FINITE ELEMENT ANALYSIS OF PLLA CARDIOVASCULAR COILED STENT

By

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***"In the name of Allah, Most gracious, -----------------
---- Most compassionate"***

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Abbreviations and symbols

Percutaneous Transluminal Coronary Angioplasty …………………………..	PTCA
Percutaneous Coronary Intervention …………………………………………	PCI
Balloon Expandable Stents …………………………………………………	BES
Polyethylene terephthalate………………………………………………….	PET
Polyethylene ………………………………………………	PE
Polyvinyl chloride ………………………………………………	PVC
Polyurethanes ………………………………………………	PU
Red Blood Cells ………………………………………………	RBC
Poly – L –Lactic Acid ………………………………………………	PLLA

Abstract

In cardiovascular field angioplasty plays an important role. It is widening of a blocked vessel by balloon catheter. Stent holds an important role in angioplasty. A stent is any medical device that supports tissue, but most commonly a stent refers to a specific medical device that is placed inside an artery after angiography to stop the artery from becoming blocked again. An arterial stent is a mesh like tube often made of metal/fiber that can expand through balloon expansion once it is inserted into an artery.

The most common problems related to stents are improper expansion and restenosis inside the vessel. The balloon transfers the pressure as load to expand the stent. Restenosis is the narrowing of artery/blood vessel. This narrowing of vessel is due to the fact that stent strength decreases with time and mechanical load is passed to the surrounding tissue.

This work presents the study carried out using carbon fiber composite poly-lactic acid as basic material for stent. The type of stent used was coiled. Stent expansion procedure was simulated using non-linear FEM model in Ansys, which is considered to be the best possible way to simulate expansion procedure for current design of stents.

Interaction between balloon material and stent surface was modeled as frictional contact. The results of stent were analyzed with respect to stress, strain and deflection which mainly contribute to cause of restenosis.

Two cases (i) Double-end constrained and (ii) single-end constrained were simulated with different boundary conditions of balloon expansion. Radial recoil, longitudinal recoil and axial displacement results were analyzed.

CHAPTER # 1

Introduction

1.1 Background:

Cardiovascular diseases are main cause of deaths all over the globe. They are class of diseases that involve heart and vessels (artery and veins) [1]. One of the main reasons of disease is narrowing of arteries referred to as Atherosclerosis. It is building up of plaque in the arteries resulting in narrowing and hardening of arteries. The complications of atherosclerosis include rupturing of plaque, blood clotting which leads to debris in the blood stream and clotting inside the artery. Smoking, drinking, diabetes and lack of physical activity are some of the reasons for atherosclerosis. The ailment progress is slow over time.

Plaque can totally or partially block the blood flow through artery. Angioplasty and Vascular stents have been used to restore arterial blood flow in patients suffering from atherosclerosis for the past two decades.

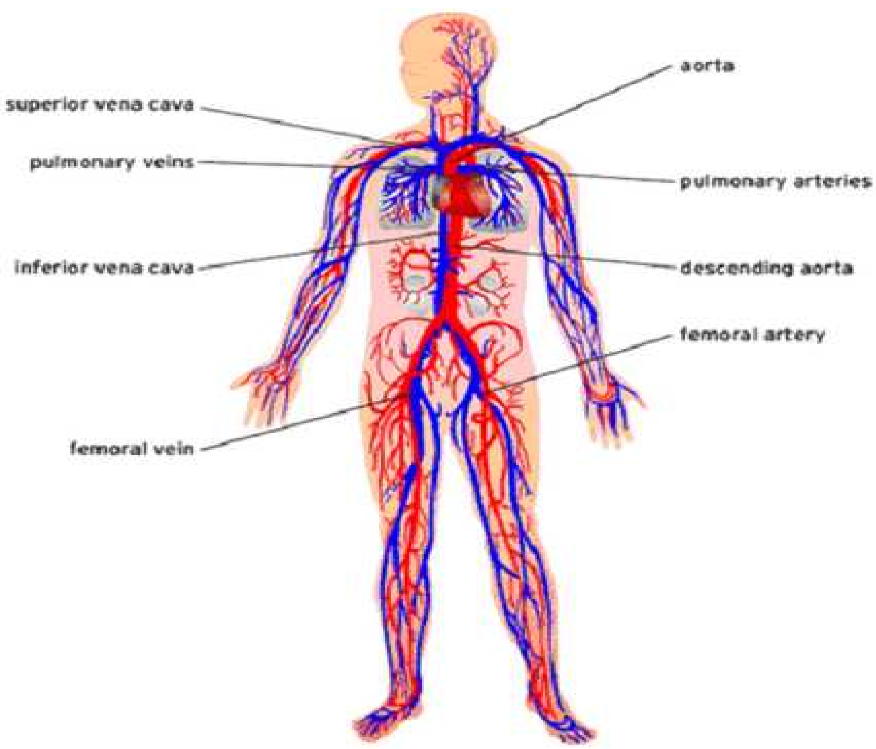


Fig. 1.1 Circulatory System [1]

1.2 Stent:

Stent can be defined as a medical device which supports tissue, but commonly stent refers to a specific medical device that is placed into an artery. An arterial stent is often in shape of tube, and of metal composition, which expands once it is inserted into an artery [2].

Stents are frequently placed in arteries which are obstructed by plaque. Stents are mainly of Stainless Steel composition [3].

A stent is injected into an artery during angioplasty and inflated with a balloon catheter. The procedure begins at the femoral artery (Fig 1.1) in the groin, or the axillary artery located in the armpit and the stent is guided to the desired artery. The stent is placed in the artery permanently where the stent supports the narrowed or blocked artery, keeping it open for blood to flow more freely.

1.2.1 Types of Stent:

Stents can be used for

1) Short term effect 2) Long term effect

In short term effect the elastic recoil effects are encountered, where as in long term effect the Restenosis effect is overcome [4].

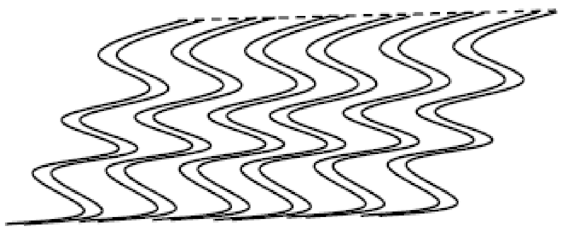
There are two main types of stents

- Balloon expanding stents (BES)
- Self expanding stents

1.2.2 Balloon Expanding stents (BES):

The balloon stents are further divided into coil and tube design [4].Fig 1.2 shows the two main balloon expanding stent designs. The coil designs have large strut width and have no connections between struts. The coil designs have high flexibility. The tube design stents are made from metal sheets. They have high radial strength.

Balloon expanding stents are plastically deformed by high pressure from angioplasty balloons. This plastic deformation causes them to deploy in a vessel/arteries.BES are the stents being used in majority that is due to their long term effect and good expansibility ratio [5].



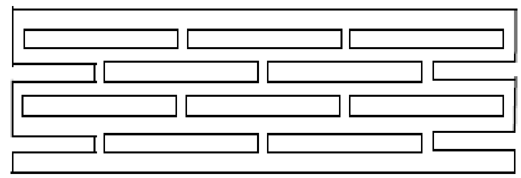


Fig. 1.2 (a) Coil design [4] (b) Tube design [4]

Self Expanding Stents on the other hand do not require angioplasty balloons for their deployment. On reaching the site of deployment the constraint is removed and they open elastically like an umbrella. Fig. 1.3 shows the procedure for self expanding stent.

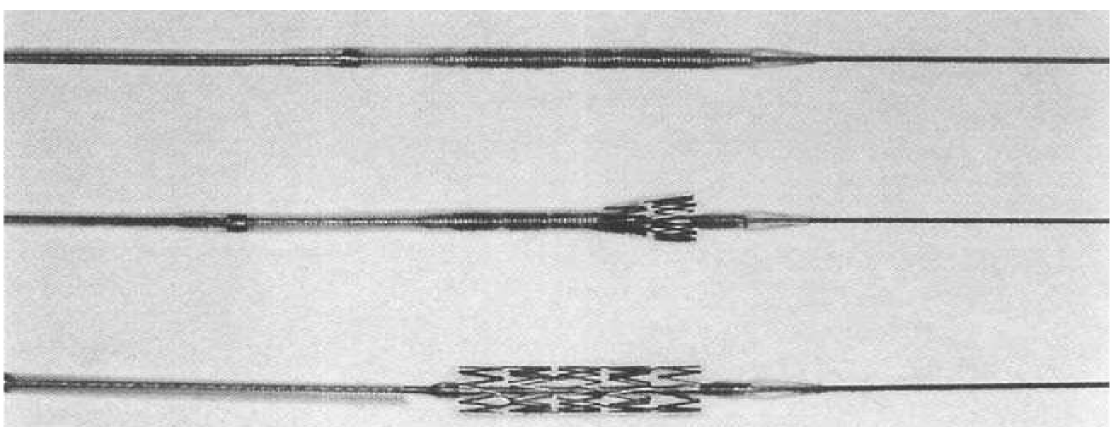


Fig. 1.3 Procedure of Self Expanding stent [6]

1.3 Restenosis:

The narrowing of blood vessel is called Stenosis. Restenosis is the re-occuring of stenosis. Stents implants in human body may result to complex tissue interactions. Ratner et al [3] discussed the deployment of the stent leading to damage to endothelial lining and vessel wall stretching leading to restenosis, which increases the accumulation of platelets and leukocytes. The stent is initially covered by a platelet fibrin coating and then finally covered by an endothelium-lined neointima. This causes the muscle cell to embed with stent wires. The thickening of this tissue layer releases the growth and chemotactic factors, inflammatory mediators from platelets and other inflammatory cells. Smooth muscle cell migration and proliferation is observed with a rise in the extracellular matrix molecules causing the narrowing of the lumen which leads to restenosis [2].

Other contributing factors to restenosis include the post-stent plaque burden being the immediate effect of intervention on the vessel wall [7]. This causes in-stent restenosis in 20-30% of patients which then requires repeated procedures.

1.4 Angioplasty:

Angioplasty with or without vascular stenting is an invasive process performed to improve blood flow in the body's arteries and veins. Angioplasty is called PTCA (Percutaneous Transluminal Coronary Angioplasty) but it is also referred as dottering after the name of Dr. Charles Theodore Dottor. Dr. Melvin P. Judkins combined with Dottor described angioplasty in 1964[8]. PCI (Percutaneous Coronary Intervention) refers to as procedures range performed on coronary artery. PTCA is one of the most common PCI procedures [9].

In an angioplasty procedure, imaging techniques are used to guide a balloon-tipped catheter, into an artery or vein and forward it to the point where the vessel is narrow or blocked. The balloon is then inflated to open the vessel, deflated and removed [10].

During the angioplasty procedure, a small mesh tube called stent may be permanently placed in the recently opened artery/vein to aid it to remain open. As shown in Fig. 1.4

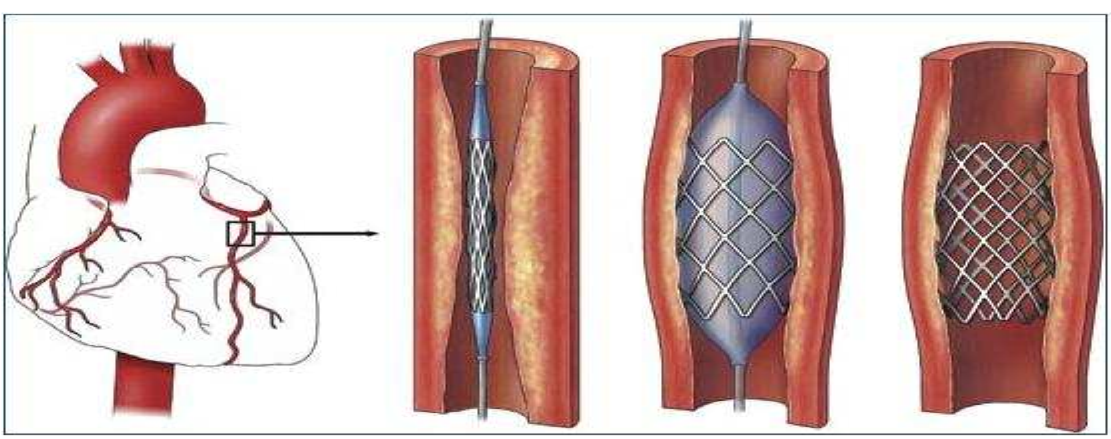


Fig 1.4 Schematic of Angioplasty [11]

1.5 Angioplasty Balloons:

Angioplasty balloon in medical terms may be defined as inflatable oval device used to retain tubes or catheters in, or distensible device used to stretch or occlude a viscous or blood vessel [12].

There are three main types of balloon materials for angioplasty.

- Semi-compliant balloons
- Non-compliant balloons.
- Compliant balloons

1.5.1 Semi-compliant balloons:

Semi compliant balloons are angioplasty balloons which can overstretch when inflated; they don’t exert equal force [13].They expand from approximately 5 to 10% of their original diameter [14]. Common examples of materials used for this type of balloon are Nylon, Poly-urethene (PU)

1.5.2 Non-compliant balloons:

The balloons which stretch to pre-defined diameter if the inflation pressure is high are called non-compliant balloons [13]. They expand less than 5% of their original radius [14]. Example of material used includes PET (poly-ethylene terephthalate). Balloon angioplasty with semi-compliant balloons produces more stresses in non-stenotic vessel than non-compliant [15].

1.5.3 Compliant balloons:

Non-compliant balloons such as composed of PVC material can expand more than 10% of their original diameter [14].PVC is the earliest type of balloon material but the trend changed in 80’s when PET and PE were used to replace PVC.

Table1.1: Comparison of balloon materials for angioplasty balloons fabrication [14]

Material	Tensile Strength (psi)	Compliance (%)	Max. Rated Pressure (atm)
PET	>40,000	<5	20
Nylon	20,000-40,000	5-10	16
PE	<10,000	>10	10
PU	10,000-20,000	5-10	10
PVC	<10,000	>10	6-8

The compliance in table 1.1 refers to percentage change in diameter over a range of inflation pressure and max rated pressure refers to burst pressure [16].

1.6 Arteries:

Arteries are defined as thick vessels that carry blood away from heart. All arteries carry oxygenated blood except the pulmonary artery (Fig 1.4).The arterial vessels divide out so that oxygenated blood is delivered to whole body [17].

The smaller arteries are called arterioles which eventually connect with capillaries. Arteries have three main layers. Tunica intima is the inner most layer which comes in contact with blood. It is composed of a flat lining of endothelial cells .The middle layer is called the tunica media, which is constructed of flexible muscle. The outermost layer is called the tunica adventitia; it is sheath of connecting tissue [18].

1.7 Objectives:

- To observe mechanical behavior of an angioplasty stent by applying pressures via balloon.
- To simulate with more realistic boundary conditions as compared to use in literature.
- Study the effects of unloading after deployment of stent.

CHAPTER # 2

LITERATURE SURVEY

2.1 Stent materials:

2.1.1 Metallic materials:

1. **Gold:**

Gold has properties of high visibility, compatibility and is an inert metal [19]. Gold-plated composite stents present good visibility and flexibility, but are quite expensive.

2. **Cobalt-chromium:**

Previously Cobalt chromium was applicable in watch springs. Lately its new version is quite effective to be used as stent material [19]. Schneider Wall stent is one of the examples of Cobalt-chromium stent.

3. **Tantalum:**

Tantalum is a rare, hard and lustrous transition metal and has a blue-gray colour. It is highly resistant to corrosion and occurs naturally in the mineral tantalite. It is used in electronic equipment but also used for stent materials. Examples of tantalum stents are Wiktor Stents and the Tantalum Cordis Stent [19].

4. **Stainless Steel**

Most stents are prepared from 316L stainless steel. It is least expensive material to manufacture the stent [19]. Examples: Cordis Palmaz-Schatz stent, Cordis Crossflex stent, and Medtronic Bestent. Disadvantage of steel stent involve it's non-compatibility with human body, thrombosis, restenosis and bleeding complications after implantation [19]. Nickel present in the stent is often concern for patients and stainless steel contains less amount of nickel [20].

2.1.2 Polymeric Materials:

1. **Silicone:**

Silicone was the first organic material selected for stenting. Silicone is a polymer with high strength and is derived from silicone and oxygen atoms which result in lower rates of tissue trauma. However, it has poor bio-durability, tensile strength, coil strength and inner to outer diameter ratio [19].

2. **Plastic biliary stents:**

Polyethylene (PE) and polyurethane (PU) are the types of Plastic stents. PU has good tensile & coil strength, plus good biodurability then PE, but both these materials produce sludge in 20 to 30 % patients [19].

2.1.3 PLLA (Poly L-Lactic acid) fiber based Stent:

PLLA is considered excellent choice for cardiovascular, orthopedic and drug delivering implants. It has high value of mechanical strength and toughness [21]. Xiaoyan Yuan et al. showed that tensile strength of PLLA fibers is around 600MPa [22]. K.T. Nguyen et al. in their paper concluded that PLLA fiber mixed with curcumin prevents in-stent restenosis and thrombosis [23].PLLA lowers the chances of bio-corrosion and is safe [24].

Table 2.1 Tensile mechanical properties of fibers [21]

Fiber	Tensile Strength (MPa)	Modulus (MPa)	Strain (%)
PLLA	967	5,000	50
PDS	583	367	161
PGACL	721	477	151

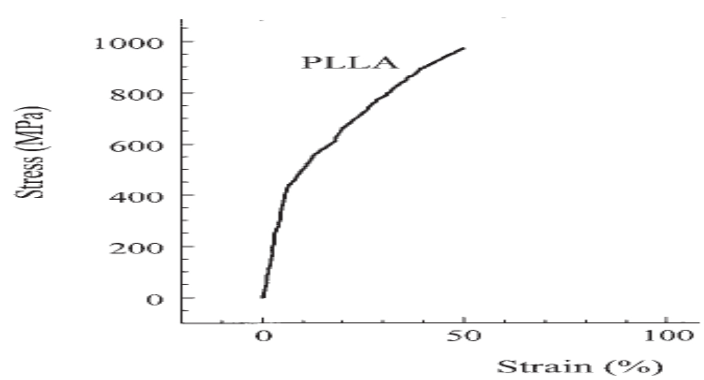


Figure 2.1 Stress-strain curve of PLLA fiber [21]

Drug coated stents; seeding stents with endothelial cells and ceramic coating are latest technology in stent design and materials [25].

2.2 Mechanical Properties for Stent:

The Mechanical properties of stent have heavy weightage in stent design and life .These include the following [2, 3]

- Radial strength and Hoop strength
- Elastic modulus
- Longitudinal flexibility
- Radiopacity

2.3 Restenosis factors:

The size of vessel/artery [26], structure, geometry and dimensions plays major part in recurrence of Restenosis [27].

2.4 Pressures:

Duerig and Tolomo [12] in their paper presented that the Stainless Steel (SS) may return to its original length by stretching up to 0.3%.Pressure inside cylindrical structure or blood vessel results in Hoop loading. Fig. 2.2 shows the circumferential loading.

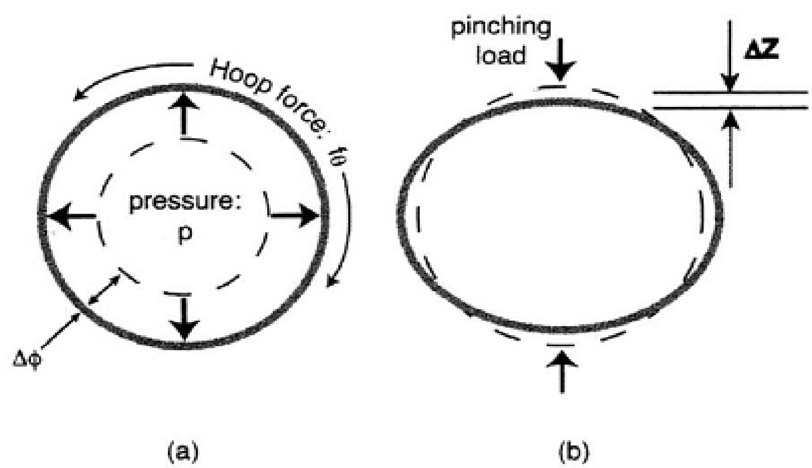


Figure 2.2 Stent loading modes (a) radial/hoop (b) Pinching [12]

They presented an equation 2.4.1 for pressure and Hoop stress for a vessel/stent.

$$\sigma = p\emptyset/t\ 2 \quad \ldots\ldots\ldots\ldots\ldots\ldots\ldots\ldots\ldots\ldots\ldots\ldots\ldots\ldots \quad (2.4.1)$$

Where $\emptyset$ the vessel diameter and t is is the vessel wall thickness

The *hoop force,* F_θ in a vessel wall is presented in the following manner:

$$F_\theta = \sigma t L = p\emptyset L/2 \quad (2.4.2)$$

L stands for length of stent and *p* is the pressure.

2.5 <u>Foreshortening, Recoil and Dogboning:</u>

Migliavacca et al [28] used FEM (Finite Element Method) to investigate effects of geometrical parameters of diamond shape stent such as thickness, metal to surface ratio and comparison with respect to internal pressure with different stent models.

The results showed that stent with minimum metal to artery surface ratio have good longitudinal and radial recoil with less effect of dogboning. Thickness of stent was considered to affect all parameters such as foreshortening, dogboning and recoil.

Elastic radial recoil, High radial strength and longitudinal recoil are some of design requirements for stents. The radial recoil and longitudinal recoil are represented by the following equations/formulas.

$$(R_{load} - R_{Unload})/R_{load} \text{ and } (L_{load} - L_{Unload})/L_{Load} \quad [29]$$

2.6 <u>Balloons Shapes:</u>

Dogboning which is also called hour glasses is also observed with semi-compliant balloon angioplasty [15]. Fig. 2.3 shows the dogboning effect of angioplasty balloon. Low diameter is observed at the middle portion of balloon.

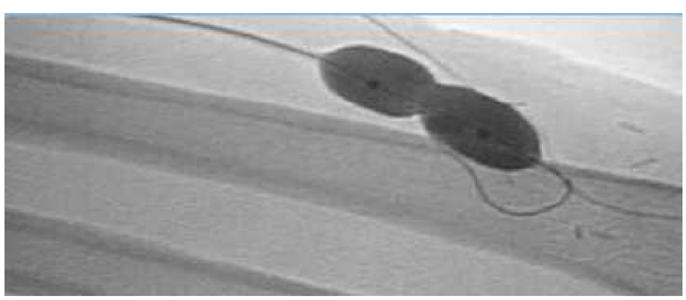


Fig 2.3 Dogboning effect [15]

Angioplasty balloons are sometimes coated with prescription drugs e.g. heparin to counter arterial buildup [30]. Various shape of angioplasty balloons exist depending on the nature of expansion. Some of those balloons are shown in Fig. 2.4

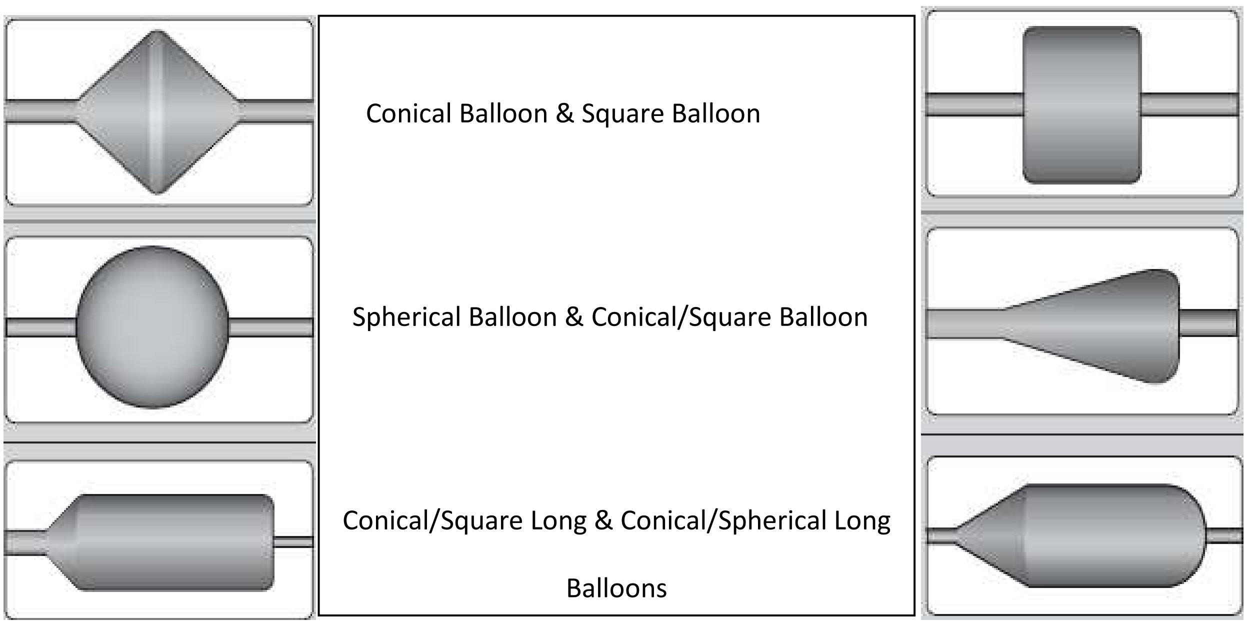


Fig 2.4 Various High Pressure Balloons shapes [16]

CHAPTER # 3

Modeling and Meshing

3.1 Model of the Stent:

Coiled stents are more flexible and they can adapt to winding blood vessel routes. They can be easily moved through branched arteries. The design of stent selected here constituted of construction on continuous coiling array principle. The advantage of this stent design is its continuity. The drawing for the stent which is in the form of third angle projection is attached as Appendix A [2].

3.1.1 3-D Model:

Pro-Engineer is a 3-D CAD geometry software. Its biggest advantage is its compatibility with Ansys. The coiled stent was created in 3-D models in Pro-Engineer. The models were exported in Ansys. The stent design is in spring shape with three internal coils creating one bigger coil. The stent is 15mm in length and has 12 big coils as shown in Fig. 3.1

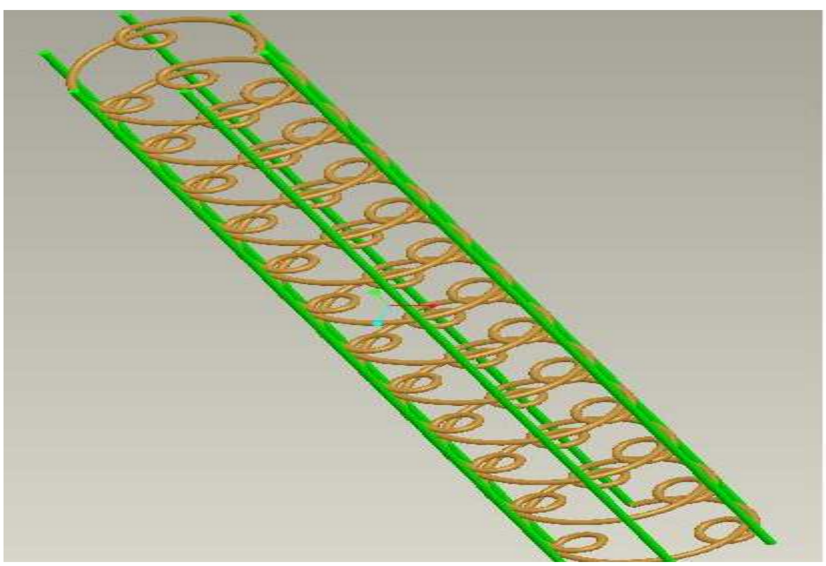


Fig. 3.1 Full model of stent

120° section segment was first made in Pro-Engineer of the outer coil. The 360° cross-section of inner coil was also made. Both the cross-section of inner and outer coil were mated (joined) in Pro-engineer. The sections joined were repeated alternatively to make a full assembly.

The internal coils had 0.75 mm radius and were at angle 120° from each other. The stent diameter was 0.10 mm. The internal coils had pitch of 0.20 mm with a diameter of 0.47 mm and outer coils had a pitch of 0.62 mm with diameter of 1.96 mm. The revolutions for outer coils and inner coils were 0.33 and 01. The above dimensions were created to complete 360° forming one loop of stent [31].

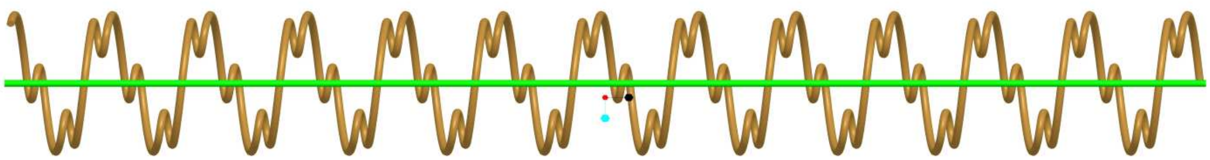


Fig. 3.2 Model of stent Side view

3.2 Finite Element Model:

As the stent was cylindrical with the repeating parts, A 360 ° part of the stent was taken from the stent for load and expansion analysis. Fig. 3.3 shows the 360 ° part with meshing. Solid 185 element was used for stent meshing. It has eight nodes with 3 degrees of freedom; this type of element has properties of plasticity, stress stiffening, large deflection and strain [32]. Elastoplastic and incompressible hyper-elastic materials deformation can also be shown in by solid 185. Mapped meshing was used with medium mesh density. The mapped meshing has the advantage of elements dimensions being controlled

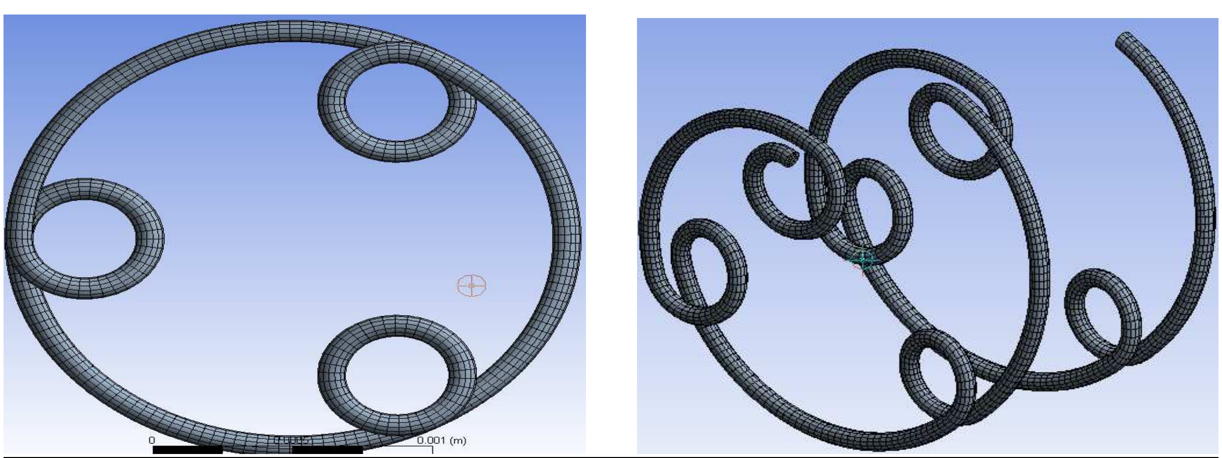


Fig.3.3. 360º part of stent with meshing

Due to repeatability of structure the whole stent was divided into 6 parts and 1 part was used for analysis.

3.2.1 Material for stent:

PLLA fiber is used for stent material. The Engineering stress strain data shown in Table 3.1 was used as input for the material [2]. Young's Modulus value of 7043MPa was used. The practical data for the PLLA fiber expansion which was in true stress and true strain form was converted to engineering stress and strain data by equations 3.1 and 3.2. The yield limit was around 120MPa with tangent modulus of 50MPa.The equations for the stress and strain are given below:

$$\varepsilon e = 1 - e^{\varepsilon t} \quad \text{--------------------------------} \; 3.1 \quad [2]$$

$$\sigma e = \sigma_t / (1 + \varepsilon_e) \quad \text{----------------------} \; 3.2$$

Table 3.1 Stress/strain values

Strain	Stress (MPa)
2.010050167	23.63083539
2.02020134	47.57960938
2.030454534	71.80441005
2.039770484	96.38885619
2.051271096	123.7189316
2.070365308	125.1642594
2.099658855	127.4656401

Fig. 3.4 shows the stress-strain curve for fiber material.

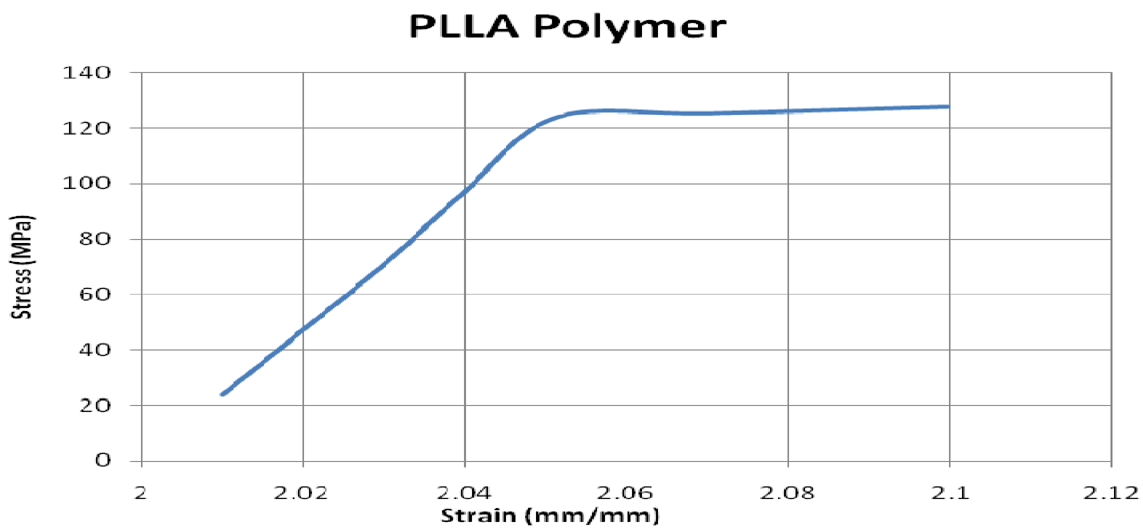


Fig: 3.4 Stress /Strain curve for fiber

3.2.2 <u>Balloon:</u>

The balloon material was given the properties of thin polymers with young modulus of 0.94 GPa, density of 1100 kg/m^3 [33] and Poisson ratio of 0.4[34].The thickness of balloon was 0.1mm[35 , 36]. The balloon was modeled as a shell and shell 181 element was used [37, 38]. The shell 181 has the features of plasticity, large deflection, stress stiffening and large strain. The interface using contact elements between the stent and the balloon was taken as frictional [39] with co-efficient of friction equal to 0.2 (Fig 3.5).

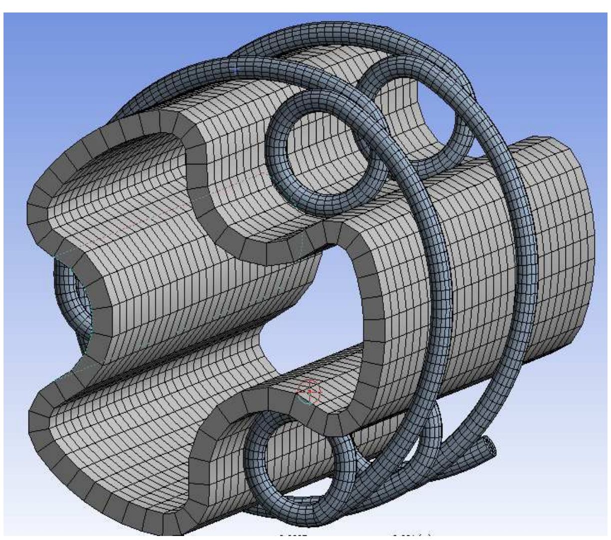


Figure 3.5(a) Meshing of balloon material

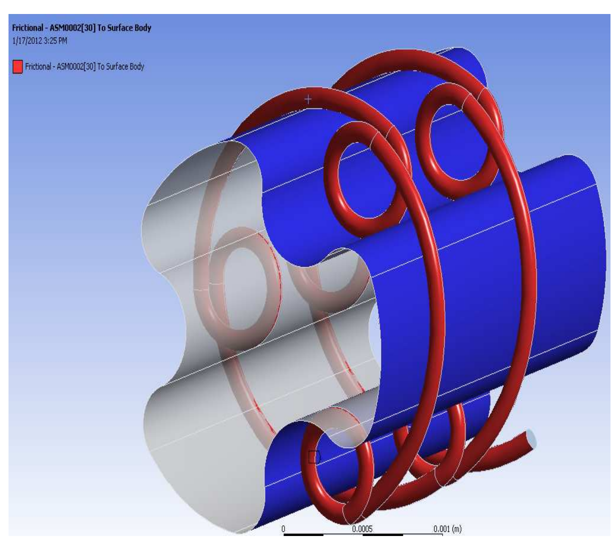


Figure 3.5(b) frictional contact surface (stent and balloon)

3.2.3 Simulation:

Two cases were assumed for the simulation: In the first case the load in terms of pressure was applied on the inner surface of balloon for expanding the stent. The value was varied from 0 to 14 atm. Figures 3.6 (a) and (b) shows the application of internal pressure which is indicated by red arrow. The balloon was allowed to expand only in radial direction [36] and axially constrained whereas the stent was free to move axially and radially. The analysis was carried out as static structural.

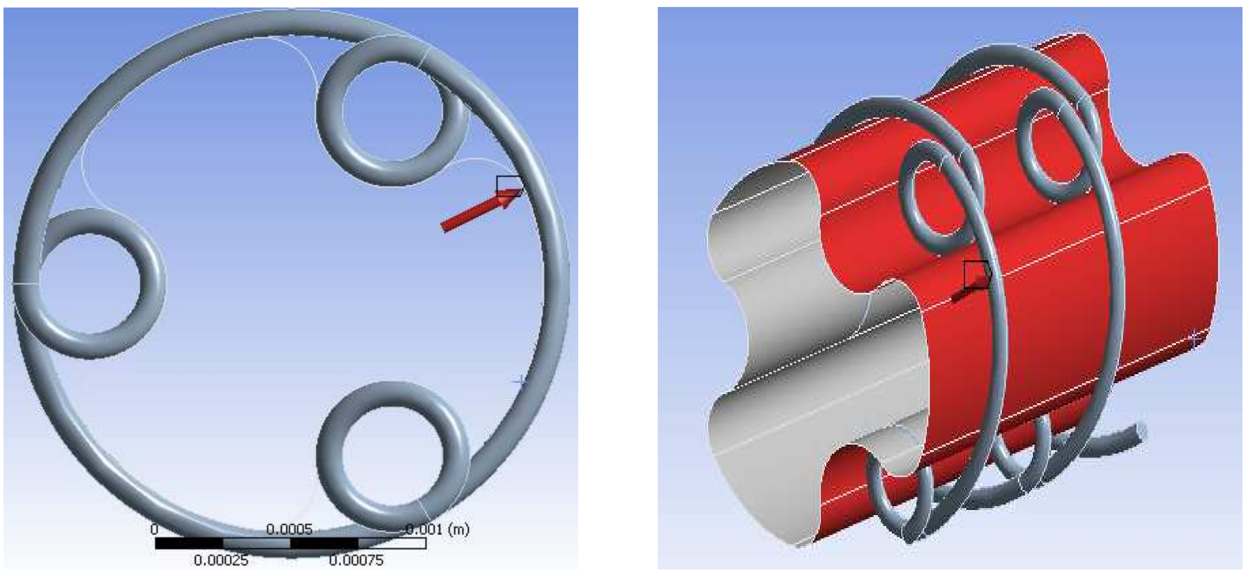


Figure 3.6 (a) and (b) Pressure Application

In the second case loading and unloading condition both were simulated. The stent was loaded to value of 14atm by balloon and unloaded. The points A, B and C are depicted in the Fig. 3.7 (a). Point A shows the area of loading and unloading of 14 atm. Point B indicates the end of balloon to be constrained in all radial and axial directions, whereas Point C indicates that this end of balloon can displace axially. Figure 3.7 (b) shows the meshing of stent and balloon.

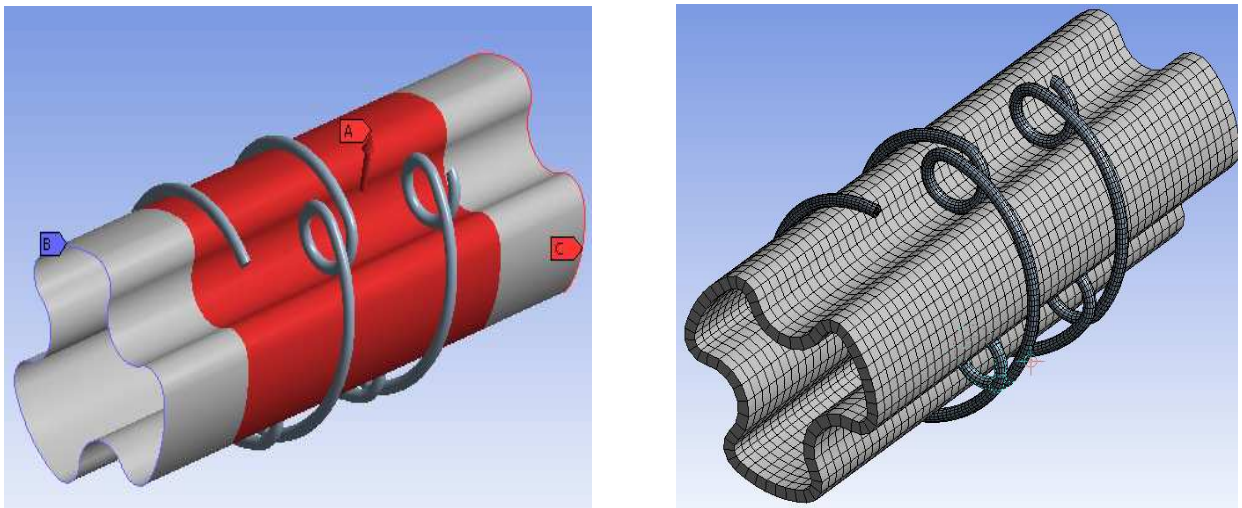


Figure 3.7 (a) Boundary conditions (b) Meshing

The maximum number of sub steps limit given to software was around $1x10^8$. The interference treatment in the software was adjusted to touch so that the contact surfaces cannot penetrate each other.

CHAPTER # 4

RESULTS & DISCUSSIONS

The study for this thesis consisted of stent combined with the balloon. The balloon was used for exerting air pressure to the stent in order to understand the stress distribution in the stent.

A solid 3D model of the stent was completed in pro-engineer and balloon was modeled in Ansys. This solid model projected an exact replica of stent, which is actually used in blocked artery. This designed stent was then exported to a commercial FEM code widely known as ANSYS. V14 version of this software was used for analysis of the physical features of the stent.

Model of the stent exported the ANSYS was meshed using mapped meshing. Solid 185 elements were used for stent and shell 181 was used for balloon. Shell 181 is mostly used for problems that have convergence difficulty. The total number of elements was around 14874 and nodes were around 19292.

The desktop computer, on which all of these simulations were done, consisted of an Intel® Core 2 Duo 2.66 GHz processor with 1.6 GHz, 2GB of RAM. It took approximately 3 to 4 hours on the average for the simulation of stent.

This study was planned to show the stress distribution along the stent. The deformations at all levels are also a point of interest, specifically deformations on the inner coils. The results in-terms of deformation, strain and von-Mises were analyzed. Two cases of stent expansion were assessed. These results achieved during this analysis, are not intended to be fully accurate analysis of any existing stent design. Rather to show, the process was able to be analyzed by computational techniques with a complex assembly with feature instances and multiple domains.

Other variables such as folded balloon need to be included in the study. Corrections and precision to the meshing algorithms were also required, to achieving a complete and fully correct solution.

4.1 Balloon Expansion Results:

At the initial stage before the pressure is applied to the balloon. Parameters like pressure input, Stress/strain material data for stent are inserted in the FEM analyzer. The contact between balloon and stent was taken to be frictional. In the first case, the balloon was axially constrained and movable in radial direction. The stent was free to move in any direction. In the second case, the balloon was axially constrained from one end and free from other end.

4.2 Deformation Results:

Table 4.1 Deformation versus pressure

Pressure (atm)	Deformation (m)
1.40E-01	3.04E-06
2.80E-01	4.99E-06
4.90E-01	7.67E-06
8.05E-01	1.21E-05
1.28E+00	1.89E-05
1.99E+00	2.97E-05
3.05E+00	4.71E-05
4.64E+00	7.49E-05
6.24E+00	1.06E-04
7.43E+00	1.32E-04
8.03E+00	1.49E-04
8.63E+00	1.70E-04
9.53E+00	1.95E-04
9.98E+00	1.99E-04
1.04E+01	2.11E-04
1.08E+01	2.20E-04
1.11E+01	2.26E-04
1.16E+01	2.27E-04
1.18E+01	2.36E-04
1.20E+01	2.43E-04
1.22E+01	2.54E-04
1.26E+01	2.72E-04
1.30E+01	2.82E-04
1.34E+01	2.92E-04
1.40E+01	3.05E-04

Table 4.1 shows the pressure versus deformation values. The values shown here are of case-1 simulation. The graph of pressure versus deformation is shown in Fig. 4.1

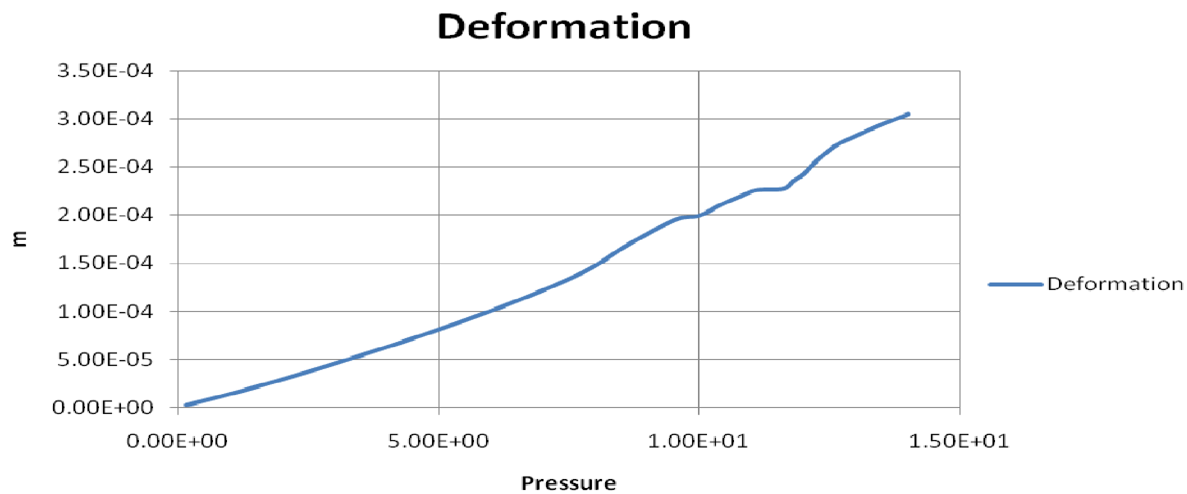


Fig. 4.1 Deformation with respect to pressure

In order to test whether this model can support large deformation and rotation, the pressure up to 14atm in different steps was applied. The 7atm pressure applied to the balloon is shown in Fig 4.2. One thing to mention is that here is, the simulation of pressure exerted on the model with stent and balloon is shown and not the pressure on artery. The purpose of this section is to visualize the deformation on the stent with the pressure exerted by the balloon.

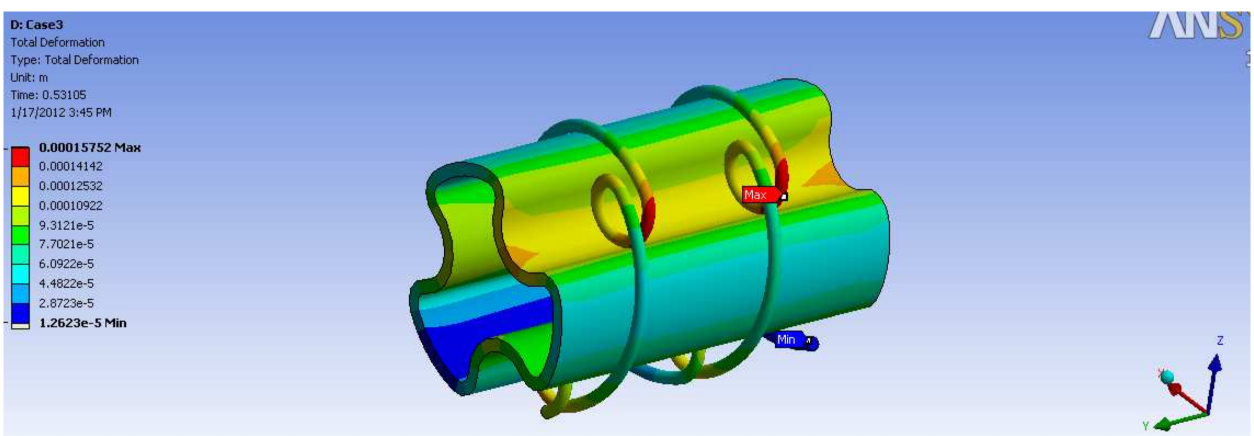


Fig. 4.2 Stent at 7atm pressure (Total Deformation)

The stresses can be seen on the inner rings from different angles at 7atm pressure from the balloon. During expansion of balloon, the inner coils come in contact with the balloon at initial, hence the deformation start on the each of these coil at contact.

Almost deformation can be seen on the outer coil. As at this stage at 7atm pressure balloon has contact with both outer coil and inner coil. The deformations on outer coils were observed minute as compared to impact of balloon with inner coils as interpreted in Fig 4.2.

Fig. 4.3 shows the total deformation for case 2 at 7atm. The numerical value for maximum deformation is around 0.17mm whereas case 1 showed the value around 0.15mm.

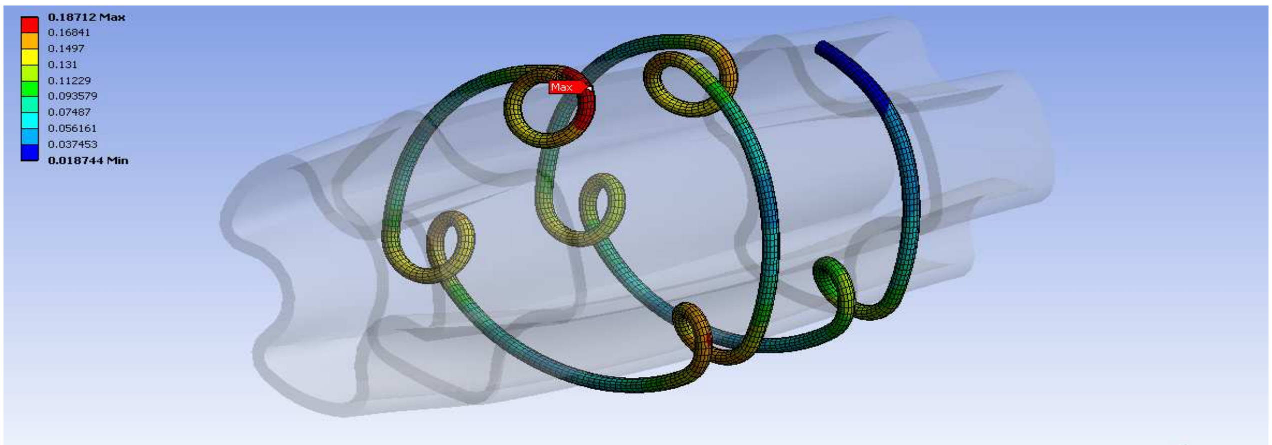


Fig 4.3 Stent at 7atm pressure (Case 2)

From the Fig 4.4 of deformation at 14atm shown below, it can be seen that with the change or rather increase in pressure, the deformation on the outer coil start to increase. It means when the balloon expands at 14atm, the force starts to transmit from the balloon the stent and hence causing increase in force on the outer ring and the stent starts to expand and shows deformations. At the point also maximum deformations are still on the inner coils because inner coils hold more pressure, applied from external source and exerted via balloon.

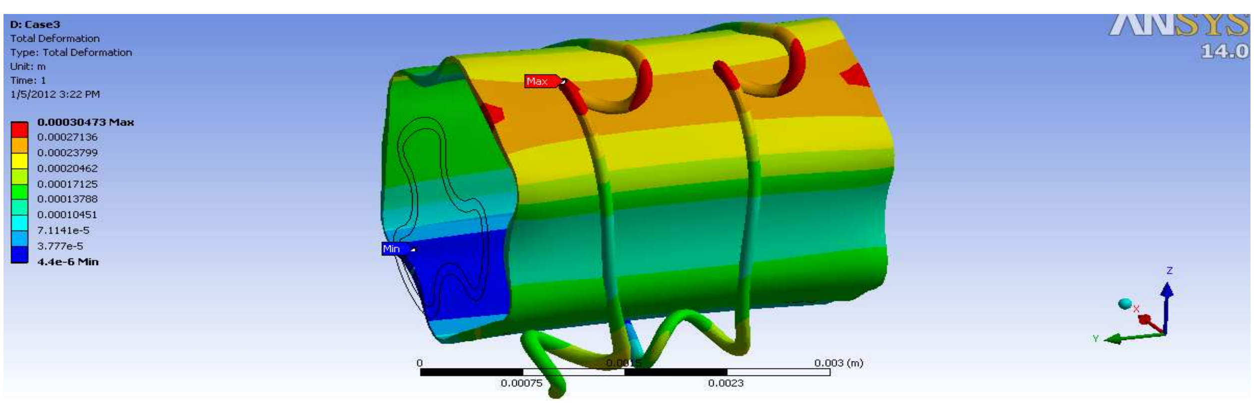


Fig.4.4 Stent in expanded form at 14atm (Case 1)

Fig 4.4 and Fig. 4.5 shows the total deformation at 14atm for both constraint conditions. The difference in due to structural shape is due to constraints of boundary conditions. The high value of deformation is observed in inner coils. The numerical values of both cases are almost same of 0.3 and 0.33mm respectively. The single Constraint result showed minimum deformed region in the middle connecting part of inner coils.

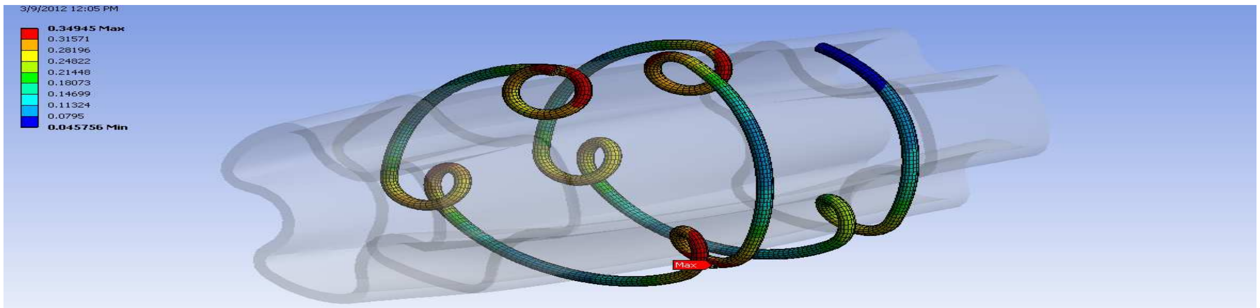


Fig 4.5 Stent in expanded form at 14atm (Case 2)

4.3 Strain analysis:

Strain analysis can be divided in to plastic and elastic.

4.3.1 Elastic Strain:

As we have discussed about the deformation at different stages in above section. So as the result of deformation strain occurs at different levels. We will observe this strain at these stages and will analyze the behavior of the stent and effect of this strain caused by the deformations.

It is seen that the strain at 7atm pressure has occurred mostly on the balloon as shown in Fig 4.6 and it is just started to transfer on the stent. This shows, at this stage the stent is in elastic region and it is interesting to see that stent has not started to deform yet and hence the strain at this point is elastic strain

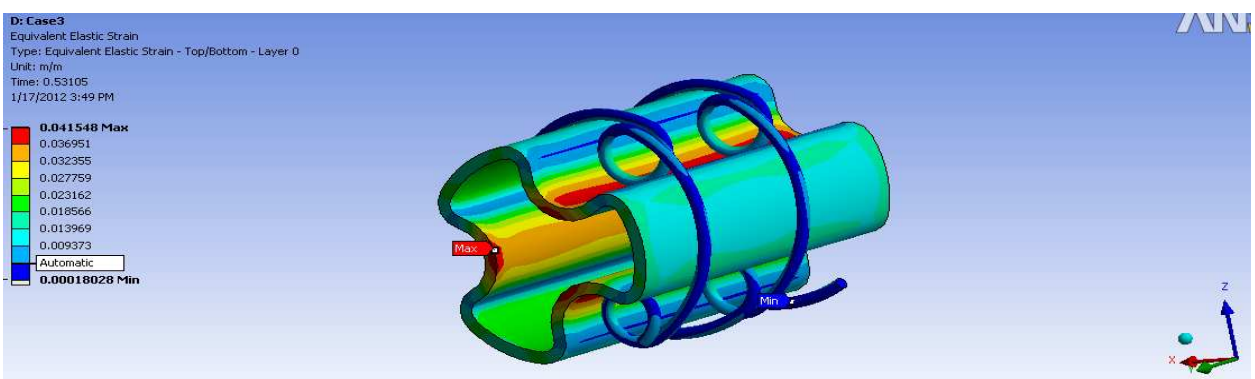


Fig 4.6 Elastic Strain at 7atm (Case 1)

The strain development is not that regular in elastic region though there is strain but no hardening has occurred so far. We know from our law of continuum theories that this shows the elastic deformation and hence results in elastic strains.

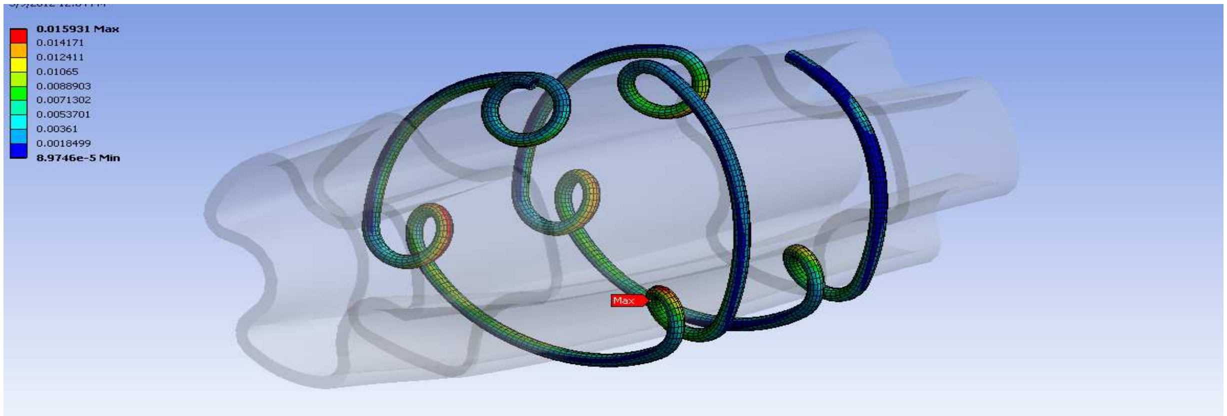


Fig. 4.7 Elastic Strain at 7atm (Case 2)

4.3.2 <u>Plastic Strain:</u>

Fig 4.8 shows the trend of plastic strain at maximum point indicating the inner coil region. As the graph shows that the value of strain up to 8atm is zero. This is because the stent is in linear region up to 8atm approximately.

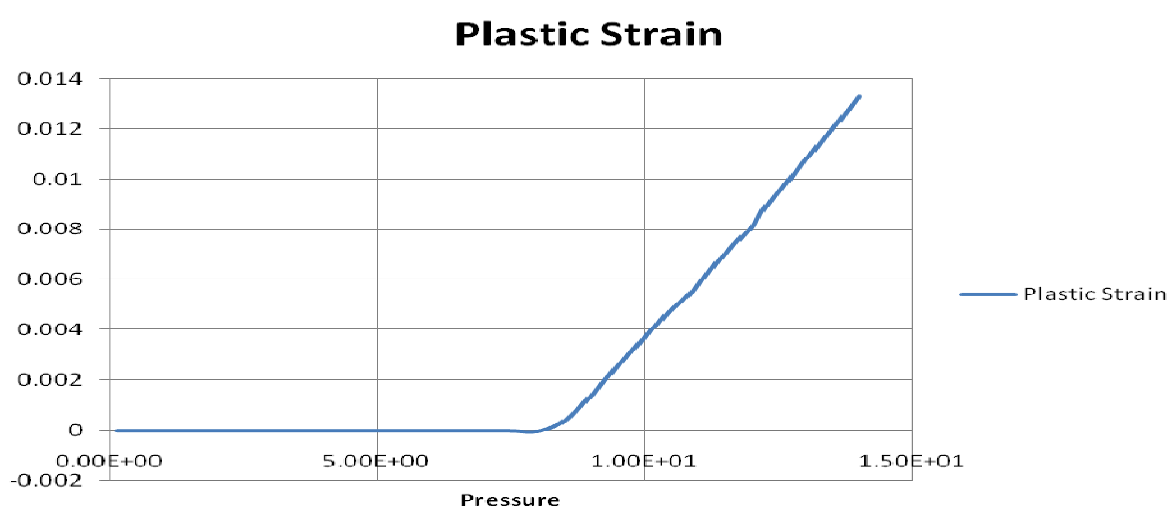


Fig 4.8 Plastic strain with respect to pressure (Case 1)

Table 4.2 Plastic strain (Case 1)

Pressure(atm)	**Plastic strain**
1.40E-01	0
2.80E-01	0
4.90E-01	0
8.05E-01	0
1.28E+00	0
1.99E+00	0
3.05E+00	0
4.64E+00	0
6.24E+00	0
7.43E+00	0
8.03E+00	0
8.63E+00	6.33E-04
9.53E+00	2.69E-03
9.98E+00	3.69E-03
1.04E+01	4.65E-03
1.08E+01	5.38E-03
1.11E+01	6.11E-03
1.16E+01	7.30E-03
1.18E+01	7.70E-03
1.20E+01	8.13E-03
1.22E+01	8.79E-03
1.26E+01	9.77E-03
1.30E+01	1.08E-02
1.34E+01	1.18E-02
1.40E+01	1.33E-02

Table 4.2 shows pressure versus plastic strain. As it is seen up to pressure of 8atm, plastic strain value remains zero. Around pressure of 8.5atm the plastic strain value starts occurring.

As evident from theories, this model accounts for the development of plastic strains by increasing pressure on the stent, and hence taking it to 14atm as shown in Fig. 4.10. The total strain is splitted into elastic and plastic regions. At this stage the strain is increased and plastic strain has already occurred.

Fig. 4.9 shows the development trend of plastic strain for Case -2 simulation. The stent enters the plastic region around 5atm and gradually increasing corresponding to applied pressure.

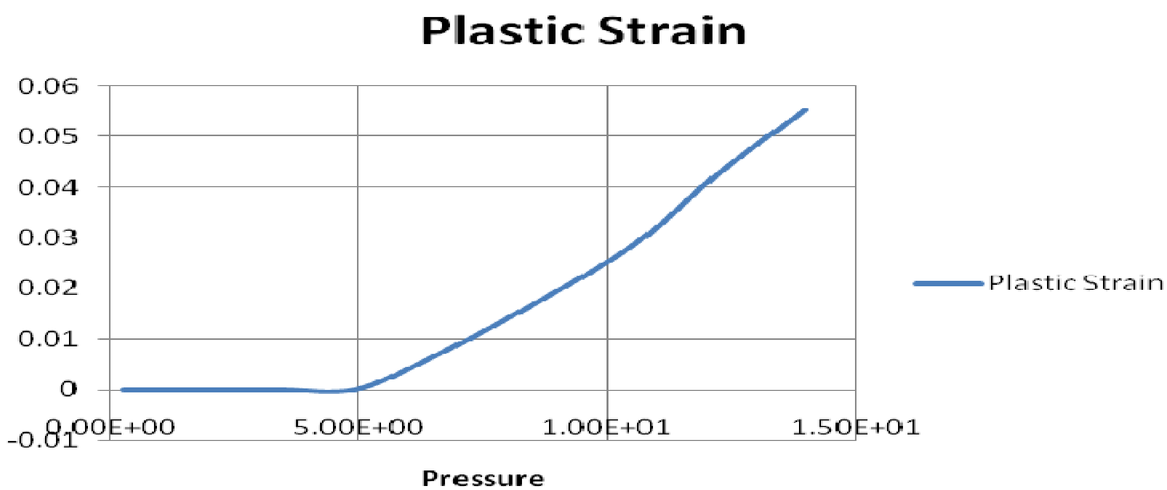


Fig 4.9 Plastic strain trend (Case 2)

The result will show that the increase of plastic deformation is very significant when the Pressure is increased. The plastic deformation increase is very significant in Fig. 4.10

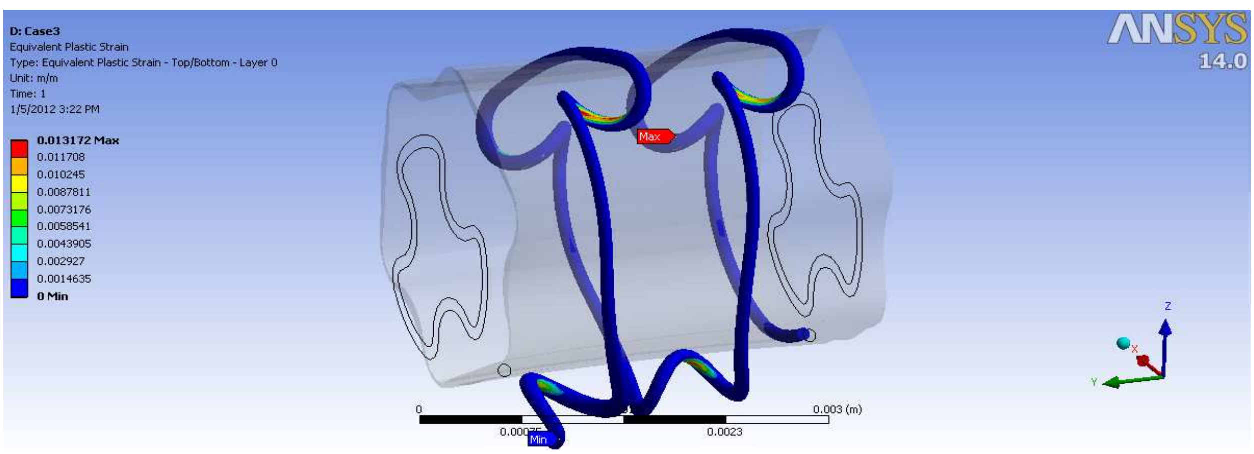


Fig 4.10 Plastic Strain in at 14atm (Case 1)

The result can be narrated, as pressure changes contributed more on plastic deformation; the stent shows a more accurate plastic deformation as shown in Fig 4.10 because the plastically deformed shape of the stent will affect the lateral contact, resulting in the change of pressure of the stent on the artery. When the plastic deformation is large, such as in Fig 4.10 the asperity with permanently deformed shape will be clearly seen after the release of the pressure from balloon. There will be more surface coming into contact because of plastically deformed stent and the pressure. Since the shape of stent will be permanently change when there is a plastic deformation, it is important to know how much of the areas are plastically deformed after the exertion of pressure.

Fig 4.10 shows the areas which are plastically deformed after contact for different angles. The inner coils have a bigger plastic deformation area than the outer coils, because the yield stress for inner coil occurs before the yield at outer coil.

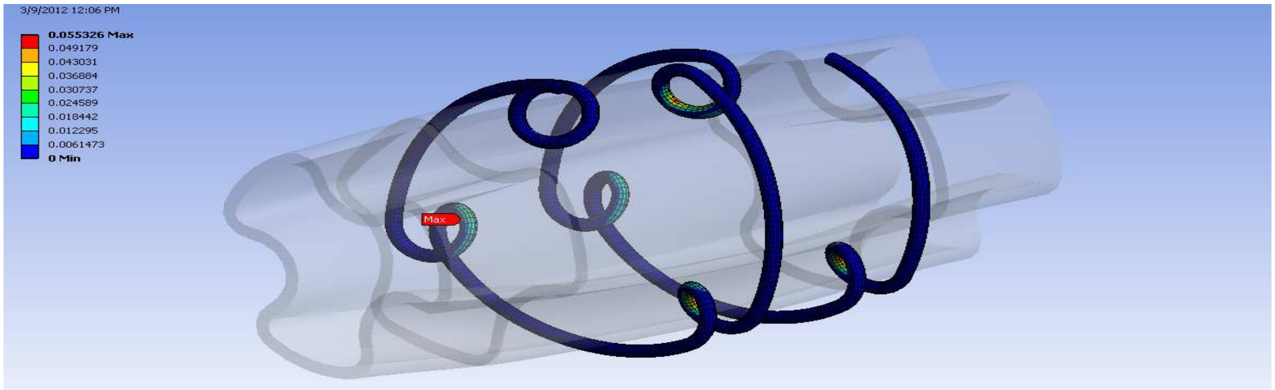


Fig 4.11 Plastic Strain in at 14atm (Case 2)

Fig 4.11 showed the plastic region for the Case-2 Simulation. The plastic deformed regions like the case -1 are observed in the inner coil regions. The outer regions of the coil observe no plastic reading.

4.4 Stress Distribution:

The distribution of von-Mises stress in stent (expanded form) is shown in Fig 4.12. The regions of high stress are observed in the middle of inner coil.

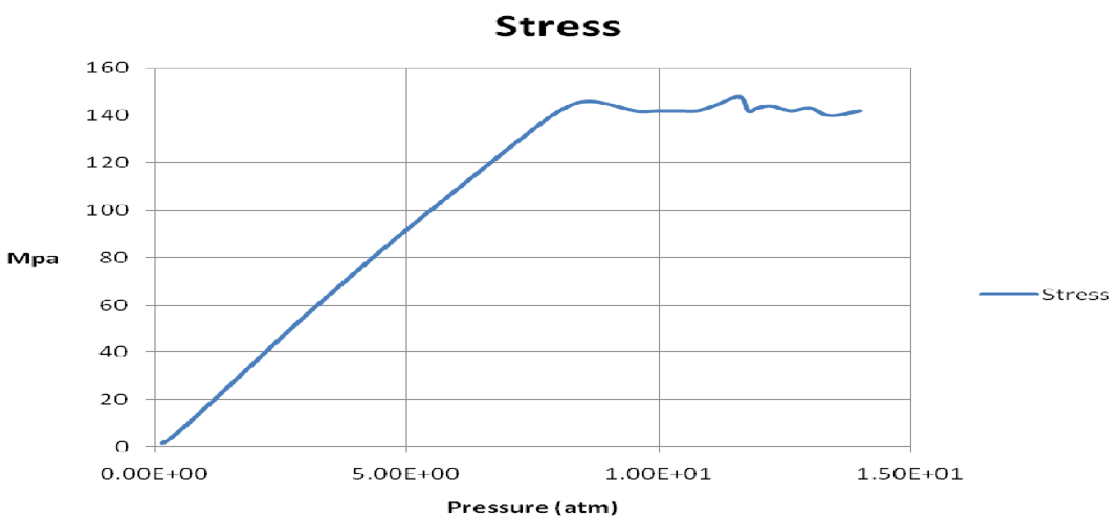


Fig 4.12 Stress versus Pressure (Case 1)

Figure 4.12 shows the development of stress. The graph trend shows a linear relationship of the stress with respect to time until the stress value reaches approximately 142MPa. It is believed that max stress produced was because of stress concentration, when material started yielding the results showed realistic behavior and the final scenario after 11atm showed the resolved stresses.

Table 4.3 stress versus time/Pressure

Time	Pressure(atm)	Stress(Pa)
1.00E-02	1.40E-01	1.66E+06
2.00E-02	2.80E-01	3.50E+06
3.50E-02	4.90E-01	7.08E+06
5.75E-02	8.05E-01	1.30E+07
9.13E-02	1.28E+00	2.22E+07
0.14188	1.99E+00	3.62E+07
0.21781	3.05E+00	5.68E+07
0.33172	4.64E+00	8.58E+07
0.44563	6.24E+00	1.13E+08
0.53105	7.43E+00	1.33E+08
0.57377	8.03E+00	1.42E+08
0.61648	8.63E+00	1.46E+08
0.68056	9.53E+00	1.42E+08
0.71259	9.98E+00	1.42E+08
0.74463	1.04E+01	1.42E+08
0.76866	1.08E+01	1.42E+08
0.79268	1.11E+01	1.44E+08
0.82872	1.16E+01	1.48E+08
0.84134	1.18E+01	1.42E+08
0.85395	1.20E+01	1.43E+08
0.87287	1.22E+01	1.44E+08
0.90126	1.26E+01	1.42E+08
0.92964	1.30E+01	1.43E+08
0.95802	1.34E+01	1.40E+08
1	1.40E+01	1.42E+08

Table 4.3 shows the time against stress. The time steps indicate here the number of sub steps in the software. The time steps are converted into the pressure and pressure versus Stress graph is plotted in Fig. 4.13. Fig. 4.13 shows that the stress development against pressure shows a linear trend up to 142MPa. The stress reached the maximum value at around 5atm, where as in Case-1 it reached 148MPa at around pressure of 8atm.

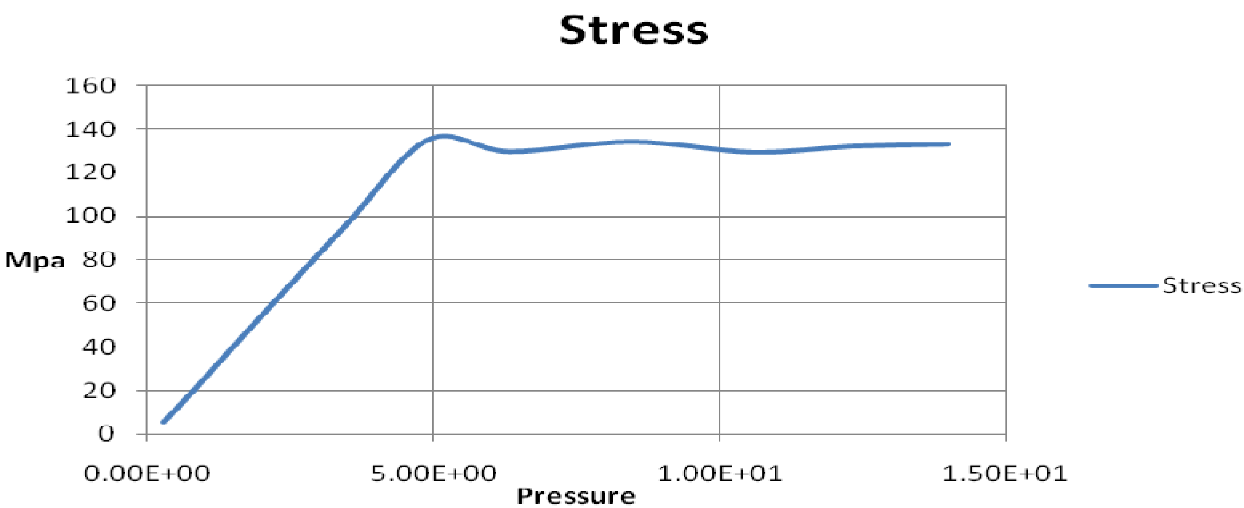


Fig 4.13 Stress versus Pressure (Case 2)

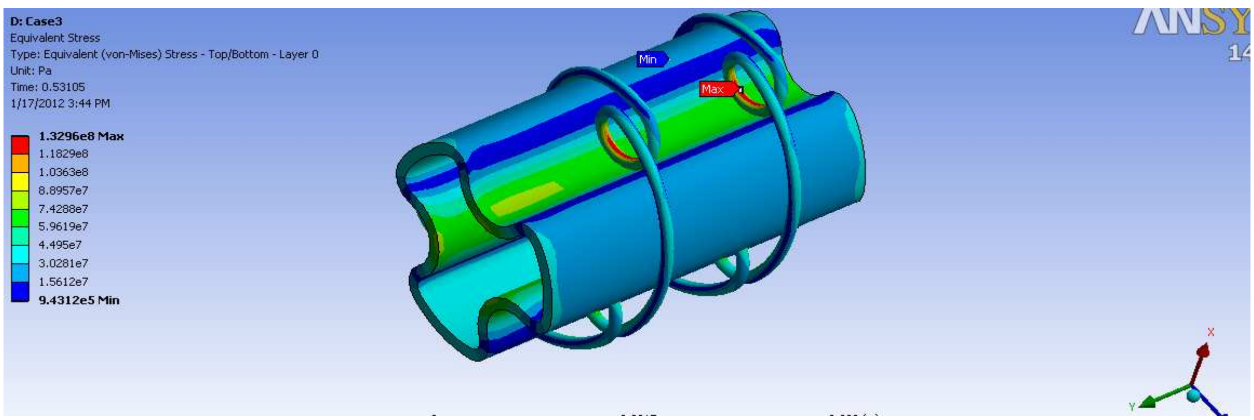


Fig 4.14 Equivalent Stress at 7atm (Case 1)

The von-Mises stress at 7atm shows a maximum stress of 132MPa. The von-Mises at 7atm reached the value of 130 MPa approximately for Case 2. This was almost same as compared to Case 1.

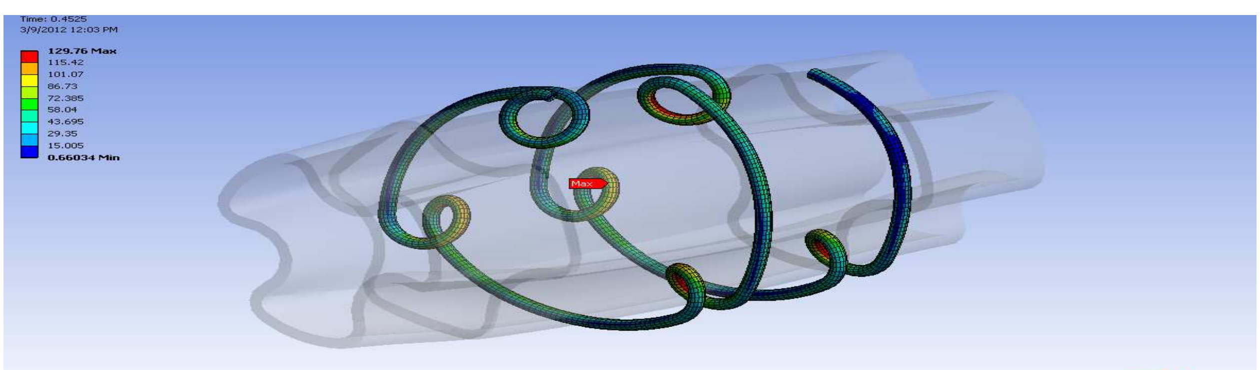


Fig 4.15 Equivalent stress at 7atm (Case 2)

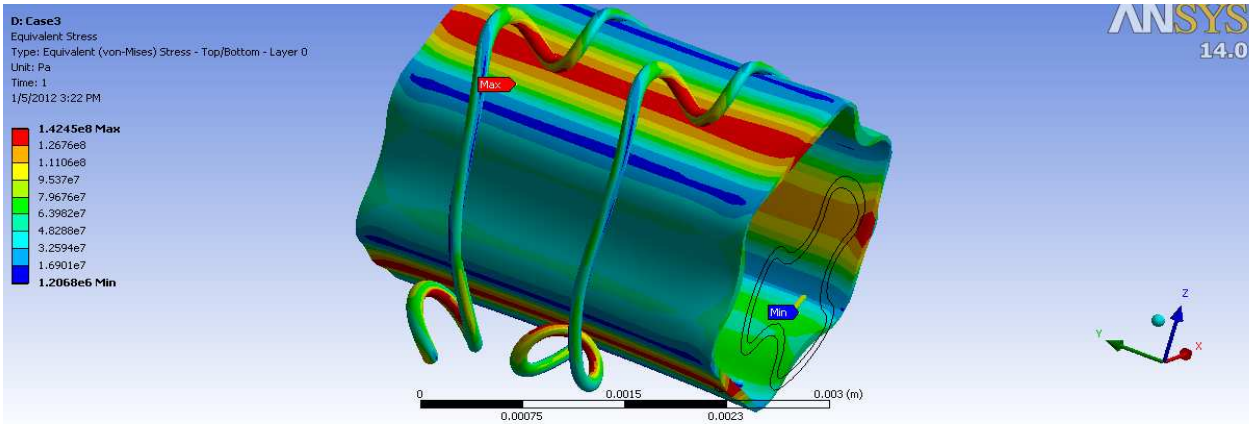


Fig 4.16 Equivalent Stress at 14atm (Case 1)

The stress level outside the inner coil is lower. This is due to forces being transmitted to inner coil by extending the region between the inner coils.

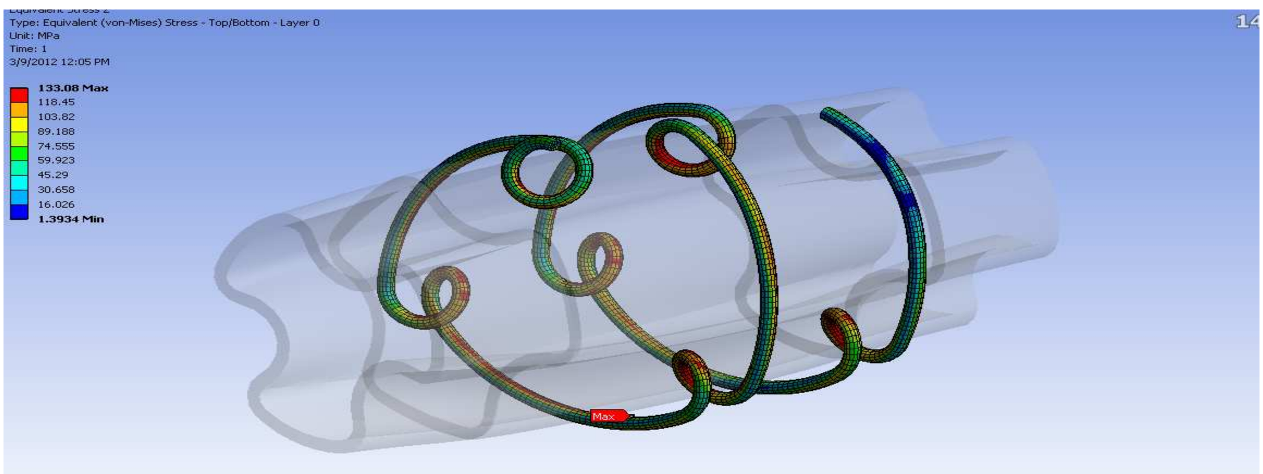


Fig 4.17 Equivalent Stress at 14atm (Case 2)

The equivalent stress at 14atm reaches the maximum value of 133MPa for Case 2 in Fig. 4.17. This is lower value compared to case 1 stress. As it can be observed from Fig. 4.17 the value of maximum stresses are observed on the left part of stent part due to the boundary condition of the balloon as it is axially and radially free on the left hand side and constrained from right side.

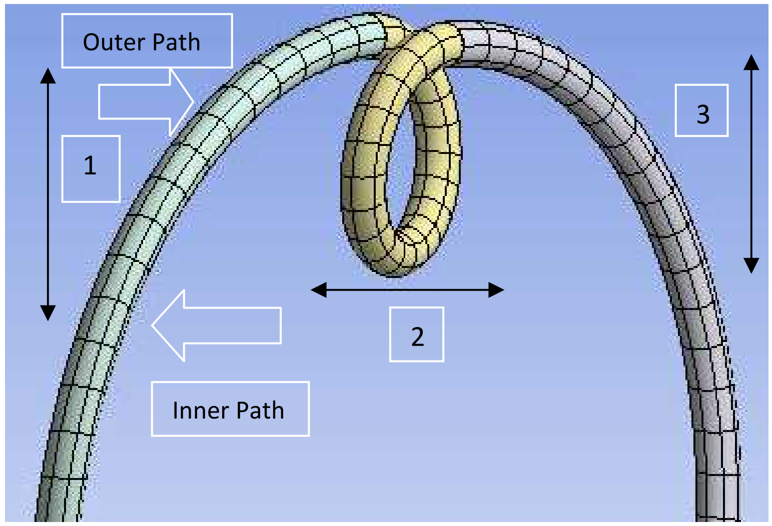


Fig 4.18 Main regions

Points 1 and 3 indicate the connecting links to inner coil. Point 2 represents the inner coil. Inner path and outer path are also indicated in the Figure. 4.19 Which shows development of stress at three main points. The difference in development of stress in region 2 with comparison to other two regions is shown. The trends of both inner and outer path are almost same.

In Fig 4.19 comparing the outside and inside surface path for region 2, the stress remains the same, but the inner path has slightly smaller range of stress according to no. of cells. For regions 1 and 3, the inner path shows a slight low stress value with comparison to outer path.

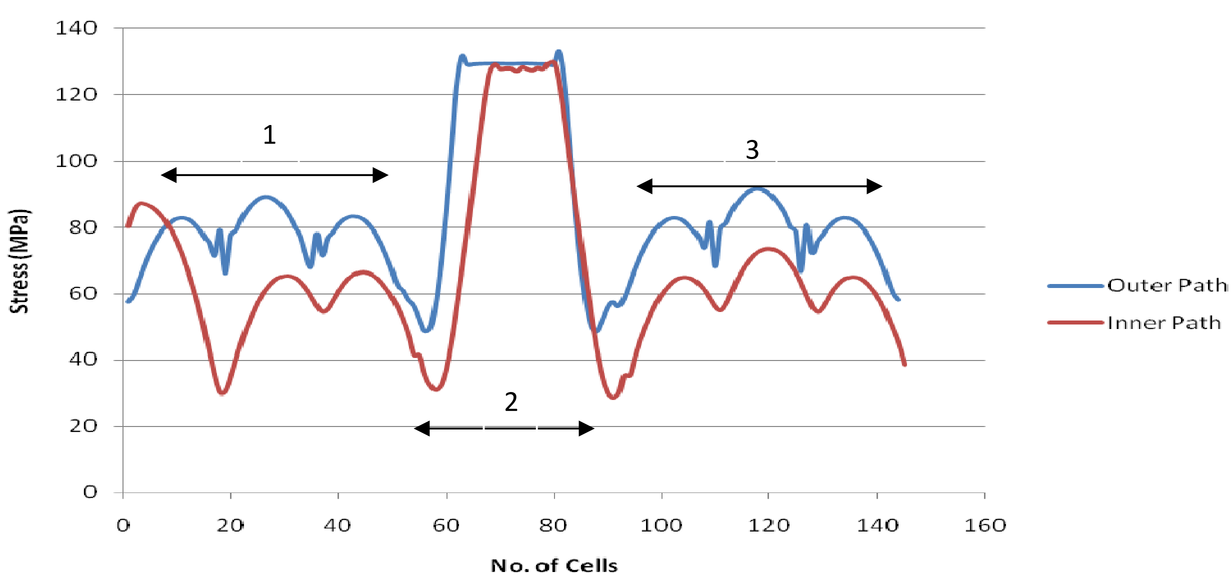


Fig 4.19 Inner and Outer Path (Case 1)

4.5 Change in Diameter and axial displacement:

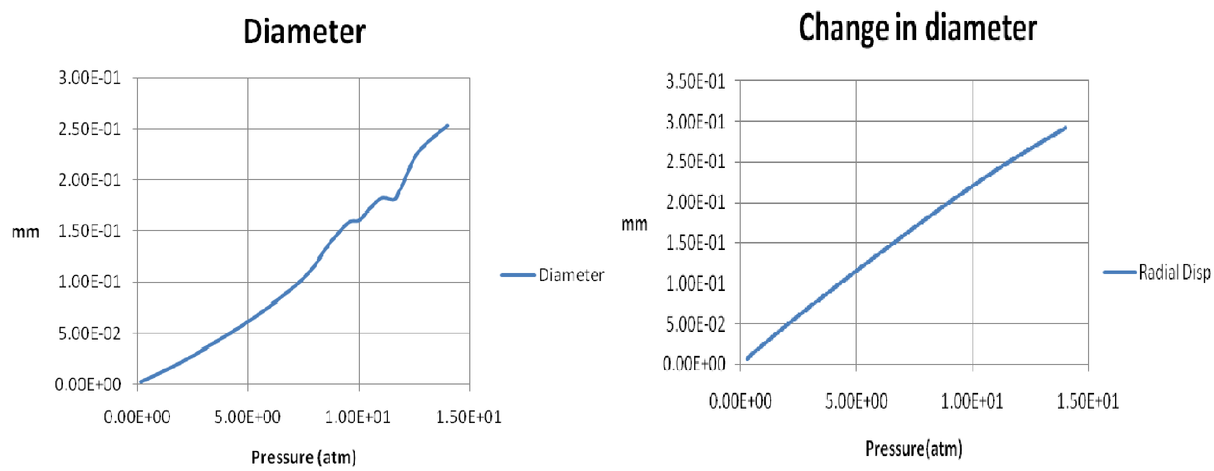


Fig. 4.20 Change in diameter (Case 1 & Case 2)

Fig. 4.20 shows the trend of diameter against the expanding pressure. The diameter of stent is function of expanding pressure. For Case 1 total change in diameter was equal to 0.25mm; whereas Case 2 showed a slight greater value than case 2 which reached numerical value of 0.29mm. The trend observed in Case 2 was linear.

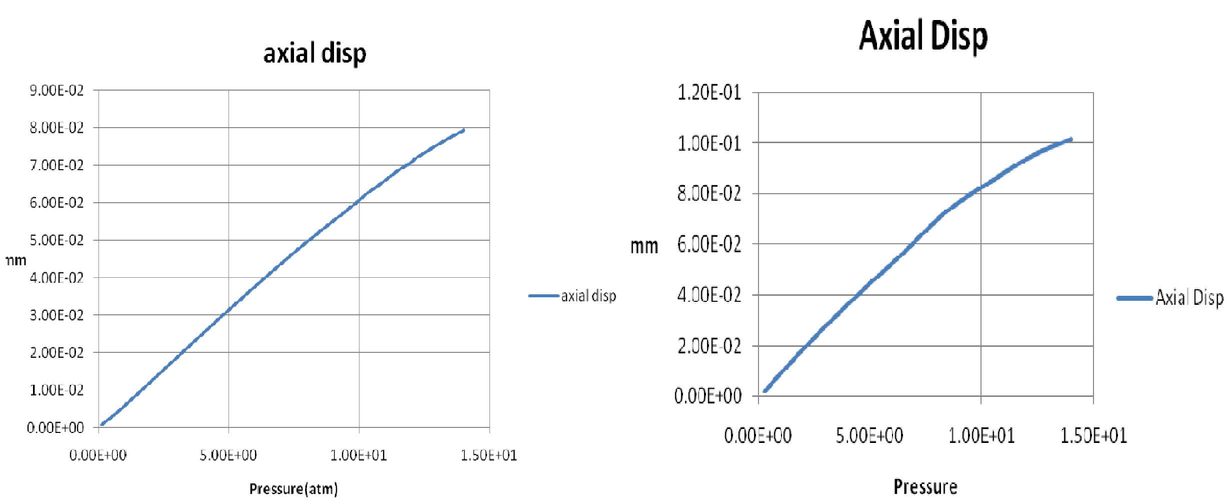


Fig 4.21 Axial displacement trend (Case 1 & Case 2)

As the stent was allowed to move freely in axial direction, Fig. 4.21 shows the trend of axial displacement. In case 1 the axial displacement of stent was around 0.08mm; Case-2 showed displacement close to 0.10mm.

The stent part shows small amount of elongation in axial direction for both cases which is very small compared to radial direction. Table 4.4 shows the axial displacement and percent elongation for both cases. The Case -2 showed greater axial displacement than Case -1, which also resulted in greater value of percent elongation of Case -2.

Table 4.4 Axial displacement and Percent Elongation

Inflation Pressure	Axial Length (Case 1)	Full length	Axial Length (Case 2)	Full length
0atm	2.50	15	2.50	15
14atm	2.57	15.42	2.60	15.6
Axial Displacement (mm)	.078	0.46	0.09	0.54
Percent Elongation %	3.15%		3.98 %	

4.6 Unloading simulation (Case-2)

In Case 2, the stent was loaded to 14atm and then unloaded back to 0atm. This simulation was carried out to see that what amount of stress and strain remains in the stent after removing the pressure load. The results represented here are in terms of von-Mises, deformation, radial displacement and plastic strain.

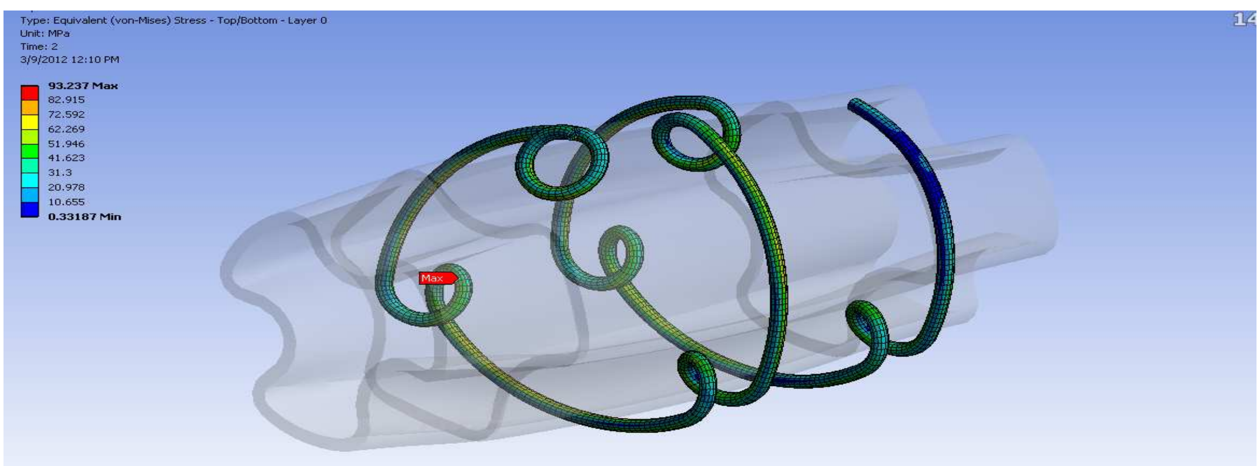


Fig 4.22 Equivalent Stress for Unloading simulation

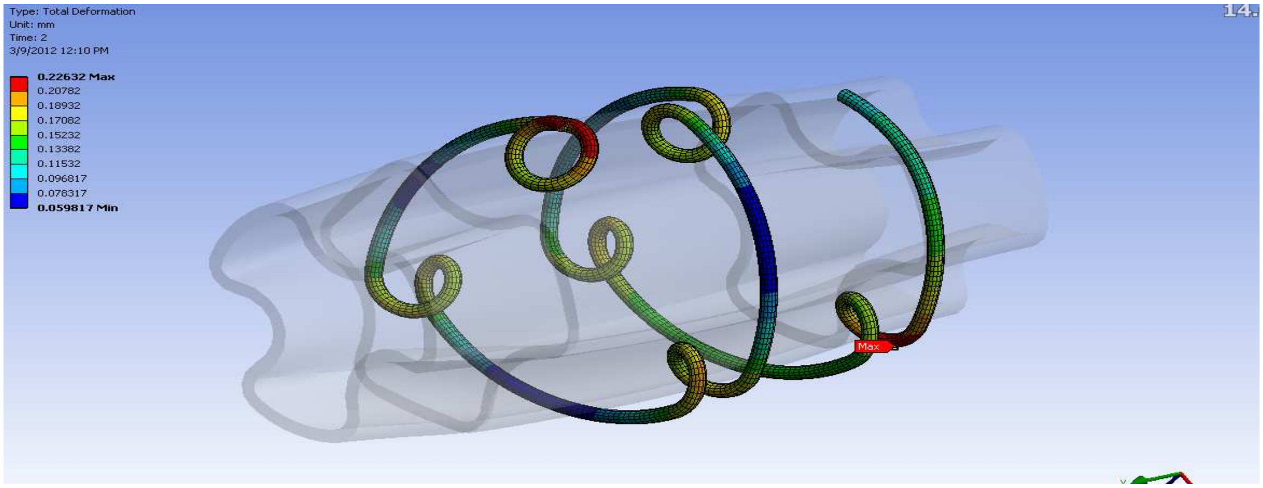


Fig 4.23 Deformation of stent (Unloading)

Fig 4.22 and 4.23 represent von-Mises and total deformation in the unloading phase, when the simulation was run to remove the balloon load from stent. The Ansys solution diverged around pressure of 5atm in the unloading phase.

Fig. 4.22 shows the values of stresses ranging 90MPa to 60MPa on the stent surface which is in direct contact with the balloon. The maximum value as expected is observed in the inner coil region. The outside surface of the stent which is not in contact with the balloon surface is shown by stresses ranging from 60MPa to minimum value of 10MPa.

The results in the figures depicted maximum value of 93MPa of von-Mises stress and retained value of 0.2mm of total deformation, which was around 0.35mm at 14atm.

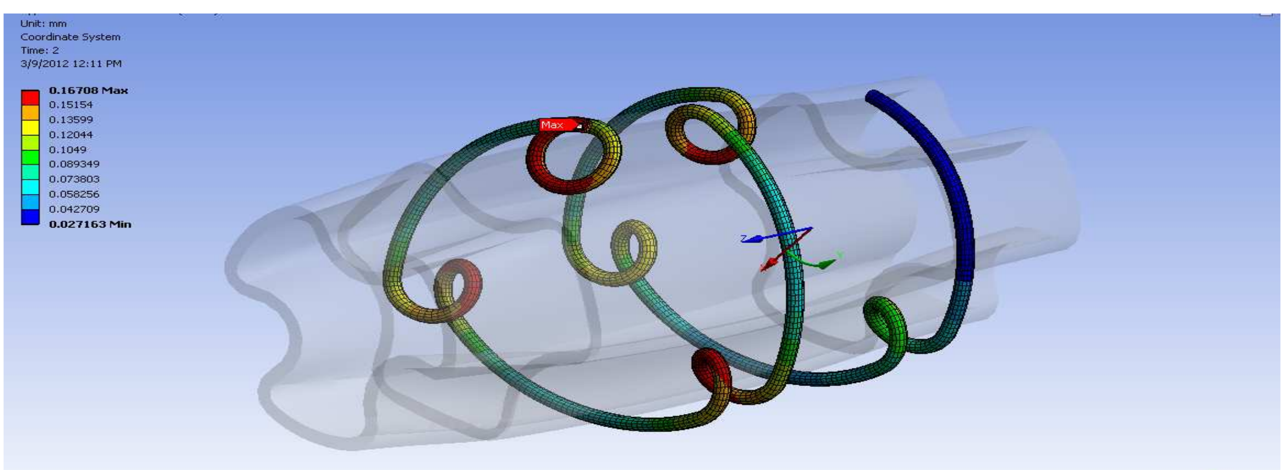


Fig 4.24 Diameter of Stent (Unloading)

The stent retains a diameter of 0.16mm as Fig. 4.24 showed. This diameter is almost half of the original expanded diameter of 0.29mm.

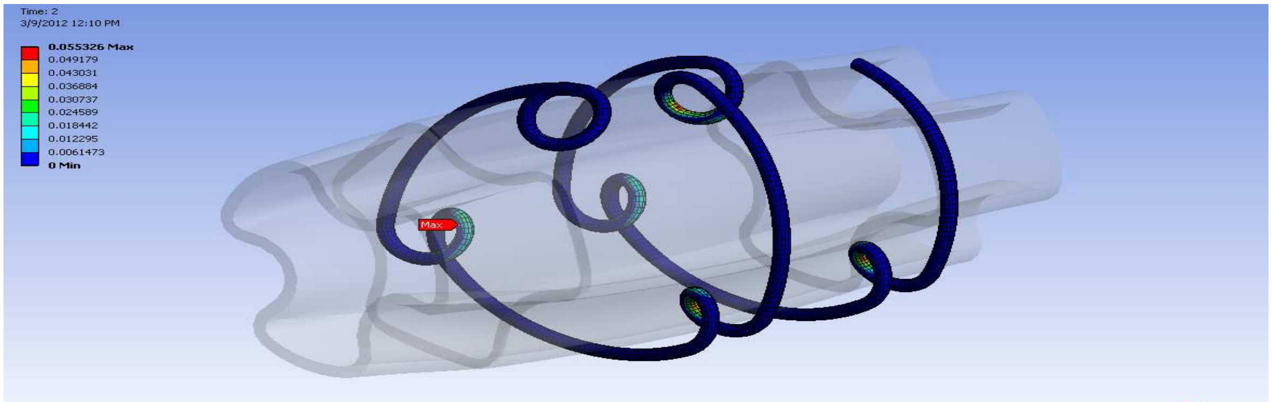


Fig 4.25 Plastic Strain (unloading)

The stent remained in the plastic region and its value remains the same throughout the unloading phase. The stent remained in plastic region showing that it has retained its shape.

4.6.1 **Force Convergence**

In the Fig. 4.26 the force convergence which is indicated by the purple color shows the divergence of solution around the last part inside the square box. The force convergence starts to oscillate at the end indicating that the software has been limited. The criteria for force which is indicated by bluish color can be seen not aligning with convergence.

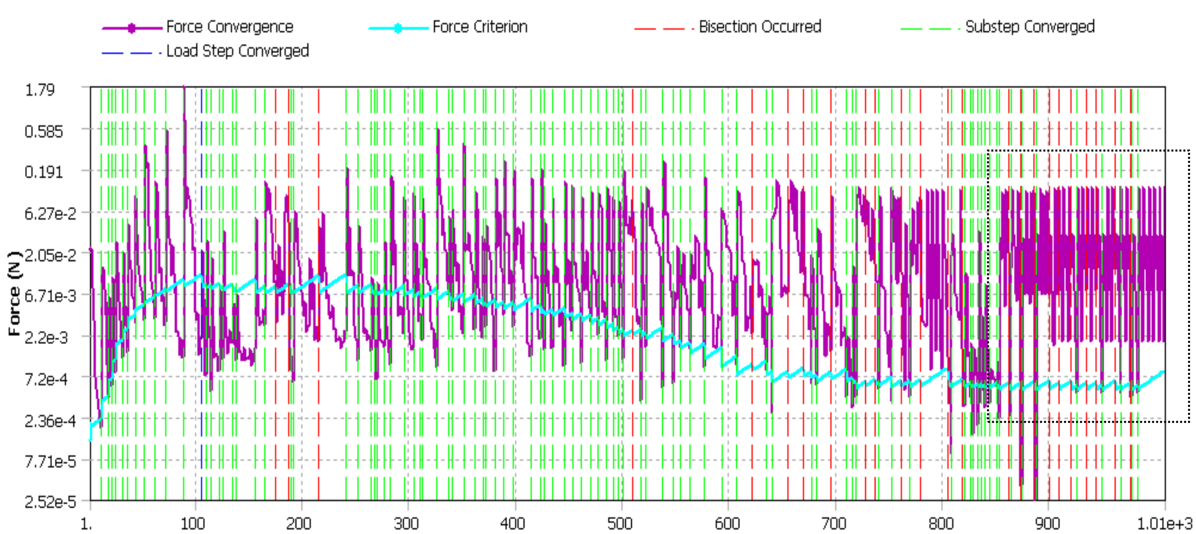


Fig 4.26 Force Convergence (Unloading Simulation)

4.6.2 Radial Spring back (recoil) and longitudinal Spring back(Recoil)

The radial recoil and longitudinal recoil percentage was calculated by the following formulae

$$(R_{Load} - R_{Unload}) / R_{Load} * 100,$$

Where R_{load} was radial displacement value of 0.29186 mm and R_{Unload} value was 0.16mm.
The percentage radial recoil was around 45.17 %.

$$(L_{Load} - L_{Unload}) / L_{Load} * 100,$$

Here L is Axial Displacement. The percentage longitudinal recoil was observed around 37 %. The recoils result obtained are of $1/6^{th}$ part of the stent.

CHAPTER # 5

Conclusions

- The analysis of stent leads to good understanding of flaws and success of design. The simulation of balloon expansion helps us to get the idea of the contact stresses between the stent and balloon. The stent and balloon contact is considered to be key factor to determine the stent behavior.
- The balloon was expanded in order to obtain maximum contact between the stent and balloon and to demonstrate realistic simulation. Performance of stent can be improved by changing the shape of the balloon according to design of the stent.
- The crimping step for stent was not modeled in the simulation.
- The stent unloading behavior was distinguished by radial and longitudinal recoil and results also represented the residual stresses and strain.
- In both cases of expansion the stresses crossed the yield limit.
- Inner coil regions have been found to be more vulnerable to failure compared to other locations. Looking closely to the region 2, it can be realized that outer path which is in direct contact with balloon is experiencing high level of stresses as compared to the inner side of the same region.
- The plastic strain value was observed high in single constraint simulation whereas relatively low values of von-Mises stresses were observed.
- Frictional contact between stent and catheter balloon did not allow large axial deformation. Axial displacement value was observed around 0.099mm at the case where axial displacement was allowed in balloon and 0.078mm in case where balloon was axially constrained. The percentage elongation difference was around 0.83% between both cases. Radial displacement is in linear relationship with the applied pressure.

- For the single end constraint case von-Mises stresses value was observed lower than double end constrain case, the plastic strain value was high was single end constraint case. This was due to the boundary conditions for both cases.
- Friction and End conditions for Balloon should be closer to Case 2, for maintaining reasonable stress levels.
- The stresses developed at inner and outer path of mesh in inner coiled region are same, whereas (inner path) stresses at connecting rod have less value then (outer path) stresses.
- For the unloading simulation for single end constraint, the solution diverged around the pressure of 5atm. The software at that point could not divide the convergence steps into smaller steps.
- The stent when entered the plastic region in the loading condition remained at the same numerical value of 0.53 in the unloading phase.
- The radial recoil in percentage was around 45.1% and longitudinal recoil was 37%.

5.1 Future Recommendations:

- The stent expansion can be modeled inside an artery and vessel wall effects on stent can be modeled.
- Folded Balloon model can be used for another expansion case.
- The stent expansion modeling can be improved by adding the crimping step in the simulation.
- Pulsatile flow which is the realistic behavior of blood can be modeled and its effect on stent can be analyzed.

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Appendix A: Coil Stent Drawing [2]