NUMERICAL SIMULATION OF THE CRIMPING PROCESS IN STENTS

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Abstract. *Cardiovascular stents are metallic devices that are used in the treatment of atherosclerosis. Mostly, this device is used in the Percutaneous Transluminal Coronary Angioplasty (PTCA) in order to decrease the restenosis occurrence. The majority of stents used in this procedure are the balloon expandable ones. Before the angioplasty, the stent is mounted on the folded explandable balloon using a radial pressure applied on its external surface. Hence, the cross section from stent is reduced in order to allow good deliverability and access to coronary stenosis. The objective of this work is to study the abovementioned process, called crimping, using hidroforming simulation by finite elements. Tube Hydroforming is defined as application of pressure to the internal or external surfaces of the tube, to obtain tubular compounds with different cross sections. The numerical simulation of crimping process has been applied to a commercially available stent model. The execution and analysis of this simulation have been carried out using the explicit finite elements software, Stampack®. Since the plastic deformation was applied only in the stent, in order to simplify simulation, the balloon/catheter device was idealized as a tubular compound with thickness close to the original ones. The results obtained illustrate the viability of using the hydroforming module of the Stampack software to study the mechanical behavior of the stent during crimping process.*

Keywords*: catheter-balloon, crimping, hydroforming, stents.*

1. INTRODUCTION

Ischemic heart disease, resulting in a reduced flow through narrowed atherosclerotic coronary arteries, is caused by accumulation of lipid and other substances derived from bad alimentation, active smoking and many other factors. Since this is an ancient problem, scientific society is trying to develop techniques and devices to decrease or maybe solve this problem. The most famous technique is Percutaneous Transluminal Coronary Angioplasty (PTCA) which was created in 1977 by a young Germany physician at a hospital in Zurich, Switzerland (Grüntzig *et al*., 1979). In this procedure a catheter with a folded balloon on its extremity is placed in the patient's blood vessel. This device is guided up to the region obstructed by the lipid plaque (lipid accumulation) and then the balloon is inflated, in a controlled manner by the surgeon. Expansion of the balloon is done by a fluid injection, causing the compression of the lipid plaque against arterial wall, liberating the arterial lumen and normalizing the blood flow. This technique is used around the world due to the satisfactory results achieved.

Unfortunately, the angioplasty procedure using only the catheter and balloon set do not solve the blocked artery problem. In most cases, there is a reduction of arterial lumen cross section area after the angioplasty and the problem is not solved. In these cases, it is recommended the use of a stent, a metallic tube that reinforces the artery wall and avoids the restenosis occurrence in the patient. Several commercial stent models have been successfully used, such as self expandable stents (Kim *et al*., 2008) and balloon expandable stents, but there are still many stent design problems that should be studied and researched. In this study only balloon expandable stents will be considered.

Many researchers of this area have studied the behavior of the stent during its mounting in the catheter-balloon, named as crimping (Serruys and Kutryk, 1998). During the crimping process, the stent can not cause damages the expandable balloon wall. Furthermore, the stent can not slip with respect to the external surface balloon after the crimping process. For this purpose, the assembly pressure to be applied on the stent should be correctly chosen. The aim of this study is to present some results of preliminary tests simulating stent mounting on the balloon during the crimping. In this study, simulation of crimping process by hydroforming was made using the finite explicit elements software, Stampack®. The preliminary tests are made to estimate some difficulties and limitations that may arise along the modeling process and adaptation of the hydroforming module of Stampack® software to the crimping process.

2. STENT EXPANSION PROCESS AND CRIMPING

Figures 1 and 2 shows a commercial model of stent mounted on a catheter balloon used in an angioplasty and the steps followed during the angioplasty process and stent implanting, respectively.

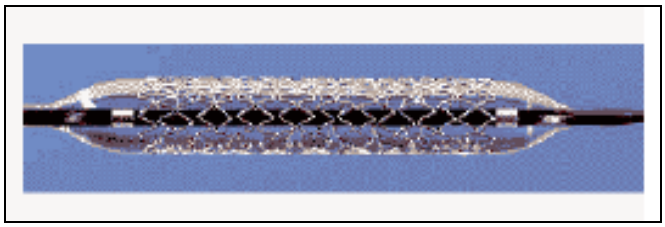


Figure 1 – Commercial stent mounted on a catheter balloon at the expanded configuration (Serruys and Kutryk, 1998).

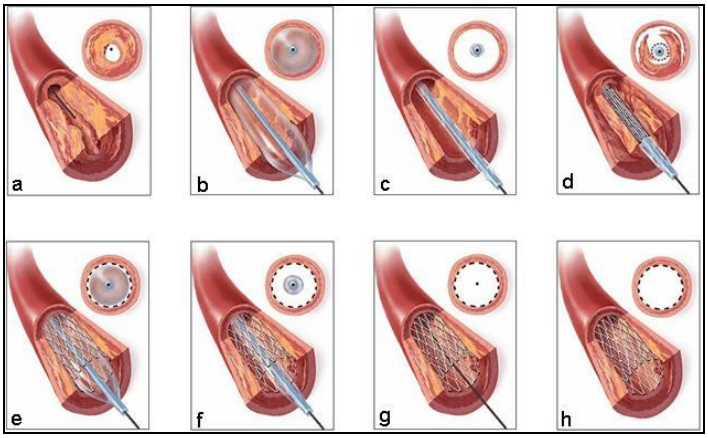


Figure 2 – Schematic illustration of the angioplasty process and stent implanting (adapted from New York Heart Associates, P.C, accessed in November 2007).

Majority of stents are made of stainless steel 304, but recently a new cobalt-chrome alloy is taking place at the market due to its mechanical properties exhibit better results when compared to stainless steel 304. Manufacturing processes of the stent is done by laser cutting on a milimetric scale, and after cutting the stent is subjected to a procedure of eletropolishing in order to remove all barbs from the cutting process. In the angioplasty process shown in the Figure 2, an outward radial pressure is applied in the expandable balloon which causes the stent expansion. Conversely, in the crimping process, an inward pressure is applied on the external surface of the stent in order to reduce its diameter through plastic deformation by allowing the mounting of the stent in the expandable balloon.

The main objective of this technique is to provide a crimping without damages to the catheter-balloon, because it may cause holes in the balloon material which may cause failure to the devices (stent-catheter-balloon). These holes may be initialized by: bad mounting of the stent in the balloon during the crimping process and/or during its navigation in the patient's artery by flexion along the irregular way.

Hydroforming simulation by finite elements was used to study the mechanical behavior of the stent during crimping process. This procedure was chosen by the fact that tube hydroforming and the stent crimping process are totally similar. Tube hydroforming can be defined as a manufactory process that combines compression and/or internal pressure applied on a fluid media, to obtain tubular compounds with different cross sections (Batalha *et al.*, 2005).

3. MATERIALS AND METHODS

The hydroforming module of the finite elements Stampack® software was used in the simulation of stent crimping. Before the simulation, it was necessary the execution of initial tests to better understand the possible difficulties to be found in this study. The objective of this previous study was to estimate the number of steps to be used and the pressure magnitude to be applied in stent simulation during the finite elements nonlinear solution process. In this way, it was possible to adapt the functions of the Stampack® software to the stent crimping simulation process.

The initial test of simulation of this process was modeled with the following devices, as shown in the Fig.3:

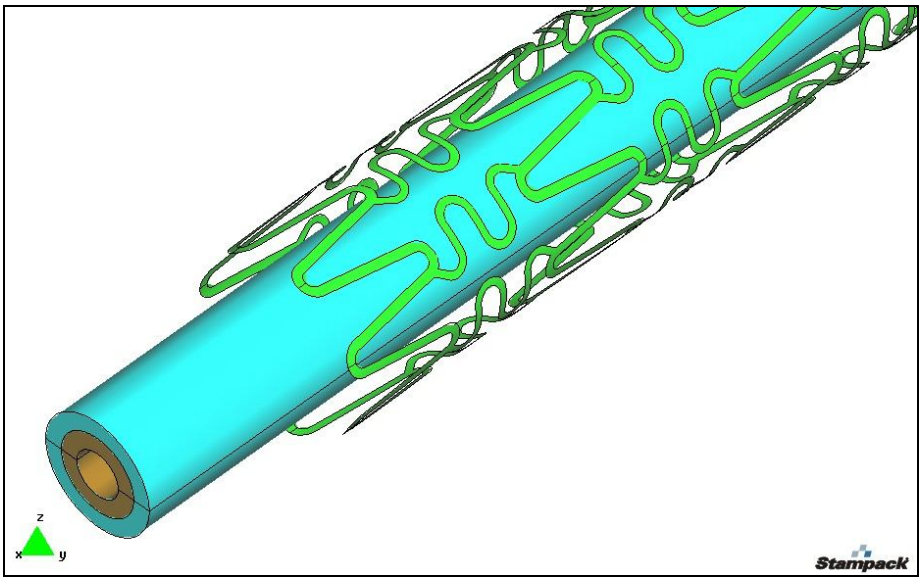
- Stent (commercial design used by Araújo (2007));

- Angioplasty balloon on its folded configuration (idealized as a cylinder);
- Catheter (idealized as a cylinder).

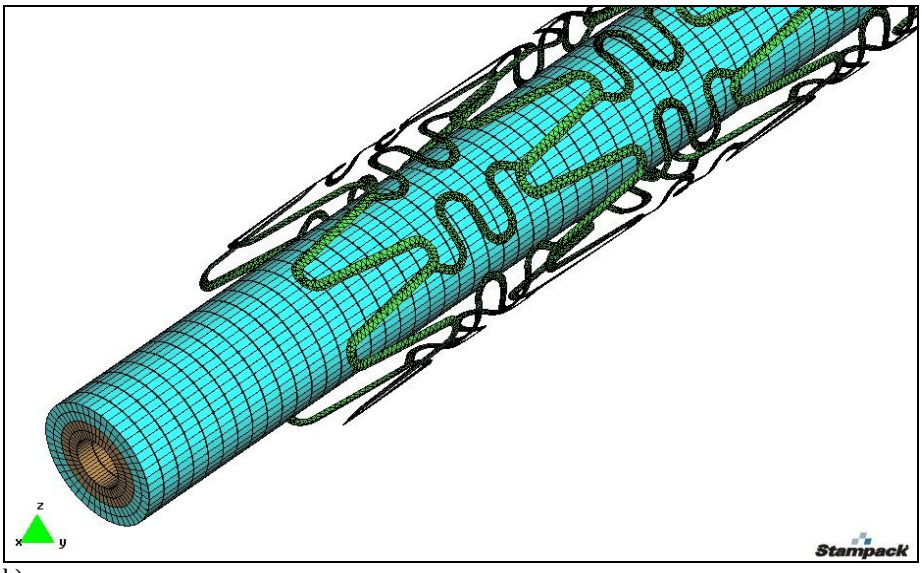
The finite elements model of the stent was meshed with an unstructured mesh using triangular elements of the shell type, the so called Basic Shelll Triangle (BST), this element is compound by two other types: Basic Plate Triangle (BPT) and Constant Strain Triangle (CST). BST element has 3 nodes with 3 degree-of-freedom, due to the linear displacements of each node in the three-dimensional space (Oñate *et al.*, 1994; Zarate, 1996).

The finite elements model of the angioplasty balloon and the catheter were meshed with solid elements (hexagonal) on a structured distribution, this element uses the 2 x 2 x 2 Gauss point integration scheme with constant pressure in order to avoid volumetric locking. The formulation is based on the hyperelastic model with Von-Mises yield criterion (Stampack® - Data Input, 2003).

The material of the stent used in this initial test, stainless steel 304 and its mechanical properties are shown in Tab. 1. The hardening law used to simulated plastic behavior was the Swift's law and isotropic hardening. The yield criterion was Hill 48 (Stampack®, 2003).



a)



b)

Figure 3. Devices used on the crimping process of the stent. Without the finite elements mesh (a) and with the finite elements mesh (b).

The model used in the simulation of the mechanical behavior of the angioplasty balloon and catheter was the hiperelastic constitutive model of Ogden for rubber like materials. Table 2 shows the parameters used in the simulation for these materials.

The software requires of its user the definition of some mechanical properties of the material and the parameters of de Ogden's model. The pressure used on the process was $4{,}2x10^7$ (Pa) on a amplified scale equivalent to approximately 0,42 (MPa) in the real scale. The pressure was applied on the radial direction at the external surface of the stent.

The tridimensional models of the devices envolved on the stent crimping process possess the dimensions represented on Tab.3. It is emphasized that these dimensions are on an amplified scale on the order of 100/1.

Table 1 – Properties of the 304 stainless steel stent

Parameters	Values
Young's Modulus	183 GPa
Poisson' ratio	0.29
Density	8030 kg/m^3
n	0.28
k	1160.4 MPa
$R_{0, 45, 90}$	1
Sy	284 MPa
Hill exponent	1.72

Table 2 – Properties of the balloon and catheter materials

Parameters	Values
Bulk Modulus	1660 MPa
Density	2160 kg/m^3
Sy	90
Hardening Modulus	16600 MPa
Ogden Parameters (Laroche et al., 2007)	
α1	0.2
μ1	154 MPa
α2	12
μ2	13 MPa
α3	0
μ3	0

Table 3 – Dimensions of the devices used on the crimping process

Device ↓ / Dimensions →	L [mm]	h [mm]	di [mm]	de [mm]
stent	1317	10	300	310
Balloon	2000	30	140	200
catheter	2000	30	80	140
L = length; h = thickness; di = internal diameter; de = external diameter;				

4. RESULTS AND DISCUSSION

The crimping process simulation was initialized after the geometry determination of expandable balloon, catheter and stent, the creation and treatment of the finite elements models, and the definition of the mechanical properties required by the Stampack® software. The total time for the numerical simulation of the crimping process by finite elements was of approximately 10 hours in a computer with two Pentium® 4 processors (3Ghz) and 1Gb RAM.

Figure 4 illustrates the final shape of the stent after crimping. Simulation shows a reduction in the stent diameter with respect to the initial diameter of approximately 35% (final diameter equal to 194 mm). Figure 5 shows the crimped stent on the balloon.

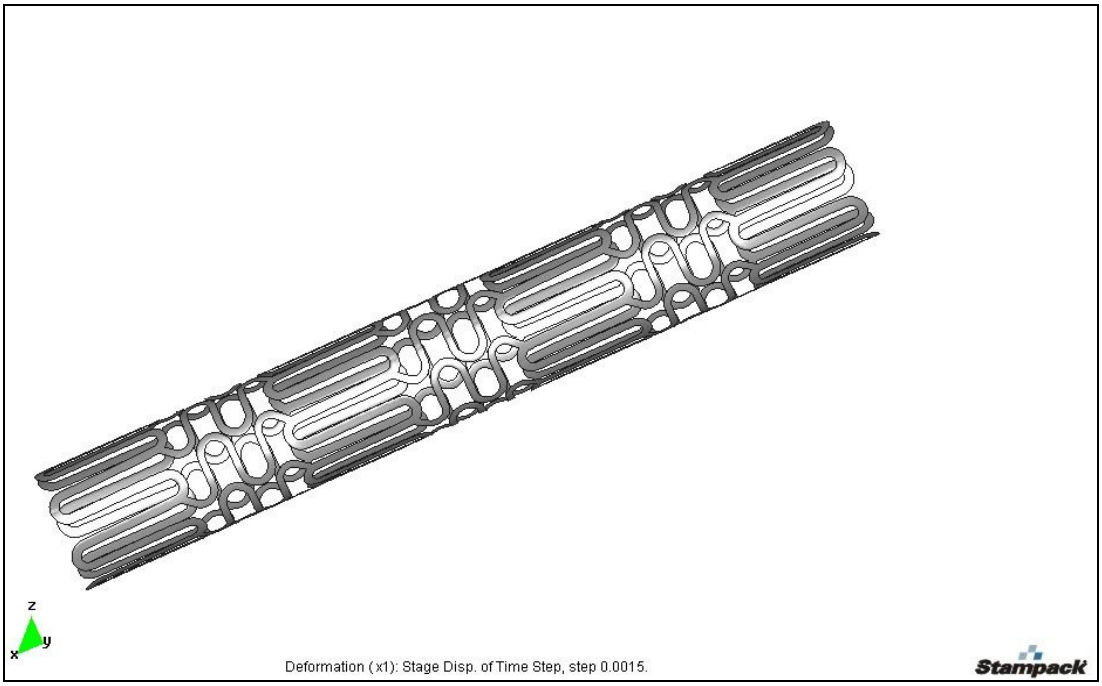


Figure 4 – Final shape of the stent after crimping process.

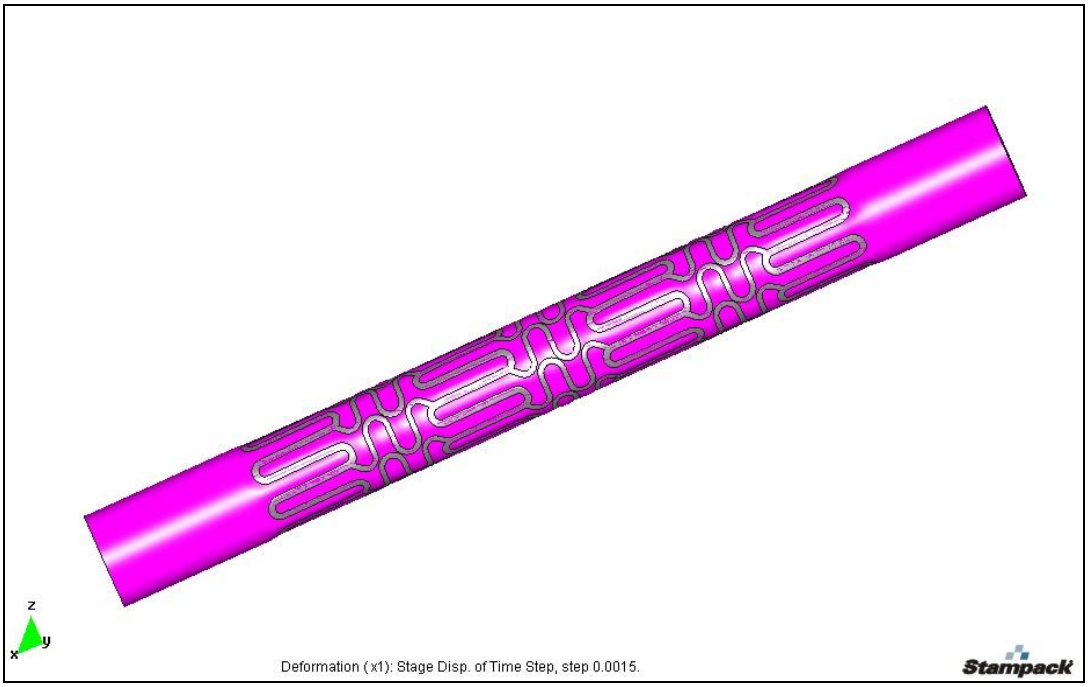


Figure 5 – Stent crimped on the idealized balloon.

The equivalent plastic strain map shown in the Fig.6 indicates the region of the stent which is subjected to more plastic deformation. It is possible to note that this deformation is rightly distributed. According to Serruys and Kutryk (1998), the larger the plastic strain, the larger the stent mechanical hardening is. Therefore, the regions subjected to larger deformations increase the stent stiffness**.** When the stent is mounted on the balloon, there is no risk of detaching

during its implantation. It is interesting to note that the elastic recoil of stent after the crimping was negligible. Therefore, the stent will not slip on the balloon external surface.

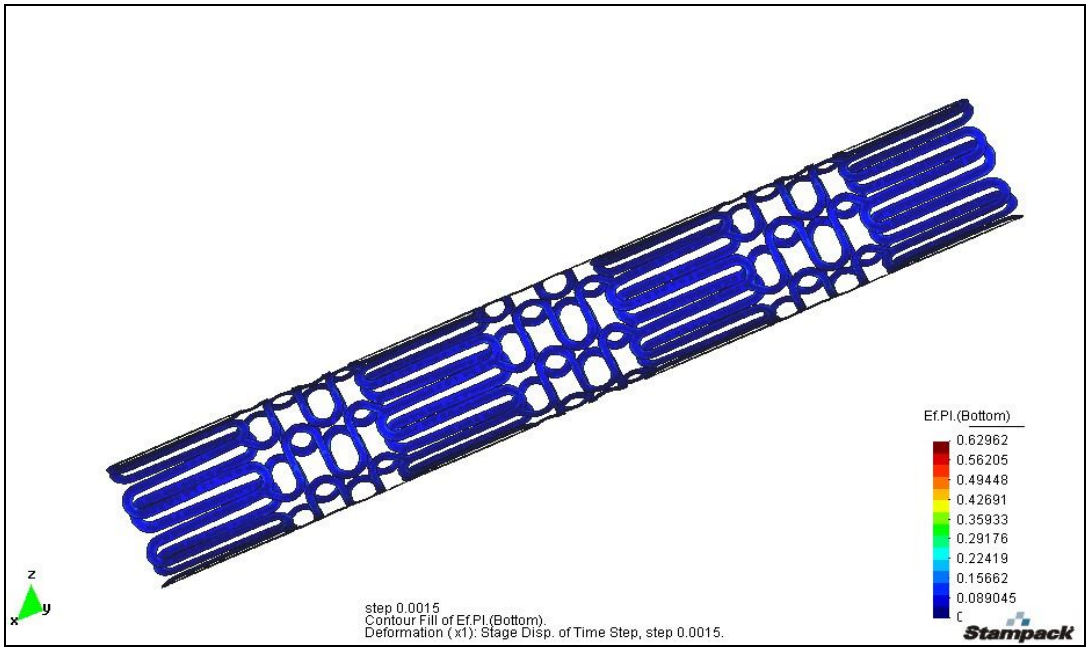


Figure 6 – Effective plastic deformation.

The analysis of the regions of the stent structure subjected to failure can be observed in the Forming Limit Diagram (FLD) illustrated in the Fig.7. This diagram shows regions where possible failures will occur, for example, wrinkling, thinning or buckling. In the regions with tendency to increase the thickness it may occurs wrinkles. In the Forming Limit Diagram each point represents the principal strains of nodes of the stent finite elements model. As shown in Fig.8, all points are below the Keeler-Goodwin diagram from 304 stainless steel stent. Thus, there is no risk of failure for the studied stent model during the crimping process.

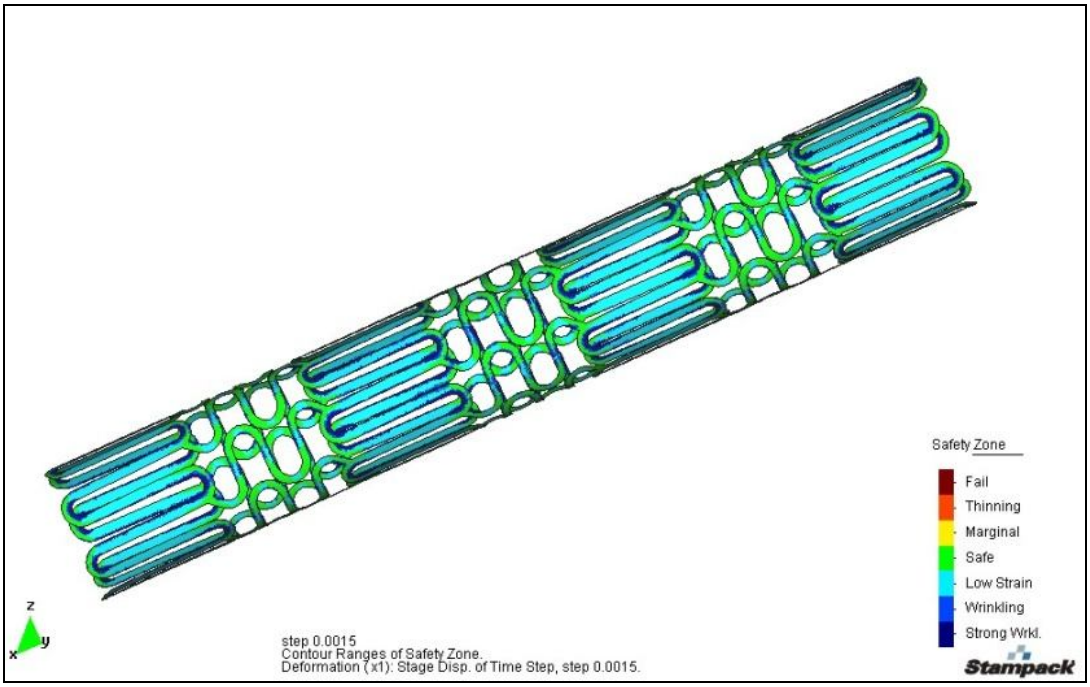


Figure 7 – Safety zone.

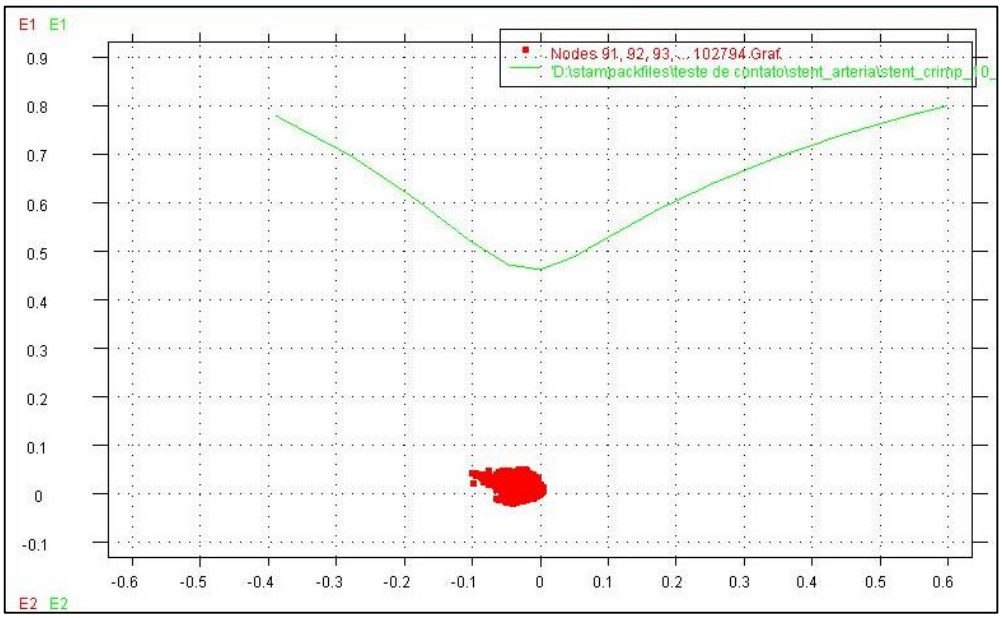


Figure 8 – Forming Limit Diagram for the stent crimping.

Is clearly possible to note on Fig.9 how much the stent deformed the external surface of the expandable balloon. The Fig. 10 shows the strain distribution due the contact between the stent and the balloon. It is illustrated that the maximum strain is relatively low (0.19) by considering that the balloon material is hyperelastic. So, it is expected that the stent crimping process do not cause any failure to the expandable balloon.

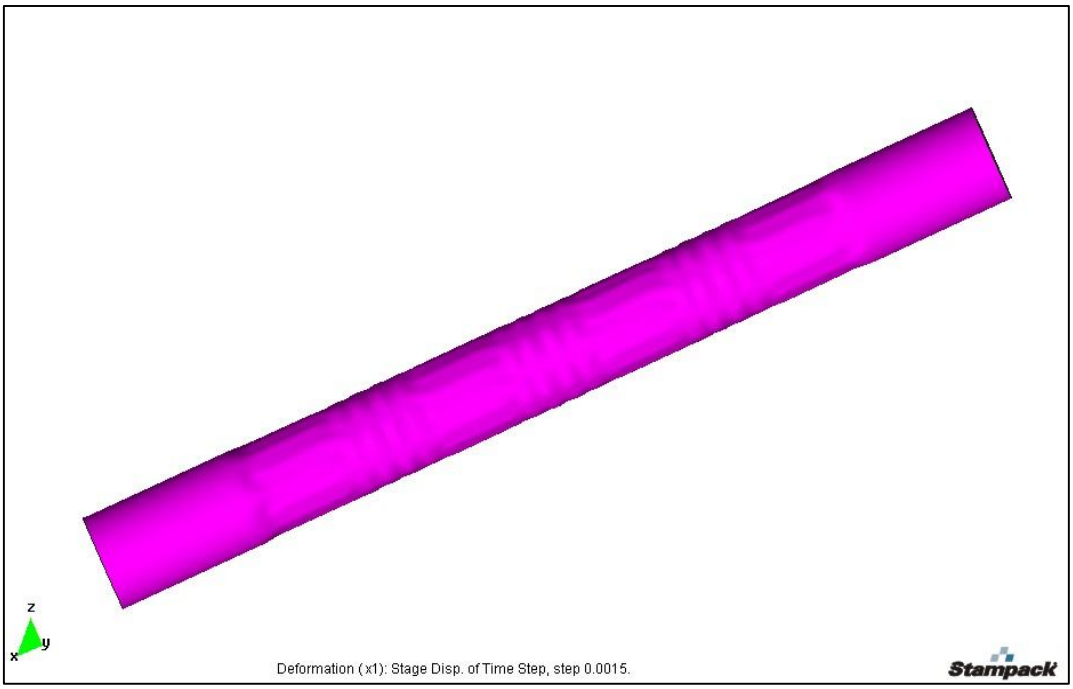


Figure 9 – Deformed expandable balloon.

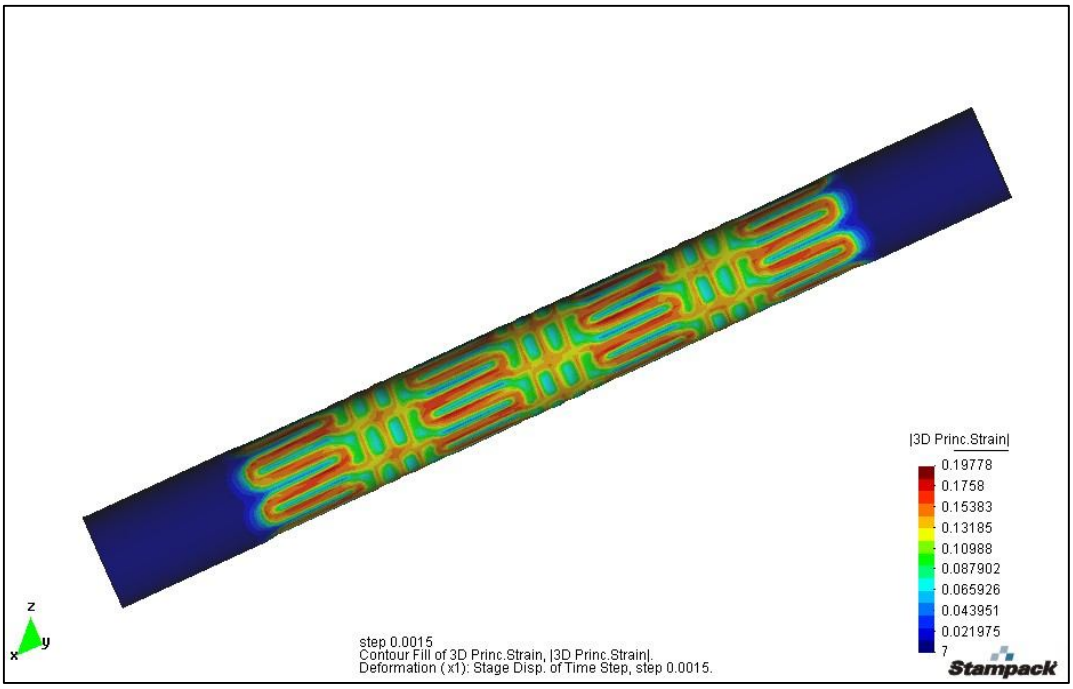


Figure 10 – Plastic deformation distribution of the balloon.

5. CONCLUSIONS

At the end of this study, it was possible to verify that the hydroforming module of the Stampack® software was able to model and to study the successfully stent crimping process. Thus, the Stampack software can be used as a viable tool for the modeling of the crimping process of any commercial stent model. From the obtained results, it was demonstrated that crimping process did not cause damages to the stent model and the expandable balloon have studied in this work. It was observed that the plastic strain distribution of the balloon has been relatively low which do not cause damages to its material. The Forming Limit Diagram do not shown any point with a strain larger the Keeler-Goodwin limits, therefore, the stent will not be subjected to failures as wrinkling, thinning or buckling. Another interesting point is the small elastic recoil from stent. Hence, it will not slip on the external surface of the expandable balloon which becomes the angioplasty procedure more safe.

6. ACKNOWLEDGEMENTS

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