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Existing Stent Design Under Combined Loading: An Investigation research

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Abstract

Intravascular stents are little tube-like structures ventured into stenotic arteries to reestablish blood stream perfusion to the downstream tissues. Surgical procedure effectiveness could be defined by stent expansion. Stent geometry plays an important part includes material, non-linearity, deformations, geometric and large displacements. Complex behaviour must solve with numerical analyses after free stent expansion. New stent designs and the previously approved stent or often called stent versus stent are the type of randomized trials to compare the superiority of the stent. However, cost and difficulty limited the clinical trials. This paper explained the analysis of the six finite element models to find out the effect of different geometry of the stent design after coronary stent placement. Six commercially available stents (NIR, Multi-Link, AVE S7, Bx Velocity, SMART and Palmaz stents) were modelled and their conduct during the arrangement is looked at as far as stress distribution and external diameter changes. Finite element analysis (FEA) was used in this study and applied to the new generation coronary stent. Results from simulations were compared with those from the previous study.

Keywords: *Intravascular stent, stenotic arteries, coronary stent placement, stress distribution*

I. INTRODUCTION

Stents conventionally are small wire work tubes used to open routes that have ended up being impeded by the work after some season of fat, cholesterol or various substances. The stent is folded to a little separation over, put over an angioplasty extend catheter and moved into the zone of the blockage. Exactly when the inflatable is expanding, the stent develops and twists plastically, verifies and shapes a framework to hold the conductor open. At the present time, swell extending accessible stents are delivered utilizing therapeutic evaluation hardened steel. Numerous techniques had been utilized to discover exact properties by utilizing an assortment of trial tests[1]–[5]. A medical device cannot carry out the test of the small and complex geometry of the stent. Stent structure did not allow the test to find out the strains easily. Researchers before had done may computational studies and optimization on the properties of the stent that lead to the better long-term efficacy of the stent itself [6]–[9]. FEA could help to provide access to an extensive amount of information. Thus, making computational analysis seem better alternatives compare to prototype fabrication. Not only that, the lack of sophisticated material makes the computational analyses provide a better understanding of typical stent performance. Because of the complexity of real-life stent behaviour, designers chose numerical methods over prototype fabrication.

The first cause of death in the United States is atherosclerosis known as cardiovascular diseases bypass surgery, balloon angioplasty, atherectomy, and stenting were the treatment of the disease [10]. In recent years, atherosclerosis was been treat by the stent placement method and commonly used by practitioners. Medical capability and confidence in tackling increasingly complex had been improved by these treatments compared to others especially the case involving coronary artery bypass graft [11].

Fatty deposits or calcium accumulations showed in Fig. 1 would narrow arteries because of vascular disease in humans and blocking blood flow to an organ. An inflatable small balloon or tip at catheter help to dilate the blockage of the artery (Fig. 1b). Fig. 1c shown the plaque is squeezed along the artery wall. Channel of constricted arterial segments in Fig. 2a opened by coronary stents like angioplasty. Balloon and a surrounding stent were delivered by the catheter during

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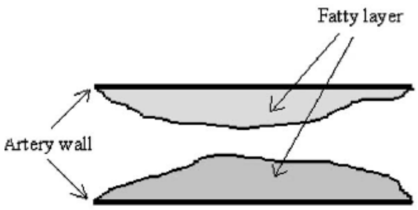
stenting to the blockage area (Fig. 2b). Before deflated, the balloon deploys the stent and remains inflated for a few seconds. Fig. 2c shown how the expanded stent holds the artery open when it's embedded into the wall of the diseased artery. The high restenosis rate was the greater weakness of the angioplasty. Restenosis occurred due to the second time blockage of the artery in the area of angioplasty. Six months after the first procedure is the period when the possibility of the vessel starting to narrow. A lower percentage of restenosis occur which is 20–30% make the coronary stents are widely used in clinical practice compared to balloon angioplasty [12].



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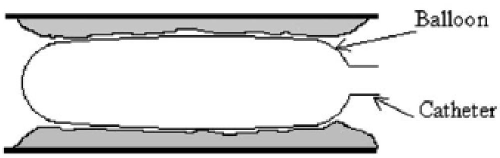

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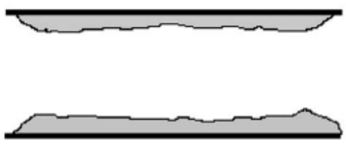

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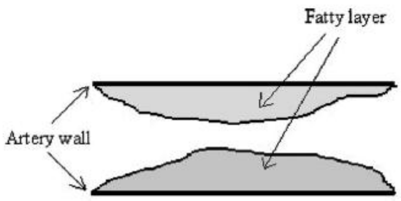
Figure 1. Angioplasty procedure [13]



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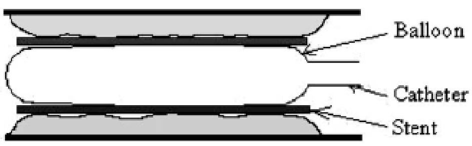

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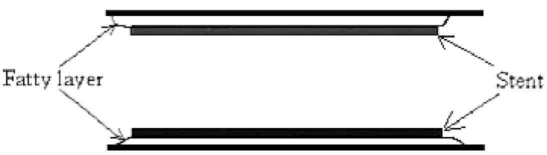


(c)

Figure 2. Stent deployment procedure[13]

II. MATERIALS AND METHODS

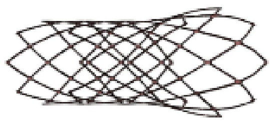
Six different stent design were developed, each established by a similar inflatable and coronary vein. The model of different parts utilized in reproducing is displayed in this segment. An analysis is performed using ANSYS 19.1 based on the finite element method. The round high – quality steel cylinders (stent) are displayed as safeguard devices to ingest a few vitality retentions when collapsible effect connected in stacking condition [14]. Subsequently, it is as yet a test to assess the fatigue harm under multiaxial loadings. The equivalent stresses got utilizing multiaxial weakness criteria were lower than von Mises stress and static FEA simulation uncovered that the equal pressure got utilizing multiaxial exhaustion criteria is the most dependable contrasted with von Mises model to guarantee safety. as proposed by [15].

A. Stent

Six different coronary stent designs were taken into consideration. They look like business intravascular stents. Each of the stents will be referred to as Stent A (NIR) Stent B (Multi-Link), Stent C (AVE S7), Stent D (Bx Velocity), Stent E (SMART) and Stent F (Palmaz). Commercially available software SOLIDWORK was used to produce the primary model of the stents.

Fig. 3 shown the basic model of the stent constructed by SOLIDWORK. The main structural elements of the reproduced models are thought to be the equivalent or nearly the equivalent. The stents were thought to be made of stainless steel 316L. A bi-linear elastoplastic material model was utilized as the behaviour of stents material.

(a) NIR Stent



(b) Multilink Stent

(c) AVE S7 Stent

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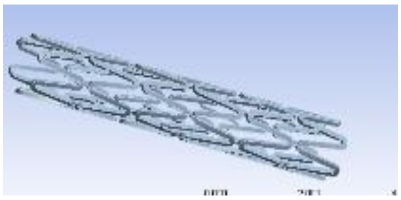
(d) Bx Velocity Stent



(e) SMART Stent

(f) Palmaz Stent

Figure 3. The stent used in the analysis

B. Balloon

Fig. 4 show the design of the balloon in its initial undeformed configuration with deflated tips at both ends. Appropriate pressure was applied to inflate the balloon with the catheter located inside the balloon. All directions were fixed at the ends as shown. Nylon was used as material for the balloon as the material made of very stiff polyamide with Mooney–Rivlin description and modelled as the hyper elastic material

Figure 4. Balloon geometry before inflation

C. Geometry and finite element discretization

Stent A (NIR) and Stent B (Multi-Link) have the same geometrical dimensions. Table 1 shown the outer diameter, length, and thickness for all stents. The geometry of the stents was taken from the previous study [14]–[18]. Table 2 showing the geometry of the balloon. The stent comprises of sinusoidal strut sections that are interconnected by versatile fragments in a closed-cell design. The stent was at first displayed in a SOLIDWORK as shown in Fig. 1 and imported in ANSYS 19.1 for further solution and analysis.

TABEL I.DETAIL OF GEOMETRY OF THE STENTS

Stent	Outer diameter (mm)	Length (mm)	Thickness (mm)
A	3	10	0.05
B	3	10	0.05
C	1.4	10	0.05
D	1.18	13	0.14
E	7	20	0.2
F	1.4	10	0.05

TABEL II. DETAIL OF GEOMETRY OF THE BALLOONS

Stent	Outer diameter (mm)	Length (mm)	Thickness (mm)
A	2.9	12	0.1
B	2.9	12	0.1
C	1.3	12	0.1
D	1.08	15	0.28
E	6.9	22	0.4
F	1.3	12	0.1

D. Material Properties

316L stainless-steel chose as the main material for the stents that manufactured from medical-grade and undergoes plastic deformation during its deployment. Rate-independent elastic-plastic material model test was used to describe its mechanical behavior with the hardening of isotropic. Poncin et al. in his analysis describe the behaviour of the stent by performed uniaxial tension tests. Full anneal stent tubing of medical-grade 316L stainless steel was used as samples [19]. Poisson's ratio of 0.3 and Young's modulus of 193 GPa used to describe the elastic behavior of the stent. Then, the ultimate tensile stress of 670 MPa and yield stress of 360 MPa were characterized to describe the plastic behavior of the stent by multi-linear function. The material properties used for the stent shown in Table 3.

TABEL III. PHYSICAL ANDMECHANICAL PROPERTIES OF 316L STAINLESS STEEL [19]

Stent Material	SS 316L
Density ($gCm3$)	7.95
Elastic Modulus (Gpa)	193
UTS (Mpa)	670
Yield Strength (Mpa)	360
Elongation (%)	43
Poisson ratio	0.3

Nylon-based was used for the material of the balloon [20]. Linear flexible material models used to portray the mechanical behavior of the components. De Beule et al. [4]research the sending of inflatable expandable coronary stents and work for the finite element method. Balloon elastic behavior was described using Young's moduli of 920 MPa, 1 GPa and 62 GPa and Poisson's ratios of 0.4. For the simulation, Mooney–Rivlin description used to model the balloon with a hyperelastic material

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TABEL IV. RESULT OF VON MISES STRESS FOR BX VELOCITY

Size of elements (mm)	Von mises stress (Mpa)
0.4	350.5
0.3	385.98
0.2	401.41
0.1	443.38
0.05	449.35
0.025	449.35
0.00125	449.35

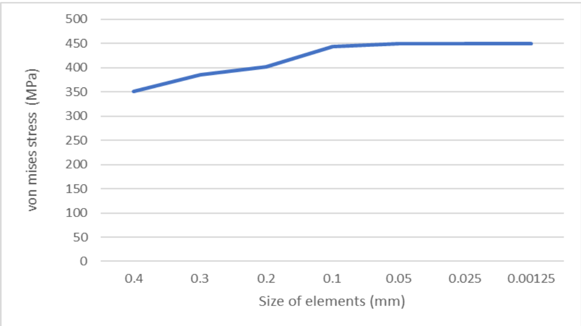


Figure 5. Meshing Sensitivity test

TABEL V. PARAMETERS USED FOR THE STENTS

Stent	Elements
A	10060
B	26140
C	99050
D	69593
E	127050
F	85710

TABEL VI. PARAMETERS USED FOR THE BALLOONS

Stent	Elements
A	9099
B	22450
C	98051
D	68444
E	112090
F	83433

E. Loading and Solution

The expansion of the stent was mimic by performed the numerical solution. The pressure was applied to the internal of the stent for a constant rate of 0.4 MPa from 0 MPa to 1.2 MPa without considering the existence of the balloon. Next, the same pressure applied to the internal of the stent at a constant rate considering the existing of the balloon. The stent expanded due to the pressures that simulate the blood flow in the artery.

III. RESULTS AND DISCUSSION

A. Validation

To validate the present method, the models identical to those presented by [21] were constructed with the results obtained with the present study. Von Mises stress obtained in the stent demonstrates that the outcomes are in great understanding for the validity of the present result. Fig. 6 show the previous study while Fig. 7 shown the present study. Based on both results of the study, the percentage difference was 8.02% and acceptable

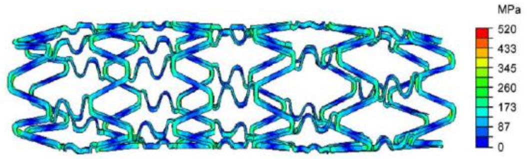


Figure 6. Von Misses stress of previous Bx Velocity stent [21]

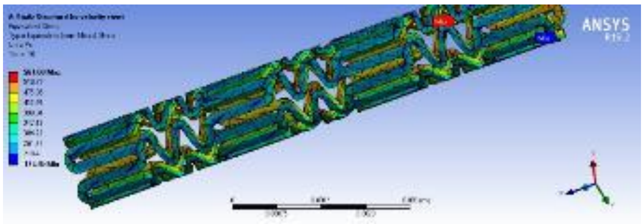


Figure 7. Von Misses stress for present work

B. Outer diameter changes

For the results of the stent deployment simulation using FEA, the main objective is to study the stent deformation during deployment. Organization of the stent during inflatable development at various time steps shown in Fig. 8. The stent could expand radially outward because of the pressure applied to the inner surface of the balloon and then inflates the balloon. Fig. 9 show the deformation of the stent at different time steps. Table 7 shows the increment of the diameter of the stents during deployment. The stent expanding twists consistently its outspread way by using the stainless steel. Stent expansion during balloon inflation considered realistic as can be seen in Table 7 and Figure 10.

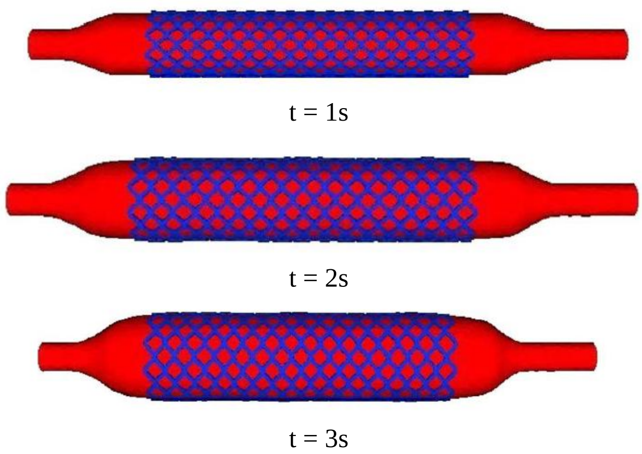


Figure 8. Deployment of the AVE S7 stent during balloon expansion at different time steps

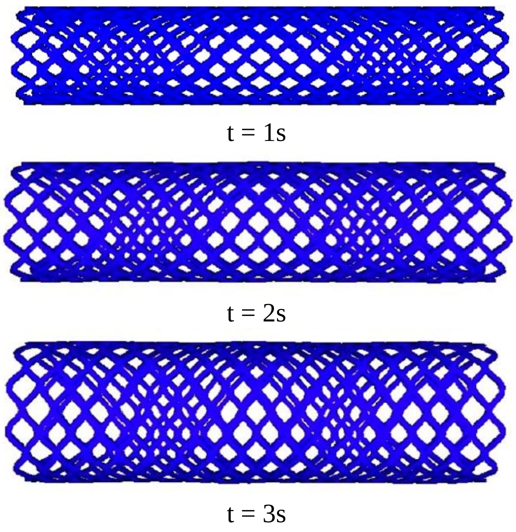


Figure 9. Deformation of the AVE S7 stent at different time steps.

TABEL VII. INCREMENT OF STENT DAIMETER DURING DEPLOYMENT

Stent	Outer diameter (mm)	
	Initial	Last
A	3	4.74
B	3	4.07
C	1.4	2.21
D	1.18	3.04
E	7	11.06
F	1.4	2.34

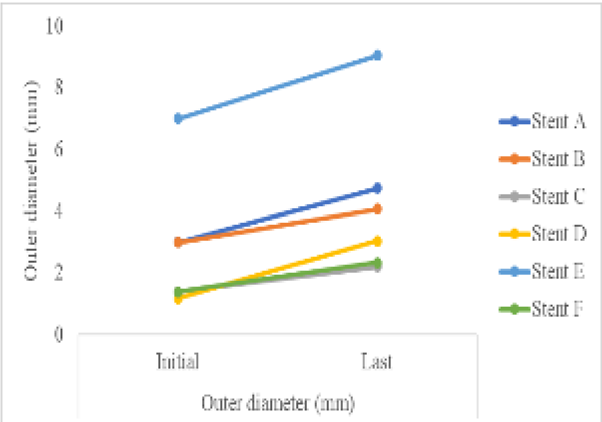
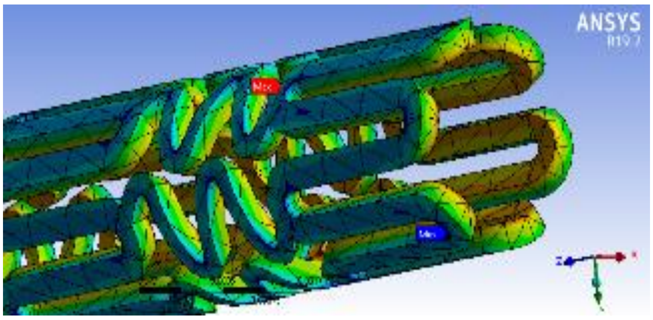


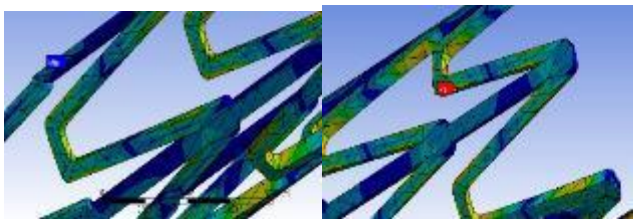
Figure 10. Outer stent diameter variation during simulation

C. *Stress distribution*

The performance of the stent could be determined from the stress distribution to find out its weakness and strength to minimize vascular injury. During deployment, the distribution of stress varies along the stent. In the last phase of expansion, the estimation of the most noteworthy pressure shows up as the Von Misses pressure pursues a direct variety during the whole simulation. These qualities are basic and significant for recoil and failure investigation. It tends to be inferred that the pressure conveyance is a component of stent geometry, inflatable and stent material properties, and pressure. Fig. 11 demonstrates the maximum and minimum Von Mises stress for the study stent.



(a) Bx Velocity



(b) SMART

Figure 11. Maximum and minimum Von Mises stress Bx Velocity and SMART stent after expansion.

The appropriation of von Mises stress in the six-stent models is appeared in Fig. 12 at greatest extension moment. As can be found in this figure, the estimation of greatest stress in the stent is 297.7 MPA, 254.7 MPa, 300 MPa, 520 MPa, 100 MPa and 350.6 MPa for NIR, Multi-Link, AVE S7, Bx Velocity, SMART and Palmaz, respectively as shown in Table 8. While Table 9 shown the value of maximum stress for the expansion of the stent with a balloon. The distribution of the maximum von Mises stress in the expanded stent as illustrated in Fig. 12 for the six geometries examined. The most elevated stent stresses are in the territories where greatest changes happened in stents diameter. Conceivable harm to the artery may happen at these basic focuses.

TABEL VIII. ANALYSIS OF STENTS WITHOUT BALLOON

Stent	NIR	Multi Link	AVE S7	Bx Velocity	SMART	Palmaz
Maximum Stress (MPa)	161.5	123.5	150.6	282.64	66.71	198.8
Maximum Von mises stress (MPa)	297.5	254.7	300	561.68	100	350.6
Maximum total deformation (m)	3.85e-13	2.22e-13	3.32e-13	1.12e-13	0.22e-13	1.16e-13

TABEL IX.ANALYSIS OF STENTS WITH BALLOON

Stent	NIR	Multi-Link	AVE S7	Bx Velocity	SMART	Palmaz
Maximum Stress (MPa)	297.5	254.7	300	520	100	350.6
Maximum Von mises stress (MPa)	332.5	287.7	330.5	570.7	118.2	360.9
Maximum total deformation (mm)	3.46e-13	2.02e-13	3.12e-13	1.01e-13	0.13e-13	1.09e-13

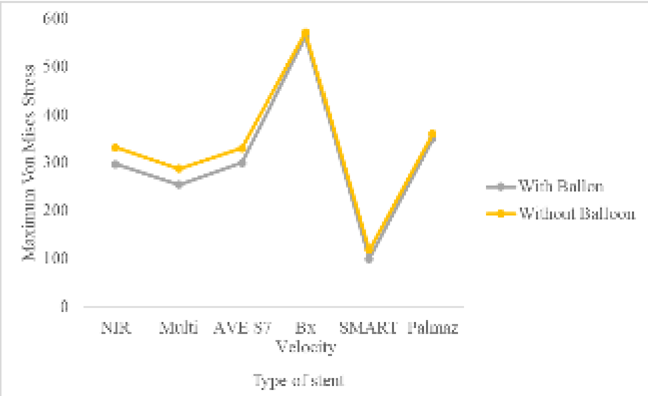


Figure 12: Distribution of maximum Von Mises stress of stent

IV. DISCUSSION

It was very crucial when designing geometry stents as demonstrated by FEA in this study. The pressure was subjected within the stent and expandable balloon during the deployment process. However, cyclic blood pressure load to the stent would affect the stent in the long term. Structural behavior of the stent could be improved by optimizing the stent geometry and the stress could be reduced during the deployment process.

When designing the stent, two different failure possibilities must be alert. Firstly, deformation of plastic involving a great deal during the initial deployment of the stent due to the expansion of the balloon inside the artery. Another possibility of failure is due to cardiac pulse pressure that causes a great number of arterial dilation.

Clinical complications due to fatigue failure of these devices are important for the designer to design the best stent. More sophisticated numerical models needed to improve and develop by optimizing the design of the stent in the future so many lives could be saving.

V. LIMITATIONS

So far, the analysis showed positive results for stent deployment but the interactions between the stent and fatty layer or plaques did not take into account. However, the plaques not fully required in this study although it is important to determine the stress distribution of the stent.

Next, geometry and material models that were generated suffer from the limited number of dimensions as the previous study did not put full information. So, the model build represents merely an approximation of the actual stent model. This limitation should not harm the results of the analyses as the data referred from many sources.

VI. CONCLUSION

An analysis study of comparison conduct of various stent structures had been available in this paper and can be utilized as a basic and affordable option for confused clinical investigations.

The model including a stent, balloon, and internal pressure had been designed to accomplish an increasingly practical portrayal of the stent implantation technique. Comparison of a stent in this study involving six different types of commercially stent design.

Three-dimensional stent model and balloon had been simulated by FEA to study the stress distribution and deformation during deployment of the stent. The design of future stents would be great as the computational method provides a very useful tool. Experiments are expensive and difficult to perform making computational study important. Result in this paper can be used for future study to optimize the stent design. Finally, the connection between the in-stent restenosis and the geometrical plan is very difficult to investigate from such analysis in this paper.

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