Stent Classifications and Effect of Geometries on Stent Behaviour Using Finite Element Method

Abdul Fattah Mat Beyi *, Al Emran Ismail, Ishkrizat Taib, Mohd Norihan Ibrahim
Faculty of Mechanical and Manufacturing Engineering (FKMP), Universiti Tun Hussein Onn Malaysia (UTHM), Batu Pahat, Malaysia
Email: abdfattah43@gmail.com, emran@uthm.edu.my, al_emran@hotmail.com

***Abstract*— For the past year, stents have become very important in medical and engineering field. Hundreds of stents have been designed to solve the problem of lesion and anatomy. Design of new stent is needed so uniform drug distribution to the vessel wall and lumen gain at the time of stent implantation would be maximized, also distribution of the stent to the lesion would be ensure its reliability. This article explained about various design of stent that have different geometries and shape and withal to study the effect of different design of stent on clinical outcomes. Different structures of intravascular stents have diverse in stent restenosis that was used to prop open artery diseases routes. Majority of economically accessible stents are planned conventionally to fit all patients. Considering the assortment of injury types, it is visualized that better results will be accomplished if a stent is hand crafted so that it has variable outspread firmness longitudinally to hold the changing weight of plaque and sound course in the meantime while keeping up an adequate lumen distance across. The essential point of this review is to describe previous stent designs for an arrangement of plaque types and research of the lumen after stent implantation. Limits consistence by stent geometry of topology enhancement because of plaque materials and different stenosis levels.**

***Index Term*— stent, lesion and anatomy, stent implantation, clinical outcomes**

I. Introduction

During the most recent 20 years, many meditations for coronary diseases have been tested by medication and engineering involving the design of stent. Inflatable angioplasty procedure after the inflation of the stent to remove plaque need to handle carefully and safe strategy for the safety of the patients. Two milestone ponders have demonstrated that balloon expandable stents, opened tube, tempered steel, could altogether diminish restenosis rates in chosen sores. Various research and study about stent have expand and develop from time to time until too many designs of new stent have been proposed. Stent material also plays an important part in the technology.

Atherosclerosis is a disease in which plaque builds up inside the arteries. Part of body that carry oxygen to heart called artery or blood vessels. Blood with oxygen was carried out by artery. The plaque is the main reason why the artery is narrowing or blocked. Plaque consists of fat, cholesterol, calcium and other substances in the food that human take every day. Dynamics of blood flow is called hemodynamics and the circulatory system is controlled by homeostatic mechanisms. This hemodynamic continuously response and adapt to the conditions and environment in the body. This concept explains the physical law that control the blood flow in the artery. When this happened, cardiovascular disease or restenosis occurred as the blood flow is blocked by the plaque. Bypass surgery is the most popular surgical to overcome this blocked artery. However, there are several problems with this in-stent restenosis which are accumulations of plaque after implantation, injuries of artery wall and fracture of stent due to the interactions of hemodynamic and artery wall. Failure of stent was due to the cardiac pressure causing high number of arterial dilations, long term fatigue failure may occur [1]. Stress concentration causing damage or microcrack at surface irregularities also one of the main factors of fatigue failure of balloon expandable stent during expansion of balloon because of high deformation of plastic. A wide research needed to study the performance of stent during the stent implantation to decrease the rates of stent failure.

II. Classification of Stent

Stents can be classified according to their mechanism of expansion which are self-expanding and balloon expandable, their composition such as stainless steel, tantalum, nitinol, cobalt-based alloy, inert coating, active coating, or biodegradable, and their design such as slotted tube, mesh structure, ring, coil, custom design and multi-design.

Stents are divided into two type which are balloon expandable stent and self-expanding stent. A good stent must exhibit biocompatibility and excellent resistance to corrosion. As MRI test done, the results of the stents must show that the stents adequately radiopaque and must create minimum artifacts. Materials that have high deformation of plastic during balloon inflation are very suitable for balloon expandable stents. As the balloon is deflated, the stent remained in its expanded shape. Low yield stress of stent is very useful as at the manageable pressure of balloon, it can deform and for minimal recoil, it must possess high elastic modulus. Usually, manufacturer produce self-expanding stent in its expanded shape. This type of stent ideally has high yield stress and

Manuscript received July 3, 2019; revised January 5, 2020.

doi: 10.18178/ijmerr.9.3.329-340

low elastic modulus for large elastic strains. Self-expanding stent are being used a lot in medical to treat occlusions in endovascular arterial lumens where narrowing of the blood vessels caused by accumulations of plaque. Fig. 1 shown the mesh tube structure Nitinol stent.

316L stainless steel is most typically used material for stents because of its resistant of corrosion behavior material consists of low carbon content and addition of niobium and molybdenum. Moreover, easily deformable nature of stainless steel and exhibits enough elasticity for certain self-expanding stent designs. Other material used are shown in Table I.

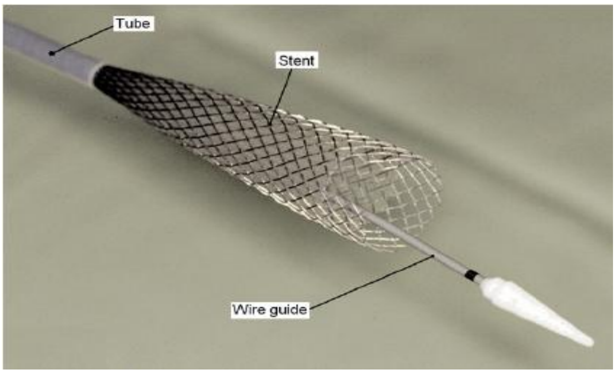


Figure 1. Self-expanding stent [2]

TABLE I. OVERVIEW OF MATERIALS UTILIZED IN STENT MANUFACTURE [3]

Material of the Stents	Balloon Expandable Stents (BE)	Stainless Steel (316L)	Vast majority of BE
		Tantalum	Medtronic: Wiktor
			BSC: Strecker
			Cordis: CrossFlex
		Martensitic Nitinol	PAS: Act-One
			Vascular Therapies/US Surgical: Paragon
		Platinum Iridium	AngioDynamics: Angio Stent
		Polymers	Igaki-Tamai Stent, Tamai Medical, Biodegradable PLLA
		Niobium alloy	InFlow Dynamics: Lunar StarFlex
		Cobalt alloys	
	Self-Expanding Stents (SE)	Superelastic Nickel-Titanium	Majority SE
		Cobalt alloy	BSC: Wallstent
			BSC: Magic Wallstent (latinum Core)
		Full Hard Stainless Steel	Cook Z-Stent

Stents are made of from wire, sheet or tubing with the majority are from wire or tubing as shown in Table II.

TABEL II. OVERVIEW OF STENT FORMS [3]

Form	**Tube**	Majority
	Wire	BSC: Wallstent (Cobalt alloy)
		Medtronic AVE: Bridge, S7, S660 and S670 (Stainless Steel, Welded rings)
		AngioDyamics: AngioStent (Platinum Iridium
		BSC: Strecker (Tantalum)
		Medicorp: Expanded (Nitinol)
	Sheet	BSC/Medinol: NIR (Stainless Steel)
		Navius: ZR1 (Stainless Steel)
		Cook: GRII (Stainless Steel)
		Endotex (Nitinol)
		Vascular Architects: aSpire (Nitinol)
	Ribbon	Endocare: Horizon Prostatic (Nitinol)
		InStent: EndoCoil, Esophacoil (Nitinol)

Braiding, coiling and knitting are the ways how the wire was formed with the coiling is the simplest one. Fig. 2 show BSC 'Symphony' self-expanding Nitinol stent type. It was a closed cell wire stents that have been welding at specific locations after wire forming to increase longitudinal stability such as balloon expandable stent, Cordis 'Crossflex' stent type. While Walls tent BSC, self-expanding wire-based stent was the common braided design using various cobalt based alloy as shown in Fig. 3. Table III show the overview of stent fabrication.

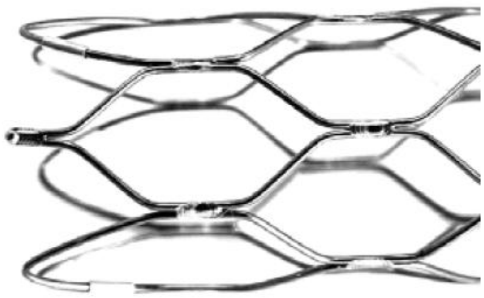


Figure 2. Symphony Nitinol stent, a closed cell wire stents structure [3]

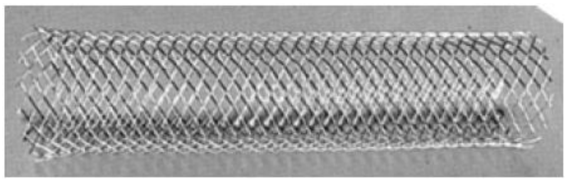


Figure 3. Cobalt alloy wire stent, a braided stent named Wallstent [3]

TABLE III. OVERVIEW OF STENT FABRICATION [3]

Fabrication of the Stents	Laser cutting	Majority
	Photochemical Etching	BSC/Medinol: NIR
		Interventional Technologies: LP
		Endotex (nitinol sheet)
		Vascular Architects: aSpire (coiled nitinol framework, ePTEE covering)
	EDM	Cordis: Palmaz (early production)
	Water Jet	St. Come: SCS-Z Stent
	Braiding	BSC: Cobalt Alloy WallStent
	Knitting	BSC: Tantalum Strecker
	Vapor deposition	

III. Geometries of the Stent

Palmaz Schatz stents, a slotted tube geometry was one of the early designs of the stents while Gianturco Rpubin Flex stent early designs of the coil geometries. Although slotted tube had excellent radial strength, they lack flexibility. Nowadays, marketing crowded with the new design of stent to produce the stents that have both strength and flexibility. Stent geometries has been classified into five high-level categories which are coil, helical spiral, woven, individual rings, or sequential rings,

Coil design is the most common non-vascular applications as these designs allows for retrievability after implantation. Their strength is limited but extremely flexible results in high profile device because of low expansion devices. Example of the Instent Esophacoil device shown in Fig. 4. Different with helical spiral design, they are advanced in adaptability but need longitudinal help. The Crossflex stent delineated in Fig. 5 is one of the examples.

Figure 4. Esophacoil coil stent fabricated from nitinol ribbon [3]

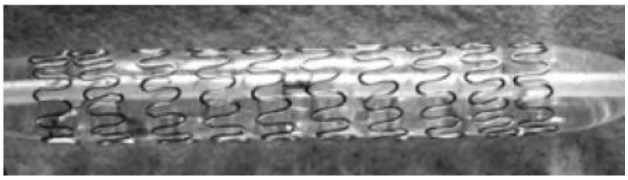


Figure 5. Minimally connected helical spiral Crossflex stent fabricated from stainless-steel wire [3]

This classification incorporates an assortment of designs developed from at least one strands of wire. Meshed plans are frequently utilized for self-expanding stent geometries, such as WallStent shown in Fig. 5. As the plans gave fantastic inclusion, they regularly abbreviate generously during expansion. The outspread quality of such a twisted structure is additionally exceptionally subject to pivotal obsession of its closures. Cook ZA stent in Fig. 6 exhibits a self-extending knitted nitinol wire design.

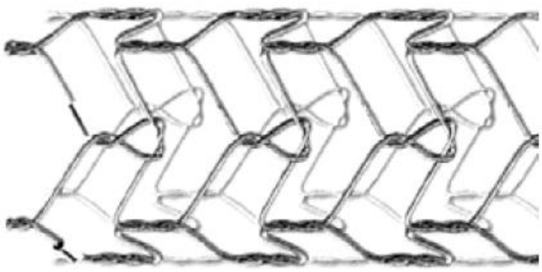


Figure 6. Knitted nitinol Cook ZA wire stent design, sleeve-type gold markers [3]

Sequential rings stents are series of expandable Z-shaped geometrical elements knowns as struts and bridges as its connecting elements. Coronary metal stents can be described and isolated into two types of groups known as open and closed cell configure. The difference between these two stent is open cell change adaptation of the region when the cells are develop while close stent design do not change the adaptation of the region when the stents are flexed. Fig. 7 shown geometry of the stent with adapted profile and variable stiffness sections while Table IV shown the stent geometry of the stents.

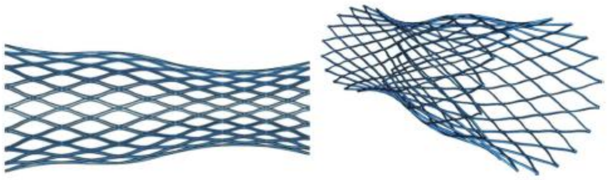


Figure 7. Adapted profile and variable radial stiffness sections stent geometry [4]

TABLE IV. Stent Geometry of the Stents [3]

Stent geometry of the stents	Helical Spiral	Periodic Peak-Peak Connections	Cordis: CrossFlex LC
			Orbus Medical: Coronary R-Stent
			JOMED: JOSTENT Flex
			Igaki-Tamai Stent (biodegradable polymer
		Nominal Connections	Cordis: Crossflex
			Cook: Freedom
		Axial spine	AngioDynamics: OmniFlex and VistaFlex
			Cook: Gianturco-Roubin Flex-Stent
			Cook: GRII
		Integral with graft	Gore: Exluder endoprosthesis support structure
			Gore: Hemobahn endoprosthesis support structure
			World Medical: Talent support structure
	Woven	Braided	BSC: Wallstent (Cobalt alloy)
			BSC: Magic Wallstent (Cobalt alloy, platinum core)
			Medicorp: Expander (Nitinol)
			Stent Tech: Pyloric/Billary (Nitinol, covered or bare)
		Knitted	BSC: Strecker
			Medtronic: Wiktor
			Cook: ZA Stent
	Coil	Engineers and Doctors: Memokath (Nitinol Wire)	
		Endore: Horizon Prostaic (Nitinol Wire)	
		IntraTherapeutics: Intarcoil	
		InStent: Esophacoil, Endoil (NiTi Ribbon)	
		InStent: CardioCoil, VascuCoil, ProstaCoil (NiTi Wire)	
		Vascular Architects: aSpire (coiled NiTi framework, ePTEE covering	

Single Z shaped rings are typically used to help joins or comparable prostheses as they can be exclusively sutured or generally connected to the unite material during manufacture. These geometries as vascular stents are not regularly utilized alone. Individual rings stent geometry shown in Table V.

TABLE V. INDIVIDUAL RINGS STENT GEOMETRY [3]

Individual rings	World Medical: Talent Support Stents (Nitinol wire with backbone
	MinTec: CraggStent (Nitinol wire) (peak-peak structure connections)
	Meditronic: AneuRx support stents (Nitinol)
	Cook: Zenith AAA Support Stents (Steel Wire)
	Cook: Z-Stent (Stainless Steel Wire)
	Cordis: Teramed AAA leg support stents (Nitinol)

Fig. 8 shown Palmaz Schatz stent, early generation of slotted tube designs, for example, yet unyielding. Fig. 9 shown NIR stent, an updated geometrical design of stent, enhanced this idea by including a flex connector. U, V, S and N molded components plastically distort amid twisting, enabling neighboring auxiliary individuals to separate or home together, to more effortlessly suit changes fit as a fiddle. In any case, these focal points gave result to geometrical that was commonly less adaptable than a comparable open cell design. This condition is commonly just conceivable with regular peak to peak associations as shown in Table VI.

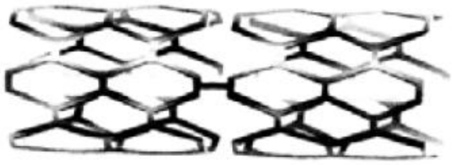


Figure 8. Palmaz Schatz, early generation of slotted tube closed cell stent [3]

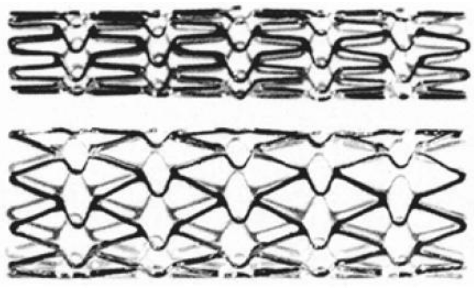


Figure 9. V flex hinges of NIR closed cell stent [3]

Figure 10. Self-expanding SMART stent open cell with periodic peak-to-peak non-flex connections sequential ring design [3]

This classification portrays development wherein a few or all the inner articulation purposes of the auxiliary individuals are not associated by bridging components. Intermittently associated top to-top structure is basic among self-expanding type stents, for example, the SMART stent shown in Fig. 10, and balloon expandable type stents, for example, the AVE S7 shown in Fig. 11. Fig. 12 shown ACS Multilink, peak to valley connectors, essentially wipes out foreshortening and guarantees that adjoining auxiliary pinnacles are adjusted top to-valley all through the development scope of the stent, enhancing framework qualities. As peak-to-peak peak-to-valley connections associations are most normal, there are likewise precedents of different varieties, for example, the BeStent shown in Fig. 13 knows as mid-strut to mid-strut connectors. At last, the Fig. 14 shown Navius ZR stent that is an extraordinary tightening plan that resists categorization.

TABLE VI. CLOSED CELLS OF SEQUENTIAL RINGS STENT GEOMETRY [3]

Closed cell	Regular peak-peak connections	Non flex-connectors	Cordis: Palmaz
			Cordis: Crown, MINI (sinusoidal struts)
			BSC: Passager (with graft)
			St. Come: SCS
		Flex-connectors	BSC/Medinol : NIR NIRROYAL (“V” hinge)
			Cordis: BX Velocity (“N” hinge)
			Cordis: Palmaz Genesis (“N” hinge)
			Cordis: Palmaz Corinthian IQ (“omega” hinge) (sinusoidal struts)
			Stent Tech (‘S” hinge)
			US Surgical / Vascular Therapies: Paragon (“N” hinge) (Martensitic Nitinol)
			Uni Cath: IRIS (“C” hinge)
			JOMED: JOSTENT Plus (flex hinge integral to strut design)
			InFlow Dynamics: Antares Staflex (Stainless Steel)
			InFlow Dynamics: Lunar Starflex (niobium alloy, iridium coating
		Combined Flex/Non Flex-connectors	PlasmaChem: BioDiamond (non-flex + “ omega” hinge)
			Devon: Pura (“V” hinge
			Phytics: Diamond Flex AS (“U” hinge)
			St Come: SCS-Z (non flex + “Z” hinge)
		Hybrid	JOMED: JOSTENT Sidebranch, JOMED Bifurcation (Combination of JOMED “Plus” and “Flex”0

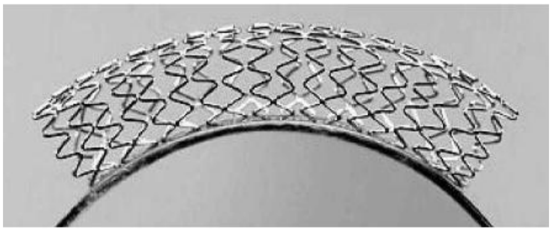


Figure 11. Balloon expandable AVE S7 stent open cell with periodic peak-to-peak non-flex connections sequential ring design [3]

Figure 12. Balloon expandable ACS Multilink open cell with peak-to-valley connections sequential ring design, [3]

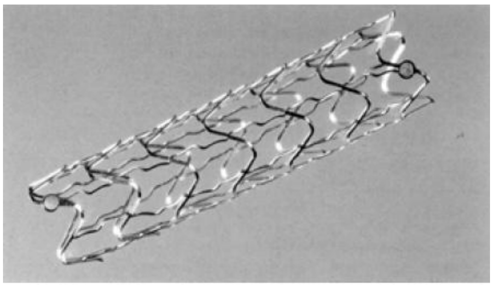


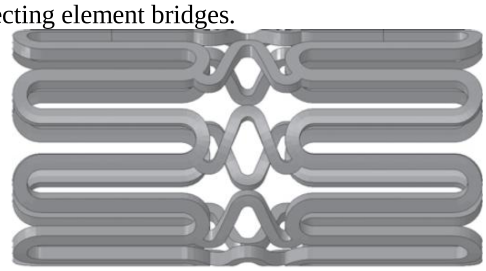
Figure 13. Balloon expandable BeStent open-cell, with integral gold markers and midstrut-to-midstrut connections sequential ring design [3]

Figure 14. Stainless-steel sheet ratcheting Navius ZR1 stent design [3]

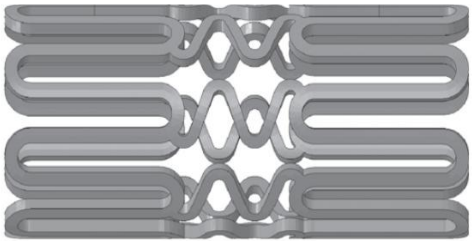
IV. Previous Work of FEA on Stent

According to the research by Puértolas et al., (2017), they proposed a tube based model stent with closed diamond shape, Palmaz Schatz type or coil type geometries using finite element ABAQUS to determine the behavior of stent by using several factors such as length of slot , circumferential slots number, tube thickness and shape of the stent. First factor which is slot length varying from 8mm to 18mm by fixed the other two factors. The force is between 10 and 25 N for an inner diameter variation while using the diameter larger than 20mm, 16N is the maximum force of the stent. For circumferential slots, the simulation proved that the force will be between 10 and 40 N by using the circumferential grooves from 24 to 48. Tube thickness of the stent was changed from 12 to 26 mm resulting the force became 6 and 16 N Variations of the thickness of tube produce the lowest Chronic Radial Expansion Force (CEF).

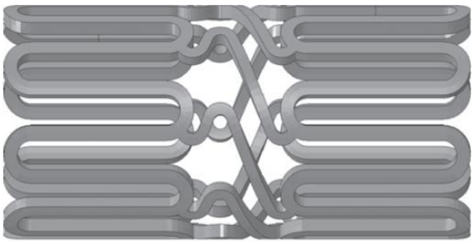
McGrath, O'Brien, Bruzzi, & McHugh, (2014) study the effect of bridges geometry of the stent on the structural behavior of the stent by using numerical investigations performed by ABAQUS. Stainless steel material AIS1316L balloon expandable stent was used in this investigation to discuss about it structural behavior which are bending, torsion and expansion. According to the simulation, different bridges give different maximum stress of magnitude. Unsymmetrical bridges are considered more flexible than symmetrical bridges at the early stage of bending. Symmetrical N-shaped bridges is two times more flexible than symmetrical V-shaped. Different with unsymmetrical V-shaped that is two times less flexible than unsymmetrical N-shaped. Flexibility of the stent is lowest by symmetrical V-shaped and symmetrical N-shaped gave the best flexibility of the stent. Symmetrical N shaped and unsymmetrical V shaped gave same magnitude of the rotation proved that same torsion obtained by two different bridges is possible. Torsion and bending of the stent are the best in term of flexibility by using the symmetrical N-shaped and unsymmetrical V-shaped. Previous study gave result that can be concluded, the stent flexibility can be improved by optimizing the bridges shapes and its structure. Fig. 15 shown types of connecting element bridges.



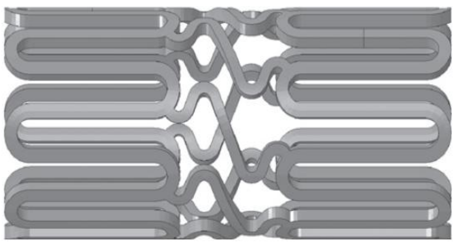
(a) V shaped bridge



(b) N shaped bridge



(c) Unsymmetrical V shaped bridge



(d) Unsymmetrical N shaped bridge

Figure 15. Type of bridges geometry [3]

There are also stent that covered by the coating. This coating are useful in the study of the stent to prevent restonosis and thrombosis after transluminal angiplasty. 316L stainless steel (alloy) is a most common material of stent used. Biocmopatible material are used to covered the stent for aneurysm after vessel injury. Strut thickness plays an important role related to restonosis where as the thickness increase, radiopacity and radial force will increase and will have better support of arterial [6]. However, it will increse the chance for the injury of the vessel wall. This case provide balance within thickness of struts and give long term results. Example of coating is heparin coating, phosphorylcholine coating, gold coating, silicon carbide coating, and others materials such as anti-proliferative drugs with and without polymer. Tubular designs of stent give better result than coil stents while gold stent does no decresase restonosis. Silicon carbide, Heparin and phosphorylcholine did not show the superioty over stents that is standard bare metal. It shown that even drug eluting stent has limitations.so, while improving the design of the stent, these coating also must advanced with the technology.

Plastic deformation of the stent material can be found by using crystal plastic theory and flow theory [7]. Two different result was shown by both theory to find the ballon expandable mechanical behaviour. Material microstructure of crystal plastic theory shown non unifor localised stress and strain fields, different with flow theory that varying smoothly. Structure and long term behaviour of Palmaz stent investigated shown that migration risks can be prevent by knowledge of stent recoil to adapt angoplasty balloon [8]. Linear buckiling refer to the stent that provide uniform external and assumed elastic. Buckling means that the stent develop to a new deformation. Eigenvalue buckling easy to find and manage but lack imperfections and usally overestimates the critcial load.

Study on patients with coronary artery disease using different type of stent design was eligible and tested according to the pricnciple of the Declaration oh Helsinki and was given licence by ethics committees [10]. Five stents used were Inflow, Multi Link, NIR, Palmaz- Schatz and PURA-A stent. All these stents are 316L stainless steel and have same material composition. For the first month, there was no significant difference outcome but the clinical result for 6 month and 1 year shown parallel manner depend on the design of stent. Thiss reseach prove that stent design have impact for a long term result of coronary displacement.

New generation of stent are expanding day by day as the design have been modified to imporove safery and precutaneous coronary intervention. Small diameter of stents becomes a choice as the diameterr of vessels is small and more easier to treat abrupt closure or acute. For example, Bx Velocity coronary stent is a new design develop from original Palmaz-Schat and Cown stent [10]. This new design of stent have strong scaffolding and great flexibility, S-shaped that support each closed cell connecting to each other shown in Fig. 16.

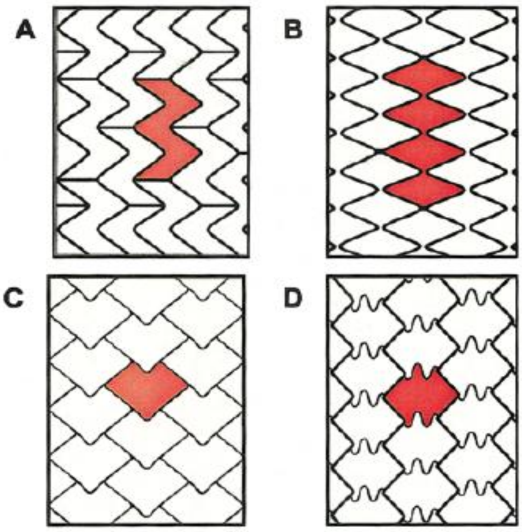


Figure 16. Tetra open cell design (A), S670 (B), NIR closed-cell design (C) and Velocity (D) stents.

S670 coronary stent evolves to S7, a seven crown, ring geometry consist of repeating ellipto rectangular elements. S7 has greater flexibility and scaffolding shown in Table 2 compared to S670 as the stent is arranged in a 10 crown design that characterised by shortened elements range from 1.0mm to 1.5mm. Because of the limitations to small diameter, S8 was designed made from cobalt chromium. Thinner strut thickness give advance as it can retain opacity and radial strength. Another example of stent is laser cut, slotted tube BeStent 2. Rotational expansion of ballon inflatation of V and S shaped crowns that permitted. Alhough diameter of BeStent 2 less than 3mm, it help in small coronary arteries. NIR Elite and NIROYAL stent was designed to provide greater flexibility that retained high radial strength with low crossing profile. Each of the cell are cconnected close to each other till there are no more internal loops or ends that free that can release the plaque. The efficacy of the selected stent as investigated by Kandzari et al., 2002 was illustrated in Table VII and Table VIII. Scale 1 was the worst and scale 5 was the best.

TABLE VII. STENT CHARACTERISTIC WITH DIAMETER LESS THAN 3.0MM [11]

Stents > 3.0 mm diameter	BX Velocity	BeStent 2	Penta	S7	NIR	Palmaz-Schatz
Scaffolding	5	5	4	5	5	3.5
Flexibility	4	4	4.5	5	4	2
Confornmity	4	3.5	4.5	5	3	4
Radial strength	5	5	4.5	4.5	5	4.5
Visibility	5	5	5	4	3	3
Side branch access	3.5	3	4	4	3	3
Size and lengths	4.5	4.5	5	4.5	4	2
Ostial placement	Yes	Yes	Yes	Yes	Yes	Yes
securement	5	5	5	5	4.5	5
Deliverability	5	5	5	5	5	2

TABLE VIII. STENT CHARACTERISTIC WITH DIAMETER MORE THAN 3.0MM [11]

Stents > 3.0 mm diameter	BX Velocity	Pixel	S660	NIR
Scaffolding	5	4	4.5	5
Flexibility	4	4.5	5	4
Confornmity	4	4	5	3
Radial strength	5	4.5	5	5
Visibility	5	4	5	3
Side branch access	4	3	4	2
Size and lengths	3	4	4	3
Ostial placement	5	5	5	4
Securement	5	5	5	5
Deliverability	4.5	5	5	4.5

Palmaz-schatz is the most popular stent for tubular type made by Johnson company while most typical coil stent is made by Global Therapeutics [9].Turbular stent TS1 consists of slotted tube about 8mm in length and the TS2 have same geometry but with two times strut thickness was proposed by [9].The other one is coil stent divide into two model CS1 and CS2 in the form of helical round wire. The geometries were same but the height of CS2 was twice of the CS1. This was intended to study the impact of these dimensions on mechanical behaviour. ABAQUS finite element was used. Result shown that stent deployment pressure for TS (2.10 atm) was significantly higher than CS (0.71 atm). Elastic recoil or the condition of the diameter of the stent at the end of inflation shown seen more flexible in TS1 compared to TS2. This is due to strut thickness of TS1 that is less thick. For coil stent, elastic recoil for CS2 in more than CS2 due to height of CS2 that is twice than CS1. Result of stiffness shown that increase the height of CS will decrease the stiffness. Conclusion that can be made from the study in turbular type stent is more rigid while coil stent is more flexible.

3D diamond shape intravascular stent as proposed by Imani et al., (2015) to investigated stent perfomance using different design was compared with GEO1 model that has a corrugated ring ring pattern and GEO2 model that exhibits a cellular geomtry as shown in Fig. 17. For 3D diamond shape stent, radial coil seen not influenced by the thickess variation and increasing the length of slot will result in increasing of the radial recoil (19). Distribution of Von Mises stress along the stent were concentrated in the area of connection between slots as expected can be seen in Fig. 3. In model GEO1, the expansion is smaller causing by the inclusion of the ballon that mitigated or reduce. Distal radial expansions for GEO2 is almost same with GEO1 but the no sight of the dogboning effect. Diamond shape (DS) model have same radial recoil with GEO2 but the longitudinal recoil is negligible. GEO1 and GEO2 as in Fig. 18 shown the Von Misses contours value and higher value of foreshortening compared to diamond shape stent.

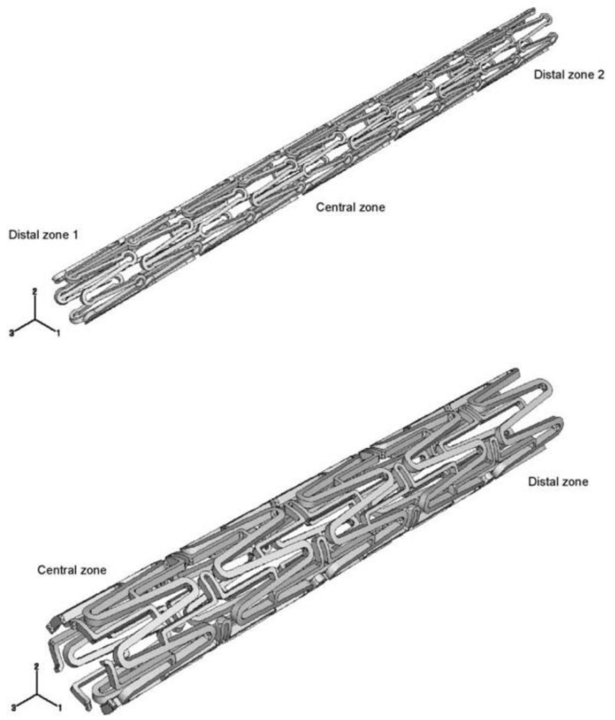


Figure 17. GEO1 (top) and GEO2 (bottom) model

Self expanding Cordis SMART stent investigated by Ghriallais & Bruzzi, (2014) divided by three different geometries which are 1/6th unit cell constraints, 2-ring unit cell periodic and full stent structure [12]. Full stent geometry gave the highest maximum strain result compare to the others. Same stent by Azaouzi et al., (2013) simulated using ABAQUS to find stent deployment shown that the stent expand progressively follow the loading path of the curve inside the artery and the tip region of the bridges was where the fatigue fracture occured [13]. Self expanding Nitinol type stent was used to study the nature of the contact of the stent and artery by Azaouzi et al., (2012) and to determine the impact of different stent design on vessel wall [2]. Numerical studies shownn that as the strut thickness increase, the stent performance will increase as well the support of arterial wall, radial stiffness and radiovisibility. Studies by Kumar & Cui, (2016) also shown that as the strut thickness increase, the crimping stain directly proportional increase [14]. MAC-Plus stent placed concentrically over the folded balloon [15] were used to extract data such as deformation and and stress to find standard deviation and mean.

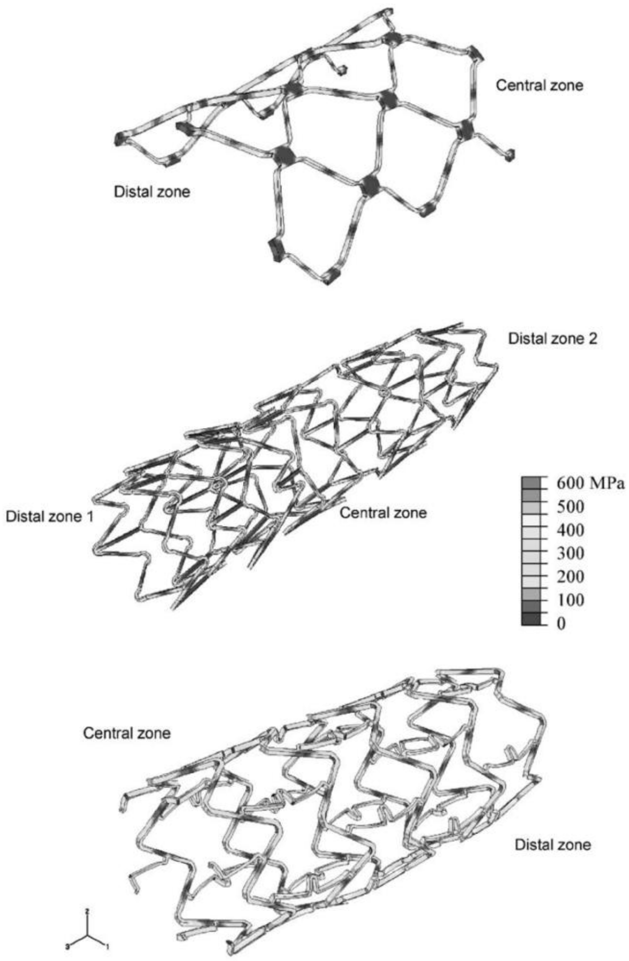


Figure 18. Von Mises contours for models DS, GEO1 and GEO2

Deployment analysis of balloon expandable BX-velocity stent varies with its length and and circumference significantly [16]. As the Palmaz-schatz and Freedom stent geometry were compared, these two types of stent show different quite behaviour. For the cases of the Freedom, plastic hinges formation at the geometry of the loop casuing limited radial expansion. While for Palmaz-Schatz, plastic deformation occur uniformly throughout the geometry. This was because the geomtrical construction of Freedom that that able to withstand initial cramping. Another study by Khosravi et al., (2017) of the Palmaz stent to investigate dogboning effect. Based on the simulation, functionally graded material (FGM) stents have much lower dogboning effect compared to metallic stents [18]. This was due to different mechanical propoerties of the stents that react differently to the plaques.

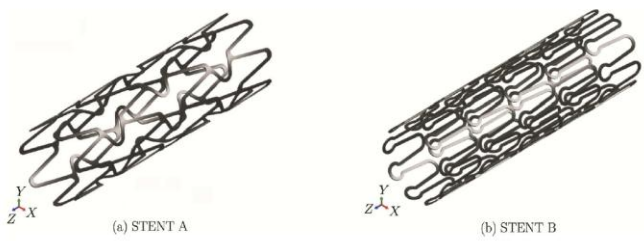


Figure 19. Geometry for (a) NIR and (b) Multi-Link stent

Comparison between NIR and Multi-Link stent (Fig. 19) in term of their behaviour during deployment were studied by S. M. Imani et al., (2015). Result obtained for Von misses stress was higher for NIR compared to Multi-Link as well as the maximum stress [19]. This result prove that using NIR stent was more dangerous as it will causing harm to vessel that will also increase the rate of restenosis. Stent design and geometrical of the stents plays an inportant role to find the correlation between the in-stent restenosis. Fig. 2 ilustrated Cordis BX-Velocity and Sirius Carbostent that have different geometry. From the analysis , it shown that CV model interpret independent response from the axis of solution while SV gave different response based on rotation axis [19]. This result because of the the different of geometry of the stent where one crest of SV stent that connected to the center of the ring, meanwhile CV model have two crest connected to the top of the ring as shown in Fig. 20.

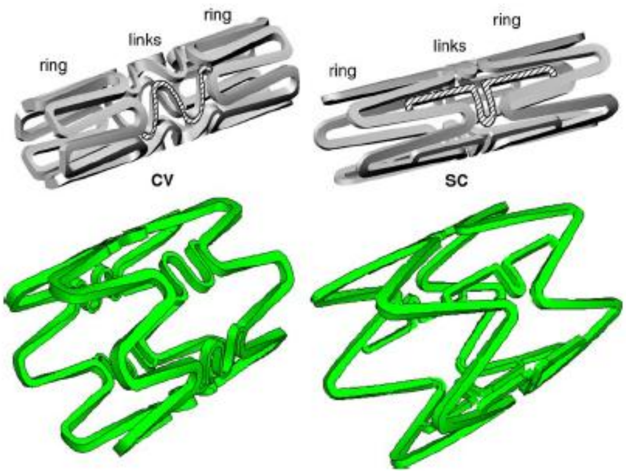


Figure 20. CV and SC structural models in the unexpanded and expanded configurations.

As the stent been redesigned its behaviour also will be different. For example Multi-Link stent that had six circumferential cells and links and the other one had eight circumferential cells and links proposed by Petrini et al., (2004). Compressive stress for M1 did not exceed 15kPa at the cells but greater at the links with the value of 70kpa. For M2, at the cells, it compressive stress greater than 15kPa but at the links only 40kPa. This was due to the nmber of circumferential cells and links as the angles increase due to the increasing the number of plygons [20]. A numerical analysis of interaction between balloon angioplasty and slotted tube stent during stent implantation were studied to obtain stress in the artery due to slotted tube interference [21]. ANSYS was used in this research focused about the mechanical properties of both tubular and coil stents by using ABAQUS [9]. The weakness of the geometry of balloon-expandable stents, the shortening percentage, longitudinal recoils and radial were investigated, generic part of the structure with periodic boundary conditions was used for special type of stent [22]. FEM studied of 2D unit cell to find balloon expandable using computational micromechanics by previous research [4].

V. Stent Fracture

Stent fracture is referring to the separate on stent struts incompletely or completely. Mindfulness has been raised to anticipate stent fracture. Stents may crack incompletely, or totally. Hence, a more drawn out individual up after stent implantation is required to to prevent long-term consequences.

Finite element analysis was a common software to find mechanical behavior and integrity of the stent as well to study the interaction and contact between the stent and artery of balloon expandable and self-expanding stent. Nowadays, stents were routinely and successfully used in the world of medical. However, research and development were still needed in order to improve and optimizing the design of stent and to overcome the long-term failure. With the perspective and view from the practices, the optimization of the stent design would lead to a better understanding of the failure of design and success of the design of stent and geometry. Most BE stents are made from laser cut tubing. For example in Nitinol stent case, stress was locally high at the corners, holes and joints and the failure may potentially occur at these locations [2]. During the implantation of the stent into the cloaked artery, its reliability wad determined by the design of stent which was a major factor that throughout in vivo service. For balloon expandable stent case, requirements such as good fatigue properties, high radial strength, good flexibility, low elastic radial and longitudinal recoil and optimum scaffolding needed to be considered when designing the stent. Due to cardiac pressure because of high number of arterial dilation, long term fatigue failure may occur [23]. Successful treatments for established in-stent restenosis depend on the practical elements underlie in stent restenosis that crucial to identify. From the research by Youngner & Kelly (1965), they state that most common cause of mortality in the developed world is failure of coronary circulation or heart disease [16]. It was very crucial as failure can happened when provide an adequate supply of oxygenated blood to the heart.

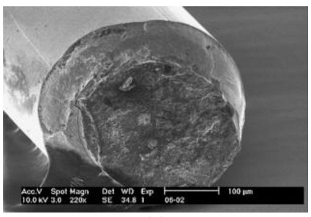
Development of stent designs day by day in today's market always increase and it is very necessary to understanding the effects and functions of each stent designs. When designing the stent, there were two different cases that should be considered. Firstly, possibility of failure occurs during using a balloon catheter inside the stenosed artery at the early deployment of the stent as the device was expanded which involves larges amount of plastic deformation. Secondly, long term fatigue failure also may occur as the number of arterial dilations caused by cardiac pulse pressure (typically 4 x10^7 cycles/year) higher. Fatigue failure could contribute to the medical complications as these devices was critical to the designers with deign lives of 10 to 15 years [23]. As stated by Bosiers, Scheinert, Simonton, & Schwartz, (2012) in their studies, thrombus formation, focal restenosis or in perforation of the vessel was one the cause failure of a stent [24].

Stress concentration occurred because of damage or microcrack at surface irregularities also one of the main factors of fatigue failure of balloon expandable stent because of high plastic deformation during expansion of balloon. High stress due to stress concentration was the starting point of the microcrack. It will rapidly increase until the critical zone break apart to brittle fracture but as the surface fail, there was no plastic deformation occurred. There were two phases of fatigue failure which can be observed. Firstly, first grain boundary from its growth up and crack initiation and the second one is crack of the strut's cross section remainder of subsequent propagation[23]. Physical test also can be done to evaluated fatigue life requirement, but it is very costly and consume more time. Heart rate of 75 beats per minute project a 400 million cyclic pulsatile loading was under a 10 year device fatigue life on the stent[25]. Finite element was a useful tool that effective and able to explain the analysis of design and fatigue life effectively.

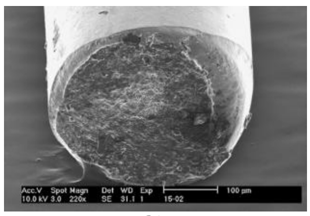
Failure of planar diamond shape specimens tested by Tammareddi et al., 2016 under various combinations of ε m and ε a, first principal strain value ε_a strongly effect the fatigue strength of the stent [15]. Usually high risk of failure occurred at the outside part of the crown. Balloon expandable stent were often used for radial strength testing. It diameter will instantly decrease then mechanical stability and buckling will disappear slowly. As demonstrated by Dumoulin & Cochelin, 2000, they prove that for the balloon expandable stent, a small increasing in load due to the collapse cause by limit load and plastic flow ensures would result in failure of the stent [22].

Tubular like rings curvature had more possibility of failure as the stress were maximum at these regions. The arterial wall was the places where maximum changes in stent diameter and the place of the critical point occurred [26]. Thrombosis, inflammation and neointima formation were the early biocompatibility problems with stents. There were two late problems happened in the failure of the stent, mechanical and chemical failure. Mechanical failure occurred due to material fatigue imposed by considerable stress to stents. High failure rates because of stenting in the femoropopliteal artery been associated, in addition, dynamic forces such as bending, tension, torsion and compression was a challenge of dynamic force faced by the environment leads to fracture if stent [27]–[29].

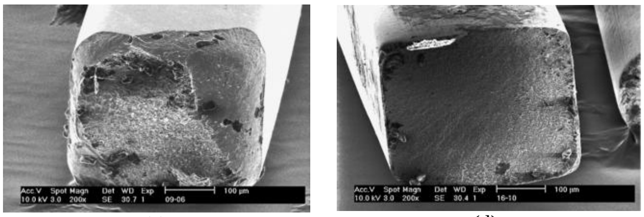
Implantation of the stent in the artery would lead to failure due to restenosis as the stent was a foreign material [30]. Process of neointimal hyperplasic (NH) such as inflammation, thrombus formation and smooth muscle cell proliferation was the reason of restenosis. [31]. Device failure also may happen because of neointimal hyperplasia due to restenosis in the place where stent was implanted. Formation of neointimal tissue was the indicator of the implantation of the stent in the body [32].



(a)



(b)



(c) (d)

Figure 21. Fracture surfaces of scanning electron micrographs of Nitinol stents, (a) 0.40-mm received wire (b) 0.40-mm retrieved wire, (c) 0.40mm×0.56mm received wire and (d) 0.40mm×0.056mm retrieved wire [35]

Although there were many researches and studies about stent, researchers still cannot fully understand the reason of the high failure rates of stents placed in the femoral and popliteal arteries. Despite that, success rate variation between coronary and peripheral arteries could be explained by the size of stent. Typically, the size of stent implanted into the coronary arteries less than 4mm in diameter while peripheral arteries stents been implanted into could be up to 10mm in diameter, depend on the areas of implantation. Longer stents if 80mm was required as the peripheral arteries blocked. Commonly, peripheral arteries were more muscular while arteries become more elastic as it was close to the heart. This in intended to allow the change of volumetric during blood flow pulsatile.

Study about the failure strain of stent show that hardening behavior of the grains effected by the stent struts and their thickness [33]. An analysis shown that the core of the junction of the stent degrades faster than the average rate of the device [34]. The stents would fail and collapse if the junction lose its ability. Design of the junction plays important part so the premature failure could be avoided. A wide research needed to study the performance of stent during the stent implantation to decrease the rates of stent failure. Such previous studies had proven that success or failure of stent depend on its stent design.

A consequential stent feature contrivance is the resistance to fatigue damage and fracture. Bourauel et al., (2008) induce fracture of NiTi arch wires by experiment to investigate the number of cycles required as shown in Fig. 21. These researches demonstrate that stent and fatigue fracture can be related main factors which is design of stent. for example, the thickness of strut, and natural variables, for example, the plaque structure and the process of deployment. As the thickness of strut increase the strength of fatigue of the device also improve. Stent excessive dilation amid the development can prompt the arrangement of micro-stresses become residual high, which encourage the stent failure. In view of all these, how to debilitate or stay away from these unwanted outcomes, to a greatest degree, is the way to decrease these persistent injuries. So it is particularly vital to focus on the design on going for the closures of stent or balloon get together and process of design of the stent delivery system can be done smoothly.

VI. Discussion

Introduction of coronary angioplasty had been starting point as the stents have been a major advance. As stents might be embedded in more complex lesions and in littler vessels sooner rather than later, the biocompatibility perspectives should be additionally breaking down and analyzed. There is little uncertainty that the following decade will observe the development of substantially less thrombogenic coronary endoprostheses fit for being acknowledged and endured by the body condition. Without a doubt, the research toward decrease in stent thrombogenicity and in giving better tissue similarity may significantly affect stent viability in an assortment of clinical conditions and may additionally grow the utilization of stents.

Another issue of stent configuration in drug eluting device is the way a stent is connected to an inward lumen. This issue is called connection of stent-vessel wall. Medication will be conveyed straightforwardly to the divider, with the goal that spaces among stent and vessel dividers ought to be dodged. In the event that stent is not specifically opposed to the vessel wall, eluted medication ought to be discharged and go to the systemic circulation from the blood flow, with proper medication focuses not be acquired at the vessel wall that had been stented. As the drug eluting system had lessen the in stent restenosis after coronary intercessions, configuration of stent is still important.

Endovascular stents have changed the treatment of atherosclerotic vascular disease. Be that as it may, from a designing point of view, the coming of the stent did not instantly proclaim a structural move in clinical practice. Or maybe, the endovascular stent embodies the marriage among building and empiric clinical research, an association that develops gradually. More than four decades, clinicians and patients, vascular scientists and clinical specialists, architects and business visionaries teamed up nearly to convey the coronary drug eluting stent, arguably one of the best achievements in cardiovascular prescription in the past 50 years. Critical exercises gained from the coronary experience have converted into novel utilizations of stents in other vascular fields. Other works can be found in [36-43].

VII. Conclusion

In the present paper, the focus has been made to give an overview of classification of stent geometry and its effect on mechanical behaviour of stent. There are always have imporovement and enhancement in the design of stent. Recoil accuracy, foreshortening and predictations for fatigue safety factor can be improve by performing 3D stent modelling analysis. Stent failure could be prevented by performed analysis include the representation of microscale for stents and the modelling framework. Fatigue life always become an issue in device lifetime for medical implants or in engineering aspect. Interplay of stent and balloon must be considered to design stent that had less injurious delivery system to obtain a high rate of success in stent implantation. Strain recovery of the stents depend on the difference of the stent over sizing or often called difference of the initial stent diameter and artery diameter. Stent behavior during deployment can be improve by the optimazation of the stent design. Optimization of the material and geometrical features of the stents is a very important information. Results obtained are very useful in the study of the mechanical performance or the stent. Not only that, radial expansion of the calssical stent also can be optimized.

The advancement of the role of stents has brought about a huge change in stent configuration, essentially determined by the requirements of the disease that is being dealt with. Almost certainly, the treatment of huge vessel bifurcations will turn into a standard use of PCI over the expected years. Manufacturers may need to consider creating devoted stages for the treatment of these vessels. As more patients with multivessel illness are dealt with more prominent consideration will likewise should be set on longer-term results in all the more requesting clinical settings. The dangers of idle stent break may expect a more conspicuous job in clinical examinations in future. At last, as the clinical routine with regards to PCI keeps on advancing, makers and clinicians should work intently in association to ensure that the device that are embedded can give astounding safety and long haul efficiacy for patients. The significance of stent configuration has been re-underscored and is probably going to wind up progressively applicable in future, where the patient and sore being dealt with are probably going to order extremely cautious determination of the stents that implant in every individual setting. The center ought to be moved far from creating always deliverable stent stages and ought to be moved back to the crucial properties of what the device has been worked to accomplish.

Conflict of Interest

The authors declare no conflict of interest.

Acknowledgment

This research is supported by the Ministry of Education Malaysia under the Fundamental Research Grant Scheme (FRGS) Vot. 1592.

References

[1] M. Azaouzi, A. Makradi, and S. Belouettar, "Numerical investigations of the structural behavior of a balloon expandable stent design using finite element method," Comput. Mater. Sci., vol. 72, pp. 54–61, 2013.

[2] M. Azaouzi, A. Makradi, and S. Belouettar, "Deployment of a self-expanding stent inside an artery: A finite element analysis," Mater. Des., vol. 41, no. October 2017, pp. 410–420, 2012.

[3] D. Stoeckel, C. Bonsignore, and S. Duda, "A survey of stent designs," Minim. Invasive Ther. Allied Technol., vol. 11, no. 4, pp. 137–147, 2002.

[4] S. Puértolas et al., "A methodology for the customized design of colonic stents based on a parametric model," J. Mech. Behav. Biomed. Mater., vol. 71, no. May 2016, pp. 250–261, 2017.

[5] D. J. McGrath, B. O'Brien, M. Bruzzi, and P. E. McHugh, "Nitinol stent design - understanding axial buckling," J. Mech. Behav. Biomed. Mater., vol. 40, pp. 252–263, 2014.

[6] J. P. McGarry, B. P. O'Donnell, P. E. McHugh, and J. G. McGarry, "Analysis of the mechanical performance of a cardiovascular stent design based on micromechanical modelling," Comput. Mater. Sci., vol. 31, no. 3–4, pp. 421–438, 2004.

[7] W. R. Burns, Z. Zheng, S. A. Rosenberg, and R. A. Morgan, "Lack of specific γ-retroviral vector long terminal repeat promoter silencing in patients receiving genetically engineered lymphocytes and activation upon lymphocyte restimulation," Blood, vol. 114, no. 14, pp. 2888–2899, 2009.

[8] G. Catalano, A. G. Demir, V. Furlan, and B. Previtali, "Use of Sheet Material for Rapid Prototyping of Cardiovascular Stents," Procedia Eng., vol. 183, pp. 194–199, 2017.

[9] F. Etave, G. Finet, M. Boivin, J. C. Boyer, G. Rioufol, and G. Thollet, "Mechanical properties of coronary stents determined by using finite element analysis," J. Biomech., vol. 34, no. 8, pp. 1065–1075, 2001.

[10] A.-M. Lézine, "Evolution of the West African Mangrove During the Late Quaternary: A Review," Géographie Phys. Quat., vol. 51, no. 3, p. 405, 1997.

[11] D. E. Kandzari, J. E. Tcheng, and J. P. Zidar, "Coronary artery stents: Evaluating new designs for contemporary percutaneous intervention," Catheter. Cardiovasc. Interv., vol. 56, no. 4, pp. 562–576, 2002.

[12] R. N. Ghriallais and M. Bruzzi, "Self-expanding stent modelling and radial force accuracy," Comput. Methods Biomech. Biomed. Engin., vol. 17, no. 4, pp. 318–333, 2014.

[13] M. Azaouzi, N. Lebaal, A. Makradi, and S. Belouettar, "Optimization based simulation of self-expanding nitinol stent," Lect. Notes Mech. Eng., vol. 1, pp. 423–450, 2013.

[14] G. P. Kumar and F. Cui, "Stent design parameters and crimpability," Int. J. Cardiol., vol. 223, pp. 552–553, 2016.

[15] S. Tammareddi, G. Sun, and Q. Li, "Multiobjective robust optimization of coronary stents," Mater. Des., vol. 90, pp. 682–692, 2016.

[16] J. S. YOUNGNER and M. E. KELLY, "Inhibition by Exogenous Interferon of Replication of Poliovirus," J. Bacteriol., vol. 90, no. May, pp. 443–445, 1965.

[17] L. B. Tan, D. C. Webb, K. Kormi, and S. T. S. Al-Hassani, "A method for investigating the mechanical properties of intracoronary stents using finite element numerical simulation," Int. J. Cardiol., vol. 78, no. 1, pp. 51–67, 2001.

[18] A. Khosravi, H. Bahreinizad, M. S. Bani, and A. Karimi, "A numerical study on the application of the functionally graded materials in the stent design," Mater. Sci. Eng. C, vol. 73, pp. 182–188, 2017.

[19] S. M. Imani, A. M. Goudarzi, P. Valipour, M. Barzegar, J. Mahdinejad, and S. E. Ghasemi, "Application of finite element method to comparing the NIR stent with the multi-link stent for narrowings in coronary arteries," Acta Mech. Solida Sin., vol. 28, no. 5, pp. 605–612, 2015.

[20] L. Petrini, F. Migliavacca, F. Auricchio, and G. Dubini, "Numerical investigation of the intravascular coronary stent flexibility," J. Biomech., vol. 37, no. 4, pp. 495–501, 2004.

[21] M. Early, C. Lally, P. J. Prendergast, and D. J. Kelly, "Stresses in peripheral arteries following stent placement: a finite element analysis," Comput. Methods Biomech. Biomed. Engin., vol. 12, no. 1, pp. 25–33, 2009.

[22] C. Dumoulin and B. Cochelin, "Mechanical behaviour modelling of balloon-expandable stents," J. Biomech., vol. 33, no. 11, pp. 1461–1470, 2000.

[23] M. Azaouzi, A. Makradi, J. Petit, S. Belouettar, and O. Polit, "On the numerical investigation of cardiovascular balloon-expandable stent using finite element method," Comput. Mater. Sci., vol. 79, pp. 326–335, 2013.

[24] M. Bosiers, D. Scheinert, C. A. Simonton, and L. B. Schwartz, "Coronary and endovascular applications of the AbsorbTM bioresorbable vascular scaffold," Interv. Cardiol., vol. 4, no. 6, pp. 621–631, 2012.

[25] R. V. Marrey, R. Burgermeister, R. B. Grishaber, and R. O. Ritchie, "Fatigue and life prediction for cobalt-chromium stents: A fracture mechanics analysis," Biomaterials, vol. 27, no. 9, pp. 1988–2000, 2006.

[26] M. Imani, A. M. Goudarzi, and M. H. Hojjati, "Finite element analysis of mechanical behaviors of multi-link stent in a coronary

artery with plaque," World Appl. Sci. J., vol. 21, no. 11, pp. 1597–1602, 2013.

[27] A. Nikanorov, H. B. Smouse, K. Osman, M. Bialas, S. Shrivastava, and L. B. Schwartz, "Fracture of self-expanding nitinol stents stressed in vitro under simulated intravascular conditions," J. Vasc. Surg., vol. 48, no. 2, pp. 435–440, 2008.

[28] D. Sh, B. Pusich, and G. Richter, "Sirolimus-Eluting Stents for the Treatment of Obstructive Superficial Femoral Artery Disease Morphologic and Angiographic Features of Coronary Plaque Rupture Detected by Intravascular Ultrasound Feasibility and Ef fi cacy of Balloon-Based Neuroprotection," pp. 62–63, 2003.

[29] D. Scheinert et al., "Prevalence and clinical impact of stent fractures after femoropopliteal stenting," J. Am. Coll. Cardiol., vol. 45, no. 2, pp. 312–315, 2005.

[30] E. C. Teo, Q. Yuan, and J. H. Yeo, "Design Optimization of Coronary Stent Using Finite Element Analysis," ASAIO J., vol. 46, no. 2, p. 201, 2000.

[31] A. Kastrati et al., "Restenosis after coronary placement of various stent types," Am. J. Cardiol., vol. 87, no. 1, pp. 34–39, 2001.

[32] I. H. Bae et al., "Mechanical behavior and in vivo properties of newly designed bare metal stent for enhanced flexibility," J. Ind. Eng. Chem., vol. 21, pp. 1295–1300, 2015.

[33] M. Abbaszadeh, J. Kadkhodapour, S. Schmauder, and M. Hoseinpour, "A study on the effect of grain dimension on the deformation of stent struts in tension, bending and unbending loading modes," Int. J. Mech. Sci., vol. 118, pp. 36–44, 2016.

[34] X. Han, Finite element analysis (FEA) of biodegradation of polymeric medical devices. Woodhead Publishing Limited, 2014.

[35] Bourauel, C., Scharold, W., Jäger, A., & Eliades, T. (2008). "Fatigue failure of as-received and retrieved NiTi orthodontic archwires". Dental Materials, 24(8), 1095–1101.

[36] M.N. Roslan, A.E. Ismail, M.Y. Hashim, M.H. Zainulabidin, S.N.A. Khalid, "Modelling analysis on mechanical damage of kenaf reinforced composite plates under oblique impact loadings". Applied Mechanics and Materials, 465-466, 1324-1328, 2014.

[37] A.E. Ismail, A.K. Ariffin, S. Abdullah, M.J. Ghazali, R. Daud, "Mode III stress intensity factors of surface crack in round bars". Advanced Materials Research, 214, 192-196, 2011.

[38] A. Hamdan, F. Mustapha, K.A. Ahmad, A.S. Mohd Rafie, M.R. Ishak, A.E. Ismail, "The Effect of Customized Woven and Stacked Layer Orientation on Tensile and Flexural Properties of Woven Kenaf Fibre Reinforced Epoxy Composites". International Journal of Polymer Science, 2016, 6514041, 2016.

[39] A.E. Ismail, M.A. Hassan, Low velocity impact on woven kenaf fiber reinforced composites. Applied Mechanics and Materials, 629, 503-506, 2014.

[40] A.E. Ismail, M.H. Zainulabidin, M.N. Roslan, A.L. Mohd Tobi, N.H. Muhd Nor, "Effect of velocity on the impact resistance of woven jute fiber reinforced composites". Applied Mechanics and Materials, 465-466, 1277-1281, 2014.

[41] A.E. Ismail, A.L. Mohd Tobi, "Axial energy absorption of woven kenaf fiber reinforced composites". ARPN Journal of Engineering and Applied Sciences, 11(14), 8668-8672, 2016.

[42] A.E. Ismail, "Multiple crack interactions in Bi-Material plates under mode I tension loading". Applied Mechanics and Materials, 629, 57-61, 2014.

[43] A.E. Ismail, A.K. Ariffin, S. Abdullah, M.J. Ghazali, "Stress intensity factors for surface cracks in round bars under combined bending and torsion loadings". International Review of Mechanical Engineering, 4(7), 827-832, 2010.