Design, Analysis and Manufacturing of Bare Metal Coronary Stent using PCM

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Abstract

The paper presents the design, analysis, and manufacturing of bare metal coronary stent using Photochemical Machining (PCM). The stent is used to overcome the coronary Heart diseases (CHD) by inflating the narrowed of arteries. The finite element analysis has been carried out to investigate critical region and parameters in the perspective of efficient mechanical performance for the designed stent. The numerical simulation of crimping process and balloon expanding has been carried out. The crimping is done up to 2 mm mean diameter with the external pressure of 0.42 MPa. And again by applying internal pressure of about 1.2 MPa expand stent up to original dimension of 4 mm. The Photochemical Machining is a new approach of has been characteristically employed in the manufacturing of stent. In this work 3D micro image printing incorporated with UV light curing for production of required pattern. This work aims to manufacture designed shaped bare metal stent prototype with minimum surface roughness. The wet chemical etching process is used for manufacturing a stent from the optimised etching parameters. Input parameters are a concentration of etchant 500 g/*l*, time of etching 50 minutes and etching temperature is 50°C.

Keywords: Static Structural Analysis, Stent, SS316L, Photochemical Machining

1. INTRODUCTION

When artery collapse against the balloon angioplasty then angioplasty starts with the use of a supportive device called the stent. The stents are come in existence to overcome incapability of the balloon angioplasty. Stents are the mesh-like devices that appear to spring in pen. The stent is an expandable tube of biocompatible material which holds the structure open and left there permanently for free circulation of oxygen-rich blood to activate the desired function of the heart. They ultimately become covered with the cells and in essence part of the artery over time. The chance of disease like a heart attack is decreased by use of a stent which keeps open arteries permanently or a long time depending on the type of stent placed in the artery. A crimped stent is placed on the balloon-tipped catheter is inserted into an artery and moved to the point of blockage. Then the balloon is inflated which expands the stent with compresses the plaque and act as scaffolds. This cause the unobstructed flow of blood through vessel then the balloon is deflated and the catheter is withdrawn. The various design parameters of coronary stents viz. structure, geometry and dimensions are studied [1]. Stents are classified according to the mechanism of expansion, the raw material used, forms of raw material, geometrical configuration, manufacturing methods and additives used for stent [2]. For the stent design, various parameters are considered viz. diameter of the stent, the thickness of strut, length of the strut, and Young's modulus and Poisson ratio of the material [3]. The materials used in coronary stents must be flexible, supportive, capable of expansion, and biocompatible. There are various materials used for stent manufacturing are stainless steel, cobalt chromium alloy, nitinol, gold, tantalum alloy, titanium and several types of polymers etc. Ideal stent surface does not cause any reaction with the body. The attempt has been made with the using the SS316L seamless tube. SS316L is low cost and readily available biocompatible material than cobalt-chromium, Nitinol etc. The study of material in the perception of geometrical properties of the stent can provide useful indications of its performance and on its interaction with the target vessel. It possesses properties like radiopacity, biocompatibility, corrosion resistance, excellent fatigue strength. It provides various characteristics which biocompatible material need to have. Seamless steel tubes exhibit the structural stability to the product after chemical etching. SS316L has improved pitting corrosion resistance and has excellent resistance to sulphates, phosphates and other salts. In this study, we used 6 loop strut middle connector design. Steel tubes with outer diameter 4 mm and thickness 0.2 mm are used for the experiments. The stent analysis is carried out in the static structural module of ANSYS software.

Recently, stents are typically manufactured by laser machining process. It gives the most suitable combination of higher accuracy, precision, and speed with lower machining time. But, the laser machining fabricates the stent by melting, sublimation, and oxygen reaction. It leads to the formation of dross and sputters; it is an adherence of solid impurities over the surface, oxidation of machined surface, burr formation, and extent of heat affected zone that transform the microstructure and mechanical properties of the adjacent layer. Apparently, these are removed using allied processes. Ultimately, it seems to be higher cost in laser machining due to the involvement of the allied processes, time-consuming and controlling it. Therefore, contextual forces to have an alternative to laser machining in stent fabrication. Simultaneously, the other manufacturing processes like PCM, electroforming, micro-electro-discharge machining (μEDM), and 3D printing as emerging field are alternative methods for laser machining. These processes have potential and capability to fabricate the stent burr and dross free with minimum surface roughness [1-4]. But, from the all, PCM has most economical viability and characteristically different that produces stress-free and burr free micro-component within tightest tolerance in a low cost without any alterations in microstructural and mechanical properties in the machined component. Hence, PCM can be explored as a non-conventional material removal engineering technique for the manufacture of burr free and stress-free for

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intricated shape and size component over the 2D surface using controlled chemical etching through selective unmask surface.

Photochemical Machining (PCM) is used for machining of microcomponents where tooling cost is very high. The proposed work of PCM can play an essential role in micro-components manufacturing and also reduces a cost of tooling. The components produced by using PCM have wide applications in the field of medical, automobile field and aerospace industries [2]. Micro-components like micro-fluidic channels and bio-implants are the most rapidly growing domains of scientific research and technology development [3]. PCM industry plays a valuable role worldwide in the production of precision parts and decorative items. PCM is also known as photo etching, photochemical milling, photo milling, photofabrication, photochemical etching and chemical blanking [4-9].

There are several applications of photochemical machining in the field of micro-engineer. Allen et al. studied the characterisation of aqueous ferric chloride etchant used in industrial photochemical machining [4]. The study of copper etching with cupric chloride ($CuCl_2$) as an etchant and regeneration of the etchant has been carried out by Cakir. Cakir also reported the survey of ferric chloride ($FeCl_3$) as a suitable etchant for aluminium etching [10]. The PCM process would make the overall manufacturing cost lower [4]. The $FeCl_3$ is the most commonly used etchant [6]. Saraf et al. have been developed a magnetic field assisted model for PCM which defines influences on measures of performances. Also, produced stent using photochemical machining. Patil et al. have studied in metallurgy in the perspective of PCM [5, 7].The proposed work of PCM can play an essential role in micro-components manufacturing and reduces a cost of tooling [4-10].

2. STENT DESIGN AND ANALYSIS

The work is focused on the parameters of the balloon expandable cardiovascular stent.

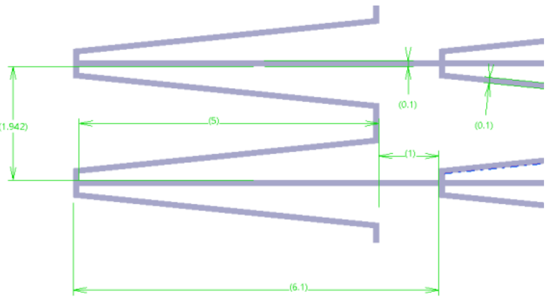

Fig.1. 2D design of 6- loop stent

The 6 loop strut middle connector design stent is drawn with specified details on CATIA software as shown in fig. 1.

Stent Design Inputs Parameters are-

1. Number of columns of struts along the length of the Stent (N_{col}) = 8

2. Number of columns of struts around the circumference of the Stent (N_{struts}) = 6

3. Outer diameter of the tube from which the Stent is fabricated (D_{tube}) = 4.0 mm

4. Wall thickness of the tube from which the Stent is manufactured (t) = 0.2 mm

5. Axial gap between adjacent columns of struts (X_{bridge}) = 2.041 mm

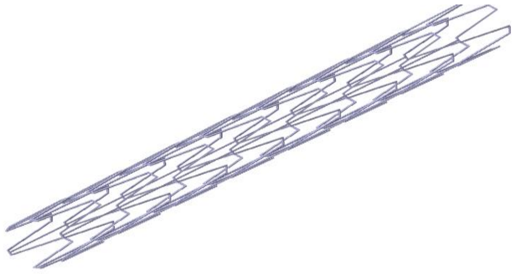

Fig. 2. 3D view of 6-loop strut middle connector stent

The designed stent is compatible with the working condition is decided with the analysis of that design by giving the functional limitations or constraints the design. Before angioplasty stent is placed over balloon by applying the radial pressure on the outer surface called crimping. The crimping is done up to 2 mm mean diameter with the external pressure of 0.42 MPa. And again by applying internal pressure of about 1.2 MPa expand stent up to the original dimension of 4mm.

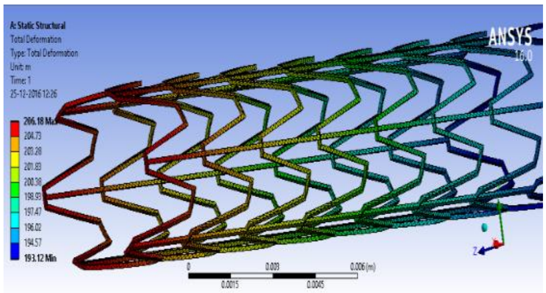

Fig. 3. Total Deformation

Both external pressure and internal pressure are directed in the radial direction. The total deformation, normal stresses, and critical regions are obtained as shown in figures 3, 4, and 5.

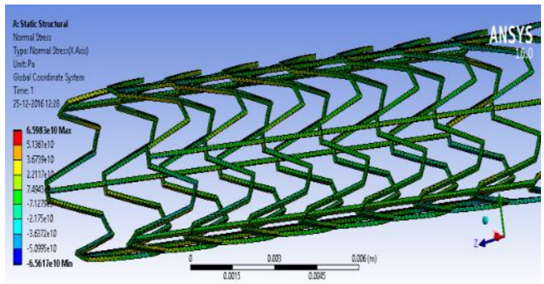

Fig. 4. Normal stress

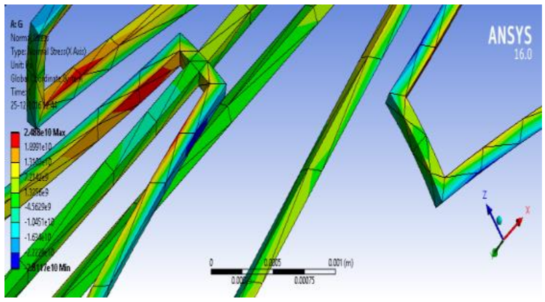

Fig. 5. Locations of Critical points

3. STENT MANUFACTURING

The experiments are conducted using dip chemical etching. In which workpiece material is immersed in an etchant. The PCM process is performed in two steps, i.e. sample preparation and wet corrosion of metal in a controlled manner. The sample preparation comprises with cleaning of the contaminated surface by ultrasonic cleaning and polishing. The contaminated surfaces are an impedance to the etching process. Ultrasonic cleaning is done at 50ºC for 30 minutes. This step is followed by 3D micro image printing of stent pattern over a surface of the seamless tube using metallic ink. It is a thin layer of polymer applied to adhere to the surface. After the image printing on tubes, it is in a kept dry air environment for 4-5 hrs then expose to UV rays for curing of the ink. The UV curing of ink is completed about 10-12 minutes with the use of UV curing machine (Phonix electronics, Mumbai). Subsequently, it is placed in an oven for 20 minutes at 70-80ºC for pre-baking. Both UV curing and pre-baking is aimed at increasing the bonding strength of ink with the surface of the tube; by enhancing adhesivity of tube and ink, and cohesivity through cross-linking polymerisation within the ink. It helps in resisting of ink peel off during the etching process.

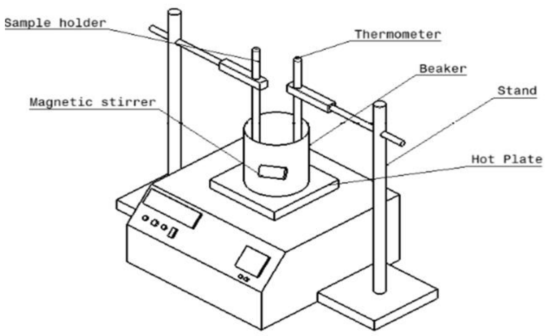

Fig. 6 Schematic of Experimental Setup

The PCM process employed to the manufacturing a stent of the dimensions such 100 µm strut width, 100 µm thickness, whereas 6mm long column along the length, and six columns around the circumference of the 4 mm OD and 3.8 ID seamless tube. The experimental study is carried out by the hot plate with a magnetic stirrer. Fig. 6 shows the schematic of the experimental setup. In this study ferric chloride ($FeCl_3$) is used as crucial etchant with HCl and HNO_3 as an additive; they act as a catalyst to increase the etch rate. Fig.7 shows the effect of HNO_3 on the depth of etch. This graph indicates that the addition of HNO_3 gives rise in etch rate (Etch rate is defined as the depth of etching to the time). Etchant concentration, etching temperature and etching time are the input process parameters studied concerning response parameters viz. depth of each, Material removal rate (MRR), and undercut. From the literature survey and preliminary experiment, the levels of etching parameters viz. etching concentration 400-800 g/l, etching temperature 40-80ºC and time 30-50 minutes were fixed. Experimentation for stent was carried out by considering the above parameters. The Fig.8 shows that the effect of temperature on the depth of etch at a constant time 50 minutes. The increase in etchant temperature of a reaction enhances the rate of corrosion. It is because the advancement of the reaction is not in a smoother manner. The rise in the temperature directly affects the viscosity of the etchant and the mobility of the ions; it increases with temperature that imparts agitation and turbulence to the etchant. The agitation of the etchant increases the kinetic energy level of atoms spontaneously.

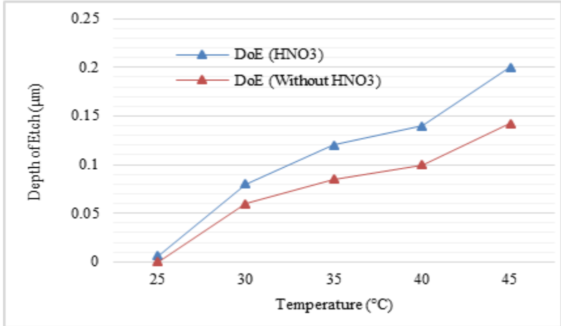

Fig. 7. Effect of etchant additives on depth of etch

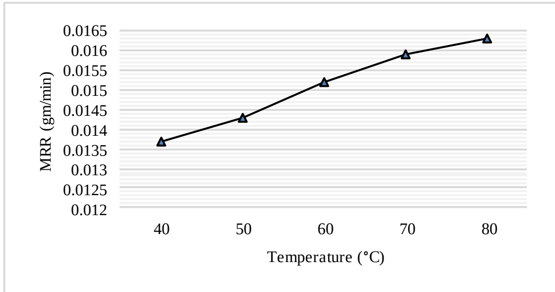

Fig. 8. Effect of temperature on MRR

The Fig. 9 shows the effect of the concentration on MRR. The concentration 500 g/*l* gives higher whereas about it goes on decreasing. It is due to a higher concentration, the density and viscosity of the etchant solution increases. It retards the movements of the atoms present in the solution. It brings down the energy level of the atom.The slower atoms were unable to hit the new surface, stuck to the surface, and carry back another atom along with it. Hence, it decreases the chemical corrosion action. Therefore, it lowers the MRRat higher concentration. The Fig.10 depicts time is inversely proportional to MRR. The maximum MRR 0.0162 gm/min is obtained at 30 min. Initially, the reaction rate is higher it is because of the fresh and new etchant. It possesses more atoms to react. Also, it offers faster movement to the atoms. Therefore, material removal by chemical dissolution is higher. Whereas, MRR is calculated in weight loss to the time required. The increase in etching time decreases the ratio of MRR to etching time. Simultaneously, reaction progresses more smoothly. It gives material removal, i.e. weight loss is constant. Hence, the calculation of MRR gives out is inversely proportional to time.

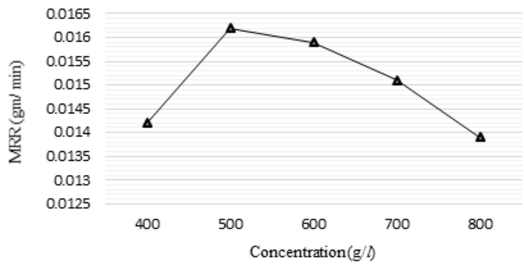

Fig. 9. Effect of Concentration on MRR

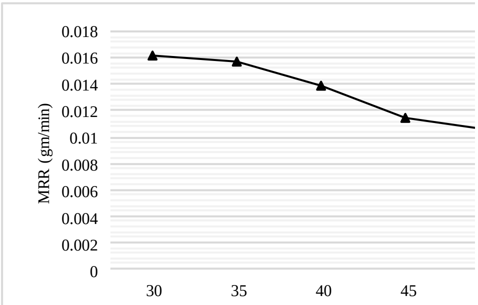

Fig. 10. Effect of etching time on MRR

Numerous experiments were carried out to the manufacturing of stent. The manufactured stent prototype is as shown in Fig. 11.

Fig. 11. Stent prototype fabricates using PCM

4. CONCLUSION

The investigation has dealt with design, analysis, and manufacturing of stent prototype using PCM. It was observed that static structural module of ANSYS software was able to simulate crimping and inflation process of the stent. The critical regions are found at connectors and sharp corners of the struts. The maximum normal stress is 6.59E04 MPa. PCM is an efficient and progressive alternative for stent manufacturing. Optimized input parameters are a concentration of etchant 500 g /*l*, time of etching 50 minutes and etching temperature is 50°C.

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