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# A Systematic Review on Cardiovascular Stent and Stenting Failure: Coherent Taxonomy, Performance Measures, Motivations, Open Challenges and Recommendations

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Abstract: Cardiovascular stenting is a mature topic but it is still being developed in the research community because of its importance. To provide worthy information about cardiovascular stenting environments and to give support to the researchers, attention must be given to understand the obtainable choices and gaps in this research field. This work aims to examine and examine the literature of each work related to the placement of cardiovascular stents, the failure of the stents and the models of stent designs to provide a good understanding through the investigation of articles published in various contextual aspects, such as motivations, open-challenges and recommendations to improve the field of stent placement. A systematic review is carried-out to map and examine the articles related to cardiovascular stents, the failure of the stents and the models of stent designs through a coherent-taxonomy used in three well-known scientific databases: ScienceDirect, IEEE Explore, and Web of Science. These databases involve literature that highlight arterial stenting. Based-on our inclusion and exception, a total of 90 articles composed the final set that offer various classes and sub-classes. The first class includes the development studies with (42/90) of experimental, computational and combined experimental and computational studies related to stent models performance and stent failure, the second class discussed studies that have been performed on stent design with (32/90), the third class is focused on the framework studies with (10/90), and the fourth class includes problems of stenting long-term with (6/90). The performance of stent designs, which is a research area that requires periodic controls, tools and procedures that could provide a stent design with good mechanical performance, reduce restenosis in the stent and increase fatigue resistance and durability. There have been numerous studies on stent performance that could promise good results in this field. The fields of research in stent designs vary, but all fields are fundamental equally. The expectation of this work could help to emphasize present research chances and, therefore, expand and make further research fields.

Keywords: Cardiovascular stents, in-stent restenosis, fracture, fatigue, FEM, stent design

#### 1. Introduction

The number of patients in the cardiovascular diseases are rising, therefore, the number of cases of mortality and morbidity are rising too. One of the main methods to treat the cardiovascular diseases and to keep a narrowed artery open via is implantation of a small mesh medical device named as stent, which have been used widely for the last decades [1]. Nevertheless, after the stent has been employed at the semi-closed arteries, the stent drawbacks appear [2], such as instent restenosis, thrombosis and stent fracture because of many factors that related mainly to the stent design [3]-[5]. The stent design concept is specified one of the main limitations of in-stent restenosis averages [6]-[8]. There are different models of stent designs that affect blood hemodynamics [9]. Various categories were discussed and investigated such as different geometrical parameters, the stent flexibility with bending loads and long-stand term [10], as well as fatigue behavior and influence on stent structures [11, 12]. However, experimental studies focused on effect of mechanical loads on different stent models [13], and influence of the longitudinal anatomical gap in the mechanical environment [14]. The computational and experimental studies were combined to investigate the mechanical performance [15], computational works contributed to investigate the mechanical behavior such as radial loads [16], and stress-strain loads [17]. In addition, the finite element method was used to assess stent performance in different cases such as the mechanical behavior [18], analysis the accessing of side-brunch during the bifurcation stenting [19], and to investigate free expansion of biodegradable-polymeric stent [20]. Moreover, the properties of the material must be taken into account due to its effect on the mechanical performance of the stent [21].

While many innovative stent designs have been introduced, such as a biomimetic-approach for design stentgraft [22], and a resonant-heating-stent to treat restenosis [23], the design of the reliable stent remains a challenge for the researcher. The aim of this review is to provide worthy ideas related to the criteria that are essential to the stent design concept and to give the support to the researchers to understand the options these are available in this field of research. This review is structured as follows. Section-1 produces the study introduction, Section-2 presents the protocol of systematic review. In Section-3, the coherent-taxonomy are discussed in-depth. Section-4 reviews the previous FEM works. Section-5 is focused on stent models. Section-6 outlines the distribution of articles. Section-7 discusses the performance measures, motivations, challenges and, recommendations taken from reviewed-articles. Section-8 describes the limitation of study and conclusion is presented in Section-9.

#### 2. Protocol of Systematic Review

#### 2.1. Data-bases Information

Three scientific resources were sought to search for the desired articles. (i) "IEEE Xplore" is a source for academic researchers, which provides reliable and widespread papers in areas such as biomechanics, electronics, computer science, and electrical and mechanical engineering. (ii) "Web of Science" (WoS) provides interdisciplinary research in different scientific fields. (iii) "Science Direct" is a large resource of medical researches. These aforementioned databases sufficiently cover stenting drawbacks associated with stent design and show a broad view of present research in an extensive but applicable domain of specialties.

#### 2.2. Research Study Selection

The collection of study consists of search for literature sources followed via three steps of filtering. The first step is filtering, where not all non-related articles were removed. Then, the next step is the unrelated and duplicate articles were removed via reading the titles and summaries. Finally, the results of the resulting articles were reviewed in depth.

#### 2.3. Start Searching

This search was started in January/2018 utilizing the search-boxes of "Science Direct, IEEE Xplore, and WoS" to classify the articles linked-to "In-stent restenosis", "ISR", in various variations and linked by the operator "OR", and "Stent graft", "Stent-graft", "Fatigue Life", "Coronary Stent", "Stent Fracture", "Braided Stent" in various variations, linked via "AND". The exact query-text is illustrated in Figure 1. The advanced-search choices in the search-engines were utilized to except short communication, book-chapters, letters, correspondence and to increase access to up to date scientific papers related to our review on this emerging study of stenting performance. Table 1 shows the setting information used to start the research query.

Tuble T Search query settings										
Databases	ScienceDirect	IEEE Xplore	WoS							
Language	Only English	Only English	Only English							
Search on	Full text	Full text	Full text							
Thematic areas	All available	All available	All available							
Run date of the research string	2018	2018	2018							

Table 1 - Search query settings

#### 2.4. Suitability Criteria

Every single article related to criteria considered in Figure 1 were involved. We established an early objective to map the research on cardiovascular stenting parameters in general and general taxonomy of four-classes. These sections were derived from a previous articles of the literature.



Fig. 1 - Selected search flow diagram, including the search query

Next, the primary elimination of duplicates, the papers were excluded in two selection and filtering iterations if they did not agree with the eligibility criteria. The exception-criteria include the following; (1) articles that are not in English language. (2) articles focused on a specific feature such as the shape or angle of plaque. (3) articles that do not into account the designing parameters or mechanical behavior such as radial strength and mechanical flexibility.

#### 2.5. Procedure for Collecting Data

WORD® format was used for simplifying the steps of reading and analyzing articles. Moreover, the taxonomy and a large group of comments and highlights were utilized to classify the articles in detail. The taxonomy proposed several topics and sub-topics, inclusive four-categories: development, framework, study conducted to stenting concepts, and others. The texts were classified according to the preferred style of the authors, and the data collected and the relevant inputs were saved in Word-files. All papers from different resources were examined in depth to offer readers a synopsis of the subjects.

#### 2.6. Statistical Information and Results of Articles Databases

The primary-query resulted in 370 papers: 51 from WOS-database, 284 from Science-Direct, and 35 from IEEE-Explore. The clarified-articles published from 2008 to 2018 were taken on in this research and grouped into three classifications. In the three databases, 10 out 370 papers were iterated. After read the titles and abstracts, 191 articles were removed, for a whole of 169 articles. The last full-text review excepted 79 articles, for a total of 90 papers at the final-set. The taxonomy showed in Figure 2 was utilized to analysis the main lines of research focused on stenting parameters. This classification shows the integral development-of several applications and studies. The taxonomy offers various topics and sub-topics. The first class includes studies with real-attempts to develop stent placement parameters using experimental or simulation or both (42/90) articles. The second-class includes studies performed on stent designs (32/90) articles. The third-class includes framework-proposals (10/90 papers). The final class comprises stenting long-term problems (6/90) articles. The observed groups are planned in the following-sections for statistical-analysis.



Fig. 2 - The taxonomy of research literature

#### 3.1. Articles based on Development Studies

This part reviews articles that include development work that contributed to improving stent performance based on experimental and computational data. This section has (42/90); these papers were separated into several areas and applications. The designated articles were distributed in broad-categories that depend on the kind of development.

#### 3.1.1. Experimental Studies on the Performance of the Mechanical-Structural Stent

This subclass section has 16/42 articles; these articles show the contributed researches to enhance the stent performance based on experimental works. Mechanical performance, control of in-stent restenosis and blood-flow effects are all examples of development articles related to stent design.

First, mechanical performance assessment; diametrical-compliance, bending-strength, radial-strength and recoil were developed by using next generation of non-thrombogenicity of polyhedral oligomeric silsesquioxane-poly urethane via silanisation and coating [24]. However, the feasibility of a CoCr stent manufacturing by using the selective laser melting developed industrial grade CoCr powder with shape and size that will contribute with micro devices [25]. Moreover, the poly (p-dioxanone) self-expandable stents were thermally treated for 1 hour under different temperatures (60 °C, 80 °C, and 100 °C), the properties of these stents were then compared via wide-angle X-ray diffraction and different scanning calorimetry with stents that were not treated, a new approach for developing mechanical performance [26]. Furthermore, finite element analysis, a traditional method to analyze mechanical properties of the stents, was applied to simulate the experiment results for the fully covered biodegradable biliary stent to investigate the effect of braid-pin numbers and polydioxanone diameters on the compression properties of the stents [27]. Surface composition, corrosion resistance, endothelial-cell adhesion and image artifact were assessed by seeking how the material properties may perform in the intended physiological and MR imaging environments [28]. On the other hand, the inflection in the limp effects the performance of stent in mechanical characteristics under axial tension, axial compression, torsion, radial compression, and bending [13]. After employing the stent inside the in-vivo will expand at the plagued artery, to control of the surface free energy of a C:H:Si film and the surface behavior of a-C:H:F/a-C:H:Si/a-SiC:H has been investigated [29]. Many parameters effect the braded stents design, some of them in terms of mechanical performance or in the braided tools like braiding angle, monofilament type and diameter, and mandrel diameter on the porosity [30]. In 2017, Guerra et al. [31] studied the feasibility of stent manufacturing in terms of cutting speed, peak pulse power, and number of passes upon dimensional and material properties by using 1.08 µm wavelength fiber laser to cut polycaprolactone. For visualizing the stent-tissue interface morphology sough the methodology by taking the stented coronary arteries embedded in JB-4 glycol methacrylate or Technovit 9100 methyl methacrylate flexibly media [1].

Second, control the return of restenosis; one of main causes of in-stent restenosis is neointimal hyperplasia, therefore, to restrain neointimal hyperplasia by the new design of stent-based circuit serves as a frequency-selective wireless heater that is controlled by using a tuned radiofrequency (RF) electromagnetic field radiated externally, locally applying thermal stress to the stented site [23]. On the other hand, fatigue durability is one of more dangerous causes of restenosis in stent, for that reason the size of 316L stainless steel struts examined fatigue testing of micron-size [32]. In addition, in 2017, Nakazawa et al. [33] evaluated the impact of preoperative inflammatory status in patency of the femoropopliteal (FP)

stenting on 12 and 24-month as determined by complete blood count test parameters. The report was based on 5-year outcome relative to endovascular repair of the common femoral artery for occlusive disease and the influence of lesion classification on restenosis or thromboses [2].

Third, effects of blood flow on the structures of the stents; a physical feature such as blood flow is one of the more important parameters in stent manufacturing. Therefore, a novel 3D additive manufacturing machine was used to produce biodegradable stents (BRSs) based on polymers to seek the effect on physical properties such as fluid-flow-rate, printing speed, and printing trajectory strategies. The printed sample was analyzed using optical microscopy, differential scanning calorimetry, and the Radial Expansion Test to study the effects of printing parameters [34]. Furthermore, to examine the in-stent restenosis, blood pressure development to assess the restenosis without a catheterization procedure, a novel implantable X-ray-detectable MEM Blood Pressure sensor (the X-BP micro sensor) was used for measuring the FFR non- invasively [35]. For a brief summary of the experimental works, Table 2 presents the articles that are in the core of the real data related to the failure of the stent performance in the characteristics of the stent designs.

Table 2 - Synopsis of the real-data

Author/ vear	Aims of study	Artery name	Equipment	Methods and technologies	Outline	Outcomes
Mayurachat et al./ 2014 [34].	Cyclic monitoring of in-stent restenosis.	Coronary artery	X-BP micro- sensor.	Measuring the visible changing of X-BP micro-sensor with blood-pressure.	Designed, invented and examined a novelty of X-BP micro-sensor.	<ul> <li>Reduce the time of results (few minutes at the ambulatory care).</li> <li>Possibility of short-term observation every 3-6 months, because low price of radiographs and the terrible exposure to radiation.</li> </ul>
Yasmin et al./ 2015 [24].	. Reduce of restenosis and thrombosis. . Beneficial pediatric application	Coronary artery	Covered stents of POSS-PCU.	Developed a nanocomposite polymer (POSS-PCU), which was used to coat the struts to avoid exposing the blood directly to the surface.	POSS-PCU has been developed regarding its performances in symmetry, safety and biomechanical.	There are three important elements for performance optimizing of the covered stents: 1) Type of coating material. 2) Bonding between polymer-metal interface. 3) Method of fabrication.
Luo et al./ 2015 [23].	The long-term prevention and management of restenosis.	Not specific	<ul> <li>Fabricated stent.</li> <li>Resonant heater circuit.</li> <li>Artificial artery.</li> </ul>	Explores a procedure and technology developed to wirelessly monitor the heating of the stents used with high qualification and accuracy.	Fabricate a wireless heater stent-based on circuit by utilizing a tuned RF electro-magnetic field.	<ul> <li>Treat the instent restenosis with several kinds of stents.</li> <li>May also treat the cancers invivo conduits.</li> </ul>
Maleckis et al./ 2017 [13].	Test the mechanical loads performance on common of 12 PAD stent models.	FP artery	12 PAD stent models.	Mechanical deformations test under: 1) Axial tension/compression, 2) Three-point bending, 3) Radial compression and, 4) Torsion.	The mechanical tests were performed for all stent models in the same sequence.	Under one or multiple tests, some stents showed better mechanical performance, but none of stent models showed a

						superior mechanical performance under all deformations.
Nakazawa et al./ 2017 [33].	Assessment of ISR risks after FP stenting.	FP artery	Records of clinical and angiographic patients from January 2005 to October 2014.	The retrospective analysis of clinical and angiographic records in 138 patients.	The mechanisms of the pathophysiology of restenosis in the stent include severe inflammatory procedures performed through neutrophils and circulating platelets.	The determination of the inflammatory case from preoperative checks could give a strong clinical supply.
Guerra et al./ 2018 [31].	The influence of the manufacturing parameters of the stent on the physical characteristics.	Not specific	<ul> <li>Poly-caprolactone (PCL)</li> <li>CAPA 6500.</li> <li>3D printer.</li> <li>Matlab software.</li> </ul>	The screening experiments has been done to find the suitable process parameters stages to manufacture whole stents.	The 3D printing is very important to save post- processing costs because of the smallest effected on the stents structures.	The printing temperature and the printing flow have an impact effect on the dimensional accuracy.

To clarify the long-term stent challenge posed by in-stent restenosis [13], [23], [24], [35], these articles examined the effect of ISR on the stent performance and how to monitor, reduce, prevent and assess ISR. However, although the mechanical behavior of different stent designs for several mechanical loads with 37°c were approved, no superior characteristics were found in all tests [31]. The effect of the manufacturing parameters on the physical properties were also sought in [33].

#### 3.1.2 Computational Studies Related to Stent Geometry

This section presents the works based on simulation that contributed to develop stent performance by analysis of 19/42 articles based on different geometric factors, effect of different loads, computational models and fatigue lifetime realization.

First, geometric factors in the performance of the stents; variable geometries can help to customize the stent colonic obtained with different radial force reactions, however, the computer simulation design proposed corresponds to a tubebased stent with closed diamond-shaped cells made from a Nickle-Titanium (NiTi) alloy [36]. To recognize any structural weakness points on the straight strut stent geometry in 2014, Kapnisis et al. [37] examined any potential variations in the local mechanical properties during operation that will lead to the premature failures in stent device. On the other hand, an analytical solution to develop the stress state in an idealize stent geometry gives a novel understanding of the role of coating thickness and stiffness and substrate stiffness and geometry on the normal and shear stresses at the interface [38]. Moreover, to simulate the stent geometry as close as possible to real life, stent design or strut dimensions (length, thickness, width) and were varied while keeping the same boundary condition; stent models were then compared to suggest possible technical prescriptions to increase their durability [9]. In 2014, Grogan et al. [39] simulated the deformation of individual magnesium stent struts by using crystal plasticity finite element in mechanical behavior (bending and tension) to predict strut ductility, failure risk and the highest load bearing capacity for various numbers of grains through the strut dimensions. A comparison simulation has been made between deployment of the Absorb (Abbott Vascular, USA) and Xience V stent (Multi Link Vision platform design, Abbott Vascular, USA), for seeking the crimping process, which is an essential step for fixing the as manufactured stent onto the balloon catheter and tends to create high level residual stresses on the stent [17]. Second, effect of different loads on the geometric of the stent; the bending load and structure parameters (monofilament diameter and braid-pin number) for biodegradable polydioxanone biliary braided stents have been investigated via electrospinning method, then bending was simulated to evaluate the bending flexibility [10]. However, for seeking feasibility of investigating bifurcation stenting techniques, an innovative simulation by using finite element analysis strategy was conducted for studying the interactions between balloon, stent and arterial wall during dilatation stent implanted in the main branch [19]. In 2015, Pauck et al. [16] reported a series of material tests to calculate the mechanical properties of PLLA, then used the data from these tests in a computational realization to assess the radial action of polymeric stents. Geometric parameters such as strut section and diameter influence on the radial force of selfexpanded stents were also examined [40]. Third, computational models related to the performance of stents; for checking the hypotheses of mechanobiological model arterial tissue response to injury as calibrated previously, it may be possible

to predict the long-term outcomes of stent design using a computational pattern of arterial tissue response for stenting applied on three clinically relevant to stent designs [41]. In 2017, Gudiño et al. [42] proposed a novel fully coupled pattern for plasma filtration, blood flow and drug release kinetics that takes into account the viscoelastic properties of the polymeric coating of the stent by providing a mathematical instrument to adapt the material of the coating to improve the efficiency of the controlled drug delivery. Optical coherence tomography and CT images are used to simulate the 3D models of the coronary bifurcations according to a specific patient report of stent deployment to replicate the complete execution followed by clinicians to treat the coronary bifurcation [43]. O the other hand, by using the finite element solver ABAQUS, a computational analysis of many stent-graft material combinations and their impact on mechanical properties while undergoing cyclic pressure loads has been carried out [44]. Moreover, for modeling a coronary stent that is more accurate and closer to the real condition of stent deployment by such a modeling that contains internal blood pressure, stent, balloon, plaque and vessel, finite element analysis has been done [18]. Fourth, fatigue lifetime realization in the geometry of the stents; there is a mechanical explanation of increase in stent fracture and the effect of plaque classification, a model simulating of epicardial atherosclerotic coronary artery according to blood pressure and wall artery moving [45]. However, to provide useful input either to be used for product perfection or for clinicians to make lifesaving decisions, researchers presented a numerical fatigue life model for the analysis of cardiovascular balloonexpandable (stainless steel) stents [46]. On the other hand, to clarify how the stent proceeds and to study the factors that have an influence on the fatigue lifetime of the cardiovascular balloon expandable (BE) stent, the numerical realization will provide quantitative information of stresses over the bridges of the stent that are created by mechanical forces [47]. Furthermore, the collected date from simulation intravascular stents, a tabard strut design that will provide the fatigue life performance under the mechanical various loadings is presented [48]. For a brief summary of the computational works, Table 3 presents the articles that are at the core of the simulation data related to the failure of the stents in the characteristics of the stent geometry.

Author/ year	Highlight	Stent computational models	Cell designs	Expansion style	Stent material	Case study				
Kleinstreuer et al./ 2008 [44].	• Mechanical behavior. • Fatigue performance.	Stent–graft	$\diamondsuit$	Balloon- expandable	Nitinol	The impacts of: 1) Crimping, 2) Deployment, and 3) Cyclic pressure loading.				
Balossino et al./ 2008 [9].	The disturbances of fluid dynamics.	Stent A (Cordis BX velocity)		Not specified		Analyze the alterations in fluid dynamics produced when a stent is incorted into a				
		Stent B (Jostent flex)			Nitinol for	coronary blood- vessel.				
		Stent C (Sorin Carbostent)	Constant of the second	_	models					
		Stent D (Palmaz– Schatz)								
Eshghi et al./ 2011 [18].	The characteristics of stent deployment and implantation within an artery.	Palmaz-Schatz		Balloon- expandable	Stainless- steel 304	Analysis of mechanical behavior to introduce simulated study close to a real process.				
Boyle et al./		Multilink								

Table 3 - Synopsis of the simulation-data



The mechanical behavior and fatigue-life performance are important factors impacting stent design. The production of stent integrity, the radial forces, bending loads, stresses on wall arteries and fatigue performance were analyzed in [17], [18], [39], [44], [46], and the impact of designs and mechanobiologicals and stent stricture behavior have been studied in [41], [47].

#### 3.1.3 Experimental and Computational Development Studies of Stent Performance

This section displays the articles based on real data and simulation data with 7/42 articles under development class. Many studies have discussed and investigated the use of experimental method, while many other studies have employed simulation for making models with more accuracy than real models. In this part we sought to combine both realsimulation articles in development section. In 2013, Hopkins et al. [49] investigated the combination of experimentalsimulation methodology seeking the interface strength and characteristic length from a peel test in stent polymer coatings by measuring peel radius at the interface and peel force. Moreover, the verification of design and experimental for expansion mechanism of a stent vascular that reported in clinician reports caused foreshortening and placement accuracy [50]. However, for assessing and comparing the conduct of primary of four stent graft (SG), the computational and empirical model have been examined [51]. Also, the comparison of FEM simulation and empirical for the mechanical properties of anti tetrachiral auxetic stents with elliptical nodes was sought [52]. In 2015, Ratnovsky et al. [53] based on numerical simulation, evaluated different air way stents by exerting radial forces which may assist in selecting, for a proposed method, the most adequate commercially airway stent. Furthermore, to improve the sensibility in observing change in pressure, an alternative approach was offered, namely active telemonitoring that uses an integrated circuit (IC) established on the structure of smart-stent [54]. Therefore, to store a huge number of results in the software data base, to predict the real time of stent fatigue conduct, a 3D finite element model was developed based on number of parameters inclusive of stent type, length, and size degree of stenosis, and features of patient stenosis [55].

#### **3.2 Studies Performed on Stent Designs**

This part presents a number of studies (32/90) related to stent design. This part is divided into mechanical efficacy, performance of stent designs and investigation of mechanical behavior. First, mechanical efficacy of stents; this section identifies the mechanical efficiency studies revolving around the performance of stent design. Sufficient scaffolding for chosen arteries without creating too much recoil after deployment were provided by Poly-L-Lactide Acid coronary stents [15]. However, by using finite element method, the mechanical performance of two commercially available stents (same material and different design), STENT A (NIR, Scimed, Boston Scientific Europe, Verviers, Belgium) and STENT B (Multi-Link, Guidant-Advanced Cardiovascular Systems, Inc., Santa Clara, CA, USA), were compared in terms of stress distribution, radial gain, outer diameter changes and foreshortening as illustrated in Figure 3 [56]. In 2017, Fan et al. [14] based on MRI images of particular patient, numerically analyzed Von Mises stress (VMS) allocation, the influence of several stenting scenarios on the VMS distribution in the treated arteries.



#### Fig. 3 - Distributions of Von-Mises-stress on (a) Stent model A; (b) Stent model B [56]

Moreover, numerical CFD model was validated via comparison with vitro empirical data and the CFD model was applied to compare the various stenting technique and stents, which permitted assessment of how traditional and deducted bifurcation stents effect hemodynamics in coronary stent bifurcation [57]. The mechanical properties and material ranking used in stent manufacturing were used to compare by means of experimental versus simulation models with various designs structure and included the types of stent ends of braided stent [52], [58]–[60]. In the other view, it is more important to realize that in stent design phase that is not enough to study the mechanical behavior and material properties alone, Gervaso et al. [61] reported that the arterial stress status caused by the stent device. In 2017, Shanahan et al. [62] studied the evaluation of the time-dependent viscoelastic response for a braided stent undergo to crimp via in-vitro and numerical simulation by using ABAQUS software. Moreover, many studies sough into many topics that will related to

stent design such as, the developing of stent resistant through estimate the effect of various textile parameters on the fatigue effectiveness [6], [63] and balloon expendable coronary stent widening inside a tapered vessel [64].

Second, performance of stent designs; this portion centered on these studies are evaluated based on stent design performance which are discussed here. However, to further information for the application of curvature fatigue in stent-graft as well as connection their design and bending strength [64]. Moreover, by using such delicate reconstructions of in-vitro (polytetrafluoroethylene tube, PTFE) and ex-vivo (canine artery) deployed self-expanding intracranial stents could be analyzing blood flow through a stented "vessel' [65]. On the other hand, for summarizing the development of cardiovascular stents designs as well as mechanical, metallurgical, surface and biological-performance of new materials with short corrosion period design and evaluated, compared with current stent performance [66], [67]. Moreover, finite element and computational fluid dynamics (CFD) were used to evaluate performance of self-expanding carotid artery stent designs on key mechanical and hemodynamics behavior [12], [21], [68]–[71]. However, to evaluate the long-term of fatigue and durability of degradation model for sub-unites of absorbable cardiovascular stent, addressed the non-pulsatile musculoskeletal deformation conditions, also within the context of "test to fracture" methodology described [72]. In the other hand, laser interference lithography was used for modifying the surface of coronary stent by mimic the repellent of lotus leaf [73]. Moreover, for treating patients via using Supera stent in peripheral stenting, many cases were reported [74].

Third, investigation of the mechanical behavior of stents; this section seeking on these studies are investigated in the cardiovascular stenting which effected on stent design and performance after and before deployment inside the human body. Furthermore, mechanical behavior of braided stents included a classification of materials used and a characterization of manufacturing style were investigated via analytical and numerical methods [57]. Moreover, the effects of the artery tapering level on the structural properties of coronary stent design as well as its biomechanical influence on the blood-vessel during stent deployment were sought [75]. In 2014, McGrath et al. [76] investigated the axial buckling which observed through crimping of a long diameter Nitinol stent and through clarification of the buckling mechanism to remove it from the design. However, for investigating whether stent and blood-vessel deformation have a main effect on the hemodynamic environment in stented coronary arteries [77]. Furthermore, the life time estimate of balloon expandable stents the introduction of a universal computational design method was investigated via mechanical analysis calculates the plastic or elastic shakedown mechanical state of the stent [78].

#### **3.3. Framework Proposals**

In stent design concept many opinions were inspired for making stent performance more helpful during impact with the obstacles, framework proposals come with ideas that discussed many ideas to improve the designs and stent deployment in general by analysis (6/90) works; that were divided into two-groups such as, first group improvement of stent designs performance and second group blood-flow contributions. First, improvement of stent designs performance; An earlier examined that intends to optimize a new kind of stent that is able to collect all advances studies in this field for making stent with self-expandability without using the classical balloon inflation approach and decreasing foreshortening [79]. As well as finite element method (FEM) contributed for assessing the mechanical performance for the commercial stent BVS [20]. Moreover, the cellular grows in the arterial wall one of the major reason cause stent-induced injury, furthermore, a continuum and computational framework model for automatically obtain a suitable stent discretization from a CAD model [80]–[82]. The stent translating requirements such as flexibility, robustness and radial distension which are important for the stent structural parts, therefore, caterpillar's hydro-skeleton mechanisms used to mimic the stent graft (SG) devices which that also appears much near to realistic aortic mechanics as illustrated in Figure 4 [22].



Fig. 4 - Cuticle-design of caterpillar. (a) Lateral-view; (b) Mechanical model of cuticle [22]

Moreover, for enhancing the fatigue strength, multi-objective improvement procedure has been examined including cell-geometry and strut shape for a Nitinol stent [3]. Second, blood-flow contributions to improve stent designs; A framework for CFD analysis was proposed an optimal coherence tomography based on rebuilding method of patient specific for coronary artery models [83]. Therefore, with several types of arrangement for the non-stented and stented arterial that used to simulate the evaluation of computational fluid dynamics information which to be useful for assessing in stent design such that aneurysm growth can be reduce [84]. On the other hand, in design optimization uncertainties

and noise factors are most important to be taken into account which involves into during stent deployment or these are causes by arterial injury in which their effects are hoped to be minimized, thus assuring the robustness of stent design [85].

#### 3.4 Stenting Long-Term Problems

The resent sections were examined various ideas worth which sought the parameters impact with stent design and performance. Well, remains other thoughts most taken into account that influence on stenting procedure in direct or none direct way. Therefore, for the better understanding of the factors that impacting fatigue life of Nitinol stent the strain amplitude and mean strain were generated [86]. Moreover, to realize the connection between device geometry and the long-term scaffolding effectiveness, the newly advanced techniques by using computer simulation named absorbable metal stent examined the effects of corrosion on the mechanical performance [87]. On the other hand, pre-operative planning tool, Aima-Simul, and implement ways for stent posture and deformation were studied [88]. Furthermore, the review articles contributed by providing a clear reference on drug eluting stents (DESs) and tribology researches in cardiovascular apparatus [89], [90].

# 3.4 Stenting Long-Term Problems

The resent sections were examined various ideas worth which sought the parameters impact with stent design and performance. Well, remains other thoughts most taken into account that influence on stenting procedure in direct or none direct way. Therefore, for the better understanding of the factors that impacting fatigue life of Nitinol stent the strain amplitude and mean strain were generated [86]. Moreover, to realize the connection between device geometry and the long-term scaffolding effectiveness, the newly advanced techniques by using computer simulation named absorbable metal stent examined the effects of corrosion on the mechanical performance [87]. On the other hand, pre-operative planning tool, Aima-Simul, and implement ways for stent posture and deformation were studied [88]. Furthermore, the review articles contributed by providing a clear reference on drug eluting stents (DESs) and tribology researches in cardiovascular apparatus [89], [90].

## 4. FEM Investigation Details

The computational studies are provided and supported a good research tool to simulate the stent models and make a specific analysis for getting results which are closed to the experimental and reality outcomes, Table 4 presents the numerical summary for articles which are sought by utilizing numerical software for seeking many study-cases.

Author/ year	No. of stents	1	Stent models	Stent dimensions	Software used	Method	Element mesh				
0: (1)	1	~	D 1 I			EEM					
Qian et al./	1	~	Poly-L	Outer diameter = $3.40 \text{ mm}$ ,	ABAQUS/	FEM	1/3,968/				
2017 [15].			lactide Acid	Strut thickness= 0.15 mm.	Standard		hexahedral				
			(PLLA)	~			(C3D8R).				
Schiavone	2	$\succ$	Absorb	For both:	ABAQUS/ CAE	FEM	8-node/				
et al./			(Abbott	• Outer diameter= $3 \text{ mm}$ ,			hexahedral				
2016 [17].			Vascular)	$\blacktriangleright \qquad \text{The length} = 10 \text{ mm},$			(C3D8R).				
		$\succ$	Xience	Strut thickness= 80 μm							
			V(Abbott	and150 µm for Xience V							
			Vascular)	and Absorb,							
				respectively.							
XIANG et	1	$\triangleright$	Palmaz-	Length= 16.08 mm,	ABAQUS/	FEM	3316/				
al./			Schatz	• Outer diameter= 1.36 mm,	Explicit		hexahedral				
2016 [75].				• Strut thickness $= 0.09$ mm,	•		(C3D8R).				
				. Strut width= 0.09 mm.							
Auricchio et	1	$\triangleright$	Boston	outer diameter= 0.876 mm,	ABAQUS/	FEM	57,600/ brick				
al./			Scientific	length = 8.049 mm,	v.6.11		elements				
2015 [78].			NIR	strut thickness and width=			(C3D8)				
				0.10 mm.			. ,				
Debusschere	1	$\triangleright$	Absorb BVS	thick struts= 150 µm	ABAQUS/	FEM	Not specified				
et al./				•	Standard		•				
2015 [20].											
Misagh et	2	$\succ$	NIR,	For both:	Not specified	FEM	10060 and				
al./		$\triangleright$	Multi-Link.	$\blacktriangleright$ Outer diameter= 3 mm,	•		26140/				
2015 [55].				$\blacktriangleright$ The length= 10 mm,			3D block				
. J.				Strut thickness= $0.05$			elements.				
				mm.							

#### Table 4 - Numerical studies on FEM analysis

Elyasaf et al./ 2015 [71].	1	•	S.M.A.R.T. CONTROL	Outer diameter= 9 mm, Strut thickness= 0.2 mm.	ABAQUS	FEM	52,944/ (super- elasticity), elements (C3D8R).
Graeham et al./ 2014 [49].	3	A A A	Diamond, Auxetic, Hybrid C.	<ul> <li>For all:</li> <li>outer diameter= 4 mm,</li> <li>the length= 50 mm,</li> <li>strut thickness= 0.3 mm,</li> <li>strut length= 5 mm.</li> </ul>	ABAQUS/ CAE 6.8-4	FEM	4-noded/ tetrahedral elements (C3D4).
Azaouzi et al./ 2013 [86]	1	4	SMART control.	For the strut: Length L = 2.5 mm, Width W= 0.15 mm, Thickness T = 0.3 mm.	ABAQUS/Standard	FEM	hexahedron element (C3D20
García et al./ 2012 [39].	1	~	ACCULINK design (Abbott Vascular)	Not specific	ABAQUS/ Standard v6.9.	FEM	216,573 linear hexahedral elements
Auricchio et al./ 2011 [68].	3	A A A	The ACCULINK, The XACT, The Wall- stent.	<ul> <li>For all:</li> <li>Outer diameter= 8-9 mm,</li> <li>The length= 30 mm,</li> <li>Strut thickness= 0.24 mm.</li> </ul>	ABAQUS/Explicit	FEM	2760 Three dimensional (C3D8R).
Eshghi et al./ 2011 [18].	1	~	Palmaz- Schatz	<ul> <li>Outer diameter= 3 mm,</li> <li>The length= 10 mm,</li> <li>Inner diameter= 2.9 mm.</li> </ul>	Not specified	FEM	2700 elements
Claudio et al./ 2009 [91].	5		A (Palmaz- Schatz), B (CordisBX- Velocity), C (Multi- Link), D (Jostent Flex), E (Carbostent).	<ul> <li>Internal diameter(mm)=         <ol> <li>1.20,1.19,1.20,1.19,1.19                 for A, B, C, D, E                 models, respectively,</li> <li>The length (mm)=3.20,                       3.68, 3.22, 3.37, 3.50,                       for A, B, C, D, E                             models, respectively,</li> </ol></li></ul> <li>Strut thickness for all         (mm) = 0.14.</li>	ABAQUS/Explicit	FEM	87,750 hybrid brick elements
Peter et al./ 2009 [92].	2	A	A (Cypher), B (MULTI- LINK Vision).	<ul> <li>Inner diameter(mm)= 0.9,0.895 for A, B, models, respectively,</li> <li>The length (mm)=8.5, 7.9 for A, B, models, respectively,</li> <li>Strut thickness (mm)=0.15, 0.08 for A, B, models, respectively,</li> </ul>	ABAQUS/Explicit	FEM	25,992/29,73 CypherTM, MULTI- LINK VisionTM respectively, hexahedral elements (C3D8R).

Table 4 shows the numerical works for the most common stent models that used to treat the restenosis which occur in various arteries in human body. Therefore, in 2009 each of (Claudio et al.) and (Peter et al.) [91], [92], [93] are examined 5 and 2 stent models respectively; via utilizing ABAQUS/Explicit with different dimensions and mesh nodes elements. Also, in 2011 (Auricchio et al.) and (Eshghi et al.) [18], [68] are sought 3 and 1 stent models respectively; the FEM applied by using ABAQUS/Explicit with different elements. In 2012, 2013 and 2014 each of (García et al., Azaouzi et al. and Graeham et al.) respectively [39], [49], [86], by utilizing ABAQUS/Standard v6.9., ABAQUS/Standard and ABAQUS/ CAE 6.8-4; the hexahedral, hexahedron and tetrahedral elements applied respectively. While, in 2015 each of (Auricchio et al., Debusschere et al., Misagh et al. and Elyasaf et al.) [20], [55], [71], [78]; they are searched 1,1,2 and 1 of stent models with ABAQUS software to generate of brick, Not specified, 3D block and super-elasticity elements respectively. In 2016 (Schiavone et al. and Xiang et al.) [17], [75] are sought 2 and 1 stent models with hexahedral elements for both respectively. And, Qian et al. [15] in 2017 used 1 of stent model with hexahedral elements.

#### 5. Designs of Stent Models

Cardiovascular stent models vary according to the geometric shape of the stent struts, which differ from one design to another. In this review; we discuss common stent models that have been used to treat different clogged arteries in vivo as explained in Table 5 with their references.

Stent models	References
Palmaz–Schatz	[9, 18, 40, 45, 59].
Jostent flex	[9,91].
Cordis BX velocity	[9, 91, 60].
Stent-graft	[43, 50, 82].
Sorin Carbostent	[9].
Multi-link	[40, 55, 91, 92, 83, 19, 58].
Nir	[40, 51].
Cypher	[45, 92, 19, 8, 36].
Acculink design	[39, 68].
Absorb-scaffold	[17, 70].
Xience V-stent	[17, 59].
Poly-L lactide Acid	[15, 72].
Boston Scientific NIR	[78].
Absorb BVS	[20].
S.M.A.R.T. CONTROL	[71, 86, 13].
Diamond	[49, 33].
Auxetic	[49, 79].
Hybrid C	[49].
XACT	[68].
Wall-stent	[68, 57].
Carbostent	[91].
Drug-eluting	[41, 48, 37, 67].
Monarch caterpillar	[22].
Neuroform Treo	[65].
Absolute Pro	[13, 54].
Supera	[13, 74].
Lifestent	[13, 54].
Innova	[13].
Zilver	[13].
Smart Flex	[13].
EverFlex	[13].
Viabahn	[13].
Tigris	[13].
Misago	[13].
Complete SE	[13].
SMART	[12].
WallFlex	[57].
MAC-Plus	[85].
Express	[36].

The most common design that used in review is Palmaz–Schatz design with 18% of stent models, as well as, 16% of stent models for Multi-link design, and, the third level comes with 11% of models to the Cypher design. In fourth grade the Drug-eluting with 9% of stent models. Each of Cordis BX velocity, Stent–graft and S.M.A.R.T. CONTROL take 7% of stent models designs, also, the Jostent flex model take 5% and, 4% for each of Nir, Acculink design, Absorb-scaffold, Xience V-stent and Poly-L lactide Acid as it illustrated in Figure 5.



Fig. 5 - Common stent models with their percentages

#### 6. Distributions of Articles in Different Databases

Three digital databases store many research works as shown in Figure 6. The outcomes of the review are divided into the four main classifications, namely: development, design, framework and analysis. The overall number of chosen publication articles in ScienceDirect is 74 articles, consisting of 36 articles for development, 25 for design, 9 for framework and 4 for stenting long-term. The overall number of selection publication works in WoS is 6 articles, consisting of 3 articles for development and design, 0 articles for framework and stenting long-term. The overall number of selection publication articles in IEEE is 10 articles, consisting of 3 articles for development, 4 articles for design, framework 1 article and 2 articles for stenting long-term.



Fig. 6 - Number of articles listed in different categories according to publishing journal

#### 6.1. Distribution According to Publication Year

The articles by years' distribution from 2008 to 2018 included into four categories according to the publication years as shown in Figure 7.



Fig. 7 - The distribution by year of publication including different categories

The highest number of research rate with 17 articles have been done in 2017 as well as the exactly of 12, 11 and 10 articles were published in 2014, 2016 and 2013, respectively. Among to the chosen articles, both of years 2012 and 2018 were published 7 papers. Yet, the lowest years publishing according to this study were in 2010, 2009 and 2008 with 2, 3 and 5 articles respectively.

# 6.2. Distribution According to the Author's Nationality

The articles belong to the cardiovascular stenting based on stent design were examined in this study hailed from 19 nationalities and countries as illustrate in Figure 8 these papers mostly involve study status in the 19 countries.



Fig. 8 - Distribution by nationality of the authors

Value n =90 articles in particular, the geographical allocation of the selected articles on the topic of study in terms of percentages and numbers proves the most productive researchers are from China with 15 study cases, it was followed by Ireland and Italy with 13 published study cases each; USA with 8 study cases; Spain with 7 study cases; also UK and Canada with 5 study cases each; Portugal and Iran with 4; Belgium, Australia and Luxembourg with 3 study cases each; France, Taiwan and Israel with 2 study cases each and Japan, Cyprus, Republic of Korea and South Africa with 1 study case each of them.

#### 7. Discussion

The work of this paper shows the most closely related researches on state-of-art of the cardiovascular stenting based on stent-design. The main objective of this study is to focus on research trends of this field. This study varies from past reviews because of it is current study and highlights on the literature with more wide evaluations on the cardiovascular stenting and stent long-term that related to stent performance. The taxonomy of concerning literature is suggested. Improving a taxonomy of literature in a research domain, specially an emerging one, can give several benefits. On one hand, a taxonomy of the published articles arranges various publications, so, a new researcher who searches on vascular stenting behaves could be overwhelm via the big number of articles on the subject area and the absence of any type of structure and, therefore, cannot get a general overview in this research area. Several articles approach the subject from a preliminary perspective, while other papers seek existing applications in stenting of semi-blocked in a blood-vessel. Several studies developed real parameters for enhancing of stent long-term. A taxonomy of regarding literature assists to organize different articles and activities into a manageable, meaningful and coherent design. On other hand, the taxonomy structure provides to the researchers' important information that pertain to the research topic in many ways. First, it describes the possible directions of the research topic. For instance, the taxonomy of this review shows that, the researchers are disposed to offer frameworks to improve the using of stents, such providing acceptable methods in this area. Second, the taxonomy can discover gaps in research. The mapping of the literature on cardiovascular stenting and divided into categories that could highlights the strong and the weak points and features in the vision research coverage. For instance, the taxonomy of this article presents how individual application groups receive worthy attention in the review and evaluation (as presented in the proliferation of its categories) at the quality and expense of perfect frameworks and solutions. The study revealed four sides of the literature content: the criteria that used to evaluate the performance of the search methods, the benefits behind improving stent design and stenting long-term, the challenges for the successful use of these medical devices and the author's recommendations to relieve these obstacles.

#### 7.1. Performance Measures

Most common process used to evaluate the studies was the use of criteria that are involved in our review to perform evaluations of different categories; this portion measures the efficiency of the ranking methods. The performance of the classifiers was evaluated via various measures such mechanical performance, radial expansion, fatigue-life, material performance, in-stent restenosis, quality factors, dimensional precision, stress distributions, biomechanical performance, dog-boning, adhesion properties and hemodynamic behavior. In this part; all these parameters are debated. Table 6 shows the measurement parameter included in the reviewed works. Table 6 shows different studies related to stent designs and stent failure that could affect stent performance, as well as, a general analysis of several criteria and sub-criteria for valuation and benchmarking. The parameter used to evaluate stent performance that linked to stent designs and stenting failure were mechanical performance, radial expansion, fatigue-life, material performance, stress distributions, in-stent restenosis, biomechanical performance, hemodynamic behavior, dimensional precision, adhesion properties, quality factors and dog-boning in 26%, 16%, 8%, 6%, 4%, 2%, and 1% of works, respectively as it illustrated in Figure 9.



Fig. 9 - Criteria percentages

Conflicting sub-criteria are present; as clarified by the variations in the proportion of use of these criteria-among several studies. On the other hand, no study utilized all of these criteria. The difference in these criteria marks a challenge in adopting particular criteria for the evaluation and comparative evaluation of the detection of stent performance.

Table 6 - Measurement parameter included in the reviewed works												
References	Mechanical performance	Radial expansion	Fatigue-life	Material performance	In-stent restenosis	Quality factors	Dimensional precision	Stress distributions	Biomechanical performance	Dog-boning	Adhesion properties	Hemodynamic behavior
[33]		*		*		*	*					
[20]	*											
[22]									*			
[48]											*	
[78]			*									
[80]					*							
[35]		*										
[49]		*										
[26]		*										
[65]												*
[40]		*			*				*			
[55]		*					*	*				
[23]					*							
[10]		*						*				
[68]								*				
[93]				*								
[27]							*	*				
[13]	*											
[17]	*							*				
[16]	*			*								
[15]	*			*				*				
[77]												*
[43]	*		*									
[38]	*											.1.
[69]	*	ste		ste								*
[79]		*		*								

[64]	*		*									
[65]	*			*								
[14]	*				*							
[70]	*											
[56]												*
[9]												*
[72]			*									
[21]			*	*								
[31]			*	*								
[12]			*									
[11]			*						*			
[45]			*									
[50]	*	*										
[18]	*											
[94]												*
[29]	*			*								
[39]		*					*					
[44]		*	*									
[81]	*											
[57]	*	*										
[51]	*								*			
[52]	*	*										
[8]	*	*	*					*	*			*
[7]	*		*									
[85]		*		*				*		*	*	
[36]	*		*									
[26]	*	*							*			
[26]		*										
[46]	*	*										
[60]		*										
[95]			*									
[86]	*		*									
[87]	*											
[47]	*		*									
[82]			*					*				
[58]	*				*							
[50]	*											
[75]									*			
[63]		*										
[59]	*											
[92]			*									
[92]			*									
[3/]					*							
[71]	*							*				
[8/1]							*					
[52]					*							
[53]			*									
 Total	31	20	20	10	7	1	5	10	7	1	2	7
<u> </u>	26%	16%	16%	8%	<u> </u>	1%	<u> </u>	8%	<u> </u>	1%	2%	6%
, <b>u</b>						- / •	- / 0	- / ·		- / -	- / •	

# 7.2. Motivations of the Stent Performance Study

Cardiovascular diseases are the one of main reasons for increasing number of mortality and morbidity, therefore, the treatment of these diseases become more necessary. Furthermore, stent device innovated to be employed inside plugged artery, as well as, the obstacles of stenting are limited the using of stents, so, the optimization of stent performance has been taken into account last decades. Here in this section sought the benefits of factors which are related to stent performances, as illustrated in Figure 10.



Fig. 10 - Groups of motivations

#### 7.2.1 Motivations Related to Obstacles and Optimization of ISR

Even though a huge number of past clinical and investigation studies focused on in-stent restenosis (ISR), there is a significant number of limitation and drawbacks of stent-deployment, which bounds the long-term success of the process which may cause of pain, heart attack and late stent thrombosis for human body or can be caused by an injury to the artery wall, especially in tapered vessels [1], [18], [32], [36], [63], [73], [75], [81], [85]. Moreover, the tissue of wall vessel in growth into the stent that causes restenosis also the longitudinal anatomic mismatch (LAM) of stenting (a stenotic artery part in not fully wrapped by implanted stent) that associated high dangers of restenosis, as well as, the renarrowing of the artery that responses to "heal" cause in-stent restenosis, which accurse during 6 months after operation, while the complication arising into common femoral artery (CFA) including the risk of kinking leads to in-stent restenosis [2], [14], [40], [53]. On the other hand, many ideas inspired to treat in-stent restenosis such as, an electrothermally active stent chosen at the employment to endohyperthermia treatment of ISR as illustrated in Figure 11 [23]. Bioresorbable stent and the X-BP micro-sensor appear a promising technology optimized in the cardiovascular stenting field because their ability to avoid long-term side effects such as ISR [20], [30], [34].



Fig. 11 - Design of the proof-of-concept device (a) top view of the capacitor strip; (b) and (c) respectively top and side views of the stent coupled with the capacitor strip [23]

#### 7.2.2 Motivations Related to Mechanical Performance and Blood Flow Relation

Biomechanical mismatch and the relationship between the altered vessel hemodynamic and the stent design are major reasons behind post-operative hemodynamic problems, as well as, the influence of the viscoelastic characteristics on the pulsating pressure and the catheter of crimped stent with bent balloon through coronary artery stent have been examined [22], [26], [41], [77], [94]. However, advanced software technique may provide detailed knowledge of pre-intervention as well as post-procedure for vessel anatomy by analyzes the blood flow and mechanical integrity performance comparing with in-vivo experiment data [42], [65], [69], [83]. In 2008, Rossella et al. [9] searched on the effects of the deployment of a coronary stent and disruption of an atheromatous plaque which leads to deform the arterial wall, as well as, the existence of stent strut may create a new fluid dynamic field that can caused an abnormal biological reaction. On the other hand, the use of computational fluid dynamics to simulate the evolution of aneurysmal flow to achieve an

equilibrium to prevent aneurysmal rupture and thromboses formation that give a most suitable stent configuration for the stent employing operation [84].

# 7.2.3 Motivations Related to Effects of Durability Problem on Stents

Under the complicated stress conditions that which experienced physiologically (daily body activities, blood pressure and various cyclic motions) could be short of accuracy to evaluate the fatigue durability of stent graft when compared with the cyclic fatigue in bending, as well as, the data from fatigue analysis allow to search several thoughts on stent life-time [44], [47], [54], [64], [72], [78], [88]. However, the use of polymer or metallic based on bioabsorbable stents is possible solution to reduce these problems, that head for to be degraded by corrosion and completely eliminated [67], [79]. Moreover, the properties such as biocompatibility, fatigue and corrosion resistance which products from non-ferromagnetic austenitic stainless steel (316 L) and Nickel, Titanium (NiTinol) are special suited for used in balloon expandable stents that effected in treating in vivo artery diseases [11], [12], [31], [82], [86]. Furthermore, to provide bases foundation for making better fatigue resistance in stent graft (SG) tubular fabrics the woven construction, yarn type and yarn size had impact influence on the fatigue performance [24], [62]. Therefore, the numerical simulation have been a promising and effective approach to evaluate the in-vivo action of stents and most important to assess the potential of stent failures [45], [94].

#### 7.2.4 Motivations Related to Long-Term Improvement of Stent Structures

The mechanical performance in stent structure is very important to improve long-stand for stent structure, further development and with substantial platinum additions the mechanical properties (such as tensile and etc.) and radiopacity have been enhanced [21], [29], [35], [51], [61], [66]. As well as, the biodegradable stent (BDS) give the possibility to improve long-term patency rates for supporting the artery wall to heal, other researchers examined the mechanical properties for fully covered biodegradable stent by using finite element method (FEM) [16], [27], [33], [43], [56], [76]. Nevertheless, the geometric of stents design response on the mechanical behavior which leads to innovate or develop the new generation of stent geometry, however, stent versus stent researches one kind of randomized trials to show superiority of the new stent designs that should be guarantee fatigue strength and a sufficient vessel scaffolding [3], [4], [15], [39], [50], [55], [71], [74]. The reports from previous studies are necessary to improve a fundamental explanation of the mechanics of such a bi-layered structure geometry of the stent and coating, as well as, additive manufacturing techniques often by simulation analysis for developing of next generation polymer especially their mechanical performance [17], [25], [28], [37], [48], [49], [70]. In 2018, Yanhui Liu et al. [10] indicated that the simulation analysis out comes can provided a useful fundamental reference to the investigation bending behavior for various types of stents (such as fully covered biodegradable polydioxanone biliary stent) that may approve a good agreement with the experimental results as illustrated in Figure 12. The FEM and computational structure analysis were used to evaluate performance of several stent kinds that indicate a significant tool for both procedure planning and device chosen while it is challenging to examine the flexion-induced deformation in vivo [10], [13], [19], [46], [57], [59], [60], [68], [81], [87].



Fig. 12 - Stent model under three-point bending test [10]

#### 7.3. Issues and Challenges of Stent Performance

Although the surveyed studies about stent designs and its performances were not enough, these techniques are not approved to get an integrated stent design, as well as, the long-term for stenting durability for facing all the factors which affected on stenting field. Therefore, the major challenges in agreement with stent design are classified below according to their kinds as shown in Figure 13.



Fig. 13 - Groups of issues and challenges

#### 7.3.1 Challenges related to weaknesses of the existing stent designs

Even the design of a stent is a relatively mature subject, fatigue failure has recently appeared one of main disadvantages while accurately the limited information about the relationship between fatigue and degradation, as well as, the wide variations from patient specific aortic arteries in terms of shape, material properties, size, and leading conditions that impacted with mechanical properties [12], [42], [64], [72], [78]. Arising number of cyclic loads on stent device after implantation has been often connected with fatigue issues [45]. Yet, the various cyclic motions caused by body movement and pulsatile blood pressure which lead to the fatigue fracture [47], [54], [88]. So it is compulsory to optimize long-stand of stent device such as developing stent designs by analysis stent geometry and its structural [3] or by using stress-based Goodman diagram [57]. Therefore, the Supera helical Nitinol stent has improved the flexibility by confrontation fractures when the stent graft implanted in the FP arteries [74]. The material properties are issued the bridge between the material and stent device performance as well as with physical characteristics and conveniently compatible with X-ray fluoroscopy which is optimum within stent geometry and dimensions of stent strut [31], [36], [93].

#### 7.3.2 Challenges related to implications of mechanical performance in stent designs

According to specific requirement, the adjustment of stent design is important to get better fit of the diseased artery and reduce the complication as well as to seek on the relationship between the bending and structure parameter [10], [31]. The large of numbering studies on stent design helped to create a good fundamental information for understanding and comparative of the stent types to recognize the suitable stent design for specific case, despite the promising outcomes, but still the design of novel biodegradable stent challenge because of high cost of precise engineering modelling tools [20], [49]. A mechanobiological model of arterial tissue adaptation is necessary for optimizing long-term lumen gain, furthermore, many studies were examined the mechanical characteristics by using experimental and simulation analysis works to help of getting the novel stent design [13], [16], [21], [40], [67], [68]. Whereas, for decreasing the risks of arterial injury that caused by effected several factors like dog-bone, foreshortening, stress developed and elastic radial recoil, the design of the cardiovascular stent most taken the first researchers attention [85]. Mechanical behavior of stent under bending, compression, tensile and crashing make a good sense to understand the relation between the radial expansion and geometric parameters, thus, an ideal stent design should provide mechanical performance as well as, large radius expansion and high flexibility [39], [51], [52].

#### 7.3.3. Challenges Related to Complications of in-stent Restenosis (ISR) in Stent Design

ISR has been one of main drawbacks which cause failure and short time of stenting long-term standing, therefore, many researchers have been examined the factors in designing stent could lead to ISR, such as, the regrown of arteries tissues [80] or employ of permanent stent metal alloys [79], also, the strut thickness, width and longitudinal anatomic mismatch are most important roles in the restenosis [14], [69], likewise, the stent fracture and the risk of kinking in common femoral artery, which may also be accountable for in-stent restenosis [2]. A new type of coronary stent surface was modified via laser interference lithography that could lead to get high long-term restenosis rate [73]. In 2015, Yi Luo et al. [23] indicated that for ISR treatment, an electrothermally wireless stent active was developed and demonstrated in experimental tests, by integrating a flexible capacitor strip of a stainless steel inductive stent to build a resonant circuit.

On the other hand, multiple stenosis can happen at the superficial femoral artery (SFA) because of its long could reach length (28-32) cm, in such cases, two or more overlapping stents most deployed inside the vessels blood [71]. Stent designs continue to optimize the integrity of stent design and get the perfect stent design which involve more flexibility via using thin struts, or undulating links in stent open cell [58].

#### 7.3.4. Challenges Related to Implications of Blood Flow in the Designs of the Stent

Inside the stented arteries, there are many several stent characteristics like orientation, strut dimensions, angle with respect to flow direction, intrastate surface area and length effect on the flow and distribution of hemodynamic forces [65], [94]. The comparative between the experimental and computational fluid dynamics analysis of cardiovascular stented artery models via using CT scanning data after stent implantation for representing of stent geometry inside silicone paradigm [56], [83]. Also, for the stented coronary arteries were CFD analysis used to simulate pulsatile flow conditions in each of the non-deformed and realistically-deformed models [41], [77]. The novelty of 3D computational models was used to simulate the expansion of resembling a number of commercially stents inside a blood-vessel plaque as illustrated in Figure 14 [9].



Fig. 14 - 3D CAD geometry of a plugged artery, (a) deformed configuration after stent expansion; (b) fluid domain; (c) particular of the fine discretization in the vessel area within the stent struts and (d), (e) are the coarser mesh [9]

#### 7.4. Recommendations Related to the Stent Design Performance

The previous topics of this survey were examined many subjects that related to the main stent design performance, however, the authors recommendations in their research papers kind of future work most taken into account such as, there are few research papers focused on the bending performance of fully covered biodegradable polydioxanone biliary stent which simulated via finite element method and still numerical mimic bending topic lack to accurately [10], also, may the results be inspired to develop of stent-graft fatigue evaluation and new prospects of deformation mechanisms [18], [64]. Yet, the results which come out of deformation modes in this paper may help to guide the optimization of new stents which improved the mechanical performance [13]. Moreover, the optimized analytical/design schemes allow to evaluate the mechanical/hemodynamic performance for various stent design [47], [69], also, the outcomes of this paper reinforced the possibility of getting a new design via limiting the high contact pressure regions lumen zones of a ill artery [39]. Further investigation, in order to enhance the structure behavior of the stent may be conducted by combining FEM with optimization strategies [46]. In 2016, Xiang Shen et al. [75] suggested that, in tapered vessels this analysis provides the proposals for clinical application in tapered arteries via using FEM to evaluate the mechanical performance in stent behavior for tapered vessels. Moreover, the methodology proposed can be expanded to synthesize the geometry of other stents types, such as the superficial femoral artery stent, to be suitable for specific requirements [83].

#### 8. Limitations

Firstly, the identity and number of the selection of the source databases, even though the chosen source are credible and are extensive representative combinations. Secondly, rapid advance in this area limits the opportunity of the research. Thirdly, a summary of the effectiveness of the research on these stents applications based on the design of the stent, does not mainly reflect the existing use or influences of the applications. The outcomes of this review reflect the answering of the research society to the current trends, which that the purpose of this systematic review.

#### 9. Conclusions

The subject of the cardiovascular stenting is a mature research topic, but it is still being developed in the research community because its importance. Research on this field is ongoing, so, earning information on this trend is quite important because it is related to the human being. The objective of this article is to contribute with these ideas through the study and taxonomy of related works. The particular patterns can be obtained from the different articles on stent long-term in the arterial stenting. These papers are divided in approximately into four groups, namely, development attempts, studies conducted to stent design, framework studies and stenting long-term problems. An in-depth examination of the

papers helps describe and identify the benefits, challenges and recommendations related to stent long-term and vascular stenting applications. The results point out the kinds of studies already have been sought and resolve the existing gaps in the use of said arterial stents applications. The researchers have specified problems and offered recommendations including the issues related to the material of stent that could take a big attention in stent design and the stent long-stand. Numerous authors recommendations that could help the researcher to seek on, such, improving of mechanical performance, enhancement of stent-long-term, optimizing stent design, enhance the durability of stent structure behavior via utilizing FEM, syntheses the stent geometry, also, many proposed designs suggested to evaluate the clinical application and the framework suggestion for getting better resistance to in-stent restenosis. These recommendations can help to solve the challenges and obstacles that facing in the cardiovascular stenting and give space to research opportunities for seeking in this field. The review resent and previous works may serve such a good reference to help researchers. At present the arterial stenting has yet search explore based on stent design that could bring smart stent technique such combine of two stent designs models in on design could give good results in-stent restenosis area or create a new stent design with good mechanical characteristics in case of self or balloon expanding stents.

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