



COMPUTATIONAL MODELING AND ANALYSIS TO INVESTIGATE AND COMPARE THE MECHANICAL BEHAVIOR OF VARIOUS STENT DESIGNS USING FINITE ELEMENT METHOD

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Abstract

The most prevalent health problem is coronary artery diseases which may cause pain and heart attack. Coronary stents are tubular, often mesh-like, structures which are deployed in diseased artery segments to provide a scaffolding feature that compresses arteriomatous plaque, hence restoring luminal area and blood flow resumes as usual. Stent implantation is non-surgical method to treat the coronary artery diseases that can support arterial wall and reduce the risk of heart attack. To improve these coronary revascularization procedures the optimal strategy lies in the further development of stent design, material and coatings. In context of optimizing the stent design, computational models plays an important role. In the present paper, the finite element method (FEM) was applied to simulate the transient expansion process of stent and balloon system. To study the characteristics of stent geometry four different stent designs are modeled and analyzed with same internal pressure, material property and boundary conditions. The stress strain values were compared and the best design was identified in terms of stress and strain. The selected design is again analyzed with variable inflating pressures to get the exact pressure for a radial expansion of 1 mm. Finally the selected stents were analyzed under more realistic conditions (considering plaque and artery wall together with balloon and stent)

to realize the pressure requirement in the real situation.

Keywords: Coronary stents; Restenosis; FE analysis; Stent design;

1. Introduction

Coronary heart disease is leading cause of death worldwide. Most recent technology to overcome coronary heart disease is stenting. In stent angioplasty a stent is implanted inside the blood carrying vessel to recover normal flow and to reduce restenosis. Coronary stent is a mesh tube inserted into a diseased artery to recover the natural blood flow. Due to its simplicity and efficiency, the use of coronary stent has increased rapidly. In the last three decades computational studies have vital role in simulating complex nonlinear boundary value problems in all aspects of engineering science. The finite element (FE) method has facilitated simulation of stent deployment in diseased arteries in both idealized and patient specific geometries .

Presently, significant efforts are being made in the field of stent biocompatibility as well as drug eluting application and biodegradable coronary stent to improve the life of the patient. The most common problem that still exists in stent implantation is restenosis. Restenosis is the re-narrowing of artery lumen even after angioplasty or stenting by plaque deposition covering the stented portion. Studies have shown that restenosis can be correlated with geometrical properties of stent such as number of struts, strut width and thickness, and geometry of cross section of each strut. The

geometric characteristics of stent determine the mechanical properties and the pressure load that a stent can withstand when inserted into the lesion site or the effected coronary artery. With an advanced finite element approach it is possible to simulate non-linear problems, characterized by high displacements and analysis of the stent with diseased artery is considered. Elasto plastic deformation, non-linear material properties and sophisticated contact mechanism are non linear characteristic [9]. In an ideal scenario the suitability of patients with atherosclerotic plaques to undergo stenting could be assessed prior to treatment by reconstructing an accurate geometry of the diseased location with the related tissue components such as lipid pools and micro calcifications with incorporated residual stresses. A set of models (geometrical and material) for a stent used during the treatment could then be deployed in this reconstructed model by using the FE method, and a clinician could be better informed, e.g., to choose the most suitable stent (geometry and material) for a specific patient. Also we could find the optimum pressure required for stenting and hence it acts as an aiding tool for selecting the stent during angioplasty.

In this study, we created four new stent models similar to promus stent by varying the shape and width of strut and connector. Finite element analysis of various models was done by applying internal pressure for inflating the stent. Among the different models the best one is selected by studying the stress strain distribution along the stent at same load and boundary conditions. The inflating pressure required for the optimum opening of the artery is determined by varying the pressure load from 0.2 to 0.4 MPa. For more realistic approach FE analysis of the stent with diseased artery is considered.

2. Finite element Modeling

Four new stent designs and Palmaz-schatz were re created using SOLID WORKS software. The stents are modeled by varying strut geometry, strut width and shape of linkage and position of linkage. All stents were modeled with inner diameter of 2.9mm, outer diameter of 3mm, length of 10mm and thickness 0.05mm.

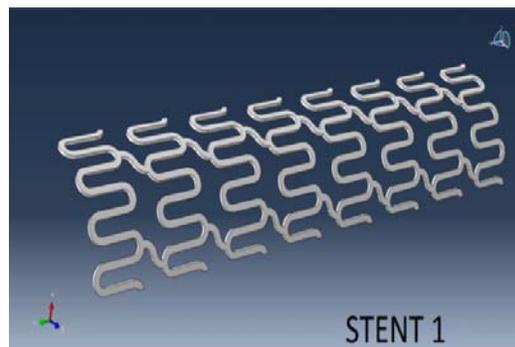


Fig-2.1: stent 1

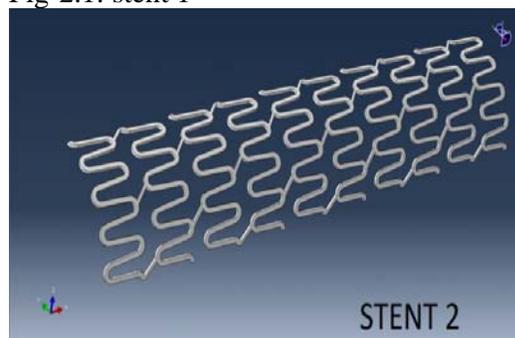


Fig-2.2: stent 2

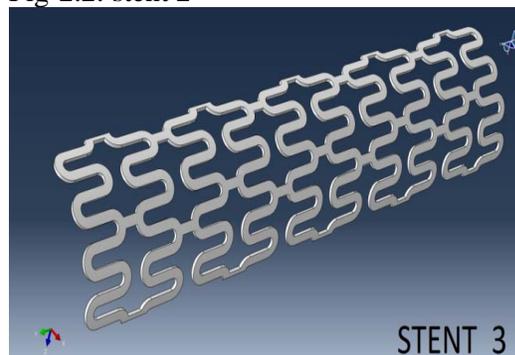


Fig-2.3: stent 3

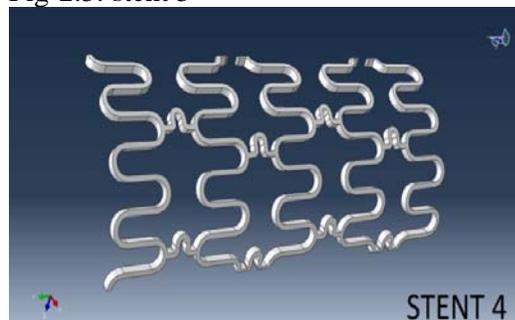


Fig-2.4: stent 4

In stent 1 series of strut patterns are connected with curved connector. Also strut patterns are of same orientation and in stent2 model the connector is straight and the curve of the main strut is reduced. Strut pattern of stent 3 is same as stent 1 but its orientation is opposite and the connector is straight and parallel to the longitudinal axis. Stent 4 is more or less similar to stent 3 except in the shape of the connector and the thickness of the strut.

3. Analysis

3.1 stress strain analysis on palmaz stent

Assembly of balloon and Palmaz stent is considered for this analysis to validate the methodology as shown in fig-3.1. A bi-linear elasto-plastic material model was assumed for the stent material. The material properties were chosen to approximately represent stainless steel 304 (Young's modulus=193GPa; shear modulus =75×106MPa; tangent modulus=692MPa; density=7.86×10-6kg/mm³; yield strength=207MPa;Poisson's ratio=0.27). The balloon modelled to be 12mm in length. The outer diameter and the thickness of the balloon were 2.9 mm and 0.1 mm, respectively. Material of the balloon is polyurethane rubber . It is incompressible and was modelled by using a nonlinear first-order Mooney–Rivlin hyper elastic constitutive equation. The energy function's constants used are: C(10)=1.06881MPa, C(01)=0.710918MPa and $d=1070\text{kg/m}^3$. Where C(10) and C(01) are the energy function invariants, and d is the density of polyurethane [8]. The analysis is done by ABAQUS software to calculate stress distribution and deformation. Due to symmetry of stents and balloon only one fourth part was used to simulate the expansion process. Symmetrical boundary conditions were imposed on the nodes of the stent and balloon in the planes of symmetry all the nodes perpendicular to y-axis and x- axis were allowed to move in y-direction and x-direction respectively. Both the end of stent were free from any constrain so that the expansion and shortening behavior of the stent would be observed. For modeling purpose, the balloon was assumed to be fully tethered at both ends and hence only the expansion in radial direction was permitted. The pressure load was applied as a surface load on the inner surface of the balloon and was subjected to a uniform internal pressure of 0.409MPa.

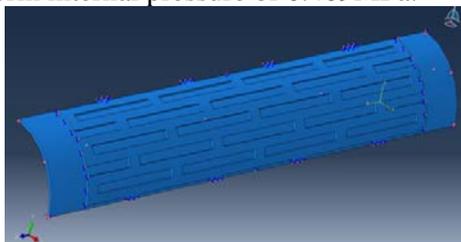


Fig-3.1: Assembly of Palmaz schatz stent
The balloon was discretized by 60 elements along its modeled length and 20 elements in circumference with 2 elements across the

thickness. Surface to surface contact algorithm was used in order to cope up with the non linear contact problem between the two component surfaces. Material non linearity was accounted for the analysis. The outer surface of the balloon was taken as master surface and inner surface of stent as slave surface for the interaction. A penalty friction formulation with a frictional coefficient of 0.25 was assumed as interaction property. A static general step with non linear geometry was used to analyze the expansion of stent along with balloon. Time period of 1.635ms was used with initial increment size of 0.1 and maximum increment of 1.635. The results obtained from the analysis was maximum von Mises stress of 210MPa and maximum strain of 0.556 for Palmaz stent which is at par with the values shown in the reference journal [8]. Small difference in the value is due to the variation in the element size and the software. Hence the methodology is validated. The results are shown in Fig-3.2 , Fig-3.3 and Table-3.1

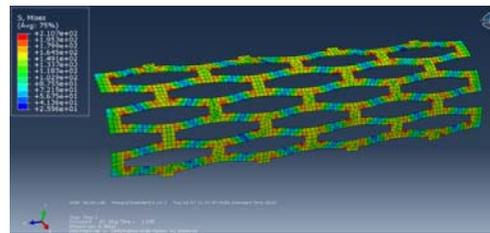


Fig-3.2 Maximum and minimum von Mises stress of Palmaz stent.

Table-3.1: comparison with previous studies

Paper	Maximum stress (MPa)
Present Work	210.70
N Eshugi et al[8]	257.50

3.2 Analysis of various models with same inflating pressure

In this study four different stent models were expanded with an internal surface pressure of 0.409 MPa to analyse the variation in stress and deformation in different geometry. By comparing the results of this analysis the best design can be selected based on the stress and deformation. An elasto-plastic material (SS-304) was assumed for stent material and hyper elastic material for balloon for all the four models. All other conditions such as loading, assembly, meshing and boundary conditions for this analysis is same as the previous one.

Assembled model of stent3 and balloon is shown in Fig 3.4

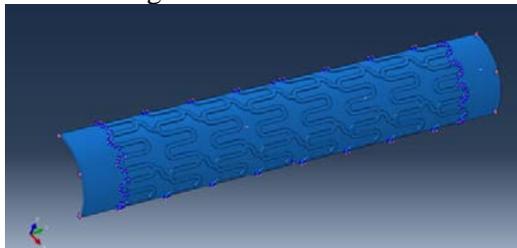


Fig 3.4: FE model of stent3 and balloon assembly

3.3 Stent analysis at varying inflating pressures

From the previous analysis, the stent 1 was found as the best design because it gives minimum stress for maximum deformation with uniform stress distribution. In this analysis stent model 1 is loaded with an internal pressure of 0.2MPa , 0.3MPa and 0.4MPa to identify the optimum inflating pressure for the radial expansion of of 1 mm. An elasto-plastic material (stainless steel 304) was assumed for the stent material.

3.4 Analysis of stent, balloon and artery assembly

This study is to mimic the real situation by considering both artery and plaque together with stent. Symmetric boundary conditions were imposed on the nodes of the stent, balloon and diseased artery in the planes of symmetry where all the nodes perpendicular to y-axis and x-axis were allowed to move in x and y-directions respectively. Both ends of the diseased artery and stent were given z-symmetry constraints. The balloon was assumed to be fully tethered at both ends and hence only expansion in radial direction was permitted. Both the artery and plaque are assumed to be a hyper-elastic material. The balloon was subjected to a uniform internal pressure of 0.6 MPa.

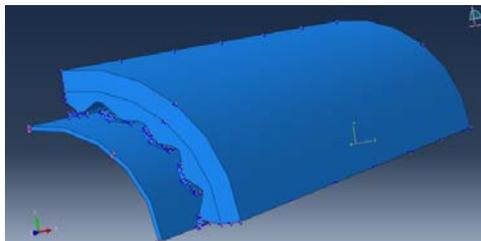


Fig-3.5: Assembly of stent with balloon and diseased artery

Surface to surface contact algorithm was used in order to cope up with the non linear contact

problem between the two component surfaces. The three interactions in these models are balloon-stent interaction, stent-plaque interaction and plaque- artery interaction. For balloon-stent interaction, the balloon outer surface is taken as the master surface and stent inner surface is taken as slave surface and a penalty frictional formulation with 0.25 as frictional coefficient was assumed as interaction property. For stent-plaque interaction, the outer surface of the stent was taken as master surface and inner surface of the plaque was taken as the slave surface. For plaque- artery interaction, the outer surface of the plaque is taken as master surface and inner surface of the artery is assumed as slave surface. A penalty frictional formulation with 0.05 as frictional coefficient was assumed as interaction property in both the cases. Assembly of stent with balloon and diseased artery is shown in Fig3.5

4.Results and discussions

In this section, the results of the finite element analysis of the coronary stents are presented. The results include stress distribution, stent expansion and comparison.

4.1 Different models at same inflating Pressure

The maximum stress on stent 1 is on the bends of the middle strut and the stress on the connector is less. The deformation is more at the middle as there are large void space between the connectors and the expansion is more uniform without any distortion. Fig-4.1 and 4.2 shows the stress and strain distribution.

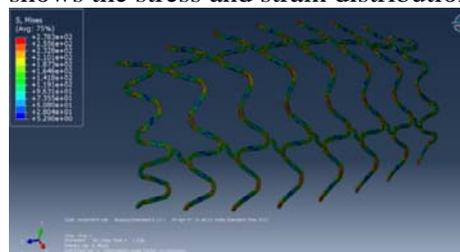


Fig-4.1 Maximum and minimum von Mises stress of stent 1

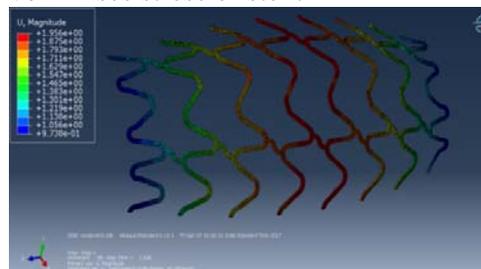


Fig-4.2 Maximum and minimum deformation of stent 1

In stent 2 design the bridge connector elongates and stress increases. High distortion takes place during expansion (Fig-4.3)

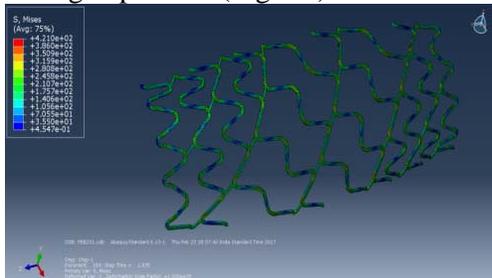


Fig-4.3 Maximum and minimum von Mises stress of stent 2

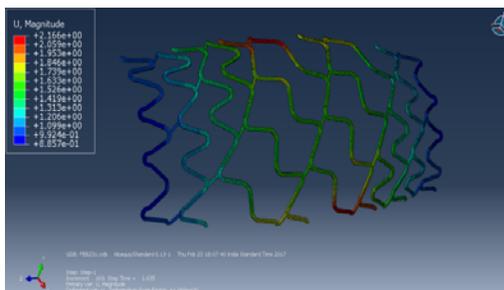


Fig-4.4 Maximum and minimum deformation of stent 2 in stent3 design maximum stress is observed at the bend of the strut where there is no bridge connector. As the struts are connected with straight link the expansion is minimum compared to other design.(Fig-4.4 and Fig-4.5)

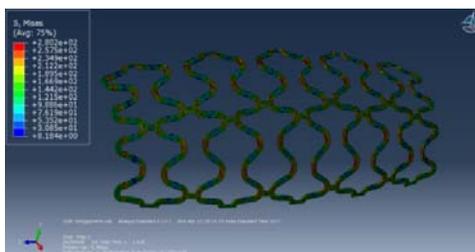


Fig-4.5 Maximum and minimum von Mises stress of stent 3

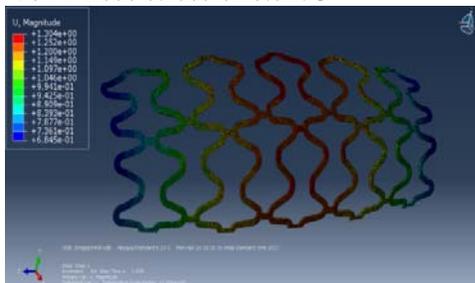


Fig-4.6 Maximum and minimum deformation of stent 3

Stent design 4 gives large deformation due to smaller width of the strut and distortion takes place on strut. The curve provided in the connector is not in a position to become straight

(Fig-4.6 and Fig-4.7). The table 7.1 gives the comparison of different models with respect stress and strain. Stent 1 shows better result as it gives more deformation with comparatively less stress and minimum distortion.

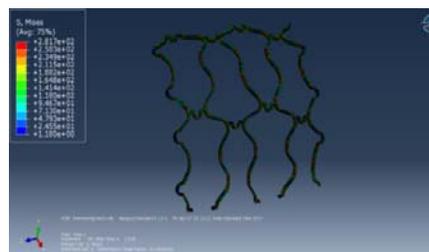


Fig-4.7 Maximum and minimum von Mises stress of stent 4

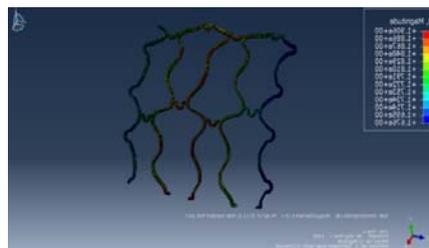


Fig-4.8 Maximum and minimum deformation of stent 4

Table-4.1: comparison of stent designs

Stent model	Maximum stress (MPa)	Maximum strain
Stent 1	278.30	1.96
Stent 2	421.00	2.16
Stent 3	280.20	1.30
Stent 4	281.70	1.90
Palmaz	328.10	0.55

4.2 Stent 1 at varying inflating pressures

Stent 1 has been selected as best design among the four models, Since it gives maximum deformation with minimum stress and the expansion is uniformly distributed. The analysis of stent 1 with various pressures was conducted to investigate the expansion characteristics in different pressures. The result will give an idea of input pressure for a required amount of expansion for a given stent. From the graph shown in Fig-4.14 get an idea how the deformation changes with pressure load. This variation is different for different design (geometry).

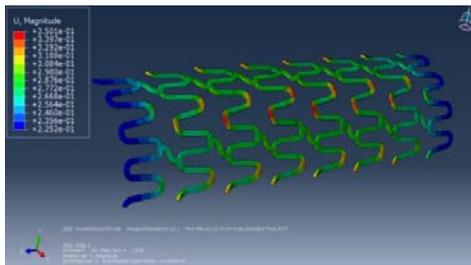


Fig-4.10 Maximum and minimum deformation of stent 1 at 0.2 MPa.

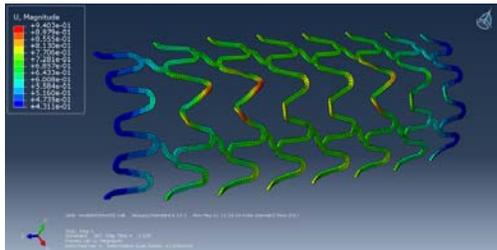


Fig-4.12 Maximum and minimum deformation of stent 1 at 0.3 MPa.

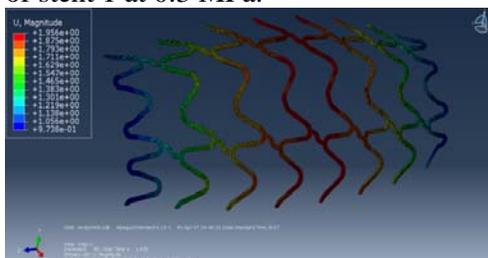


Fig-4.14 Maximum and minimum deformation of stent 1 at 0.4 MPa.

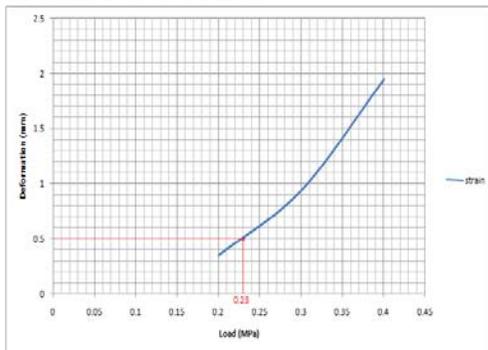


Fig-4.15: graph: load Vs deformation

From the graph, it is observed that the inflating pressure for a radial expansion of 0.5mm is 0.23 MPa on stent 1 and the deformation increases with inflating pressure.

4.3 Analysis of stent 1 design with different materials

In this study three commonly used stent materials (Stainless Steel 304, Nitinol and Titanium) were analysed to study the impact of material property on design. stent 1 design is considered for this analysis. Input pressure taken is 0.23 MPa, which is the value obtained from previous result for 1mm expansion (Fig.4.15). Without changing design and

pressure the analysis was carried out by changing the material properties. All other conditions such as loading, assembly, meshing and boundary conditions for this analysis were same as the previous one. Table- 4.2 shows the result of this analysis. For this design SS 304 gives comparatively good performance.

Table- 4.2 comparison of stress/strain for different materials

Materials	Maximum Stress (MPa)	Deformation (mm)
SS 304	210.70	0.455
Nitinol	439.10	0.737
Titanium	242.70	1.003

4.4 Stent with balloon in diseased artery

In this analysis a pressure load of 0.6 MPa is applied on the inner surface of the balloon, stent and artery assembly. As there are plaque and artery on the stent it needs more pressure to get the required expansion. Maximum stress of 235.9 MPa and maximum strain of 0.7 was obtained.

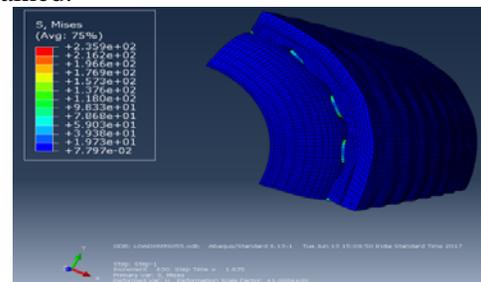


Fig-4.14: balloon, stent, plaque and artery assembly.

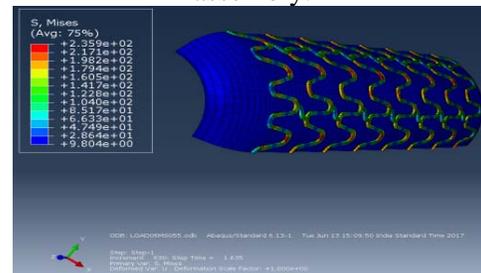


Fig-4.22 Stress distribution over stent

5. Conclusion

The paper present a methodology for modeling the expansion of coronary stent used in the treatment of blood vessel stenosis. Comparison of mechanical behavior of different stent designs are made by FE analysis. The increase in the number of link in the stent design increases the maximum stress and decreases the expansion of the stent. The shape of the link greatly affects the expansion capabilities of the

stent. By analyzing all the models it was observed that more stress is seen at the connector if the connector is straight and the strain is observed to be more at the middle of the stent, due to encastering of the ends of the balloon during expansion. The stent 1 and stent 4 have more diverse stress and strain distribution. The stent 1 is able to withstand more stress and has high strain at the given pressure of 0.409Mpa. The amount of material in the strut also affects the strain induced in the element. When the amount of material decreases the strain increases and vice versa. If the width of the strut is substantially increased then the stress it can withstand also increases, but the strain in-turn decreases which reduce stent flexibility and expansion. The shape of the link is another major factor that affects the strain in the stent. A curved link is always preferable since it can expand more efficiently without distorting the shape of the strut. Strut design should be such that the localized stress distribution should be less. As the design becomes more fluidic, more evenly distribution takes place and strain increases.

From this study, it was observed that the maximum stress concentration was found to be at curved edges because no connector is provided at these points. The stress at these points can be reduced by adding a linkage but it will increase the stent materials and reduce the expansion. In the analysis of stent-1 on diseased artery observes that the stress strain values are almost same as that of only stent even though the load applied on both cases are different. It is due to fact that the diseased artery will be exerting an inward radial pressure which will resist the expansion of the stent. From the analysis by applying different stent materials it was observed that stainless steel stent has minimum stress compared to Nitinol and Titanium stents. This is a clear indication that the SS304 is a suitable material for the selected design (stent1) and the restenosis behavior is comparatively minimum. It was also observed that for different stent materials the deformations at same inflating pressure are different for different stent design. The stent 1 shows uniform deformation in SS304 but non-uniform deformation in Nitinol and Titanium. Moreover it is observed that certain material is suitable for certain design and can be found from this analysis.

It is concluded that before undergoing percutaneous coronary intervention the selection of stent design and material is a critical task and can be done after conducting FE analysis on artery stent assembly. Hence the mechanical behavior of the stent is predicted and the inflating pressure is predetermined.

Acknowledgement

The authors would like to acknowledge the funding from All India Council for Technical Education (AICTE) under research promotion scheme.

6. References

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