Computational Analysis on Commercially Available Stent Designs

K. Basu[1], P. Ghosh[1], S. Das[2], S. Bhattacharya[2], A. Chanda[1]

[1]School of Bio Science and Engineering, Jadavpur University, Kolkata- 700032, India

[2]Department of Mechanical Engineering, Jadavpur University, Kolkata- 700032, India

*Corresponding author: Kristi Basu, kristi_basu@yahoo.com

Abstract: Cardiovascular disease has become a major healthcare problem. To tackle this along with bypass surgery, the use of the Cardiovascular Stent is considered promising and effective. In this study, we aim to find the effectiveness of stent deployments and their influence on haemodynamics post their deployment. For the study we have reconstructed single unit of two commercially available stent designs: PS Stent and Bx Velocity Stent using COMSOL. Five different commercially used stent materials (SS-316L, PT-Cr alloy, Co-Cr alloy, Nitinol and Tantalum) were considered. Also three different stent strut geometries (rectangular, square and circular) were analyzed to study the heamodynamics post stent deployment and eventually find out the risk of restenosis.

Keywords: Stents, Atherosclerosis, Stress Analysis, Restenosis, Haemodynamics, Stent Struts, Recirculation region

1. INTRODUCTION:

Today Coronary Arterial Disease is found to be one of the leading causes of untimely deaths. For single vessel and bi-vessel diseases of atherosclerosis Coronary Stents are becoming increasingly popular owing to its minimally invasive method. 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 and could trigger chances of restenosis [2]. To model the effects of PTCA procedure analysis of mechanical behaviors of stents was found to be an important aspect [3 & 4]. Mechanical properties for appropriate stent fabrication, like radial strength, elastic modulus have been 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]. Lie modeled blood flow in curved tubes with stenosis and found a strong dependence of flow pattern on geometry of carved artery [10]. 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 [11]. Evidences of stent fracture have been related with deployment pressure of stent, stent design as well as fluid structure interaction [12]. Gay et.al considered analyzing fluid- structure interaction of stents using computational technique and found that stress distribution is a function of applied pressure, balloon and stent material properties, fluid properties and stent geometry [13]. Lally et al hypothesized that level of vascular injury caused by vessel determined by level of restenosis [14]. Gijsen et al showed that higher stresses in the arterial wall were present behind strut regions and in regions where walls were thin [15].
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 two commercially available stent designs namely PS Stent and Bx Velocity Stent and the changes in blood flow post their deployment in human arteries; thereby making a preliminary observation on the performance of these stents.

2. METHODOLOGY AND MODELING

To analyze the effects of stent deployment a computational study is designed. Two different designs of stents that have been commercially introduced by Cordis- JnJ, USA have been considered for the analysis:

a) PS Stent (introduced in 1986)
b) Bx Velocity Stent (introduced in 1999).

Two different types of studies were conducted:

i. A three dimensional stationary analysis of expansion of a single unit of stent
ii. A two dimensional blood flow analysis post stent deployment

<u>i.A three dimensional stationary analysis of stent expansion</u>:

This was done on a unit cell of each stent design employing Finite Element Method using the Structural Mechanics Module of 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. Figures 1 and 2 show the images used for the analysis.

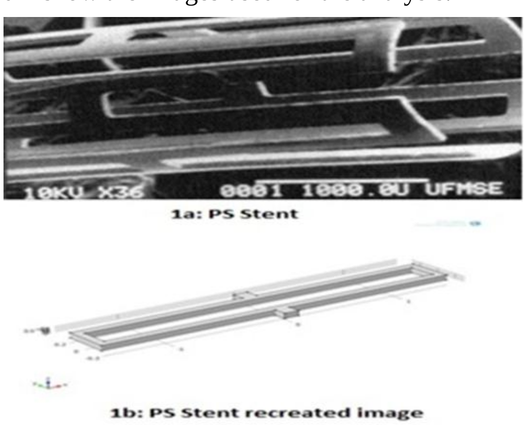


Fig 1: PS Stent

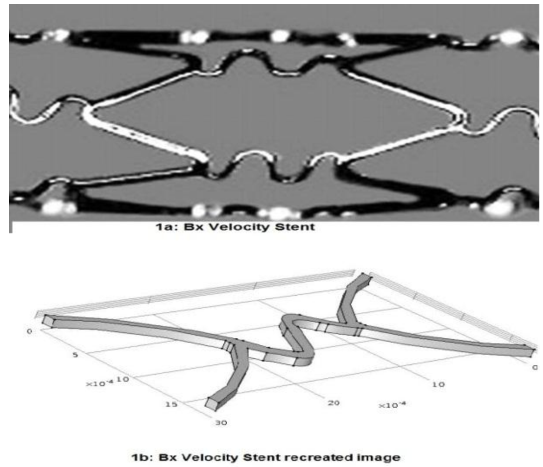


Fig 2: Bx Velocity Stent

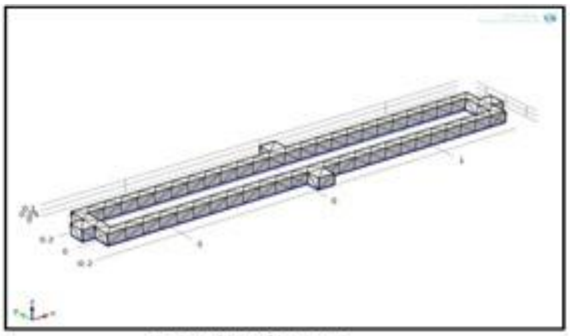
Boundary conditions for stationary expansion: For the stationary analysis the clinically used stent deployment pressures of 14atm, 15 atm and 16 atm respectively were considered at the inner wall of the stent. The pressure given by the atherosclerotic plaque at the outer wall of the stent was chosen to be 780 K Pa.

Materials used for stent analysis: 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 properties of which are tabulated in Table 1.

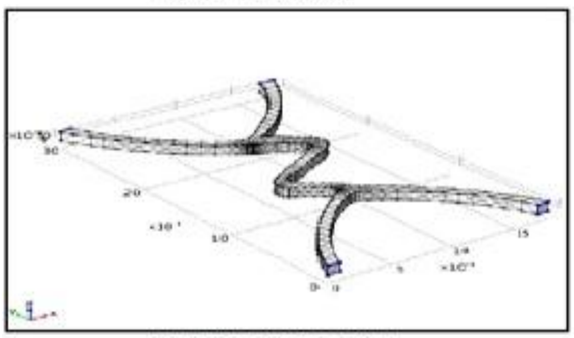
Table 1: Material properties of stent materials

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

Meshing of stents: The meshing was done for the simulation of resultant domain (Fig: 3). 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.



3a: Meshing of PS Stent



3b Meshing of Ex Velocity Stent

Fig 3: Meshing of Stents

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.

ii. Two dimensional analysis of blood flow post stent deployment

The laminar flow module of COMSOL Multiphysics was used for the purpose. The study chosen was a time dependent analysis available in COMSOL Multiphysics using the Navier- Stroke's equation.

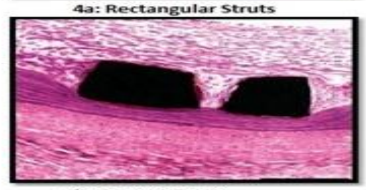
Here blood was assumed to be an incompressible fluid (Mach<3) with density 1060 kg/m^3. Both Newtonian and Non Newtonian behavior was considered for the study as blood behaves like Newtonian fluid while flowing through large arteries and exhibits non Newtonian behavior when it flows through smaller blood vessels. For the cases of Newtonian behavior of fluid (which holds true for blood flowing in the large arteries), the blood viscosity was chosen as 0.004 Pa.S. For the cases of Non- Newtonian behavior of blood (which is true for blood while flowing through smaller arteries and arterioles), the Power Law Model was considered for analysis.

$$\mu = m\left(\frac{\partial \gamma}{\partial t}\right)^{n-1}$$

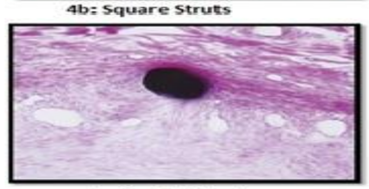
Here m= 1.029 which represents the consistency index has SI unit Pa.s^n and n= 0.703 represents flow behavior index (dimensionless).

Geometry of stent struts: Stent struts of different dimensions were analyzed in a two dimensional (2D) plane. Three real life geometries defining strut structures of various stents were considered. They were Rectangular struts (0.2mm X 0.1mm), Square struts (0.1 mm X 0.1mm) and Circular struts (diameter 0.1mm). These different strut shapes can be found in real life scenario when PS stents and Bx velocity stents are deployed in human arteries and are demonstrated in Fig. 4.

4a: Rectangular Struts



4b: Square Struts



4c: Circular Struts

Fig 4: Different stent strut geometries observed

Strut Shape Optimization: The rectangular shaped and square shaped struts were optimized by filleting the edges with radiuses of 0.01mm, 0.02mm, 0.03mm, 0.04mm, and 0.05mm.
Strut Spacing Optimization: For rectangular shaped struts we chose different spacing of struts in case of Newtonian and Non Newtonian flow as demonstrated in Table 2.

Table 2: Intra Strut spacing of Rectangular struts

Spacing during Newtonian Flow	Spacing during Non Newtonian Flow
0.4mm	0.4mm
0.6mm	0.6mm
0.8mm	0.8mm
1.4mm	1mm
1.5mm	1.25mm
1.6mm	1.5mm

Ideally, we should have chosen equal strut spacing of rectangular stents for both Newtonian and Non Newtonian fluids. Instead of choosing the intra strut spacing as control, we chose the recirculation lengths as the control of the experiments. This is because our basic area of interest was minimizing the recirculation lengths in each case so as to enhance stent performances.

For square shaped and circular shaped struts, for both Newtonian and Non Newtonian blood behavior intra strut spacing of 0.2mm, 0.4mm, 0.6mm, 0.7mm and 0.8mm were chosen.

Boundary conditions for two dimensional flows: The top of the rectangle has been considered as the inlet of the artery and the base of the rectangle has been considered as the artery outlet. A ‘no slip’ condition has been considered for the arterial wall that is in boundary with the stents. Symmetry has been assigned to the other side of the figure.
The inlet was given a flow velocity of 0.25*f where f represented the frequency at the inlet represented as the pulsatile equation shown below [17].

$$f(t) = \begin{cases} \sin \pi t & 0 \le t \le 0.5s \\ 1.5 - 0.5\cos\big(2\pi(t-0.5)\big) & 0.5 < t \le 1.5s \end{cases}$$

The outlet was given pressure as input with no viscous stress.

Meshing of two- dimensional fluid flows: The meshing operation was performed for all the cases using physics controlled mesh (Fig. 5). Grid sensitivity test was done to analyze the simulations and was found to be satisfactory with the predefined physics controlled ‘fine mesh’.

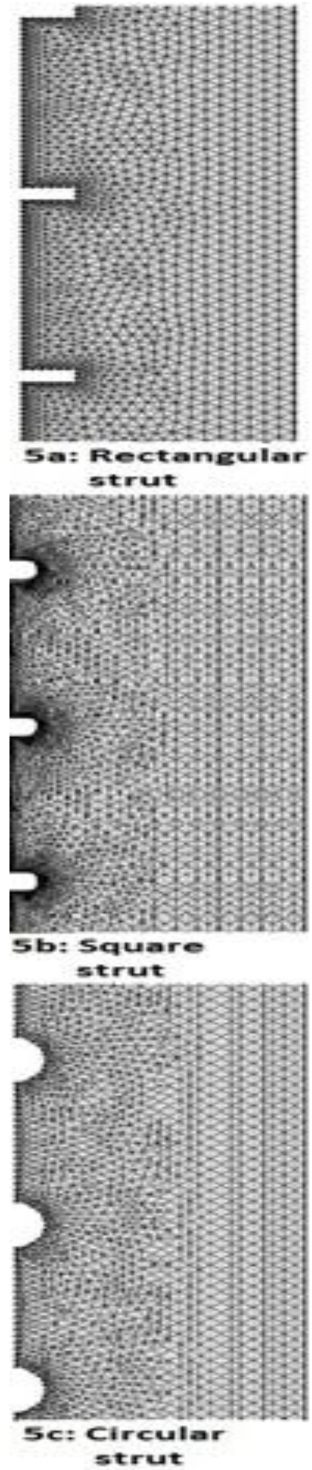


Fig 5: meshing of rectangular, square and circular shaped geometries

By way of this analysis the recirculation length of fluid flow after stent deployment was found out. The recirculation length actually determines the depositions of lipids, fats, debris and unwanted products during blood flow. A comparative analysis of recirculation lengths caused by different stent strut geometries is brought out.

3. RESULTS AND DISCUSSION

i. Stationary analysis of stent expansion

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 6. From figure 6 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, one finds that values of stress is maximum in the arms of stent struts and lesser at intra strut regions. In case of Bx Velocity stents we see that the stress distribution is non-uniform with maximum stress concentrations at the bending regions of the geometry. Unlike PS Stents the arms in Bx Velocity shows much lower values of stress distribution.

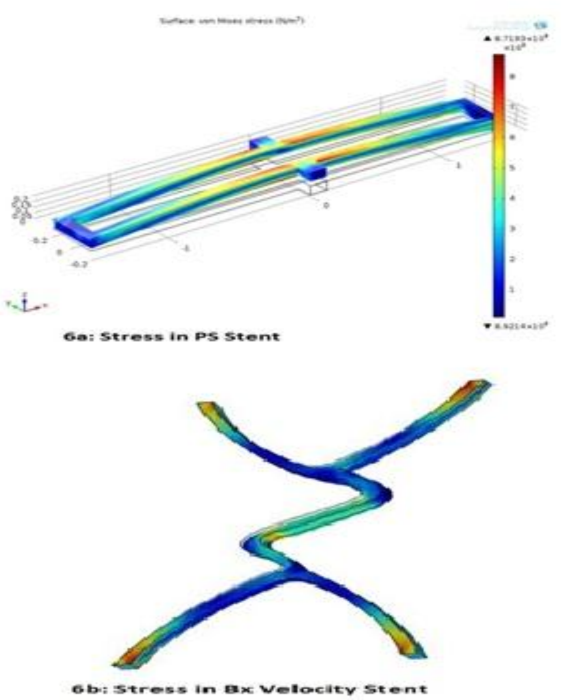


Fig 6: Von Mises Stress developed in different stent Geometries

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). While conducting stress analysis of Bx Velocity stents it was seen that maximum values of Von Mises Stress was found in case of SS- 316L(475.59- 628.96 MPa). Cobalt Chromium Alloy stents and Nitinol stents showed almost similar range of stress values. Tantalum exhibited a low range of stress values in this geometry when compared with PS geometry. Pt- Cr alloy showed stress distribution ranging from 469 to 620.66 MPa when tested for 14 to 16 atm pressure. The results of the same have been tabulated in Table 3 below:

Table 3: Von Mises Stress in different geometries at different deployment pressures

PS STENT			BX VELOCITY STENT		
Stent Deployment Pressure (atm)	Von Mises Stress (MPa)	Will failure occur	Stent Deployment Pressure (atm)	Von Mises Stress (MPa)	Will failure occur
Stainless Steel (UTS: 595 MPa)					
14	878.53	Yes	14	475.59	No
15	1020.3	Yes	15	552.28	No
16	1162	Yes	16	628.96	Yes
L 605 Cobalt Chromium (UTS: 1020 MPa)					
14	558.96	No	14	470.66	No
15	649.15	No	15	546.56	No
16	739.35	No	16	622.45	No
Platinum- Chromium (UTS:834 MPa)					
14	599.56	No	14	*469.0*	No
15	696.22	No	15	*544.88*	No
16	792.88	No	16	620.66	No
Nitinol (UTS: 1100-1200 MPa)					
14	871.93	No	14	470.62	No
15	1012.6	No	15	546.51	No
16	1153.3	No	16	622.39	No
Tantalum (UTS: 285 MPa)					
14	866.85	Yes	14	466.79	Yes
15	1006.7	Yes	15	542.06	Yes
16	1146.6	Yes	16	617.32	Yes

In terms of material it was found that Stainless steel (which is the most used alloy for stent manufacture) showed high Von Mises Stress beyond the UTS of the material and thus at high deployment pressures may lead to mechanical failure of the stents. Tantalum also showed unsatisfactory results in terms of Stress Distribution within the material. Nitinol, Co- Cr Alloy and Pt- Cr Alloy were found to be most suitable material in terms of our study for stent manufacture.

In terms of design, our analysis revealed that Bx Velocity stent was found to show best results with least Von Mises stress developed in all the cases. In case of PS Stents stress formed were higher than those observed in Bx Velocity stent cases. The high values of Von Mises Stress in the stents might lead to arterial injury which might trigger high rate of 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.

ii .Two dimensional analysis of blood flow post stent deployment

Rectangular strut optimization was carried out followed by fillet operation of their edges. Same was done for square shaped struts. In case of circular struts, only intra strut optimization was done. The recirculation lengths were found out by way of streamline analysis (Fig. 7)

For all the cases of Newtonian and Non Newtonian behavior of blood, we first underwent intra strut optimization. After finding out the lowest recirculation lengths, fillet optimization was conducted to find the lowest possible recirculation region for each case. It was seen that at maximum fillet radius of 0.05mm minimum recirculation lengths were achieved in all cases except in case of square struts in Newtonian blood flow were minimum recirculation was achieved at fillet radius of 0.03mm. The results are tabulated in table 4.

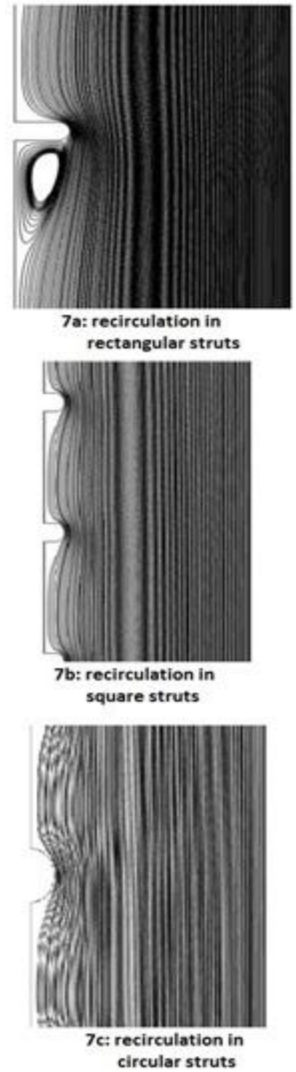
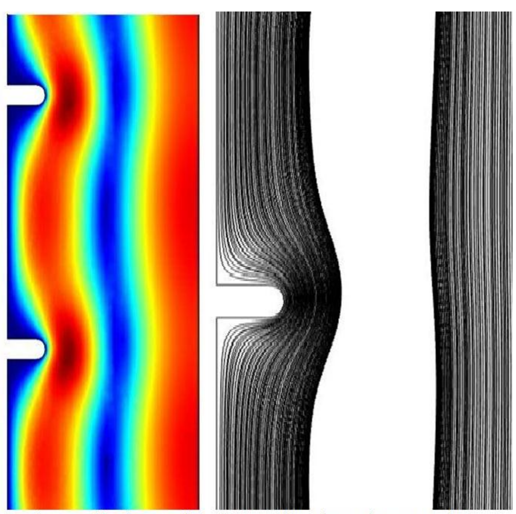


Fig 7: Recirculation in different strut geometries

Table 4: profile of fluid- structure interaction

Shape of strut	Newtonian	Non Newtonian
Recirculation length (mm)		
Rectangle	1	0.4
Square	0.4	0.4
Circle	0.5	0.5
Max Velocity (m/s)		
Rectangle	0.547	0.1532
Square	0.4998	0.4982
Circle	0.4985	0.5018
Max Pressure (Pa)		
Rectangle	1116.9	18.839
Square	1094.5	16166
Circle	1092	16191

We found that in case of Newtonian blood behavior of rectangular struts, there was high value of velocity and pressure which decreased appreciably in case of square and circular struts. While modeling Non Newtonian behavior it was evident that in case of rectangular struts though the recirculation length was appreciably low but the values of velocity and pressure were conflicting with the rest of the cases. Figure 8 shows the fluid structure interaction between rectangular struts and Non Newtonian blood. The velocity profile shows the erratic behavior of blood while flowing through the stented region. The streamlines depict the large gaps created as a result of flow. The probable reason of this behavior might be that the rectangular strut intrudes so much into the vessel that the pulsatility gets disturbed. This produces an erratic flow behavior which might have resulted in unwanted gaps. These gaps allow deposition of fats, lipids, cholesterol and unwanted debris in the stented region which later lead to restenosis of the stented region thereby causing stent failure.



8a: Velocity profile of rectangular struts in Non Newtonian flow

8b: Streamlines observed in reactangular struts in Non Newtonian flow

Fig 8: Behavior of rectangular struts in Non-Newtonian Haemodynamic flow

4. 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. Bx Velocity stents show better performance when compared to PS Stent owing to its innovative design development from the simple slotted tube of PS Stent.
2. 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).
3. L 605 Cobalt Chromium Alloy is highly acceptable biomaterial. Platinum Chromium alloy also makes a very good metallic alloy for coronary stent design.
4. Nitinol can also be considered as a good biomaterial provided other aspects of the material like nickel release and corrosion gives satisfactory results.
5. Tantalum should be avoided when considering stent designs as it failed in all our test conditions.
6. Rectangular shaped struts for stent geometries initiate higher recirculation regions and might trigger erratic blood behavior. This would trigger more deposition of fats, lipids and unwanted debris thereby causing restenosis of the stented regions.
7. Circular struts can be used for designing stents for both smaller and larger arteries as they initiate very small recirculation regions.
8. Square shaped struts prove to be best designs when considering recirculation lengths. Filleting of edges is preferable as they aid in generating minimum recirculation thereby minimizing the chances of atherosclerotic deposition.

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.

5. ACKNOWLEDGEMENT

The authors are highly indebted to the School of Bio Science and Engineering, Jadavpur University, and the team of COMSOL Multiphysics Pvt. Ltd. for their extensive help and technical support. The authors acknowledge support from DST PURSE project of Jadavpur University.

6. REFERENCES

[1] Fernando Alfonso,Javier Zueco, MD,Angel Cequier, Ramo´n Mantilla, Armando Bethencourt, Jose R. Lopez-Minguez, Juan Angel, Jose´ M. Auge, Manuel Gomez-Recio,Cesar Morı, Ricardo Seabra-Gomes. A Randomized Comparison of Repeat Stenting With Balloon Angioplasty in Patients With In-Stent Restenosis. J Am Coll Cardiol. 2003 Sep 3;42(5):796-805.

[2] Fry. Acute Vascular Endothelial Changes are associated Increased Blood velocity Gradients. Circ Research, 1968; 22: 165-197

[3] Frank JH Gijsen*1, Francesco Migliavacca2, Silvia Schievano3, Laura Socci2, Lorenza Petrini, Attila Thury, Jolanda J Wentzel, Anton FW van der Steen, Patrick WS Serruys, Gabriele Dubini. Simulation of stent deployment in a realistic human coronary artery. BioMedical Engineering OnLine 2008, 7:23

[4] Mohammadi H, Bahramian F. Boundary conditions in simulation of stenosed coronary arteries. Cardiovasc Eng. 2009 Sep;9(3):83-91

[5] Azadeh Farnoush , Qing Li. Three Dimensional Nonlinear Finite Element Analysis of the Newly Designed Cardiovascular Stent. Australasian Congress on Applied Mechanics, ACAM 2007.ISBN: 0 8582 5862 5. Pg: 277-82

[6] Lally C, Dolan F, Prendergast PJ. Cardiovascular stent design and vessel stresses: a finite element analysis. J Biomech. 2005 Aug;38(8):1574-81.

[7] Lorenza Petrinia, Francesco Migliavacca, Ferdinando Auricchio, Gabriele Dubini. Numerical investigation of the intravascular coronary stent flexibility. Journal of Biomechanics 37 (2004) 495–501

[8] Gerard A. Holzapfel, Michael Stadler. Changes in the mechanical environment of stenotic arteries during interaction with stent: computational assessment of parametric stent designs J Biomech 2006. Eng 127:166–180

[9] Potkin BN, Roberts WC: Effects of percutaneous transluminal coronary angioplasty on atherosclerotic plaques and relation of plaque composition and arterial size to outcome, Am J Cardiol 1998; 62:41

[10] Biyue Liu. Computer simulations of flows in curved tubes with stenosis. Proceedings of the COMSOL Multiphysics User's Conference 2005 Boston

[11] Rogers C, Tseng DY, Squire JC, Edelman ER. Balloon-artery interactions during stent placement: a finite element analysis approach to pressure, compliance, and stent design as contributors to vascular injury. Circ Res. 1999 Mar 5;84(4):378-83.

[12] Foin N, Alegria E, Sen S, Petraco R, Nijjer S, Di Mario C, Francis DP, Davies JE. Importance of knowing stent design threshold diameters and post-dilatation capacities to optimise stent selection and prevent stent overexpansion/incomplete apposition during PCI. Int J Cardiol. 2012 Oct 31. pii: S0167-5273(12)01291-0

[13] Mickae¨l Gay,Lucy Zhang, Wing Kam Liu. Stent modeling using immersed finite element method. Comput. Methods Appl. Mech. Engrg. 195 (2006) 4358–4370

[14] Lally C, Dolan F, Prendergast PJ. Cardiovascular stent design and vessel stresses: a finite element analysis. J Biomech. 2005 Aug;38(8):1574-81.

[15] Frank JH Gijsen*1, Francesco Migliavacca2, Silvia Schievano3, Laura Socci2, Lorenza Petrini, Attila Thury, Jolanda J Wentzel, Anton FW van der Steen, Patrick WS Serruys, Gabriele Dubini. Simulation of stent deployment in a realistic human coronary artery. BioMedical Engineering OnLine 2008, 7:23

[16] Basu K, Ghosh P, Das S, Chanda A, Computational Assessment of Stress Development during Deployment of Commercially Available Stents, IJSET, ISSN No: 2319-5967 , July 2013, Vol 2, Issue 4: 458-464

[17] K. Dasgupta, A study on haemodynamics of atherosclerotic carotid artery, M.E. Thesis-2011, Jadavpur University.