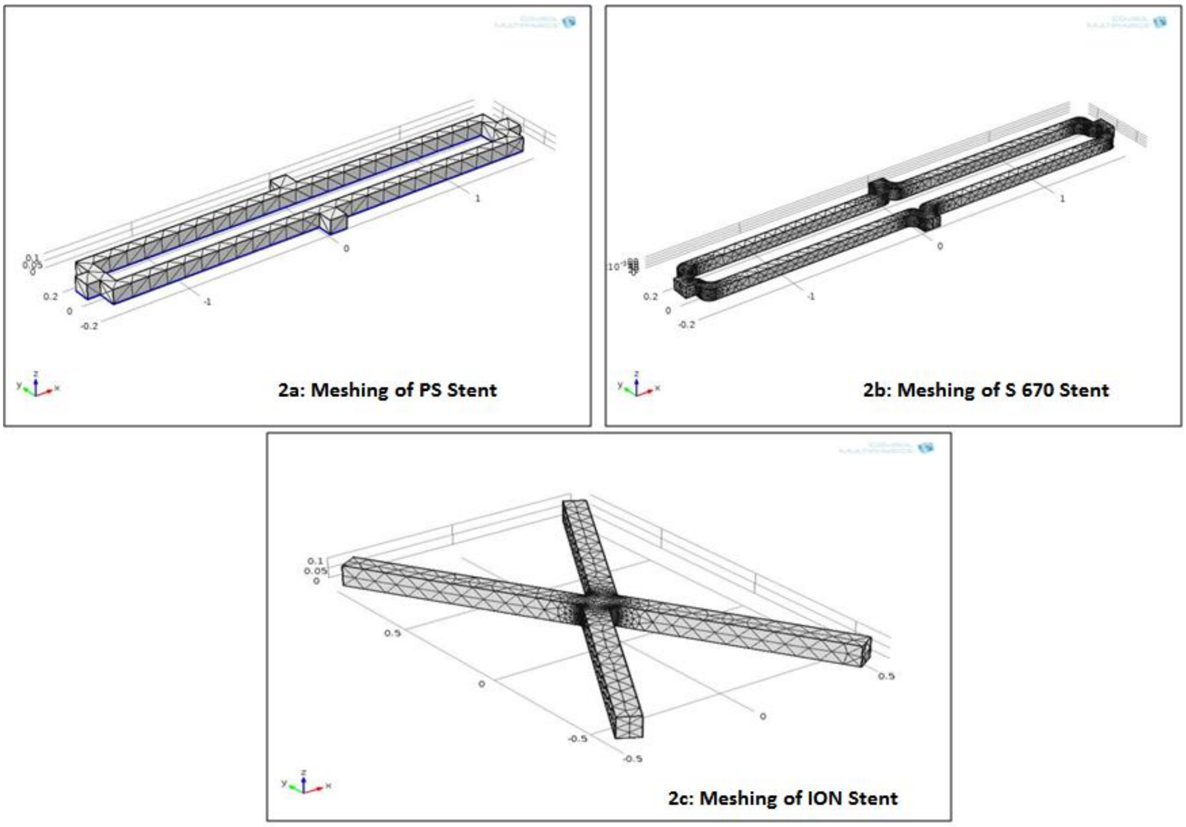

Fig. 2: Meshing of different stent designs

The Von Mises Stress that builds up as a result of combined effect of deployment pressure and pressure by the atherosclerotic plaque is obtained. This obtained stress is then compared with the UTS of the materials of the different designs. This comparison is utilized to predict the efficacy of the various commercially available stent designs at different stent deployment pressures.

III. RESULTS AND DISCUSSION

In the current study the results of Von Mises Stress caused into the stent geometries due to expansion and the blood flow in the coronary artery post deployment have been simulated. The observation of the Von Mises stress that develop after expanding the stent using different deployment pressures can be described in Figure 3.From figure 3 it is observed that the distribution of Von Mises Stress is different at different regions of each of the stent geometry. In case of PS Stents (Fig. 3a), one finds that values of stress is maximum in the arms of stent struts and lesser at intra strut regions. This behavior is repeated in the case of S 670 stents (Fig. 3b) where high stress regions are observed in the arms of the stent struts which are kept free. In case of the ION Stents, one finds that the stress in the design is distributed differently (Fig. 3c). In this case the regions of high stress are limited to the ends of the stent struts. Through the length of the strut, the stress values are optimum which wouldn't normally reach high values at the clinically used deployment pressure.

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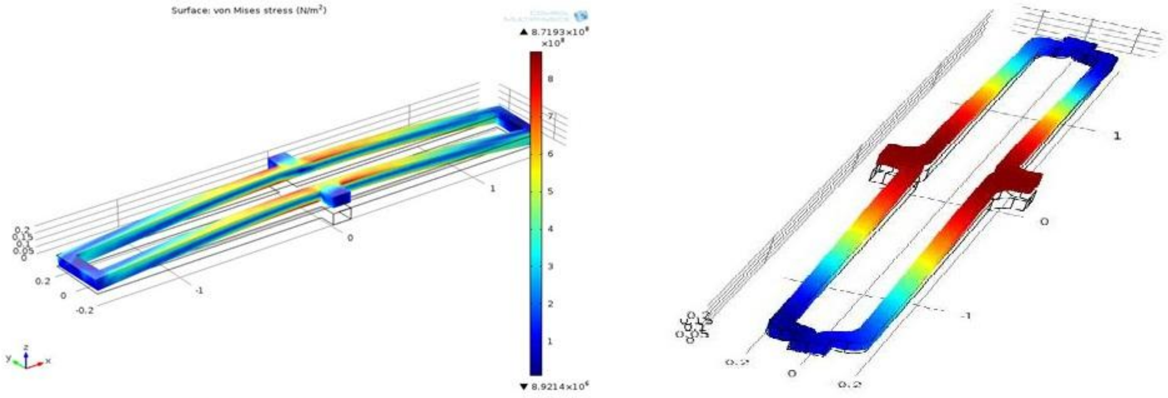
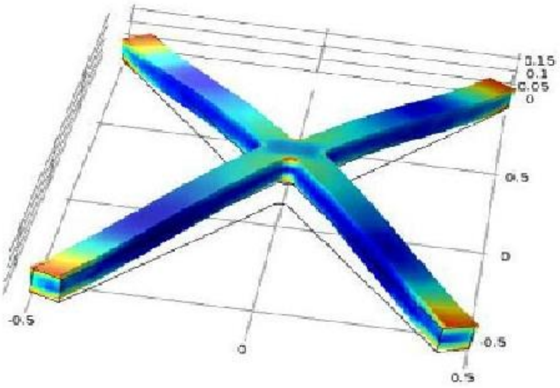


3a: Von Mises Stress in PS Stent

3b: Von Mises Stress in S 670 Stent



3c: Von Mises Stress in ION Stent

Fig. 3: Von Mises Stress developed in different stent designs

In case of PS Stents when Stainless Steel 316L and Tantalum was chosen, in all the three different deployment pressures the Von Mises Stresses developed in the stent (878.5-1162MPa in case of SS- 316L and 866.8-1146.6 MPa in case of Tantalum)was much higher than the UTS of the materials. But in the same design in the case of newly developed materials Von Mises Stress did not reach the UTS of the materials: L 605 Co Cr Alloy(558.9-739.3 MPa), Pt- Cr Alloy (599.5- 792.8 MPa) and Nitinol (871.9- 1153.3 MPa). Thus they were considered to be safe materials for stent design. The design of S670 stent was considered to be the most stable one where Von Mises Stress developed was within the UTS of all materials except Tantalum (UTS is 285MPa and Von Mises Stress was 355-470.12 MPa). In case of ION Stent designed by Boston Scientific, it was found that at lower deployment pressures the Von Mises Stress observed in SS 316L design was within the UTS range of the material but at higher pressures of 15-16atm the material was bound to undergo failure as the Von Mises Stress developed (615.8- 701.3 MPa) would exceed the UTS of the material. Again the use of Tantalum was found to be unsafe in the ION geometry as the Stresses (530.8- 702.7 MPa) developed was higher than the ultimate strength of the material. The results of the same have been tabulated in Table No. 2 below:

Table 2: Results of Von Mises Stress at different stent deployment pressures

Material	Von Mises Stress (MPa)	UTS of material (MPa)	Will failure occur
Stainless Steel			
PS Stent at 14 atm	878.53	595	Yes
PS Stent at 15 atm	1020.3	595	Yes

PS Stent at 16 atm	1162	595	Yes
S670 Stent at 14 atm	382.49	595	No
S670 Stent at 15 atm	444.21	595	No
S670 Stent at 16 atm	505.94	595	No
ION Stent at 14 atm	530.2	595	No
ION Stent at 15 atm	615.8	595	Yes
ION Stent at 16 atm	701.3	595	Yes
L 605 Cobalt Chromium			
PS Stent at 14 atm	558.96	1020	No
PS Stent at 15 atm	649.15	1020	No
PS Stent at 16 atm	739.35	1020	No
S670 Stent at 14 atm	370.17	1020	No
S670 Stent at 15 atm	429.93	1020	No
S670 Stent at 16 atm	489.68	1020	No
ION Stent at 14 atm	457.43	1020	No
ION Stent at 15 atm	531.22	1020	No
ION Stent at 16 atm	605.02	1020	No
Platinum- Chromium			
PS Stent at 14 atm	599.56	834	No
PS Stent at 15 atm	696.22	834	No
PS Stent at 16 atm	792.88	834	No
S670 Stent at 14 atm	368.41	834	No
S670 Stent at 15 atm	427.88	834	No
S670 Stent at 16 atm	487.35	834	No
ION Stent at 14 atm	357.39	834	No
ION Stent at 15 atm	415.09	834	No
ION Stent at 16 atm	542.78	834	No
Nitinol			
PS Stent at 14 atm	871.93	1100-1200	No
PS Stent at 15 atm	1012.60	1100-1200	No
PS Stent at 16 atm	1153.3	1100-1200	No
S670 Stent at 14 atm	365	1100-1200	No
S670 Stent at 15 atm	424.07	1100-1200	No
S670 Stent at 16 atm	483.01	1100-1200	No
ION Stent at 14 atm	527.69	1100-1200	No
ION Stent at 15 atm	612.8	1100-1200	No
ION Stent at 16 atm	697.9	1100-1200	No
Tantalum			
PS Stent at 14 atm	866.85	285	Yes

PS Stent at 15 atm	1006.7	285	Yes
PS Stent at 16 atm	1146.6	285	Yes
S670 Stent at 14 atm	355.37	285	Yes
S670 Stent at 15 atm	412.75	285	Yes
S670 Stent at 16 atm	470.12	285	Yes
ION Stent at 14 atm	530.83	285	Yes
ION Stent at 15 atm	616.45	285	Yes
ION Stent at 16 atm	702.07	285	Yes

In terms of design, our study (Table 2) revealed that S-670 stent was found to show best results with least Von Mises stress developed in all the cases. The newly developed design of ION Stent was found to be the next best design showing considerably less failure rates. The PS Stent was found to be the worst of the three when it came to the design aspect of stents as the mechanical failure undergone would be disastrous for the patient. The high values of Von Mises Stress in the stents lead to arterial injury which leads to neo intimal hyperplasia resulting in Restenosis. Even if the stresses exceed the UTS of the material, it doesn’t necessarily lead to immediate breakage of the metallic stents. But as a result of this phenomenon micro cracks are likely to develop in the body of the stents which due to fatigue loading over time ultimately contributes to mechanical failure of the stents.

IV. CONCLUSION

The results obtained in the study can be comprehended as follows:
Stent deployment technique was an important factor that determined the success or failure of stents. So attention should be drawn into the deployment pressure that is being delivered while placing a stent into the artery. While considering the material aspects for stent manufacturing processes these factors should be kept into consideration:

1. Stainless Steel stents might experience Mechanical failure under high deployment pressure and thus was not a very favorable material for stent design (though commercially it’s the most widely used material for stent design).
2. L 605 Cobalt Chromium Alloy is highly acceptable biomaterial. Platinum Chromium alloy also makes a very good metallic alloy for coronary stent design.
3. Nitinol can also be considered as a good biomaterial provided other aspects of the material like nickel release and corrosion gives satisfactory results.
4. Tantalum should be avoided when considering stent designs as it failed in all our test conditions.

However, this is just a conjecture and more detailed analysis should be performed to find the determining factors of stent designs so as to develop newer materials and improved geometries for better stent performances.

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