Developing Advanced Computational Models for Real-Time Monitoring of Vascular Stent Performance

Marta Mendoza

University College London, UK.

Abstract

In silico modelling of medical devices is a very promising strategy for minimizing the requirement for in vitro research and animal testing while boosting device efficiency and cutting development costs. In the current work, in silico models of two commonly used endovascular devices, one interventional and the other implantable, were created. The first device designed was a stentriever for mechanical thrombectomy in the treatment of acute ischaemic stroke. Although stentrievers are routinely utilized in clinics, their true function is not well known. The modelling sought to determine how arterial geometry, thrombus characteristics, and the thrombus' interactions with both the artery wall and the stentriever influence the effectiveness of stentriever thrombectomy. To this goal, we ran finite element simulations of the complete stentriever technique. The modelling included thrombus rupture in order to quantify the risk of embolism. The simulations produce an atlas of failure risk as a function of thrombus composition and artery occlusion site. The modelling findings were then fed into machine learning algorithms to produce a proof-of-concept demonstration of the computational model's use as a real-time patient-specific prediction tool for the likelihood of success of stentriever thrombectomy.

Keywords

Developing Advanced Computational Models (DACM), Real-Time Monitoring (RTM), Vascular Stent Performance (VSP).

Disclosure: The authors have no conflicts of interest to declare.

Received: 20 May 2024 Accepted: 15 October 2024 Citation: *Vascular & Endovascular Review* 2024;7: e03. DOI: https://doi.org/10.15420/ver.2024.07.02.03

Correspondence: Marta Mendoza, University College London, UK. Email: marta.mendoza_UK@hotmail.com

Using computer programs to trigger and analyze complicated setups by using algorithms and monotonous approaches comes under the category of computational models. Its uses can be seen in various areas, including physics, engineering, chemistry and biology, economics, psychology, cognitive science, and computer science[1]. Computational methods involve four methods, which are described below.

- Decomposition is the very first thing that comes into computational thinking.
- The recognition of patterns is the second thing that is found in computational thinking.
- The third step is abstraction, which involves deducting required data from every problem.
- I was thinking of an algorithmic type.

Computational models, which are at the primary level, involve six steps: von Neumann, dataflow, applicative, object-based, and predicate logic-based. These are named fundamental models as they can be announced quickly by applying basic-level abstractions. A method of representation of a problem in mathematical and logical ways so that various intelligence properties can be stimulated and verified effectively[2]. All of these phenomena are discussed under the term computational modeling. Let's examine the method by which different computational models can be created. Identification of various parts of the system is shown in the model. Find the interconnection between various parts of the system. They develop connections between different system parts with the help of flowcharts, programming, or modeling software. In recent ages, advancements in computer models have made therapeutic efficiency possible. Learning opportunities can be improved quickly with the aid of computational models for progress in the manufacture of drugs and bringing measures responsible for safety and efficiency. Machine learning, deep learning, and innovation in statistics are used to analyze the efficacy and toxicity of data sets within various pharmaceuticals. The study is based on the questioning of data maintenance for different sources to ensure the effectiveness and toxicity of interested drugs[3]. Such trials are taken in this phenomenon, which is publicly possible and involves all databases. All the data will be preprocessed by removing outliers and values in which any absence can be seen. The application of sophisticated statistical techniques carries out all these things. The last and essential step is building prediction models to watch the efficiency of pharmacology and the technology's progress in terms of its toxicity. A complete program that will be all about selecting features, analyzing selecting features, and analyzing traits will be held to know the primary qualities that directly influence pharmacology's efficiency and toxicity. A comparison between computational and existing models is held to reveal our models' accuracy and power of models' prediction[4]. The technique that allows you to determine the recent condition of queues and channels within the queue manager range comes under the real-time monitoring category. The knowledge is considered exact and trustworthy when the command is just declared. Various commands in that form can provide real-time information about their understanding of queues and channels. The transfer of information periodically as it is updated, and that data gives us complete information about systems, processes, and events. This monitoring proves helpful in providing information found at zero or a low latency rate. A delay between the collection of data and its analysis can be seen. Let's discuss the example of real-time monitoring, which comes under the category of system management[5]. The industry at this time involves using real-time monitoring tools in business to observe workings like CPU performance, network traffic, and memory utilization. The connection of this phenomenon can be seen with the detection of staff and fixed abnormalities to maintain the system's performance. A tube of tiny size is located within a blood vessel that is blocked to keep it open. Stent plays a significant role in the restoration of the flow of blood through the vessel. The material utilized in the manufacture of stents is mostly plastic or metal. Stent grafts are large stents that are sage in those large arteries, and a specific type of fabric is utilized in their manufacture. Applying stents of different sizes and compositions in all vessels almost restores blood flow within ischemic tissues[6].

With time, advancements are coming that are all about treating cardiovascular and cerebrovascular diseases. To treat these diseases, intravascular stents are inserted into the areas specified as lesion areas by the intimal balloon expansion to provide support, which is narrow in size, and occluded vessel segments. They can reduce the elasticity of the boat. The study about the working and functioning of intelligent stents is very comprehensive. Smart sensors of the present time focus significantly on pressure sensors. Here, we will discuss the situation in which stents are utilized. The abnormality of arteries and veins which constrict them is known as stenosis[7, 8]. One cardiovascular disease is atherosclerosis, in which arteries become narrow due to plaque building, known as the appearance of stenosis. As a result, the transfer of blood is hindered, and obstruction of the transfer of nutrients and oxygen is also observed, which will become the reason for stroke myocardial infarction. Along with there are also the chances of happening off cerebral ischemic attacks. Angioplasty involves the procedure applied to lessen the narrowing of arteries and veins by introducing flexible balloons within them, which will expand the arteries and veins of patients. Endovascular methods, like endoluminal or endovascular repair, are now the preferred treatment for ruptured and unruptured aneurysms, which replaces surgical open procedures in most instances. The minimally invasive approach has been proven to have higher surgical outcomes and reduced mortality rates.

Before starting the surgery, neuroradiologists rely on their knowledge and experience, as well as visual aids using medical imaging methods, to determine the right endovascular option and the size and model for every patient[9]. While there are numerous benefits to using endovascular procedures, severe complications may occur during and following the procedure, such as intraprocedural perforation of aneurysms, delays in the rupture process, aneurysm regrowth restenosis within the stent, and thromboembolic incidents. Computer-aided modeling allows the simulation of various treatment options based on the most relevant clinical immediate and long-term results of the procedure and postoperative complications that can develop over time[10].

Research Objective

The primary purpose of this research is to know all current computational techniques for controlling the widespread diseases of the heart that occur primarily due to the narrowing of arteries and veins. These recent techniques of introducing stents for controlling these hectic diseases prove very beneficial. The research paper describes that developing advance computational models related to the real time monitoring of vascular stent performance. the research study divided into five specific research chapters first portion represent that introduction included objective of research. The second section describe literature review the third portion describe methodology related to them. the fourth section represent that result and its description also that last section summarized overall research study and present some recommendation about topic.

LITERATURE REVIEW

Researchers predict that different types of stents are used for treating Aortic Aneurysm. for effectively treating cerebrum aneurysms the self-extendable stent is used for implantation. the general name used for these stents is flow diverter. The stents are placed in the patient's body using a computerized system to help physicians during the surgery procedure[11]. Studies reveal that for detecting thrombosis at an early stage the use of TAVs is installed in the patient body. this catheter is designed using silicon sensors and it works on machine machine-learning algorithm to monitor the process of thrombosis formation. the reduction in leaflet movement and the serious complications associated with it is predicted using ML sensors[12]. Studies claim that the process of open surgery is complicated. To replace open surgery new techniques have been developed using advanced technology. Endoluminal surgery is one of the modern techniques that treats the rupturing of aorta in intracranial aneurysm patients[1]. Studies suggest that computational surgery is a technique employed in surgical procedures to make the surgical process smooth. The planning before the surgical operation is guided through computed technology Due to technology revolution the environment of surgical areas has been fully equipped with computer-based systems. this culture software minimizes the statistical risk during surgical operations[13]. Studies claim that technology-based medical devices have replaced the traditional method used during surgical procedures.

Medical devices built using silicon models are highly effective as the need to conduct in vitro testing decreases with the use of these models. implantable medical devices have been developed that are used for different endovascular vascularization processes. The stroke condition due to acute thrombosis is treated by using a newly developed stentriever. Stentriver is a medical device that is used during the clinical process for ischemic stroke treatment[8]. Studies suggest that for treating cardiovascular problems physicians have developed biodegradable stents. these stents are not metallic and are made of biodegradable substances to avoid any complications. The biodegradable stents in most patients are implanted permanently as they have no side effects [14]. Studies predict that cardiovascular diseases cause atherosclerosis which is one of the main causes of mortality around the globe.

The commonly prescribed treatment by health professionals for atherosclerosis is angioplasty but advancement in technology has resulted in the use of stents Also, soft and moldable implants have been developed that are built using bioelectric systems. The use of a monitoring system in these implants provides aid in treating restenosis[15]. Studies claim that vascular stents are widely used for vascular surgery but the efficiency of these stents is limited because they are not biodegradable.to replace vascular stents BCS stents are made that have great significance over the traditional stents These stents are highly flexible making their use more suitable for implants[16]. Studies predict that atherosclerosis is an endovascular disorder that is prevalent in elderly people and that shows poor outcomes with therapeutic interventions .using computational models for understanding the reason behind atherosclerosis onset act as a great medical aid[17]. Studies show that certain serious health problems occur due to the use of traditional stents in people.to avoid these problems hybrid stents have been developed. These stents are developed using polymer material to make them more reliable For managing blood pressure problems due to cardiovascular disease the use of smart polymer-made stents is made in clinical practices[18, 19]. Studies conclude that computational systems are developed to understand the pathology behind the onset of atherosclerosis.

ESS as well as PSS are the two main reasons that develop atherosclerosis condition[20] For studying the details of anatomical behavior the use of 3D models is made in clinical procure. The 3D models provide better understanding of the type of plaques formed during atherosclerosis. the detail regarding the size of the plaque is clearly observable trough the 3D models that aid the treatment process[21]. The death rate due to cardiovascular disorders is prevalent among people. this rise in mortality rate due to CVD requires the manufacturing of catheter stents traditional stent manufacturing process was costly and the stent quality was also not reliable. but modern biomedical stents are developed using PAT.

The PAT testing approach for biomedical devices is utilized in CPPS to improve the quality of these devices[22]. Studies predict that surgeons are provided with virtual training for polishing their skills in surgery. A virtual learning environment enables the surgeon to learn using real-life examples and models. these virtual training programs are developed to allow surgeons trained to perform surgery with little chance of complications[23]. Studies elaborate that computational models built on IST allow physicians to predict the performance of medical devices. The use of IST in medical surgery procedures has faced some challenges. the first challenge is high cost due to complex systems. the second challenge is the lack of ability of IST to improve the performance of medical devices. The third challenge is the blackness of IST to be reproducible due to the manual operating system. these challenges are overcome using ML-based ISTs[24]. Studies claim that before real implants are made for TEVAR the use of computational implants is made in clinical processes.

The computational model predict the outcomes that can possibly occur when real stent is used in patients body[25]. Studies claim that treating the AAA condition timely is advisable .AA is characterized by fast spreading of disease that creates complication during the treatment process.to determine the growth of aortic aneurysm in patient the 3D models along with CTA is used by physicians[26]. Scholars claim that Neuroineterventionalists faces problem while dealing with many computer software while performing the intervention process. To helps them the use of Ai based software have been developed that uses intelligence-based system to simultaneously control different computer operated programs. the stenting process during cardiovascular disease treatment process is monitored using AI models[27]. Studies claim that computational systems based on AI models are the invention of twenty first century. This computed system has improved the health systems gertaly.by combining AI with computer-based stimulation models the cardiovascular intervention process becomes easier. Aong with computational models that virtual reality models use has increased in the last few years because of its high demand during the pre-operative practices[28].studies claim that in some patient the use of stents causes in stent restenosis. this problem is overcome by developing stents that are safer to use for implants. H-BVS is stent that has in built sensor that make its use effective in cardiovascular related treatments[29].

METHODS

The research study determines the computational models for real time monitoring of vascular stent performance. the research study based on primary data analysis for determine the data used SPSS software and generate result included descriptive statistical analysis, the correlation coefficient analysis, the ANOVA test analysis also that it explains the linear regression analysis between them (Figure 1).

COMPUTATIONAL MODELS

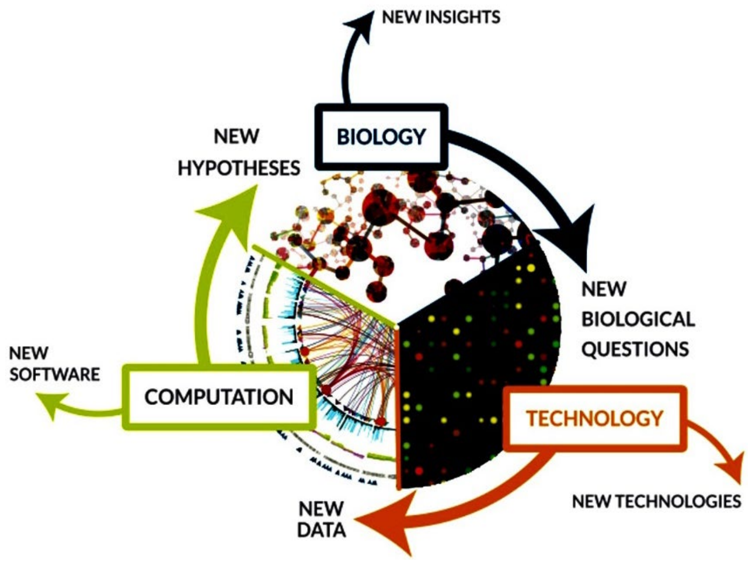

Figure 1: Computational Models

Device Development and Design Optimization

Early in the TPLC, computational solid mechanics, commonly implemented as finite element analysis (FEA), is a method for optimising a device design to the intended design inputs. For example, FEA may be used to optimise stent characteristics (such as strut width and thickness) in order to balance radial support with deliverability, as well as to analyse fatigue performance under simulated usage settings. FEA facilitates the interaction of design inputs and outcomes, which is helpful since each design input frequently has inherent tradeoffs. However, successful execution of this phase demands a thorough understanding of the simulated in vivo loading circumstances. Furthermore, FEA is utilised to create therapeutically appropriate simulated-use models that work in tandem with patient-specific image-based techniques. Similarly, if multiple designs are available for a device family (e.g., different stent platforms, strut designs, and delivery system profiles), they can be simulated under the expected implantation and in vivo loading conditions to determine the optimal design performance envelopes and to better understand the design features that can be easily modified to directly impact performance attributes (e.g., flexibility). For example, FEA has previously been used to assess migration of endovascular stent-grafts by comparing active fixation mechanisms between designs. More typically, FEA is used to design an implant for a specific place based on simulated usage and loading circumstances. However, peripheral vascular devices can be used in a variety of vascular beds, including the carotid, iliac, superficial femoral, renal, and below the knee, as well as the arterial and venous sides of the circulation. As a result, FEA allows for a better understanding of a device's mechanical performance across diverse vascular bed(s) and the selection of an optimal implantation location based on this performance. Finally, FEA may show that it is conceivable to have a single stent platform that can be employed in numerous vascular beds. Computational fluid dynamics (CFD) allows for the optimisation of blood-contacting device design in order to reduce wall shear stress and perhaps reduce the risk of thrombus formation or haemolysis. For endovascular stent-grafts, the distal ends might interrupt flow and cause recirculation or stagnation. Thus, CFD may be utilised to better comprehend input and outflow corridors, as well as to analyse flow interruptions around the graft material's proximal and distal margins. Furthermore, CFD may be used to examine the ability of IVC filters to catch blood clots of various sizes, allowing for design optimisation to maximise clot capture efficiency.

Table 1: Result of Paired Samples Statistics

Paired Samples Statistics					
		Mean	N	Std. Deviation	Std. Error Mean
Pair 1	Computational Models	1.5098	51	.61229	.08574
	Vascular Stent Performance	1.5098	51	.57871	.08104
Pair 2	Computation	1.5686	51	.57463	.08046
	Vascular Stent Performance	1.5098	51	.57871	.08104
Pair 3	Biology	1.7059	51	.70126	.09820
	Vascular Stent Performance	1.5098	51	.57871	.08104
Pair 4	New Technology	1.6471	51	.59409	.08319
	Vascular Stent Performance	1.5098	51	.57871	.08104

The above result shown in table 1 demonstrates that paired sample test statistical analysis the result describes mean value, standard deviation, also that standard error mean. The first pair is computational models and vascular stent performance result shows that its mean value is 1.5098 the standard deviation rate is 61% and 57% deviate from mean value. According to the result the error value of mean rate is 8% respectively related to computational models for real time monitoring of vascular stent performance. the second pair is computation and vascular stent performance result shows its mean value is 1.5686 and 1.5098 shows that positive average rate. The standard deviation rate 57% the error value is 8% shows positive error value. The third pair is biology and vascular stent performance its shows 1.7059 and 1.5098 the standard deviation rate is 70% and 59% deviate from mean. The last pair is new technology and vascular stent performance its mean rate is 1.6471 and 1.5098 the standard deviation value is 59% and 57% deviate from mean. The error rate of standard level is 8% and 81% respectively.

Table 2: Result of Paired Samples Correlations

Paired Samples Correlations				
		N	Correlation	Sig.
Pair 1	Computational Models & Vascular Stent Performance	51	-.297	.035
Pair 2	computation & Vascular Stent Performance	51	-.167	.240
Pair 3	Biology & Vascular Stent Performance	51	-.067	.642
Pair 4	New technology & Vascular Stent Performance	51	.068	.633

The above results of table 2 demonstrates that paired sample correlation in between computational models and vascular stent performance. the first pair shows that correlation value is -0.297 its significant rate is 0.035 shows negative but its 35% significant level between them. the second pair is computation and vascular stent performance result shows that its correlation value is -0.167 also that its significant level is 24% respectively between them. The third pair is biology and vascular stent performance its correlation value is -0.067 the significant rate is 64% the last pair is new technology and vascular stent performance its shows that correlation value is 0.068 the significant rate is 63% respectively (Figure 2).

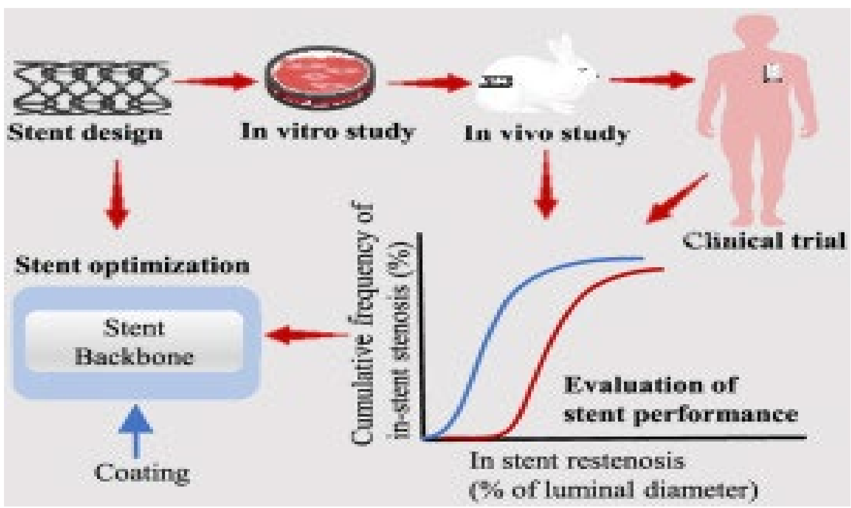

Figure 2: Cycle

Table 3: Result of Paired Samples Test

Paired Samples Test									
		Paired Differences					T	Df	Sig. (2-tailed)
		Mean	Std. Deviation	Std. Error Mean	95% Confidence Interval of the Difference				
					Lower	Upper			
Pair 1	Computational Models - Vascular Stent Performance	.00000	.95917	.13431	-.26977	.26977	.000	50	1.000
Pair 2	computation - Vascular Stent Performance	.05882	.88118	.12339	-.18901	.30666	.477	50	.636
Pair 3	Biology - Vascular Stent Performance	.19608	.93850	.13142	-.06788	.46004	1.492	50	.142
Pair 4	new technology - Vascular Stent Performance	.13725	.80049	.11209	-.08789	.36240	1.224	50	.227

The mentioned result shown in table 3 shows that the paired sample test analysis result describes the 95% CI, mean rate, standard deviation rate, t statistic, and significant value of each pair. The mean value for the first pair of vascular stent performance and computational models is 0.000. 95% is the standard deviation rate. Both the t statistic value and its significant value are 0.000 and 1.000, respectively.

The second pair shows the 63% significant rate and positive mean value between the vascular stent performance and the calculation. The mean value of the third pair, which consists of biology and vascular stent performance results, is 0.19608. 93% is the standard deviation rate.

The value of the t statistic is 1.492. The corresponding significant figure is 14%. The performance result for the last pair, which is new technology and vascular stents, indicates a t statistic rate of 1.224, which is 22% of the significant rate between them.

Table 4: Result of Test Statistic

Test Statistic					
	Computational Models	Computation	Biology	New Technology	Vascular Stent Performance
Chi-Square	19.176[a]	19.882[a]	33.941[b]	18.353[a]	20.588[a]
Df	2	2	3	2	2
Asymp. Sig.	.000	.000	.000	.000	.000
a. 0 cells (0.0%) have expected frequencies less than 5. The minimum expected cell frequency is 17.0.					
b. 0 cells (0.0%) have expected frequencies less than 5. The minimum expected cell frequency is 12.8.					

The chi square analysis results above shown in table 4 reveal that the chi square values are 19.176, 19.882, 33.941, 18.353, and 20.588, all of which indicate a positive rate. The overall variable's significant value is 0.000, indicating a 100% degree of significance between them. The second device simulated, according to the research, was a paediatric aortic valve that can develop with the child, obviating the need for several treatments. The ultimate objective of this research is to develop a biostable leaflet-based valve that is inserted into a biodegradable tube that acts as the point of contact with the aortic tissue. The biodegradable tube disappears as the child grows, and normal tissue replaces it. The biostable leaflets are still present, but they need to change to accommodate the aorta's growing diameter. All of the components in the current study were considered biostable, and the main goal was to build a novel valve leaflet that provides the necessary blood flow while functioning competently across all relevant aorta diameters. In order to examine the impact of blood flow on valve kinematics throughout the cardiac cycle, the constructed valve was computationally simulated in a fluid-solid interaction (FSI) framework.

The results of the model were then contrasted with experimental data. The results of the simulation demonstrated that the novel leaflet design could accommodate a 100% increase in aorta diameter while maintaining a suitable valve orifice area and acceptable aortic regurgitation rates.

Table 5: Result of ANOVA[a]

ANOVA[a]						
Model		Sum of Squares	df	Mean Square	F	Sig.
1	Regression	1.948	4	.487	1.514	.214[b]
	Residual	14.797	46	.322		
	Total	16.745	50			
a. Dependent Variable: Vascular Stent Performance						
b. Predictors: (Constant), new technology, computation, Computational Models, biology						

The result above shown in table 5 explains how the results of the anova test analysis show that each model's regression and residual contained the sum of squares value, mean square value, F statistic value, and significant rate. According to the regression model, the sum of squares rate is 1.948. 0.487 is the mean square value. The positive and 21% significant level between them is indicated by the significant value of 0.214. 14.797 is the residual value. 32% is the mean square rate. 16.745 is the total value, respectively. While being equally resistant to collapse, the cross-linkage configuration (stent-B) minimises circumferential stresses (hoop stress $\sigma\theta$).

Compared to stent-A, stent-B's elastic recoil was much larger. Consequently, the vascular layers had very little stresses. For the same reason, there was a lower percentage increase in stent peak stresses with limited deployment. It is recommended that any new emerging design adopt head-to-head crown joining of stent-A, even if there is not enough evidence to make definitive judgements. This prevents the curved crown from moving forward, as was seen with the stent-B design, and permits more controlled growth.

It increases the risk of damage since its absence results in considerable prolapse in the plaque material and consequent contact stresses. Second, the phenomenon of foreshortening may be significantly reduced by combining the bridge connection linkage with a wave-shape design, such the N-shape in stent-A. Additionally, when using the Abaqus/Explicit approach for future computational mechanics research and validation (study of global behaviour), greater attention should be paid to the balloon's folded pattern and its attachment to the catheter shaft. However, to reduce computer work, the folded structure might be ignored for stress analysis (study of local behaviour). For such studies, particularly in the design of future generation stents, the Abaqus/Stand simulation technique is more suitable. This eliminates the potential for inertial impacts while also significantly cutting down on processing time.

Table 6: Result of Coefficients[a]

Coefficients[a]						
Model		Unstandardized Coefficients		Standardized Coefficients	t	Sig.
		B	Std. Error	Beta		
1	(Constant)	2.252	.474		4.747	.000
	Computational Models	-.259	.137	-.274	-1.885	.066
	Computation	-.172	.148	-.171	-1.161	.251
	Biology	-.065	.120	-.079	-.542	.590
	New Technology	.018	.149	.018	.118	.906
a. Dependent Variable: Vascular Stent Performance						

The result above shown in table 6 illustrates how the unstandardized coefficient values, such as the beta value and standard error rate between the independent and dependent variables, are described by the linear regression analysis. Each independent variable's beta rate is described by the standardized coefficient analysis. Each independent variable's significant value and t statistic are described in the outcome. According to the computational model, the beta value is -0259. 0.137 is the standard error value.

The value of the t statistic is -1.885. The significant rate between them is 6%, as indicated by the 0.066 value. According to the computation, its beta value is 0.148. The value of the t statistic is -1.161. 0.251 is the significant rate. It indicates that there is a 25% significant difference between the computational model and the performance of the vascular stent. The t statistic value for the new technology, another independent variable, is 0.118. The significant rate is 0.906, indicating a 90% significant and 11% positive relationship between the new technology and the performance of vascular stents.

DISCUSSION

ASME focusses on strengthening the credibility of numerical simulation through verification and validation initiatives, hence model construction is not described in depth. However, there is broad agreement with NASA's suggestions on the significance of establishing the QOI, COU, and intended application early in the modelling phase. Pathmanathan et al. observed that in biomedical modelling, a mismatch might exist between model validation and subsequent implementation. In the realm of biofluid mechanics, in particular, considerable assumptions must be made throughout the model construction process to handle complicated haemodynamic situations such as the coagulation cascade. As a result, the V&V plan confronts significant hurdles and necessitates well-constructed in vitro standards. Currently, it is not possible to assess flow velocity, rheological characteristics of the blood, and thrombogenic indicators simultaneously.The model must be decomposed into sub-models and the associated V&V operations performed on these sub-aspects. Additional sources of evidence, such as a literature study, should be considered. An applicability analysis is advised for structuring V&V operations, as shown in collection. Despite the fact that there are several research works on the issue of CFD modelling of stents that have gone through the model development process, a systematic step-by-step guidance might assist to hasten the bench-to-bedside transition.

Due to the paper's restricted length, only a few significant points could be discussed. Furthermore, the technical documentation for model creation may be viewed as a communication tool, resulting in enhanced understanding in interdisciplinary teams.

CONCLUSION

The ability of CM&S to simulate numerous design factors and in vivo usage circumstances, forecast relevant results, and visualise complicated processes has the potential to revolutionise medical device research and patient data utilisation. As a community, we have been successful in using CM&S at various stages of the TPLC. However, in order for CM&S to play a larger role in regulatory decision-making, serve as a significant source of valid evidence, predict successes and failures, and fully realise the FDA's vision of virtual physiological patients, virtual clinical studies, and personalised medicine, stakeholders must have ready access to verified and validated CM&S tools.

The success of stakeholder-driven projects will get us closer to that future. In this work, the deployment of two distinct stent types was simulated using a complex balloon design, taking into account the influence of the guide wire and catheter-shaft effectively coupled together. The numerical analysis of stent angioplasty is advanced by the restricted deployment of stents under the influence of different arterial layers. The purpose of this study was to determine the clinical effectiveness of a recently commercialised Saviour Stent by comparing it to a well-known and well-documented Cypher Bx_Velocity stent. Design parameters such pressure expansion, foreshortening, dog-boning, elastic recoil, and maximum stress distribution served as the basis for the comparison. These qualities are crucial for long-term sustainability, flexibility, outstanding deliverability, and stent restenosis.

With high stiffness, increased resistance to radial recovery, lumen shape retention, and suitable stress output, Stent-A was demonstrated to be more persistent in following the lesion profile and to have good durability. Conversely, a thinner strut stent design, like stent-B, permits greater deliverability, ease of expansion, high flexibility, access to more challenging stenosed areas, and less foreign material. Improvements are being developed in order to achieve the necessary design attributes. This shows that in order to have a better qualitative design, these aspects must constantly be properly balanced. Second, the overall function of the stent is significantly influenced by the connections made between sinusoidal portions via different interconnections. For instance, the N-shaped head-to-head connection (stent-A) reduces the chance of foreshortening by allowing for a little amount of longitudinal expansion.

REFERENCES

1. B. Bisighini, M. Aguirre, B. Pierrat, and S. Avril, "Patient-specific computational modelling of endovascular treatment for intracranial aneurysms," *Brain Multiphysics,* vol. 5, p. 100079, 2023.
2. A. Molloy *et al.*, "Challenges to the development of the next generation of self-reporting cardiovascular implantable medical devices," *IEEE Reviews in Biomedical Engineering,* vol. 15, pp. 260-272, 2021.
3. D. Rivas-Marchena, A. Olmo, J. A. Miguel, M. Martínez, G. Huertas, and A. Yúfera, "Real-time electrical bioimpedance characterization of neointimal tissue for stent applications," *Sensors,* vol. 17, no. 8, p. 1737, 2017.
4. E. E. Antoine, F. P. Cornat, and A. I. Barakat, "The stentable in vitro artery: an instrumented platform for endovascular device development and optimization," *Journal of The Royal Society Interface,* vol. 13, no. 125, p. 20160834, 2016.
5. X. Chen, B. Assadsangabi, Y. Hsiang, and K. Takahata, "Enabling angioplasty-ready "Smart" Stents to detect in-stent restenosis and occlusion," *Advanced Science,* vol. 5, no. 5, p. 1700560, 2018.
6. T. M. Morrison, M. L. Dreher, S. Nagaraja, L. M. Angelone, and W. Kainz, "The role of computational modeling and simulation in the total product life cycle of peripheral vascular devices," *Journal of medical devices,* vol. 11, no. 2, p. 024503, 2017.
7. E. L. Boland, J. A. Grogan, and P. E. McHugh, "Computational modeling of the mechanical performance of a magnesium stent undergoing uniform and pitting corrosion in a remodeling artery," *Journal of Medical Devices,* vol. 11, no. 2, p. 021013, 2017.
8. M. D. Daei, "Computational modeling of interventional and implantable endovascular devices," Institut Polytechnique de Paris, 2023.
9. S. Avril, M. W. Gee, A. Hemmler, and S. Rugonyi, "Patient-specific computational modeling of endovascular aneurysm repair: State of the art and future directions," *International journal for numerical methods in biomedical engineering,* vol. 37, no. 12, p. e3529, 2021.
10. B. D. Chaparro-Rico, F. Sebastiano, and D. Cafolla, "A smart stent for monitoring eventual restenosis: Computational fluid dynamic and finite element analysis in descending thoracic aorta," *Machines,* vol. 8, no. 4, p. 81, 2020.
11. R. Abdollahi, A. Shahi, D. Roy, S. Lessard, R. Mongrain, and G. Soulez, "Virtual and analytical self-expandable braided stent treatment models," *Medical Engineering & Physics,* vol. 126, p. 104145, 2024.
12. S. Bailoor, J.-H. Seo, L. Dasi, S. Schena, and R. Mittal, "Towards Longitudinal Monitoring of Leaflet Mobility in Prosthetic Aortic Valves via In-Situ Pressure Sensors: In-Silico Modeling and Analysis," *Cardiovascular Engineering and Technology,* vol. 14, no. 1, pp. 25-36, 2023.
13. M. D'Oria *et al.*, "Computational Surgery in the Management of Patients with Abdominal Aortic Aneurysms: Opportunities, Challenges, and Future Directions," in *Seminars in Vascular Surgery*: Elsevier, 2024.
14. D. D. Nikolić and N. Filipović, "Use Case: Stent Biodegradation Modeling," in *In Silico Clinical Trials for Cardiovascular Disease: A Finite Element and Machine Learning Approach*: Springer, 2024, pp. 303-334.
15. B. Rigo *et al.*, "Soft implantable printed bioelectronic system for wireless continuous monitoring of restenosis," *Biosensors and Bioelectronics,* vol. 241, p. 115650, 2023.
16. W. Shi, C. Zhang, A. Xie, K. Mitchell, Y. Jin, and D. Zhao, "Development of a Computational Framework for the Evaluation of Biodegradable Cerebral Stents With Enhanced Bending Performance," *Journal of Medical Devices,* vol. 17, no. 1, p. 011007, 2023.
17. T. N. A. M. Vuong *et al.*, "Integrating Computational and Biological Hemodynamic Approaches to Improve Modeling of Atherosclerotic Arteries," *Advanced Science,* p. 2307627, 2024.
18. L. Wang *et al.*, "The PolyCraft Polymer–Metal Hybrid Smart Stent System: The Future of Cardiovascular Blood Pressure Management," *Advanced Functional Materials,* p. 2408022, 2024.
19. O. Akman, L. Arriola, R. Schroeder, and A. Ghosh, "Quantum Mechanics for Population Dynamics," *Letters in Biomathematics,* vol. 10, no. 1, pp. 105–115, 2023.
20. M. Çap *et al.*, "Computational modeling for assessing coronary artery pathophysiology," vol. 10, ed: Frontiers Media SA, 2023, p. 1113835.
21. C. Capelli, M. Bertolini, and S. Schievano, "3D-printed and computational models: a combined approach for patient-specific studies," in *3D Printing in Medicine*: Elsevier, 2023, pp. 105-125.
22. B. Guha, S. Moore, and J. Huyghe, "Towards Non-Destructive Quality Testing of Complex Biomedical Devices—A Generalized Closed-Loop System Approach Utilizing Real-Time In-Line Process Analytical Technology," *NDT,* vol. 2, no. 3, pp. 270-285, 2024.
23. P. Li, B. Xu, X. Zhang, D. Fang, and J. Zhang, "Design and development of a personalized virtual reality-based training system for vascular intervention surgery," *Computer Methods and Programs in Biomedicine,* vol. 249, p. 108142, 2024.
24. M. MacRaild, "Efficient ensemble simulation methods for in-silico trials of endovascular medical devices," 2024.
25. T. J. Mandigers *et al.*, "Thoracic stent graft numerical models to virtually simulate thoracic endovascular aortic repair: a scoping review," *European Journal of Vascular and Endovascular Surgery,* vol. 66, no. 6, pp. 784-796, 2023.
26. M. Rezaeitaleshmahalleh *et al.*, "Computerized differentiation of growth status for abdominal aortic aneurysms: a feasibility study," *Journal of cardiovascular translational research,* vol. 16, no. 4, pp. 874-885, 2023.
27. Y. Sakakura, K. Kono, and T. Fujimoto, "Real time artificial intelligence assisted carotid artery stenting: a preliminary experience," *Journal of NeuroInterventional Surgery,* 2024.
28. S. Samant *et al.*, "Artificial intelligence, computational simulations, and extended reality in cardiovascular interventions," *Cardiovascular Interventions,* vol. 16, no. 20, pp. 2479-2497, 2023.
29. J. Wei *et al.*, "Enhancing Flexibility of Smart Bioresorbable Vascular Scaffolds through 3D Printing using Polycaprolactone and Polylactic Acid," *Sensors and Actuators B: Chemical,* p. 136667, 2024.