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A FINITE ELEMENT ANALYSIS OF THE PERFORMANCE OF STENTS FOR ANGIOPLASTY USING THE HYDROFORMING PROCESS

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Abstract. Nowadays, stent implantation is the most used procedure to treat restenosis of coronary arteries. To prevent restenosis, a stent must absorb a large amount of plastic strain energy during its expansion to avoid the re-closure of artery wall after the implantatioon. According to this design criterion, it was applied the topological optimization technique to provide the best layout of a unit or cell to be used in the formation of the tubular structure of a stent. Subsequently, the topologically optimized stent cell was employed to create the three dimensional stent structure using the software Autocad/Mechanical Desktop® for the generation and treatment of this model. To test this model it was applied the software Stampack® of explicit finite elements to simulate and analyse the expansion process of optimized stent during the angioplasty by hydroforming. Although the hydroforming has been extensively employed in forming process of tubes used in the automotive industry, it was used in this work to study mechanical behavior of stents during the angioplasty. From the simulation by finite elements, it was possible to predict some design parameters of this novel optimized stent model, such as, the pressure of expansion to be applied in the balloon and the plastic strain field of the stent structure after the implant.

1 INTRODUCTION

In most cases, only the expandable balloon and catheter therapy are not able to avoid the elastic recoil or restenosis of the artery wall after angioplasty [9, 17]. In order to maintain the luminal diameter of the artery opened to receive the blood flow, cardiologists are induced to implant a metallic tubular device, known as stent, during angioplasty procedure. After [19], the major role of a stent is to reinforce artery wall and support arterial compression pressure after implantation.

Although restenosis in coronary arteries is immediately solved by the angioplasty, there is still a risk of its incidence in 30 to 50% of cases [9]. By considering that coronary heart disease a common reason for death, it is still necessary to search alternatives to reduce restenosis rates in coronary arteries submitted to the angioplasty process with stents. Usually, restenosis is caused either by the insufficient stiffness of a expanded stent implanted in the artery or due to lesions produced in the artery wall due to contact stress provided by the interaction between stent and artery. Nowadays, drug-eluting stents have been applied to hyperplasia and restenosis treatment. Even so, coronary revascularization problem still lies in further developments in the design of drug-eluting stents [9, 16]. Stiff stents have also been used in order to reinforce the arterial wall after balloon angioplasty [17]. Recently, it was applied the topological optimization technique as a design tool for stents geometry [8]. Since ductility of the structure was maximized, it is expected that this novel stent geometry design may be an appropriate choice for the cardiologist among the several commercial stents models [7].

Guimarães [8] developed optimal topologies designs of the stent cell plane model using boundary conditions by simulating the balloon expansion process in two dimensional space. It is interesting for the cardiologist and stent designers in some situations to study the mechanical behavior of the whole three-dimensional model of the set balloon and stent [6, 7, 16]. In this work, it is developed a methodology for the generation of a three-dimensional stent from the planar optimal topologies to analyse angioplasty procedure using the tube hydroforming simulation process. In this manufacture process, an internal pressure is applied into the die which is used to deform a metallic tube [2, 4]. Tube hydroforming has been extensively applied in the automotive components forming, but because of its similarity with the stent expansion process, it will be used in this work to simulate ballon angioplasty by finite element.

The aim of this study is to evaluate the expansion pressure of the balloon and the plastic strain field of the stent by the finite elements simulation using tube hydroforming process.

2 STENTS FOR ANGIOPLASTY

Figure 1 shows the catheter, expandable balloon and stent commonly used in the angioplasty process to unblock coronary arteries [17]. It can be seen that the catheter is the minor diameter tube and the balloon and stent are in the expanded state. When the balloon expands, the stent is subjected to the outward internal pressure. Consequently, the stent diameter is increased until its external surface to be in contact with the internal surface of the artery wall. After angioplasty, the stent should reinforce arterial wall in order to prevent restenosis or reduct artery diameter.

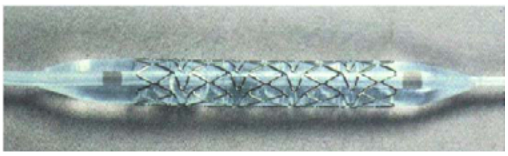

Figure 1: Stent, expandable balloon and catheter.

Stent structure consists of a repeating unit which is distributed along the cylindrical surface of a metallic tube with diameter between 1.5mm to 3.0mm before the angioplasty. The material used in the manufacturing of an expandable-balloon stent is usually stainless steel 316L or an alloy of cobalt, titanium, platinum or gold [17]. For these metals, when the stent expands, each repeating unit is subjected to a large displacement in the traction at vertical direction, as can be seen in the Figure 2 [1]. From this diameter expansion, each repeating unit undergoes plastic strain and the hardening of the stent material reinforces the arterial wall. Additionally, the stent geometry is also designed to be structurally stiff in order to improve the support capacity of the artery after the angioplasty.

When catheter and stent move inside the blood vessel with a small radius, they should bend before the balloon expansion. Thus, a stent should also be flexible during the angioplasty since the catheter is usually subjected to large deflections in the elastic range [15]. The stents from the first generation were exclusively designed to be stiff after the angioplasty and the flexibility was not considered [17]. However, in some situations, the angioplasty procedure could not be carried out because the set catheter, stent and balloon simply could not move inside the vessel. Since then, the stents geometries have been modified and flexible elements have been incorporated in most of commercial stents designs. For example, in the Figure 2, it is observed the presence of structures with the sinusoidal shape in the longitudinal direction placed between the structures subjected to plastic strain. These structures should improve flexibility of the stent in the longitudinal direction.

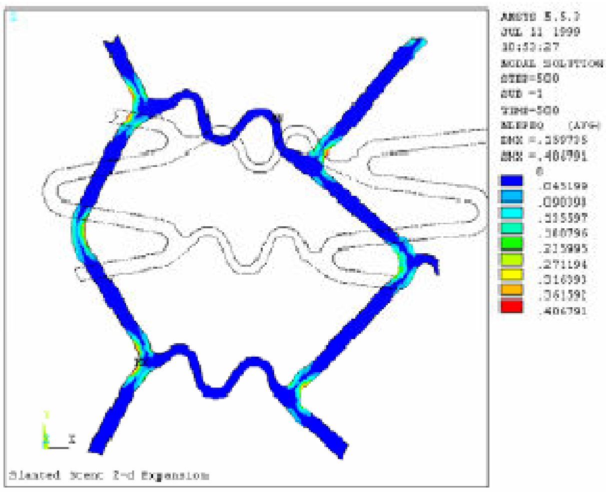

Figure 2: Geometry of the commercial stent cell [1].

3 GENERATION OF THE THREE-DIMENSIONAL STENT MODEL

3.1 Topological optimization of the stent cell

Optimization of geometry of the hardened and flexible structures from repeating unit, similar to that shown in the Figure 2, has been the starting point for the creation of the three-dimensional stent model to be studied in this work. For this purpose, it was applied the topological optimization technique to some plane structural models with the boundary conditions by simulating the expansion balloon process and the elastic deflection of stent cell inside the vessel. In the case of expansion balloon, it was maximized the ductility of the stent cell topology. Hence, it is expected that the stent cell topology may absorb a large amount of plastic strain energy and to reinforce the arterial wall [17]. For the stent flexible structure, its elastic strain energy was maximized improving its navigation before expansion. Figure. 3 shows optimal material distribution or topologies for both cases. A detailed discussion of the topological optimization technique formulation and its application to the stent design can be found in Guimarães [8].

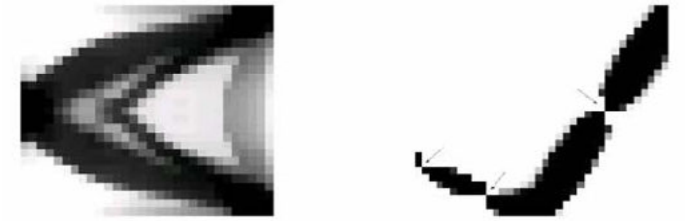

Figure 3: Hardened and flexible optimal topologies of the stent cell [8].

3.2 Methodology for the creation of the three-dimensional stent and balloon model

The stent cell topologies shown in the Figure. 3 represent images from the relative densities matrix extracted of the optimization process. The elements of these matrix can assume only values between zero and one, where one indicates the presence of material in the topology and zero represents the absence [18]. From these images, it is possible to view only the structural aspect of the plane model of the flexible and hardened stent cell in the non-deformed state. In addition, it is also interesting to develop some procedure to study the mechanical behavior of this novel stent model and to predict some parameters in order to quantify its performance when compared with the commercial stent models.

The first step of this methodology was to extract the contours of the relative density matrix using the software Matlab®. These contours are isolines of relative density or material distribution of the optimized stent topologies shown in the Figure. 3. The function “contour”, available in Matlab®, was used to generate the position of the isolines points of each region in the stent cell plane model. The relative density used as threshold to generate isolines of relative density was also calculated automatically by the function contour.

Next, the file generated in Matlab® was imported by the software Autocad/Mechanical Desktop®. Once the contours from the topologies were irregular and non-smoothed, a procedure based on the splines had to be applied to smooth points of the stent cell isolines. This smoothing process is necessary since jagged boundaries in a structure subjected to large plastic strain cause artificial stress singularities [11]. After the definition of contour lines from the hardened and flexible topologies shown at Figure. 3, a mirror procedure was applied to both structures to provide the right hand of the stent cell. In fact, topology optimization was only applied to the half of flexible and hardened structures design space, due to longitudinal symmetry of the stent cell illustrated at Figure. 2.

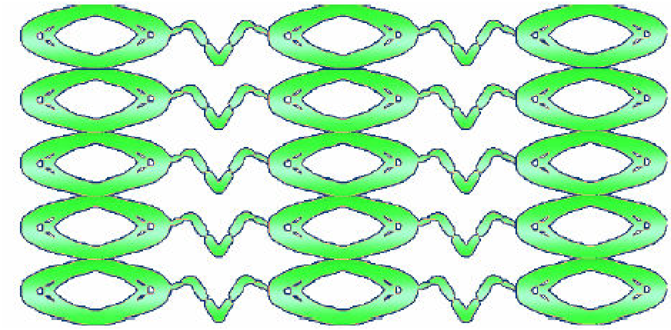

Figure 4: Plane model from the stent.

The next step was the reproduction and repetition of stent cell lines in the horizontal and vertical direction in a plane. The planar stent structure, shown at Figure. 4, has 3 cells or repeating units distributed in the horizontal direction and 7 cells placed on the vertical direction. Subsequently, the whole plane structure was wrapped into a cylindrical shape to generate the three-dimensional stent structure. In this way, stent geometry became a volume or a cylindrical three-dimensional solid model. A file format .igs was created from the three-dimensional stent model in the software Autocad/Mechanical Desktop® and imported in the explicit finite elements Stampack® software. Finally, the geometrical model of the balloon and their rings was created in the Stampack® software using the available drawing tools.

4 FINITE ELEMENTS MODEL OF THE STENT AND BALLOON

4.1 Simulation of the stent expansion using the tube hydroforming process

In the tube hydroforming process, a combined loading of compressive forces and internal pressure is applied by a fluid medium to obtain tubular components with different crosssections [4]. With the advancements in computer controls and high pressure hydraulic systems, this process became a viable method for mass production of automotive components, such as, crankshafts, camshafts, exhausts parts, radiator frames, front and rear axles, body parts, etc. [2]. In fact, tube hydroforming has several advantages when compared with the conventional stamping process, as for example, the consolidation of parts in only one operation and the production of components with improved structural strength and stiffness. However, this technology still needs of development and research since the most of knowledge is based on the experimentation and simulation by trial-and-error [3].

Hydroforming simulation by finite elements will be used in this work to study the mechanical behavior of the stent during the balloon expansion. This procedure was selected because the hydroforming of a tubular sheet subjected to an internal pressure with a fluid medium inside a polymer pad and the expansion process of balloon and stent are totally analogous. The unique difference is that in biomechanics, angioplasty of the balloon has dimensions of the order of millimeters and the automotive components dimensions manufactured by hydroforming are of the order of meters.

In practice, tube hydroforming is a nonlinear deformation process and the prediction of quality from analytical parameters of the manufactured component, such as, the wrinkling, buckling and formability, are available only for some cases of the blank with simple geometry. In this context, the finite elements method proved to be an indispensable simulation tool to analyse these parameters [2, 3, 4].

Hydroforming is a dynamic manufacturing process dependent of the time of contact between plastically deformed solid surfaces, therefore, most of the finite elements codes to simulate this process use an inverse or explicit approach. The incremental or implicit approach gives a detailed description of the whole process and the time history of stress and strain components in any time instant during simulation may be obtained. Nevertheless, the incremental approach requires efficient and robust contact algorithms since the physical presence of tools and blank and all parameters of the process are considered. Hence, the explicit approach is more computationally efficient as compared to the incremental one. In the explicit approach, final shape and stress and strain field of the blank and tools are computed from the initial and boundary conditions and no contact algorithm is requested.

The total time of simulation using hydroforming process depends on the size of the smallest finite element in the mesh. The minor is the size of the finite element, the larger is the time increment required to computate strain and stress fields of the blank and the tool. As the stent cell length is equal to 1.5x10-3m, the total time for the finite elements simulation can become impractical.

In this study, it will be used the similitude theory in engineering to simulate stent and balloon expansion. The idea is to multiply dimensions of the stent and expandable balloon by a scale factor to obtain a model for angioplasty in increased scale. In this way, the smallest finite element dimension is increased and the critical time for simulation of finite elements is reduced. From the results of model with the increased dimensions, it is possible to extract the stent design parameters of the original model by means of the theorem of pi of similitude between the models [12].

4.2 Material models of the stent and expandable balloon

Stampack® software was designed and created to simulate using finite elements the stamping process of metallic sheets subjected to dynamic pressure loading. Some practical examples from the stamping process have already been validated numerically by this software, as shown in its tutorial. Material models available in the software stampack® are exclusively dedicated to this kind of process. In stamping, the blank material models are not usually isotropic since the rolling process provides different properties through thickness and in the plane of the sheet. Pad used for the internal pressure application in tube hydroforming is a rubberlike hyperelastic material subjected to large strains. Adaptation of these material models to the stent and balloon expansion problem in angioplasty will be discussed in the following.

Elastic-plastic material model of the stent. In this stud, it will be considered only expandable balloon stents made of stainless steel 316L. In the literature, most of papers are related to models made of this material using a bilinear with hardening isotropic model [6]. As the stent material is isotropic, a Von Mises model for the equivalent stress calculation is used in the estimative of elastic-plastic stress state. In the stampack® software, equivalent stress, σ_{eq}, of the blank material subjected to a general stress state is computed by considering the material anisotropy:

$$\sigma_{eq}^2 - \sigma_{11}^2 + \frac{r_0(1+r_{90})}{r_{90}(1+r_0)}\sigma_{22}^2 - 2\frac{r_0}{1+r_0}\sigma_{11}\sigma_{22} + \frac{(1+2r_{45})(r_0+r_{90})}{r_{90}(1+r_0)}\sigma_{12}^2, \tag{1}$$

where σ11, σ22 represent the normal stress components and σ12 is the shearing stress. Parameters r0, r45 and r90 known as Lankford coefficients, determine the plastic anisotropy of the material. Subscripts 0, 45 and 90 are the material anisotropy angles measured in degrees. The larger is the magnitude of the Lankford coefficients, larger is the anisotropy between the directions. To stainless steel 316L used in the manufacturing of the stent, Lankford coefficients are equal to one since material does not have anisotropy in any direction. In this case, it can be demonstrated that the material model described in Equation (1), called Hill 48, corresponds to the Von Mises material model [10].

Evolution of yield surface defined in the Equation (1) depends on the relation between equivalent stress and plastic strain. For the bilinear with hardening isotropic material model, the equivalent stress changes linearly with strain within the plastic range. This model has been commonly used to simulate stent expansion. In the simulation of stamping process, different exponential material models have been used as the hardening law instead of the linear model. In these models, the error between experimental and theoretical strain and stress behavior is reduced. In this work, it will be used the Ludwik-Nadai model:

$$\sigma_{eq} = K(\varepsilon_{po} + \varepsilon_p)^n \tag{2}$$

where K, n, ε_{po} and ε_p are material parameters to be determined experimentally through uniaxial tensile test in a stainless steel 316L piece. Values of these parameters for several metallic materials used in the construction of sheets, including stainless steel 316L, are available in the software Stampack®. Stainless steel stent parameters are described on Table. 1.

Table 1: Parameters from the Ludwik-Nadai model for the stainless steel.

Parameter	Magnitude
K	1160.4 MPa
n	0.28
ε_p	0.21

Rubberlike material model of the expandable balloon. The material of the balloon for angioplasty is a polymer with tubular shape and small thickness subjected to large elastic strains. There are several rubber type materials to be used in the manufacturing of expandable balloon. Materials for angioplasty ballons of first generation were flexible and the final shape of the stent after expansion had some irregularities. Nowadays, balloon material is stiffer and stent expansion is more uniform. Polyurethane rubber is the base material used to manufacture the balloon. It can be combined with another material, such as, nylon in order to improve some mechanical properties, as for example, strength or stiffness of the balloon in the expanded state.

Calculation of the stress in a rubber type material is based on the finite strain theory. Once defined the strain-energy density function, W, or constitutive law for the rubber, stress components are derived by differentiating W with respect to the strain components [14]. The software Stampack® employs Ogden's model to define strain-energy density:

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

where λ_1, λ_2 and λ_3 are the main stretch ratios of the material, and μ_i and α_i are scalar parameters from the Ogden's model. In this formulation, polyurethane rubber is considered incompressible, that is, the ratio between its deformed volume and original volume of the balloon is equal to one. The parameter N defines the order of Ogden's model. In this study, it will be used a model with three parameters (N=3) for the balloon polyurethane rubber. The strain energy density function parameters for the stiff rubber of balloon to be used in the stent expansion are shown on Tab. 2. A Mooney-Rivlin type function has been also applied to model hyperelastic balloon polyurethane rubber [6]. However, Ogden's model provides a best fitting to experimental data of the rubber strain energy, particularly for large strain, when compared to the Mooney-Rivlin model [14].

Table 2: Parameters from the Ludwik-Nadai model for the stainless steel.

Parameter	Magnitude
α_1	1.3
μ_1	6.3
α_2	5.0
μ_2	0.013
α_3	-2.0
μ_3	-0.1

4.3 Design parameters of the stent and expandable balloon

After finite elements simulation, stent and balloon design parameters were extracted and analyzed in the post-processing step from Stampack® software. A complete description of the displacement, strain and stress fields of the stent and balloon in the expanded state after hydroforming simulation can be obtained from results analysis. Other parameters, such as, wrinkling, forming and stretching of the final part can also be analyzed in the post-processing stage. The analyzed parameters were the following:

Internal pressure to be applied in the balloon. Usually, balloon manufacturers provide a curve of internal pressure versus final diameter of the stent after expansion. Thus, cardiologists know what is the internal pressure to be applied in the expandable balloon to increase stent diameter until the diameter specified. In practice, this curve is experimentally determined by means of trial-and-error since expansion process is highly nonlinear due to large plastic strain and the geometric complexity of the stent design. In general, the curve of internal pressure versus diameter is defined analytically only for the simple blank geometry in hydroforming process [2, 3].

In our study, magnitude of internal pressure to be applied in the balloon will be estimated by running some iterations of the stent hydroforming simulation process. An initial value for internal pressure will be input in the simulation and the diameter of the expanded stent will be checked. Subsequently, internal pressure will be adjusted by trial-and-error according to final diameter observed in the balloon and stent. The maximum pressure to be applied in the expandable balloon for angioplasty is 12 atm or 1.21 Mpa [17]. An extremely high pressure can cause the rupture of balloon material or damage the arterial wall during expansion.

Plastic strain distribution in the expanded stent. After angioplasty, it is desired that the plastic strain fields of the stent structure are uniformly distributed. It means that the formability or ability of stent structure to absorb plastic strain energy is high. In this way, stent diameter can increase during expansion without rupture of the material. These hardened regions in the stent structure material also improve the support ability of artery wall.

5 ANALYSIS OF THE RESULTS

Figure 5 shows balloon and stent geometries before expansion process. Indeed, geometry shown at Figure. 6 represents the model in increased scale of the original balloon and stent. To obtain this amplified model, dimensions of the original geometry were multiplied by 100. Stent geometry design was created using the methodology described at section 4.1. Rings illustrated at the figure restrict expansion movements at the ends of the balloon. Stent internal diameter is equal to the balloon external diameter. Both are equal to 278mm. Lengths of the expandable balloon and stent are 4000mm and 1298mm, respectively. Constant thickness of the stent was assumed to be 10mm. The balloon has variable thickness in its ends. The ends of the balloon were modeled to be 1000mm in length and thickness linearly increases from 30 to 100mm. At the middle of the balloon thickness is constant and equal to 30mm. Figure 6 illustrates the geometry of the variable thickness from the balloon.

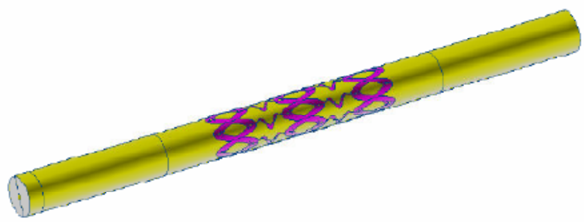

Figure 5: Stent and balloon geometries before the angioplasty.

In Stampack® software, the pad or expandable balloon is a volumetric solid model and the blank is considered as a shell model. As the pad is a regular geometric solid, it was meshed using structured volume hexahedral elements. On the other hand, the blank meshing was created from unstructured triangular shell elements due to the irregularity of its geometry. Another advantage of shell finite elements is the reduction of total processing time in the nonlinear finite elements analysis. Stent thickness is taken into account in the formulation of shell finite elements in its surface mesh. Figure 6 shows the stent surface mesh, the rings structured at the surface mesh and the internal surface of the expandable balloon which will be subjected to the internal pressure. Stent meshing has 9086 nodes and balloon meshing has 48000 nodes.

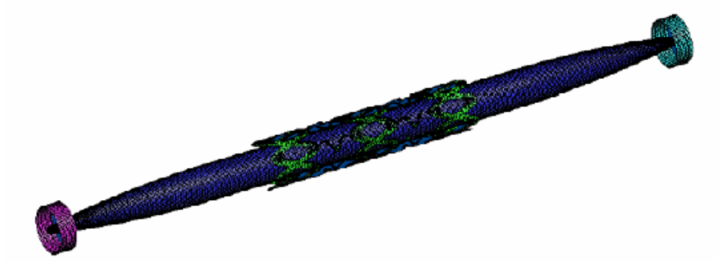

Figure 6: Surface meshing from the stent and expandable stent..

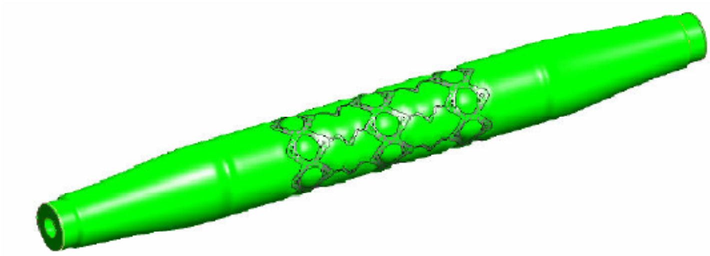

Figure 7: Final shape of the stent and balloon after the expansion process.

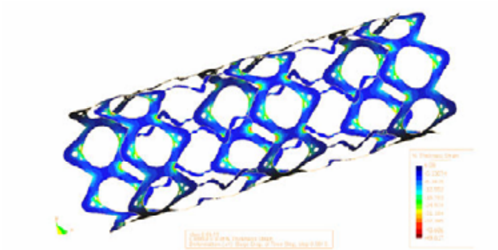

Figure 8: Plastic strain distribution in the stent material after the angioplasty.

After some simulations, the maximum pressure to be applied in the internal surface of the balloon was selected by trial-and-error to be 0.25×10^9Pa. Total time to simulate balloon and stent expansion was 1 hour and 28 minutes. This pressure increased the stent original diameter in about 60%. Final shape of the stent and balloon after expansion are shown at Figure. 7. Using similitude theory, it can be demonstrated that the internal pressure to expand the original model is the pressure to be applied in the increased scale model multiplied by 10-4 [12]. Hence, the pressure to be applied in the pad of the actual model is 0.25MPa. As this value is smaller than the maximum nominal pressure (1.21MPa) used in the commercial balloons angioplasty, it is expected that angioplasty is a safe procedure and without damages to arterial wall.

Plastic strain distribution of the expanded stent is illustrated at Figure. 8. As can be seen, plastic strain field is concentrated in regions near to the 3 holes of the stent structure in the left edge. Hardening of these plastically deformed regions added to the stiffness of each repeating unit from the stent maintains arterial wall opened. The maximum Von

Mises plastic strain observed in the expanded stent was 58% and the strain corresponding to rupture stress for stainless steel 316L is 50%. However, due to the high ductility of the stainless steel 316L, it is expected that stent structure may expand and deform without rupture of the material

6 CONCLUSIONS

In this study, it was developed a methodology to analyses stent and balloon three-dimensional model using hydroforming simulation by finite elements. The optimal topologies from the stent repeating unit were the starting point to create three-dimensional model. From the simulation of the model in amplified scale, finite elements processing time was reduced and the internal pressure to be applied in the balloon, as well as the plastic strain field of the stent were analyzed. This proved that the tube hydroforming simulation by explicit finite elements, extensively used in the study of automotive components hydroforming, is also a viable tool to be employed in the analysis of the mechanical behavior of stents for angioplasty.

Design parameters extracted in the post-processing stage proved that the stent and balloon geometries satisfy required specifications for the angioplasty procedure. Expansion pressure to be applied into the balloon is significantly less than the maximum nominal pressure commonly used in the practice. Consequently, the risk of rupture of the balloon and the damage of artery wall is decreased. It was also proved that plastic strain field is more distributed in the three-dimensional stent model as compared to the traditional stent cells (for example, see Figure. 2). This improves stent stiffness and capacity of support in the arterial wall reducing restenosis risk after angioplasty.

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