Patient Specific Coronary Stent Designing and its Computational Analysis using Ansys

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Abstract: The optimal patient-specific stent technique for minimizing/eliminating coronary artery blockage is an ambitious field of medical science and technology. Patient specific stents are the type of stents which are designed according to the dimensions of one particular individual, hence they vary from person to person. With the amelioration of computational simulations, it is quite useful as we can produce or manufacture a stent that is of a specific size, strength and more tenacious to suit the patient’s specific requirement, not only that but it is also a cost-effective method. It is very compatible and is a time tested structure with hemodynamic results in order to suit patients’s requirements based on their anatomical structure. In this study the coronary artery of a patient was constructed using Mimics and 3-Matic software (Materialise,NV ), with reference to patient’s MRI angiography, subsequently with the help of the coronary artery measurements we formulated patient-specific coronary artery stents using Autocad-2016 and we used Finite Element analysis to find the structural strength of the designed patient-specific coronary artery stent. With the help of ANSYS we constructed a few sample stents using different biocompatible materials and we used Finite Element Analysis method to find the most compatible/ adaptable biomaterial, simultaneously we carried out the process of assessing the mechanical properties which are associated with restenosis. We created a simulation using Computational Fluid Dynamics (CFD) and we tested the accuracy of the stent in an artery with blood flow. The pre-operative computational simulations results are helpful in diminishing the chances of stent failure without performing actual Angioplasty which is both cost-effective as well as beneficial to reduce post-operative trauma faced by cardiac surgery patients. Keywords- Computational Fluid Dynamics, Finite Element Analysis,Autocad, Mimics,Ansys.

1. INTRODUCTION

Atherosclerosis, a common condition of deposition of fat, cholesterol and calcium in coronary arteries which causes obstruction in artery and insufficient blood supply to the heart tissues which finally leads to heart failure. To lower the obstruction the most common surgical procedure is Percutaneous Transluminal Coronary Angioplasty (PTCA) [1,2]. However, restenosis which is the reappearance of abnormal tapering of an artery, is most common problem in 30-40% patients within six months who had gone through PTCA[3,4]. Even application of intra-arterial support with bare metal stents (IABMS) extremely elevates the chances of restenosis rate of 20-30% [3,4],even in-stent restenosis is a major problem associated with PTCA and a major cause of intimal hyperplasia [5]. The phenomena of restenosis in stents occurs due to thrombosis, neointimal hyperplasia and plaque restructuring, hence causing necessity for replacement of old stent with a new one and a need of a new surgery [6]. Due to complex nature, restenosis is a dynamic area of research and further study. [7-9].

Due to current imperfections of IABMS, there is a multiplicity in the kinds of designs, materials and techniques have been screened to get a sublime stent design. Due to computational advancement and enhancements in cardiac magnetic resonance imaging (MRI) we are in the era to generate patient’s specific stent design which can be used to lower down restenosis rate and further reduce the chances of repetitive surgery which result in overall better health of the patient. In this technique remodeling a coronary artery from its MRI image is done using MIMICS (Materialise) software. This helps in getting
measurement to design the patient specific stent which has dimensions which is closer to the actual value for the patient specific application.

The stents models were designed based on the dimensions of coronary artery using AutoCAD (Autodesk) with three different materials. Computational Fluid Dynamics (CFD) and Finite Element Analysis (FEA) were carried on the designed model using Ansys. Computational fluid Dynamics (CFD), is a specialized field of mathematics, science and branch of fluid mechanics, which is routinely being applied to the cardiovascular system due to its fluid nature. CFD and rapid prototyping has led to a revolution in the field of medical science and technology as it has led to the development of devices such as ventricular assist devices, valve prosthesis and stents. CFD simulations in combination with cardiovascular imaging can be used in order to diagnose and detect the characteristics of physiological pressure, degree of blockage and flow rate. These parameters cannot be pre-determined directly without any appropriate tools. CFD modeling and its application has recently been incorporated in the field of medical sciences and has created a large impact. These simulations are now being bought into clinical application for better diagnosis by the physician. Cardiovascular imaging can be used to detect the degree of severity of the myocardial, valvular, congenital and peripheral vascular diseases. Computational methods are very useful as they are non-invasive and do not cause any discomfort or further complications to the patient. [10]

The use of finite element analysis (FEA) method has bought a revolutionary change in the field of medical science and technology. It is useful in biomechanical analysis and its use has been increased significantly since the past decade. The FEA method is a simple, effective and cost efficient procedure which can be used to perform real time simulation computationally. This method can be used to determine the distribution of stress over the entire implant, it is also useful to know the stress bearing capacity and the breaking point of the implant. This method makes it convenient for studying and analyzing the biomechanical properties along with the structural characteristics of the implant. This is useful to determine the success rates of the implant in real time as well as in clinical condition. It can also be used to understand and study the biomechanics of bone fracture and bone crack. FEA is very handy and plays a significant role in determining the mechanical characteristics and properties of any implant. Hence FEA has many advantages over the conventional real time analysis of the models [11]

The pre-operative computational simulations results obtained from Finite element analysis (FEA) and Computational fluid dynamics (CFD) are helpful in minimizing the chances of stent failure without performing actual Angioplasty which is both cost-effective as well as beneficial to reduce post-operative trauma faced by cardiac surgery patients.
2. MATERIALS AND METHODS

A. Coronary Artery design

The coronary artery was designed using the mimics software (Materialise) [Fig 1]. A cardiac MRI image of the heart was used to extract the patient specific coronary artery model which provided dimension for the stent designing. The coronary artery has a length of 30mm and a diameter of 3.78mm.

B. Stent Design

![Fig. 2: Stent models produced with varying pattern](image-url)
The patient specific stents were designed using Auto CAD 2016[Fig2]. The length and the diameter of all the stents are same. They have a length of 30mm which is similar to that of the coronary artery with a diameter of 4mm, which is slightly bigger than that of the diameter of coronary artery. The stent was designed with a slightly higher diameter so that the stent is properly fixed in place, thereby avoiding lateral shift. Four material were assigned to the stent model which were stainless steel(SS), Platinum Chromium(PtCr), Cobalt Chromium, and Nititol which can be used for different patient specific application. [11]

C. Computational Fluid Dynamics

Computational fluid dynamics is a field of science that uses applied mathematical, numerical analysis, physics, data structures, and computational software in order to solve, analyze, and visualize how a gas or liquid flows and how the gas or liquid effects objects as it flows past or through it. In this paper we performed CFD of artery along with the stent placed in the affected region. The analysis was carried out through ‘Fluent’ module in ANSYS workbench.

An artery was designed in the Autocad software. The ‘3’ stent models were placed in the artery individually and were tested for the proper flow of blood through artery. The designed artery with stent were given with some Named Selections namely- Inlet, Outlet, Wall. The meshing of the 3D object was performed with a relevance of 3mm. The density of the blood was given as 1060 Kg/m3 with a viscosity of 0.0035 Kg/m-s. Later the inlet region was mentioned as the source of entrance for the flow of blood. The conditions and parameters were computed for the analysis, and visualization of blood flow through the artery along with the stent. The velocity of the blood is minimum at the affected region (0.04496 m/s). The velocity of the blood at the ends of the artery is minimum (0.1798 m/s).

Blood flows through the bifurcating artery from the inlet and exits from the outlets (to the right). The diameter of the artery at the inlet is around 2.7mm. The diameter of outlet 1 is around 4.5mm and the diameter of outlet 2 is around 3.0mm. The density of blood is 1060 kg/m^3 [12]. As blood is a non-Newtonian fluid, the coefficient of viscosity of blood was defined as 0.004 Kg/m-s. Since blood flow is pulsatile and cyclic, the velocity profile at the inlet is a function of time.

a. Boundary Condition:

Wall: Using the Fluent option in Ansys workbench the wall regions of the designed artery was selected and specified as ‘wall’. From the viewpoint of physics, the velocity of the wall was defined as zero.[12]

Inlet: Mammals have a cyclic and pulsatile blood flow. Hence, the velocity of the blood at the artery inlet is not set to be a constant, but instead, in this case, during the systolic phase of the heart it has a peak velocity of 0.5m/s and a minimum velocity of 0.1m/s. Therefore the average velocity was defined as 0.3m/s.[12]
Outlets: In a healthy human, the systolic and diastolic pressure is around 120 mmHg and 80 mmHg respectively. Hence, by taking the average pressure of both the phases, we get 100 mmHg (around 13332 Pascal) as the static gauge pressure at the outlets.[12]

D. Finite Element Analysis

Finite element analysis is a numerical method for solving problems related to engineering and mathematical physics. FEA is generally carried out to determine - heat transfer, structural strength, mass transport, electromagnetic potentials and fluid flow. FEA was carried out through ANSYS software. The analysis was carried out through ‘Static Structural’ module in the ANSYS workbench. The designed stent models were imported into the ANSYS software in IGES format. The meshing of all the ‘3’ designed stent was done using the default mesh option on ANSYS Mechanical toolbox with a relevance of 3mm. The designed stents were tested for structural strength with ‘8’ different materials namely – Stainless steel 316L, Platinum Chromium, Cobalt Chromium L605, Cobalt Chromium MP35N, Nitinol, Elgiloy, Tantalum, Magnesium WE43. The material was presumed to be homogeneous and isotropic which is on basis of optical microscopy [13]. The mechanical properties of every material such as young’s modulus, poisson’s ratio and density were feed into the ‘Engineering data source’ which is present within the ANSYS software. The poisson’s ratio was assumed to be 0.3 for conclusion [14]. A pressure of 13.3 Kpa was applied on the inner walls of the stent. [15]

3. RESULTS AND DISCUSSION

A. Finite element analysis

Finite element analysis is used to test compressive and effective tensile modulus of different stent geometries and shapes. The Finite element analysis data generally has a 30% error. A total of ‘3’ stent models were designed and tested for its structural strength. We tested the ‘3’ models for ‘8’ different materials namely Stainless Steel 316L, Platinum Chromium, Cobalt Chromium(L605), Cobalt Chromium (MP35N), Nitinol, Elgiloy, Tantalum, Magnesium(WE43). The mechanical testing showed us better results of the design in Fig. 3. The material that can bear highest amount of stress is Elgiloy, and the material with lowest amount of stress is Cobalt Chromium MP35N. The highest amount of strain is for Magnesium WE43 and the lowest one is for Cobalt Chromium L605. The material Nitinol has the maximum strain and Cobalt Chromium L605 has the least value of strain. The material Elgiloy has the least amount of deformation and Magnesium WE43 has the highest value of deformation.

Fig. 4: Comparison Plot of equivalent strain (mm/mm X 10^5) of all models made up of Stainless Steel 316L, Platinum Chromium, Cobalt Chromium L605, Cobalt Chromium MP35N, Nitinol, Tantalum, Elgiloy, Magnesium WE43
Table 1: Deformations in $10^{-6}$ mm values obtained by FEA analysis

| S.NO | STAINLESS STEEL 316L | PLATINUM CHROMIUM | COBALT CHROMIUM L605 | COBALT CHROMIUM MP35N | NITINOL | TANTALUM | ELGILOY | MAGNESIUM WE43 |
|------|---------------------|-------------------|----------------------|-----------------------|---------|----------|---------|----------------|
| MODEL 1 | 6.44 | 6.19 | 5.17 | 5.28 | 14.97 | 6.65 | 6.69 | 28.74 |
| MODEL 2 | 4.28 | 4.09 | 3.41 | 3.53 | 9.95 | 4.43 | 4.40 | 18.93 |
| MODEL 3 | 1.92 | 2.01 | 1.68 | 1.47 | 4.47 | 1.92 | 2.49 | 9.95 |

Table 2: Equivalent Strain In $10^{-5}$ (mm/mm) values obtained by FEA analysis

| S.NO | STAINLESS STEEL 316L | PLATINUM CHROMIUM | COBALT CHROMIUM L605 | COBALT CHROMIUM MP35N | NITINOL | TANTALUM | ELGILOY | MAGNESIUM WE43 |
|------|---------------------|-------------------|----------------------|-----------------------|---------|----------|---------|----------------|
| MODEL 1 | 11.75 | 11.33 | 9.46 | 9.64 | 27.33 | 12.14 | 12.54 | 53.00 |
| MODEL 2 | 6.13 | 5.81 | 4.85 | 5.15 | 14.26 | 6.40 | 6.69 | 27.65 |
| MODEL 3 | 4.85 | 5.17 | 4.32 | 3.66 | 11.27 | 4.81 | 6.80 | 26.23 |

Table 3: Equivalent Stress (MPa) values obtained by FEA analysis

| S.NO | STAINLESS STEEL 316L | PLATINUM CHROMIUM | COBALT CHROMIUM L605 | COBALT CHROMIUM MP35N | NITINOL | TANTALUM | ELGILOY | MAGNESIUM WE43 |
|------|---------------------|-------------------|----------------------|-----------------------|---------|----------|---------|----------------|
| MODEL 1 | 22.162 | 22.469 | 22.469 | 21.957 | 22.162 | 22.06 | 23.276 | 22.784 |
| MODEL 2 | 11.831 | 11.719 | 11.719 | 11.985 | 11.831 | 11.899 | 12.66 | 12.099 |
| MODEL 3 | 9.3329 | 10.473 | 10.473 | 8.5117 | 9.3329 | 8.9289 | 12.89 | 11.514 |
Computational Fluid Dynamics

Computational Fluid Dynamics is the analysis of fluid flow through any closed surface using physics and numerical solution methods. Computational fluid dynamics method was used to determine the proper flow of blood through the coronary artery after the stent is placed in it. This process ensures the proper, adequate and sufficient flow of blood through the coronary artery for the supply of fair amount of oxygenated blood to the heart. The coronary artery was designed and all the three stent designes were placed into the coronary artery individually and were tested for ample amount of blood flow through it. The stent model 1 has a maximum velocity of 0.1862 m/s at the ends of artery and a minimum velocity of 0.04656 m/s at the region where stent is placed, model 2 has a maximum velocity of 0.1715 m/s at the ends of
artery and a minimum velocity of 0.04286 m/s at the region where stent is placed, and model 3 has a maximum velocity of 0.1704 m/s at the ends of artery and a minimum velocity of 0.04260 m/s at the region where stent is placed. Out of the three stent designs the model 1 shows better and more efficient flow of blood through the artery.

Fig. 7: Velocity of blood through the artery with stent obtained by Computational Fluid Dynamics

4. CONCLUSION

Various stents were modeled using different materials based on their mechanical strength and the results were compared. Computer Aided Designs were developed by varying the stent design for different severity of plaque. Structural analysis was carried out using ANSYS to obtain mechanical properties of the designed stent.

On basis of the results obtained from computational FEA and CFD we conclude that the ‘stent model 1’ with the material of ‘Elgiloy’ has the maximum von mises stress of 23.276MPa and ‘stent model 3’ with the material of ‘Cobalt Chromium MP35N’ has the minimum von mises stress of 8.5117MPa. The pressure applied on the inner walls of the stent explains the mechanical strength of the stent.

The mechanical properties of the stent are strongly dependent on the design and material used. The software based approach helps in the designing of patient specific stent and reduces the problem and inconvenience of restenosis. The data from the software’s is immensely helpful in developing physical stents by rapid prototyping technology using various metal alloys and biopolymers.

The use of 3D image based modeling of realistic geometry of arteries using MRI and CFD studies of blood is extensively used to study the hemodynamics. The use of realistic 3D models and simulation help in the better understanding of the hemodynamics of blood through the affected artery. The stent model 1 has proven to be the most efficient design and the stent model 3 is the least efficient design as per the hemodynamic studies carried out through CFD using ANSYS. Over the past few years the use of computational methods for the simulation of blood through the artery have gained large amount of importance in understanding the human cardiovascular system. The results of the study show that the development of patient specific stents and the data obtained from simulations are very helpful in minimizing the chances of stent failure without performing actual Angioplasty, which is both cost-effective as well as reduces post-operative trauma faced by cardiac surgery patients.
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