

The Development and Designing of Stent for Treatment of Atherosclerosis

By

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A thesis submitted to the Department of Pharmacy in partial fulfillment of the requirements for the degree of Bachelor of Pharmacy (Hons.)

Department of Pharmacy
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October 2019

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Declaration

It is hereby declared that

1. The thesis submitted is my own original work while completing degree at Brac University.
2. The thesis does not contain material previously published or written by a third party, except where this is appropriately cited through full and accurate referencing.
3. The thesis does not contain material which has been accepted, or submitted, for any other degree or diploma at a university or other institution.
4. I have acknowledged all main sources of help.

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Approval

The thesis titled “The Development and Designing of Stent for Treatment of Atherosclerosis” submitted by Monika Nasrin Munni (15346026) of Summer 2015 has been accepted as satisfactory in partial fulfillment of the requirement for the degree of Bachelors of Pharmacy on 10th October, 2019.

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Ethics Statement

This study does not undergo any ethical issues.

Abstract

A stent implantation nowadays is the most common percutaneous coronary intervention. Stent restenosis is a major problem for stent implementation into the body. Stent restenosis is a vascular reaction which leads to stent injury. This study describes the the process of three dimensional stent designing for the treatment of atherosclerosis. Three-dimensional (3D) printing is an additive manufacturing technique that holds great significance in the future of medical technology. As a potential method for preventing stent restenosis, the drug eluting stent has recently been suggested. Moreover, this study is originally designed to examine the firm mechanical effects of the dynamic stent design and atherosclerotic plaque coarseness in a diseased artery wall model on the heart muscle. 3D software often used to design a more efficient stent for the treatment which contains the Evarolimus drug. This project puts emphasis on establishing a 3D stent for the medication of atherosclerosis.

Keywords: Stent; BMS; DES; Restenosis; Stent design; Atherosclerotic plaque

Dedication

I want to dedicate this thesis paper work to my respected supervisor Dr. Md. Jasim Uddin, Assistant professor in Department of Pharmacy, Brac University who continuously help me throughout my project.

Acknowledgement

I would like to proceed by thanking Allah Almighty in the accomplishment of my project for His infinite blessings and compassion, my source of strength, knowledge and experience. All praise to Him for helping blessed me with the tremendous patience, strength and assist required to perform this project. That is why I am really grateful to some people for their continuous oversight and guidance without which this project seemed quite difficult to accomplish. Therefore, to express my gratitude, I acknowledge them here.

I would like to honor my supervisor, Dr. Md. Jasim Uddin (Assistant Professor, Department of Pharmacy, Brac University), whose constant involvement and supervision in every step have helped me to accomplish this project efficiently. I thank him for his great advice and patient behavior whenever throughout this phase I encountered difficulty. I would also like to express my gratitude to Dr. Eva Rahman Kabir (Chairperson and Professor, Department of Pharmacy, Brac University).

Subsequently, I would also like to thank my parents for their persistent support and encouragement to work harder at every point of my life. I might not think without their prayers and unconditional love I would have come so far.

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List of Acronyms

3D

Three dimension

BMS

Bare Metal Stent

DES

Drug Eluting Stent

Glossary

Thesis: An extended research paper that is part of the final exam process for a graduate degree. The document may also be classified as a project or collection of extended essays.

Glossary: An alphabetical list of key terms

DES: A drug-eluting stent (DES) is an external or cardiac arrest stent (a canopy) in narrow, sick, external or myocardial infarction capillaries that releases a medicine slowly to lock the growth of cells.

BMS: A bare-metal stent is a stent without any adhesive or concealing. It is also a thin pipe mesh-like casing.

In Stent Restenosis : Diagnosis of an uncontrollable artery or valve reinstatement after prophylactic invasion.

Chapter 1

Introduction

1.1 Description on Stent

Stenting refers to stent implementation by using angioplasty surgery. Stent implantation is the first choice to re-vascularize patients presenting with acute myocardial infarction (Barbato, et al., 2003). When the fatty deposits called plaque are developed, an arterial blood vessel will decrease its blood flow. If blood flow to the heart muscle is lowered, that may cause pain. When coagulation forms part of the heart muscle and utterly prevents blood flow, an attack results in atherosclerosis (Iantorno, 2019). The central pulmonary-artery malformation is a fatty tissue or fibrofatty plaque that causes aneurysmal contractions, occlusion predisposes, decomposed and impairment in the body. Coronary artery disease can be both lifelong and vascular infections involving various cells and monocytes, macrophages, T-lymphocytes, endothelial cells, soft muscle cells and mast cells (MCs). The substantial reduction in the percentage of stent restenosis and persistent stent myocardial infarction prompted rapid development (Douglas et al., 2009). However, preliminary studies indicate that atherosclerosis individuals have always been influenced by stent tubing and stronger longevity (Douglas et al., 2009; Lin et al., 2016), as nothing more than a result of which stent had been used. Stenting has shown that the occurrence of perennial revascularization processes is inferior to the balloon operation. In patients with single-de-novo atherosclerotic focus point disorders with tremendous aboriginal capillaries, stenting has therefore been described particularly with a balloon approach (Boyer et al. 2019a; F.A. et al. 2000). In addition to the greater angiographic studies acquired by stenting the data from stent restenosis research and the European Country the Netherlands randomized tests led to a real explosion

in the uses of tubes on the far side of the Food and Drug Administration-approved evidence (O Oyewumi, 2015).

Atherosclerosis : The primary intention of atherosclerosis avoidance is to avoid the occurrence of atherosclerosis risk mechanisms, and the secondary intention is to avoid the growth or aggravation of the disease along with reducing or controlling current hazards (Conti & Shaik-Dasthagirisaeab, 2015). Primary prevention should begin as soon as possible, even in adolescence, establishing a healthy diet, eliminating smoking, periodic physical activity, preventing or at least slowing atherosclerosis growth. The effects of atherosclerosis seem to be: coronary or ischemic heart disorder, particularly myocardial infarction, cerebrovascular disorder and cerebrovascular disease (80% of all atherosclerosis-related heart attacks and brain), peripheral artery narrowing or blocking, carotid plaques. Because there is no particular atherosclerosis cure, prevention is the best way to avoid this disease (Conti & Shaik-Dasthagirisaeab, 2015).

1.2 Types of Stent in Treatment Sectors

1.2.1 Bare Metal Stent

Here, a significant amount of patients with peripheral artery disease (PAD) has arterial blood vessel infection that needs treatment. The development of bare metal stents has improved the short and semi-permanent outcomes like endovascular repair and has become first-line medical aid for the treatment of arterial blood vessel disease. Instead of people with extremely sophisticated anatomically correct morphologies or interventional abnormalities, an open surgical bypass has been reserved (Jaya,et al., 2016). It is unclear whether or not primary stenting is superior to surgical process if angioplasty is employed alone; it is probably solely applicable for the foremost focal lesions. Self-expanding and balloon-expandable stents have distinctive characteristics that are appropriate for various lesion

morphologies (Brancati et al., 2017). Numerous investigations have been included in BMS (Brancati et al. 2017) procedure to maintain and perform the unmonitored left pulmonary arteries (LMCA). The primary restriction to the long-term reliability of respiratory insufficiency is absolute restenosis that must be associated with aggravated long-term survival in unmonitored LMCA implementation. In obstetric patients with reasonably simple pulmonary embolism diseases, the Everolimus polymerizing stent significantly reduces in-stent restenosis. Early reports from the exploration profile indicate that LMCA fibrosis might indeed result in a narrowing restenosis by much of the implantation of the stent. Nevertheless, the small proportion of all such trials, methodological limitations of acceptance factors and limited angiographical lead-up performance have also been restrained. This prospectus both interventional and angiographical gains after just EES insemination inside an exceptionally large ratio of cross-protected LMCA patients (Fomby, et al., 2011) and compares those very same outputs from those of bare metal stent implantation (Park et al., 2005).

1.2.2 Drug eluting Stent

Drug-eluting stents seem to be biomaterials intended and provide treatment which is intensely activated and specific way to mitigate additional neural growth accompanying the insemination of synthetic stent. Transplanting therapy eluting stents had already suggested the surgical and fast-term effectiveness in combatting improper post-intimal thrombosis and sometimes highlighted relevant obstacles to thrombosis (Naganuma, 2018). This analysis expands on current projections in epidemiology experiments but instead generates a computer-controlled glimpse through the processes involved and establishes the minimum requirements for future experiments. Deep knowledge of the fundamental biological phenomena arising in in-stent restenosis and stent thrombosis is critical to the appreciation of important innovation-driven values in this sector. Some more bends contain about 25 percent of all strokes and up to 20 originate from atherosclerotic vertebral stenosis (ova) (Pal et al.

2019). While ovaries have not been best managed, an honest clinical agreement has been reached that medical therapy (MT) with antiplatelet agents and control of cardiac risk variables should be included in original administration (Fomby et al. 2011). Notwithstanding maximum possible standard treatment that continuity with infections translates to that of the possibility of transplant or laparoscopic options. Furthermore, the need for invasive surgery or endarterectomy in hypothetical scenario of initial cranial femoral disease is reportable without the competitive rate of stroke (1.9 percent) or death (0.6 percent). Minimally invasive intervention had already proven to have become stronger and therefore less invasive than some of currently open military operation. The blood vessel stent (VAS) varies significantly by 9% to 2,96% (Degertekin, Regar, Tanabe, Lee & Serruys, 2002) per procedural risk of complications level. Although, before using bare metal (BMS) stents (Ramadugu, et al., 2016) a significant restenosis prevalence must have been noticed with testes. Crystal shunt resistor to reduced restenosis outcomes during such a vascular sleep seemed to have counter-proliferative drug-eluting stents (DESs) for the assessment of pulmonary embolism coronary artery disease which lead and the use of this technology by neurointerveners in ova surgery. This stent offers various local, federally regulated planned release from inside-stent restenosis (ISR) rabid anti-proliferating federal agents directly aimed at violently suppressing neontimal atherosclerosis (Puranik. et al. 2013). The first batch has been shown greater efficiency in so many cases compared with BMS (bar-metal stents), like sirolimus and paclitaxel-eluting stents, anyway without enrichment in others. The second-generation conductive DES had already been designed to increase reliability, comfort, and effectiveness of appliances (Vanags et al., 2018). In surgery of myocardial infarction interstitium sickness, these contemporary instruments had already emerged clinically superior to preceding DES. In general, DES have been shown to be smaller in quantity and prevalence of in-stent restenosis (Brancati et al., 2017).

1.2.3 Bioabsorbable Stent

Presently, there are more than fourteen completely different biodegradable stents (BDS) which are in diagnosis and clinical testing worldwide. This research created a numerical model to explore bioabsorbable cardiac stents degradation mechanism and conduct. The degradation features were defined with user-defined field factors to produce the constitutive degradation material model. The test and evaluation of the radial resistance bench was used to check the model of the material. For both the assessment of the depletion approach, in-vitro and in-vivo transplantation assessments have all been brought under the biochemical and standard requirements (Bukhanán, et al. 2012). The outcome illustrated that six months of depletion didn't affect intermolecular interactions and physical stability in either the stent while being in the molecular weight of the stents was injected. The degradation rate, critical places and modifications of stent diameter of the numerical model were also reported in vivo and in vitro research to be coherent. This implies that the degradation model could offer useful physical thoughts and the prediction of stent degradation and to some extent evaluate the in vivo effectiveness of the stent. In the end, this model could be used for the construction and optimisation of bioabsorbable stents (Fan et al. 2019b).

1.2.4 Vascular Stent

The institution had already successfully employed vascular stenting with its blessings due to moderate turbulence and convenient therapy (Chichareon et al., 2019). The mechanical activity of a myocardial infarction stent well into the human body characteristics both the therapeutic potential impact of threaded rod-formed matrix stenting at present and future times (Schrade et al., 2018). For further enhancement in stent design and efficient therapy (Xu, et al. 2016), analysis of mechanical characteristics of the stent is of tremendous interest.

During the heart beating the tube-shaped structure motion affects stent mechanical attributes like sleeplessness and fracture. Hence it is feasible to try to determine whether the momentum of either the artery changes stent pneumatic reliability during heart contractions unfavourably (Xu, et al., 2016).

1.2.5 Ureteral Stent

Ejaculation of common bile duct stent is a frequent urological procedure with tactics including such lithotripsy (URS), transdermatic nephrolithotomy, and ureter lithotripsy. External irrigation by ureteral stents could still start ureteral obstruction from stone fragments or oedemas and can help to rectify severe biochemical lasting harm and ureteral punchings (Chew & Lange, 2016). In patients with lateral or suprapubic pain, excessive urination and frequency, sinus inflammation, pericardial effusion, pulmonary embolism, sickness, and alternative triggers for suppression, hazards of beatific vision common bile duct children are commonplace. Many such ailments negatively impact the health and quality of life of patients at different levels (Li et al., 2017). Therefore, it is feasible to implant a stent persistently following gastrointestinal trigonometry ureteroscopy (Yang et al. 2019). The risk of operations and maintenance symptoms had already been diminished by scheduled pericardial effusion angiography despite the unpretentious ureteroscopy in patients. Likewise, the scheduled layout of stents had been recommended after uncomplicated, non-ureteroscopic lithotripsy, particularly in the incomplete fragmentation of the stones (Zhang et al., 2016). Innumerable uratic stents and diagnostic agents, including ureteral stents of weaker biomaterials, stents with various dimensions and forms and ureteral medicine-restrictive stents with multiple coverings, have been studied in order to reduce their ability to reduce ureteric stent-connecting symptoms (USS). In addition, in subsequent therapeutic attempts to limit USS in patients following ureteral stenting, nonsteroidal anti-inflammatory drug,

calcium channel antagonists, α -adrenoceptor blockers and anticholinergics have all been studied (Zhang et al. 2016).

1.2.6 Prostatic Stent

Cutaneous stents have been around since 1980 with modifications in composite materials in their appearance, gene expression and strategies, and perhaps even the degree of gastrointestinal stromal responsivity produced (Lee & Banka, 2016). This minimized complications, such as troubling local anesthesia removal, urethral injury, incrustation and migration (Sethi et al., 2017). The Memokath (Penn Medical) stent, made from a memory alloy of nickel and titanium, is the third generation non-epithelisable (inert) thermo-expandable (24 to 42 F) stent.

1.2.7 Esophageal Stent

The disease of the gastrointestinal tract is a devastating syndrome, classified sixth among all mortality disorders (Kang, 2019). Approximately 17 000 confirmed cases of esophageal cancer in the United States (Yank Cancer Sociedad) are admitted to the hospital annually, and about 16 000 deaths a year. In 2012, there were an estimated 456,000 fresh instances in the world and more than 500 in 2018 (Kang, 2019) in new instances. A self-expanding esophagus stent, the central primary care intervention of irritable bowel syndrome, is frequently used for irrigation and nutrition to open an occluded oesophagus (Kang, 2019). Just on the other side, the investigators have only been evaluated in pain management healthcare by applying a pharmaceutical composite film to specific recreational applications for an esophageal stent. This film boxes texture to facilitate expansion of a disease by supplying an antineoplastic medication. An effort of most of these vascular stents had been illustrated to consolidate blood vessel interventions which might subsequently be described as pathological gastrointestinal cancer (Kang, 2019) in disease-related stenosis (Kang, 2019). The most

typical type of GI atresia, occurring at 1 in 3 thousand to 5 thousand births, is oesophageal atresia (EA) with or without the tracheoesophageal fistula (TEF). The other most prevalent type of surgical excision could be a blind upper esophagus with a fistula between the lower esophagus and the trachea (Zhong et al., 2018). Even so, anastomotic intracranial conditions that also endoscopically regulate balloon dilators would render this complicated. A retrogressive abdominal ultrasound scan, which has a large multitude of problems, is an alternate solution methodology investigated in patients with chronic impositions. The predominant inconveniences of this system have included the possibility of hypopharyngeal malformation and abdominal illnesses in patients who require a mini-laparotomy and gastrostomy for the backward diagnosis of oesophagery. This may be the most prevalent hindrance of this framework. Endovascular furnishings (balloons and stents) have been used to change shape specialized gastrointestinal impositions that are not transversible.

1.3 Life after Stent Placement

Stents, small tubes that will open the artery, are often placed during or right after angioplasty, a procedure performed to permit blood to flow through narrow or blocked blood vessels (D'onofrio, 2019). The purpose is to keep the artery exposed over time with just a stent. Stents frequently have always been made from only a stainless steel breathable mesh, yet sometimes they can be created from fibers, that are the most prevalent in the medical care of substantial arterial walls (Kayssi and others, 2019). As with any procedure, patients receiving a stent can possibly wonder what to expect subsequently (Meng, et al., 2018)

1.3.1 Recovery and Return to Normal Activities

Patients who endure non-emergency treatment can probably stay in the hospital overnight to be monitored. Over the first few days when all the protocol comes to an end, they are eager to return to daily workout activities (G. * et al., 2016). Bruising or discoloration may occur at

the catheter insertion site, as well as soreness when pressure is applied, and patients can expect to feel more tired than usual for a few days. About a week after the procedure, the doctor might suggest the patient to return to more moderate activities and work. However, it is wise to avoid any activities that cause shortness of breath or chest pain (Vanags, et al., 2018). About three to four weeks after the procedure, it might be safe to resume strenuous physical activity and lifting heavy objects, patients must receive clearance from their doctor (Pierce et al., 2009). Mostly during recovery time older patients should first seek medical treatment, even if they are expected in excessive bleeding, inflammation and pain, discomfort at the catheter insertion site of the catheter, facial redness, inflammation in the body, poor drainage or fever, ambient temperature or color changes in arm or leg, faintness or perceived weakness, chest pain, shortness of breath, and more often. Patients may be encouraged to attend at least one follow-up appointment to make sure the catheter insertion site is healing properly (G.* et al., 2016). Depending on the stent used, patients may have to be monitored to ensure the stent is functioning properly and is in the right place. Airway stents may be checked through bronchoscopy many weeks after the procedure; a chest X-ray or CT scan might also be used. Angiography or ultrasound can be performed to check that stent graft is not leaking several weeks following placement, and possibly for the long-run. If leaking or another issue happens, the stent may need to be continuously monitored, and if the leak is severe, surgical intervention might also be necessary (Iantorno, 2019).

1.4 Mechanism of stent implementation in body

Perhaps an investigator adequately instructed in each of these laparoscopic procedures should always be able to execute angioplastic as well as stenting. Perhaps the patient will be mostly immediately placed on the minimally invasive surgical table. Terminally ill patients must be very hyperlinked to control systems that monitor the pulmonary rate, heart rate, oxygen and heartbeat frequencies. In a vein of just the side or arm of a caring or research scientist, an

intramuscular (IV) line is embedded into your pain killer (Larrabide et al. 2012). A catheter is not recommended. Nevertheless, procedural sedation might have been expected in some patients. The intervention should also be placed in the position of the body of which the catheter must have been fastened. The cardiologist then dodges the area with a conscious sedation. Before the region grows numb, it can sometimes briefly burn or sting. There is a very small cut on the site. First, in the blood vessel, a sheath is placed (Bowen et al., 2016). The health care provider whereupon inserts the tube through the skin to live x-rays and directs them through the blood vessels until either the obstruction is approached. The complementary medium will still be poured into the artery to perform an angiogram once the stent is in shape (Kubota et al., 2016). Ultrasound scan has always been a x-ray photograph of the vessels in the blood. It would also expedite the proof of identity of the specific place of the blockage. The doctor navigates the narrowing and perhaps blocking with a trying to guide wire with x-ray under steer. It already signifies the catheter with a balloon is able to omit the wire. The ball will be inflated for a short time once through the blockage. The balloon generally needs to be more than once inflated. During the same procedure, other blood vessels should be treated. There are a lot of x-rays to check how much blood flow improves. The catheter, cord and sheath of the balloon will be removed (Arenillas, 2011). Stents have to be inside the blood vessel many times to help keep it open. Several stents can be managed to open by themselves. Others have to open a balloon. Typically, balloons are expanded across the wall of the blood vessel. The stent remains when the balloon is deflated and removed. The continuous stent acts as an artery scaffold. Approved for use by the USA for drug-coated stents Administration of Food and Drugs (FDA). The medicine is released slowly to help to keep the blood vessel from clamping. This is a disease known as restenosis. For patients with PAD or dialysis fistula, drug-coated balloons may also be used. The drug enters the wall of the ball when it is inflated (Kubota et al., 2016). Even when the balloon was removed, he remains

there for some time. After completing the procedure, the catheter is removed and the pressure is put on to prevent trauma. Sometimes a closing device can be used to screen the small hole in the artery (Larrabide et al., 2012). It already allows the patient to move a lot fast. There are no stitches on the skin. A dressing is covered with a small opening in the skin. Whereupon, for plenty of hours, the person can have to lie straight in bed with his legs. The patient may be subject to activity restrictions once an arm or wrist is in use for access. The patient is transferred to a rehabilitation room or to a room after the procedure is over. Before you get back, your IV line will be removed (Puranik et al., 2013). This is usually done on a patient basis. However, following the procedure, certain patients may need admission.

1.5 In-Stent Restenosis

Immediate mechanical health issues such as unexpected freighter shutdown, myocardial infarction deconstruction and a high rate of restenosis up to 40.0-5% of cases were present in conventional transcutaneous luminous coronary angioplasty sickness (PTCA).

Pulmonary embolism stents were simultaneously even had to strengthen sustained success, whereas hematopoietic stem cell and medically important restenosis have all been reduced significantly after the coronary surgery. Thus, almost 70 percent of coronary interventions will be carried out by 2025 and will involve the transplantation of a bare metal stent (BMS).

None the less, the prevalence of restosis among the imbedded BMS (unexpected restenosis (ISR) manages to be which is around two billionth in approximately with rates broader than four billionth in the bound, high-risk medication categories, notwithstanding advances in the engineering and delivery system and in procedural technique and pharmacological therapy (Brancati et al., 2017).

The incidence of ISR is additionally related to the arrival of medication-eluting stents (DES), although the decrease determined absolutely depends heavily on the angiographical and clinical characters in use (Lee & Banka, 2016).

1.6 Stent design for atherosclerosis

About 280,000 heart valve surgical procedures are launched internationally each year and, with something like a range of healthcare professionals permitting replacement of heart valves predicted to triple through 2050 (Guerra et al. 2018). Indeed, the lack of restoration and growth efficiency necessitates rolling military action in younger patients, because although they surmount partial denture. In terms of consolidation throughput, recent improvements in membrane-engineered highly vascularized valves (DTEHV) are encouraging (Guerra, et al., 2018). More such valves were transplanted in sheep minimally, illustrating rapid host cell colonization and epithelial production, which seem to be emblematic of potential for growth. Catheter technologies are crucial to permit prosthetic limb delivery and even provide instant approval after combat operations for just a noninvasive heart valve implantation.

Furthermore, the stent is feasible only until the ascending aorta is fully integrated into the host membrane. In conjunction, it is important that the stent accommodates growth as an alternative to pediatric patients. The metal stents currently being used that permanently reside inside the body do not have growth capacity and cause long-term complexities, such as hyperplasia. Bio absorbed polyethylene are such an expensive choice which have been widely explored for their applicability in-stent devices. That they now alone could cause the formation of thrombus and dramatically reduce external interference with methods and techniques that are minimally invasive, including functional magnetic resonance imaging (Guerra et al. 2018).

Synthetic polymer stents must meet criteria such as adequate medical radial power (RF) for current minimum invasive species heart valve new applications, maintain a good the position after combat deployment and limiting plastic deformation in order to ensure the initial operation of the valve until integration of most of the host body. We aim at providing a computer-based, self-expandable prototype polymer stent with biodetermination potential in this evidence-of-concept study (Boyer et al., 2019). With our whole ultimate objective is to achieve the same mechanical and implantation strengths as a stent in sintered metal currently used in sheep preclinical DTEHV transplantation. A finite component (FE) software development model of a sintered metal tube was used as a regard for assembling a polymer stent with such regulations. Amalgamate deposition modeling (DMM) technology was combined with a commercially available versatile co-polyester elastomer (TPC) (Guerra, et al., 2018), to convert computational simulations on physical polymer prototypes. Depolyesters are an interesting category of edible fibers because they are prone to hydrolysis by organismic compound bonds (Boyer et al. 2019). A compressive strength experiment was administered and indeed the TPC was instantaneously used as an input for the genetic algorithm. 3D printed stents were obtained and subjected to crush and crushing tests for mechanical validation based on this computer-generated design. Finally, the TPC's biodegradability via hydrolysis was assessed by accelerated in vitro Polymer Stent Degradation Test (Guerra, et al., 2018). Time breakdown was determined by mechanical tensile tests, differential calorimetry scanning (DSCs), GPCs and SEMs (Guerra et al. 2018) (EMS) scanning (Guerra, et al. 2018)

1.7 Objectives of the study

- To increase the use of stent for the treatment of atherosclerosis. Avoiding bypass surgery and establishing easy treatment for atherosclerosis.
- To be aware of stent restenosis. By designing drug eluting stent can avoid stent restenosis.
- Preparing market size cardiovascular stents. Increasing the availability of market size stent availability and ensuring the cost effectiveness.
- Designing more preferable design by using 3D software. Changing the shape of the stent on the basis of the plaque developed.

Chapter 2

Methodology

Designing of stent can be done through various number of software. For example, Rhinoceros, Auto CAD, Autodesk Maya, sketch up etc.

2.1.1 Rhinoceros

Behind this study 3D models were designed denigrating a standard III jawbone section consisting of an implant of a corresponding entity in the middle and walled by one mm of cortical bone in the geographical area, corresponding to the maxillary molar. Vesalius software was acquired to replicate the cross-molar computational tomography area, enabling the production of sectional cross-sectional virtual 3D models. Trabecular and cortical Bone Geometry in order to simplify geometry and improve the layout, the image has been subsequently exported to Rhinoceros Software 4.0. Perhaps the study was conducted on either the axial load of 200 N, that has been implemented to that of the surface. The load has always been divided into 4 statements by force more for each area of around 0.17mm² (Gorjanc & Jurkin, 2015). The results were subsequently fully reimported into the FEMAP 10,0 stress map and post processing software of von Mises (Gorjanc & Jurkin 2015). The results have been re-imported.

2.1.2 AutoCAD

The design of the department of machinery and equipment is based on the main company drawing software. The AutoCAD software is the most commonly used drawing software. It not only offers users with a user-friendly interface, strong analytical skills and strong pre-and post-processing features, it's easy to know and guarantees the user's graphic designing job. In the present, a significant indicator of a country's design level is the sophisticated industrialized productivity(Ziden, et al., 2012).

In order to customize, specialize in, and integrate the manufacturing industry, the advancement of CAD technology toward smart information technology is inevitable. The open architecture of AutoCAD enables users and developers to expand and alter sophisticated programming language is secondary growth (Ziden, et al., 2012). VBA (Visual Basic for Application) The end-user programming application language of Microsoft is one of the development instruments for sharing memory with AutoCAD space and quicker developing the system program.

The software VBA has a powerful interactive capability, Windows resources are simple to manipulate, and information management skills can be easily shared. ActiveX technology, ADO link technology in a database, and ActiveX Automation technology offering fully-objective programming benefits, ensuring a high degree of flexible selection of language in production, with the VBA programming activities and AutoCAD control in order to perform drawing function. ADO (ActiveX Data Objects) is a data object of ActiveX and a set of Microsoft COMs supplied (Ziden, et al., 2012).

The automated, object-oriented, programming interface that allows implementations to access and modify a range of easy, complicated and unskilled information sources and is a connection between AutoCAD and Access databases (Ziden, et al., 2012).

2.1.3 Autodesk Maya

A fresh approach to computer animation using the software is currently being developed (Kushwaha, 2015). It is implemented as a text for graduates and postgraduates at the professional level. It is also helpful for those who want to become programmers or experts in computer graphics. It is new methods, where everyone can produce games, education or entertainment animations (Kushwaha, 2015).

It discusses the problem of computer-based animation, which focuses on several 2-dimensional levels. This study focuses on the complete 3D computer animation by using the

recent animation software from Autodesk Maya to identify useable methods and techniques for interesting gestures. Many filmmakers are currently using it to create cartoon characters to characterize their display(Kushwaha, 2015). A lot of software is accessible on the market, which can use computer graphics to produce such animations and effects(Kushwaha, 2015).

2.1.4 SketchUp Software

The study had already been specifically designed to assess the economic impact of Google Sketch-Up, the 3D manufacturing engineer operating systems, on both the fundamental skill sets of sided argument solid cognitive health care writings. A research sample was made up of 72 educators in 2009-2010 who studied the basic mathematical education at a State university in central Anatolia in Turkey. Traditional learning tools such as paper, pencil and class writing panels were used for the work (Kurtuluş & Uygan, 2010). Storage capability had already been gauged with that of the Georgia tech Quantitative reasoning Test and Santa Barbara Solid Test. It consists of three components: the "improved performance" evaluating the ability to visualize a 3D artifact by its surface advancement; and "rotations," measuring the capacity to pull 3D articles mentally (Kurtuluş & Uygan, 2010).

2.2 Software Used for this Study

In this study, sketch up is used to design 3D printed Rhinoceros 6.0, Auto CAD.

2.2.1 Image Acquisition

3D rotational angiography (3DRA) images taken using an AXIOM Artis (Siemens Medical Solutions; N= 17) are the foundation for anatomical pre-treatment models of the vasculature. Voxel sizes of 3DRA images ranged from $0.208 \times 0.208 \times 0.208$ mm to $0.378 \times 0.378 \times 0.378$ mm. 2D post sequences were used to locate the anatomy's proximal and distal ends of the stent and to evaluate its length after implantation. The angiographic sequence was 0,200 €

to 0,200 mm in 2D spatial resolution. During the same intervention, both 3D and 2D pictures were obtained.

2.2.2 3D Anatomical Model

Images have been segmented using a segmentation technique based on a threshold. In each case, a neurovascular angiography expert chose the threshold value to best fit the anatomy of the patient according to the amount of contrast seen and picture quality. The first priority for rebuilding is regarded when the threshold value is chosen, both the treated vessel and aneurysm. The second priority is given to smaller and branching ships. Four of the 13 instances (31 per cent), owing to low contrast dilution or bad picture quality, needed extra mesh editing and post processing.

Triangular mesh (triangular mesh) is used to remove three-way buttons, close hole and smooth the mesh to take away objects produced from low contrast density or the existence of bowls. This method involves separating brackets from the mesh. This procedure is identical to the one used for anatomical systems for the analysis of linear fluid dynamics⁴. Then professional interventional neuro-radiologists validated the 3D model visually. The centerline for the treated branch is calculated and the descriptors of vascular morphology along the vessel are calculated (Oliveira et al., 2019).

Stent Length Measurements 2D-angiographic sequences measure the length of the implanted stent within the patient. For a generation of a centerline, the 3D model extracted from 3DRA illustrations is acquired. In the same way as pictures were obtained, the 3D model was manually matched (recorded). The 2D sequence comparison stage has been used to determine the anatomic position and direction for an accurate line between the 3D model and the 2D picture sequence after treatment (Kurtuluş & Uygan, 2010).

Finally, the unit has been recognized on the 2D picture and placed in the centerline with distal and proximal indicators (Zhang et al., 2016). The length of the apparatus as the space between the distal and proximal ends was measured along the centerline (Barbarawi et al., 2019). When biplane purchases were accessible, the perspective was selected where the endpoints were clearer (Kandaswamy, et al., 2018).

2.2.3 Simulation of Stent Length

Using the braided device foreshortening (BDF) algorithm, braided stent length is simulated. This technique needs a vessel's 3D model from which to calculate the center line and characterize the vessel's local morphology (Pal, et al., 2019). The computational models used to simulate each machine are based on the number of stent cables and the length of two distinct diameters accessible from the requirements of the device maker. This data was used after a unique operation to parameter the simulation (Xu, et al., 2016).

Local morphology is connected with the cross-section of the vessel (perpendicular to its centerline) and is characterized by the diameter of the peak sphere, vessel perimeter, and cross-sectional range (Jafary et al., 2018). ANKYRAS acquired the centerline of these 3D meshes and the local morphology descriptors along the centerline.¹⁹ The centerline was split into sufficiently tiny sections to allow local morphology descriptors to be deemed constant along each section (Kumar, et al., 2019).

The distal end position of the simulated stent was matched to the position observed on the angiographic 2D sequences and by running the BDF algorithm the proximal one was obtained (Huang, 2018). The BDF algorithm is described in detail by Fernandez et al.⁵ The distance between the distal end and the proximal end of the braided stent along the centerline is the final length of the braided stent. The BDF algorithm is integrated in ANKYRAS

software, which enables a single software package to perform the complete image processing and morphology quantification workflow (Iantorno, 2019).

2.3 Instruments

Used to finish this project have been HP laptops, software design, converters, calculators, Microsoft word file, Mendeley. Mendeley is an academic social network and study workflow tool that helps organize files and references. By entering and working together in organizations, Mendeley helps work with fellow scientists online. Mendeley can provide statistics and suggestions on readership to assist remain up-to-date and learn more. It can also assist to store information sets safely so that they can be quoted and communicated.

2.4 Steps for designing stent

First of all, to take a perspective view of rhinoceros 6.0 software by double-clicking. Then press options from there to select the unit for the calculations. Furthermore, by selecting ellipse radius can be fixed. Then offset the structure and offer room about around 2mm - 10 mm (the quantity or distance by which something is out of touch). After that, extrude and take a curve and cylindrical shape and Boolean difference has to be made on them. Boolean difference is fundamentally the same operation as Boolean Union, Difference, and Intersection (Pant, et al., 2012). At the end, there are just different parts of the objects. For example, with Boolean Union, the overlapping parts are thrown away and the rest are united. After taking the shape of a cylinder, some measurements such as length, radius, and rotation angle, direction of axis, distance and width must be placed (Jaya, et al., 2016; Yin, et al., 2014). Press the array curve and pick the "gumble" or shit shoot to get the correct shape after receiving a required shape stent. To get a strong perspective, press "strong" and rotate the used "rotate camera" framework and add requirements to the design by using the drafting (Meng, et al., 2018).

Chapter 3

Results

Table 1: Stent specifications

Stent models	Specifications
Stent model 1	Closed ground polysurface, 483 surfaces, seam edge 2, total edge 1446, median = 0 average = 5.4, p value of less than 0.000001, cylinder area 613.5153 millimeter square, 191.134 mm square ball surface area.
Stent model 2	Closed polysurface, 644 surface areas, Seam edge 18, Total edge 1974, Median = 0 medium = 1.3, P value below zero, Cylindrical area 633,73 mm square, Ball area 203,077 mm square.
Stent model 3	Open area, 3.13 mm diameter, 18.75 mm long, corner 15,0 mm, cylindrical area 430,300 mm sq.
Stent model 4	Linear dimensions (rotated), Height 10.78 , Radius 3.86, Cylindrical surface area 35.88 millimeter square
Stent model 5	Valid mesh closed, Polygons 33554, bounding box 0.0025 to 67.43 millimeter, height 31.76 millimeter, radius 6.14 millimeter, cylinder surface 7570.78 millimeter square.
Stent model 6	Closed surface, polygons 48226 ; index = 1 ; height 31.91mm ; radius 4.36mm ; surface area of Cone 508.86 ; millimeter sq.
Stent model 7	Closed valid polysurface surface, Surfaces 238, Edge 630, Median 6.1199 Average 1.20, Polygons 7854, Height 26.06mm , Radius 3.9mm , Cylindrical surface area 734.152 millimeter square

In Table 1 the first stent model represents the closed poly-surface, it has 483 surfaces, seam edge a layer in a mineral or metal ground is 2, total edge 1446, median= 0 average= 6.4, p less than 0.000001, cylindrical surface area 613.5153 mm square, ball surface area 191.134 mm square. The second stent model Closed polysurface, 644 surfaces, Seam edge is 18, Total edge 1974, Median 0 average 1.3, P value less than 0, Cylindrical area 633.73 mm square, Ball area 203.077 mm square. The third stent model defines the surface area of Open surface stent diameter is 3.13 mm, length 18.75 mm, angle 15.0, cylindrical surface 430.300 mm square. The fourth stent model depicts (rotated) linear dimensions, 10.78mm height, 3.86mm radiuses, and 35.88 millimeter square cylindrical surface. The fifth stent model represents Valid mesh closed, Polygons 33554, Bounding box 0.0025 to 67.43 mm, Height 31.76 millimeter, Radius 6.14millimeter, Cylindrical surface area 7570.78 mm square, Conical frust surface area 8758.75 mm square. The sixth model is Closed surface, Polygons 48226, Index= 1, Height 31.91mm, Radius 4.36mm, Cone surface area 508.86, millimeter square, Cylindrical surface area 993.60 millimeter square. The seventh model has closed valid polysurface, surfaces 238, edge 630, median 6.1199, average 1.20, polygons 7854, height 26.06mm, radius 3.9mm, and cylindrical surface 734.152 millimeter square.

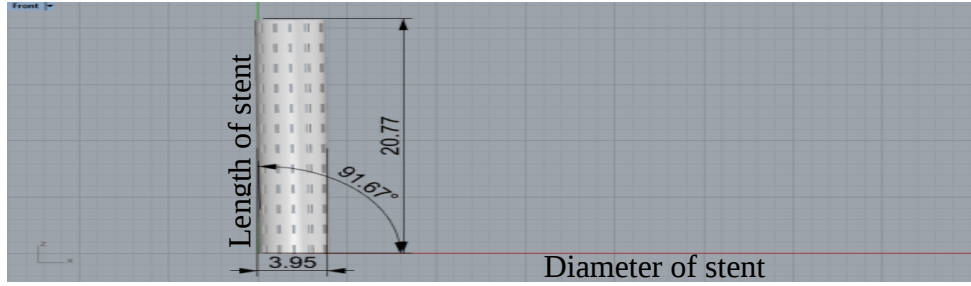


Figure 1: Stent model 1

In Figure 1 the height of the stent is around 20.77mm which indicates the ideal height of a stent. Here the diameter is around 3.95mm. This information indicates that the stent can provide satisfactory action because the ideal range for height is around 12-57 mm (Medtronic.com, 2019). Moreover, the diameter is also representing the patient friendly diameter because it is within the range like (5-10mm) (Medtronic.com, 2019). In X axis it shows diameter and in y axis it shows

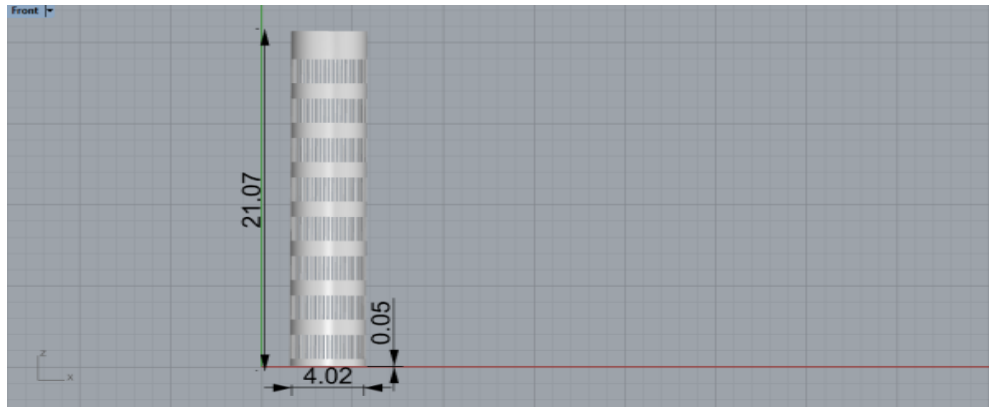


Figure 2: Stent model 2

In Figure 2 the height of the stent is around 21.07 mm which indicates the ideal height of a stent. Here the diameter is around 4.02 mm. This information indicates that the stent can provide satisfactory action because the ideal range for height is within 12-57 mm (Medtronic.com, 2019). Moreover, the diameter is also representing the patient friendly diameter because it is within the range like (5-10mm) (Medtronic.com, 2019). In X axis it shows diameter and in y axis it shows

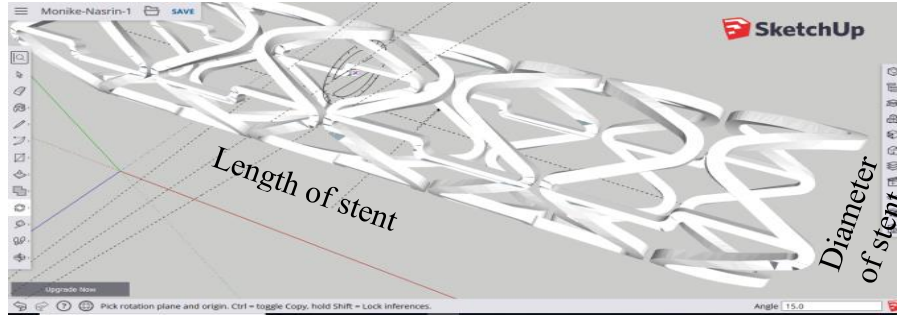


Figure3: Stent model 3

In Figure 3 the height of the stent is around 18.75 mm which indicates the ideal height of a stent. Here the diameter is around 3.13 mm. This information indicates that the stent can provide satisfactory action because the ideal range for height is within 12-57 mm (Medtronic.com, 2019). Moreover, the diameter is also representing the patient friendly diameter because it is within the range like (5-10mm) (Medtronic.com, 2019).

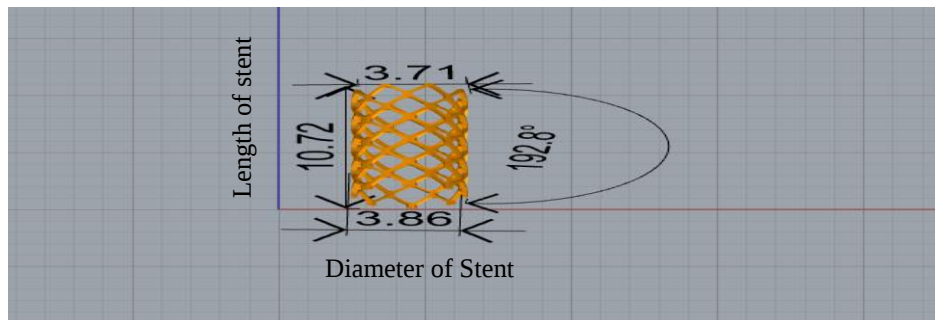


Figure 3: Stent model 4

In Figure 4 the height of the stent is around 10.72 mm which indicates the ideal height of a stent. Here the diameter is around 3.86 mm. This information indicates that the stent can provide satisfactory action because the ideal range for height is within 12-57 mm (Medtronic.com, 2019). Moreover, the diameter is also representing the patient friendly diameter because it is within the range like (5-10mm) (Medtronic.com, 2019). In X axis it shows diameter and in y axis it shows

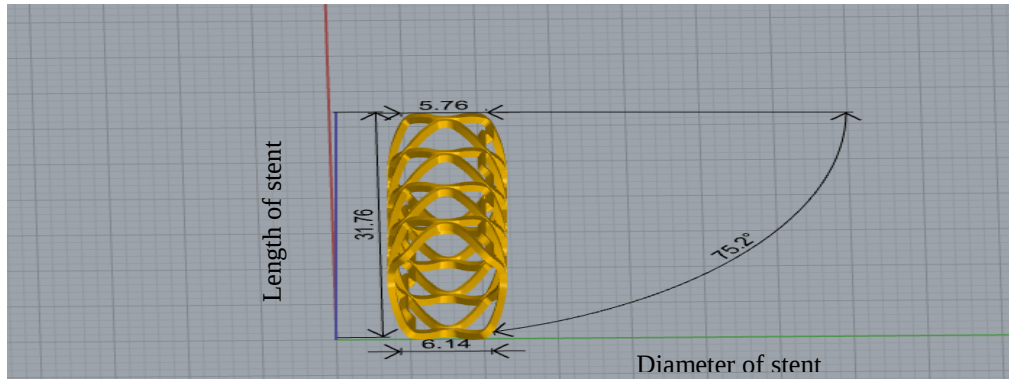


Figure 4 : Stent model 5

In Figure 5 the height of the stent is around 31.76 mm which indicates the ideal height of a stent. Here the diameter is around 6.14 mm. This information indicates that the stent is falling under the ideal range for height is within 12-57 mm (Medtronic.com, 2019). Moreover, the diameter is also representing it is within the range like (5-10mm) (Medtronic.com, 2019). In X axis it shows diameter and in y axis it shows height.

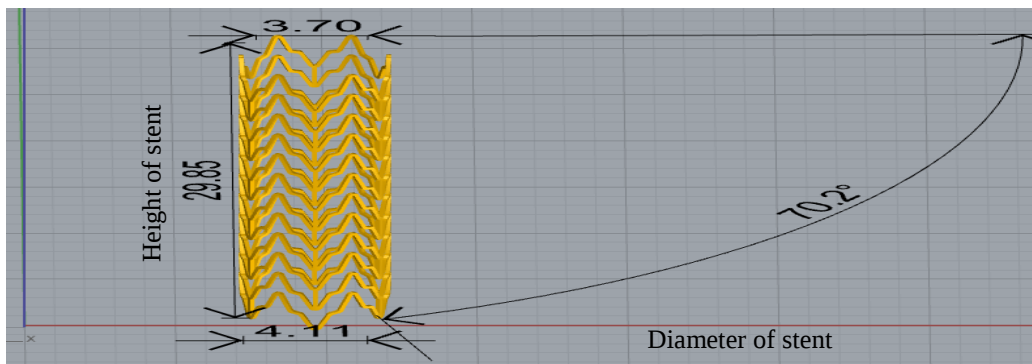


Figure 6: Stent model 6

In Figure 6 the height of the stent is around 29.85 mm which indicates the ideal height of a stent. Here the diameter is around 4.11 mm. This information indicates that the stent can provide satisfactory action because the ideal range for height is within 12-57 mm (Medtronic.com, 2019). Moreover, the diameter is also representing the patient friendly diameter because it is within the range like (5-10mm) (Medtronic.com, 2019). In X axis it shows diameter and in y axis it shows height.

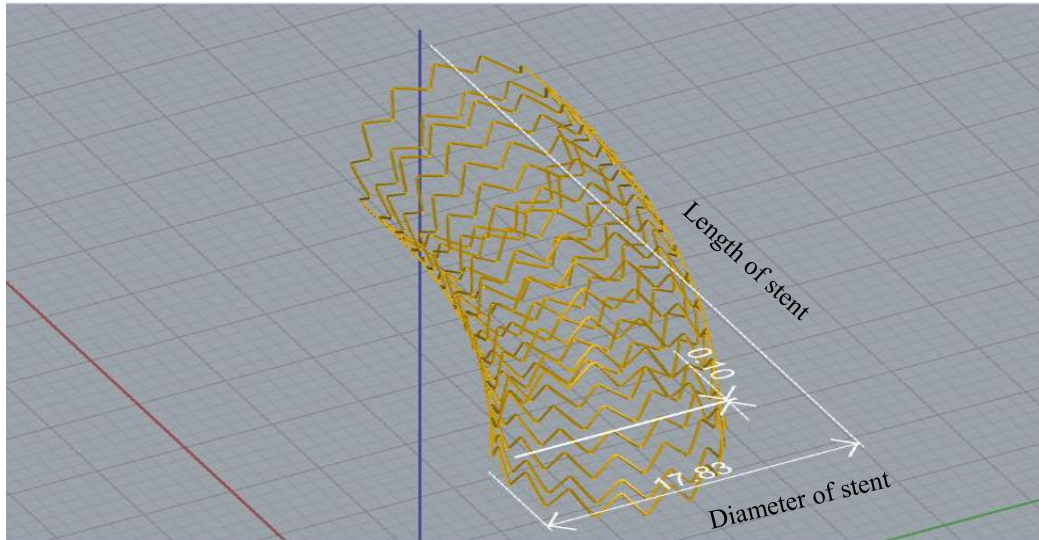


Figure 7: Stent model 7

In Figure 6 the height of the stent is around 17.83 mm which indicates the ideal height of a stent. Here the diameter is around 4.11 mm. This information indicates that the stent can provide satisfactory action because the ideal range for height is within 12-57 mm (Medtronic.com, 2019). Moreover, the diameter is also representing the patient friendly diameter because it is within the range like (5-10mm) (Medtronic.com, 2019). In X axis it shows diameter and in y axis it shows height.

Chapter 4

Discussion

4.1 The Effect of System Parameters on the Quality of Stent Formation:

Various considerations influence the quality of stent formation, including the geometry of the pin, nozzle thickness, rate of the shaft and amount of the connector. In cellular biology the quality of vascular stents is expressed primarily. Mechanical characteristics include primarily support radial and support flexibility. The mechanical characteristics of 3D scaffolds of biodegradable vascular scaffolds are modified by distinct parameter configurations. The impacts of system parameters on the stent quality were researched and the 3D printing of biodegradable stent has been based on experiments.

The combination of mathematical models and 3D printing software has been examined in this proof-of-concept research, which has been designed to produce large, diameter bioabsorbable, minimally invasive polymer stents that permit human development. The absence of mechanical characteristics is the weak point of large diameter bioabsorbable polymer stent development. Conventional bioabsorbable plastics, such as PLA, involve advanced fabric treatment, so that the RF 12 (radio frequency) is sufficiently high and only smaller diameters can be used. Other large stents handle issues of stent migration owing to small RFs.

This study will demonstrate that easy-prototyped polymer stents can also obtain RF concentrations comparable to those of nitinol. The printing technology of FDM (Fused Deposition Modeling) is an emerging and successful handling method. It can be used in a variety of heat products where, thanks to their particular handling method, other fast prototype techniques such as photo sintering or stereolithography give smaller choices. One disadvantage of this procedure is that the structured aspect of handling technology is less

precise and could lead to less mechanical power than the bulk material in areas. Furthermore, for the original stage of bioassimilable construction, 3D printing has been regarded as an acceptable prototype method, allowing a good balance among product characteristics and the possibility of developing models that can be further tested.

4.2 Stent design and host tissue:

Even though polymers have to be Impressionable. Geometric compensation is needed for thickness and length of strut that may result in stenosis. Further modifications of prototype length and density must be made in the case of pediatric apps where a stent is needed to adjust to the patient's volume and power demands. This method provides a useful solution to reducing RF while keeping the steady oversizing rate and enhancing the decomposition of power during stent operation. It is also possible to decrease the length of the operating table. A further advantage of a reduced RF is to use less power after crimping when pushing the stent out of the supply unit during implantation, which enables greater control of the valve placement. For DTEHV (Decellularized Tissue-Technologied Cardiac Valves), nitinol stent used as a baseline for the construction of the polymer stent was effectively used in human ovine pulmonary arteries of 24-26 mm. The respective RF is 15–17 N in this spectrum of diameters. The polymer stent would be adapted to implant diameters of 22.4-24.43 mm, to be oversized in the same degree as the nitinol stent. For this diameter range, the experimental force of the polymer stents will show 13.5–18.9 N, being comparable to the nitinol alternative.

4.3 Material properties

A freely accessible TPC must be used for manufacturing 3D painted stents in this proof-of-concept research. In addition to the correct mechanical features and degrading capacities, the biocompatibility and degradation of copolyester products have to be given unique

consideration. The polyester used in the business sectors, for its biocompatibility mostly, are of great mechanical resistance, however, are hydrolytic more susceptible to degradation. The polyester is a poly (butylene terephthalate) or poly (Ethylene terephthalate). Aliphatic biocompatible polyesters such as PLA and polyesters such as caprolactone have excellent hydrolytic biodegradability, but have a poor mechanical resistance. Aromatic and aliphatic layers tend to be possible and may be able to adjust mechanical and degrading characteristics. The TPC selection has been focused on his mechanical characteristics and his possibility for hydrolytic degradation for this proof-of-concept research. However, will not biocompatible, which means that translation studies are not subject to consideration. Decomposition based on different aspects such as the chemistry of the monomer, relative humidity, heat, and bioactivity for the current enzymes depends on how quickly polyesters hydrolyze takes place in vitro.

Oxidative and enzyme degradation also leads to in vitro degradation of polymers, in addition to hydrolytic degradation. Furthermore, it is necessary to further investigate to what magnitude these tracks affect the complete velocity of degradation. The TPC has chosen for this proof-of-concept trial prove hydrolytic that can be an exciting way of adapting the stent to the patient's development, in conjunction with 3D FDM printing. A visible layered structure is a philosophy as a consequence of the use of FDM, which involves the heating of a material to create small cut strings which allow molten layers to deposit. This complex picture can cause default marks over time. These disruptions in conjunction with the material's growing fragility could interrupt the stent model of the physiological cyclic charge, resulting in an open framework that does not hinder the development of the artery. Due to the past knowledge of in vitro, after 8 to 16 weeks of implantation the stent and the heart valve are completely dissolved into the existing membrane. Once integrated into the stent by the tissue of the victim, bloodstream blood suppressed pieces of stent that can occur during the

degradation cycle. The degradation of polymer components by cellular means can lead to the suppression of polymer particles after tissue encapsulation. Macrophages could either phagocytize the residue or construct giant cells in order to observe the residue.

Granulocytes like mast cells, eosinophils and basophils can instead secrete cytokines, chemokines and cell metalloproteinase to increase the degradation of polymers. Quality of the 3D printing method some limits are imposed by the small precision of the technique that can eventually influence stent efficiency. For the breadth of this research, stent results are determined as its capacity to perform DTEHV effectively for preclinical assessment in a minimally invasive way. That implies the stent must be in a position. The mixture of the chosen fabric and 3D printing techniques reduces the ability to make exact adjustments in density. Furthermore, the reduction of below 21 mm struts creates disturbed models of struts when the specimen is displayed. These obstacles restrict the ability to change the prototype's capabilities and RF. The 3D painted model varies from the theoretical model once the best layout is achieved. Combining the selected material with the 3D printing method, the prototyped strains will have a relatively low resolution that deviate from the straight theoretical or computational straight shape, defining in practice a more curved and uniform profile.

Furthermore, the molten material and the 3D printing nozzle can be transported to the next strut after deposition of one layer, creating thin cables that link up the struts. The manufacturing process imperfections have a negligible impact on the sticking power of the stent and a significantly higher impact in crimping stage on stent RF. This difference is due to the slender cables which join the struts, a physical barrier that provides some strength to crushing. For crimping diameters larger than 20 mm. However, the crimping power does not identify the stent efficiency that is defined by the RF during self-expansion. Theoretical and test self-extension RF does not indicate any distinctions for diameters similar to the

implantation location. While these discrepancies do not lead to important improvements in stent efficiency, they bring characteristics of poor quality that should never be available in other experimental variants... In the case of this study, the stents designed for atherosclerosis are preferable as they are between 17 mm and 31 mm long. After their execution, they provide adequate outcomes. Additionally, the fourth layout shows a greater effectiveness based on the studies if the stent carries fewer readings of height or duration that will provide more effective exercise. The stent length is 10.72 mm and will rotate at 192.8 degrees in order to contain less medicine in it and to demonstrate efficacy within a brief span. From this viewpoint, all the designs can be produced good results as they show under the range. In addition to the initial design, is preferable for the coronary artery stent implementation the implementation of the stent in for atherosclerosis treatment is easier. The less restenosis the stent size and diameter will show because of Stent Implementation.

Chapter 5

Conclusion

The new generation of low-profile, self-expanding, braided stents are available now a days. Many software-based tools are developed to combat this downside and to facilitate decision-making and treatment planning for clinicians. These tools provide correct, clinically targeted results with a high standard of usability and automation at low operating prices. Code simulation will allow for almost patient-specific vascular geometry deployment of endovascular devices. It allows safe and pre-treatment comparison of different devices to improve the choice of the device.

Chapter 6

The Future Direction of Stent

A stent is a tiny, metal mesh tube that is implanted in an artery wall during an angioplasty procedure. Stents were developed to solve a problem sometimes encountered with angioplasty: the artery would collapse after a blockage had been cleared. The stent is a medical device which acts as an injection for the opening up of the artery. Stents are currently in two classes: bare metal or drug eluting. Bare metal stents are the original stents and newer generation ones are still used today. Drug-eluting stents were designed to prevent a problem sometimes encountered with bare metal stents: restenosis –growth of scar tissue within the stent. While generations of stents now available in the United States are permanent medical devices that become embedded within the artery wall that may one day change. A bioabsorbable stent – one that is able to be absorbed by the body -- was recently approved for use in Europe. Bioabsorbable stents allow time for the artery wall to heal before being metabolized by the body and “disappearing.” These stents, in addition to other possible benefits, hold out the promise of making long-term medical therapy (medication) to prevent blood clots (thrombosis) from forming in the stent unnecessary. Bioabsorbable stents are still being studied and are not yet available in the United States. So in near future it will be available in worldwide including our country Bangladesh. By doing some clinical trial in future better performed stent can be developed.

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