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Stent design and Mechanical Behavior of stents and analysis

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Abstract-Problem Statement

This research will propose to examine commercially available stent from leading manufacturers. The stent will be examined in a static phase to determine

(a) Mechanical behavior of stent (b) Stress and strain distribution (c) Fatigue life of stent.This process will be done to determine the optimal conditions for stent design. A new stent design will be developed from the data gained through analysis. The factors such as mechanical stress and strain are considered as the main aspects of findings.

Keywords: Atherosclerosis, mechanical stress,analysis,stent design

1.1 Introduction Atherosclerosis

Coronary heart disease (CHD) is a leading cause of death worldwide, Killing almost 7 million people every year. CHD is a disease in which a waxy like substance called plaque builds up inside your arteries.The formation of these plaques is a slow and gradual process. The process can be simply explained as follows: first they are composed of lipids, mainly cholesterol, then plaques become larger and larger building a support structure composed of fiber and connective cells, resulting in an occlusion of the artery, the so-called stenosis.Atherosclerosis can affect almost any artery in the body. But in the heart its effects can be crucial. The body depends on a strong pumping heart to circulate life-giving blood, and this includes to the heart

muscle itself. If the coronary arteries become blocked, the cardiac muscle begins to fail, and so the blood circulation decreases, reducing also the circulation to the heart muscle itself.

Angioplasty is far less invasive than traditional surgery. Rather than constructing a new route for blood flow, as in bypass surgery, these procedures open or widen existing ones.

As depicted in Figure 1, the procedure is simple:

• Through a small incision in the femoral artery2, a Teflon-coated catheter is inserted and threaded to the vessel obstruction;

• A thin, flexible guide wire is moved in the guiding catheter beyond the afflicted area;

• A balloon catheter is moved over the guide wire and accurately positioned in the blockage;

• The balloon mounted on the distal tip of the catheter is inflated;

• The plaque is compressed by the balloon and the arterial lumen is restored;

• The balloon is deflated and then removed with the catheter, leaving the vessel widened.

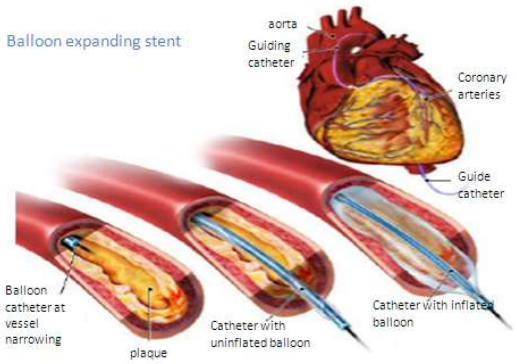


Fig 1 Detail view on stent model

1.2 Assumptions

An assumption about obtainable results will be made. This research will assume that the results obtained by static and dynamic finite element analysis and the results obtain through actual fatigue testing are not statistically different. Under this assumption, all results obtained through software based simulation would be the same as those obtained through physical testing. It will also be assumed that the forces inside an artery are periodic and therefore repeatable. The forces inside an artery are assumed to be periodic because of the cyclic loading and unloading of the artery because of heart beat.

1.3 Limitations

This research will be limited to software analysis. These stents have high costs. Therefore, Destructive testing cannot be performed to compare actual obtainable results

and obtained software derived results

2.1 Stent Materials

The correct choice of the stent material is an essential step of stent design process as well as for every other medical device. In this chapter, we want to provide the current stent metal options available and discuss the influence of their features on this choice. The stent material choice is a symbiosis between the required mechanical properties (flexibility, ability to support the duct wall, ability to expand) and the biocompatibility.

2.1.1 Biocompatibility

It is not easy to provide a unique definition of biocompatibility. In fact the interaction of a material with the body involves many factors and a single test is not able to define whether a material is biocompatible or not. Here, we consider the biocompatibility of a stent. This device is (in general) a long-term implanted device so its biocompatibility can be defined as the property of the device to perform its task, not providing any undesirable local or systemic effects in the host body. A biocompatible material may not lead to a toxic or harmful immunological response. The way to assess the biocompatibility or the tissue reaction is to test the substances firstly in vitro then in vivo. The usual response of the host to an implant includes:

- Trauma;
- Inflammation;
- The immune system reaction;

The biocompatibility of the metals is directly related to their ability to resist to the aggression of biological fluids. In fact the biological fluids have a well-known corrosive action. The corrosion has consequences on the mechanical properties of the metal implant and a toxicological action since it leads the release of metallic ions in the body. The anti-corrosion features of the metals can be improved applying technologies acting on the chemical stability of the device surface (i.e. passivation) and on the surface geometry (i.e. electrochemical polishing).

2.1.2 Current Metallic Stent Materials

The stent market is a very interesting research field also from the point of view of material science, the discovery of a new material can lead to a sudden wide and rapid revolution as e.g. happened with Nitinol and polymeric materials. Furthermore, the rapid influx of the new stent material requires well understanding of the relative strengths and weaknesses of the

various materials. In the following, we will discuss the mechanical and chemical properties, highlighting their role in the stent design, of the following materials:

- Stainless steel;
- Gold;
- Cobalt Chromium alloys;
- Magnesium;
- Nitinol.

2.1.2.1 Stainless Steel (SS)

Steel is an iron alloy. It includes 2% of carbonium (at most). The stainless steels are specific types of steel which well resist to the chemical agents. It is includes chromium (Cr) (more than 10%) and nickel (Ni). By the crystal microstructure, the SSs can be classified as:

- Martensitic SSs;
- Austenitic SSs;
- Ferritic SSs.

Here, we will focus the attention on the austenitic SSs which are the most important class of materials
for medical device applications and most BX stents, which are based on the metal plastic deformation, are stainless steel made (SS). These types of SSs are interesting because they propose a good compromise among corrosion resistance, strength, formability, weld ability, and cost. They are also non-magnetic allowing magnetic resonance imaging (MRI) of the device. The first austenitic SS used in the medical application was the Type 302 but it became obsolete since its scarce corrosion resistance. Nowadays the most widely used SS is the Type 316L, a variation of Type 316 including molybdenum, which provides more resistance to the salt water: the Type 316L contains less carbon than Type 316.

3.1 Material

The stent in this section was manufactured from wrought Co-Cr alloy, commonly referred to as L-605.The use of this material enables reduction in stent wall thickness relative to traditional stainless steel.
While retaining adequate visibility under fluoroscopy,i.e., clinical X-ray based imaging. The solid-solution alloy evaluate is nominally comprised 20wt% chromium,15wt% tungsten , 10wt% manganese , 0.1wt% Carbon ,3wt% iron, trace amounts of silicon, phosphorus and sulphur, and the balance consisting of cobalt.
The mechanical properties of the L-605 alloy were measured from standard uniaxial tensile tests, with the exception of endurance strength which was measured from rotary beam testing of wire (*Ramesh V. Marrey, Robert Burgermiester, Randy B. Gris Haber, and R.O.*

Ritchie).Statistical analysis of the experimental results gathered was used to determine the conservative values. yield and ultimate tensile strengths and the fatigue endurance strength of the material. The young's modulus value was taken from ASM, *Manufacturer's and handbook data,2004.*

3.2 Theory

In order to perform an initial stress-life analysis for fatigue loading in a simulated in vivo environment, the steps involved in preparing and deploying an interventional stent consistent with clinical practice need to be addressed. First, the fabricated stent is loaded onto the intravascular delivery system (i.e., balloon catheter) and then temporally affixed or 'crimped' (i.e., plastically deformed) onto the inflatable balloon portion of catheter forming the stent delivery system. Upon insertion into the in vivo vascular environment, the delivery system must be manipulated within the tortuous anatomical pathways leading to the a priori targeted vessel. Deployment of the stent into the artery is accomplished by gradual inflation of the balloon portion of the delivery system via manually applied hydraulic pressurization, thereby inducing expansion (via plastic deformation), into the neointimal Lumina of the targeted site. Upon reaching the intended deployment diameter, the balloon catheter is removed by first deflation and then extraction of the deflated delivery system through the vasculature. The final step occurs during deflation when the Hookean stent material elastically recoils to a smaller diameter, which is also influenced by end luminal loading imparted onto the deployed stent. The subsequent cyclic loading is then provided by cyclic systolic/diastolic pressurization due to cardiac heartbeats.

3.3 Loading and Solution

In present analysis, modelling and simulation is done on stent without considering balloon and vessel. To perform the numerical stress-analysis for cyclic radial loading, the stent was modeled with 3D 8-node brick Solid 185 elements using Ansys. A constant internal pressure=13.3KPa or 9.4N force was applied to the vessel and the plague .This pressure equals to the blood pressure of 100mm of Hg. The pressure simulates the internal pressure of the blood and causes the vessel to expand, and also, induces an internal stress. Maximal and minimal pressure loads bounded by the 100mm Hg pressure range, were then sequentially applied to the internal faces of the tube to conservatively represent physiological systolic and diastolic

blood pressure loads within the artery.

3.3.1 Blood pressure and corresponding value of force

Diameter of stent d=3mm

Area of stent A= 7.068 x10^{-4} m^2

Pressure P= hρg

Where h is height of mercury column in mm

ρ is the density of mercury in Kg/m^3

We know

Force F= P/A

Solid 185 element is used for 3D modelling solid structure

Element has plasticity, hyper elasticity, stre stiffening, creep, large deflection and large strain capabilities

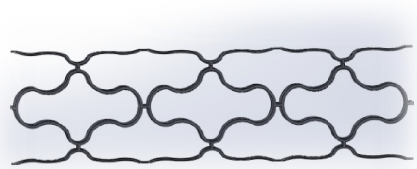
- Cobalt-Chromium alloy (L605)
- 20wt% chromium
- 15wt% tungsten
- 10wt% nickel
- 3wt% iron
- 1.5wt% manganese
- 0.1wt% carbon
- Balance consisting of cobalt

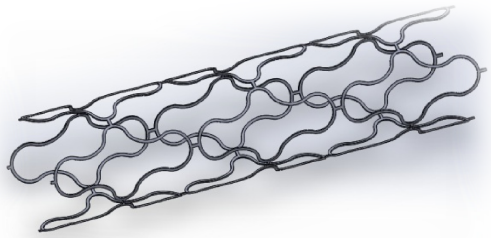
PROPERTY	VALUE	UNIT
Density	9100	Kg/m^3
Young's modulus	243	GPa
Poisson's Ratio	0.3	
Bulk modulus	202.5	GPa
Shear modulus	93.463	GPa
Coefficient of thermal expansion	1.2E-5	$^0C^{-1}$
Strain hardening exponent	0.2	
Tensile yield strength	547	MPa
Compressive yield strength	547	MPa

Tensile ultimate strength	1449	MPa

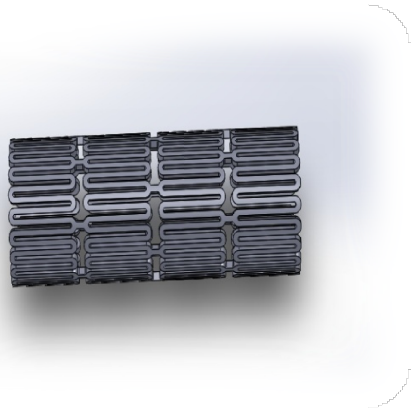
3.4 Stent Models

3.4.1 Model 1





3.4.2 Model 2



3.5 Results and Discussion

Following results regarding the life, factor of safety and damage can be obtained from the fatigue analysis which are discussed below:

3.5.1 Life

Figure 2 shows the available life of stent for the given fatigue analysis. The loading is of constant amplitude so this figure represents the number of cycles until the part will fail due to fatigue. In the present analysis minimum life of stent comes out to be 3.8546e7.

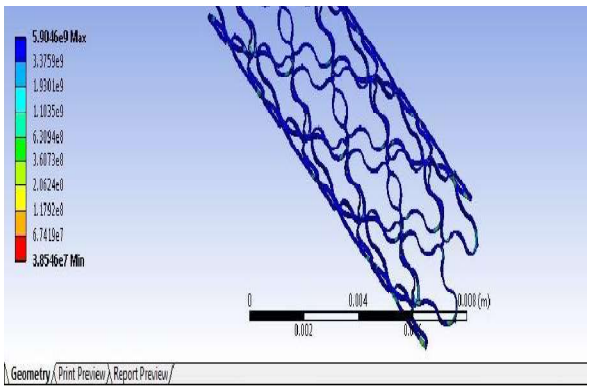


Figure 2Model 1: life of stent

Minimum life comes out to be 5.9046e9 cycles i.e. approximately 583 days.

But life of commercially available stent ranges from 5 to 6 years.

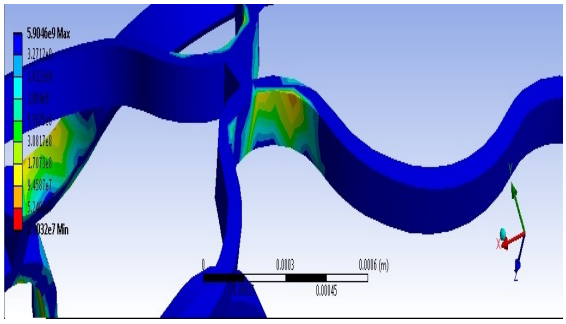


Fig.3 Stresses are mainly distributed near the connecting bridge and on the curvature.

For this model the Minimum life comes out to be 1.0607e5 cycles.

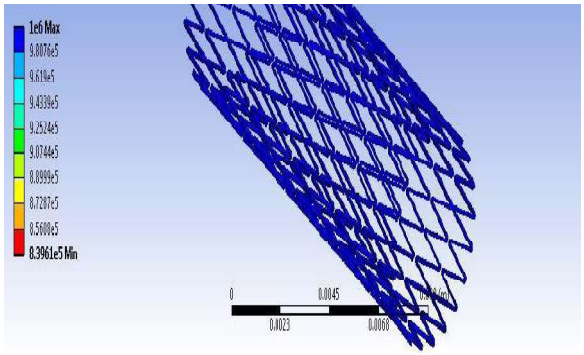


Fig. 4Model 2 life of stent

3.5.2 Damage

Fatigue damage is defined as the design life divided by the available life. The default design life may be set through the options dialog box. A damage of greater than 1 indicates that the part will fail from fatigue before the design life is reached. In the present analysis as shown in figure 5 maximum damage of stent comes out to be 259.43 meaning that the stent will fail from fatigue before the design life of 1e10 (assumed before the analysis of stent) was reached.

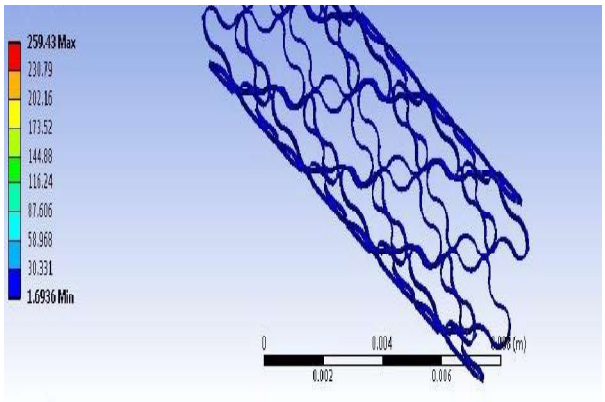


Fig. 5Model 1 Damage in stent

Maximum damage of stent comes out to be 259.43.

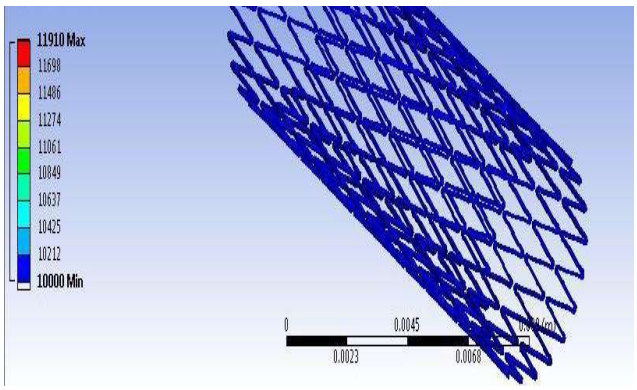


Fig. 6 Model 2 Damage in stent of has an minimum value of 10000 cycles and a maximum value of about 11910

3.5.3 Factor of safety

This result is a contour plot of the factor of safety (FS) with respect to a fatigue failure at a given design life which is 15 (maximum) for this analysis.

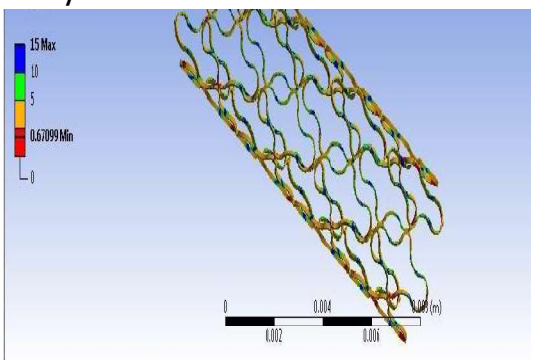


Fig. 7Model 1 Factor of safety

The minimum FOS comes out to be 0.67099

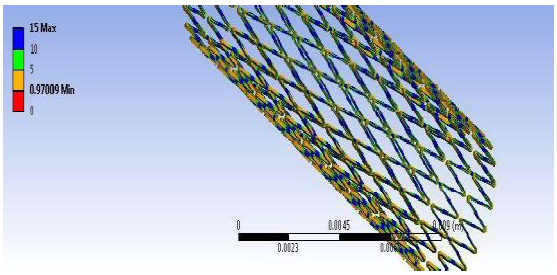


Fig. 8 Model 2 Factor of safety
In this model the minimum FOS comes to be 0.9007

3.6 Conclusion

In the present work two commercially available stent design and one concept stent design were modeled. The materials used were 316L stainless steel and L-605 Co-Cr alloy. Fatigue analysis result shows that minimum life of stent is 3.8546e7 cycles for L-605 alloy. In the conditions of normal blood pressure of 100 mm of Hg.

A new stent was designed and fatigue analysis was done under static conditions

The design life was 1e10 and actual life came out to be 3.8546e7 .

Damage as 259.43 and FOS as 0.60799

- Present design has sufficient strength but cannot be commercialized.
- More design improvements need to be done to reach the target of 5years life.
- The thermal stresses can also be taken into account in further analysis.
- Other trending materials can also be used like SMA and Bio-absorbable materials.

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