

An Investigation on Strength of SS316L and Cobalt-chromium used as Cardiovascular Stent Materials by Non linear FEA

¹Sujith Kumar S G, ²Dr. Hanumantharaju H G

¹Department of Mechanical Engineering, UVCE, Bangalore– 560001

²Faculty, Department of Mechanical Engineering, UVCE, Bangalore – 560001

Abstract

Aim of this study is to provide a computational approach for evaluating the effect of Stents on biomechanical outcome of deployment of stent in different condition. Nonlinear FEA software has been used successfully on balloon expandable stents. Projects often require modelling systems that consist of multiple components with nonlinear materials, complex 3D geometries. The ABACUS, handles the full range of nonlinear material properties for the stent, the catheter balloon, and the artery wall.

The objective of research carried out was to simulate the mechanical behaviour of the stent using finite element analysis. Implantation and in vivo loading are considered. Finite element analysis provides a quick and cost-effective method for evaluating stent performance, yielding accurate information about the expanded geometry and the stress and strain deformation fields with in the stent for various loading conditions.

With appropriate applied internal pressure, the balloon inside the stent is deployed which linearly expands the diameter of a Modular Stent until it reaches 1.7 times of its original diameter. The results will assist in the development of novel stent designs and stent deployment to minimize vascular injury during stenting and reduce restenosis.

The results obtained for the selected stent material are compared. The Cobalt-chromium undergone plastic deformation at 0.44 MPa and SS316L at 0.3 MPa pressure load.

Key Words: Non linear FEM, stents, Stainless steel (SS316L), Cobalt-chromium plastic deformation.

1. Introduction

A stent is an expandable tube-like device that is inserted into a natural conduit of the body to restore a disease-induced localized stenosis..

The introduction of drug eluting stents further improved the outcome and the occurrence of restenosis was reduced to less than 10% for branched vessels.

A stent is very often used with or in substitution of PTA (Percutaneous Trans luminal Angioplasty). In fact this technique has shown many drawbacks as vessel dissection and elastic recoil . Thus the use of the stent has two main goals.

1. Short term effect: to avoid the effects of intimal dissection and the elastic recoil.
2. Long term effect: to avoid restenosis due to the neointimal hyperplasia.

Dotter first introduced the idea of using stents in percutaneous applications in 1969 so, clearly, many improvements have been done up to now in the device design and in the stenting procedure.

The study of the material and the geometrical properties of the stent can provide useful indications on its performance and on its interaction with the target vessel.

Biomechanics, by its characteristic multi-disciplinary approach, may provide the right key to investigate these devices

The biomechanics requirements for the stent can be summarized as follows.

1. Good contour-ability to obtain an adequate fixation to the duct's wall.
2. Adequate resistance against the elastic recoil.
3. Resistance to fatigue due to the pulsate flow and/or body kinematics.
4. High size minimization of the device to make easier the percutaneous procedure.
5. High biocompatibility.

1.1 Classification of Stent

From a mechanical point of view, stents can be classified as.

1. Balloon-expanding.
2. Self-expanding.

This classification is based on the way how they are deployed. Balloon-expanding stents are deployed and plastically deformed applying a high pressure to their inner surface by a balloon. Instead Self expanding

stents are constrained into a catheter imposing a diameter reduction and when the desired delivery site is reached, the constraint is removed and the stent elastically deploys. Clearly, both devices have the same goal but a very different mechanical behavior.

1.2 Balloon-Expanding (BX) Stents

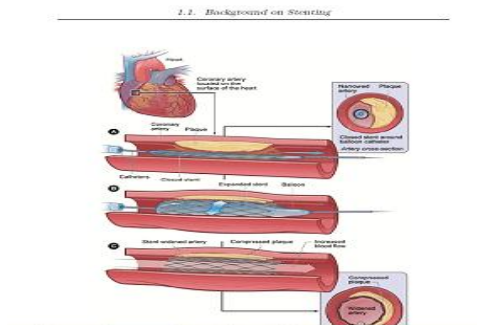


Fig 1.1 Balloon expanding Stent deployment method

Balloon-Expanding stents can be divided into two groups.

1. Coil design.
2. Tube design.

Coil design stents, as shown in Fig.1.2 (a), incorporate a continuous wound wire as in Wiktor stent or a series of flat sheet coils as in Gianturco-Roubin stent. They have a large strut width a gap and no connections between struts provide them high flexibility. However, the design lacks radial strength, and the wide gap allows tissue damage since the tissue prolapses between the wire elements.

Tube design stents, as shown in Fig 1.2 (b) are cut from a steel tube, i.e. Palmaz-Schatz stent (Johnson & Johnson/Cordis Corporation) obtained from a metal sheet which is rolled and welded stent

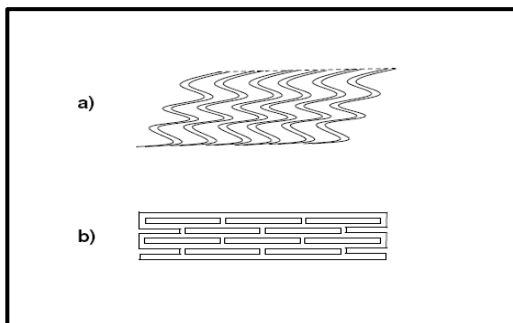


Fig 1.2: (a) Coil (b) tube design.

From the figure 1.3 shows the Palmaz stent made from 316L steel can be considered as the first tubular stent. This stent is manufactured through laser cutting (thus, without welding) and has a tubular shape with rectangular holes.

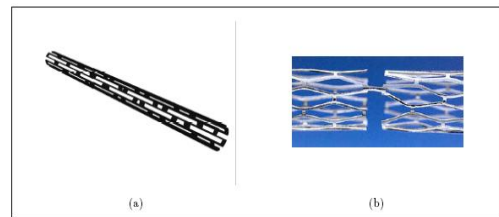


Fig 1.3: Palmaz stent (a) and expanded Palmaz Schatz stent (b)

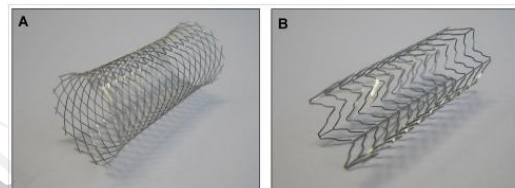


Fig 1.4: SX Palmaz stent (a) and expanded SX Palmaz Schatz stent (b)

Many different types of SX stent designs are available in the market. In the following, provide a brief overview of self-expanding stent designs.

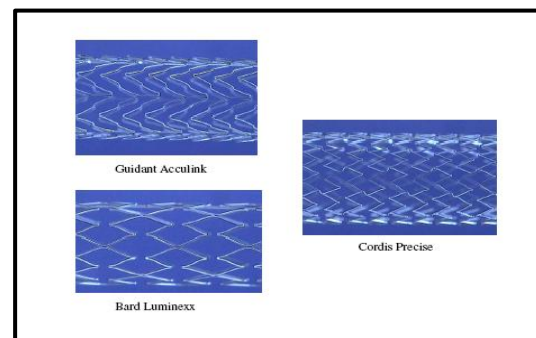


Fig 1.5: Overview of SX stents

1.3 Balloon-Expandable Super Elastic Stents

As previously illustrated, both BX and SX stents have limitations. As a consequence, efforts have been made to combine both the features of BX and SX stents, creating a balloon-expandable super elastic stent. The first approach is based on the idea to add an extra constraint to a SX stent. Proposing the

development of a stent with a progressive expansion device made of polyethylene, allowing smooth and gradual contact between the stent and the artery wall by creep effect as shown in Fig.1.8. In the second approach, proposed by Besselink the stent design proposes a SX stent modified in order to produce two stable states.

1. Closed
2. Open

Wire stent drawbacks

As previously introduced, wire stents have a very wide application field and many clinical studies can be found in literature, but drawbacks in its use are still present. The main problems in wire stent applications are:

- a. Restenosis.
- b. Inflammation provided by body immune response.
- c. Hyperplasia, the abnormal growth of the cells between the wires.
- d. Stent migration, a complication of stent placement, in which the stent is displaced proximally or distally.

Stent implantation was developed to overcome the acute recoil and high restenosis rate of balloon angioplasty (PTA), but they may lead to chronic in-stent restenosis related to specific factors regarding patient stent lesion and procedural characteristics. After stent implantation the mechanism of Restenosis is principally hyperplasia, as stents resist arterial remodeling.

Wall stent

Constraint, the braided wire stent with a certain diameter at the expanded configuration, is inserted into a catheter with a smaller diameter to perform the percutaneous implantation. When the delivery site is reached constraints are released and the stent elastically deploys. Fig.1.6 illustrates the Wall stent and the unit step delivery system. The Wall stent is mounted between two coaxial catheters. The exterior tube serves to constrain the stent. Retraction of the external tube allows the partial stent expansion.

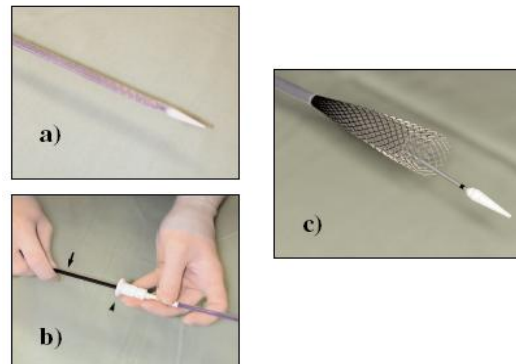


Fig 1.6: (a) Wall stent before deployment (b) the inner tube is held fixed while the outer sheath is withdrawn in order to push out the stent(c).

1.4 Wall Stent Applications

Braided stents tend to be very flexible, having the ability to be placed in tortuous anatomy, still maintaining patency. Many cases are present in clinical literature about the successful use of SX braided wire stents. A first application is to treat carotid artery stenosis and to exclude subclavian and other peripheral artery aneurysms from the pulsatile blood flow. These implants are also used to re-open collapsed airways and to treat obstructing bronchial lesions. In addition, they can be used for the palliation of symptoms provided by malignant lesions or (benign) stenosis in the esophagus and gastrointestinal tract and urethral strictures. More recently, a partially deployed Wall stent has even been used as a temporary inferior vena cava filtration device during coil embolization of high-flow arteriovenous fistula.

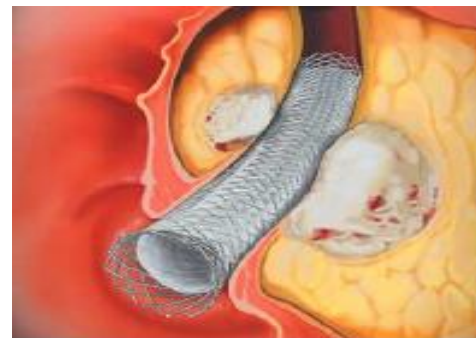


Fig 1.7: Covered Wall Stent

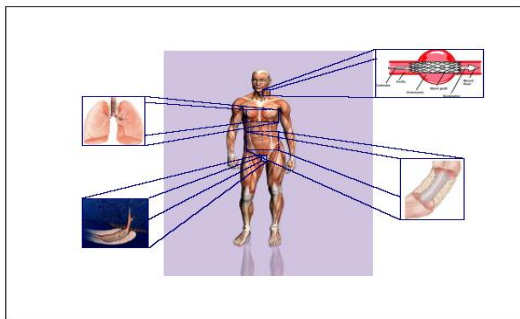


Fig 1.8: Application of Wall Stent in Human Body

1.5 Necessity of alternate material for cardiovascular stent

It is seen from the literature survey/review that large progress has been indicated in need of more investigation of mechanical parameters on different alternative bio-materials for human cardiovascular stent implants.

Literature survey indicates that the material used for human cardiovascular stent implants are conventional materials, with heavier in density, not economical and unstable. It is observed that implant materials are affecting the coronary vessel where the failure of implant is maximum due to wear, corrosion and fatigue, the above problems are due to improper material selection.

Therefore in this project work, Economical, low density and stable materials are selected. Hence it is intended to analyze strength of selected materials, linear static analysis and non linear static analysis by using commercial available FEA package.

Materials subjected to various loads condition to conduct FEA on new materials expansion behavior of the stent model in non linear static analysis

In this paper, we analyzed and compared the suitability of following material for balloon expandable stent.

1. Stainless steel.
2. Cobalt-chromium

1.6 Stainless steel (SS316L)

Most stents are made from 316L stainless steel. Current examples include the Palmaz-Schatz stent, and the Guidant Multilink stent,. Disadvantages of stainless steel stents include the high occurrence of sub acute thrombosis and restenosis, bleeding complications, corrosion, and restenosis of the stented vessel segment.

Stent failures potential adverse events are stent thrombosis, bleeding complications, stroke, and vascular complications. The radiopacity or viewing capacity of stainless steel stents could also be improved.

Steel is an iron alloy. The stainless steels are specific types of steel which will resist to the chemical agents. It includes chromium (Cr) (more than 10%) and nickel (Ni). By the crystal microstructure, the stainless steel can be classified as.

1. Martensitic
2. Austenitic
3. Ferritic.

Here, will focus the attention on the austenitic stainless steel which is the most important class of materials for medical device applications and most BX stents, which are based on the metal plastic deformation, are stainless steel made (SS). These types of stain less steel are interesting because they propose a good compromise among corrosion resistance, strength, and formability, weld ability, and cost.

They are also nonmagnetic allowing Magnetic Resonance Imaging (MRI) of the device.

Mechanical Properties

Table 1: Mechanical properties of SS316L

Properties	Value
Density	7850kg/m ³
Hardness, Rockwell B	79
Tensile Strength, Ultimate	560 Mpa
Tensile Strength, Yield	290 Mpa
Modulus of Elasticity	193 Gpa
Thermal Conductivity	16.2 W/m-K
Melt temperature	1300 ⁰ C

1.7 Cobalt-chromium (Co-Cr)

Co-Cr-Mo alloys have been widely applied to artificial joints because of their excellent mechanical properties, wear resistance and biocompatibility. Co-Cr alloys are standardized in the ASTM standards. ASTM F75 is for as-cast alloy, which should be less than 1.0 % content because Ni is the most common metal

sensitizer in the human body. Alloying Ni to Co-Cr-Mo alloy results in the stabilization of FCC structure. Thus it is inevitable that Ni is added to Co-Cr-Mo alloy to enhance the plastic property at the present time.

This alloy are non-magnetic characteristics can be safely imaged using magnetic resonance. This cobalt alloy has high yield strength and high elastic and shear module it shows excellent fatigue properties. These mechanical properties make it an ideal material for medical implants which utilize spring designs, such as self-expanding stent, which require high yield strength and fatigue resistance.

Mechanical Properties

Table 2: Mechanical properties of **Cobalt-chromium**

Properties	Value
Density	8800k g/m ³
Hardness, Brinell	125
Ultimate tensile strength	614.14MPa
Yield tensile strength	337.84 MPa
Modulus of Elasticity	211 GPa
Passion ratio	0.32

The cobalt alloy offers several key advantages over 316L stainless steel:

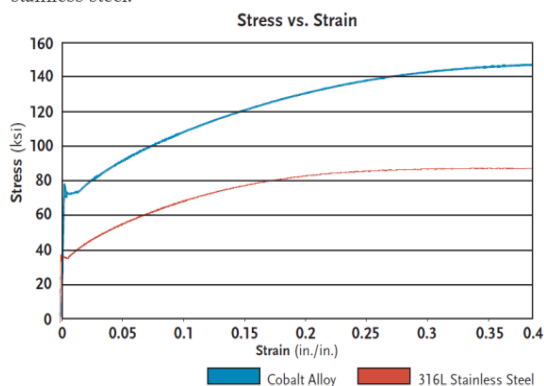


Fig 1.9: stress strain diagram of SS316l and Co-Cr

1.8 Selection of Mechanical Properties

The mostly used stents these days are balloon expandable stents. During stenting procedure the mesh structured implant mounted on a balloon – the stent – is placed into the closure through a catheter with a guide wire. After the balloon is inflated at high pressure (8-20 bar), the expanded stent keeps the way of the blood open through the artery. The base material of these implants has to be capable of plastic deformation, which takes place during the expansion of the balloon. After the balloon is deflated, the stent keeps its expanded form despite a little recoil.

Solid Model of cardiovascular Stent

It would be challenging to describe the design process for a stent without referring to an actual stent design. Since virtually every stent design in existence is proprietary, a new generic design was created. The GENERIC STENT is designed for no particular purpose other than provide a realistic example for utilizing the tools of computer aided stent design. The Open Source Stent described here was designed with Dassault Systems CATIA VR20.

CAD Model

The first sketch in the stent part is the Strut Sketch. This sketch is carefully constructed such that its entire feature. The sketch is fully constrained without being over constrained, which is a balance that can be challenging to achieve with stent models in CATIA VR20

It should also be noted that the expanded configuration assumes that the strut will be perfectly straight, while in reality an expanded strut bend with a curvature that is too complex to represent in this simple model. The finally create a Generic Stent 3 Dimensional model as shown in figure 1.10.

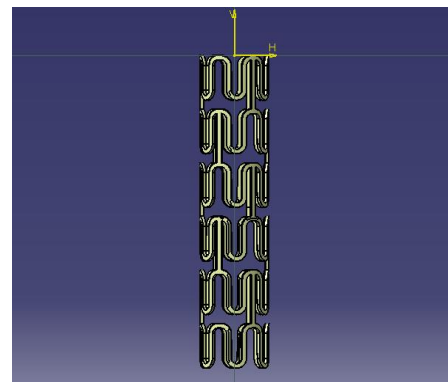


Fig 1.10: Stent Implant model

Finite element analysis of Stent implant model

The model shown in the figure 1.10 is exported as IGES file. This file is imported into the HYPERMESH11 software where the implant model is opened. The 3D finite element model required for analysis is created by discretizing the geometric model as shown in the figure 1.10 the discretization was performed in HYPERMESH 11 software. Finally the model is prepared for analysis. 20318 elements are created and C3D8II elements are used.

ABACUS is primarily a solver for finite element analysis. The tools allow the user to submit an analysis to ABACUS, and import the results and show them graphically. ABACUS is compatible with a large variety of computers and operating systems ranging from small workstations to the largest supercomputers.

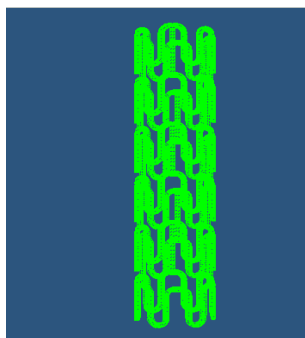


Fig 1.11: Meshed Model of Stent.

Non Linear Static Analysis

Non Linear static analysis allows engineers to test different load conditions and their resulting stresses and deformation. Knowing how a design will perform under different conditions allows engineers to make changes prior to physical prototyping, thus saving both time and money.

The term “stiffness” defines the fundamental difference between linear and nonlinear analysis. Stiffness is a property of a part or assembly that characterizes its response to the applied load.

Nonlinear analysis becomes necessary when the stiffness of the part changes under its operating conditions. If changes in stiffness come only from changes in shape, nonlinear behavior is defined as geometric nonlinearity. Such shape-caused changes in stiffness can happen when a part has large deformations that are visible to the naked eye.

If changes of stiffness occur due only to changes in material properties under operating conditions, the problem is one of material nonlinearity.

A linear material model assumes stress to be proportional to strain. If the loads are high enough to cause some permanent deformations, as is the case with most plastics, or if the strains are very high (sometimes > 50 percent), as occurs with rubbers and elastomers, then a nonlinear material model must be used.

In Non linear static analysis the material is in static equilibrium. The pressure must be “slowly applied,” in the inner surface of the element in vector direction which means that they induce no dynamic effects.

Boundary and Loading Conditions

For valid results, an FE mesh should only be subjected to realistic boundary and loading conditions that are representative of the actual conditions. For the analysis of stent deployment, the stent must be free to expand and contract in the radial and longitudinal directions yet fixed such that rigid-body motions are prevented as shown in fig 1.12. Generally, a small number of nodes in each of the discretized components in the analysis are constrained from movement in a very specific number of directions to avoid any rotational or translational movement. In terms of loading conditions, stent expansion is typically achieved through displacement control, pressure control while studies in which stent expansion has been achieved through pressure load on the inner surface of the stent as shown in fig 1.12.

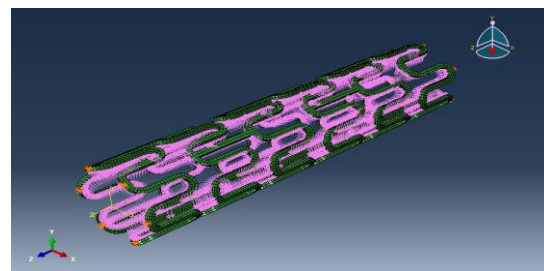


Fig 1.12: Boundary and Loading Condition Plot

1.9 Results and Discussion

In this present study, this chapter Results and discussion is the heart of the thesis in which all the results obtained by conducting Non linear F.E.A, on cardiovascular implant (Stent) materials are tabulated, compared and discussed carefully in the following sections.

Finite element analysis

Static analysis done on stent implant model considering the pressure loads exerted by human body

viz, 0.1MPa,0.4MPa,0.6MPa, results are tabulated and discussed for the realistic use for considered materials in this analysis.

Static analysis

The following figures 1.13 to 1.18 shows the Displacement, Von Misses Strain, Von Misses Stress for the loads 0.4MPa for SS316L and 0.6MPa for Cobalt-chromium on all the materials.

Results analysis of SS316L

Case 1 : Pressure Load 0.4 MPa

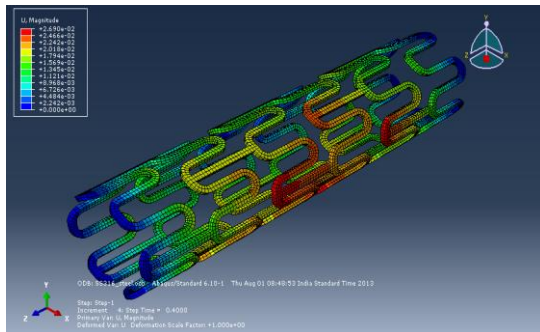


Fig 1.13: Displacement Plot of SS316L for 0.4MPa

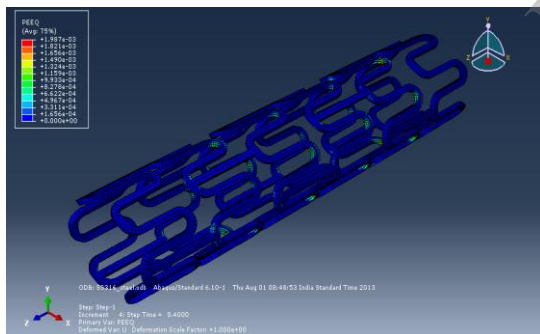


Fig 1.14: Von-Misses Strain Plot of SS316L for 0.4MPa

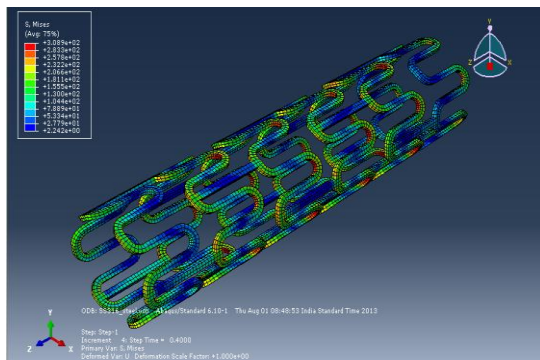


Fig 1.15: Von-Misses Stress Plot of SS316L for 0.4MPa

Results Analysis of Cobalt Chromium

Case 2: Pressure Load 0.6 MPa

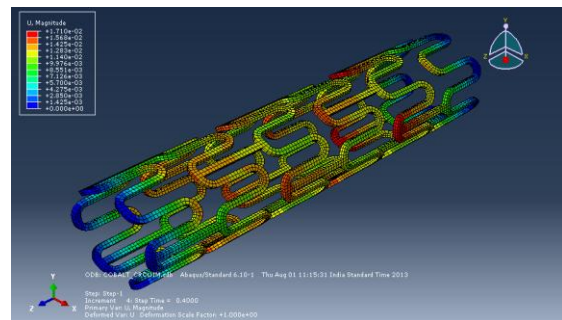


Fig 1.16: Displacement Plot of Cobalt Chromium for 0.6MPa

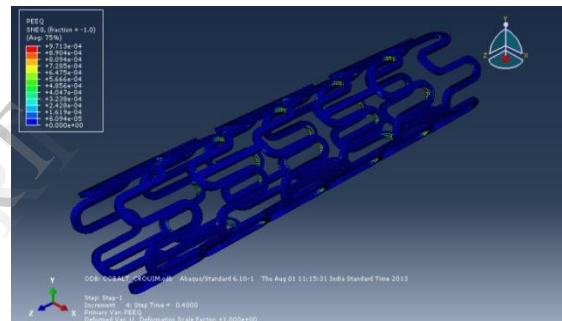


Fig 1.17: Von Misses Strain Plot of Cobalt Chromium for 0.6MPa

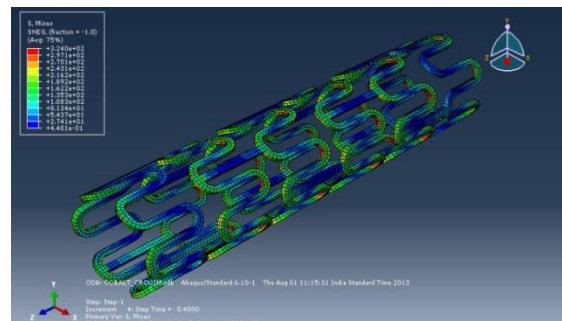


Fig 1.18: Von Misses Stress Plot of Cobalt Chromium for 0.6MPa

1.10 Result Summary

Analysis of Stent materials are given in the following table in terms of Displacement, Von-misses strain ,Vonmisses stress, 1st principal stress, 2nd principal stress .

Table 3: Results Summary of SS316L

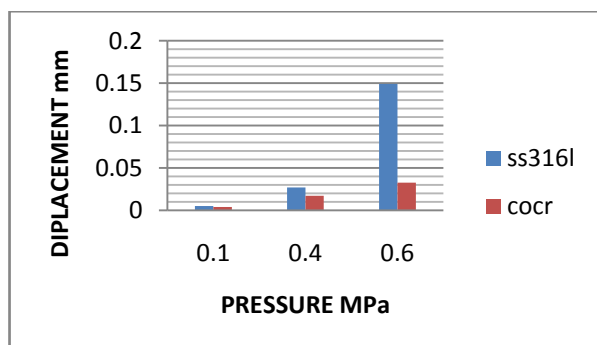
Sl no	Pressure Load (MPa)	Max Displacement (mm)	Max Von misses Strain	Max Von misses Stress (N/mm ²)	Max 1 st Principal Plane stress (N/mm ²)	Max 2 nd Principal Plane stress (N/mm ²)
1	0.1	5.9E-03	0	113.5	101.2	-0.1385
2	0.4	2.69E-02	1.987E-03	308.9	292.3	46.56
3	0.6	1.49E-01	2.905E-02	405.2	495.9	-1.19

Table 4: Results Summary of Cobalt Chromium

Sl no	Pressure Load (MPa)	Max Displacement (mm)	Max Von misses strain	Max Von misses Stress (N/mm ²)	Max 1 st Principal Plane stress (N/mm ²)	Max 2 nd Principal Plane stress (N/mm ²)
1	0.1	3.9686E-3	0	105.5	104.7	2.962
2	0.4	1.71E-02	9.713E-04	324	343.4	14.21
3	0.6	3.258E-02	2.144E-03	540.6	547.5	28.55

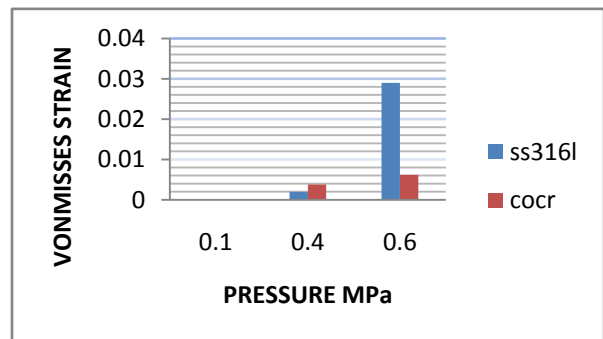
BAR CHART:

The graph 1 shows the displacement of all considered materials are shown in the form of bar chart.. It is seen that displacement for SS316L with 0.149mm for the pressure load of 0.6MPa & minimum displacement for Co-Cr with 0.0325mm under pressure load of 0.6MPa.



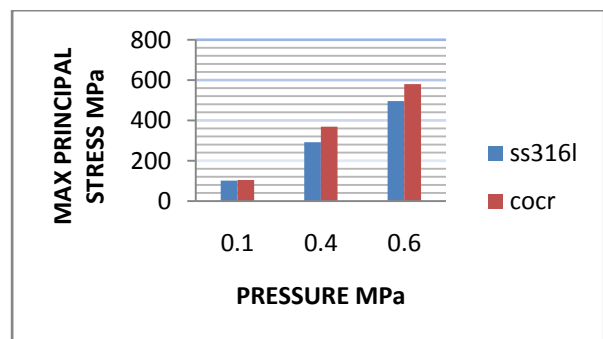
Graph1: Bar chart of displacement of different cardiovascular stent implant of materials.

In the graph 2 shows the strain developed for considered materials when subjected to the pressure loads of 0.1MPa, 0.4MPa and 0.6MPa are shown in the form of bar chart. The maximum von misses strain is being observed that 0.0291 for SS316L under 0.6MPa and a least strain of 0.00618 seen for the Co-Cr material under load of 0.6MPa.



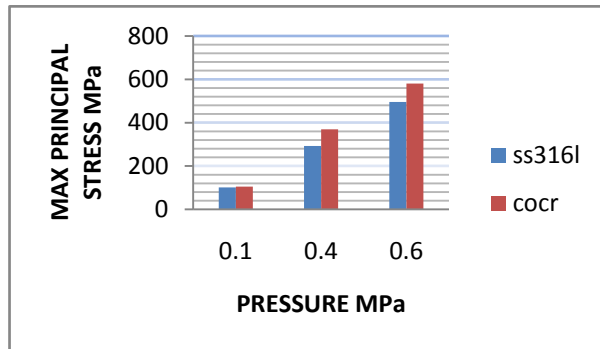
Graph 2: Bar chart of Von-misses strain of cardiovascular stent implant of different materials.

In the graph 3 shows the von misses stress developed for considered materials when subjected to the pressure loads of 0.1MPa, 0.4MPa and 0.6MPa are shown in the form of bar chart. It is observed that SS316l has crossed yielding stress of 290 MPa at 0.3 MPa. Co-Cr has crossed yielding stress of 337MPa at 0.4 MPa.



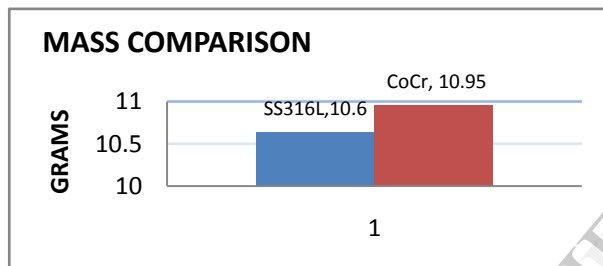
Graph 3: Bar chart of Von-misses stress of cardiovascular stent implant of different material.

In the graph 4 shows the 1st Principal stress developed for considered materials when subjected to the pressure loads of 0.1MPa, 0.4MPa and 0.6MPa are shown in the form of bar chart.



Graph 4: Bar chart of Max Principal stress of cardiovascular stent implant materials

In the graph 5, the Mass comparisons of the considered materials.



Graph 5: Bar chart of Mass comparisons of stent of considered materials

1.11 Conclusion

Realistic features of materials on the basis of results obtained by Finite Element Analysis, considering the different pressure loads exerted by balloon on stent implants to make plastic deformation are concluded as follows with respect to von-mises stresses, maximum principal stresses, displacement, and density are as follows.

- ❖ For the plastic deformation of Cobalt Chromium more pressure load of 0.44 MPa is required where as 0.3 MPa is enough to make plastic deformation of SS316L.
- ❖ At plastic deformation, Displacements for the material Cobalt Chromium is 0.017 mm and SS316L is 0.0269 mm.
- ❖ From the displacement analysis cobalt chromium is found to be more suitable than SS316L. Higher density of the cobalt chromium enables to reduce the strut thickness which reduces the restenosis to a great extent.

- ❖ The difference in the applied pressure load for the plastic deformation of SS316L and Cobalt Chromium is not very high.
- ❖ The Mass of GENERIC stent model of considered materials, SS316L with 10.63 gm of mass, Cobalt Chromium with 10.956 gm of mass.

1.12 Scope for the future work

- ❖ Suitability of shape memory alloy Nitinol should be studied.
- ❖ Compressive and Bending strength of stent materials may be studied.
- ❖ Fatigue life of stent material may be studied.

1.13 REFERENCES

1. W. Walke, Z. Paszenda, J. Filipiak, Experimental and numerical biomechanical analysis of vascular stent. *Journal of Materials Processing Technology* 164-165 (2005) 1263-1268.
2. Francesco Migliavacca,*, Lorenza Petrini, *Journal of Biomechanics* 35 (2002) 803-811, "Mechanical behavior of coronary stents investigated through the finite element method"
3. C. Lally, F. Dolan, P.J. Prendergast, *Journal of Biomechanics* 38 (2005) 1574-1581 "Cardiovascular stent design and vessel stresses: a finite element analysis"
4. Won-Pil Park, Seung-Kwan Cho, Jai-Young Ko, *World Academy of Science, Engineering and Technology* 37 2008 "Evaluation of Stent Performances using FEA considering a Realistic Balloon Expansion".
5. Tho Wei Tan, Graeham R. Douglas 2009, "Compliance and Longitudinal Strain of Cardiovascular Stents: Influence of Cell Geometry," *Philos. Trans. R. Soc. London*, 367(1902), pp. 3585-3606.
6. David Martin, Fergal Boyley, Dublin Institute of Technology, Year 2010 "Computational Structural Modelling of Coronary Stent Deployment" Published in *Journal of Biomechanics* 38:6 (June 2005), pp. 1221-1227
7. Mickael Gay a, Lucy Zhang a, WingKam Liu b a Department of Mechanical Engineering, Tulane University, 6823 Saint Charles Avenue, New Orleans, LA 70118, USA b Department of Mechanical Engineering, 2145 Sheridan Road, Northwestern University, Evanston, IL 60208, USA Received 9 December 2004; accepted 14 September 2005
8. Azadeh Farnoush, Qing Li *School of Aerospace, Mechanical and Mechatronic Engineering, The University of Sydney, Sydney, NSW 2006, Australia*
9. Philippe Terriault, Patrick Terriault, *Journal of Biomechanics* 39 (2006) 2837-2844 "Finite element modeling of a progressively expanding shape memory stent"
10. Ryhänen, Jorma. "Biocompatibility evaluation of metal alloy." University of Oulu. 1999.