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ANALYSIS ON THE EFFECT OF CONNECTING LINKS IN THE FORESHORTENING OF A BIOABSORBABLE STENT FOR THE TREATMENT OF AORTA COARCTATION IN CHILDREN: A FINITE ELEMENT STUDY

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Abstract. *Coarctation of the Aorta (CoA) is a congenital heart disease that causes a narrowing of the aorta 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. Thus, the development of a bioabsorbable stent was idealized, an ideal scenario for children. Limited foreshortening is one of the key features of a stent during CoA treatment. The finite element method is widely used in the development of biomechanical devices and this study aimed to evaluate the influence of the connecting links in the bioabsorbable stent performance in terms of foreshortening for the treatment of CoA in Children. Three different types of connecting links were analyzed: beam, bracket, and braces. All geometries had an outer diameter of 6.75 mm, a wall thickness of 0.25 mm, and they were modelled in CAD software. During the simulations at ANSYS software, a surface-type balloon was used to expand the geometries until reaching a varied maximum diameter ranging from 11 to 15 mm. It was found that the type of connecting links highly impacted the foreshortening performance during the expansion of the stent, as the geometry with braces' connecting links elongated instead of shortening, which occurred with the other two geometries. An evaluation of the stent's performance in terms of foreshortening during its implantation as well as the influence of the type of connecting link was assessed.*

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

1 – INTRODUCTION

Coarctation of the Aorta (CoA) is a Congenital Heart Disease, in which there is a decrease in the available area (lumen) for blood flow, causing obstruction to the flow of blood (Nguyen and Cook 2015). It is a disease that occurs more frequently in men and it is the seventh most common congenital heart disease (6-8% of all CHDs)(Nguyen and Cook 2015). 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, which disappear after some time. 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.

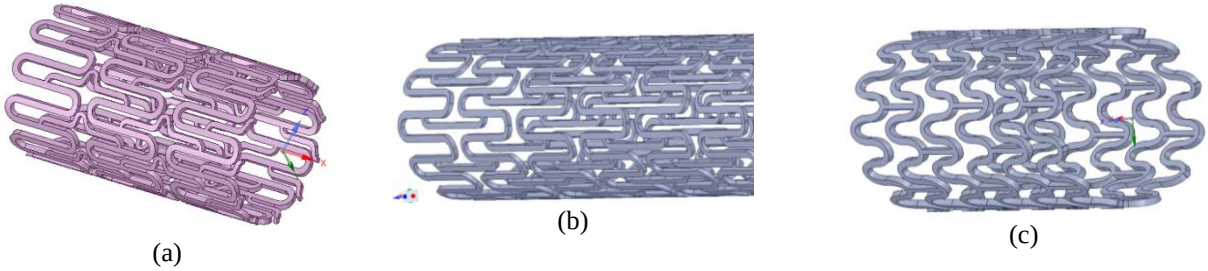
Gervaso et al. (2008) conducted a study to analyse the stent expansion of a coronary artery using three different approaches to the model stent-artery system. According to the author, it is important to analyse not only the mechanical response of the stent but also the arterial stress levels caused by 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 large displacements, plasticity, element distortion, problems of contact among others. Limited foreshortening is one of the key features of a stent during CoA treatment and this study aimed to evaluate the influence of the connecting links in the bioabsorbable stent performance in terms of foreshortening for the treatment of CoA in Children using MEF.

2 – MATERIALS AND METHODS

The stent geometries were developed by the Adib Jatene Foundation, associated with the Dante Pazzanese Institute of Cardiology (IDPC, São Paulo). Three different types of connecting links were used: braces (Figure 1a – Geometry 1), brackets (Figure 1b – Geometry 2) and beams (Figure 1c – Geometry 3). The geometry 1 and geometry 2 are 40 mm long while the geometry 3 is 25 mm long. The external diameter and thickness of the geometries are 6.75 mm and 0.25 mm, respectively. The geometries were created in CAD software and modelled using Ansys' SpaceClaim software (v19, ANSYS, Inc., Canonsburg, PA, USA).



(a) (b) (c)

Figure 1 – Types of connecting links: (a) braces, (b) brackets and (c) beams.

It was assigned for geometries 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 behaviour 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).

The stent was expanded from its initial diameter of 6.75m to a maximum diameter, which ranged from 11 to 15mm. A mesh convergence study for the stent was performed varying the sizes of the stent elements and an element size of 0.1 mm was assumed, according to Table 1.

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

As can be seen in Table 1, the difference was only 1.19% from an element size of 0.12mm to 0.1mm.

Solid quadratic elements were used to improve accuracy. A cylindrical coordinate system was adopted and the boundary conditions were set as shown in Figure 2: the application of a displacement by a surface, the balloon, with a diameter of 6 mm to expand the stent. For the balloon, a hyperelastic material was used according to the second-order Mooney Rivlin equation (Schiavone and Zhao, 2015), with constants $C_{10} = 1.03$, $C_{01} = 3.69$ and $D_1 = 0$. The stent was restrained in y and z directions, with a symmetry plane on the x-axis.

The load was divided into just two stages:

1) Application of a radial displacement in the balloon until the external diameter of the stent reached a maximum diameter that varied from 11 to 15 mm.

2) Removal of balloon displacement.

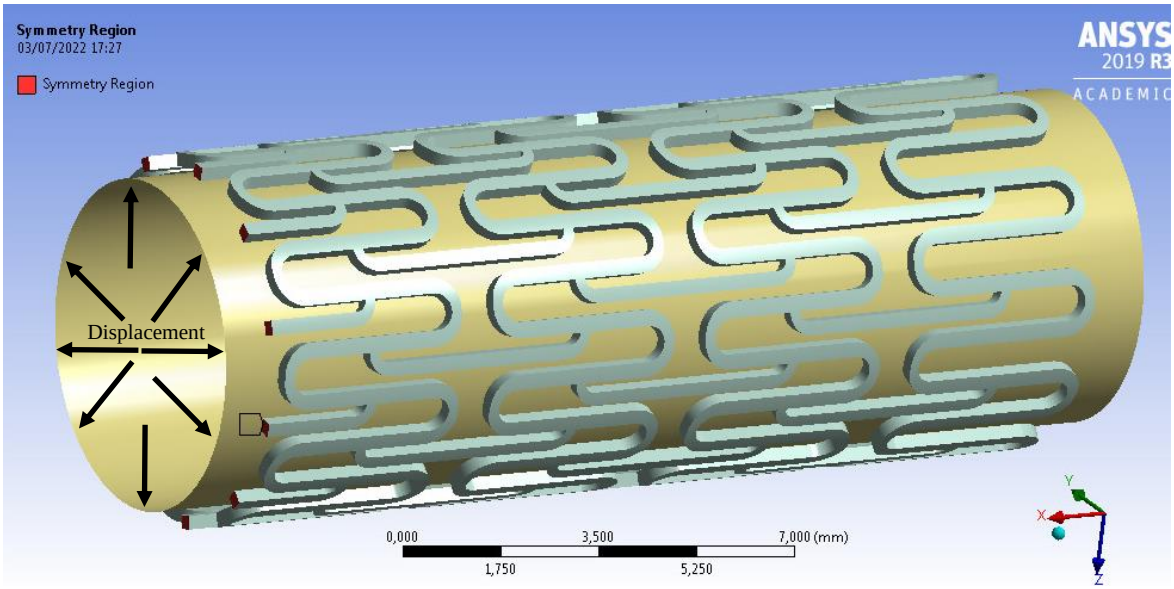
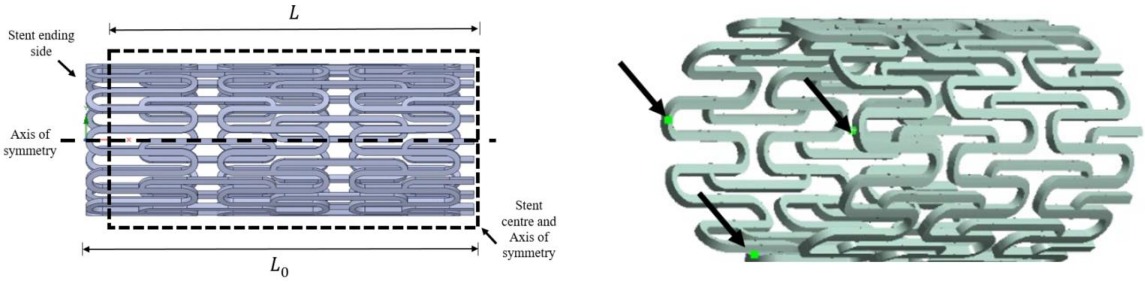


Figure 2 - Boundary conditions.

To calculate the foreshortening effect, Figure 3a, the axial displacement at three points at the end of the stent was measured and averaged, Figure 3b. The foreshortening was calculated as:

$$foreshortening(\%) = \frac{L_0 - L}{L_0} x100 \quad (1)$$

where L is the final length, after the loading was removed, and L_0 is the initial length of the stent.

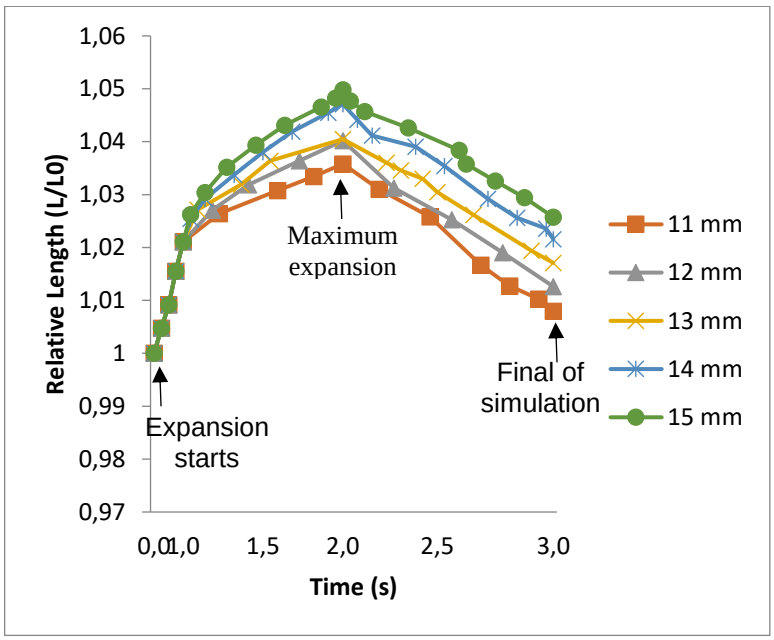


(a) (b)

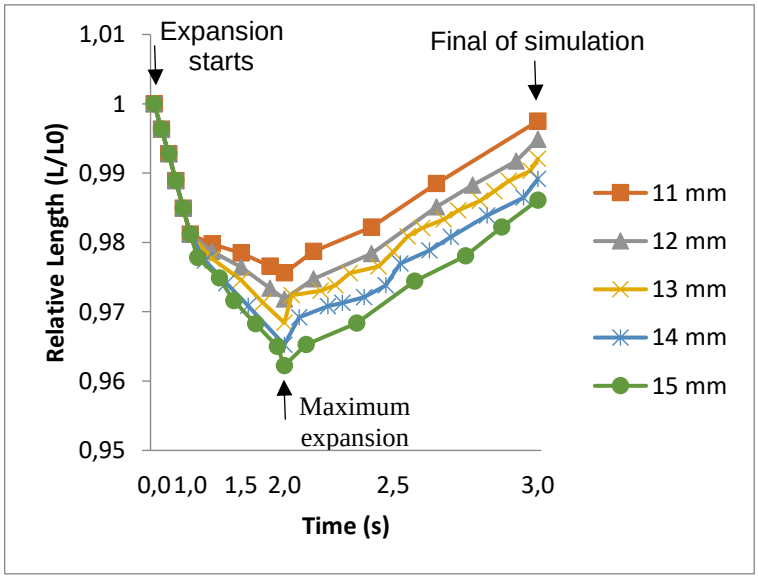
Figure 3 - (a) The parameters used to calculate the foreshortening effect; and (b) the axial displacement at three points at the end of the stent was measured and averaged.

3 – RESULTS

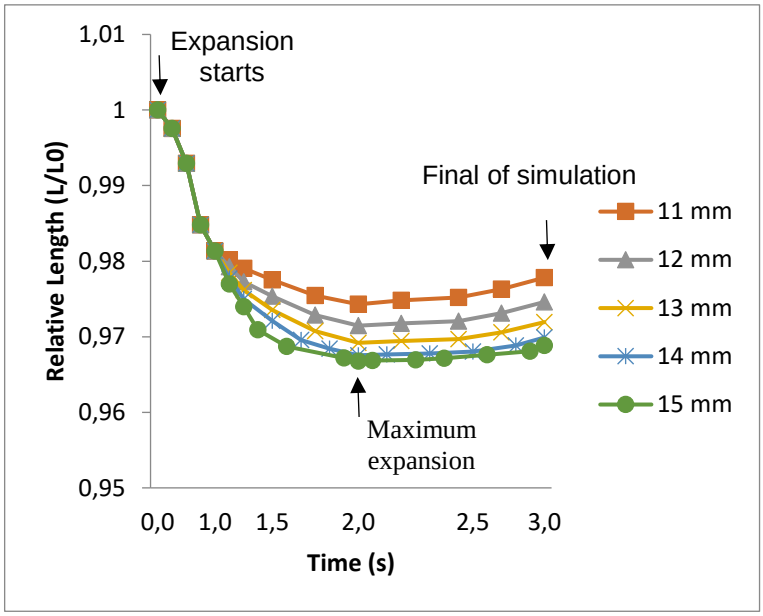
The foreshortening results are shown below:



(a)



(b)



(c)

Figure 4 – Effect of *foreshortening* - (a) Geometry 1, (b) Geometry 2 and (c) Geometry 3.

It can be observed for geometries 2 and 3 that the greatest shortening occurs at time 2s, during maximum stent expansion. For geometry 1 there was a lengthening instead of a shortening.

4 – DISCUSSION

Coarctation of the Aorta (CoA) is the seventh most common Congenital Heart Disease (CHD), in which there is a decrease in the available area for blood flow. The preferred treatment is the use of metallic stents, which is not suitable for young children due to their constant growth and the need for new surgeries. One option to metallic stents would be the use of bioabsorbable stents, which degrade and disappear over time. Based on this idea, Adib Jatene Foundation, associated with the Dante Pazzanese Institute of Cardiology (IDPC, São Paulo), developed a new bioabsorbable for treatment of CoA in children. Finite element models were thus used to assess the stent performance. One of the main characteristics of a stent is foreshortening. An ideal stent must have a small foreshortening to ensure the right positioning of the stent after implantation. Therefore, this study aimed to evaluate the influence of the connecting links in the bioabsorbable stent performance in terms of foreshortening.

Observing Figure 4 (b), geometry 2 reaches a maximum foreshortening of approximately 4%, while geometry 3 presents a maximum value of approximately 3.5%, Figure 4 (c). It was also noted that the final shortening is greater for geometry 3 than for geometry 2, both for expansion up to 15mm.

According to Forbes and Gowda (2014), limited foreshortening is one of the main characteristics for a stent during the treatment of CoA. Forbes et al. (2003) conducted a study with 3 different metallic stents for the treatment of CoA and found that when opening to 10 mm in diameter, all stents had a foreshortening of less than 5%, but when opening the stent up to 15mm, the models had a foreshortening of 6%, 16% and 25%. Danon et al. (2016) conducted a study with various types of stents used for the treatment of congenital heart diseases, including the Palmaz - Genesis series stents, widely used for the treatment of CoA. The authors found foreshortening ranging, on average, from 7.1% to 35.2% for this type of stent.

It can be seen from Figure 4 that for both geometry 2 and geometry 3, foreshortening increases as the diameter increases. The shortening at the end of the simulation, with the removal of the load, was approximately 1.5% for geometry 2 and 3% for geometry 3.

Note that geometry 2 has a significant variation while geometry 3 practically did not change with the removal of the load. This phenomenon is caused by the bracket-shaped connecting element in geometry 2. In comparison with the studies carried out by Forbes et al. (2003) and Danon et al. (2016) both geometry 2 and geometry 3 showed very promising foreshortening results. Comparing the results, the proposed geometries had an improvement of around 50% for the best scenario presented by the authors, in terms of foreshortening. and this contributes to the stent not having a problem of malposition during its opening in a large calibre artery such as the aorta.

Finally, analysing Figure 4 (a) it is observed that, unlike the other geometries, geometry 1 presents an elongation during its expansion, reaching a maximum value of approximately 5% and ending with an elongation of approximately 3%, for opening up to 15mm. This phenomenon is caused by the key-shaped connecting element. Although a large shortening is an undesirable characteristic, an elongation of the stent can also be harmful, especially if the insertion site is close to bifurcations.

5 – CONCLUSION

The finite element method has been increasingly used in the bioengineering field to support the development of new devices, inclusive stents. Limited foreshortening is one of the key features of a stent during CoA treatment. Thus, the development of a bioabsorbable stent was idealized, as these devices degrade over time and remain temporarily in the patient's body; an ideal scenario for children.

This study aimed to evaluate the influence of the connecting links in the bioabsorbable stent performance in terms of foreshortening for the treatment of Aorta Coarctation in Children. An evaluation of the stent's performance in terms of foreshortening during its implantation as well as the influence of the type of connecting link was assessed. It was found that the type of connecting links highly impacted the foreshortening performance during the expansion of the stent, as the geometry with braces' connecting links elongated instead of shortening.

The results presented in this study were encouraging to geometries 2 and 3, and a small foreshortening was observed. This characteristic is paramount to avoid stent placement problems during its expansion, especially in larger vessels. However, other parameters, such as recoil and dogboning, still need to be assessed to have a complete understanding of stent functionality.

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