European Journal of Mechanics / A Solids 101 (2023) 105071

Contents lists available at ScienceDirect

European Journal of Mechanics / A Solids

journal homepage: www.elsevier.com/locate/ejmsol

A review on the use of finite element simulations for structural analyses of coronary stenting: What can we do nowadays and what do we need to move forward?

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ARTICLE INFO

Keywords:
Coronary stent
Finite element simulation contexts of use
validation

ABSTRACT

In silico studies to perform structural analyses of coronary stenting have attracted the attention of many researchers in the last 25 years. As a consequence, the finite element models used to describe the fundamental elements of stenting simulations, namely the delivery system (consisting of stent and balloon), the diseased artery, and the deployment procedure have had considerable development, paving the way for the application of numerical analyses in both manufacturing and clinical contexts. Indeed, in accordance with the logic of the 3Rs (refine, reduce, and replace), simulations can play a fundamental role in developing new devices and as a support tool for training/education and operational planning activities for clinical personnel. However, the application of such numerical methodologies in the aforementioned contexts of use requires an adequate level of credibility of the models with respect to the risk associated to their use in the decision-making process. Within this framework, this paper proposes a review of the modeling approaches available today for *in silico* stenting of coronary arteries and a discussion of their actual or potential application areas. In particular, the attention is focused on the different levels of credibility required by the presented contexts of use with respect to the validation activities of numerical models developed up to now.

1. Introduction

Atherosclerosis is the immune-inflammatory condition underlying coronary artery disease. This pathology is characterized by the proliferation of smooth muscle cells and the growth of plaque in the vessel lumen preventing proper tissue perfusion. This disease is often associated with critical outcomes such as acute coronary syndromes and infarction, making it the leading cause of disability and death in Western countries (Bentzon et al., 2014; Canfield and Totary-Jain, 2018; Falk, 2006; Sanchis-Gomar et al., 2016). Approaches for the treatment of this disease vary depending on the severity of the patient's condition, providing a first line of intervention through prescriptions of an appropriate diet coupled with the administration of anti-hypertensive drugs. In more critical cases, when these methods are not sufficiently effective, surgical approaches via percutaneous coronary intervention or bypass surgery are required (Libby et al., 2011; Mortier et al., 2008).

In particular, the possibility of intervening with a minimally invasive approach has prompted significant investment in treatment by stent implantation (Bergström and Hayman, 2016; Byrne et al., 2018). The clinical procedure involves reaching the atherosclerotic site by sliding along a guide wire the delivery system, namely the stent crimped around the folded balloon and embedded in the catheter. Once reached the target position, through a pressure increase applied by the clinician, the balloon unfolding and expansion causes the dilation of the stent and consequently the compression of the atherosclerotic plaque restoring proper perfusion of the cardiac tissue. The first type of devices proposed for this application were bare-metal stents (BMS), later replaced by drug-eluting stents (DES), which are metal devices coated with an antiproliferative drug to limit the occurrence of intima hyperplasia. The introduction of this new category of devices has significantly reduced the incidence of in-stent restenosis, which previously ranged around 30% with the use of BMSs (Condello et al., 2023; Moussa et al., 2020; Nicolas et al., 2022; Singh et al., 2010). However, the permanent presence within the vessel causes long-term complications, such as

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https://doi.org/10.1016/j.euromechsol.2023.105071
Received 6 February 2023; Received in revised form 4 June 2023; Accepted 4 July 2023
Available online 7 July 2023

hypersensitivity and thrombosis. Specifically, although the incidence rate of in-stent restenosis is typically below 2% with the use of DES, approximately 10% of stent implantation procedures are performed to address this condition (Condello et al., 2023; Moussa et al., 2020). To solve this limitation, bioresorbable vascular scaffolds (BVS) have been proposed, which are devices composed of degradable materials designed to support the vessel wall only temporarily and be reabsorbed when their function is no longer required (Canfield and Totary-Jain, 2018; Mortier et al., 2008; Wang et al., 2018). The primary source of information regarding the performance of BVS comes from the outcomes of trials conducted on the different versions of the ABSORB BVS (Abbott Vascular, Santa Clara, CA, USA), which have revealed significant limitations with respect to the metallic counterpart, such as higher 3-year rates of target lesion failure and occurrences of thrombosis (Ali et al., 2018; Gallinoro et al., 2022; Musumeci and Quadri, 2023; Nicolas et al., 2022; Stone et al., 2017).

The treatment of coronary atherosclerosis by stent implantation has been the subject of numerous scientific papers to evaluate the mechanical performance of different devices through *in vitro* tests (e.g., Barragan et al. (2000); Rieu et al. (2003, 1999); Schmidt et al. (2009)), or to assess the biomechanical interaction between the stent and the artery in *in vivo* studies (e.g., Huang et al. (2010, 2009); Vogt et al. (2004)). Furthermore, over the years, such works have been gradually joined by an increasing number of studies in which computational analyses were proposed to exploit the ability of numerical simulations to evaluate quantities that would be impossible to observe *in vitro* or *in vivo*, and thus comprehensively investigate the performance of coronary stents implanted in arteries (Gastaldi et al., 2010; Morlacchi et al., 2014b; Mortier et al., 2010). Since the early 2000s, several authors have emphasized the potentialities of digital analyses to be used as a tool for stent design optimization (e.g., Blair et al. (2019); Pant et al. (2011); Tan et al. (2001); Timmins et al. (2007); Wiesent et al. (2019); Wu et al. (2010)), for the comparison of different devices' performance (e.g., Capelli et al. (2009); Mortier et al. (2010); Tan et al. (2001)), and to evaluate how variations in the treatment procedure might influence the clinical outcomes taking into account the mechanical interaction between the device and the artery in which it is implanted (e.g., Morlacchi et al. (2014a, 2013); Mortier et al. (2010, 2015); Rogers et al. (1999)), commonly using finite element analyses. At the same time, computational fluid dynamics (CFD) simulations have been widely used to assess how blood flow is disturbed by the presence of stent struts (e.g., Chen et al. (2017); Chiastra et al. (2016); Ladisa et al. (2003); Martin et al. (2014)) and drug delivery simulations in the arterial wall have been exploited to estimate the drug coating performance of drug-eluting stents (e.g., Escuer et al. (2021); Vairo et al. (2010)). Whereas in the past, the attention of researchers was mainly devoted to demonstrating the capacity of numerical tools in correctly describing the behaviors of the single components of the stenting procedure (the delivery system and the artery) (Martin and Boyle, 2011), the goals and expectations have progressively changed (Morrison et al., 2022). Nowadays, there have been tremendous advances in both modeling skills and computing power, and this has opened up a new perspective on the use of computational analyses. The ability of simulations to produce accurate and credible results is closely linked to the possibility of faithfully representing the reality of interest through digital models. However, the simulations are generally affected by the presence of uncertainties in the input data that typically relate to the assumptions made to determine the boundary conditions, the accuracy of the 3D reconstruction of the artery under investigation, and the inability to evaluate the patient-specific mechanical properties (Redaelli and Votta, 2020). It follows that even if there are numerous works in the literature that propose sophisticated models and computational strategies to replicate *in silico* the complex phenomena associated with the mechanics of biological systems, validation of such methodologies is often critical (Morrison et al., 2022).

The aim of this paper is twofold. Focusing on *in silico* studies dedicated to structural analyses, in the first part, the computational strategies proposed to model the main components of stent deployment simulations, namely the delivery system, the diseased artery, and the clinical procedure are summarized. The purpose is to trace the development path that in the last 25 years, within the framework of the finite element method, has led to the refinement of the computational strategies used to study the performance of coronary stents in the treatment of atherosclerotic pathology. Finally, the second part of the paper offers a discussion regarding the future prospects of coronary stent simulations in relation to the different potential areas of application. Particular attention will be paid to how the models' credibility requirements should adapt according to the addressed contexts of use.

2. Delivery system models

The delivery system of a coronary stent consists of the stent, the balloon, and the catheter. Considering that the action of the catheter plays a role only during the positioning phase of the delivery system within the artery lumen, the numerical strategies related to it will be discussed in the paragraph dedicated to the deployment procedure, while the following section will focus on the stent and the balloon.

2.1. Stent models

Developing a finite element model of the stent involves defining and discretizing the 3D geometry and choosing an appropriate constitutive model to describe its mechanical behavior.

Regarding geometry, works in the literature are mainly divided into two groups. On the one hand, there are the studies in which there is direct access to the 3D model or where the geometry is reconstructed on the basis of detailed information available, for example, in the device patent (Antonini et al., 2021b, 2021c; Bukala et al., 2020; Filipovic et al., 2021; Zhao et al., 2021). On the other, when such information is not available, it is necessary to proceed with the reconstruction of the geometrical model on the basis of measurements acquired by analyzing the device itself (Antonini et al., 2021a; Debusschere et al., 2015; Migliavacca et al., 2005; Morlacchi et al., 2013; Mortier et al., 2008, 2011; Wang et al., 2020; Zhao et al., 2021). In this case, the accuracy is inherently dependent on the quality of the method adopted to collect the dimensions of the various geometrical features.

For the discretization, although different strategies have been proposed over the years (e.g., 2D elements (McGarry et al., 2004) and beam elements (Hall and Kasper, 2006)), the choice of representing the device with a 3D meshed structure using hexahedral elements with reduced integration has been consolidated. Considering that bending is the main condition to which stent struts are subjected, the choice of elements with reduced integration is to be preferred, since full integration would be susceptible to shear locking, potentially making the structure too rigid in bending (Mortier et al., 2010; Wiesent et al., 2019). An example of stent

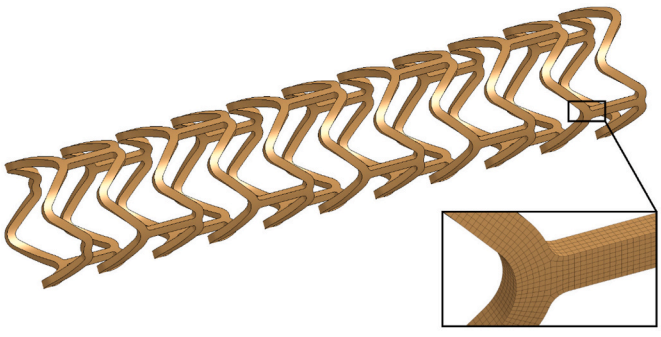

Fig. 1. Depiction of the 3D geometry of a polymeric (PLGA) BVS with detail on the mesh discretization by means of hexahedral elements. Image copied with permission from Bukala et al. (2020). http://creativecommons.org/licenses/by/4.0/.

design with detail about the discretization into hexahedral elements is reported in Fig. 1.

For what concern the materials, when the mechanical behavior of BMSs and DES needs to be described, being metallic, simple elastic-plastic bi-linear models can be used (e.g., Antonini et al. (2021b); Brauer et al. (1999); Chiastra et al. (2018); De Beule et al. (2008); Hall and Kasper (2006); Migliavacca et al. (2002, 2005); Petrini et al. (2004); Wang et al. (2006)). On the other hand, the recent introduction of BVSs, which are made of biodegradable polymers or corrodible metal alloys, has requested the development of new constitutive models able to describe the complex time-dependent mechanical behavior of these devices. The development of sophisticated models capable of faithfully replicating phenomena related to the mechanical behavior of biodegradable materials is often limited by the availability of data or samples through which to calibrate the model. Consequently, it is common in the literature to find simplified approaches that employ phenomenological models specifically tuned to address the objective of the study. This is the case of the poly (L-lactic acid) (PLLA), a polymer that has recently emerged for the manufacture of BVS (Muliana and Rajagopal, 2012; Pauck and Reddy, 2015) exhibiting an anisotropic mechanical behavior highly dependent on working environment and strain rate (Antonini et al., 2021c; Bobel et al., 2016; Pauck and Reddy, 2015). Up to now, most researchers preferred to neglect the well-known non-linearities of polymer mechanics in favor of models that are simpler to implement. For example, simple elastic-plastic models are widely used (Qiu et al., 2018; Schiavone et al., 2016; Wang et al., 2017), while Pauck and Reddy (2015) proposed an anisotropic elastic-plastic model calibrated on experimental test on PLLA samples to evaluate *in silico* the mechanical performances of three different stent geometries. The dependence of mechanical behavior on the strain rates mainly affects the performance of the polymer once the yield stress has been exceeded, thus allowing the behavior to be defined as viscous-plastic (Bergström and Hayman, 2016; Bobel et al., 2015). A Johnson-Cook plasticity model was selected in the studies of Wang et al. (2018) and Antonini et al. (2021c), to describe the polymer as elastic-viscous-plastic. The viscous behavior was taken into account in the work of Debusschere et al. (2015), in which, adopting a material model based on the Parallel Rheological Framework (PRF) and derived from the literature (Bergström et al., 2002; Eswaran et al., 2011), the authors discussed the importance of simulating the stent expansion considering a step-wise procedure for the pressurization of the balloon. The modeling of the PLLA dependence on the working environment and specifically on the temperature was considered in some literature works: elastic-plastic (Wang et al., 2017) and rate-dependent material models (Antonini et al., 2021c; Bobel and McHugh, 2018; Hoddy et al., 2022) were used to describe the material behavior at different temperatures of interest. The temperature modeling proves significant when aiming to accurately simulate not only the stent deployment at body temperature but also the preceding crimping phase usually performed at temperatures close to that of glass transition (Jow et al., 2012). In parallel to the study of temperature dependence, some works in the literature investigated and modeled the anisotropic behavior of PLLA stents using elastic-plastic (Blair et al., 2019; Pauck and Reddy, 2015) or rate-dependent material models (Eswaran et al., 2011; Hoddy et al., 2021).

The PRF scheme was selected also in the work of Antonini et al. (2021a) to describe the viscous-elastic and viscous-plastic behavior of the Tyrocore™, a tyrosine-derived polymer used for the manufacturing of Fantom® Encore Sirolimus-Eluting Bioresorbable Coronary Scaffold (REVA Medical Inc., San Diego, CA, USA). Another polymeric material used for manufacturing bioresorbable coronary stents is the poly (lactic-co-glycolic acid) (PLGA), which, was modeled by Bukala et al. (2020) with an elastic-viscous-plastic model.

Also resorbable metallic stents (RMS) have been studied for several years and a number of these devices have been approved for use in the European market (Sotomi et al., 2017). Both magnesium and iron-based alloys have been considered for RMSs because their degradation products are naturally present in the human body and don't cause toxicity (Hermawan et al., 2010; Zheng et al., 2014). However, to the best of the authors' knowledge, only magnesium stents have reached a stage of development that enables implantation in humans. Accordingly, they have also attracted the attention of researchers and several papers have been published in the last decades aiming to adequately describe the degradation of magnesium stents (Boland et al., 2016). The developed phenomenological models are able to describe uniform and stress corrosion (Gastaldi et al., 2011; Wang et al., 2021), uniform and pitting corrosion (Grogan et al., 2011), also considering the effect of plastic strain (Galvin et al., 2017). A physics-based model has been proposed by Grogan et al. (2014) to describe the diffusion-controlled corrosion of a pure magnesium stent strut section. Computational simulations using the previous material models have been used to evaluate the stent performance, to aid design and to understand the interaction of the stent with the vessel wall after implantation (Boland et al., 2019; Wu et al., 2011).

2.2. Balloon models

For the balloon, different technological solutions have been proposed over the years, ranging from simulations in which its action was replicated by boundary conditions applied to the stent, to more recent works that have invested in an extremely sophisticated and realistic representation of the real object. The refinement path has led to proposals for different modeling approaches that can be divided into three domains. In the first (Fig. 2-left), the presence of the balloon is completely neglected in favor of an exclusive representation of the action it exerts on the stent. Thus, the expansion is achieved by applying pressure or radial displacement directly to the internal surface of the stent (Dumoulin and Cochelin, 2000; Etave et al., 2001; Migliavacca et al., 2002; Petrini et al., 2004), or through contact with an internal cylinder whose radial displacement is controlled by a specific boundary condition (Hall and Kasper, 2006; Marrey et al., 2006; Wang et al., 2006). The second domain (Fig. 2-center) comprises idealized balloon models whose expansion occurs by simulating the same condition that occurs in the clinic, namely an increase in pressure inside the balloon. To this group belong both works in which the balloon is modeled as a simple cylinder with elastic (Wang et al., 2006), hyperelastic (Liang et al., 2005) and non-linear anisotropic properties (Debusschere et al., 2015; Kiousis et al., 2009), and studies that represent the balloon in its initial configuration as an idealized structure (Antonini et al., 2021b; Chiastra et al., 2018; Gastaldi et al., 2010; Morlacchi et al., 2011; Poletti et al., 2022). Finally, the last group (Fig. 2-right) includes all those approaches that aim at an extremely realistic representation of the balloon considering its folded shape (De Beule et al., 2008; Geith et al., 2019; Mortier et al., 2011; Wiesent et al., 2019). It is clear that the computational powers available today no longer justify the use of the extremely simplified approaches belonging to the first domain, which does not allow describing correctly the stent expansion. Instead, with the other strategies, it is possible to obtain realistic results and correctly catch the final shape and stress state of the stent. On the other hand, although modeling methods belonging to the second and third domains can provide comparable performance in studies in which the focus is the analysis of stent expansion, when the aim is to investigate the behavior of the balloon in its contact and interaction with the stent and/or the arterial wall, an accurate description of the morphology of the device could not be disregarded. So, for such applications approaches belonging to the third group, in which the geometry and dynamics of balloon folding and unfolding are properly described, are recommended.

With regard to discretization into finite elements, the literature mainly presents approaches exploiting membrane (Antonini et al., 2021b; De Beule et al., 2008; Gastaldi et al., 2010; Morlacchi et al., 2013; Wiesent et al., 2019; Zhao et al., 2021) and shell elements (Bukala et al., 2017; Geith et al., 2019). Membrane elements do not account for bending or twisting but can lead to more efficient simulations. On the

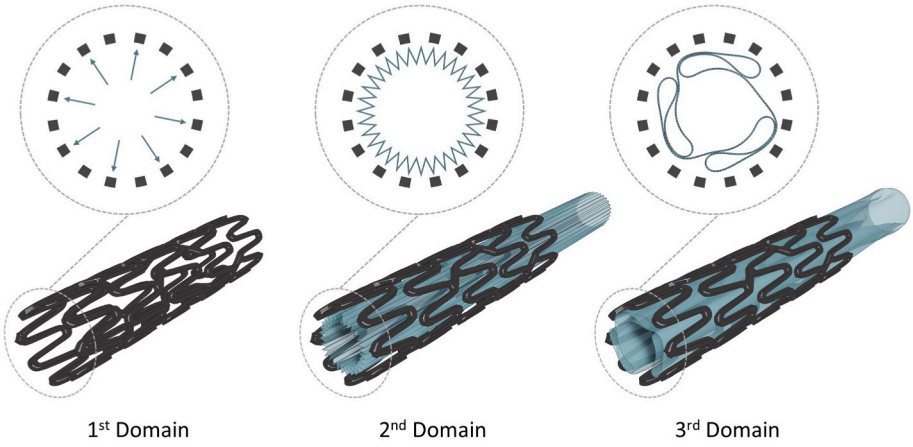

Fig. 2. Schematic representation of the three main strategies adopted to model the balloon. To the first domain (left) belong approaches in which the balloon is replaced by boundary conditions directly applied to the stent. The second domain (center) considers idealized models of the balloon that replicate its physical behavior in terms of the diameter-pressure relationship. The third domain (right) includes modeling strategies that aim at a realistic description of the balloon, considering its tri-folded shape.

other hand, shell elements are able to model the behavior of thicker-walled structures and account for bending and twisting. However, they are more computationally intensive.

3. Coronary artery models

In parallel with the refinement of stent models, a similar path was also undertaken for the representation of the artery in stent deployment simulations.

3.1. Mechanical description

The starting point was to adopt idealized stenotic geometries, typically cylindrical with a parabola-shaped plaque, mechanically described in a simplified manner by assigning homogeneous, isotropic linear (Chua et al., 2004) or hyper-elastic material models (Auricchio et al., 2001; Lally et al., 2005; Liang et al., 2005), calibrated on the basis of literature studies. Even when the analysis involves models obtained on the basis of patient-specific reconstructions, the impossibility of knowing individual properties forces reliance on average values derived from the studies on the characterization of the behavior of various arterial tissues (Redaelli and Votta, 2020). Specifically, two main publications can be considered of fundamental importance for modeling the mechanical behavior of coronary arteries: that of Loree et al. (1994), which presents a collection of experimental data on which material models can be constructed to describe atherosclerotic plaques, and the study by Holzapfel et al. (2005), which provides data on the mechanical performance of the three arterial wall layers, namely intima, media, and adventitia, in the circumferential and longitudinal directions. Based on these studies, some works such as the one proposed by Cilla et al. (2012) exploited fiber-reinforced models to accurately study the mechanics of the plaque and arterial wall in idealized stenotic coronary arteries. Generally, such complex models were not involved in patient-specific stenting simulations, with the exception of the work of Mortier et al. (2010) where an innovative algorithm was proposed to account for fiber orientation in a patient-specific geometry based on angiographic data. Phenomenological models based on homogeneous hyperelastic materials, often calibrated on circumferential data, were widely used in the literature (e.g., Chiastra et al. (2016); Gervaso et al. (2008); Morlacchi et al. (2013); Poletti et al. (2022); Samant et al. (2021); Zhao et al. (2021)) to describe the arterial wall mechanics for patient-specific stenting simulations. The importance of considering different tissue components and atherosclerotic plaque in stent simulation was investigated through the use of idealized artery models, demonstrating their impact on simulation outcomes (e.g., Conway et al. (2017, 2014) and Pericevic et al. (2009)). Consequently, different detail levels were involved in accounting for arterial wall layers and plaque components, ranging from models with a single wall layer outside the plaque and a unique plaque composition (e.g., Morlacchi et al. (2013); Ragkousis et al. (2015)), to others including media and adventitia layers and/or heterogeneous plaque based on clinical images (e.g., Chiastra et al. (2016); Poletti et al. (2022); Zhao et al. (2021). An example of an idealized bifurcated artery derived from the study of Gastaldi et al. (2010) is reported in Fig. 3 to show the subdivision of the arterial wall into adventitia, media, intima, and plaque.

3.2. Patient-specific coronary artery models

Alongside the improvements in the mechanical description of the arteries, significant efforts have been invested in simulating stent deployment in anatomically accurate vessels. While the utilization of idealized geometries is valuable for enhancing numerical methodologies in studying coronary stent deployment and leveraging simulations as digital bench tests for comparative analyses of various devices and treatment techniques (e.g., Iannaccone et al. (2017); Migliavacca et al. (2015); Mortier et al. (2009, 2014)), the incorporation of realistic and/or patient-specific anatomies provides opportunities for more dependable and clinically-oriented analyses (Antoniadis et al., 2015; Morlacchi and Migliavacca, 2013; Redaelli and Votta, 2020). Therefore, research has also addressed the issue of suggesting methods for reconstructing patient-specific geometries based on clinical images (such as the ones reported in the study of Morlacchi et al. (2013) and shown in Fig. 4). Conventional coronary angiography (CCA) is recognized as the standard technique to collect clinical images of a stenotic coronary artery, however, nowadays additional methods are available such as computed tomography angiography (CTA), intravascular ultrasound (IVUS) and optical coherence tomography (OCT). In particular, the last two techniques are characterized by high spatial resolution and allow the detection of the plaque and its components (Lederlin et al., 2011; Morlacchi and Migliavacca, 2013; van Soest et al., 2010).

One of the first attempts to consider imaged-based coronary models is the one proposed by Gijsen et al. (2008), where the 3D shape of the vessel was derived from a combination of images collected through CCA and IVUS. Although studies have been proposed in which artery reconstruction was based exclusively on CCA images acquired from two different angles (Dvir et al., 2007; Galassi et al., 2010), following what was proposed by Gijsen et al. (2008), the method of reconstruction based on hybrid-imaging, i.e. the combination of different imaging techniques, has been established to produce reliable patient-specific arteries (e.g., Cárdenes et al. (2011); Chiastra et al. (2016); Morlacchi et al. (2013); Ragkousis et al. (2014); Tu et al. (2011); Wu et al. (2020); Zhao et al. (2021)). By combining different imaging modalities, it is in fact possible to exploit the strengths of each method by obtaining exhaustive and essential information for accurate 3D reconstructions, such as vessel

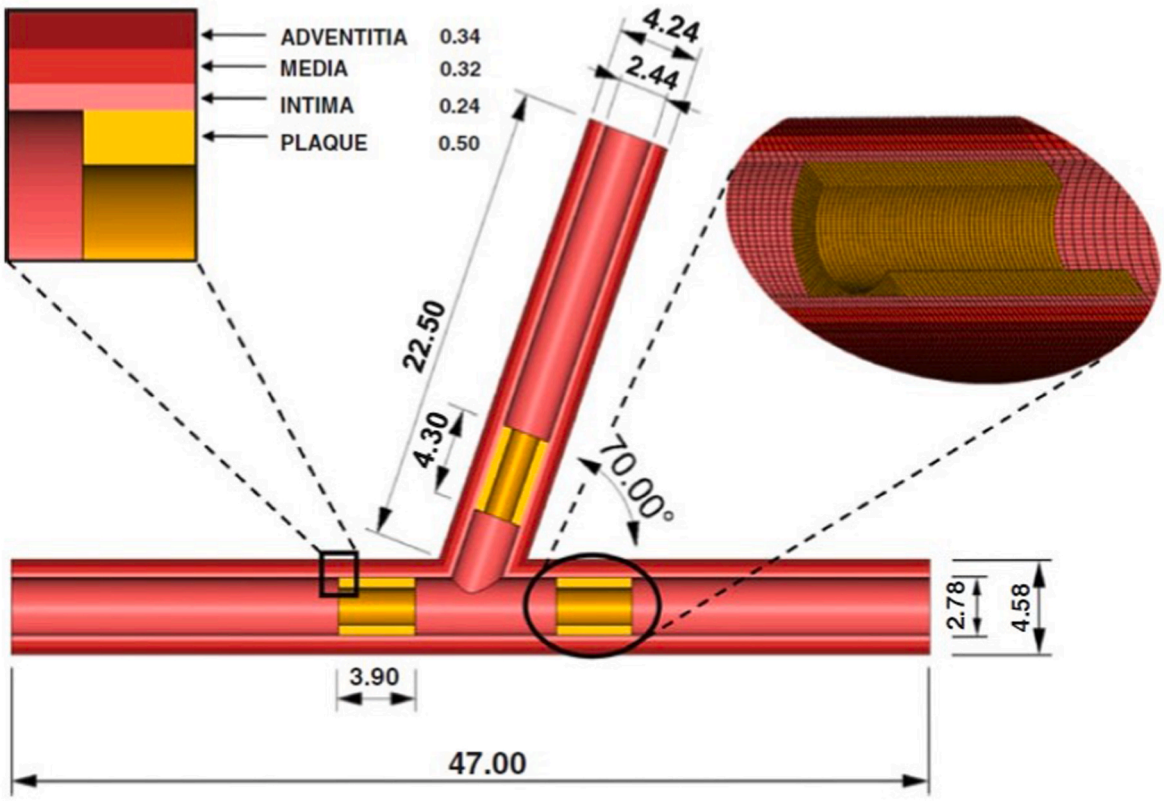

Fig. 3. Example of an idealized bifurcated artery with the depiction of the different tissue layers (adventitia, media, intima, and plaque). Image copied with permission from Gastaldi et al. (2010).

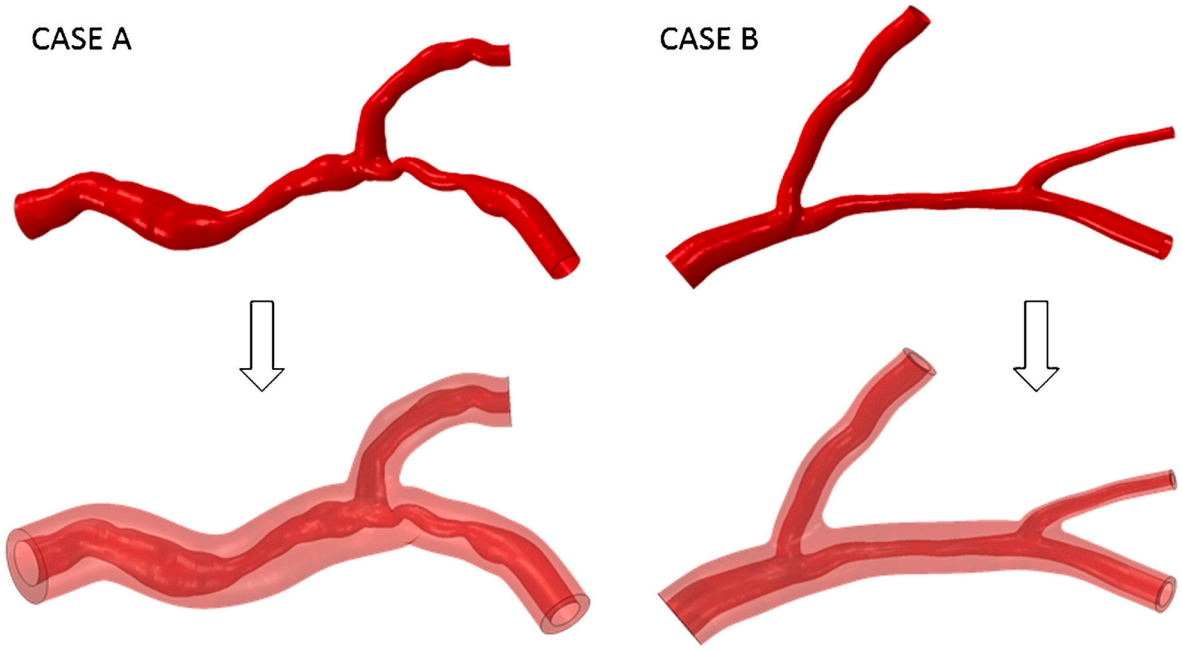

Fig. 4. Example of bifurcated arteries derived from the reconstruction of clinical images. Image copied with permission from Morlacchi et al. (2013).

centerline, lumen shape, and plaque composition (Antoniadis et al., 2015). An example of hybrid imaging method for 3D geometry reconstruction is reported in Fig. 5.

Once reconstructed, the 3D model of the artery has to be spatially discretized into finite elements to allow the computational study. Given the tube-like shape that characterizes coronary arteries, for both single and bifurcated vessels, whenever possible, it is recommended to opt for a structured mesh with hexahedral elements. Similar to stents, in fact, the use of mapped meshes is preferable to unstructured tetrahedral meshes, as it ensures greater reliability of results (Antoniadis et al., 2015; De Santis et al., 2011; Morlacchi and Migliavacca, 2013). On the other hand, the use of a tetrahedral mesh can be advantageous to easily

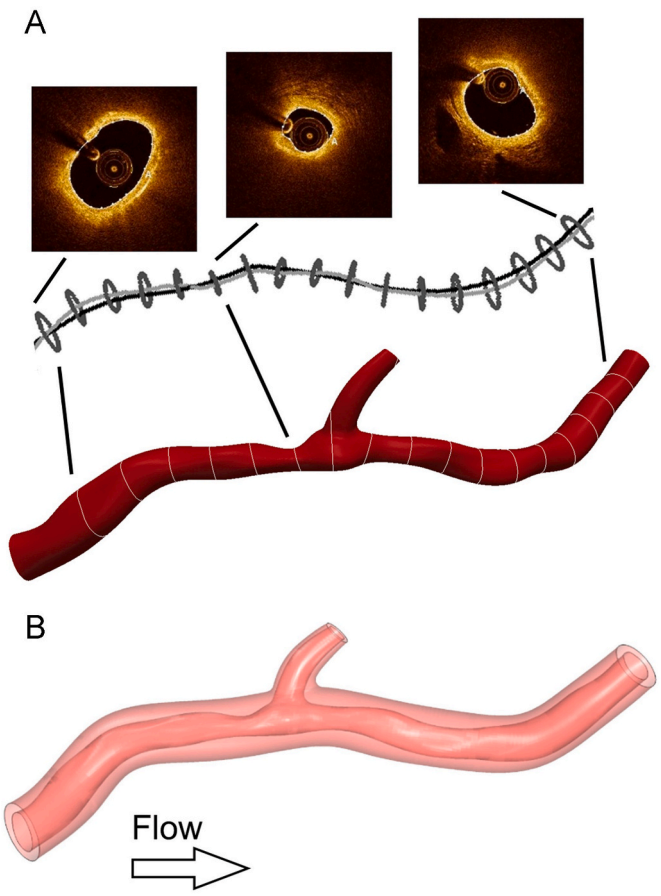

Fig. 5. Example of patient-specific artery reconstruction based on hybrid imaging methods. (A) Through the OC-CT method, the lumen contours identified by OCT imaging can be arranged along the vessel centerline to reconstruct the 3D lumen geometry. (B) Representation of the complete vessel geometry. Image copied with permission from Chiastra et al. (2016).

incorporate the presence of different components of atherosclerotic plaque into the model, as reported, for example, in the works of Gharaibeh et al. (2020) and Kadry et al. (2021).

4. Replication of the clinical procedure

Once the finite element models of the various parts that will interact in the simulation (i.e. stent, balloon, and artery) have been generated, the reliability of the deployment analysis results is closely linked to the realism of the boundary conditions (constraints and loads) used to replicate the clinical procedure (Martin and Boyle, 2011).

4.1. Crimping procedure

It is important to note that, although the surgical act of implanting the stent begins with its placement inside the artery followed by balloon expansion, the device mounted on the catheter has already undergone an initial loading history. The delivery system presents indeed the stent crimped onto the balloon and therefore plastically deformed by a crimping procedure. Although many studies in the literature overlook the fact that the undeformed stent configuration is the post-laser-cut one and not the crimped one (De Beule et al., 2008; Mortier et al., 2008, 2010), the crimping procedure induces the occurrence of deformations and residual stresses that play a significant role in the expanding performance (Schiavone et al., 2017; Zhao et al., 2012) or that can be potentially critical for bioresorbable vascular scaffolds (Antonini et al., 2021c). It follows that, in an accurate *in silico* analysis, the crimping phase must be considered and appropriately simulated (Wiesent et al., 2019). The most widely used numerical crimping techniques exploit a deformable cylinder or rigid surfaces arranged circumferentially around the stent (Fig. 6 - top), which are in contact with the device and reduce its diameter moving radially. Once the minimum diameter is reached, the crimping surfaces return to their initial configuration allowing the elastic recoil of the stent, which will remain plasticized in the crimped configuration (Antonini et al., 2021b, 2021c; Geith et al., 2019; Morlacchi et al., 2013; Wiesent et al., 2019; Zhao et al., 2021).

4.2. Stent positioning

The step following the crimping of the stent is the placement of the delivery system in the lumen of the vessel in correspondence with the stenosis (Fig. 6 - upper center). During the actual clinical practice, this procedure is performed by inserting a guide wire into the arterial tree until the point of interest is reached, and then sliding the catheter with stent and balloon over it. It is evident that this simulation step is neglected in the numerous literature studies dealing with deployment in straight vessels, whereby the stent, balloon, and artery models are generated already properly aligned. On the other hand, in simulations with patient-specific anatomies, it is necessary to suggest a numerical strategy aimed at deforming the delivery system to adapt it to the tortuosity of the artery to be treated. Although the stent reaches the target site by following a tortuous path potentially capable of changing the stress state of the crimped device, the literature regarding stent deployment simulations neglects this aspect and is limited to proposing methodologies to simulate only the last phase of this pathway, i.e., the positioning of the stent within the stenotic lumen. A possible approach is the one proposed by Mortier et al. (2010), which considers a guide wire model inserted into the lumen of the artery along which to push and slide the catheter with the stent and the balloon. Differently, the solution employed by Morlacchi et al. (2013) involves the generation of two cylindrical guides that share the centerline with the vessel and are used as internal and external constraints during the sliding of the stent to the desired position. The stent movement along the track formed by these two rigid surfaces is performed by controlling the displacement of nodes

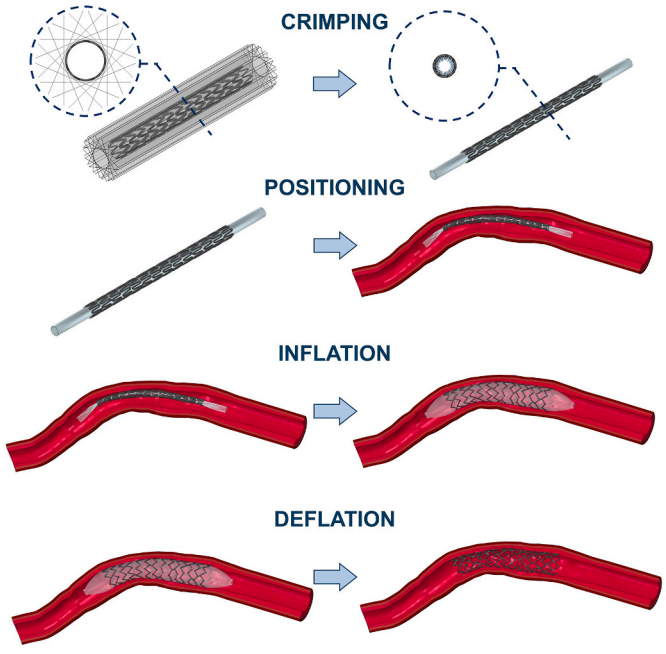

Fig. 6. Schematic representation of the standard phases of stent deployment simulations: stent crimping (top), device positioning inside the vessel lumen (upper center), balloon inflation and stent expansion (lower center), and final balloon deflation (bottom).

positioned in the proximity of the struts' links. A similar approach was adopted to obtain the curved configuration of the balloon, which was guided inside the two cylindrical surfaces through the definition of concentrated forces applied to the distal balloon extremity. Instead of replicating the sliding of the device into the lumen of the vessel, another method was proposed simulating the device positioning by exploiting cylindrical surfaces generated around the stent and balloon models that are bent in displacement control so that their axis coincides with the centerline of the vessel (Berti et al., 2021; Chiastra et al., 2018; Poletti et al., 2022). Through contact, these surfaces deform the delivery system, adapting it to the curvature of the artery with a relatively simple and efficient simulation step.

4.3. Balloon inflation and deflation

The last phase of the simulation involves pressurizing the balloon that expands the stent against the artery lumen to reduce its stenosis (Fig. 6 - lower center). The pressure is then released to deflate the balloon and to allow the elastic recoil until a balanced configuration is reached (Fig. 6 - bottom).

4.4. Fatigue analysis

Furthermore, it is relevant to point out that, although most studies concerning mechanical simulations of stent deployment focus on the replication of the implantation procedure, the mechanical interaction between the device and the vessel continues over time. Indeed, the stented artery undergoes cyclic deformation due to blood pressure and the contraction of the cardiac muscle during the heart cycle. This induces mechanical solicitations that might result critical to the fatigue life of the stent. The analysis of the fatigue life of coronary stents has been the subject of studies in which simulations are used to investigate the stresses induced by cyclic pressure (e.g., Argente dos Santos et al. (2012); Azaouzi et al. (2013); Barrera et al. (2014); Li et al. (2010); Marrey et al. (2006); Sweeney et al. (2012)), bending on the device (Auricchio et al., 2015), or multimodal loading conditions (e.g., Everett et al. (2016); Wang et al. (2020). Such issues were addressed also by the work of Morlacchi et al. (2014c), in which the authors simulated the stent implantation in an idealized stenotic artery subjected to boundary conditions representing blood pressure fluctuation from 80 to 120 mmHg and myocardial motion. Another example is the study of Xu et al. (2016) that evaluated how dynamic artery bending affects the fatigue performance of the stent implanted in the vessel. In the simulation, the stent was deployed within an idealized artery with uniform curvature which was subjected to a change in the curvature radius to represent the heartbeat motion. A comprehensive literature review addressing numerical studies for the evaluation of fatigue life of coronary stents is reported in the work by Conway (2018).

4.5. Numerical approach

As emerges from this brief overview of stenting simulations, this kind of analysis involves high deformations, complex non-linearities, and severe contact issues. For this reason, an explicit solver is generally preferred to overcome the convergence issues that might arise using an implicit scheme. Specifically, these simulations are performed assuming that the stent deployment can be considered a quasi-static procedure and thus ensuring that during the whole computation, the ratio between the kinetic and the inter-nal energy is always below the values of 5–10% (Geith et al., 2019; Martin and Boyle, 2011; Morlacchi et al., 2013; Wiesent et al., 2019). There are several strategies to achieve the quasi-static condition (mass scaling, modification of loading rate, application of viscous pressures, etc.) nevertheless, there is little about this issue in the literature, and papers on stent deployment simulations often omit the statement of the numerical methods selected to satisfy this condition. An example is provided by the work of Antonini et al. (2021b), where the authors present and compare two different numerical strategies to obtain a simulation of stent expansion operating in a quasi-static regime and comment on the result reliability compared to what was observed in experimental tests.

5. Near and far future developments

This review demonstrates that computational tools in the area of coronary stenting, which occurred over the past 25 years, have reached a level that has the potential to innovate both the manufacturing and clinical use of new devices. *In silico* analyses are ready to be used not only to refine *in vitro* or *in vivo* studies, but also to reduce and potentially replace them. Clearly, this requires being able to assess the accuracy with which digital models represent the reality of interest. Intuitively, the greater the impact of a decision derived from data generated by an *in silico* analysis, the greater the reliability of the model will have to be.

The set of activities required to assess and certify the predictive capability of a computational model is called Verification, Validation, and Uncertainty Quantification (VV&UQ). Recently the American Society of Mechanical Engineers (ASME) has released a specific guideline (ASME, 2018) for a credibility assessment framework dedicated to *in silico* models of medical devices. In particular, the term validation refers to the assessment of the model's capability to represent the reality of interest. The validation process requires the comparison of the model performances with evidence deriving from a comparator, that might be *in vivo*, *ex-vivo* (i.e. cadavers), or *in vitro* data which are considered relevant for the selected context of use. During this assessment also uncertainty quantification and sensitivity analysis should be considered to take into account how errors in model input may affect the output reliability. Applying VV&UQ concepts to coronary stent simulations, it follows that in order to determine the level of credibility of the considered models, it is necessary to estimate the risks associated with respect to each context of use.

The objective of this second part of the paper is to discuss what contexts of use can be identified for coronary stenting models today, what credibility level is required in the different application fields, and where we are with respect to meeting this requirement.

5.1. Simulations for industrial applications

The first beneficiaries of *in silico* stenting are for sure the biomedical companies manufacturing coronary stents. The design and development of a new device is a long and complex process that starts with product specification definition and ends with clinical trials to prove the device's safety and efficacy. The screening phase that allows the selection of the candidate product to be tested in clinical studies requires several steps, as depicted in Fig. 7 - top, involving *in vitro* experiments, animal studies, and tests on cadavers. Even if cadaver studies provide a first hint of the device's interaction with a human artery, a comprehensive stent assessment in an active human environment is carried out only at the final stage of the product development process. This implies that prior to clinical assessment, all causes of failure potentially attributable to the interaction of the device with a large variety of patient-specific anatomies are impossible to identify. Moreover, considering the high costs of producing different prototypes to be tested, only a limited number of designs can be considered.

In Fig. 7 a view of how the introduction of computational activities can change the development path of a new device is proposed. In the screening phase, the activities performed *in vitro* and *ex vivo* could be completely replaced by virtual bench tests, opening up the possibility of computationally testing a large number of prototypes (Zhao et al., 2021). Accordingly, a similar impact can also be achieved with respect to the animal study, decreasing the number of involved test subjects. At this stage, it is required that the exploited computational models have credibility compatible with the execution of comparative studies, aimed at selecting designs that express the best performance. Once a few

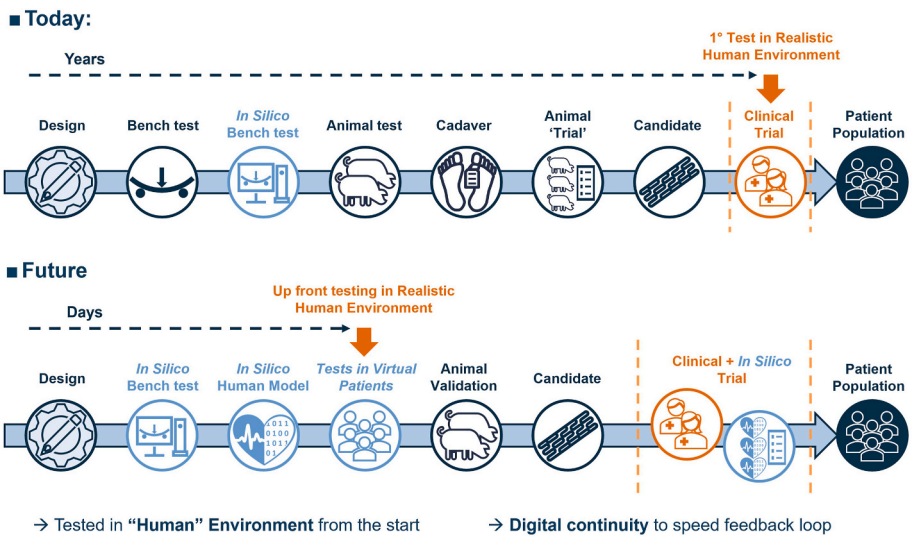

Fig. 7. Comparison between the current and future development paths for a new medical device. Representation inspired by the presentation of T. Morrison (FDA), *Advancing in silico Medicine at the FDA: Perspectives on Simulations in Medical Devices.*

candidates are selected, the winner's definition can be based on the results of simulating implant procedures inspired by clinical practice guidelines in a virtual patient population. In this case, the artery model must be able to ensure similar behavior to that of real humans but without the need to faithfully mirror patient-specific cases. Rather, the rationale should be to generate a database of virtual patients that, taken as a whole, can be representative of a cohort of human subjects (Morrison et al., 2022). Although the test carried out in the screening phase may have a high influence on the decision-making process leading to the definition of the final candidate, the risks associated with the simulations are limited and, accordingly, the credibility of the proposed models should be medium. During the testing phase, on the other hand, simulations involve a single device, i.e. the candidate, and *in silico* clinical trials are conducted with the dual purpose of refining and reducing clinical trials. In this case, the simulation results would have a strong impact on the final assessment of the device to be proposed for extensive use on human patients. The risks associated with potential wrong decisions made on the basis of simulation results are high, and therefore a

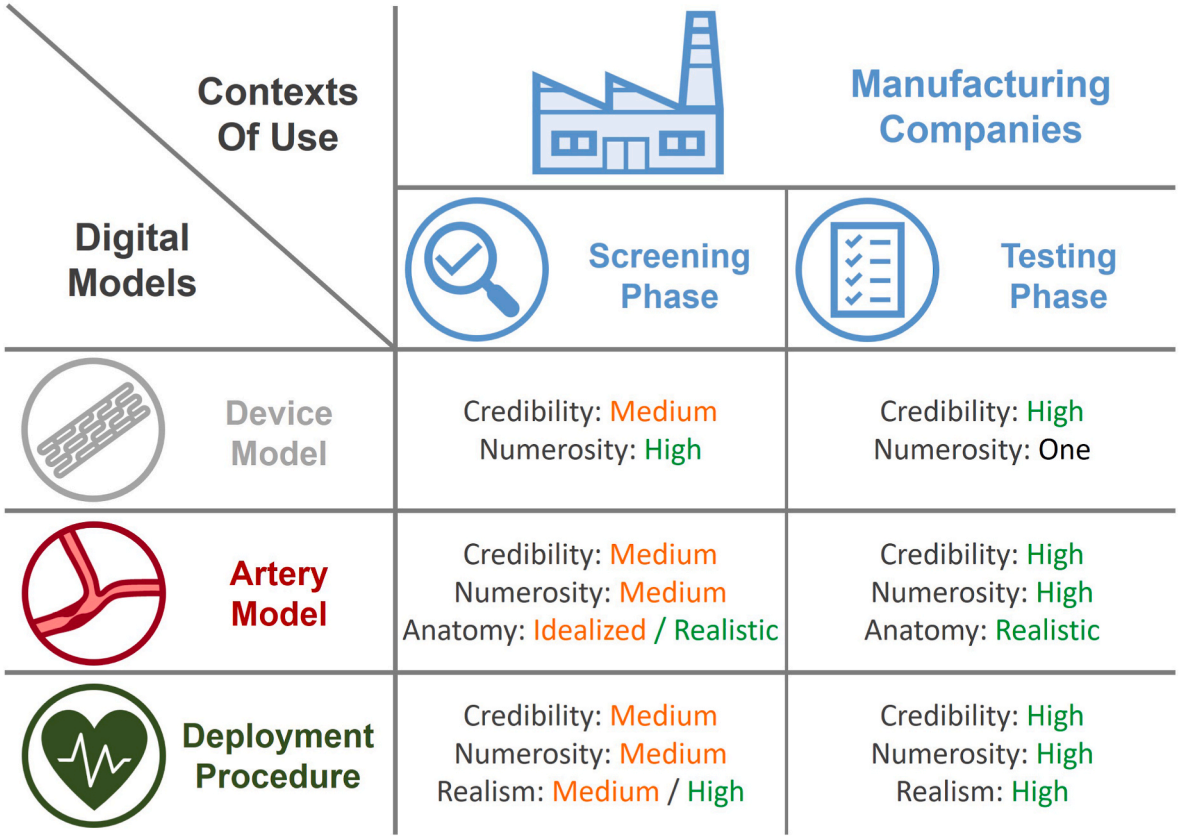

Fig. 8. Schematic summary showing the requirements for the device, artery, and deployment models declined in the contexts of use proposed for manufacturing companies.

high level of model credibility for the device, the artery, and the deployment procedure is required. A schematic summary showing the requirements for the device, artery, and deployment models with respect to the different contexts of use for company applications is depicted in Fig. 8.

5.2. Simulations for clinical contexts

Additionally, performing *in silico* analyses of stenting procedures, may also improve the clinical practice in two main application fields: education of the medical personnel (Mortier et al., 2015) and treatment planning.

Concerning the education, numerical simulations open the possibility of comparing several different stenting techniques in the same virtual patient, or, vice versa, testing the same approach in a large number of cases, without any risk for real patients. Through stenting simulations on virtual patients, therefore, medical personnel could increase awareness and consequently the competence in selecting the optimal device/procedure to be applied in real cases. For this application, as for the screening phase, a medium level of credibility for the device, the artery, and for the deployment procedure are sufficient, since these numerical analyses are used to provide additional experience in comparing devices and treatment approaches.

In terms of operative planning, the use of patient-specific simulations could help to decide how to intervene. The study of Chatzizisis et al. (2022) reports the first example of pre-procedural planning in which patient-specific computational simulations are used to guide clinical staff toward a successful treatment procedure (Fig. 9). Nevertheless, while certain fluid dynamics analyses have achieved clinical application (e.g., the HeartFlow FFR_{ct} Analysis [HeartFlow, Redwood City, CA, USA] (Min et al., 2015)), some technological limitations still restrict the extensive utilization of structural simulations of stent deployment for clinical planning. Indeed, reliable reconstruction of a patient-specific vessel should derive from image modalities that ensure good resolution on the arterial lumen (e.g. OCT or IVUS). However, these techniques are invasive, expensive, and not always performed for all clinical cases. Moreover, even when available, it is necessary to consider that commonly the clinical practice requires the collection of such images during surgery, immediately before the stenting treatment. As a result, it would be impossible in this time frame to perform reconstruction, finite element discretization, and multiple simulations in which the treatment strategy is varied to select the best one. Even disregarding the time dedicated to pre- and post-processing, with the current computational power, finite element analyses of stents demand hours of calculations for the simplest cases, and up to several days for the most complex anatomies and treatments. On the other hand, clinical planning does not have to be limited to the selection of the optimal combination of device and implantation procedure; it can also involve defining post-operative therapies. Assuming that a reliable model of the delivery system and an accurate reconstruction of the patient-specific anatomy are available, a high level of credibility also to the vessel model is obtained by replicating the stenting treatment and calibrating the properties of the artery to produce results corresponding to those clinically observed. Under these conditions, the clinicians may derive insights on vessel deformation at maximum balloon expansion (high strain values are indicators of potential damage to the vessel wall), on the presence of malapposed struts, and on the maximum stresses within the device (surrogate of device failure). These concepts are presented and discussed in the work of Poletti et al. (2022), where the authors also identified the possibility of coupling the outcomes of structural simulations with subsequent analyses of fluid dynamics, drug release, and degradation in the case of BVS involvement. All the collected information could help clinicians in selecting dedicated therapies or in scheduling additional controls for critical cases. Also in this application, the maximum level of model credibility should be ensured since numerical simulations for pre- or post-operative planning will directly guide the clinicians in the decision on intervention procedures or follow-up therapies. A schematic summary showing the requirements for the device, artery, and deployment models with respect to the different contexts of use for clinical applications is depicted in Fig. 10.

5.3. Model credibility and validation

Concerning the credibility assessment of the virtual device through

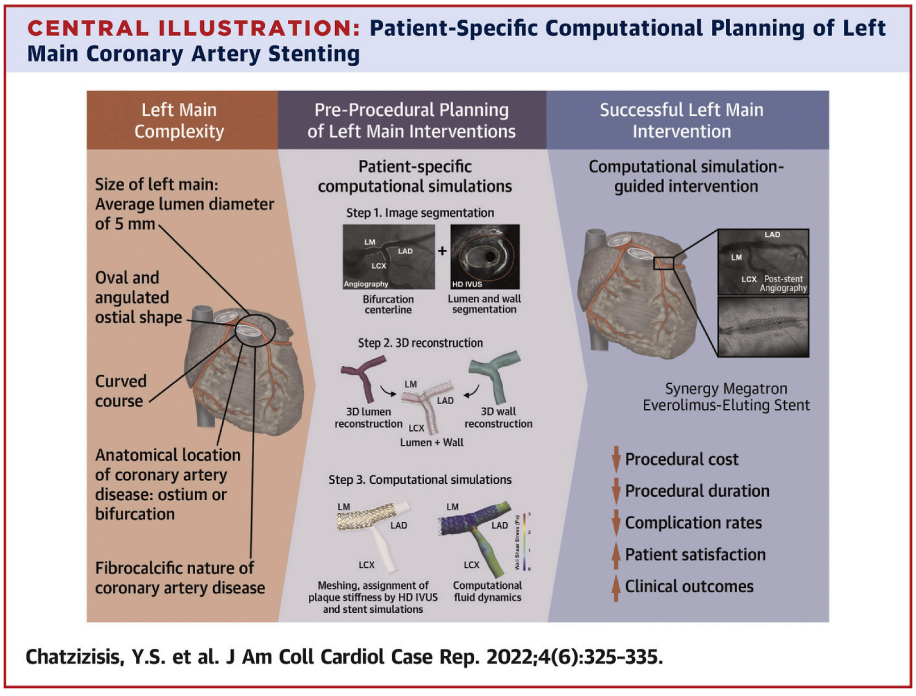

Fig. 9. Representation of the workflow for patient-specific computational planning on left main coronary artery stenting. Image copied with permission from Chatzizisis et al. (2022). http://creativecommons.org/licenses/by-nc-nd/4.0/.

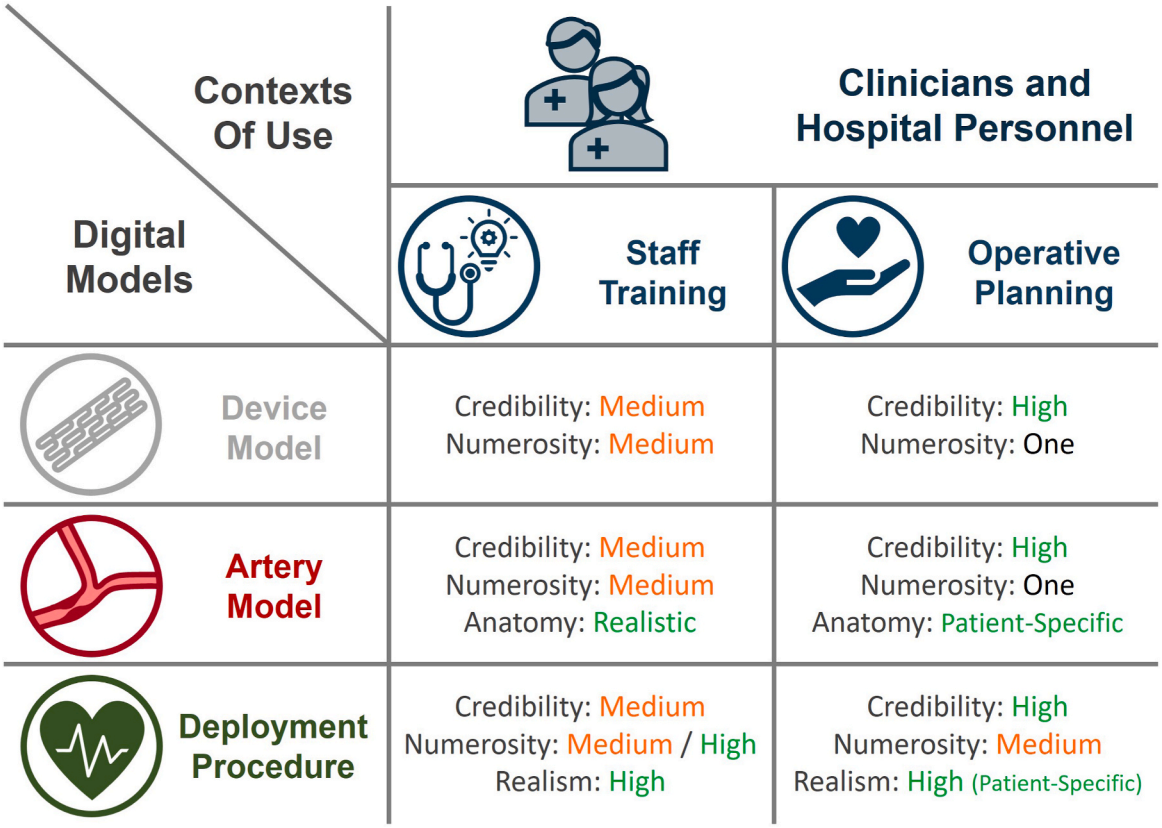

Fig. 10. Schematic summary showing the requirements for the device, artery, and deployment models with respect to the different contexts of use for clinical applications.

validation activities, a number of literature works couple the development of the numerical model with a comparison with data deriving directly from the manufacturer or from experimental activities of stent free expansion (e.g., Chiastra et al. (2015); Geith et al. (2019); Mortier et al. (2011); Wang et al. (2006); Wiesent et al. (2019)). Antonini et al. (2021b) also validated the model's ability to predict the device behavior considering multiple test conditions: in addition to stent free expansion tests, post-expansion tensile test and stent deployment into PVC tubes were considered as comparators in the validation process. Regarding BVS models, validation studies focused mainly on the evaluation of the calibrated material model replicating experiments performed on the pre-crimping stent configuration, namely crush, tensile, and radial compression tests (Bukala et al., 2020; Wang et al., 2018). To the best of the authors' knowledge, the recent work of Hoddy et al. (2021) represents the first attempt to validate a BVS delivery system replicating *in silico* the post-crimped stent expansion and subsequent crush test.

With respect to the validation of the deployment procedure of coronary stents, a study by Berti et al. (2021) discussed strategies and limitations in the selection of comparators. *In vitro* tests of stent deployment into 3D-printed vessels with patient-specific geometries and materials properties comparable with coronary arteries were used to validate the modeling of the procedure. Furthermore, some studies in the literature aimed at evaluating the capability of the vessel model to describe the arterial mechanical response to the stenting procedure. This implies the reconstruction of the patient-specific vessels, modeling of the devices, and the simulation of the step sequence followed during the stenting procedure. Morlacchi et al. (2013), in a study considering two clinical cases of coronary bifurcation treatments, evaluated the model's ability in describing the vessel straightening after stenting by qualitative comparison of the simulation results with the post-treatment vessel geometry reconstructed from clinical images. A similar study was performed by Chiastra et al. (2016) that validated the stenting simulation of a bifurcated vessel comparing the obtained stented geometry with the one reconstructed from clinical images. Poletti et al. (2022) replicated two clinical cases of stenting with the aim to validate a new approach for patient-specific artery modeling that was able to account also for *in vivo* pressurization and axial pre-stretch conditions. The ability of the model in predicting quantities of clinical interest such as the vessel lumen gain and the presence of malappositions was evaluated with respect to post-treatment data. A study including a higher number of clinical cases was carried out by Zhao et al. (2021): the deployment procedure and the artery model were first trained by replication of *in vitro* deployment tests and five clinical cases and then tested in their predictive ability against five other clinical cases (Fig. 11).

5.4. Future perspectives

This considered, it is possible to conclude that, even if still in an initial stage, the path for developing credible device models has been indicated and they can be successfully used in the screening phase or for clinical staff education. However, some limitations still prevent the extensive application of computational simulations in contexts of use where high credibility is demanded. Indeed, while it is possible for standard metallic devices to achieve high reliability through rigorous model validation (as described above), for degradable stents some open issues are still present in comprehensively describing their complex mechanical behavior. Concerning the vessel, the accuracy of the model of a patient-specific artery is limited by the need to rely on literature data for the mechanical description, and by the uncertainties related to the 3D reconstruction from clinical images. Moreover, despite the exception represented by the work of Chatzizisis et al. (2022), the significant time investment necessary for configuring, executing, and post-processing simulations renders this type of numerical analysis impractical for widespread application in pre-operative settings. While

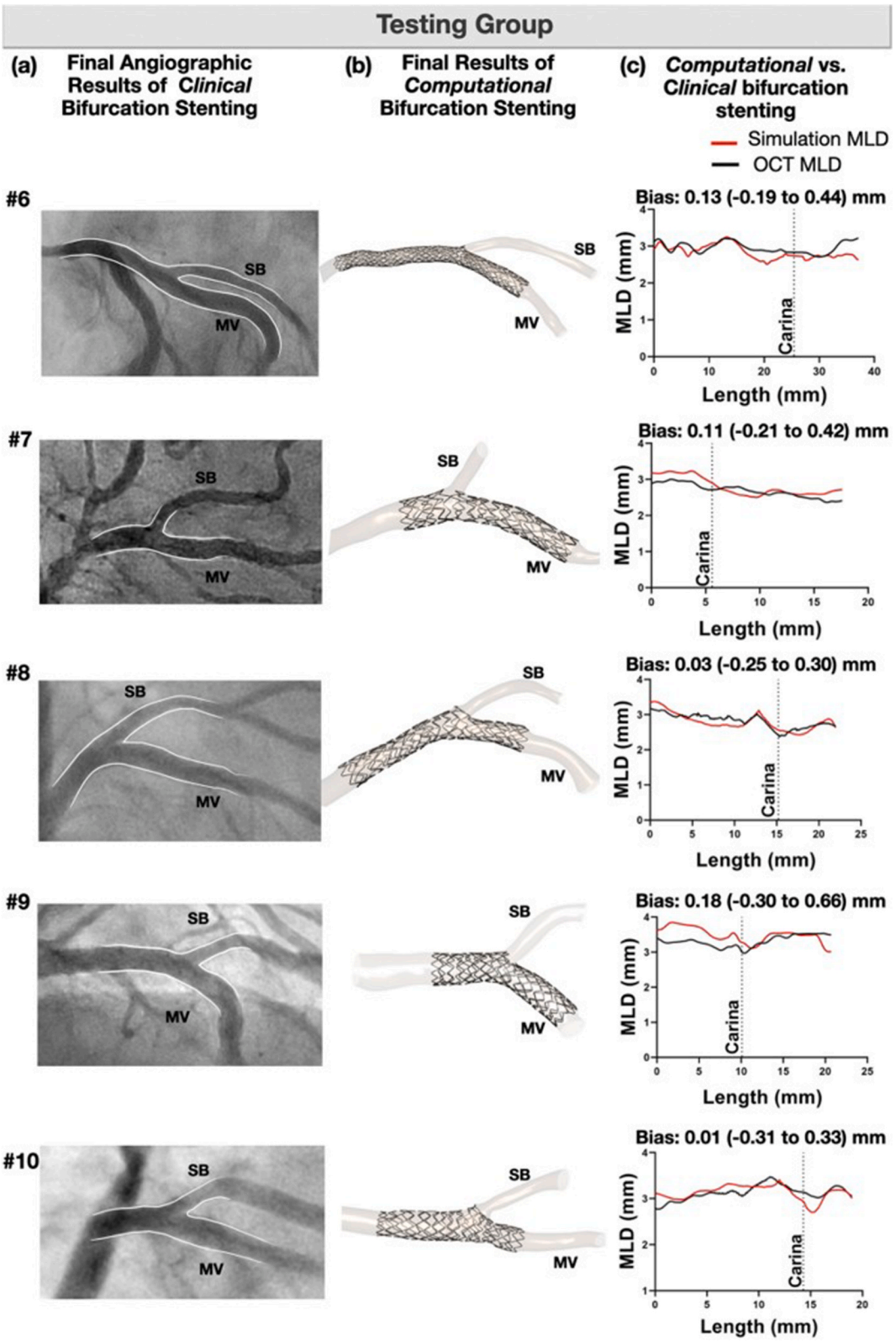

Fig. 11. Simulation assessment with respect to angiography and OCT data. Image copied with permission from Zhao et al. (2021). http://creativecommons.org/licenses/by/4.0/.

recent technological and methodological advancements hold promise, the realization of real-time analysis remains elusive at present. Consequently, it is reasonable to assume that in the immediate future, the application of operational planning will mainly be declined to support post-operative decision-making rather than to select the optimal stenting procedure for a specific intervention.

6. Conclusion

Great improvements in modeling stents, patient-specific arteries, and

the deployment procedure lead to exploiting more and more *in silico* studies in the assessment of percutaneous treatment for coronary disease.

The idea behind this concept is encapsulated in what is commonly referred to as the 3Rs logic, which stands for *Refine*, *Reduce*, and *Replace* (Morrison et al., 2022; Viceconti et al., 2021). Under this view, it follows that *in silico* analyses may be of significant interest to manufacturing companies and medical personnel. So nowadays, the relevant issue concerns the validation of models and the definition of their level of credibility and, consequently, whether they can be used to innovate:

- the procedure that a manufacturing company must follow to put a new device on the market;
- the education activities that are carried out in the clinic when a new device or implantation procedure is to be evaluated;
- the treatment planning methods of patient-specific cases.

Currently, although there are models available in the literature whose credibility is sufficient for such contexts of use as the screening phase in industry and education of clinical staff, open issues are still present concerning the applications demanding high model credibility.

Credit author statement

Luca Antonini: Writing original draft; writing review & editing; conceptualization; methodology; investigation. Gianluca Poletti: Writing review & editing; methodology; investigation. Giancarlo Pennati: Conceptualization, review; Lorenza Petrini: Conceptualization; review; methodology; investigation.

Declaration of competing interest

The authors declare that they have no known competing financial interests or personal relationships that could have appeared to influence the work reported in this paper.

Data availability

No data was used for the research described in the article.

Acknowledgements

This article has been partially founded by the European Union's Horizon 2020 research and innovation program under grant agreement n° 777119. This article reflects only the authors' view and the Commission is not responsible for any use that may be made of the information it contains.

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