AN ANALYSIS OF THE STRUCTURAL INTEGRITY OF STENTS FOR ANGIOPLASTY USING THE FORMING LIMIT DIAGRAM

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Abstract. *The simulation of the angioplasty process by finite element analysis has been extensively studied in order to predict the stiffness and the flexibility of a stent in the expanded state. Usually, the stent expansion process simulation does not depend on the time and the Von Mises plastic strain distribution is used in the analysis of the structural integrity. However, in practice, the stent is subjected to dynamic pressure which changes with the time during the angioplasty procedure. The purpose of this work is to predict the regions of the stent structure after the expansion process subjected to the strong wrinkling, buckling and thinning. In this work, the explicit finite elements Stampack® program was used for simulating the angioplasty and checking the plastic strain field of the expanded stent. From this analysis, it is possible to estimate the maximum diameter of the expanded stent and to avoid the presence of damage in its structure.*

Keywords: *angioplasty, cardiovascular engineering, hidroforming simulation, stent, structural integrity*

1. INTRODUCTION

Coronary heart diseases are most common reason for death in the western countries. In the United States, half a million people die every year due to the cardiovascular diseases (Gun et all., 2002). In most cases, the accumulation of the substances in the coronary arteries, such as cholesterol, is one of the principal causes of the heart diseases known as estenosis. Angioplasty using a catheter, balloon and a metallic tubular device, called a stent, has been extensively used to maintain the luminal diameter of the artery opened to receive the blood flow. The major role of the stent is to reinforce the artery wall and support the arterial compression pressure after the implant (Sigwart, 1997).

Although the restenosis problem is immediately solved by the angioplasty, there is still a risk of its incidence in 30% to 50% of cases (Gun et all., 2003). In this sense, several works have been published in the literature in order to improve the performance of stents implanted in patients and decrease the restenosis rate. Usually, a stent should be stiff after the angioplasty to reinforce the artery wall (Chua et all., 2003; Prendergast et all., 2005; Guimarães et all., 2006). During the angioplasty, the stent should be flexible as well, since it should bend and track the catheter movement into the vessel (Petrini et all., 2004). Moreover, the stress caused by the stent expansion process in the angioplasty could not be larger than the ultimate strength of the material.

In particular, this work will use a different approach to predict the structural integrity of a stainless steel stent after the angioplasty simulation by finite elements. Usually, most of papers found in the literature simulate the stents expansion process using the finite elements method and compare the maximum Von Mises stress with the ultimate strength (Serruys and Kutryk, 1998; Ahmad and Barrett, 1999; Etave et all., 2001; Chua et all., 2003; Prendergast et all., 2005). However, the pressure applied on the expandable balloon and stent increases with respect to the time during the angioplasty procedure. Since the load changes with the time and the stent is subjected to the plastic strain field, the static analysis based on the Von Mises stress will not provide correct results. In this case, an accurate procedure for the structural integrity analysis should be employed and the dynamic effects of the plastic strain with time, as well as, a more appropriate constitutive law for the stent material have to be considered.

The objective of this work is to estimate the regions of the stent structure subjected to the strong wrinkling, buckling and thinning after the expansion process simulation. For this purpose, the finite elements Stampack® program will be used for the simulation of the stent expansion and the plastic strain maps available in the post processing stage. Because of the angioplasty simulation depends on the time and the stent is subjected to the large plastic strain, an explicit finite element analysis is more realistic than the conventional implicit analysis (Stampack user guide, 2002). For the qualitative analysis, it will be used the Forming Limit Diagram (FLD) in order to provide the strain from the stent finite elements nodes and estimate its structural integrity. From this analysis, it is possible to estimate the maximum diameter and pressure that the stent may be subjected to and the regions of its structure that are considered safe.

2. STENTS FOR ANGIOPLASTY

A stent is a thin metallic tube with diameter between 1.5mm to 3.0mm before the angioplasty. Figure 1 shows that a stent is built from a repetitive unit, called cell, which is distributed along the cylindrical surface. Usually, the geometrical pattern of the cells is obtained from a laser cut process in a tube made of 316L stainless steel or an alloy of cobalt, titanium or gold (Serruys and Kutryk, 1998). During the angioplasty, a outward internal pressure is applied in a expandable balloon which expands or increases the stent diameter until its external surface to be in contact with the internal surface of the arterial wall. When the stent expands, each cell undergoes a large displacement in the vertical direction and the material hardening, due to the plastic strain, reinforces the arterial wall. Furthermore, the stent will be subjected to the large deflections in the elastic range during the movement of the catheter inside the vessel. Therefore, structures with a sinusoidal shape have also been incorporated in commercial stents in order to improve their flexibility in the longitudinal direction.

In the present paper, the performance of a stent designed by the topological optimization technique will be evaluated (Guimarães, 2005). This design technique has been applied in the definition of the geometry of one repetitive unit of the stent. The idea of this technique is to optimize the material distribution of the stent cell such as its structure has maximum hardening and flexibility. Subsequently, the cell with optimal geometry was distributed in the plane and wrapped into a cylinder to generate the three-dimensional stent model shown in the Fig. 1. The topology optimization program was written using the softwares Matlab® and ANSYS® and the creation procedure of the 3D stent geometry was developed in the AutoCAD® and Stampack® programs (Guimarães et all., 2006).

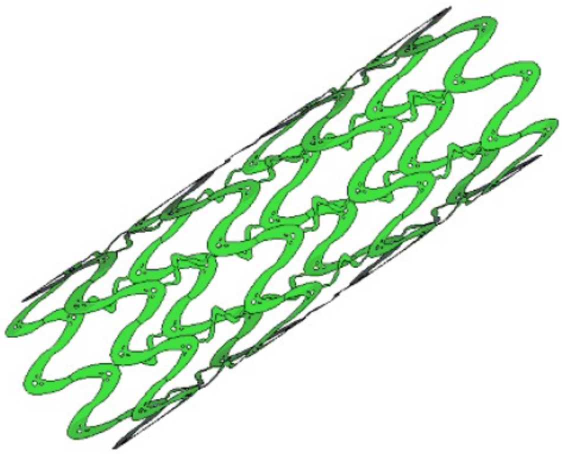

Figure 1. Stent geometrical model (Guimarães et all., 2006).

3. TUBE HIDROFORMING AS A TOOL OF STENTS EXPANSION PROCESS SIMULATION

Tube Hidroforming is a manufacturing process that uses the internal pressure applied by a fluid medium to obtain tubular components with a desired cross section (Batalha et al., 2005). Nowadays, this forming process has extensively been used in the mass production of automotive components, such as, exhausts parts, radiator frames, camshafts, etc. In hidroforming, the fluid medium applies an outward pressure in a polymer pad which expands the tubular blank. In practice, tube hidroforming is highly non-linear manufacturing process since the blank is subjected to large plastic strain and the contact between the plastically deformed solid surfaces is dependent of the time. For this reason, the analytical prediction of the pressure magnitude to be applied and the plastic strain field only is possible when the manufactured component has a simple geometry. In most cases, the prediction of these parameters is evaluated using a finite elements software for the hidroforming process simulation.

The stent expansion process in an angioplasty and the tube hidroforming are totally analogous. Then, in this work, it will be used the explicit finite elements Stampack® program for simulating the stent expansion by hidroforming. An incremental approach could also be employed but it requires efficient and robust contact algorithms in the processing of the strain and stress distribution between the blank and the polymer pad. On the other hand, the explicit approach is more computationally efficient, since the final shape and the stress and strain field of the tubular blank and tools are computed from the initial and boundary conditions and no contact algorithm is required. After the simulation, the regions of the stent material structure subjected to the strong wrinkling, thinning and bucking, will be studied and analysed as well as, the FLD available in the post-processing stage from the Stampack® program.

4. FORMING LIMIT DIAGRAM

The plot of the principal strains of some points from the deformed metallic sheet surface after the forming process is the Forming Limit Diagram (FLD). Usually, the major and minor principal strains are placed on the vertical and horizontal axis, respectively, as shown in the Fig. 5. Geometrically, before the forming process, each point on the sheet surface is the circle center with a given radius (Dieter, 1981). After the forming, the deformed circles becomes several ellipses. The major and minor axis from the ellipses are the principal strains directions. The magnitude of the principal strains is the increase of the axis length of the ellipses divided by the original length.

In a hidroforming process simulation, the circle centers on the formed sheet surface are the nodes of each finite element of the meshing. After the finite elements simulation, it is computed the percentage increase of the major and minor axes length of the ellipses and the results are plotted in the FLD (Stampack user guide, 2002). For each material, there is a diagram, known as Keeler-Goodwin diagram, which represents the maximum value of the principal strains of the sheet material before the rupture (Dieter, 1982). Hence, the FLD compares the plot of principal strain magnitude from the finite elements nodes with the Keeler-Goodwin diagram. If any point is larger than the Keeler-Goodwin diagram, it is expected a rupture of the sheet material in that finite element node. This structural integrity evaluation procedure is more accurate than the Von Mises stress method since as the dynamic effects of the pressure applied on the stent as the material constitutive law used in the forming are considered in the analysis.

5. SIMULATION OF THE STENT EXPANSION BY FINITE ELEMENTS

5.1. Geometrical and finite elements model of the stent

The minor is the size of the smallest finite element in the blank meshing, the larger is the time increment required for the computational simulation of the explicit finite elements program (Stampack user guide, 2002). Since the stent cell length shown in the Fig. 1 is very small and equals to 1,5mm, the total processing time spent on the simulation may become impractical. In this way, in this work an amplified geometrical model of the stent will be used in order to decrease the processing time. For obtaining this model, the stent original dimensions shown in the Tab. 1 were multiplied by 100. As the simulated stent model is in amplified scale, it was used the model similitude theory in order to calculate the actual pressure magnitude to be applied in the stent expansion in original scale (Murphy, 1950).

Table 1. Stent dimensions shown in the fig. 1

Diameter	3 mm
Length	10.17 mm
Thickness	0.1 mm

In the Stampack® software, the blank or stent meshing is created from the unstructured triangular shell elements. This type of finite element is employed to decrease the processing time. Moreover, due to the geometrical complexity of the stent, these elements are more appropriate for meshing its structure shown in the Fig. 1. It can be seen in Fig. 1 that the stent is only a shell model, but its thickness is also considered in the formulation of finite elements. The expandable balloon finite elements model will be not considered in the present paper. In this case, the internal pressure will be directly applied on the internal surface of the stent shell model. This is a reasonable approximation since the energy absorbed by the balloon is very small when compared with the plastic strain energy from the expanded stent.

5.2. Stent material model

The stent model considered in this work is made of the 316L stainless steel. Most of papers on the stent analysis use a bilinear with isotropic hardening model for the constitutive law of this material (Ahmad and Barrett, 1999; Etave et all., 2001; Chua et all., 2003; Prendergast et all., 2005). As the stent material is isotropic, a Von Mises model for the equivalent stress calculation, σ_{eq}, is used in the estimative of the elastic-plastic stress state. The Stampack® software uses a more general material model:

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

where σ_{11} and σ_{22} are the normal stress and σ_{12} represents the shearing stress. The parameters r_0, r_{45} and r_{90} known as the Lankford coeficientes determine the plastic material anisotropy. The subscripts 0, 45 and 90 are the material anisotropy angles measured in degress. The material model defined in the Eq. (1), called Hill 48 model, is more appropriate for the modeling of sheet with anisotropy planes produced from the manufacturing process. Because of the stent material is isotropic, the Lankford coeficients are equal to 1. For an isotropic material, the Eq. (1) corresponds to the Von Mises material model (Stampack user guide, 2002).

In the bilinear with isotropic hardening material model, the plastic range is modelled by a linear approximation of the stress and strain diagram of the 316L stainless steel. This model is more used in the analysis of structures subjected to the large plastic strain and when the loading is static and does not depend on the time (Stampack user guide, 2002). For the analysis of sheet forming, the applied load changes with respect to the time and another material model should be used. In this work, it will be used the Ludwig-Nadai model:

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

where K, n and ε_{po} are parameters material to be determined experimentally through of the uniaxial tensile test in a 316L stainless steel piece. The parameter ε_p represents the efective plastic strain caused by the equivalent stress, σ_{eq}. Equation (2) is more realistic if used in the strain and stress behaviour modeling in the forming process. The Stampack software has the values of these parameters for several materials used in the sheet manufacture. The 316L stainless steel parameters are described in the table 2.

Table 2. Parameters from the Ludwig-Nadai model for the 316L stainless steel.

Parameter	**Magnitude**
K	1161 Mpa
n	0.28
ε_{po}	0.21

5.3. Initial and boundary conditions

The hidroforming process simulation by finite elements is a problem of initial value and boundary conditions. Indeed, the pressure versus time diagram applied on the internal surface from the stent should also be provided by the user. The total time of stent expansion will be considered to be $1{,}5\text{x}10^{-3}$s (Chua et all., 2003). This parameter was estimated based on the duration of the stent and balloon expansion in a typical angioplasty. The relation between the pressure magnitude to be applied on the stent and final diameter of the artery should be evaluated by trial-and-error. It is difficult to predict what is the pressure value corresponding the stent diamater due to the material and geometrical complexity of its model. The idea is to adjust the pressure magnitude after some simulations by checking the final diameter from the stent. The pressure will change linearly with respect to the time since the zero value until the magnitude adjusted by trial-and-error.

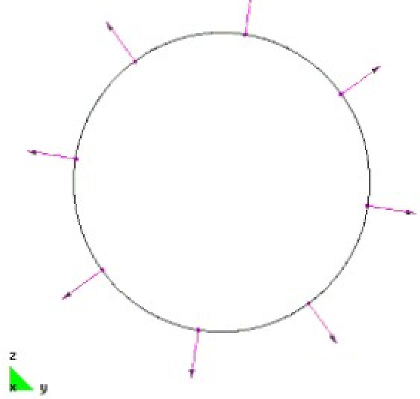

Figure 2. Cross section from the stent subjected to the outward pressure.

Figure 2 illustrates the cross section of the stent subjected to outward pressure. The arrows indicate the direction of the applied pressure on its internal surface. In the stent expansion, all nodes from the model are free to move in any direction. When the stent diameter increases, its length decreases. Although this structure is indeterminate statically, the Stampack® software will solve the finite elements non-linear equation system by considering that the number of parameters and equations is the same (Stampack user guide, 2002).

6. ANALYSIS OF THE RESULTS

Figure 3 shows the final shape of the stent obtained by the hidroforming simulation. The final diameter increased 125%, that is, the stent in original scale was implanted in a artery with a diameter equals to the 6,75mm. The pressure magnitude applied on the amplified stent internal surface was adjusted to be 63MPa. Using the similitude theory, it may be demonstrated the pressure to be applied in the stent model in original scale is minor than the rupture pressure of a expandable balloon used in angioplasty (Guimarães et all., 2006). In addition, the Fig. 1 shows that the cross section of the stent after the expansion is approximately circular and free of irregularities, which proves this stent model does not have any region of structural instability.

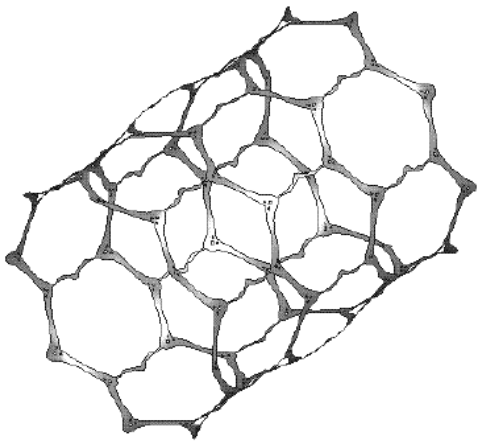

Figure 3. Final shape from the stent.

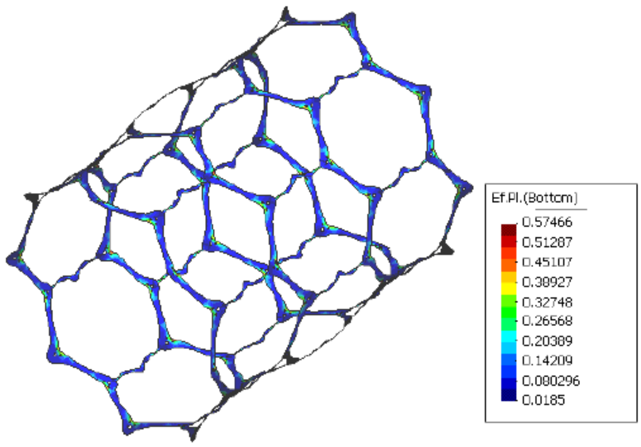

Figure 4. Plastic strain distribution of the stent.

The plastic strain distribution from the stent is shown in the Fig. 4. It can be seen that the plastic strain energy is distributed inside the cells and the hardening of the stent improves its stiffness and mantains the opened arterial wall. Figure 5 illustrates the stent structure regions subjected to the strong wrinkling, thinning or buckling due to the stress generated during the expansion. The wrinkling and the thinning are caused by the compression and tension stress, respectively. A crack placed in a region like these increases the risk the stent material rupture. Because the studied stent model does not have any region subjected to the strong wrinkling or thinning, the stent diameter could be expanded 125% without any structural integrity risk.

From the quantitative point of view, Fig. 6 proves that the stent model analysed in the present paper may increase its diameter 125%. All nodes of finite elements shown in the FLD of the Fig. 6 are below the Keeler-Goodwin diagram for the 316L stainless steel. Therefore, this stent geometrical model may be used in an angioplasty with a arterial wall diameter until 6,75mm.

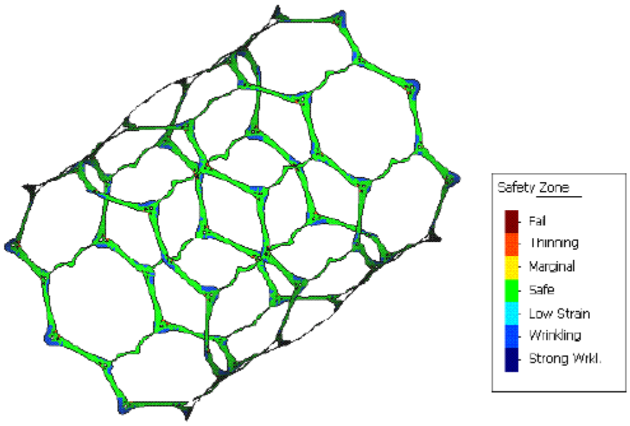

Figure 5. Stent regions subjected to the wrinkling, thinning and buckling.

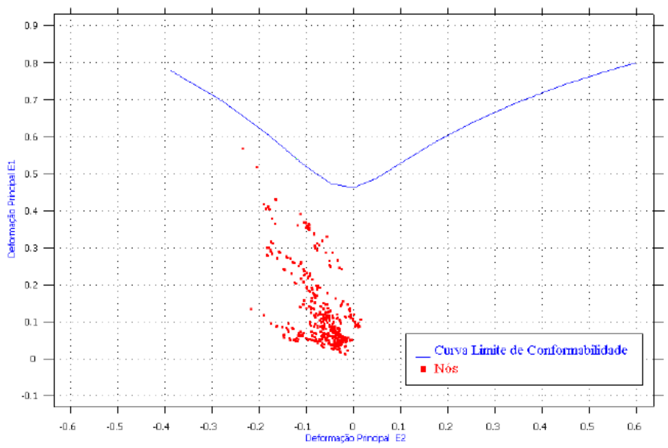

Figure 6. Forming Limit Diagram for the stent expansion

7. CONCLUSIONS

In this work, a methodology was used based on the hidroforming simulation by finite elements for the accurate computation of the structural integrity of a stent for angioplasty after the expansion process. The forming limit diagram and the plastic strain maps provided by the finite elements simulation took into the dynamic effects account of the pressure applied on the stent during the hidroforming. Although the expandable balloon was not considered in the analysis, it was possible to extract some design parameters desired in a angioplasty, such as, the pressure applied, the stent final diameter and the structural integrity analysis using the FLD. Thus, it was demonstrated that the FLD may be used as a appropriate tool for the accurate analysis of the structural integrity of any stent design in particular.

The stent geometrical model studied in this work met the design specifications of a typical angioplasty. The applied pressure on the stent during the angioplasty was not larger than the maximum pressure to be applied in the expandable balloon material. Furthermore, the stent plastic strain maps after the angioplasty did not show the presence of the regions subjected to the strong wrinkling, buckling or thinning. This situation is valid only when the final diameter of the stent increases 125% with respect to the original diameter in the expansion process. In the future, it will be studied what is the maximum pressure magnitude to be applied in the stent without the presence of damage in its structure.

8. ACKNOWLEDGEMENTS

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