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Research paper

Application of finite element analysis on balloon expandable coronary stents: A review

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Abstract

Numerical analysis of complex physical environment continues to be preferred over "build and test" approach in product development process. Finite Element Analysis (FEA) of coronary artery stenting is studied and researched worldwide for many years. Potential of using FEA for mimicking *in-vivo* is high as experimental test is ruled out for variety of reasons. This review aims at discussing issues and challenges of numerical simulation based on part of available literature on usage of FEA techniques for investigating behavior of balloon expandable (BE) coronary stents inside artery. Literatures of past 16 years of study on the structural analysis is summarized and potential issues for research is discussed. Study tries to investigate deployment characteristics and biomechanical response of artery post stenting and significance of non-physiological conditions induced. Effects of geometrical parameters, simulation strategies are summarized. Study mainly underscores the potential challenges of reliable numerical investigation. Scope of FEA in predicting contributor for in-stent restenosis (ISR), a major drawback of stenting procedure, by correlating the engineering aspect of stent design and its clinical significance supported by clinical trials are highlighted. Study is expected to serve as qualitative assessment for cardiologists to minimize procedural failure and quantitative tool for the designers for stent optimization.

***Keywords**: Coronary Stents; Finite Element Analysis; Balloon Expandable Stents; In-Stent Restenosis; Stenosis.*

1. Introduction

Cardiovascular Disease (CVD) is leading cause of death in modern world accounting for nearly 30% of death worldwide [1], [2]. Coronary Artery Disease (CAD), form of CVD, characterized by narrowing of artery by plaque accumulation leading to atherosclerosis or stenosis [3]. Stenosis deprives heart muscles of oxygen rich blood, leading to heart attack medically known as Myocardial Infarction (MI). Several health risk factors are involved in development of atherosclerotic plaque finally leading to CAD [4]. Coronary Artery Bypass Grafting (CABG), Plain Old Balloon Angioplasty (POBA) and Coronary Angioplasty with Stenting [5] are successfully employed by clinicians to treat CAD. Inherent drawbacks of CABG and POBA are overcome by Coronary Angioplasty with Stenting [1]. Past has seen exponential growth in the number of Percutaneous Coronary Intervention (PCI) performed for the deployment of stents worldwide [1]. Over 1.9 lac stents were used in the year 2011 in India alone [6]. Variety of stent designs are available in market with different levels of short term efficacy [7]. Inspite of this, in-stent restenosis (ISR) is a major concern of the cardiologist [8]. ISR is characterized by proliferation of arterial cells through stent struts making revascularization inevitable.

Though the reasons for ISR is not completely understood, researchers and cardiologists agree on fact that stent design is a major contributor. Arteries subjected to non-native stress prone to restenosis. Clinical studies correlates endothelium damage caused by stent implantation leading to neontimal hyperplasia [9]–[11].Experimental investigation of stent environment in *in-vivo* is ruled out for health risk involved in experimentation. Hence, a promising alternate, FEA, is extensively used for numerical investigation of biomechanical environment. Simulation ranging from simple free expansion of coronary stents to highly sophisticated balloon/stent/artery contact interactions were reported. [12] reported different level of non-physiological stress on artery based on stent type. [13]–[15] investigated numerically the optimization capabilities of FEA tools in complex stented artery environment. Favorable condition for minimizing the vascular injury by modified stent design were investigated by [16], [17]. Investigation on fatigue life assessment, sophisticated sequential structural and fluid dynamic investigation, multiobjective, robust optimization were attempted [18]–[20].Several review studies discussed various aspects of simulation of stented arteries. [21] In his review discussed aspects of free expansion and expansion inside stenotic artery particularly highlighting the results based on different modeling and simulation techniques. [22]reviewed with a focus on stent model reduction techniques used for stent simulations. The study discussed techniques of reduction of complex 3D stent model into 1D curved rod model and obtaining global properties based mechanical properties of each stent strut in 'stent net'. The study also demonstrated the cost-effective model reduction approach used for simulating drug interaction in DES stents. [23] summarized the structural and fluid dynamics simulations on image based coronary artery models and emphasized on the need of third generation (Biodegradable) stent revolution. [24] reviewed state-of-the-art method of stenting of coronary bifurcation lesion. This study discussed utility of kissing balloon inflation, simulation of stent thrombosis, in-vitro bench testing methods are discussed.

Though the accuracy of numerical analysis is a serious concern, a reasonable assumption to mimic physiological stent environment can produce satisfactory results. Following sections presents an overview of FEA utility in investigating structural behavior of BE coronary stents with reference to its advances and potential analysis issues.

2. Evolution and state-of-the-art FEA on BE stents

Ever since PCI revolutionized the treatment of CVD, there has been exponential growth in use of commercial stents worldwide. Initial success of Bare Metal Stent(BMS) encountered with problem of ISR, later minimized by the development of Drug Eluting Stents (DES) [25]. Researchers always tried to find new class of stents like Time Sequence Functional Stents, Endothelial Progenitor Cell Capture Stents [26] to address ISR. Clinical complications of advanced stent types emphasized on refinement of basic structural design of stents. [27] conducted in-vivo trial of two stent designs on white rabbits and endothelium damage was captured. This clinical investigation supported by in-vitro modelling validated the findings of numerical investigations on same stent designs which simulated the stent/balloon/artery wall interaction during deployment. This finding emphasized on the fact that two different stent designs subjected arterial wall to different stress levels and can stimulate the endothelium damage. Probably this was the first use of FEA in investigating stent/balloon/artery interaction and reiterated the hypothesis that vascular injury is dependent on stent design. [28] investigated structural parameters such as dog-boning, radial recoil etc. on an idealized stent resembling Palmaz P308 stent when expanded freely and its potential clinical implication. Findings may assist in selection of stents based on ability to resist the radial load. Similar work by [29] investigated the effect of the stent-to-artery ratio on radial and longitudinal recoil, dogboning, foreshortening and the pressure required to initiate the stent expansion and found out a strong correlation between them. [30] investigated flexibility of the stent using 'unit cell' model of stent resembling the commercial stent and suggested a strong correlation between flexibility index and arrangement of links.[31] validated the argument that higher arterial stress may lead ISR. This work demonstrated that high arterial stress can cause tissue prolapse and higher volume of arterial segment stressed beyond the physiologically sustainable vascular stress. Claims on computational analysis is also supplemented by the clinical evidence on the restenosis rate of two different stent designs. Well-known in the field of biomechanics [32] in his work, summarized the biomechanical response of realistic iliac artery segment constructed through MRI scan. Realistic, layer specific constitutive material model for artery is developed based on the uni and biaxial test on diseased iliac artery segment. He investigated the response of artery for three types of stent cell structure and showed that stenting induces stress concentration on non-diseased artery when diseased part is stented. This signifies the importance of right sized stent for right sized lesion. [33] assessed normal artery stress field post stenting by different generic stent models with different axial strut spacing, radius and amplitude. Results showed that stent design with small strut spacing and low amplitude induced larger stress on larger area of the artery compared to the other designs and predicted the loss of flexibility (cyclic deflection) of artery post stenting. [34] worked to validate the numerical result of stent expansion by capturing expansion Cordis Velocity BX stent using an optic estensometer and emphasized on the importance balloon during expansion simulation. [35] quantified stenting outcome in terms of contact pressure, artery wall stress and lumen gain of the three different stent designs. [36] correlated design parameter with radial strength required for stability of scaffolding. [37] modelled realistic balloon/stent using micro CT and investigated the

expansion behavior. Above studies justifies the use of FEA in design and development of stents. Major contributions in this field is summarized in Table 1

Table 1: Evolution of State-of-the-Art FEA on BE Coronary Stents (Objective, Methods & Inferences)

Author	Objective of investigation	Methods	Inference drawn
Campbell, Rogers 1998	Vascular injury, endothelium denudation, balloon artery contact stress & contact area	In-vivo, Ex-vivo and FEA analysis on different stent design	Contact stress & contact area are function of expansion pressure, stent geometry & balloon compliance
Dumoulin 2000	Radial recoil, stress/strain on stent wall, crushing criteria for external load and fatigue life assessment	Modeling and analysis on Palmaz (P308) like stent models	Consistency in manufacturers data and numerical data on diameter achieved, Higher stress region located on link. Design withstands infinite cardiac cycles
Francesco Migliavacca 2002	Effect of stent to artery ratio, slot length, strut thickness on expansion	Parametric analysis on Palmaz-Schatz like stent	Higher stent artery ratio decreases recoil
Lorenza Petrini 2004	To investigate the flexibility of two different types of generic stent	Bending on stent models resembling Cordis-BX velocity (CV) and Sirius Carbostent(SC)	SC stent is more flexible than CV. 'Unit cell' can capture full stent flexibility
Lally C 2005 Gerhard A Holzaphfel 2005 Francesco Migliavacca 2005	Correlate vascular stress and vascular injury Intimal pressure, pressure change in arterial wall, luminal gain for changes of geometrical parameters Expansion and radial recoil simulation of new generation stent.	Modelling of S7 and NIR stents. Expansion inside idealsed stenotic artery. Expansion of parametric stent designs inside realistic layer specific stenotic artery Free expansion of Cordis Velocity BX Experimental validation through estensometer and SEM images.	NIR model induces large volume of high stress region than S7 Comparative advantages/disadvantages of different designs are discussed Discrepancies due to absence of balloon in simulation is highlighted
Julian Bedoya 2006	Effect of stent parameter on the stress field	Expansion of Parametric stent designs inside normal healthy artery	Highest influence of axial strut spacing on artery stress distribution
Dimitrios E kiousis 2007	To study the effect of 3 different stent design on contact pressure, artery wall stress and lumen gain.	Realistic stent model inside patient specific stenotic artery	Inner most layer is main load carrier, effect of initial crack in the intima layer is investigated

Xiang Shen 2008 Matthieu De Beule 2008	Radial strength of different parametric stent design Effect of stent expansion strategy (no balloon, cylindrical balloon, trifolded balloon).	Free expansion and compression of Parametric stent design Commercial stent modeling, free expansion	Strut thickness a major decider of radial strength Folded balloon achieves desired expansion at lower expansion pressure
M Early DJ Kelly 2009	Effect of geometry, material on luminal gain, deformation etc.	Expansion of Nitinol & stainless steel (SS) stent inside artery of varying property	Nitinol induced lower stress on peripheral artery than SS stent inside coronary artery
Jianjun Li 2010	Fatigue life of a Co-Cr alloy stent model	Crimping, expansion and load equivalent to transmural pressure is applied to simulate fatigue, experimental fatigue test	High stress amplitude distributed around curvature of stent geometry. safe under transmural pressure load
Sanjay Pant 2011	Effect of stent parameters (longitudinal length of circumferential ring, strut width, etc. on recoil, tissue stress, hemodynamic disturbance, drug delivery, uniformity of drug distribution & flexibility)	CYPHER like stent modelling and parametrization. Structural and hemodynamic analysis	Conflict between different objectives were identified and tradeoffs are suggested
D. Martin 2011	Review on stent expansion	-	Increased complexity and sophistication in modelling and simulation are identified
Shijia Zhao 2012	Effect of stent deployment orientation and stent length on arterial stress	Self-expanding PROTEGE™ GPS™ stent indie Idealized curved artery	Considerable change in arterial stress due to change in stent orientation. Longer stent alleviate stent migration at the same time increases arterial stress
M Azaouzi 2013	Fatigue life of BE stent. Structural behavior (flexibility torsion & expansion) for different link arrangement.	Stent expanded inside stenotic artery and subjected to transmural pressure Stent model is subjected to expansion, torsion and bending	Influence of artery expansion and stent geometry on fatigue life Significant effect of link on structural behavior
Morlacchi 2013	Review on structural and fluid dynamics on image based coronary artery model	-	Emphasized on third generation biodegradable stent revolution
Graeham R Douglas 2014	Test hypothesis that foreshortening, dogboning etc. are functions of cell topology,	Different generic stent cell topology is analyzed for expansion behavior. Length diameter relation tested numerically and experimentally	Effect of unit cell geometry on expansion is discussed
David Martin 2015	Effect of six different stent designs on structural and hemodynamics behavior	Sequential structural and hemodynamics study	Role of strut thickness on behavior is highlighted
Antoniadis 2015	Review on bifurcation lesion stenting	-	Utility of Kissing Balloon Inflation, thrombosis simulation is discussed
Sriram tammareddi 2016	Multi objective optimization and uncertainties on performance outcome	Commercial stent models with parametrization. Effect of each parameter on different objectives are investigated and optimized with MOPSO algorithm	A robust optimization method is proposed taking uncertainty and noise into account
Zunino & Tamabaca 2016	Review on stent model reduction technique	-	Cost effective 3D into 1D curved rod model reduction technique is summarized

3. Components and design & performance parameters of stents

Fundamental for any numerical investigation is the identification components of the system and parameters of interest. Stenting system constitutes stent, balloon catheter and the stenotic artery. Stent geometry is characterized by parameters typical of stents viz, thickness and width (or the radius) of stent wire, radius of crown, number of cells in circumferential and axial direction, total length and radius of the stent, etc.(Table 2) [29], [33]. Thickness of stent strut plays a major role in restenosis process[38] thus emphasizing on the importance of geometrical parameters of stent on clinical outcome. Stent cells imparts scaffolding while links apart from establishing the connectivity between cells, plays a role as flexibility enhancer [30], [36], [37], [39]. The stent cell geometry and the arrangement of cells has consequences on the scaffolding character and clinical outcome of angioplasty procedure. Stent family is classified into open cell/closed cell based on presence of link in stent [35]. Another component of stent system is balloon used for transferring fluid pressure onto stent to achieve uniform expansion [27], [37]. Though balloon is folded to achieve the low profile for easy delivery, numerical simulation assumed a straight cylinder[37] Finally, patient specific, layer specific stenotic artery constitutes the important component of numerical simulation[32]. However, simplified as straight cylindrical artery, symmetric/eccentric stenosis are widely used for simulations [31]. Successful simulation should capture performance parameters (Table 3) effectively for, these parameters defines the success in terms proper scaffolding, minimum injury, easy deliverability, easy expansion etc. These parameters which are engineering in nature, has enormous clinical consequences [40]. Example, studies correlates higher arterial stress with ISR and intimal thickening [27], [31], [41].

Table 2: Geometrical Design Parameters of Stent and its Dimensions

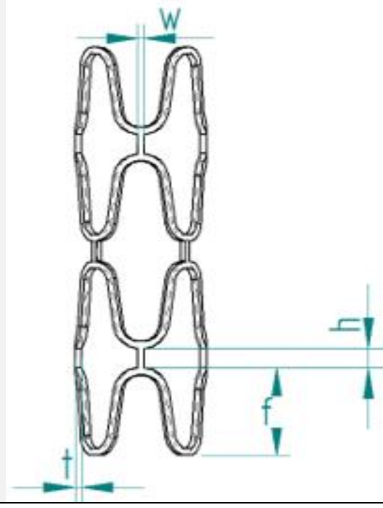
Name	Description	Geometry
Thickness of strut (t)	Difference between the outer and inner radius	
Width (w)	Width of strut	
Axial strut spacing (h)	Minimum distance between adjacent cells	
Strut amplitude (f)	Distance between the crest and trough of a cell	
Number of cells in axial direction (N_c)	Number of cell repeating in axial direction	
Number of cells in longitudinal direction (N_l)	Number of cell repeating in longitudinal direction	
Type of stent	Open cell/Closed cell (based on arrangement of links between cells)	

Table 3: Performance Parameters of Typical Stented Environment

Parameter	Description
Radial recoil	Percentage retraction of stent radially after removal of inflation pressure
Longitudinal recoil	Percentage retraction of stent longitudinally after removal of inflation pressure
Foreshortening	Decrease in stent length after deployment
Dogboning	Non-uniformity of expansion along longitudinal direction
Contact pressure	Stress induced between the stent and lumen surface
Arterial stress	Stress field on arterial wall
Lumen gain	Percentage gain in luminal area
Tissue prolapse	Cell proliferated through the stent strut under arterial stress

4. Finite element modelling of stent, artery and balloon

4.1. Geometry

4.1.1. Stent

Fundamental for stent simulation is the geometry of stent. Different modelling techniques have been employed for this purpose, ranging from generic stent modeling techniques [29], [33] to modelling using high resolution cameras and customized codes [34]. Coordinate Measuring Machine [31], Stereo microscope [30] were used to capture the stent dimensions and subsequent modelling. Micro Computed Tomography image based 3D models [37] were used for realistic modelling.

4.1.2. Stenotic artery

Though stenotic coronary artery is highly patient specific, researchers minimized the complexity by using simplified geometry. Stenotic artery is assumed as straight/curved cylinder with axisymmetric/eccentric stenosis with different levels of stenosis [42], [43], in some cases as multilayered model[44].

4.1.3. Balloon

Balloon geometry typically modelled as thin cylinder. Folded configuration balloon [37] are used by researchers to realistically model the stent expansion. Folded configuration helps to achieve low profile for crimped stent for easy delivery.

4.2. Constitutive equation

4.2.1. Stent

Majority of BE stents are made up of medical grade stainless steel (AISI316L). Other alloys like chromium cobalt are also in use. This class of material's properties are size dependent [45]. Bilinear elastic-plastic material model is widely used with Young's modulus of 196 GPa[29], [30], [37] ,200 GPa [31]–[33], [36] or 201 MPa [35]and Poisson's ratio of 0.3. Yield stress of 195 MPa[36], 205MPa[29], [30],210 MPa[32], or 305 MPa[35].

4.2.2. Stenotic artery

Highly nonlinear, anisotropic, patient specific material properties of artery/plaque pose challenge for numerical investigation. Mechanical properties of patient specific stenotic artery is quantified by experimentation through uni and biaxial tension test on artery samples and strain energy density function and polynomial material models [32], [46]. Most widely used constitutive model, 3rd order 5 parameter polynomial hyperelastic models extensively used in computational works [12], [31], [33], [47], [48]. Table 4 summarizes widely used constitutive material models assuming an incompressible material. It is noted that a strain energy density function should be positive-definite if there is no residual stress. This means that any material constant in a Mooney-Rivlin model should not be negative if residual stress is not incorporated

Table 4: Some of Widely used Artery/Plaque Material Models (E=Young's Modulus, υ =Poison's Ratio, μ=Shear Modulus, K=Bulk Modulus, C=Material Parameters/Material Constants, A=Dimensionless Parameters; I=Intima, M=Media, A=Adventitia)

Author	Material Model	Parameters and constants reported
Campbell & Rogers (1998)	Linear elastic	E= 100kPa, υ=0.3
Pant & Bressloff (2012)	Neo-Hookean	μ=60kPa, K=20μ, υ=0.3(Plaque)
Pant & Bressloff (2012)	Sixth order reduced polynomial	C_{10}=6.7e-3, C_{20}=0.54, C_{30}=-0.11, C_{40}=10.65, C_{50}=-7.27, C_{60}=1.63 (I) C_{10}=6.52e-3, C_{20}=4.89e-2, C_{30}=9.26e-3, C_{40}=0.76, C_{50}= -0.43, C_{60}=8.69e-2 (M) C_{10}=8.27e-3, C_{20}=1.20e-2, C_{30}=0.52, C_{40}=-5.63, C_{50}=21.44, C_{60}=0 (A) (C in kPa)

Martin & Boyle (2015)	Third order Ogden	μ_1=-6.22, μ_2=3.84, μ_3=2.17, α_1=23.91, α_2=24.53, α_3=22.68, D_1=0.78, D_2=D_3=0 (I) μ_1=-1.67, μ_2=1.04, μ_3= 0.64, α_1=23.17, α_2=24.45, α_3=23.62, D_1=4.35, D_2= D_3=0 (M) μ_1=-1.95, μ_2=1.18, μ_3= 0.79, α_1=24.60, α_2=25.00, α_3=23.88, D_1=3.88, D_2= D_3=0 (A) (Mean age of subject-71.4Years) (μ in MPa, D in MPa^{-1}, α dimensionless)
Lally C (2005), Julian Bedoya (2006)	3rd order 5 parameter polynomial	C_{10}=18.9, C_{01}=2.75, C_{20}=85.72, C_{11}=590.43, C_{30}=0 (Artery) C_{10}=-495.96, C_{01}=506.61, C_{20}=1193.53, C_{11}=3637.80, C_{30}=4737.25 (Plaque) (C in kPa)
M Early & DJ Kelly (2009)	3rd order 5 parameter polynomial	C_{10}=84.24, C_{01}=5.06, C_{20}=1500, C_{11}=765.06, C_{30}=42.38 (I) C_{10}=3.55, C_{01}=6.62, C_{20}=21.55, C_{11}=18.68, C_{30}=19.77 (M) C_{10}=7.15, C_{01}=6.36, C_{20}=8.04, C_{11}=95.79, C_{30}=99.31 (A) (Mean age of subjects-71.8Years) (C in kPa)

4.2.3. Balloon

Balloon in angioplasty is mainly Polyethylene terephthalate (PET) or nylon. Researchers derived properties from the compliance chart supplied by the manufacturer[37].The 2 parameter Mooney-Rivlin hyperelastic material model (C_{10}=1.0318MPa, C_{01}=3.6927MPa) is conveniently used for in simulations [49].

4.3. Boundary conditions

Realistic boundary conditions (BC) to completely mimic angioplasty procedure is challenging task. Stenting procedure starts from inserting the catheters inside the artery to the target sight, runs through inflation and deflation of balloon, ends with removal of catheter. Though entire process determines clinical success of the PCI, simulating entire process is time consuming, costly and computationally challenging. Crimping of stent on balloon and incorporating residual stresses were simulated by few researchers [47]. Majority works concentrated on expansion at the target sight. Axisymmetric nature of stent is utilized in many studies [29] to prevent rigid body motion and to save computational resources and time. Different levels of sophistications were used to simulate the nature of BE stent on expansion. Free expansion of the crimped stent by pressure/ displacement driven input to predicts expansion nature like recoil, dogboning, foreshortening uniformity etc. is reported for different geometrical parameters of the typical stent [28], [29], [34]. To investigate the realistic nature of a stents, stenosed artery is incorporated in simulation [31]–[33]. This requires most sophisticated contact algorithm to be defined during the simulation [32], [33]. This captures importance performance parameter such as lumen gain, contact pressure and arterial stress which are relevant from clinical perspective.
Different softwares used for simulations ranged from custom built codes to commercially available workbenches. Recommending a program is not the purpose of this review. However, typical software codes and packages used extensively for modeling, meshing and simulations are listed in Table 5

Table 5: Widely Used Softwares for Numerical Investigation

Authors	Geometry	Meshing	Analysis
Francesco Migliavacca (2002)		GAMBIT	Abaqus
Campbell Rogers (1998)			ADINA 7.0
C Dumoulin (2000)	SYSTUS +3		Abaqus
Lorenza Petrini (2004), Francesco (2005)	Rhinoceros	GAMBIT	Abaqus
Lally C (2005)			MSC Marc/Mentat
Julian Bedoya (2006)	Matlab		MSC Patran
Dimitrios E Kiousis, Holzaphfel (2007)		CUBIT	FEAP
Xiang Shen (2008)	Proe		ANSYS
Mathieu De Beule (2008)			Abaqus
Gerhard A Holzaphfel (2005)	Custom Built Program		

5. Observation and scope for future study

Based on the part of the literature studied following critical observations are made and scope for the potential study is highlighted.

5.1. General observations

Majority of the simulations worked on generic stent designs and simplified artery geometry (straight cylinder, axisymmetric lesion etc.). Biomechanical performance characterization of a realistic commercial stent inside realistic stenotic artery will help the clinicians to select from the range of stents available based on its suitability for a specific lesion. On simulation part simplification lead to the use of part of total geometry and also simplified material models. Apart from need for easy convergence of solution, availability of computational resources and time being the reason behind this. Therefore, many researchers modelled and simulated using symmetrical boundary conditions and homogeneous, isotropic material properties. But highly patient specific, non-uniform, non-linear, non-homogeneous, eccentrically [50] stenosed artery being simplified as straight cylinder is gross underestimation. However, approximated result certainly shows the trend.
Complex deployment procedure of stent is simulated via different simulation strategies such as free expansion, displacement driven expansion of the stent inside artery, application of pressure directly on the inside surface of the stent etc. Actual process of stent expansion wherein liquid pressurized inside the balloon drives it radially outward which in turn pushes the stent outside against the elastic artery with the pressure of flowing pulsatile blood inside. A comprehensive Fluid Structure Interaction (FSI) study on the liquid-balloon interaction and blood-stent-artery can be more realistic [51]. Important components of stent delivery system viz, balloon is most disregarded part in numerical simulations. Modelling interaction at balloon/stent interface is crucial for; fluid load is transferred to the stent through the folded balloon during deployment. Hence, a thorough FSI between fluid and balloon is certainly warranted. Trackability, the ability to deliver stent to target site can be attributed to structural property viz, flexibility. Highly rigid stent causes arterial and endothelium damage which can stimulate thrombosis formation[52]. Thus, it becomes important that stent-balloon-delivery catheter have sufficient flexibility not only to negotiate through the tortuous artery but also to maintain cyclic deflection of artery during cardiac cycle. However, there have been few studies on flexibility of stent, comprehensive study on arterial damage caused by stent delivery system, and study on improving the flexibility of existing design is rarely attempted. Though some fatigue life assessment of a stent are attempted [12], [53], FSI study on stented arteries can throw light upon the susceptibility of stent for fracture under pulsatile load. Numerical analysis validated by experimentation justifies its use. Though there have been efforts to validate through experimentation [18], more sophisticated experimentation like image based deformation analysis, motion capture analysis of arterial wall for predicting the arterial strain, change of angulation etc. can be used.

5.2. Critical issues to address

5.2.1. Stent modelling

Simulations based on generic stent designs typically evaluates performance for variations in engineering design parameters such as thickness, fillet radius, stent-to-artery surface ratio[15]. With limited knowledge on engineering consequences of these parameters, and limited influence on design and development process, clinicians solicit comparative performance of different available stent designs which differs in arrangements of struts, links, stent length etc. Hence stent geometry modelled realistically through micro CT is more relevant from clinician's point of view. Design stage usually assumes idealistic regular surface for stent geometry. Drug coating, along with crimping process results in irregularities on stent surface[54]. Hence a realistically captured stent geometry can simulate the effect of these uncertain parameters on stent performance. Folded balloon is used for achieving low profile for crimped stent and effectively transferring expansion pressure to stent surface. Realistic stent modelling through micro CT also captures balloon folding pattern [37]. Effect of folding pattern on dynamics of expansion including interaction between balloon and non-deceased artery segments can be evaluated through these models. Unwrapping of balloon and subsequent stent expansion greatly dependent on effective pressure transfer between fluid used for inflation and folded balloon surface which can be evaluated through FSI study [55].

5.2.2. Stenotic artery modelling

An effective stenting simulation invariably requires realistic artery/lesion geometry which can be captured through IVUS or other methods[56], [57]. Many researches though evaluated the effect of different lesion geometry types (eccentric, hick's bump etc.) with different material properties (calcified, cellular, hypocellular) and used layer specific artery (adventitia, media, intima), realistic lesion containing abrupt geometrical variation, non-symmetric lesion at bifurcation location[58], sub-endothelial lesions must be effectively included in stenotic artery modelling. Patient specific modelling of coronary artery is demanding for, it is influenced by the pulse generated by heart[59].Hence modelling should include for spatial and temporal variation in geometry. These highly patient specific lesion modelling not only improve the simulation outcome in terms of identifying sights of high stress gradient but also helps in selecting stent for lesion types based on its suitability.

5.2.3. Material models

Numerical investigation results and its credibility is dependent on use of relevant material models. Artery is understood to be hyperelastic and many different hyperelastic material models (with different material constants) were utilized for simulation of stent expansion inside artery. Though these models could simulate large deformation of artery during expansion, generalizing these material constants is gross underestimation of reality. Clinical study suggests dependence of arterial strength on age [60], [61]. Material constants derived from subject specific stenotic artery segment should provide better estimation of material properties.

5.2.4. Contact conditions

Permanent deformation of stent structure provides required lumen gain during angioplasty. It is essential for expanded stent to remain in target sight indefinitely and is assumed to be achieved through friction between stent and artery surface though exact nature of frictional nature is not completely understood. Frictional contact is assumed between stent /artery and stent/balloon interface during the expansion process and plaque/artery interface is assumed to be bonded in majority of work cited in this work. Though these assumptions could simulate the expansion process, non-availability of realistic estimation of contact nature and hence coefficients of friction between the concerned surfaces poses limitations on the numerical result. Hence experimental investigation methods to determine the contact nature will certainly add value for the existing stent expansion methodologies [62].

5.2.5. Boundary conditions

In majority of works symmetry boundary conditions were used to prevent the rigid body motion of stent. Nonexistence of plane of symmetry (in majority of cases) renders this assumption nonrealistic. Each point on stent surface is subjected longitudinal movement during expansion and hence more appropriate boundary conditions to prevent rigid body motion of stent geometry is to be included, which can quantify the effect of longitudinal movement on stress distribution especially near non-deceased artery segments.

Stent expansion simulations have always disregarded pulsatile flow of blood. Stent migration [63] can be expected due to repeated exposure to pulsatile flow especially in case of stent strut with large thickness (larger the thickness higher the stent area exposed to incoming flow). This stent migration may also result in longitudinal stretch of endothelial surface. Hence a simulation on stent migration during expansion is highly solicited.

Once the crimped stent reaches target lesion site it is expanded with external inflation device. The duration and rate of expansion (can be quantified as rate of pressure increase in inflation device) may influence the stenting outcome. This may be attributed to the fact that longer exposure of crimped stent to incoming flow may result in longitudinal movement of stent and slightest movement away from lesion site may subject non-deceased artery segment to unnecessary stress field. Hence optimum duration/inflation rate needs to be determined for effective stenting [64]

Table 6: Summary of Review; Issues, Challenges, Scopes and Direction for Further Study

Issues	Challenges	Scope	Direction
Geometry	Realistic modelling of stent	Effect of surface abnormalities, curvature on expansion	Modelling with micro CT, Image based model construction intravascular ultra sound (IVUS) etc
	Patient specific stenotic artery	Effect of plaque profile over stress gradient	
	Layer specific stenosis	Effect of level of calcification on arterial stress	
	Realistic folded profile of balloon geometry	To capture dynamics of expansion, effect of fluid flow on unwrapping of balloon (FSI)	
	Full length stent	Effect of stent length on artery angulation vice versa	
Material	Subject specific coronary artery/plaque material model.	Effect of age, gender, level of stenosis on material property thereby on stenting outcome	Uniaxial /Biaxial test on 3D samples and derivation of constitutive material model
	Contact between artery/plaque/stent	Effect of multiple contact nature (contact between artery/stent is different from plaque/stent and varies from point to point)	Experimentation to determination of frictional coefficients
Simulation	Prevention rigid body motion	Effect of expansion procedure on longitudinal movement of stent	More realistic boundary conditions
	Interaction between artery and stent during stent insertion	Effect of stent rigidity on artery injury during insertion	Dynamics/explicit simulation
	Interaction between fluid and balloon	Effect of fluid type, speed of inflation etc. on unwrapping of balloon thereby on artery mechanics	FSI simulations
	Incorporation of transient blood flow	Effect of Cardiac cycle on stenting performance parameters	FSI simulations

6. Summary of the review

Above review discusses the numerical simulation of BE stents in terms of issues related to geometry, material and BCs. This study also intended to provide existing numerical investigation methods available ranging from basic simulations to advance patient specific investigations and simulation tools utilized. Study mainly discusses on issues and challenges for reliable numerical study with respect to geometry creation, utilization of relevant material model and proper boundary conditions to be employed. A brief introduction to prevalence of CAD, treatment strategies available followed by evolution of stenting technique is structured in the initial part of the review. Later half discusses the challenges and potential issues to be addressed for effective stenting simulations. Table 6 summarizes the issues and challenges to be addressed, scope and direction for future study for a reliable numerical investigation BE stents. This summary intended to provide an overview of main areas of concern and probable direction for effectively addressing the issues. Each issue is discussed in detail with respect to its practical relevance. This review work is intended to be opener for stent researchers in the direction of sophisticated stent simulation. Issues discussed, if suitably investigated, should also serve as a quantitative input for stent designers for stent design optimization and as qualitative understanding for clinicians to choose from range of stent designs available for treatment of lesion.

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