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Artigo

Tube hydroforming simulation to analyze structural integrity of stent, balloon and artery during crimping and angioplasty

Simulação de hidroconformação do tubo para analisar a integridade estrutural do stent, balão e artéria durante crimpagem e angioplastia

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ABSTRACT: The increasing incidence of cardiovascular diseases and the study of the angioplasty procedure have generated many research on stent development. In order to contribute to this field of research, this work aims to analyze the complete process, beginning with the crimping of the stent up to the implantation on the artery, using tube hydroforming simulation by the Finite Element Method. In this context, it will be simulated in this paper the procedures of crimping and angioplasty of artery with fat plaque. The objective of this study is to analyze the structural integrity of the expanded stent and the artery after the implantation process. One advantage of this methodology is the possibility to verify the regions of the artery and stent subjected to the thinning and wrinkling in each step of the procedure. The obtained results proved that the tube hydroforming simulation by finite elements applied to the angioplasty process can help the stent designer or the cardiologist to analyze and optimize the balloon and stent design.

Keywords: Balloon angioplasty. Crimping. Explicit finite element method. Tube hydroforming. Stents for angioplasty.

RESUMO: *O aumento da incidência de doenças cardíacas e o estudo do processo de angioplastia tem gerado muita pesquisa sobre o desenvolvimento de stents. Com o intuito de contribuir neste campo de pesquisa, esse trabalho tem como objetivo analisar o processo completo, iniciando com a crimpagem do stent até o implante na artéria usando simulação de hidroconformação do tubo pelo Método dos Elementos Finitos. Neste contexto, será simulado neste artigo os processos de crimpagem e angioplastia da artéria com uma placa de gordura. O objetivo deste estudo é analisar a integridade estrutural do expandido stent e artéria após o processo de implante. Uma vantagem desta metodologia é a possibilidade de verificar as regiões da artéria e stent sujeitas a afinamento e enrugamento em cada etapa do processo. Os resultados obtidos comprovaram que simulação por hidroconformação do tubo por elementos finitos aplicado ao processo de angioplastia pode ajudar o projetista de stent ou o cardiologista a analisar e otimizar o projeto do stent e balão.*

Palavras-chave*: angioplastia do balão, crimpagem, método dos elementos finitos explícito, stents para angioplastia.*

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INTRODUCTION

Stents for angioplasty have been extensively used for the restenosis treatment of the arterial wall. Nowadays, different metallic alloys, such as, the 316 L stainless steel, cobalt chromium, Nitinol and biodegradable materials have been used in the stent manufacture (LALLY et al., 2006; PHANI et al., 2014; JAMES and WAISMAN, 2016; BRESSLOFF et al., 2016). In the case of the 316 L stainless steel stents, the material hardening after the angioplasty due the plastic strain increases its ability of supporting the arterial pressure (LALLY et al., 2006). Because of this, the expanded stent is able to prevent the restenosis or re-closure of artery. Another design criteria to be considered is the contact stress caused by contact of the stent with the wall of the artery. Indeed, if the contact stress is very high, the implanted stent in the stenosed artery could cause hyperplasia and eventual restenosis (PRENDERGAST et al., 2005). Furthermore, the crimping process of the stent on the expandable balloon surface also generates residual stress which is usually negligible in the analysis of the stent material hardening after the angioplasty (JIE et al., 2009; ARAÚJO et al., 2009).

In crimping procedure, the final diameter of the stent is reduced because of the application of an inward radial pressure. After the crimping, the crimped stent may not damage the expandable balloon material. On the other hand, the stent may not slip on the external surface of the balloon. Crimping is the mounting process of stent on the external surface of the expandable balloon before the angioplasty. In this context, Oberhofer et al. (2006) have simulated the whole process of crimping and expansion of the stents by the explicit finite element method. Araújo et al. (2009) also employed the explicit finite elements to analyze the crimping process of the stent on the expandable balloon before the angioplasty.

In the literature, different methodologies of design and analysis of the structural integrity of the stent during the angioplasty have been purposed by using the finite element method. Prendergast et al. (2005) applied the finite element method to study the influence of the stent geometry on the contact stress level caused in the arterial wall after the angioplasty. Gervaso et al. (2008) have investigated different strategies to be used in the modelling the 316 L stainless steel stent expansion process using the finite element method. Guimarães et al. (2008) have purposed a design methodology of 316 L stainless steel stents cells by applying the topology optimization for the definition of their geometry. Phani et al. (2014) have studied the several mechanisms of expansion of stents for angioplasty and their influence in the design of the topologies of cells. More recently, James and Waisman (2016) have also applied the topological optimization technique for the optimization of the geometry or layout of the stent cells made of a stiff biocompatible polymer. In the abovementioned works, usually the structural integrity of the stent is evaluated by the Von Mises stress level present in the regions subjected to the plastic strain. However, other parameters, such as, the wrinkling and thinning may also be used to analyze the structural integrity of the stent, balloon and artery after the expansion and crimping process. In this case, the sheet forming simulation by using the finite elements analysis, particularly the tube hydroforming (Ahmetoglu & Altan, 2000) applied to the angioplasty procedure may serve as an interesting tool to be used in the evaluation of the structural integrity of the stent, artery and balloon (ARAÚJO, 2016).

In most works have published in the literature, it is commonly used the implicit finite element codes in the analysis of the stent expansion process (PRENDERGAST et al., 2005;

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GERVASO et al., 2008, PHANI et al., 2014; BRESSLOFF et al., 2016). Since the pressure applied to the external surface from stent is changing with the time, the explicit finite elements approach provides a more accurate solution when compared to the implicit one (BELYTSCHKO et al., 2001). In this work, it will be used the explicit finite elements method for the analysis of implantation process of stent into the artery divided in 3 steps: a) crimping of stent without the presence of the balloon; b) angioplasty of the artery by using only the expandable balloon and c) expansion of stent until the contact with the arterial wall. The objective is to predict the regions of the stent and balloon subjected to the wrinkling and thinning, as well as the contact stress level present in the stenosed artery.

SIMULATION OF THE CRIMPING AND EXPANSION PROCESS OF THE STENT USING THE EXPLICIT FINITE ELEMENT METHOD

In the present paper, it will be used the explicit finite element method for the simulation of the crimping and expansion process of the stent and balloon set in an artery with a fat plaque. Another advantage of the explicit approach is that the strain and stress field of the stent and the artery is computed from the boundary conditions and pressure applied in the angioplasty procedure and no contact algorithm is required in this analysis.

In the implicit finite element method, during the solution procedure, the nodal displacements are computed by the inversion of the stiffness matrix which is multiplied by the vector of the external forces applied to the structure. On the other hand, in the explicit approach, the idea is to compute the nodal acceleration in each time step by using the external forces and the mass matrix from the finite elements model. One disadvantage of this procedure is the estimation of the critical time step, Δt_{crit}, to be used in the integration of the movement equations defined by (BELYTSCHKO et al., 2001):

$$\Delta t_{crit} = \min\left(\frac{l_e}{c_e}\right) \tag{1}$$

where l_e represents the characteristic length of the element finite present in the meshing of the model and c_e is the wave propagation velocity from the material medium. In the case of the stent, the size of the smaller element of the stent meshing is extremely small (of order of 10^{-2} mm). In this way, the processing total time to be spent in the numerical simulation of the angioplasty procedure become impractical (or order of 10^4 h).

In order to overcome this limitation of the explicit approach, the dimensions of the stent, balloon and artery were multiplied by a scale factor of 1000 (ARAÚJO, 2016). Hence, the processing total time of the angioplasty simulation was drastically reduced. Once the dimensions of the devices used in the numerical simulation were amplified, the results of the plastic strain and stress fields from stent could be modified and the results obtained would be wrong. However, Araújo (2016) verified that this increasing of the devices dimensions does not have influence in the final analysis.

For the numerical simulation of the angioplasty and crimping process from stent and balloon, it was employed the software Stampack® of finite elements (Quantech ATZ, Barcelona, Spain). This program was originally designed to be applied in the analysis of the forming process, such as, sheet forming and tube hydroforming (Stampack® used guide, 2002). Since the tube hydroforming process is similar to the angioplasty and crimping

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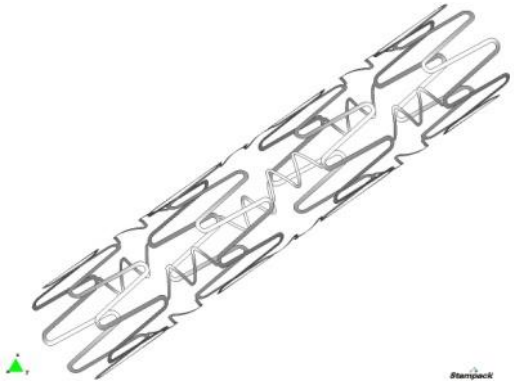
process, it was used this simulation module available in the Stampack® software for the analysis of the structural integrity of the stent, balloon and artery.

MATERIALS AND METHODS

Design of the geometrical model of the stent, balloon and artery

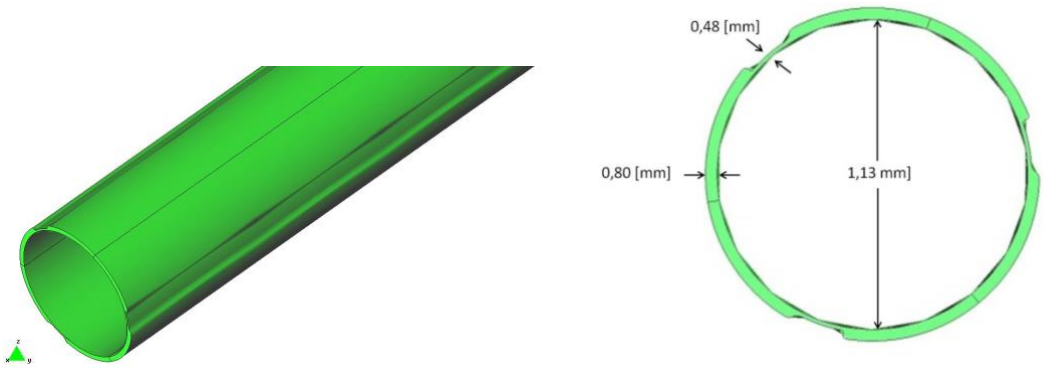
For the definition of geometry of stent to be studied in this paper, it was used the results obtained by Guimarães et al. (2008) in a previous work by the topology optimization technique. After the generation of the optimal topologies of the flexibility and stiffness cells from stent, Araújo (2016) improved these geometries by the reduction of the stress concentration regions in this model. The figure 1 illustrates the geometrical model of the stent to be studied in this work. The length of the stent is equals to 9,6 mm, the diameter is 1,8 mm and the thickness is 0,1 mm.

Figure 1. Geometrical model from stent.



The geometry of the expandable balloon to be used in the numerical simulation of the expansion process is shown in the figure 2. Because of the folds present in the expandable balloon before the angioplasty (DE BEULE, 2008; YANG et al., 2009), Araujo (2016) idealized the geometry and the dimensions of the folds as can be seen in the figure 2. On the other hand, the geometry of the artery and stenotic plaque were created based on the results presented by Prendergast et al. (2005).

Figure 2. Geometrical model from expandable balloon.



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During the generation process of the geometries from stent, expandable balloon, artery and fat plaque, it was employed the software SolidWorks® and AutoCad® (Autodesk. Inc, São Rafael, California, USA). After the development of the geometrical models of these devices, they were exported to the software Stampack® in order to simulate the expansion and crimping process by using the explicit finite element method.

Simulation of the expansion and crimping process of the stent, balloon and artery using the explicit finite elements method

One of the objectives of this work is to simulate the angioplasty process to be executed by the cardiologist by finite elements and analyze the structural integrity of the devices, stent, balloon and artery. For this purpose, the numerical simulation will be divided in 3 steps:

a) Crimping process of stent without the expandable balloon;

b) Angioplasty of the stenosed artery by using only the expandable balloon;

c) Implantation of crimped stent in the arterial wall by applying an outward radial pressure into the internal surface from stent.

In the first step, an outward radial pressure was applied on the external surface from stent in order to diminish its external diameter. Since the material from expandable balloon to be used in this work is semi-compliant, it will not be considered during the crimping process. For the crimping, the initial diameter from stent equals to 1,8 mm in the real scale (1800 mm in the increased scale) will be reduced to the 0,861 mm (861,2 mm in the increased scale). During the solution process of stent with 3664 finite elements in the crimping, all nodes from finite elements model are free to move in any direction. After the reduction of diameter in the crimping, the recoil from crimped stent was estimated by using the springback module available in the software Stampack®. The magnitude of pressure to be applied in the crimping was computed by trial-and-error due to nonlinearity of the material hardening and large deformations present in this process (BELYTSCHKO et al., 2001). Hence, this crimping pressure will change linearly with the time since the zero value until the magnitude adjusted by trial-and-error.

After the crimping simulation, the balloon without the presence of the stent will be expanded applying an inward radial pressure on its internal surface until the contact with the arterial wall and the fat plaque. Once again, since the balloon expansion process is also nonlinear, the pressure magnitude for angioplasty simulation will be adjusted by trial-and-error. In the angioplasty process, no displacement or rotation constraint should be imposed on the finite elements model, therefore, all nodes will be free to translate or rotate. The friction between the external surface from stent and the internal surface from arterial wall and the fat plaque was neglected in this analysis.

In order to end the angioplasty procedure simulation, in the last step, the crimped stent with residual stress has computed in the first step was expanded by using a pressure magnitude adjusted by trial-and-error again. For this situation, the pressure to be employed in the angioplasty will be larger than the pressure used in the crimping since the final

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diameter from stent is equal to 5,044 mm in the real scale (5044,5 mm in the increased scale). It was generated a stent meshing with 28370 finite elements in the expansion step. After some analysis, it was concluded that the stress level of the expanded stent did not change by increasing the finite elements of the model. The average size of the stent finite elements was equal to 7,53 mm. The parameters to be investigated in this step are the recoil from stent, the thinning, wrinkling, the displacements of the devices and the plastic strain level of the stent and the artery.

In the generation of the mesh of the artery, plaque and expandable balloon, it was used volumetric finite elements with 8 nodes. Since the geometrical models from artery, plaque and balloon produce a structured mesh, it is more appropriated to use this type of finite element. On the other hand, the stent geometry was meshed using triangular shell finite elements with 3 nodes due to its geometrical complexity. For the unstructured mesh from stent geometrical model, the triangular shell finite element reduces the processing total time during the solution process by explicit finite element analysis (OÑATE et al., 1998).

Materials models of the stent, artery, plaque and balloon

The crimping and angioplasty simulation from stent, artery and balloon has studied in this work may be considered as an initial value and boundary conditions problem (BELYTSCHKO et al., 2001). Since the pressure to be applied in the crimping and angioplasty procedure is dynamical, the Von Mises model could not provide the correct results. In this case, it will be necessary to use a more appropriate constitutive law for the dynamic stress analysis from stent, balloon and artery generated by the pressure changing with the time during the crimping and angioplasty simulation.

In this work, the crimping and angioplasty analysis by explicit finite elements will be investigated by using the tube hydroforming simulation. In most papers have published in the literature on the angioplasty simulation by finite elements, it is commonly used an isotropic hardening law that may be bilinear or multilinear for the stent material modelling (PRENDERGAST et al., 2005; DE BEULE, 2008; BRESSLOFF et al., 2016). In this paper, it will be applied a more appropriated material model for the stent forming. Hence, the Ludwig-Nadai law is more appropriated for modeling of the stent material:

$$\sigma_{eq} = k\left(\varepsilon_{po} + \varepsilon_{p}\right)^{n} \tag{2}$$

where k, n and ε_p are parameters of the stent material to be experimentally determined in a uniaxial tensile test of a 316 L stainless steel piece. The parameter ε_{po} and ε_p are the effective plastic strain and the initial plastic strain, respectively. The Equation (2) used as a material model for the sheets forming analysis by finite elements will be employed in the stent material modelling (ARAÚJO, 2016). For the stent made of 316 L stainless steel, the values of the parameters for this material are n=0,28, k=1160,4 MPa.

In most works on the stent angioplasty simulation (PRENDERGAST et al., 2005; GERVASO et al., 2008, PHANI et al., 2014; BRESSLOFF et al., 2016), the structural integrity from stent is evaluated by the comparison of the Von Mises equivalent stress with the ultimate stress of its material. In this analysis, the directions and degree of the anisotropy from material are neglected. For the metal sheet forming process, the anisotropy degree should be considered during the plastic strain process of the material. In this case, the

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Stampack® software uses the Hill 48 model:

$$\sigma_{eq}^2 = \sigma_{11}^2 + \frac{r_0\left(1+r_{90}\right)}{r_{90}\left(1+r_0\right)}\sigma_{22}^2 - 2\frac{r_0}{1+r_0}\sigma_{11}\sigma_{22} + \frac{\left(1+r_{45}\right)\left(r_0+r_{90}\right)}{r_{90}\left(1+r_0\right)}\sigma_{12}^2 \quad (3)$$

where the σ_{11} and σ_{22} denotes the principal normal stress and σ_{12} the shearing stress. The variables r_0, r_{45} and r_{90}, known as Lankford parameters, define the plastic material anisotropy angles in degrees. The subscripts 0, 45 and 90 represent the angles in degrees of the anisotropy directions from material. Since the stent material is isotropic, all anisotropy parameters are equal to 1 (r_0, r_{45}, r_{90}=1). In this way, it can be demonstrated that the equation (3) is reduced to the Von Mises criteria for the equivalent stress, σ_{eq}.

For the angioplasty simulation without the stent, the material from expandable balloon was assumed as elastic and isotropic. For the expandable balloon material, the density is equals to 1100 kg/m^3 (YANG et. al, 2009), the Modulus of Elasticity is 900 GPa (GERVASO et. al, 2008) and the Poisson's Ration is 0,3 (GERVASO et. al, 2008). For this reason, it was employed the Hooke law as an approximation of the material model for the semi-compliant balloon. Nevertheless, in the practice, the material model from polymer used the manufacturing from expandable balloon is hyperelastic and non-linear (PRENDERGAST et al., 2005).

For the modelling of the artery and plaque material, it was assumed a non-linear strain-stress relationship as defined by hyperelastic Ogden model (PRENDERGAST et al., 2005). During the balloon angioplasty and the stent implantation procedure, the arterial wall and fat plaque are subjected to the large strains in the non-linear elastic range. Moreover, the contact stress between the stent and the artery are properly calculated by using a hyperelastic constitutive law for the modeling of the artery and plaque material. In the Ogden Model, the stress components of the plaque and artery materials are obtained by differentiating the strain energy, *W*, with respect to the strain components defined by:

$$W = \sum_{i=1}^{N} \frac{\mu_i}{\alpha_i}\left(\lambda_1^{-\alpha_i} + \lambda_2^{-\alpha_i} + \lambda_3^{-\alpha_i} - 3\right) \quad (4)$$

where λ_1, λ_2 and λ_3 are the principal stretch ratios of the material and μ_i and α_i are parameters from Ogden model. In the case of the material models from artery and stenotic plaque, it was used an Ogden model of third order with the variable *N* equal to the 3. The parameters values used in the modelling of the stenotic plaque and arterial tissue material were extracted from Prendergast et al. (2005) and are described in the Tables 1 and 2, respectively.

Table 1. Mechanical properties of artery (PRENDERGAST et. al., 2005).

Mechanical properties	
Modulus of Bulk [MPa]	1600
Density [kg/m^3]	1200
Yield stress [MPa]	0,5
Hardening Modulus [MPa]	16000

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Parameters from Ogden's model	
$\alpha 1$	21.83
$\mu 1$ [MPa]	-13
$\alpha 2$	22.22
$\mu 2$ [MPa]	7.9
$\alpha 3$	21.15
$\mu 3$ [MPa]	5.1

Table 2. Mechanical properties of the fat plaque (PRENDERGAST et al., 2005).

Mechanical properties	
Modulus of Bulk [MPa]	3000
Density [kg/m^3]	1300
Yield stress [MPa]	0,3
Hardening Modulus [MPa]	30000
Parameters from Ogden's model	
$\alpha 1$	2
$\mu 1$ [MPa]	-4.6
$\alpha 2$	4
$\mu 2$ [MPa]	3.23
$\alpha 3$	-1.99
$\mu 3$ [MPa]	1.6

ANALYSIS OF THE RESULTS

In the first step of the numerical simulation the stent was crimped and its diameter was reduced from 1800 mm to 861,2 mm. After the crimping, the residual elastic strain of stent caused a recoil and its diameter increased from 861,2 mm to 1000 mm (about 1 mm in the real scale). The figure 3 illustrates the regions of the crimped stent subjected to the wrinkling and thinning. Since in the crimping process simulation the stent is subjected to a small plastic strain, its structural integrity is preserved, that is, no regions of its material is subjected to strong thinning or strong wrinkling. However, the recoil from crimped stent was relatively high and equals to 13%. Because this recoil is relatively high, the stent could slip on external surface from expandable balloon.

In order to decrease the stent recoil, it was evaluated a new crimping simulation and the stent diameter was reduced from 1800 mm to 1100 mm (1,1 mm in the real scale). The maximum plastic strain of the crimped stent is 0,048. Since the plastic strain magnitude is relatively low for this reduction of diameter, it is expected that the stent does not slip on the balloon surface after the crimping.

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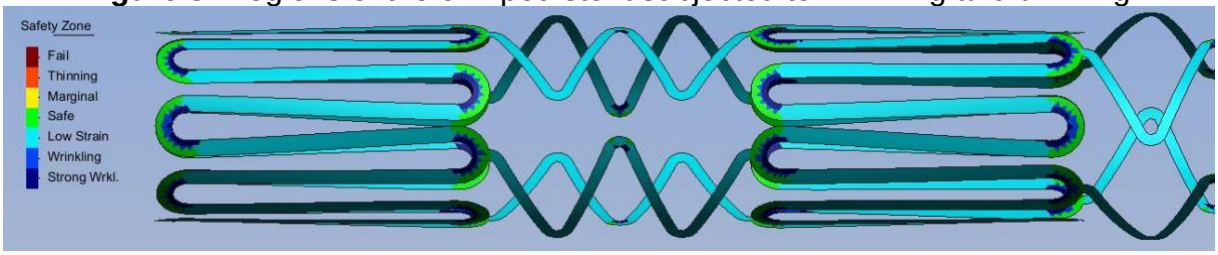
Figure 3. Regions of the crimped stent subjected to wrinkling and thinning.



After the crimping simulation of the stent, the balloon was expanded in the angioplasty procedure until the contact with the arterial wall and the stenotic plaque as illustrated in the figure 4. For this simulation, an outward pressure has applied in the internal surface from balloon was adjusted by trial-and-error and equals to 4 atm. The objective of this simulation is the compression of the stenotic plaque placed on the arterial wall. The Von Mises stress distribution has shown in the figure 5 displays that the maximum plastic stress level is equals to 0,54 MPa and is present at the ends from expandable balloon. Since the plastic stress of 0,54 MPa is smaller than the maximum stress of the artery tissue material (0,394±0,223 MPa) according to Zahadmanesh (2012), its structural integrity will be preserved.

Figure 4. Steps of the angioplasty procedure simulation for the expandable balloon.

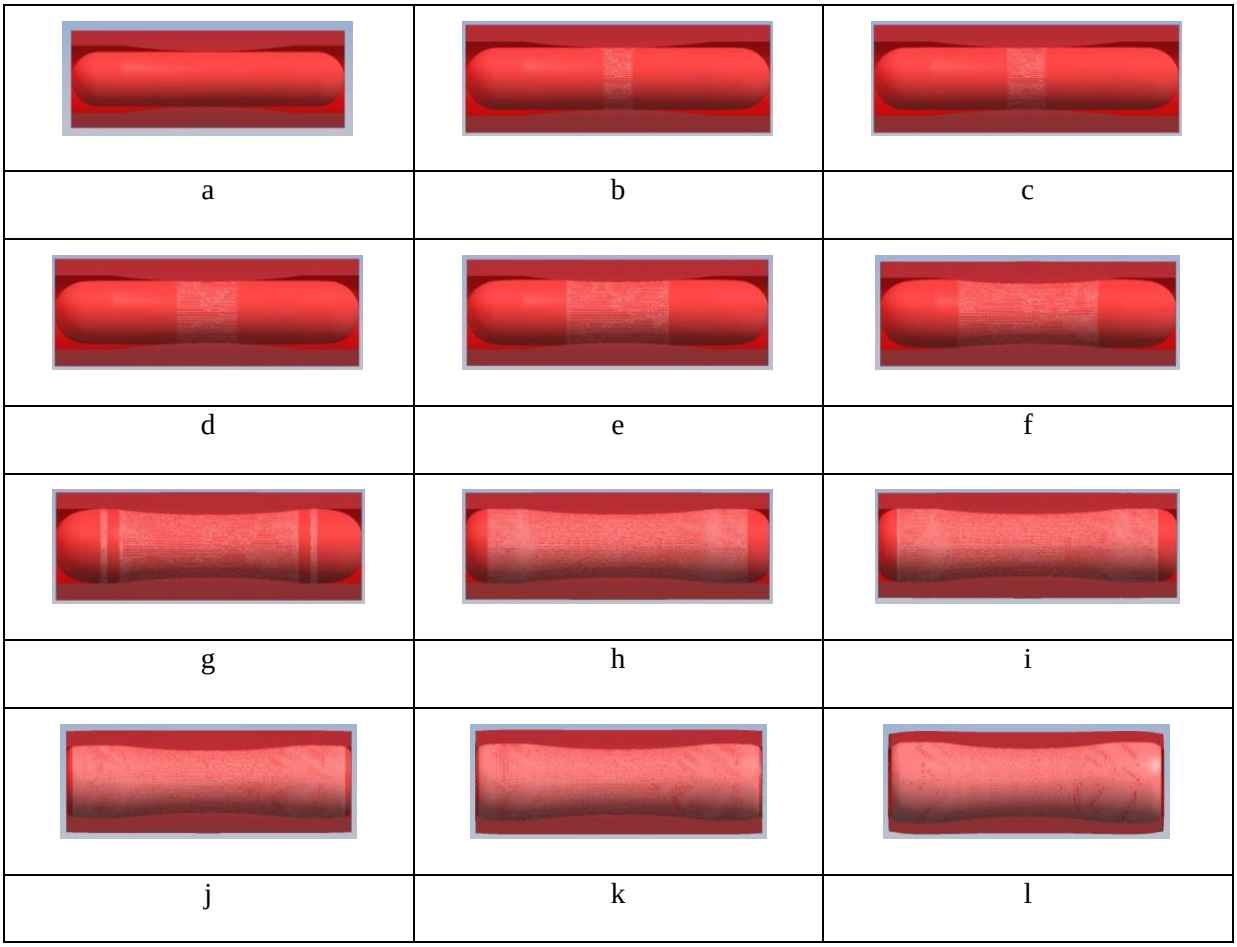


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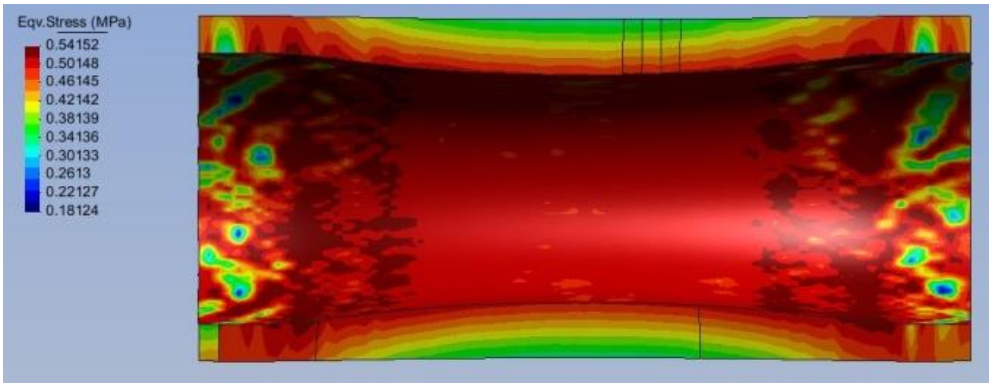
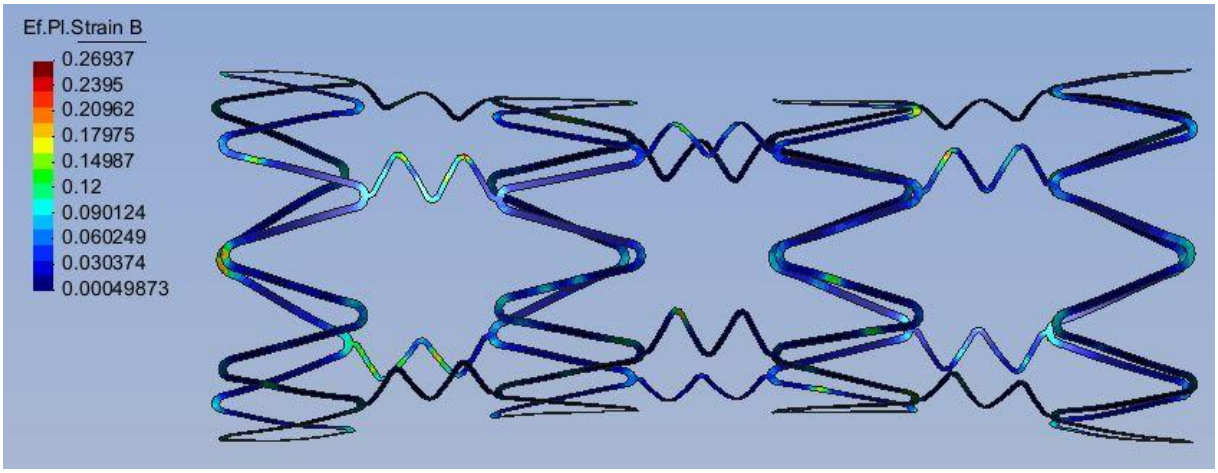
Figure 5. Equivalent plastic stress of the artery and stenostic plaque after the angioplasty.



In the last step of the procedure, the balloon is deflated and the crimped stent with residual plastic strain is expanded until the contact with the region of arterial wall subjected to the treatment of angioplasty in the previous step. The figure 6 illustrates the plastic strain distribution from stent caused by the expansion and the contact with the artery and stenotic plaque. It is interesting to note that the plastic strain due to expansion is concentrated in regions with the shaped of “V” in stent structure. On the other hand, the plastic stress generated by the contact with the artery are placed on different regions. The figure 6 shows that the maximum plastic equivalent strain is smaller than the allowable maximum strain for the 316 L stainless steel stent (about 54%). Because of this, it was demonstrated that the expansion process from stent has purposed in this work is safe and its structural integrity will be preserved during the implantation procedure.

Figure 6. Equivalent plastic strain of the stent after the expansion into the artery and fat plaque.



Another tool to be used in the analysis of the structural integrity of the stent is the thickness strain according to the figure 7. By this analysis, it is possible to identify the regions of the stent structure subjected to the thinning or wrinking generated by the plastic stress. The regions with blue color represent the wrinkling caused the plastic strain of compression and the red color indicate the thinning due to the plastic strain of traction. Once again, it is

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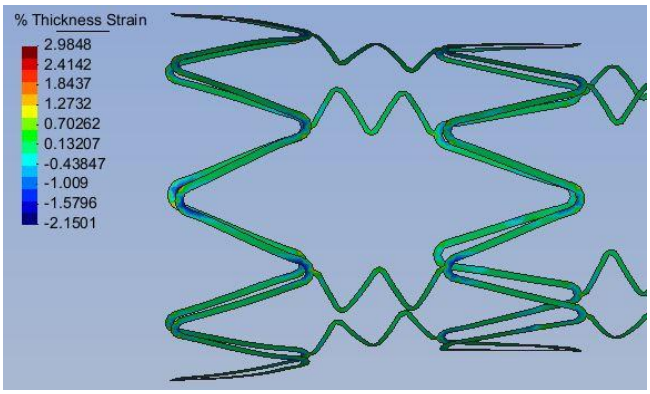
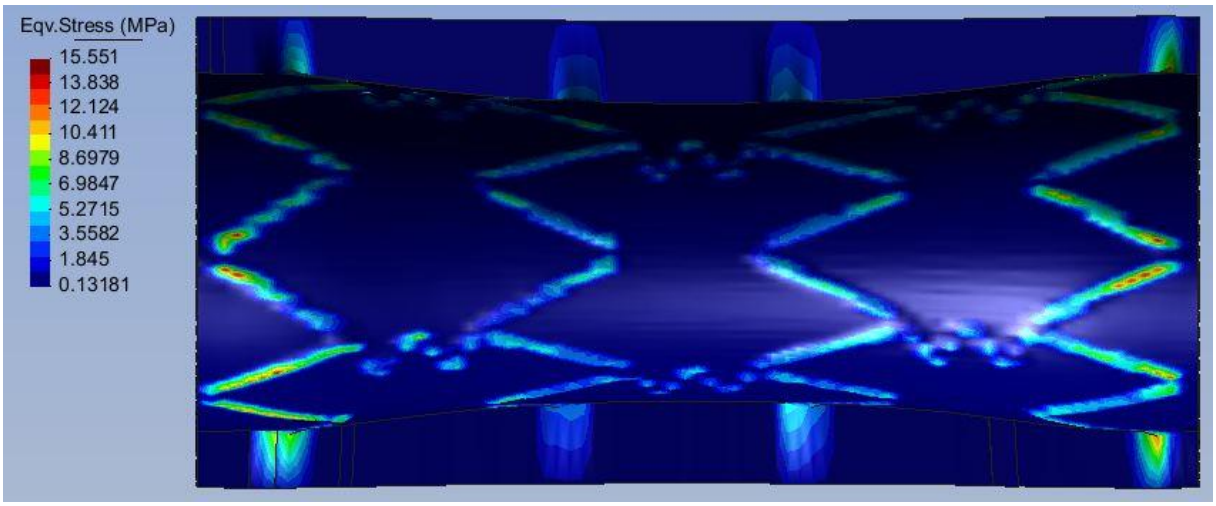
proved by using this analysis that the expansion process from stent is safe because of low plastic strain level (2,98 % and -2,15 %) has observed in its structure.

Figure 7. Thickness strain of the expanded stent into the artery and fat plaque.



About the structural integrity of artery, the figure 8 displays the Von Mises equivalent stress distribution caused by the contact with the stent. The Von Mises maximum stress has observed in the arterial tissue is equal to the 15 MPa and this is localized on the ends of the artery where the penetration due to the contact with the stent is larger. Prendergast et al. (2005) have investigated the stress in the arterial wall caused by the contact with a commercial stent and found values larger than 10 MPa for the artery tissue. Once that this stress magnitude is relatively low, it is believed that the structural integrity from arterial tissue will be preserved as well, and the implantation procedure of the stent will not cause injuries or damages in its material.

Figure 8. Von Mises stress of the arterial tissue after the angioplasty.



CONCLUSIONS

It was proposed, in this work, a methodology to simulate and analyze the structural integrity of the stent, balloon and artery has divided in 3 steps: crimping of stent, angioplasty

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from balloon and expansion from stent in the arterial wall using the explicit finite element method. For this analysis, the abovementioned procedures were simulated as a tube hydroforming process. An advantage of this methodology is that dynamic pressure applied on the internal surface from stent was considered and the residual plastic strain in stent due to the crimping process was also taken into account in the analysis. In each step of the procedure, it was possible to verify if the stent design has considered in this work has any risk of rupture in the crimping process or after the implantation in arterial wall, as well as, if the artery, stenotic plaque or the expandable balloon are subjected to the high level of stress. Moreover, the deformed shape of the stent and the maps displaying the thickness strain and the regions with thinning and wrinkling proved to be interesting tools to be used by the cardiologist or the stent designer in the analysis of the crimping and angioplasty procedures.

For the simulations have proposed in this work, it has been developed a geometrical model of a stent for angioplasty. During the crimping simulation from stent, the plastic stress level was acceptable. Nevertheless, the recoil after the reduction of diameter was high. In this way, the stent was subjected to the crimping process again in order to diminish the recoil. Subsequently, the balloon was expanded within the arterial wall with the stenotic plaque by simulating the angioplasty procedure. For this case, Von Mises equivalent stress were smaller than the allowable stress from arterial tissue material. Finally, the crimped stent was expanded within the artery region subjected to the previous angioplasty in order to simulate the implantation procedure. The analysis of the results proved that integrity analysis of the stent and artery due to the expansion and contact stress was preserved.

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