COBEM 2021 26th International Congress of Mechanical Engineering
ABCM Associação Brasileira de Engenharia e Ciências Mecânicas
November 22-26, 2021, Virtual Congress, Brazil

COB-2021-0131
FINITE ELEMENT SIMULATION AND PERFORMANCE ANALYSIS OF A NOVEL BIOABSORBABLE STENT FOR THE TREATMENT OF AORTIC COARCTATION

Santos, Flávio José dos
Hernandez, Bruno Agostinho
Souza, Mateus Piccin Duarte de
UNESP, São Paulo State University, Campus of Bauru, Brazil.
flavio.jose@unesp.br
bruno.agostinho@unesp.br
mateus.p.souza@unesp.br

Andrade, Aron José Pazin de
Adib Jatene Foundation, Dante Pazzanese Institute of Cardiology, São Paulo, Brazil.
aandrade@fajbio.com.br

Capello Sousa, Edson Antonio
UNESP, São Paulo State University, Campus of Bauru, Brazil.
edson.capello@unesp.br

Abstract. *Coarctation of the Aorta (CoA) is a congenital heart disease that causes a narrowing of the artery cross-section area, partially reducing the blood flow. One of the most traditional treatments for CoA is the use of metallic stents. However, their use in young children is limited, due to the patient's constant growth and the need for new surgeries for stent expansion, which it is only possible up to a certain diameter. In this scenario, the development of a bioabsorbable stent was idealised, as these devices degrade over time and remain temporarily in the patient's body. The finite element method is widely used in the development of biomechanical devices but the modelling of stents is a challenging task due to its many parameters. Therefore, this study aimed to develop a finite element model of a bioabsorbable stent, simulate its opening of an artery with coarctation, and evaluate which modelling parameters influence the model's performance. The analysed parameters were the type/size of the element, type of loading, number of loading steps and sub-steps, and type of coordinate system. It was found that the application of loading by displacement and a change from the Cartesian to the cylindrical coordinate system resulted in a better simulation performance, with the stent achieving the maximum opening. The developed model allowed a representation of the structural behaviour of a new bioabsorbable stent inside an artery with coarctation, and an evaluation of the stent's performance during its implantation as well as the main parameters affecting the modelling.*

Keywords: *Coarctation of the Aorta (CoA), Finite Element Method, Bioabsorbable Stents.*

1 – INTRODUCTION

Coarctation of the Aorta (CoA) is a congenital abnormality of the heart that obstructs the blood flow in the aorta vessel: it is usually located at the junction of the ductus arteriosus and the aortic arch, next to the left subclavian artery. Every year, about 51,000 newborns have some degree of Aortic Coarctation worldwide (Van der Linde et al., 2011). This is the equivalent of 1 in every 2500 births, according to some studies (Torok et al., 2015; Rao, 2005).

The treatment of patients with CoA consists of restoring the original diameter of the aorta, i.e. enlarging the narrowed section (Pádua et al., 2012). This procedure can be achieved through reparatory surgery, balloon angioplasty, and the use of metallic stents (Doshi & Chikkabyrppa, 2018; Pádua et al., 2012).

According to Alkashkari et al. (2019), the use of a metallic stent is considered the preferred treatment for teenagers and adult patients with CoA. However, stent implantation in young children is not recommended due to the need for frequent re-dilation of the stent in the growing aorta and the need for new surgeries. According to the authors, this treatment option is only indicated for children weighing more than 15 kg. Moreover, even in adults, there are still very few stent models capable to expand to an average diameter of an adult aorta (21.1 ± 3.2 mm for women, 26.1 ± 4.3 mm for men; Alkashkari et al., 2019).

An alternative to the use of metallic stents for young children is the use of bioabsorbable stents. These devices are generally made of magnesium alloys or polymers; with PLLA (Poly-L-Lactide Acid) and PLA (Poly-Lactide Acid) being the most used polymers (Qiu et al., 2018).

Numerical methods, especially the Finite Element Method (FEM), have been widely used in the analysis of new cardiovascular equipment and the development and geometry optimisation of new stents (Torki et al., 2020). The advantages of using the FEM are several: the time to prepare a model is less than an experimental procedure; it can predict local and global stress and strain distributions and it can represent complex loads and boundary conditions, as well as nonlinearities.

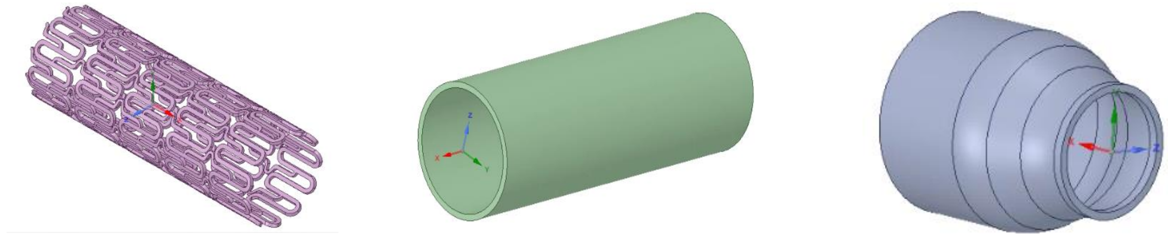
Gervaso et al. (2008) conducted a study to analyse the stent expansion of a coronary artery using three different approaches to the model stent-artery system. According to the author, it is important to analyse not only the mechanical response of the stent but also the arterial stress levels caused by the device and their effect on restoring the original diameter of the aorta.

It is observed in some studies that five main rules have been used to finite element model the expansion of a stent: 1) An application of uniform pressure to the inner surface of the stent (Migliavacca F. et al., 2005; Early et al., 2009; Zahedmanesh and Lally, 2009); 2) Sent expansion via radial displacement (Hall and Kasper, 2006; Takashima et al., 2007; Wu et al., 2007); 3) A flexible balloon model (De Beule et al., 2008; Gervaso et al., 2008, Zahedmanesh et al., 2014); 4) Aorta characterisation with hyperelastic material properties (Ju et al., 2008; Kiousis et al., 2009); and 5) analysis by hydroconformation (Araújo et al, 2013).

Despite the great advantages of the MEF, the modelling of bioabsorbable stents is not a trivial task, as it involves many variables, such as element type and size, for both the stent and artery, large displacements, plasticity, element distortion, problems of contact among others. Therefore, this study aimed to evaluate which modelling factors would have an influence on the stent performance and verify which the best strategy to achieve convergence is.

2 – MATERIALS AND METHODS

The stent geometry was developed by the Adib Jatene Foundation, associated with the Dante Pazzanese Institute of Cardiology (IDPC, São Paulo). It is 40mm long; it has 11 radial struts and 10 longitudinal struts, and external diameter and thickness of 6.75mm and 0.25mm, respectively, Figure 1a. Two types of artery geometries were created for this study. The first is a healthy artery geometry with an external diameter ranging from 10 to 14mm, Figure 1b. The thickness of the artery was 10% of the value of the external diameter. The second was an artery with coarctation, with an external diameter of 13mm in the healthy region, an internal diameter of 7.8mm in the region with coarctation, and a thickness of 1mm for the whole vessel, Figure 1c. The stent and artery geometries were created using Ansys' SpaceClaim software (v19, ANSYS, Inc., Canonsburg, PA, USA).



(a) (b) (c)

Figure 1 - a) Half of the stent; b) Healthy artery; c) Artery with Coarctation.

It was assigned for stent the mechanical properties of PLLA (Poly-L-Lactide Acid), characterised by stress-strain curve given by Qiu et al. (2018), with the following properties: Elasticity's modulus of 2.8GPa, Poisson coefficient of 0.3 and yield stress of 59.74MPa. A hyperelastic behavior with a second order Mooney-Rivlin model was assign for both aorta geometries, with the following constants: $C10 = 0.077$ MPa, $C20 = 0.836$ MPa, $d = 0.517$ (Simsek & Kwon, 2015).

Initially, the simulation was performed with all parts set as steel to evaluate the initial model computational performance. The steel properties were available at Ansys software's library. An incremental approach was then conducted following these steps:

Step 1 - Simulation of the stent only and set as made of steel;
Step 2 - Simulation of the stent only and set as made of PLLA;
Step 3 - Simulation of the stent, set as made of steel, inside a healthy artery;

Step 4 - Simulation of the stent, set as made of PLLA, inside a healthy artery;
Step 5 - Simulation of the stent, set as made of PLLA, inside an artery with coarctation.

The stent was expanded from its initial diameter of 6.25m to a maximum diameter, which ranged from 11 to 15mm. The initial simulations were performed with solid elements for the stent and shell elements for the arteries. To reduce the computational effort, symmetry was used, Figure 1. A Cartesian coordinate system was initially adopted and the boundary conditions were set as shown in Figure 2: the artery extremities were fully restrained, pressure loading was applied in the internal side of the stent, and the stent was restrained in y and z directions, with a symmetry plane on the x-axis. To improve convergence, an artery with an inner diameter close to the stent's external diameter was introduced, causing immediate contact with the stent.

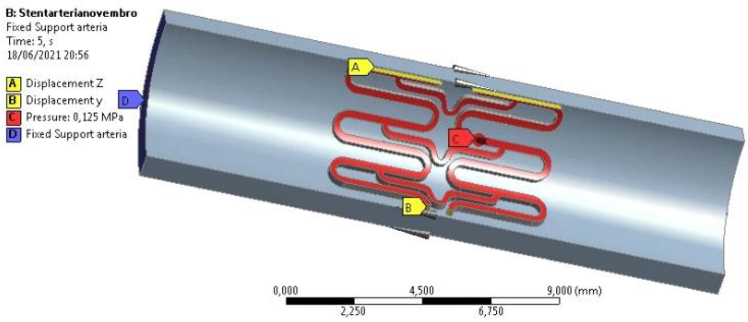


Figure 2 - Initial boundary conditions.

3 – RESULTS

The results using the aforementioned boundary conditions were not very encouraging. The coordinate system was then changed to cylindrical and a radial displacement was applied instead pressure on the inner surface of the stent, Figure 3. With these boundary conditions, the models were completely solved.

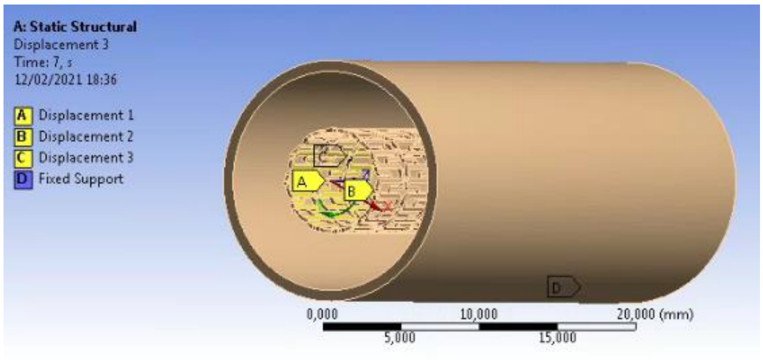


Figure 3 - Final boundary conditions.

The element size adopted for the stent geometry was 0.1mm, while it was 0.4mm for the artery, Table 1. As can be seen in Table 1, the error was only 1.19% from an element size of 0.12mm to 0.1mm.

Figure 4 presents the results with the Cartesian coordinate system with pressure applied to the internal surface of the stent. Note that the stent achieved a displacement of 0.42mm. Figure 5 shows a result of the simulation with the cylindrical coordinate system, with the application of radial displacement in the internal part of the stent. The displacement achieved in this case was 3.3mm.

The minimum number of load steps to achieve convergence was 2 and the maximum number was 10. On the other hand, the number of the necessary substeps to achieve convergence ranged from 50 to 200.

Table 1. Mesh sensitivity test.

Simulation	Quantity*	Size (mm)	Principal Stress (MPa)	Error (%)
S1	19051	0.16	109.57	-
S2	29418	0.1 4	104.66	4.48
S3	43378	0.12	102.88	1.70
S4	70393	0.1	101.66	1.19

*Number of elements

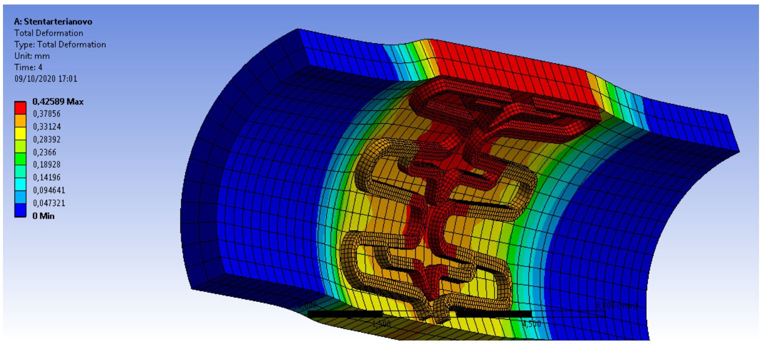


Figure 4 – Stent/artery displacement with Cartesian coordinate system.

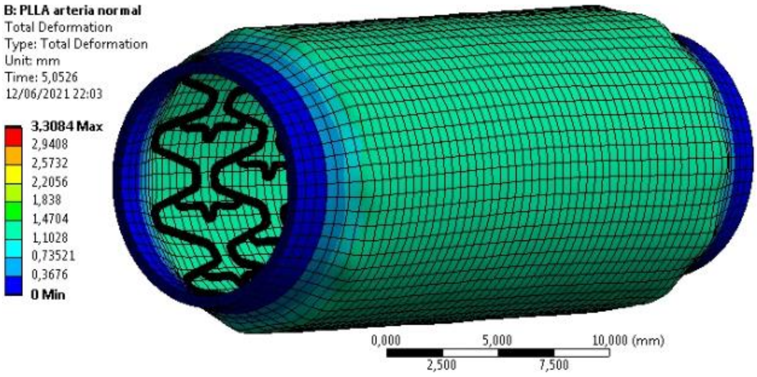


Figure 5 – Stent/artery displacement with cylindrical coordinate system.

4 – DISCUSSION

Metallic stents have been successfully used for the treatment of aortic coarctation in adult patients. However, their application in newborns and young children is limited, mostly due to the patient's continuous growth, which demands new and debilitating stent expansion surgeries.

An alternative to the metallic type is the use of bioabsorbable stents, as these devices, usually made of organic polymer materials such as PLLA or PLA, remain only temporarily in the patient's body. Still, some challenges have to be overcome to make this type of stent a reality, such as improving its low structural strength.

Numerical and computational modelling is increasingly supporting the development of new products, as it allows the physical understanding of the behaviour of the component. The Finite Element Method (FEM) has been extensively used to develop and analyse new stents, cardiac devices, and medical equipment (Torki et al., 2020). The main advantage of FE is that several and different designs can be explored before clinical trials, which would save resources and time, as an optimum design could be achieved at the beginning of the development process. However, modelling the opening of a bioabsorbable stent inside an artery is not a trivial task as it involves a high degree of non-linearity, plasticity, and large displacements (as it is in this case of the aorta artery, the largest vessel in the human body).

Applying pressure on the internal surface of the stent, and using a Cartesian coordinate system (Figure 4), led to a small opening of 0.42mm. This methodology also resulted in a high degree of element distortion and convergence errors. Similar errors were also found by other studies, which suggested the use of radial displacement to simulate the opening of stents in finite element simulations to overcome this issue (Hall & Kasper, 2006; Takashima et al., 2007; Wu et al., 2007). Thus, a change in the coordinate system to cylindrical (Figure 5) and the application, instead of pressure, of a radial displacement on the stent, led to an opening of 3.31mm, eight times higher than the previous configuration, causing the necessary deformation in the aorta.

Initially, the modelling was performed using solid elements for the stent, and shell elements for the artery. With this configuration, it was not possible to achieve the model's convergence. Then, the artery's element type was changed to solid, resulting in a full convergence of the model. A 10-node 3D tetrahedral structural solid element (SOLID 187) was used for the stent and a 20-node 3D structural high-order solid element (SOLID186) was used for the artery.

Another point analysed in this study was the number of load steps and substeps necessary to fully solve the model, which ranged from 2 to 10, and from 50 to 200, respectively. In the cylindrical coordinate system configuration, a minimum of 2 load steps was necessary to represent the application and the removal of the load during the surgery. The increase to 10 load steps did not affect the simulation drastically. On the other hand, the number of substeps significantly influenced the simulations. A higher number of substeps was necessary so that the model could identify the contact between the stent and the artery.

Finally, the element size played an important role in the computational effort and in the convergence of the model. The study shown in Table 1 indicated that for an average element size of 0.1mm for the stent, an error of 1.19% was achieved, and this element size also led to a fully solved model.

5 – CONCLUSION

The finite element method has been increasingly used in the bioengineering field to support the development of new products. As bioengineering deals with biological tissues, which have complex structures and behaviours, such as seen in arteries, the continuous development and improvement of models is important to increase the accuracy and precision of such models.

Therefore, the aim of this work was to evaluate the influence of the modelling parameters in the performance of the modelling of a bioabsorbable stent expansion inside an aorta artery. The change of the coordinate system from Cartesian to cylindrical, and the application of loading through radial displacement instead of pressure on the stent wall were the main variables affecting the convergence of the model. The next step of this study will be the validation of the model with experimental data.

Limitations of work

For simplification purposes, the artery geometries were created in a CAD software, and did not represent a real human artery. Furthermore, the hyperelastic material was adopted using parameters in the literature, which also does not accurately reflect the true behaviour of a human artery.

6 - REFERENCES

Alkashkari, W., Albugami, S., & Hijazi, Z. M. (2019). Management of coarctation of the aorta in adult patients: State of the art. *Korean Circulation Journal*, *49*(4).

Araújo, R.; Guimarães, T. A.; Oliveira, S. A.G. An analysis of the contact between the stent and the artery using tube hydroforming simulation. *International Journal for Numerical Methods in Biomedical Engineering*, v. 29, n.11, p. 1214–1222, 2013.

De Beule, M.; Mortier, P.; Carlier, S.G.; Verhegghe, B.; Vanimpe, R.; Verdonck, P. Realistic finite element-based stent design: the impact of balloon folding. *Journal of Biomechanics*, v.41, n.2, p.383-9, 2008.

Doshi, A. R., & Chikkabyrappa, S. Coarctation of Aorta in Children. *Cureus*, 10(12): e3690, 2018

Early, M.; Lally, C.; Prendergast, P.J.; Kelly , D.J. Stresses in peripheral arteries following stent placement: a finite element analysis. *Computer Methods in Biomechanics and Biomedical Engineering*, v.12, p. 25–33, 2009.

Gervaso, F., Capelli, C., Petrini, L., Lattanzio, S., di Virgilio, L., & Migliavacca, F. (2008). On the effects of different strategies in modelling balloon-expandable stenting by means of finite element method. *Journal of Biomechanics*, *41*(6), 1206–1212.

Hall, G. J., & Kasper, E. P. (2006). Comparison of Element Technologies for Modeling Stent Expansion. *Journal of Biomechanical Engineering*, *128*, 751–756.

Ju, F.; Xia, Z.; Sasaki, K. On the finite element modelling of balloon expandable stents. *Journal of the Mechanical Behavior of Biomedical Materials*, v.1, p. 86–95, 2008.

Kiousis, D.E.; Wulf, A.R.; Holzapfel, G.A.. Experimental studies and numerical analysis of the inflation and interaction of vascular balloon catheter–stent systems. *Annals of Biomedical Engineering*, v. 37, p. 315–330, 2009.

Migliavacca, F.; Petrini, L.; Montanari, V.; Quagliana, I.; Auricchio, F.; Dubini, G. A predictive study of the mechanical behaviour of coronary stents by computer modelling. *Medical Engineering and Physics*, v.27, p. 13–18, 2005.

Pádua, L. M. S., Garcia, L. C., Rubira, C. J., & de Oliveira Carvalho, P. E. (2012). Stent placement versus surgery for coarctation of the thoracic aorta. *Cochrane Database of Systematic Reviews*.

Qiu, T. Y., Song, M., & Zhao, L. G. (2018). A computational study of crimping and expansion of bioresorbable polymeric stents. *Mechanics of Time-Dependent Materials*, *22*(2).

Rao, P. S. (2005). Coarctation of the Aorta. *Current Cardiology Reports*, *7*, 425–434.

Simsek, F. G., & Kwon, Y. W. (2015). Investigation of material modeling in fluid–structure interaction analysis of an idealized three-layered abdominal aorta: aneurysm initiation and fully developed aneurysms. *Journal of Biological Physics*, *41*(2), 173–201.

Takashima, K., Kitou, T., Mori, K., & Ikeuchi, K. (2007). Simulation and experimental observation of contact conditions between stents and artery models. *Medical Engineering and Physics*, *29*(3), 326–335.

Torki, M. M., Hassanajili, S., & Jalisi, M. M. (2020). Design optimizations of PLA stent structure by FEM and investigating its function in a simulated plaque artery. *Mathematics and Computers in Simulation*, *169*.

Torok, R. D., Campbell, M. J., Fleming, G. A., & Hill, K. D. (2015). Coarctation of the aorta: Management from infancy to adulthood. *World Journal of Cardiology*, *7*(11).

Van der Linde, D., Konings, E. E. M., Slager, M. A., Witsenburg, M., Helbing, W. A., Takkenberg, J. J. M., & Roos-Hesselink, J. W. (2011). Birth prevalence of congenital heart disease worldwide: A systematic review and meta-analysis. In *Journal of the American College of Cardiology* (Vol. 58, Issue 21, pp. 2241–2247). Elsevier USA.

Wu, W., Wang, W. Q., Yang, D. Z., & Qi, M. (2007). Stent expansion in curved vessel and their interactions: A finite element analysis. *Journal of Biomechanics*, *40*(11), 2580–2585.

Zahedmanesh, H.; Laly, C. Determination of the influence of stent strut thickness using the finite element method: implications for vascular injury and in-stent restenosis, *Medical and Biological Engineering and Computing*, v. 47, n. 4, p.385-393, 2009.

Zahedmanesh, H.; Van Ossterwyck, H.; Lally, C. A multi-scale mechanobiological model of in-stent restenosis: deciphering the role of matrix metalloproteinase and extracellular matrix changes. *Computer Methods in Biomechanics and Biomedical Engineering*, v. 17, n. 8, p. 813-28, 2014.

7 - RESPONSIBILITY NOTICE

The authors are the only responsible for the content in this paper.