

DESIGNING A STAND FOR TESTING EQUIPMENT USED IN CARDIOVASCULAR THERAPY

Abstract: In recent years, the main cause of death globally for all ages are cardiovascular diseases. Common heart conditions that appear are coronary artery disease and atherosclerosis, characterized by the buildup of cholesterol deposits, also known as plaques, in the heart arteries or in the inner lining of a blood vessel or an artery. This plaque is mostly made of cholesterol, calcium, cellular waste products or fibrin. The problem that appears in this case is that the blood flow is reduced, or stopped completely in the vessel when the disease is at a later stage, thus reducing or stopping the oxygen and nutrients supplies from reaching the vital parts of the organism. A heart attack will appear when there is a complete blockage in the heart arteries. There are two main types of treatments: angioplasty and atherectomy that are done when medication is no longer an option. The main goal of atherectomy is the removal of the plaque by differential cutting. We also must take into consideration the cost that affects each patient and try to reduce it by updating or creating new designs for specialized devices.

Key words: design, atherectomy, angioplasty, coronary artery disease, medical, Inventor Autodesks.

1. INTRODUCTION

Cardiovascular disease is affecting approximately 17.9 million people each year. In the European region, they affect the lives of 60 million people and cause up to 39% of all deaths in men and up to 45% in women [1].

Atherosclerosis belongs to the category of chronic arterial diseases and is a major cause of death and morbidity worldwide. Its major clinical manifestations include peripheral arterial disease (PAD), ischemic heart disease (IHD), and ischemic stroke. In 2010, the highest mortality rates for IHD were reported in Eastern Europe with 434 per 100,000 people in men and 235 per 100,000 people in women [2][3].

Acute myocardial infarctions are due to the rupture of the atheromatous plaque and have a high incidence in men over 45 and women over 50 [4].

In the study "Healthcare costs associated with cardiovascular events in patients with hyperlipidemia or prior cardiovascular events: estimates from Swedish population-based register data", the cost of care for patients who had a cardiovascular event increased over the three years of the study, the average cost being 8,588€ [5].

A better understanding of costs for patients with atherosclerotic cardiovascular disease (ASCVD) is represented in the following image (Figure 1):

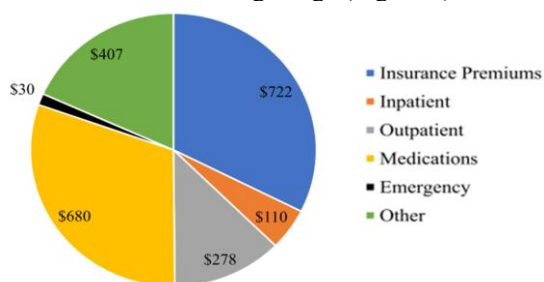


Figure 1 Mean Annual OOP Expenditures Per Capita Among Individuals with ASCVD [6].

In this paper, we aim to design a stand for testing the equipment used in cardiovascular therapy, which will be connected inside a console specific for atherectomy. A combination of angioplasty and atherectomy is carried out and of course a gearbox model design with the aim of increasing the engine revolutions, in the case of rotational atherectomy for equipment testing and cost reduction.

2. ANALYSIS FROM A MEDICAL POINT OF VIEW

The circulatory system is known as the cardiovascular system because it involves the circulation of blood from the heart through the blood vessels. The blood carries carbon dioxide using the network of arteries, capillaries and veins to the lungs to remove it (by exhaling) and to pick up oxygen (by inhaling). Nutrients from the food eaten are taken up from the small intestine and transported to the cellular tissues [7].

2.1 Atherosclerosis

Atherosclerosis or, also known as Arteriosclerosis, is characterized by the accumulation of cholesterol, calcium, fats and other biological materials in the so-called atheromatous plaque or atheroma plaque in the blood vessels. The interior of the arterial walls is targeted as an area of interest. Atherosclerosis is primarily known as a heart disease, but it can affect any artery in the human body by blocking or slowing down the flow of oxygen- and nutrient-laden blood. This process takes place over a very long period of time, with visible symptoms appearing when the orifice is more than 70% blocked or when, the plaque ruptures and the thrombus moves to an area of the same diameter. The result is a blockage of the arterial vessel [8]. A representation of atherosclerosis can be seen in Figure 2.

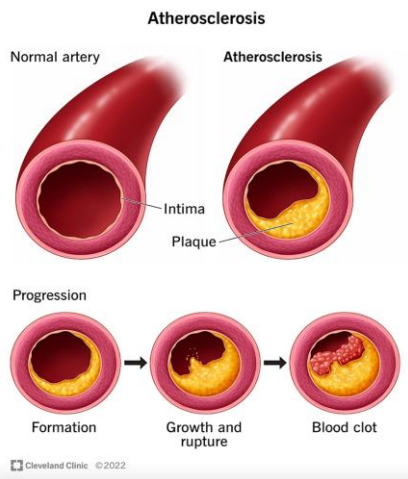


Figure 2 Atherosclerosis [9].

When drug treatment does not work, or when the situation is more serious, doctors resort to new procedures as treatment. This treatment is divided into two branches, namely angioplasty, respectively atherectomy.

2.2 Angioplasty

Angioplasty is used to reopen blocked or narrowed coronary arteries as a non-surgical procedure. Angioplasty with stenting is currently the treatment of choice for the majority of cases. The procedure consists of inserting a catheter through an artery with an inflatable balloon into the partially blocked vessel and inflating the balloon in the area of interest to increase the internal diameter of the vessel and make room for blood to pass through it [10].

Over the years, this procedure has evolved, as follows: Balloon Angioplasty, Drug Coated Balloon Angioplasty, Bare-Metal Stents Angioplasty, Drug-Eluting Stents Angioplasty, Bioresorbable Stents Angioplasty. Metal Stents are designed to maintain the opening in the vessel after the initial inflation of the balloon [11]. The metal stent is in the form of a cylindrical metal wire mesh as can be seen in Figure 3.

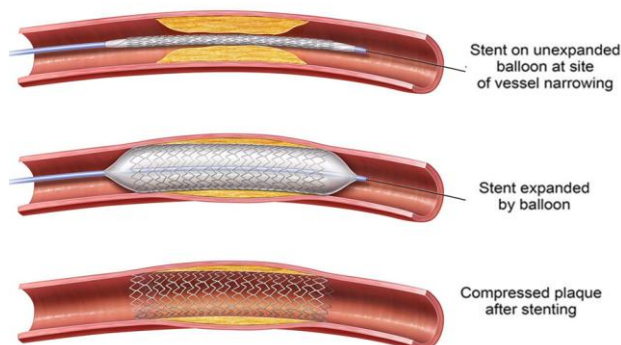


Figure 3 Angioplasty with stent [11].

2.2 Atherectomy

Atherectomy is a peripheral medical intervention that helps in the reopening of a blocked artery by cutting/breaking away pieces of plaque. The current techniques are: Rotational-, Orbital-, Directional-Atherectomy.

Rotational atherectomy (AR) or rotablation has been used worldwide to treat severe calcified coronary lesions based on the removal, by differential cutting, of the plaque using a diamond-coated burr that rotates at different speeds. This technique yields the best results when followed by the implantation of a drug-eluting stent. The principle of differential cutting selectively removes inelastic tissue while maintaining the integrity of elastic tissue. The basis of this concept is the selective ablation of one material while preserving the integrity of another material (Figure 4). The result is a smooth lumen [12][13].

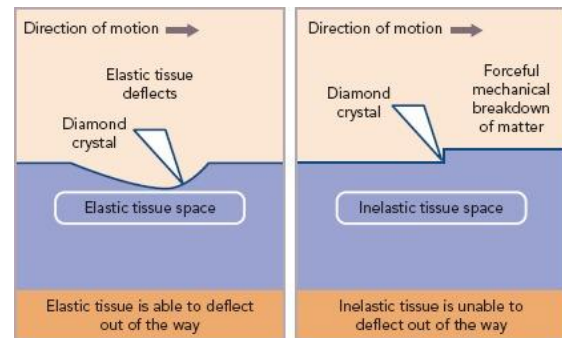


Figure 4 Mechanism of Rotational Atherectomy [12].

3. STATE OF THE ART

In this state-of-the-art chapter we can see new technology and features belonging to the most recent stage of development.

3.1 Angioplasty devices

EMERGE™ PTCA Dilatation Catheter (Figure 5) is a predilatation balloon catheter designed to easily navigate and traverse even the most difficult areas. It has exceptional delivery capacity and offers full support for vessels of any size and complexity. Available in 4.50 and 5.00 mm diameters [14]. Epic™ Vascular Self-Expanding Stent System (Figure 6) is a self-expanding Nitinol stent designed to support the patency of blood vessels. Provides improved visibility and accuracy while placing it in the area of interest. Designed to work even in tortuous vasculature with the help of its unique geometry [15].



Figure 5 EMERGE™ PTCA Dilatation Catheter [14].

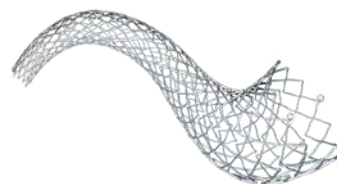


Figure 6 Epic™ Vascular Self-Expanding Stent System [15].

3.2 Atherectomy devices

Jetstream™ Atherectomy System (Figure 7), since 2008, it was designed to treat multiple morphologies, such as calcium deposits, plaque or thrombus formation, commonly found in total occlusions. The Jetstream Atherectomy System features active suction, which minimizes the risk of distal embolization. Front-cut extendable slats created significant luminal gain. The system is designed to restore blood flow through the many types of morphologies [16]. Peripheral Rotablator™ Rotational Atherectomy System (Figure 8) is an air-powered system with a 5-micron diamond-tipped burr that rotates at a maximum speed of 190,000 rpm. It modifies vessel compliance even in the most calcified peripheral lesions [17].



Figure 7 Jetstream™ Atherectomy System [16].



Figure 8 Peripheral Rotablator™ Rotational Atherectomy System [17].

4. GEARBOX CONCEPT (SIMPLIFIED)

A gearbox refers to a set of gears located in a housing/box. They are mostly found in the automotive industry where they help slow down and stop the car, as most car engines run at high speeds, transmissions allow the car to run more efficiently. It converts the available torque and speed from the engine and passes the power on. In this paper we aim to design a gearbox that produces more revolutions per minute in the case of Rotational Atherectomy.

The motor will be connected to the gearbox through a coupling, the gearbox changes the speed and sends the new speed to the medical equipment, the speed measuring system (speed transducer) converts the speed into an electrical signal, the signal is sent further to the control system, control system that acts by controlling the engine and the gearbox. The concept can be seen in Figure 9.

We chose a concept with a simplified model with 3 speeds, namely 140000 rpm, 160000 rpm and 200000 rpm. These values were chosen due to the recommendation of professionals in the medical field.

For this test stand of medical equipment used in cardiovascular therapy, we chose the Universal Motor 12-24VDC RS795 24V with 20000 rpm.

The concept can be seen in Figure 9.

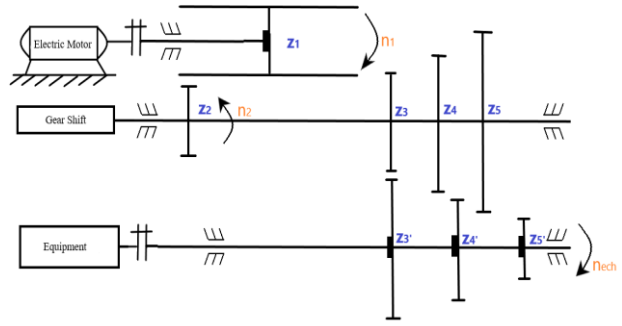


Figure 9 Gearbox.

The gear ratio equation:

$$i_{in,out} = \pm \frac{n_{in}}{n_{out}} \left[\frac{rot/min}{rot/min} \right] = \pm \frac{\omega_{in}}{\omega_{out}} \left[\frac{rot/min}{rot/min} \right] \quad (1)$$

i – gear ratio, n – gear revolution, ω – angular revolution.

The gear ratio equation in case of a series mechanism:

$$i_{1,n} = \prod_{j=1}^{n-1} i_{j,j+1} = i_{1,2} \cdot i_{2,3} \cdot \dots \cdot i_{n-1,n} = (-1)^k \frac{z_n}{z_1} \quad (2)$$

k – gears, z – the number of teeth of the (1 – first, n – last) wheel.

The gear ratio equation in case of parallel mechanism:

$$i_{1,n} = \prod_{j=1}^{n-1} i_{j,j+1} = i_{1,2} \cdot i_{2',3} \cdot \dots \cdot i_{n-1',n} = (-1)^k \frac{\prod z_c}{\prod z_m} \quad (3)$$

z – the number of teeth of the (c – driven, m – drive/motor) wheel.

The following value is the distance between the axes of rotation of the gears. In this paper we chose a as 50mm:

$$a_{m,c} = \frac{d_m}{2} + \frac{d_c}{2} \quad (4)$$

$$d = m \cdot z \quad (5)$$

$$a_{m,c} = \frac{m \cdot z_m}{2} + \frac{m \cdot z_c}{2} = \frac{m}{2} (z_m + z_c) \quad (6)$$

a – distance between the axes of rotation of the gears, d – the diameter of the dividing circle, m – module.

The modulus m of the gears was chosen from the standard $m \in \{0.25; 0.5; 0.8; 1; 2\} [mm]$, $m = 1 [mm]$. The next value was chosen for the transmission ratio between the first two gears:

$$i_{1,2} = \frac{1}{2} \quad (7)$$

i total (also known as i in,out) is equal to the product of the transmission ratio between the first two gears and the transmission ratio between the last two gears respectively:

$$i_t = i_{1,2} \cdot i_{3,3'} \quad (8)$$

The following equations and results are specific for the first case with 140000rpm (n_{ech} - equivalent). The concept is the same for all of the rpm's (rpm=rot/min).

$$\begin{aligned} n_m &= 20000 [\text{rot/min}] \\ n_{ech} &= 140000 [\text{rot/min}] \\ i_t &= \frac{n_m [\text{rot/min}]}{n_{ech} [\text{rot/min}]} = \frac{20000 [\text{rot/min}]}{140000 [\text{rot/min}]} = \frac{1}{7} \end{aligned}$$

$$\left. \begin{aligned} i_{1,2} &= \frac{1}{2} \\ i_t &= i_{1,2} \cdot i_{3,3'} \Rightarrow i_{3,3'} = \frac{i_t}{i_{1,2}} \end{aligned} \right\} \Rightarrow i_{3,3'} = \frac{\frac{1}{7}}{\frac{1}{2}} = \frac{2}{7}$$

$$\left. \begin{aligned} i_{3,3'} &= \frac{2}{7} \\ i_{3,3'} &= \frac{z_{3'}}{z_3} \Rightarrow z_{3'} = i_{3,3'} \cdot z_3 \end{aligned} \right\} \Rightarrow z_{3'} = \frac{2}{7} \cdot z_3$$

$$\left. \begin{aligned} a &= \frac{m}{2} (z_3 + z_{3'}) \\ z_{3'} &= \frac{2}{7} \cdot z_3 \end{aligned} \right\} \Rightarrow 2 \cdot a = m \left(z_3 + \frac{2}{7} \cdot z_3 \right)$$

$$\begin{aligned} 2 \cdot a &= m \left(z_3 + \frac{2}{7} \cdot z_3 \right) \Rightarrow 2 \cdot a = \frac{9}{7} \cdot m \cdot z_3 \\ \Rightarrow a &= \frac{4,5}{7} \cdot m \cdot z_3 \end{aligned}$$

$$\left. \begin{aligned} a &= \frac{4,5}{7} \cdot m \cdot z_3 \\ a &= 50 [\text{mm}] \end{aligned} \right\} \Rightarrow \left. \begin{aligned} z_3 &= \frac{50 [\text{mm}]}{\frac{4,5}{7} \cdot m} \\ m &= 1 [\text{mm}] \end{aligned} \right\} \Rightarrow$$

$$\Rightarrow z_3 = \frac{50 [\text{mm}]}{\frac{4,5}{7} \cdot 1 [\text{mm}]} = 77,7 = 78 \text{ teeth}$$

$$z_{3'} = \frac{2}{7} \cdot z_3 \Rightarrow z_{3'} = \frac{2}{7} \cdot 78 \Rightarrow z_{3'} = 22 \text{ teeth}$$

The results are as follows in the Table 1 below:

n ech	Results					
	140000 [rpm]		160000 [rpm]		200000 [rpm]	
Gear	Z ₃	Z _{3'}	Z ₄	Z _{4'}	Z ₅	Z _{5'}
Nr. Teeth	78	22	80	20	83	17
d [mm]	39	11	40	10	41,5	8,5

A design was made as a model to interpret the results using Autodesk Inventor; an extension, computer-aided design application for 2D or 3D design, visualization, simulation and documentation developed by Autodesk. Aluminium is chosen as the material used for illustration and texturing. All cases are presented in the next figures (Figures 10 and 11).

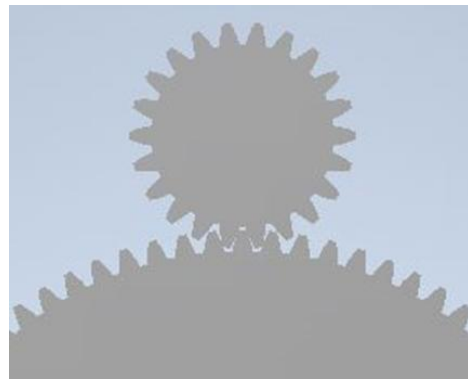


Figure 10 Gears for 140000rpm (closeup).

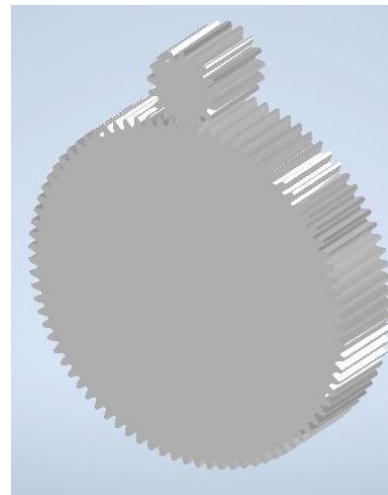


Figure 11 Gears for 200000rpm.

5. COMBINATION OF ANGIOPLASTY AND ATHERECTOMY CONCEPT

Not every blood blockage can or should be treated only with angioplasty. There are situations when patients present special cases with multiple blockages or blockages located in hard-to-reach positions. In this case, a combination of the two techniques mentioned above is proposed.

The concept consists in the presence of all components on a single "branch" (guide wire). In this case, the Rotablator (burr) will remove most of the plaque deposited on the vessel walls and create enough room for the balloon to be inflated and the stent to be inserted. Stent placement will maintain the opening over time. The combination of these techniques leads to the minimization of the time spent on the procedure. It also avoids two catheter insertions and additional costs of material.

In the following figures (Figure 12-17), the proposed model in 3D using Autodesk's Inventor application is presented.



Figure 12 Burr.

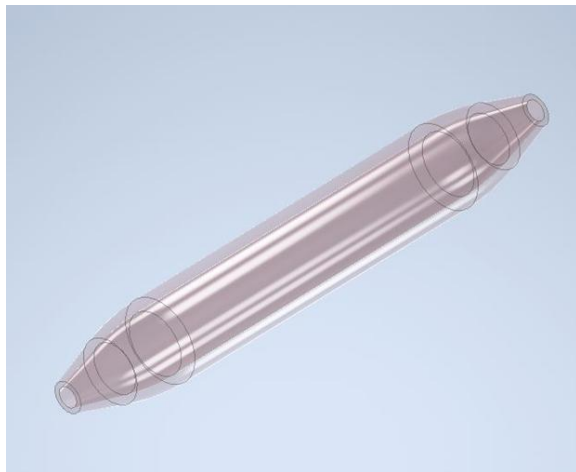


Figure 13 Balloon.

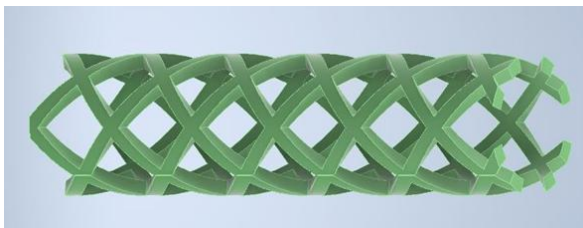


Figure 14 Stent.

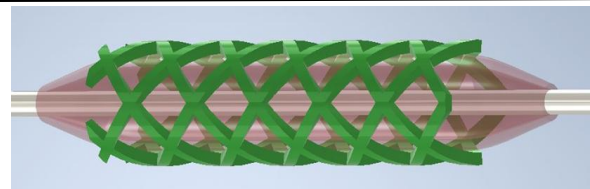


Figure 15 Balloon and stent.

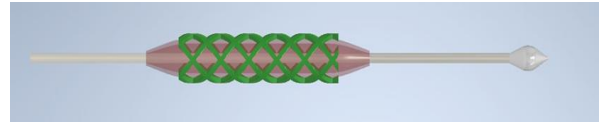


Figure 16 Balloon, stent and burr.

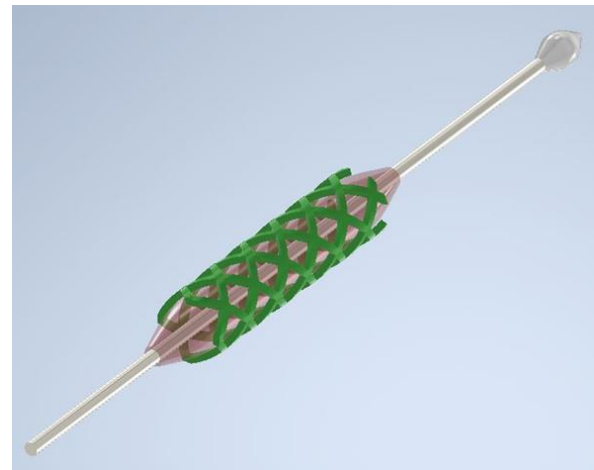


Figure 17 Assembly.

6. CONCLUSIONS

The costs of cardiovascular disease treatments are constantly increasing, thus, through the possibility of designing a gearbox along with other future improvements, the reduction of the costs of rotational atherectomy is sought. Combining the 2 techniques leads to lower total costs by minimizing material use.

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