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Design & Development of Coronary Stents

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Abstract—*The most effective stent technology use for reduce the coronary arteries blockage is critical area of medical science and technology. There stents are specific for patient and the different type of stents designed according to the patient artery dimension. With the computational simulation we can make the perfect size, strength and other requirement according to the patient. This is also cost-effective method. The deployment of Bare Metal Stent (BMS) is can achieve better performance than simple balloon angioplasty. Current generation of Drug Eluting Stent (DES) has lower death rates, thin struts and highly safety. In this study made the patient coronary artery in 3D design software. With the help of coronary artery design and we design coronary artery stent using AutoCAD for 2D and Solidworks for 3D. We do Finite Element Analysis to define the design structure strength of coronary artery stents. With the use of ANSYS. And design different geometry of stents using different materials. With results of Finite Element Analysis we find that most biocompatible material. In this study we discuss the technology of stent geometry, design and development with the balloon expandable and self-expandable stents.*

Keywords: *Coronary stent, FEA, Stent Design, AutoCAD.*

1. INTRODUCTION:

1.1 Background

In medicine, Atherosclerotic vascular diseases a common problem of growth of fat, calcium and cholesterol in coronary arteries. The blockage of the artery by plaque is called atherosclerosis. This diseases that narrow the vessels and reduce the blood supply in heart arteries [1]. There is a two types of obstruction occur. To lower the obstruction the most common surgical process is Angioplasty. Which is the reappearances of tapering of an artery within six month [2]. To major obstruction common surgery is stenting. Stent place treatment in arteries is common treatment of cardiovascular disease and the re-opening the narrowed vessels and restoring the normal blood flow. Now, most of patient choose stenting surgery for life-time problem solution. The first use of stent for medical purpose was introduced to reduce the threat of percutaneous transluminal coronary angioplasty (PTCA). PTCA was use for narrow arteries to reopen them[3].

A stent is tiny tube we place in an artery. A stent is left in permanently. Stents are used to treat a variety of artery and other problems. In artery will make a small cut in a blood vessel for place the catheter. A guide wire is passed in the narrowed artery. In the heart, a fatty part called plaque. Plaque narrows the arteries and reducing the blood flow. First crimp the stent and after stent loaded on catheter wire is inserted through guide wire and passed to the artery. After that balloon is expanded with high pressure and deploy the Stent and open the blockage, while the guide wire is removed with the catheter and balloon [4]. There are two method to deploy the stent are balloon-expandable and self-expandable. In balloon-expandable stent that expand through balloon pressure. Usually this stents are fabricated from stainless steel (316L), cobalt-chromium and platinum. In self-expandable sent are expand automatic after deploy to the catheter tube. This making for nickel-titanium alloys (Nitinol) [5].

There are a two types of stents available. 1) Bare Metal Stent (BMS) 2) Drug Eluting Stent (DES). The development of Bare Metal Stents was a significant improvement in the treatment of coronary artery disease as compared to balloon angioplasty. Initial this stents were usually made up from stainless steel but now cobalt-chromium alloys have most of the use in stents and allowing stents to significantly thinner struts stent without compromising of radial strength. Current generation of BMS is could be safe and cost effective [6]. Drug Eluting Stent were created to reduce the high rated of restenosis and resulting for additional BMS angioplasty. DES as compared to BMS can be reduced up to 70% according to medical trials. Current generation low profile DES is highly flexible and efficient. DES are permanent polymer coated stents [6].

1.2 Stent Structure

Stent design is major role in its performance. There are many design consideration for stent designing like radial strength, good flexibility, good trackability, fatigue strength etc.[7] Stents are manufactured with a perfect dimensions of patient artery. We can measure dimension with the use of computational simulation and get perfect size, shape and strength. The deployment of stents is also plays important role in size of stents if stent diameter are bigger than artery then stent are not deploy good. So, in all case stent diameter are smaller than patient artery. Some other characteristics of stents we considered during designing inner diameter, outer diameter, strut width, number of strut, strut thickness, strut length, total length [8].

Struts are the metal, plastic, or wire beams or wires that make up the stents framework which are shown in Figure 1. These struts help maintain the stent in place when it is implanted and support the vessel wall.

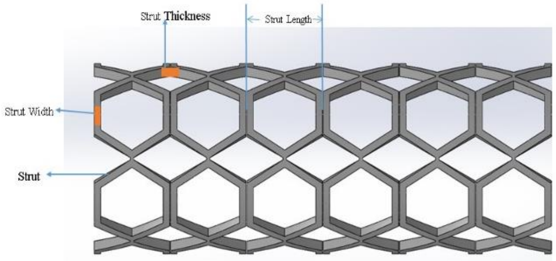


Figure 1: Stent Design

The stents design are vary with strut size, shape and diameter. Stent have different diameter. Now, small diameter (2.5mm-5.5mm) [7] with thin struts stents are very high use in vascular injury. Thick strut stent have been used in last many years. Thick struts are deploy in the arteries with high pressure. Thin are use in nowadays surgery. Thin strut contact are is high between stents and plaque and its cause is restenosis. Therefore, thin strut stents performance are better than thick strut stents.

Thin strut stents are available in different type of connectors between two strut. All these connectors with their own characteristics. This connectors are listed below:

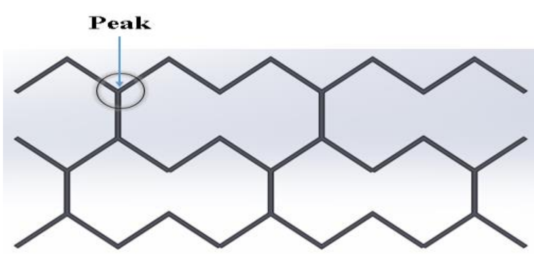


Figure 2: Peak to Peak connectors

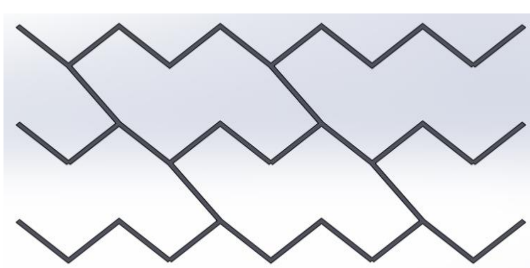


Figure 3.Offset with Peak to Peak connectors

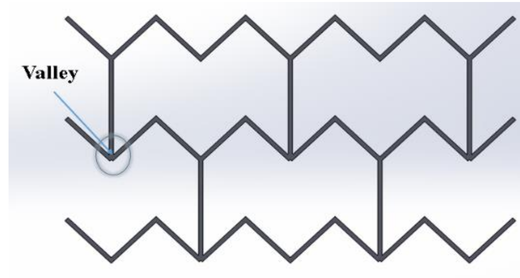


Figure 4: Peak to Valley connectors

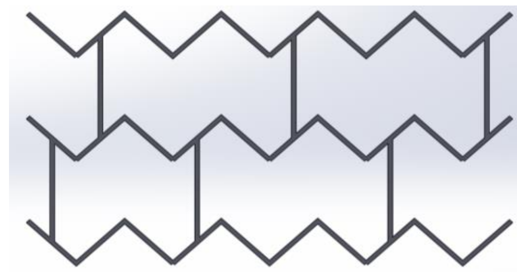


Figure 5: Mid-strut connectors

2. METHODOLOGY

2.1 Method

The coronary stents development process is shown in Figure 6. The coronary stents use for prevent the blockage in the arteries. The stents are design in software and analyse in simulation software. The data of the simulation result are checked and then select the best manufacturing technique for stent. After manufacturing the prototype of the stent is manufactured. And check the different experimental test on stent like radial force, fatigue testing etc. Then deploy the stents in patients and medical results are studied. The information are studied and there is any performance problem then changes in design and further carried to design stage.

The methodology of coronary stents design, simulation and manufacturing is proposed. Design and Simulation are classified in two parts one is concept design and other is final Design. In concept design built concept of stents and finalize the material, coating, geometry, pattern and simulation & designing software. In final design after the performance of stents in the arteries some changes in design and check the simulation results, fatigue test, deployment test, flexibility etc.[8]

The stents manufacturing are made from different of method such as laser machining, electric discharge machining, casting, wire braiding, rapid prototyping etc. Now, stents manufacturing techniques classified as traditional and non-traditional method. The traditional manufacturing techniques are forming, casting, wire braiding, joining and sheet metal processing. The non-traditional manufacturing techniques are electric discharge machining, electrical magnetic forming, laser machining, rapid prototyping, water jet machining and chemical process [4].

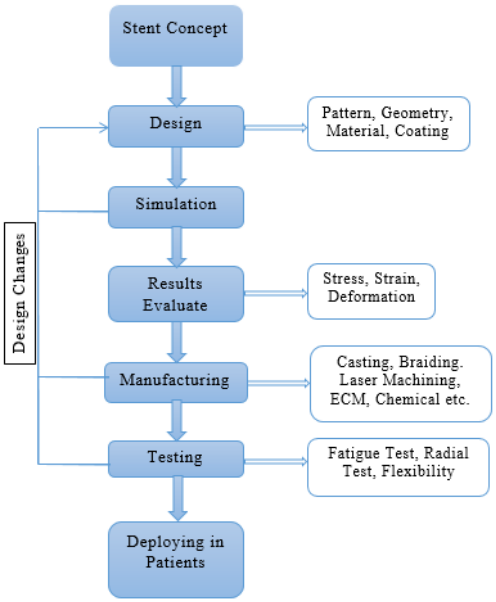
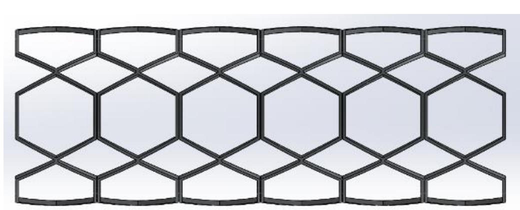


Figure 6: Methodology of Coronary Stent

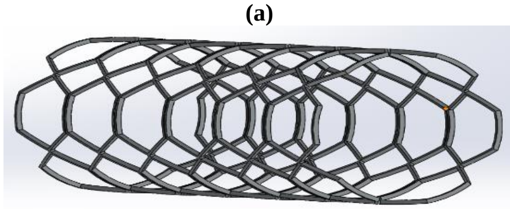
The deployment system guide wire, catheter and stent mounted on balloon. Then all systems are inserted in artery and balloon are expanded through pressure gauge and stent also expanded with balloon. Then deploy the stent of this system and remove the system to the artery [4].

2.2 Innovative Coronary Stent Design

Stents Design is important role of performance of stents. Innovative stent design are included of closed cell and open cell connected with different connectors. The two innovative design are designed in software. Design-1, this design with V shaped strut connect to peak to valley connectors. In this design take the strut thickness 0.09-0.1mm and width 0.05. This thickness and width are better wall apposition and reduce the risk of stent. This design easily expand with strut gap and connectors than normal shape design. This design expanded in circumferential form with peak and valley point as shown in Figure 7.



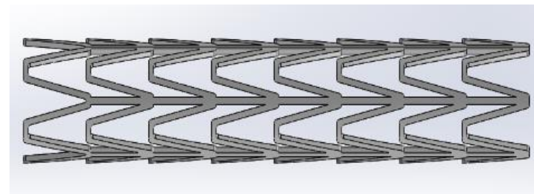
(a)



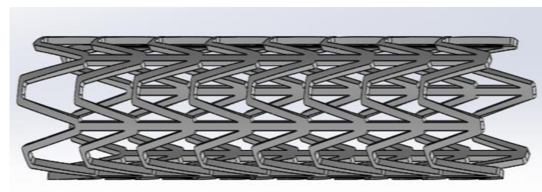
(b)

Figure 7: Innovative Stent Design-1

Design-2, in this design hexagon shaped strut connect to peak to peak connectors. Using of Hexagon shape instead of cylindrical and any other shape, this could be use less metal and improved flexibility and reduce the risk of stent. The hexagonal shaped provides more robust structure than any other shape. This strut thickness and width are 0.09-0.1mm and 0.05mm. This design expanded in circumferential form with strut connectors as shown in Figure 8.



(a)



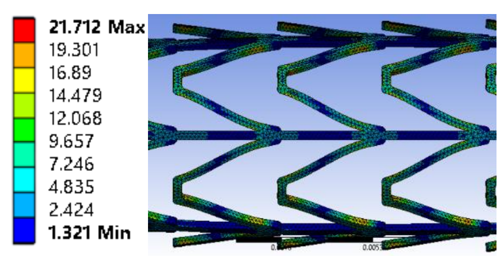
(b)

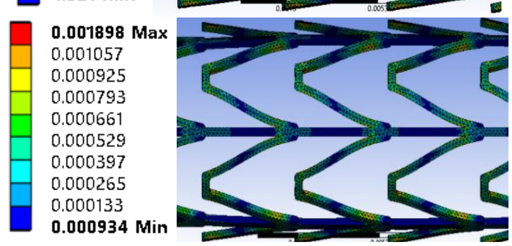
Figure 8: Innovative Stent Design-2

3. RESULTS:

In this Study, simulations results are performed on the stents. Test the simulation on new design and compare with a stent which are available in the market. The design of stents are made in Solidworks and simulation are importing and generating in Ansys Workbench. The design are tested with various material such as cobalt, stainless steel (316L) and magnesium alloys. In this paper give results of stainless steel material. The properties of materials are considered are tensile strength, young's modulus and poison's ratio. In this study, pressure are applied on the inside surface of the stent. A pressure of 13.3kpa are applied in radial manner for deploy the stent.

Design-1:





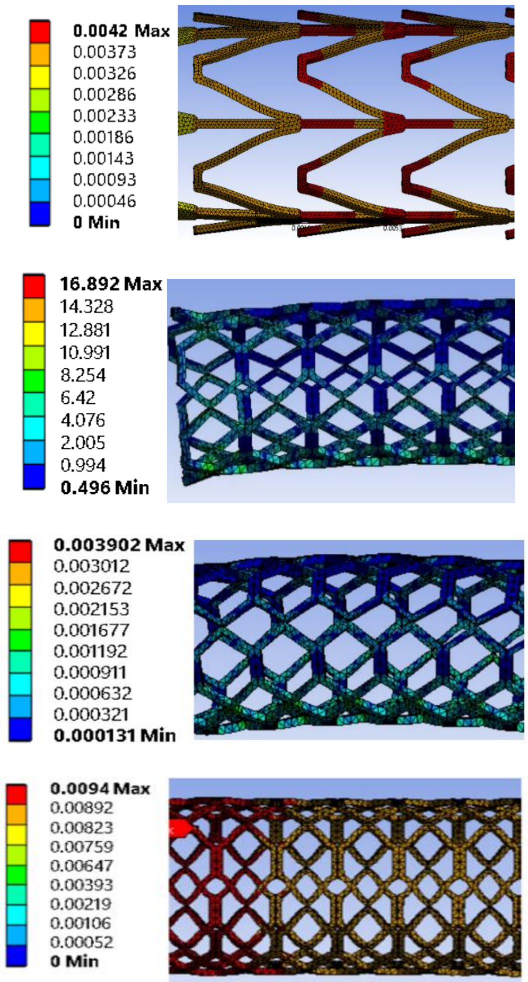
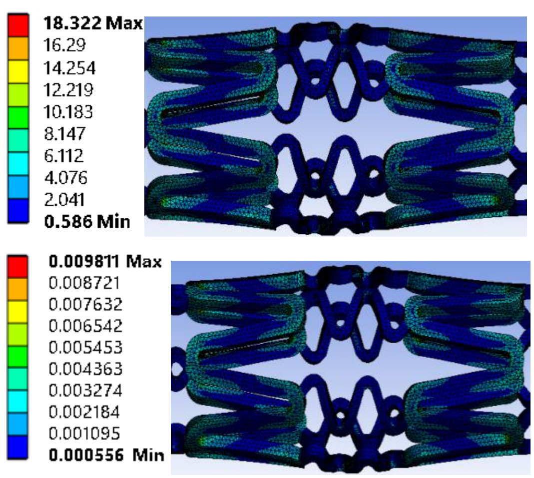


Figure 10: Von Mises stress, strain and total deformation

Cypher Stent:



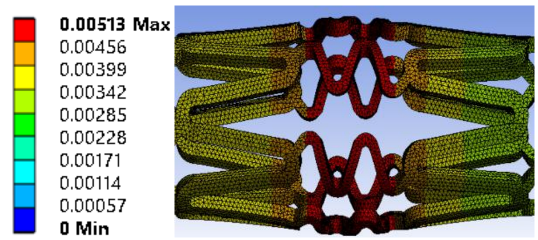


Figure 11: Von Mises stress, strain and total deformation

The stent simulation results of stress strain and total deformation for design 1, 2 and cypher are listed in below Table.

	Design-1	Design-2	Cypher
Stress (kpa)	1.321-21.7	0.496-16.89	0.586-18.3
Strain (mm/mm)	0.00093-0.0018	0.00013-0.0039	0.000556-0.0098
Total Deformation	0.0042	0.0094	0.00513

The stress values of material and simulation results values are approximately same or higher values. The strain values are different with material. Lower strain values are good for materials. Here, the stainless steel strain values are lower and its show good results. Flexibility of the stents are major parameters of the performance of stents. The total deformation are different with various material. All design stent are gradually increased the deformation with pressure increase. In stainless steel deformation are constant with pressure.

4. CONCLUSION

In this study, the designs are tested with stainless steel 316L and compared with cypher stent. The amount of pressure applied radially on the stent. With various design patterns, the performance of the stents vary. From the results it is recommended to have Innovative design-2 is good for all mechanical aspects. Development of new stent design illustrate that a using topology optimize stent have radial stiffness and flexibility, in contrast to normal stent.

The expansion of plaques inside the arteries vary from patient to patient and medical person select perfect size and shaped stent deployed in the artery. So, Manufacturers and medicals are focus on manufacturing of new stent design. There are many stents are available in the market because of severe disease needs different new design and properties.

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