Study on performance of various stent materials using explicit finite element analysis

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Abstract. In many countries, cardiovascular disease is the main cause of mortality. Stent is tiny wire mesh tube which is inserted in coronary artery to get rid of blockage. Stents are available in various types Bare metallic, Drug eluting and Biodegradable. The use of biodegradable stents reduces the threat of post-implantation effects like stent thrombosis and bleeding, it also dissolves in the body over the period of time once the healing is done while narrowing of the artery is more likely to occur in bare metal stents. Metals are important materials for stent due to mechanical properties and ease for Image processing. The objective of the work makes an effort to compare various materials used in stent using explicit analysis. For analysis, we used AISI 316L stainless steel, Nitinol and Mg alloy (WE43) which are standard materials for stent application. Explicit finite element study was done to study the performance of stent at varying pressures from 100 to 120mm of Hg, which is normal blood pressure range of a human body. This computational study found that Nitinol has stress values from 2.18MPa-2.62MPa and was less compared to other materials. Further study are planned to study the impact of coating that can enhance the biocompatibility.

Keywords - Stent; finite element analysis;

1. Introduction

Cardiovascular disease is a very saviour issue as number of deaths caused by this disease is greater than that of any other diseases worldwide. Cardiovascular diseases (CVDs) is a term which accounts coronary heart disease, cerebrovascular disease, peripheral arterial disease, rheumatic heart disease, congenital heart disease, deep vein thrombosis and pulmonary embolism. Main cause of Cardiovascular disease is related to blockage of arteries which supplies blood to the heart which is mainly due the deposition of the fats on the inner periphery of the arteries resulting in reduced cross section which is available for the blood flow. Deposition of the fat on the inner periphery of the arteries results in reduced blood flow and oxygen towards heart, leads to improper heart function. In order to open the arteries expandable metal/polymeric mesh is placed during the angioplasty surgery which is called as stent. Conceptually stent came in to the picture in 1964, this concept of stent was firstly introduced by Dotter and Judkins. Actual implementation of stent was done for the first time in 1977 for bypass graft surgery, followed by angioplasty of another patient after four months.[1] The perfect stent must have the option to be conveyed to the sore through any calcified fragments without getting disfigured from the conveyance framework.[2,3].
Different types of the stents are available like-Dual therapy stent (DTS), Bio-resorbable vascular stent (BVS), Bio-engineered stent, Drug eluting stent (DES) and Bare metal stent (BMS). Bare metal stent is the simple mesh of metal which is used to reopen the artery, healing of the artery takes place once the artery starts growing around the stent. Re-narrowing of the artery is more likely to take place in bare metal stents. [4-6] Main issue associated with the stents are- slow healing rate of artery, premature absorption of the stent. In case of bio-resorbable stents these issues lead to re-narrowing the arteries and ultimately malfunctioning of the heart. In order to overcome these issues changes in the stent design are made so that the healing of artery will speed up and chances of re-narrowing the artery will reduce.[7] Selection of proper material plays a major role in stent application. Metals, Ceramics and Polymers are available as stent material but Ceramics are strong not preferred due to lack of flexibility and plasticity. Moreover fracture toughness is also low for ceramics. While in Polymers high flexibility property alone is not sufficient. Polymers shows high flexibility but it is hard to acquire polymers with both high adaptability and strength at body temperature. Therefore, Metals are most important materials for stent due to mechanical properties and ease for Image processing. The improvement of appropriate materials for stents falls behind from the perspective of materials science[8]. This work aim is to compare the materials amongst Mg alloy, 316L stainless steel and Nitinol under specific loading conditions.

2. Methodology

Methodology is followed as shown in figure 1. Finite element method is one of the numerical methods that is pretty flexible and might offer repeated solutions as compared to other in less time. This method is used to offer solutions to troubles which are ruled by way of partial differential equations. The methodology used for the analysis of the stent is the finite element modelling.[9] For simulating the results of stent geometry ANSYS v19.2 software is used.

![Figure 1. Methodology](image)

2.1. Modeling of stent:

With the help of SOLIDWORKS CAD software, geometrical model of stent is designed with specific dimensions. Figure 2 shows the overall view of stent. In stent the distance between struts also makes impact on its results, to avoid that total length of stent model is 7.01mm which is made with consideration of size of arteries in human body. Proper size of the stent depends on the size of artery it is to be positioned. Geometrical details of the stent are provided in table no.1. Following figures 2(a) & (b) shows the various views of stent.
The reference values considered for geometrical design of the stent is given in Table 1.

Table 1. Geometric details of the stent.

| S. No. | Parameters     | Dimension |
|--------|----------------|-----------|
| 1.     | Total length   | 7.01mm    |
| 2.     | Inner diameter | 2mm       |
| 3.     | Outer diameter | 2.24mm    |
| 4.     | Thickness      | 0.12mm    |

2.2. Meshing:
Meshing is important part of simulation which helps to obtain accurate result from an FEA model where complex geometries are divided into simple elements. Typically the accuracy depends on the mesh size. Smaller mesh size gives more accuracy in results of the provided physical domain. Various mesh views of stent are show in Figure 3(a) & (b).

2.3. Materials and their properties:
For this analysis we are taking 316L stainless steel, Mg alloy (WE43) and Nitinol. Austenitic stainless steel type 316L is most commonly used stent material with outstanding corrosion resistance. Mg alloy (WE43) is also known as biodegradable material for stent which consists of lowest density. It also shows high strength. While Nitinol is alloy of Ni and Ti which is used in stents due to its super-
elasticity, shape memory effect and biased stiffness. Those material properties are shown Table 2 as follows.

### Table 2. Material Properties.

| Material                     | Density      | Young’s Modulus | Poisson's ratio | Specific heat |
|------------------------------|--------------|-----------------|-----------------|---------------|
| AISI 316L SS                 | 7850 kg/m³   | 200000 MPa      | 0.31            | 0.76986 cal/(g)(K) |
| Mg Alloy (WE43)              | 1840 kg/m³   | 44000 MPa       | 0.27            | 0.966 cal/(g)(K)   |
| Nitinol                      | 6450 kg/m³   | 28000 MPa       | 0.32            | 0.32 cal/(g)(K)    |

where m= meter, kg=kilogram, Pa = Pascal (N/m²).

2.4. **Solver setting:**

For performing the simulation the commercial software ANSYS R19.2 is used. We know that blood pressure of humans vary from 80 to 120 mm of Hg. For calculation purpose we are considering the 100 to 120 mm of Hg pressure which is common for young adults and old peoples.

Explicit Dynamics analysis system is used for specific time integration.

### 3. Results and conclusion

The stent model was subjected to FEA using three materials 316L Stainless steel, Mg alloy (WE43) and Nitinol with pressure ranging from 100mmHg to 120mmHg. The results of the stent analysis study are tabulated in Table 3.

### Table 3. Result of stent finite element analysis.

| Sr No | Material                      | Pressure (mmHg) | Von mises stress (MPa) | Equivalent strain (m/m) | Resultant deformation (m) |
|-------|-------------------------------|-----------------|------------------------|-------------------------|---------------------------|
|       |                               | Min             | Max                    | Min                      | Max                       | Min             | Max             |
| 1     | AISI 316L Stainless Steel     | 0.044698        | 2.4641                 | 2.79777e-7               | 1.3958e-5                 | 0               | 1.2103e-7       |
|       |                               | 0.049496        | 2.7095                 | 3.0462e-7               | 1.5349e-5                 | 0               | 1.3310e-7       |
|       |                               | 0.053838        | 2.9556                 | 3.3159e-7               | 1.6739e-5                 | 0               | 1.4517e-7       |
| 2     | Mg alloy (WE43)               | 0.10686         | 3.0533                 | 3.2119e-6               | 8.3344e-5                 | 0               | 6.1068e-7       |
|       |                               | 0.11745         | 3.3585                 | 3.5269e-6               | 9.1773e-5                 | 0               | 6.7175e-7       |
|       |                               | 0.12804         | 3.6635                 | 3.8423e-6               | 0.0001000                 | 0               | 7.3281e-7       |
| 3     | Nitinol                       | 0.077030        | 2.1871                 | 3.1450e-6               | 9.8089e-5                 | 0               | 7.0017e-7       |
|       |                               | 0.084824        | 2.4078                 | 3.4638e-6               | 0.0001079                 | 0               | 7.7076e-7       |
|       |                               | 0.092635        | 2.6296                 | 3.7832e-6               | 0.0001178                 | 0               | 8.4144e-7       |

The colour plots of equivalent stress and Equivalent strain are shown in figure 4 and figure 5 respectively.
Figure 4(a). Equivalent stress at 100mmHg pressure for (i) 316L SS, (ii) Mg alloy, (iii) Nitinol

Figure 4(b). Equivalent stress at 110mmHg pressure for (i) 316L SS, (ii) Mg alloy, (iii) Nitinol

Figure 4(c). Equivalent stress at 120mmHg pressure for (i) 316L SS, (ii) Mg alloy, (iii) Nitinol
Figure 5(a). Equivalent elastic strain at 100mmHg pressure for (i) 316L SS, (ii) Mg alloy, (iii) Nitinol

Figure 5(b). Equivalent elastic strain at 110mmHg pressure for (i) 316L SS, (ii) Mg alloy, (iii) Nitinol

Figure 5(c). Equivalent elastic strain at 120mmHg pressure for (i) 316L SS, (ii) Mg alloy, (iii) Nitinol
From the Table.3 it is clearly evident that Nitinol shows lowest equivalent stress values ranging from 2.18MPa-2.62MPa whereas equivalent stress for 316L stainless steel ranging from 2.46MPa-2.955MPa and for Mg alloy 3.05MPa- 3.66MPa which is highest of all. In case of equivalent elastic strain, Nitinol shows highest mean value which is $4.7477 \times 10^3$ whereas 316L SS shows lowest value. This computational study proves that Nitinol is best amongst all other materials in this analysis. Nitinol shows less stress values and high strain under the Pressure range for a stent model and remains stable under hostile environment in human body for small sized lesions. Thinner struts improve flexibility which signifies increase in inner diameter and decrease in potential injuries. Literature study shows that considering high-risk patients with small vessels, diabetes arteries shows impermissible high rate of restenosis. Mechanical properties of Nitinol ensure biomechanical characteristics to stents. Biased stiffness confirms stent recovery from the crimped position which is significantly more impervious to compression than to extension. With reference to the stress-strain curve, due to presence of the plateau it also shows good kink resistance. Not only for stent application but for orthodontic use it shows corrosion resistance as compare to stainless steel. But nickel release from nitinol indicates issue with biocompatibility. It can be improved with the help of coating. However coating processes are different for stent patterns.

4. Future Scopes

For the Biodegradable Drug eluting Stent effect of Nitinol stent with various coating materials to be studied which will be useful to overcome the current issues related to Peripheral artery Diseases.
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