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TRANSIENT STUDY BY THE FINITE ELEMENT METHOD OF THE MECHANICAL BEHAVIOR OF THE CONVENTIONAL NITINOL STENT WITH THE AORTA

ESTUDO TRANSIENTE PELO MÉTODO DE ELEMENTOS FINITOS DO COMPORTAMENTO MECÂNICO DO STENT DE NITINOL CONVENCIONAL COM A AORTA

ESTUDIO TRANSITORIO POR EL MÉTODO DE ELEMENTOS FINITOS DEL COMPORTAMIENTO MECÁNICO DEL STENT CONVENCIONAL DE NITINOL CON LA AORTA

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ABSTRACT
Thoracic aortic aneurysms are a highly serious condition whose consequences can be life-threatening. Despite diagnostic methods and intra- and postoperative monitoring, aneurysms pose a challenge for all involved professionals, especially surgeons. The finite element method is a numerical method that has been used as an innovative approach for safely evaluating stents when implanted and accommodated in the aorta. In this study, a study was conducted using ANSYS Workbench 2022 R2 software to evaluate the mechanical behavior of stents. This study simulated the dynamic response to time-varying loads, using the Transient Structural Analysis tool to calculate displacements, stresses, and deformations over time.

Keywords: Meshes. Conventional Stent. Triple Stent. Aorta Artery.

RESUMO
Aneurismas da aorta torácica constituem uma condição de alta gravidade, cujas consequências podem colocar em risco a vida do paciente. Apesar dos métodos de diagnóstico e dos controles intra e pós-operatórios, os aneurismas representam um desafio para os profissionais envolvidos, principalmente para os cirurgiões. O método de elementos finitos é um método numérico que vem sendo utilizado como abordagem inovadora para uma avaliação segura do stent quando implantado e acomodado na artéria aorta. No presente trabalho, realizou-se um estudo com o software ANSYS Workbench 2022 R2 sobre o comportamento mecânico do stent, mediante o método de simulação da resposta dinâmica

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a cargas que variam no tempo, utilizando a ferramenta de Análise Estrutural Transiente para realizar os cálculos dos deslocamentos, tensões e deformações ao longo do tempo.

Palavras-chave: Malhas. Stent Convencional. Triplo Stent. Artéria Aorta.

RESUMEN
Los aneurismas de la aorta torácica son una afección muy grave cuyas consecuencias pueden poner en peligro la vida. A pesar de los métodos de diagnóstico y la monitorización intra y postoperatoria, los aneurismas representan un reto para todos los profesionales implicados, especialmente los cirujanos. El método de elementos finitos es un método numérico que se ha utilizado como un enfoque innovador para evaluar de forma segura los stents al implantarse y acomodarse en la aorta. En este estudio, se utilizó el software ANSYS Workbench 2022 R2 para evaluar el comportamiento mecánico de los stents. Este estudio simuló la respuesta dinámica a cargas variables en el tiempo, utilizando la herramienta de Análisis Estructural Transitorio para calcular desplazamientos, tensiones y deformaciones a lo largo del tiempo.

Palabras clave: Mallas. Stent Convencional. Stent Triple. Arteria Aorta.

1 INTRODUCTION

Aortic aneurysm comprises a dilation greater than 50% of the expected diameter of the artery in that region. In the literature, there is a wide discussion about techniques for measuring the diameter in the affected area, so to consider greater dilation, anteroposterior and/or cross-sectional measurements of the external wall of the aorta, obtained by abdominal ultrasonography or computed tomography methods (Wanhainen A, et al 20191, Chaikof EL, Dalman RL, et al 2017), can be accepted.

The classification of the aneurysm refers to its location, which can occur in the ascending or descending portion, as is the case of Abdominal Aortic Aneurysm (AAA). It is known that AAA is the most recurrent type of aneurysm in the population, affecting mainly elderly individuals and whose rupture represents about 2% of mortality in this population (Lavínia Penido Safe; Bruno Seibert Pinheiro et al 2022).

AAA usually results from a degeneration process, which can culminate in necrosis of the tunica media and cause thinning of the artery wall. Among the main risk factors for the development of this pathology, advanced age, smoking, considered the most relevant factor, and positive family history for AAA, especially when diagnosed in first-degree relatives, stand out. (KASPER, 2017; KUMAR et al., 2018). The main cause is arterial degeneration due to atherosclerosis. AAA has high mortality and as an initial treatment, risk factors are controlled or, if necessary, the alternative of surgical procedure for endovascular repair (EVAR) and conventional open surgery. (Marques Meirelles, C; Corrêa Resende, I et al., 2024)

When we relate the change in artery diameter to the aneurysm, it is observed that abdominal aortic aneurysms present a risk of rupture and death, with a risk of rupture in 5 years greater than 75% for untreated AAA with a diameter equal to or greater than 7 cm, 35% for 6 cm and approximately 25% for 5 to 5.9 cm aneurysms. About 66% of patients with ruptured aneurysms die prematurely before arrival at the health service or during surgical intervention (MASTRACCI; CINÀ, 2007).

In recent years, a new technical approach has been used as a tool for the care and treatment of AAA, defined as endovascular aneurysm repair (EVAR), in which AAA is corrected without the need for open surgery, through access through the inguinal region, with the introduction of a catheter to the aneurysm region, where, After positioning in the area of injury, a stent-type prosthesis is released that lines the dilated aorta, functioning as an artificial blood vessel through which blood can flow bypassing the aneurysm. Consequently, there is a reduction in the risk of expansion and rupture of the AAA (Paravastu, 2014).

Stents are braided metal structures, with opening at the bottom and top, in the form of a mesh, which have good visibility and flexibility, introduced into the vascular lumen, whose function is to maintain the patency of the vessel and prevent restenosis resulting from the development of myointimal hyperplasia, thus avoiding the decrease in blood flow due to clogging (France; Pereira, 2008).

Several types of stents are used to restore the permeability of atherosclerotic coronary arteries, and it was found that different stents may present different rates in relation to in-stent restenosis, considering the hypothesis that the level of vascular injury caused to the vessel by a stent determines the level of restenosis. (Lally C, Dolan F, 2005).

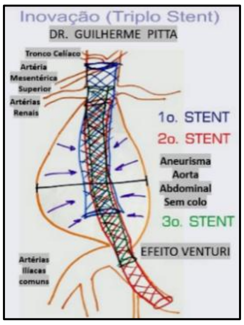
The choice of the stent to be used should be made according to the arterial anatomy and morphology of the lesion, as well as the characteristics of the stent, such as size, extension, flexibility and fracture resistance, etc. The most used are NiTi-type metal monofilaments. (RODRIGUES et al., 2014).

Currently, computational studies represent a very important tool to be used to investigate the mechanical behavior of stents and determine the biomechanical interaction between the stent and the artery in a stent placement procedure. Numerous computational studies have been carried out to investigate the expansion and mechanical behavior and to characterize and evaluate different types of stent designs, such as balloon-expandable stents (Dumoulin and Cochelin, 2000; Etave et al., 2001). However, there are still few studies investigating the interaction between the stent and the artery, although vascular injury has been hypothesized as the stimulus for the formation of occlusive intimal hyperplasia and eventual restenosis.

The main purpose of the application of the method in this study is to evaluate the mechanical behavior, the expansion mechanism, the tensions and the distribution of tensions in the stent and the changes in length, applying it to the specific case of the triple stent (US 7,588,597B2), (Figure 1) in the implantation of stents, with the objective of minimizing vascular injury during stent implantation and reducing restenosis.

Figure 1

Triple stent innovation



Source: Dr. Guilherme Pitta.

2 FINITE ELEMENT METHOD

Working with numerical simulation represents a tool of paramount importance to define important variables, which can contribute to the results of the application of this innovative technique, enabling the study of its mechanical behavior and the evaluation of parameters associated with the stent model. The study was carried out using Autodesk Inventor software, for modeling, and ANSYS, for the study of mechanical behavior.

The Finite Element Method (FEM) currently has a level of development that allows its use by most professionals in the field of projects and structures. The application of the method results in the application of finite differences, which, before the appearance of computers, had the inconvenience of requiring the resolution of large systems of linear equations, an inconvenience that is avoided with relaxation methods based on the successive reduction of a set of residuals. This method is extremely important in biomedical engineering and in the development of medical devices, due to the possibility of accurate and safe analyses as a discussion stage before implantation in humans. It is very important for a research to select the appropriate material for the specific process, since the results in the time of the process, the functionality of the part and the useful life of the element produced depend on it (Mendes CS, Garcia del Pino G, Torres AR, et al. 2021)

In this case, the formulation of the FEM can be based on the method of displacements and on equilibrium models, being associated with the method of displacements, based on the definition of the degrees of freedom, the forces, the stiffness matrix and the type of analysis.

Regarding the simulation of a stent within the aorta using finite element material (FEA), there are several studies and practices in the literature that provide data and information on how to properly model the mechanical interaction between the Nitinol stent and the aortic wall. One aspect to consider is the type of maya associated with experimental results, which reveal an increase in tensile strength with the increase in the amount of elements in contact (G Garcia del Pino g, Bezazi A., Torres AR, et al, 2023)

The stent, in turn, can be represented by bundles or rods with elements of the B31 type (beams), carefully adapted to the behavior of Nitinol via the PMC user subroutine.

Using this method, a Nitinol stent was modeled, adjusting parameters such as diameter, maximum length, in order to convert the flat model of the stent to the final cylindrical and three-dimensional shape. Figures 2, 3, 4 and 5 show the steps for modeling the Lumini stent according to the cells of the physical prototype object of the study.

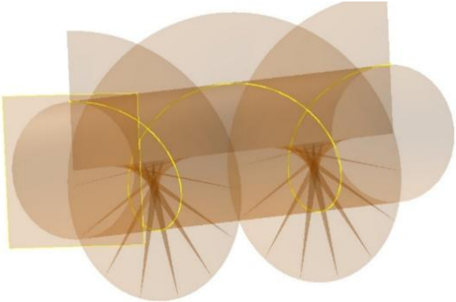
Figure 2

Lumini stent, 100mm length

Source: The authors.

Figure 3

Development of the helical step

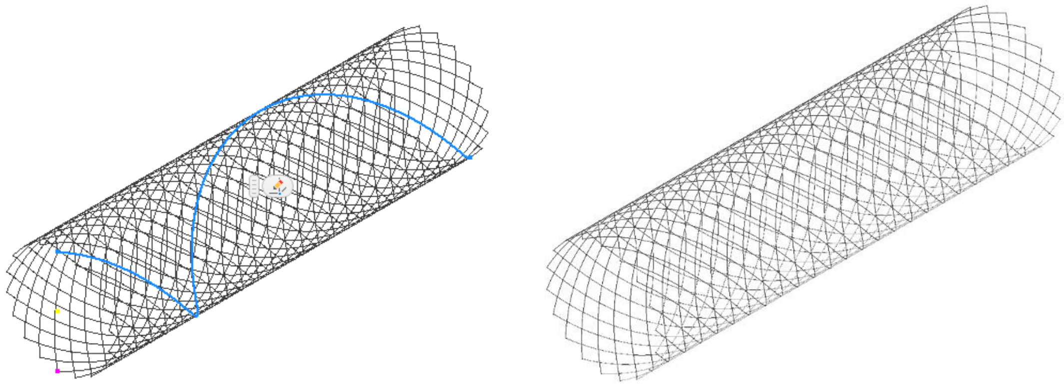


Source: The authors.

Once the basis for the development of the model has been defined (Figure 3), work is done on the creation of the model of the stent in its three-dimensional configuration, considering the diameter of the Nitinol wire and the external diameter of 19 mm for the stent, as well as the length (Figure 4).

Figure 4

Lumini model



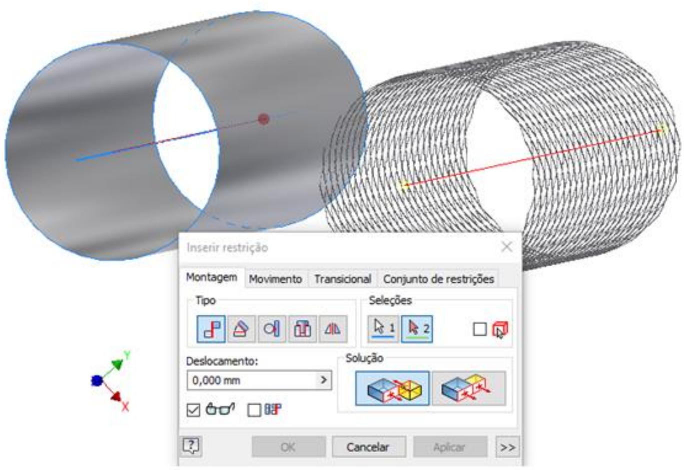
Source: The authors.

It is important to emphasize that the study considers the behavior of the stent associated with vein and blood pressure as long as it is between solids, without friction (Figure 5).

The aorta is modeled as a hyperelastic shell (shell), with a thickness of 2 mm.

Figure 5

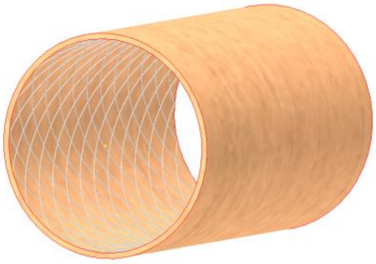
Assembly of the Stent-Aorta Set



Source: The authors.

Figure 6

Stent-aortic assembly



Source: The authors.

According to Kleinstreuer et al. (2008), Schwarz (2012) and Abad et al. (2012), the friction between surfaces can be disregarded and, therefore, the contact between solids is considered of the bonded type, without friction.

This set is exported to ANSYS and, later, in another step, the finite element mesh of the three-dimensional model is generated, using unstructured triangular elements. This model could have been created in ANSYS itself. In the program, to create a cylindrical shape, you can use the Design Modeler / Space Claim (Workbench) or APDL (Mechanical APDL) way, an ideal methodology to create solid cylinders quickly.

For the finite element analysis, a 2 mm wall artery and a heat-treated Nitinol stent are considered to optimize super elasticity and mechanical strength, considering its yield limit associated with the beginning of the martensite-austenite transformation, under load, assuming that the behavior is linear. The variables are presented in Table 1.

Table 1

Properties of Nitinol

Properties of Outline Row 4: NiTi

	A	B	
1	Property	Value	
2	Material Field Variables	Table	
3	Density	6,45	g cm^-3
4	Isotropic Elasticity		
5	Derive from	Young's Modulus and Poisson's Ratio	
6	Young's Modulus	90000	Pa
7	Poisson's Ratio	0,3	
8	Bulk Modulus	75000	Pa
9	Shear Modulus	34615	Pa
10	Tensile Yield Strength	0,0005	MPa

Source: The authors.

The typical properties of the human aorta, in this case with a weakened wall (aneurysm type), which represents the critical condition, are also considered. These data are also used as input for the study (Table 2).

Table 2

Properties of the Aorta

Properties of Outline Row 3: Aorta

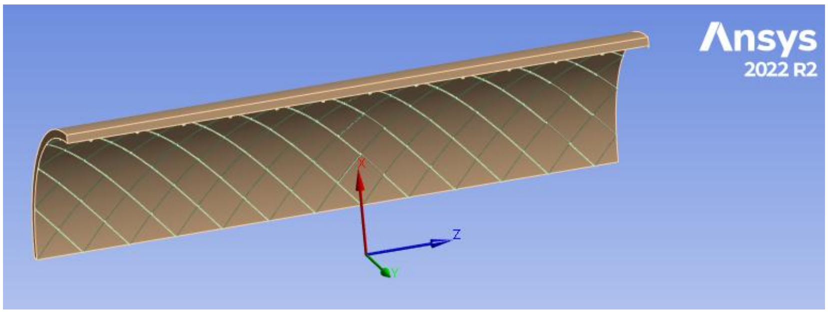
	A	B	
1	Property	Value	
2	Material Field Variables	Table	
3	Density	0,00106	g cm^-3
4	Isotropic Elasticity		
5	Derive from	Young's Modulus and Poisson's Ratio	
6	Young's Modulus	75	GPa
7	Poisson's Ratio	0,33	
8	Bulk Modulus	7,3529E+10	Pa
9	Shear Modulus	2,8195E+10	Pa
10	Tensile Yield Strength	1E-06	MPa

Source: The authors.

To facilitate the study and simplify the analysis, we chose to evaluate the behavior of a part of the stent model (half of the cylinder and the length of the stent). A cylindrical local coordinate system was defined, positioned with its origin in the center of the part of the study model corresponding to the stent and aorta, for both radial and axial study, as shown in Figure 6.

Figure 6

Cylindrical coordinate system



Source: The authors.

In ANSYS Workbench (via Mechanical or APDL snippets), one can create cylindrical local systems with the LOCAL or CSWPLA command (which aligns it to the work plane) and then define results for that system via the RSYS command.

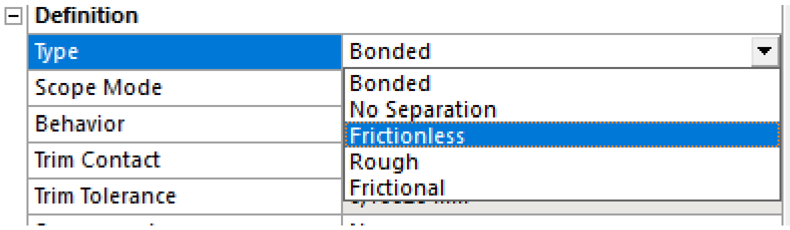
It is important to understand that for the analysis, it is essential to define the contact between the aorta and the stent. According to the Lure Engenharia website and other technical sources, the main types of contact on ANSYS are of the type:

- Bonded, which fully joins surfaces without allowing separation or sliding that is ideal for glued or welded joints.
- No Separation, which prevents normal separation but allows sliding.
- Frictionless, which admits frictionless separation and sliding;
- Frictional that allows both separation and sliding with defined friction;
- Rough, which is the non-slip contact (infinite coefficient of friction).

Focusing on the types of contact, care is taken to verify the contact between the stent and aorta elements, so that it is depreciable, defining in the program the configuration without friction between the surfaces, as shown in Table 3.

Table 3

Type of contact between surfaces, no friction



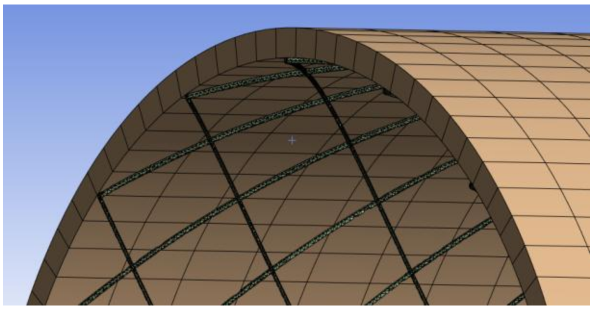
Source: ANSYS Workbench 2022 R2

Under these conditions, crimping is simulated inside a rigid cylinder, followed by release into the modeled aorta, with definition of active contact between stent and arterial wall.

From this face it is already possible to generate the finite element mesh that is not but what types of mesh elements used to transform into small elements, complex volumetric geometries, characterized by smooth transition between areas with meshes of different sizes, conditioning a good mesh that is balanced, of precision, to facilitate the computational efficiency and stability of the study (figure 7).

Figure 7

Finite element mesh for the set

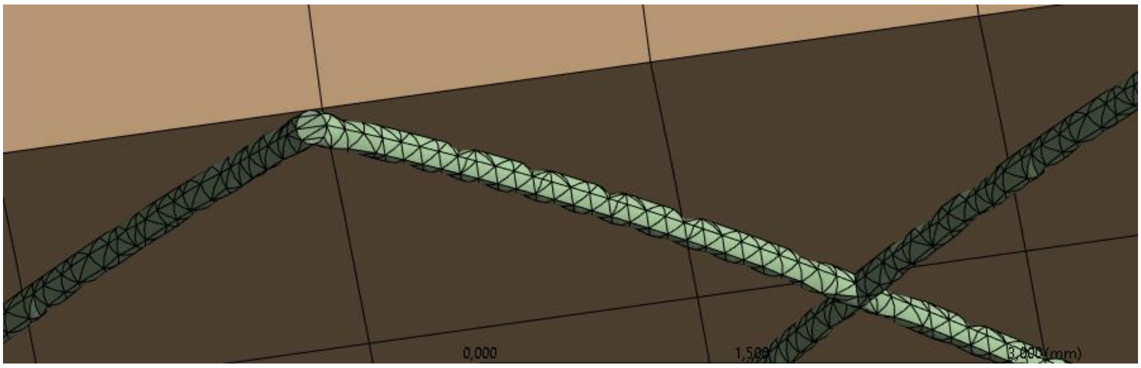


Source: The authors.

The stent mesh has been refined so that the critical parameter, e.g., the maximum radial force, varies less than 5%, ensuring good accuracy without computational excess (Figure 8).

Figure 8

Finite element mesh for the stent



Source: The authors.

Isostatic pressure generally refers to pressure exerted equally in all directions, which is most common in solid or liquid materials in equilibrium. In ANSYS Mechanical, the concept of "isostatic pressure" can be associated with hydrostatic pressure, which defines a fluid charge that is applied uniformly on surfaces perpendicular to gravity, a useful condition to simulate liquid pressures or internal isotropic situations in processes such as isostatic pressing or in submerged chambers.

However, for the study we will consider blood pressure during systole and diastole, with systolic pressure during heart contraction and diastolic pressure during heart relaxation. In the study, it is considered for systole that the heart contracts and ejects blood into the aorta at maximum pressure and that in diastole the heart relaxes and fills with blood at minimum pressure (Table 4).

Table 4

Artery pressure values in adults

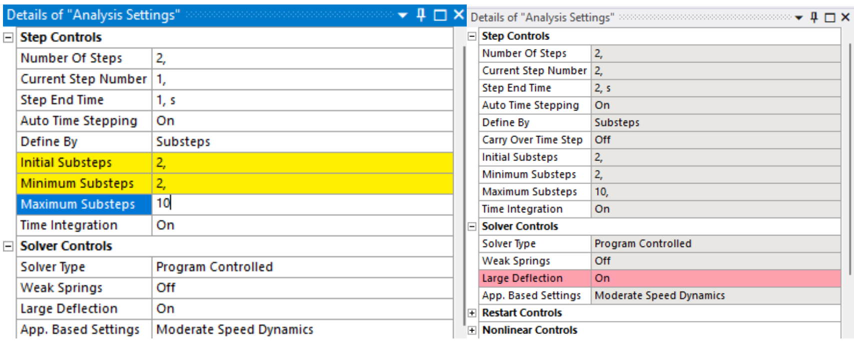
Artery pressure values in adults		
Type of heart phase	Pressure(mmHg)	Pressure (Kpa)
Systole	110-130	14,7-17,3
Diastole	70-85	9,3-11,3

Source: The authors.

As it is a transient type study, it is necessary to analyze configurations in Ansys (Analysis Settings), which determines how the simulation will be conducted from parameters such as the number and duration of load steps, number of substeps within each step, the type of solution (direct or iterative), the tolerance criterion for convergence that are fundamental for the stability and success of the simulation, all this in the project tree (figure 9).

Figure 9

Data for Transient Analysis (Step 1 and Step 2)



Source: The authors.

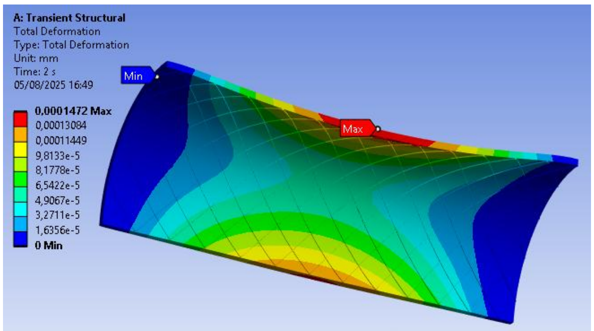
When starting the execution of the solution, which represents the completion of the simulation, it is important to consider several crucial steps, which are adjustable via "Solution Settings" and "Solve Process Settings". The solution creates temporary files that are saved only after successful completion.

It is intended to solve, in the study with Ansys of the stent-aorta model, the equivalent elastic deformation, using failure criteria based on equivalent stress, such as Von Mises, which is used to evaluate the deformation state, considering all the components of deformation (normal + shear). It expresses the magnitude of the intensity of tensions and is independent of the direction.

The detailed visualization of the execution is shown in figures 10, 11, 12.

Figure 10

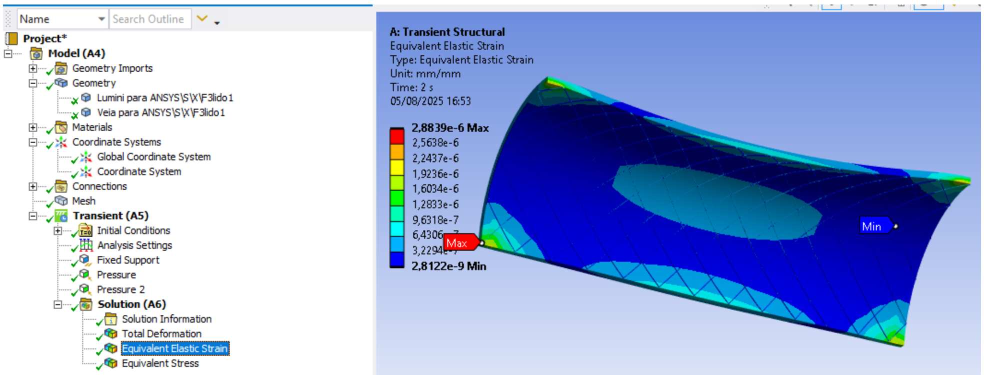
Results of deformation



Source: The authors.

Figure 11

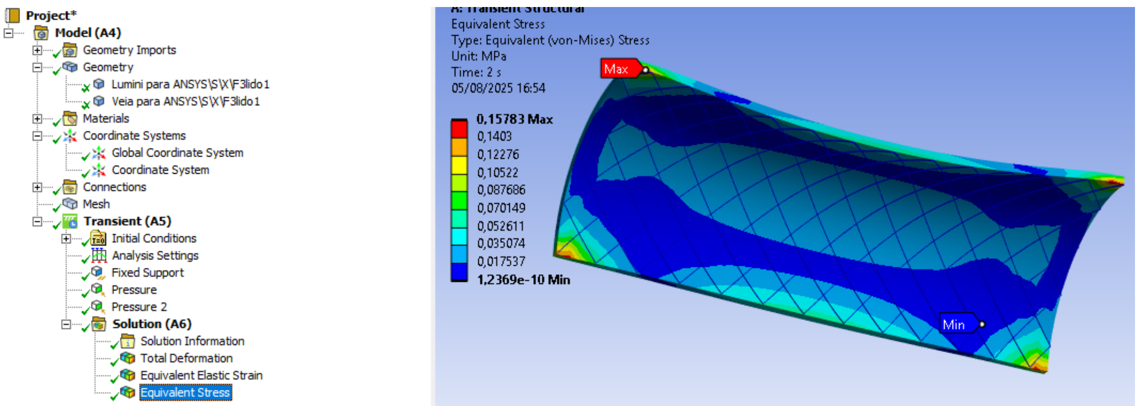
Results of the equivalent elastic strain stress



Source: The authors.

Figure 12

Von Mises' equivalent



Source: The authors.

To conclude the study, a Modal Analysis is performed to determine the natural frequencies and vibration modes of the stent structure, in order to verify resonance risks, serving as a basis for subsequent analyses (Table 5 and Figure 13).

Table 5

Natural frequencies

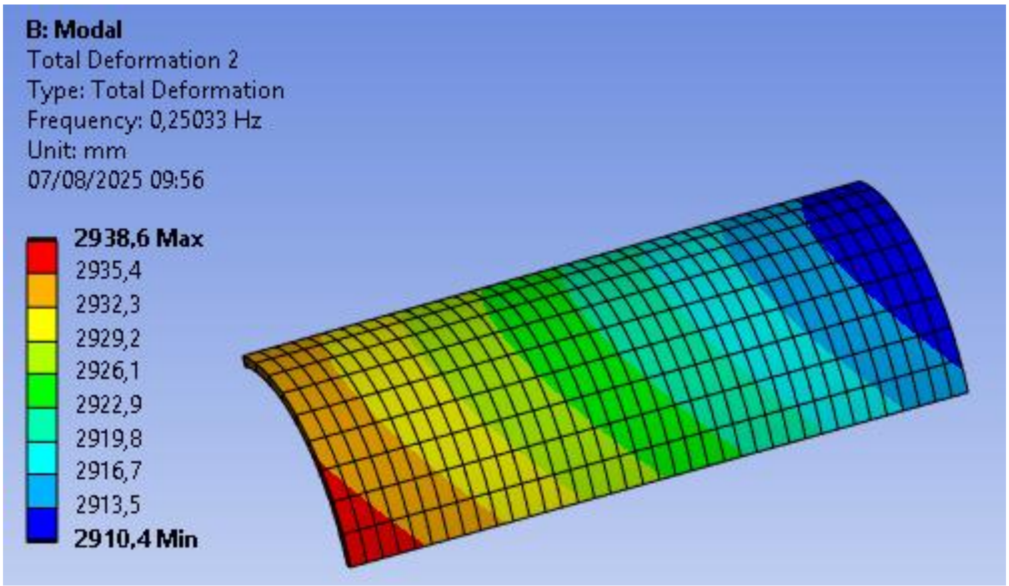
Tabular Data

	Mode	Frequency [Hz]
2	2,	0,
3	3,	0,25033
4	4,	3,6062
5	5,	4,0093
6	6,	9,733
7	7,	1375,1
8	8,	1380,6
9	9,	1381,2
10	10,	1383,4

Source: The authors.

Figure 13

Check natural frequencies with external excitations



Source: The authors.

3 CONCLUSIONS

The study made it possible to establish a methodology for the simulation of stent deformations by pressures on the aorta, demonstrating how the interaction of the aorta with the stent occurs and how this directly affects the geometry of the stent and the behavior of the maximum stresses caused by its deformation. It also made it possible to compare different states of strain and evaluate whether any element is close to the elastic limit by presenting the Von Mises stress, a scalar value derived from the stress tensor that summarizes the multiaxial state of stress in a single number, allowing to compare the value obtained with the yield strength of the material. This facilitates the analysis of failures and contributes to identifying creep points or the beginning of plasticization, making the visual analysis clearer and more objective and making it possible to compare with the yield limit.

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