



Stent length in the treatment of aneurysm determined by accommodation and variation of aortic diameter: Case Study

Comprimento do Stent no tratamento da aneurisma determinado pela acomodação e pela variação do diâmetro da aorta: Estudo de caso

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ABSTRACT

In recent years, patients with thoracic and abdominal aortic aneurysms have relied on the clinical alternative of treatment with endovascular stents to obtain relief since SLE stents support the weak area of the aorta. This type of treatment of abdominal aortic aneurysm with stents is the most applied alternative as treatment today. The aim of this study is to determine the length of the stent in the treatment of aneurysm determined by the accommodation and variation of the diameter of the aorta. , by means of a mathematical algorithm that allows the definition of an equation to predetermine the final length after being released from the stent catheter in the implantation of a stent or three stents (triple stent) and the treatment of the tomography



images. To establish the mathematical equation, a nitinol Lumini® stent, manufactured by the company Braile® Biomédica (Brazil), of the self-expanding type inserted in a tube of known diameter was used. To obtain the equation, measurements of the dimensional variation of the cells were made, from the insertion diameter to the free expansion zone of the stent, where the cells would be in their geometric form of retrieval by the memory of the material, and where there is no more dimensional variation and with the processing of the results, a mathematical model was obtained that allows to predetermine the change of extension for each stent applied in the treatment, depending on the diameter in which it will be inserted.

Keywords: Biomechanics, Stent, Triple Stent, Aneurysm.

RESUMO

Nos últimos anos, os pacientes com aneurismas aórticos torácicos e abdominais têm contado como alternativa clínica do tratamento com endopróteses endovasculares para obter alívio já que as endopróteses les oferecem suporte à área fraca da aorta. Este tipo de tratamento de aneurisma, da aorta abdominal com stents é a alternativa mais aplicada como tratatamento atualmente. O objetivo deste estudo é determinar o comprimento do Stent no tratamento da aneurisma determinado pela acomodação e variação do diâmetro da aorta. ,mediante um algoritmo matemático que permita definir uma equação para predeterminar o comprimento final depois de liberado do cateter do stent no implante de um stent ou três stents (triplo stent) e o tratatamento das imagens da tomografia. Para estabelecer a equação matemática, foi utilizado um stent de nitinol Lumini®, fabricado pela empresa Braile® Biomédica (Brasil), do tipo auto expansível inserido num tubo de diâmetro conhecido. Para obter a equação, foram realizadas medições da variação dimensional das células, desde o diâmetro de inserção até a zona de expansão livre do stent, onde as células estariam em sua forma geométrica de recuperação pela memória do material, e onde não há mais variação dimensional e com o processamento dos resultados, foi obtido um modelo matemático que permite predeterminar a mudança da extensão para cada stent aplicado no tratamento, dependendo do diâmetro em que será inserido.

Palavras-chave: Biomecânica, Stent, Triplo Stent, Aneurisma.

1 INTRODUCTION

Approximately 20% of the population has an aneurysm and most don't even know they have the disease. This pathology kills 6,500 people between 40 and 70 years a year. The traditional treatment for aortic dissection consists of surgical intervention with interposition of vascular graft. These surgeries represent a major trauma, with substantial morbidity and mortality in a group of patients often elderly and debilitated by other comorbidities.

Nowadays both to lower costs, protect the environment, ensure sustainability [1-3] and improve public health, multidisciplinary teams of engineers and physicians work in various sectors of the medical and materials field in the development of new materials, prostheses [4-5], medical instruments [6] and technologies to improve the standard of living of patients who need these devices.

The rupture of an aortic artery aneurysm is one of the most serious conditions that can reach an emergency service. Currently, medicine has a lot of interest in the treatment of peripheral vascular diseases with endoprotheses. This type of endovascular treatment refers to that region within a blood vessel where endovascular aortic repair (EVAR) is required, where Stens result in a new form of treatment for thoracic



aortic aneurysms that is less invasive than open surgery. The stent is a tube-like endoprosthesis of synthetic tissue (graft) supported by a mesh-shaped metal structure, which is inserted into the vascular lumen in the patient's compromised zone to prevent rupture of the aorta by means of mechanical pressure, whose function is to keep the arterial lumen open.

Cardiovascular stents are endoprostheses composed of metal meshes used in order to reverse conditions of blockage in arteries, caused by pathologies such as Arteriosclerosis, is a simple and minimally invasive solution for the repair of the aortic arch that allows the consistency and reliability of the procedures.

Endovascular repair of aortic aneurysm has considerable potential and advantages over the surgical approach as a treatment, due in part to surgical repair being associated with high mortality rates. Endovascular repair of aortic aneurysms shows considerable viability in patients. This procedure is especially useful in patients with significant comorbidities and high surgical risk, as it is less invasive and has a shorter recovery than surgical repair, according to the literature.

With the advancement of endovascular surgery techniques, the implantation of stents in the aorta emerges as an important alternative to conventional surgery, in order to enable a less aggressive procedure, with a mortality rate of 9% and paraplegia of 3%, with less need for blood transfusion and considerable reduction in the length of hospital stay. The clinical success in the implantation of endovascular prostheses in aortic pathologies ranges from 76% to 100%. With the advancement of endovascular techniques, the implantation of stents in the aorta emerges as an important alternative to conventional surgery. This technique has more advantages over the traditional surgical procedure, but further studies are needed to better establish these parameters.

The improvement of endovascular treatment materials and techniques has made possible the successful repair of aortic aneurysms using stents, endoprosthesis, which, implanted in the aorta, allows the exclusion of the aneurysm and revascularization of the arteries. According to the literature in recent years the use of stents the application of stents has provided a new perspective for the treatment of aortic aneurysms, subclavian artery aneurysms and arterial traumas, complications resulting from aortic dissections, occlusive disease of the lower limbs and abdominal aortic aneurysms.

The new materials and the techniques and procedures of endovascular treatment made possible the treatment of the disease through the successful repair of the aortic aneurysms using the stent endoprosthesis, which, after implantation in the aorta, allows the exclusion of the aneurysm and the revascularization of the arteries [7]. According to the literature, visceral artery aneurysms and visceral artery aneurysms can be defined as aneurysms that affect the arteries, celiac, superior or inferior mesenteric and their branches and are relatively rare. Of the aneurysms, the most commonly involved arteries are the splenic and hepatic artery and can be life-threatening conditions with a high incidence of rupture and hemorrhage [8].



The aorta is considered the main artery of the human body and has the function of carrying blood from the heart to the organs[9]. Aneurysm is when there is a dilation of the wall of an artery, that is, a permanent variation of at least 50% more than the normal diameter caused by various causes[10]. This vascular problem is the cause of higher mortality and is repeated more in men than in women, especially from the age of 50. In Brazil, about 4% of the population suffers from the problem and, in people over 60, the percentage increases to 6%. Severe disease, easily detectable. When it comes in time and correctly, it presents good results, with very low level of post-surgery complications, something around 5 to 10% of cases. [9]

The presence of an aneurysm is common, with the potential for significant morbidity and mortality. Most patients are asymptomatic, and in most cases seek medical attention for findings of pulsatile mass when performing physical examination, by abdominal imaging studies for another purpose, or through ultrasound screening programs for abdominal aortic aneurysm (AAA) [10]. Usually when symptoms occur, patients present with back pain, abdominal pain, or thromboembolism may occur, leading to symptoms of limb ischemia. Aneurysms that produce symptoms have an increased risk of rupture, which is associated with high mortality rates.

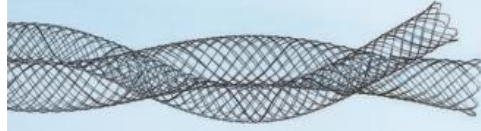
A response considered important for endovascular techniques that currently allow the correction of about 80% of abdominal aortic aneurysms is with the use of stents through endovascular stent implantation or that results in an advance of vascular surgery [11]. The Stent is a metal structure, covered with an expanded polytetrafluoroethylene (PTFEE) film. The architecture of stents is composed of rings that can be either individual assembly or sequential accumulation in a repeating pattern. The individual rings can simply be attached to each other, similar to the Gianturco (Cook) stent. Stents can be made of materials such as stainless steel 304 SS, 316 L SS, tantalum, elgiloy (SS), platinum, cobalt alloy and nitinol[8]. Dyet &Schurmann[9], mention that the stainless steel stents of the 316 L series have good biofunctionality. Nitinol is an alloy of nickel and titanium with thermal memory properties, which allows it to be compacted tightly within a release system when cooled, to expand rapidly and reacquire its pre-designated shape and size, after the release of its placement system into the bloodstream. In addition, it has great elasticity and fracture resistance. Nitinol is the acronym for Nickel-Titanium Naval Ordnance Laboratories, whose metal alloy was initially developed for military purposes [9]. In 1985, the prototype stent graft consisting of a continuous mesh expandable by a stainless steel balloon was used for the first time [11].

In recent years, several articles have been published with the results of the first generation of stents. Modifications in the original design of these devices have resulted in a subsequent generation of stents that are under constant clinical evaluation. Endoprostheses were described by Rosseau (1987) [12]. These authors described an endovascular device made of stainless mesh, with adjustable guide inside. Once located



in the appropriate endoluminal position, this guide was removed, allowing the self-expansion of the endoprosthesis, adapting even to the tortuous arteries. Figure 1

Figure 1. Stainless stent with adjustable guide [12]



Currently, abdominal aortic aneurysm can be considered as the third cause of sudden death, especially in men over 65 years of age. As an aggravating factor, it is a disease that is difficult to identify due to the low percentage of autopsies. Symptomatic abdominal aortic aneurysm (AAA) can refer to any of several symptoms that medicine can attribute to the aneurysm. Science shows that the presence of symptoms increases the risk of aneurysm rupture occurring, and therefore, for most patients with symptomatic aneurysm, repair should be performed. Artery rupture can also occur in the absence of associated symptoms. Studies show that in the United States, rupture of an abdominal aortic aneurysm (AAA) occurs in approximately 4,000 patients per year. [11].

The sad reality is that without repair, a ruptured abdominal aortic aneurysm (AAA) is almost always fatal. In addition, despite significant advances in intensive care unit management and surgical techniques, mortality after ruptured AAA repair remains high [12].

Endovascular aneurysm repair (EVAR) is an important advance in the treatment of abdominal aortic aneurysm. This repair or procedure is performed by inserting a prosthesis or stent that is compressed into a distribution sheath through the lumen of an access vessel, usually the common femoral artery. After implantation, the graft expands, coming into contact with the aortic wall and iliac vessels to exclude the aortic aneurysmal sac from aortic flow and blood pressure. Surgical outcomes can be improved with endovascular aneurysm repair (EVAR). Today the application of the aortic endoprosthesis in emergency circumstances presents many challenges. A growing number of institutions have initiated ruptured AAA endovascular repair protocols with promising results in small series, but not all institutions are equipped to treat this disease using minimally invasive technology. The increased use of EVAR favors a decrease in the incidence of ruptured AAA and associated morbidity and mortality, probably due to the ability to offer EVAR to patients who would not otherwise be candidates for open surgical repair [13,14].

In the case of abdominal aortic aneurysm, which consists of an abnormal focal dilation of the abdominal aorta, it is relatively common with potential for significant morbidity and mortality and most patients with this disease are asymptomatic, but seek medical attention, as a result of other abdominal imaging studies, or through ultrasound screening programs for AAA [15]. This type of aneurysm is a



common and potentially fatal condition. Of the 50 percent of patients with ruptured aneurysm who arrive at the hospital for treatment, between 30 and 50 percent die in the hospital [16,17].

If compared with open aneurysm repair, EVAR is significantly important in reducing preoperative mortality, mainly because EVAR does not require surgical exposure of the aorta. Since the approval of graft devices for use in the United States, there has been a 600% increase in the annual number of EVAR procedures performed, with EVAR accounting for nearly half of AAA repairs. [18,19]

In EVAR, the surgeon first inserts a catheter into an artery in the groin (upper thigh) and threads it into the aneurysm. Then, using an x-ray to see the artery, the surgeon threads the stent graft into the aorta to the aneurysm. The stent is then expanded inside the aorta and held in place to form a stable channel for blood flow. This stent graft reinforces the weakened section of the aorta to prevent rupture of the aneurysm. The incidence of long-term complications, and the need for reinterventions after EVAR remain a concern. State-of-the-art stents present encouraging results in the short and medium term, but a complete analysis of their long-term performance is required [20,21].

The robustness of the overlapping area between the aortic wall and the endoprosthesis is a determining factor for the long-term durability of aortic endovascular repair [22,23]. Stent migration has a reported prevalence ranging from 1.1 to 28% [24,25]. It is responsible for most of the late complications after EVAR, including late endoleaks related to the endoprosthesis, resulting in enlargement of the aneurysmal sac and even rupture [26,27]. Different mechanisms, such as the radial forces of the self-expanding stents due to oversizing and the pulsatile forces of blood flow, have been suggested as associated with continuous changes in the position of the endoprosthesis and decreased apposition of the stent surface, consequently causing migration over time. In addition, disease progression can trigger and accelerate both mechanisms [28,29]. The dynamics of the endoprosthesis over time is complex and three-dimensional.

Short- and medium-term clinical outcomes have improved significantly over the past 20 years and the number of patients who qualify for EVAR has increased dramatically. Late failures and the need for lifelong monitoring for complications remain the Achilles' heel for this treatment paradigm. Differences in short- and long-term outcomes, as well as overall costs related to lifelong monitoring and late complications and reinterventions, still require continuous comparison with previous devices and historically proven open surgical repair. [30]. Stent are manufactured in stainless steel (316L), cobalt-chromium (Co-Cr) and platinum-iridium (Pt-Ir), tantalum (Ta) or nitinol (Ni-Ti) alloys and in recent years coated stents, DES and biodegradable stents (BDS) have been manufactured [31]. An overview of stent technology in the treatment of aneurysms, has trends of new developments in its manufacturing technologies [32].

The importance of new studies of the possibilities of obtaining results that facilitate more viable solutions for patients waiting long lines to have this medical alternative to face this type of disease in states such as Amazonas where the presence of aneurysm is common, with potential for significant morbidity and



mortality and can be considered as the third cause of sudden death, especially in men over 65 years of age and the availability and possibilities of stent implantation for all patients who need this solution as an alternative and in relation to the technological and manufacturing specificities and that on average the cost of the endoprosthesis is still much higher in relation to open surgery.

Thus, the objective of this work was to obtain a tool that assists the medical procedure by predicting the change in the length of the Stent determined by the aneurysm and its spatial behavior, whose idea arises as part of a field research related to the implementation of the Triple Stent technique where one of the important variants is the determination of the final length of the stents that are used and that will depend on the deformation of the aneurysm in each patient. Information necessary for doctors to have a prior response to the implantation of the result in relation to covering the entire anomaly of the artery.

2 MATHEMATICAL EQUATION

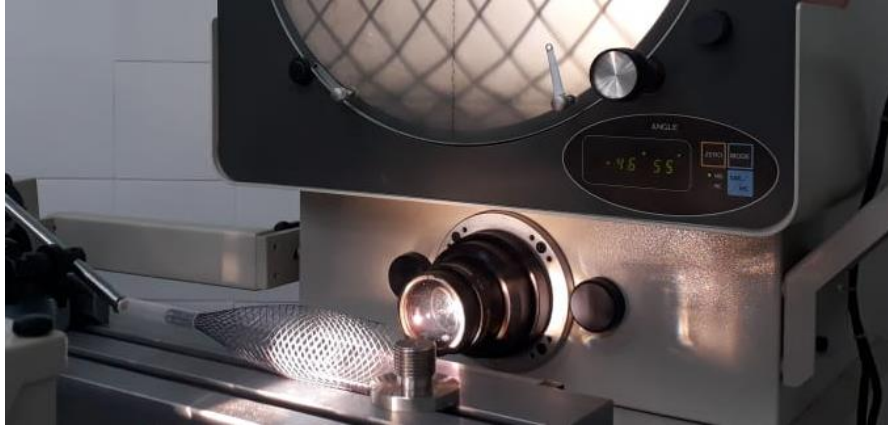
In the study carried out, the parameters for the experimental analysis are determined from the selection of the stent cells, where the variable length and height of the cells are defined according to the spatial orientation of the cells, and thus the relationship between the variation in the length and height of each cell determined by the length and diameter of the stent is obtained. For the study, two different diameters were selected and several measurements were made in the cells with changes in the radial and longitudinal directions (Figure 3), and the height and length ratio was evaluated in the establishment of the mean values.

Figure 2. Parameters to be measured in the cell



To study the changes in length in relation to the diameter variation, using a crystal diameter tube of 10 mm in diameter and 30 mm in length, and the stent is introduced to measure the variation and deformation of the cells the parameters in the transition zone with the aid of a profile projector to read the measurements of each cell in 10 repetitions (Figure 4).

Figure 3. Mounting the experiment



With the results of the measurements and the variables of length and height, it is established the mean value for the parameter is being considered as fixed value for that cell to with the means (Table # 1), and establish the parameters. The N_x and N_y variaves are considered for the study.

N_x : Number of cells in a row on the X-axis (longitudinal to the 3D model).

N_y : number of cells in a column on the Y-axis (axial to the 3D model).

Considering the cross-section as the result of multiplying this average height by the number of cells distributed in diameter in a plane crossing the circumference.

For the case in question, the values of $N_x = 27.5$ and $N_y = 18$,

Table 1: Values in mm of the variables height and length of cells in the resting state

CELL(AT REST)	
X	And
5,6090	6,4800
5,5665	6,4930
5,6800	6,5300
5,5485	6,2920
5,2635	6,4370
5,4525	6,7055
5,4730	6,5710
5,3865	6,8490
5,2390	6,6895
5,3190	6,5555
AVERAGE X (\bar{X})	MEDIA Y (\bar{y})
5,4538	6,5603

Table 1 shows the relationship between height and length of the cell without deformation in the stage of retrieval of the physical memory of the stent and the value of \bar{Y} is 6.56 mm.



The data are processed in excel and the graphical behavior is defined considering and the function was obtained by linear regression, 3rd degree polynomial type that presents more precision than a linear function and thus opt the strain formula for each cell to establish the relationship with the total stent deformation. (Equation 1)

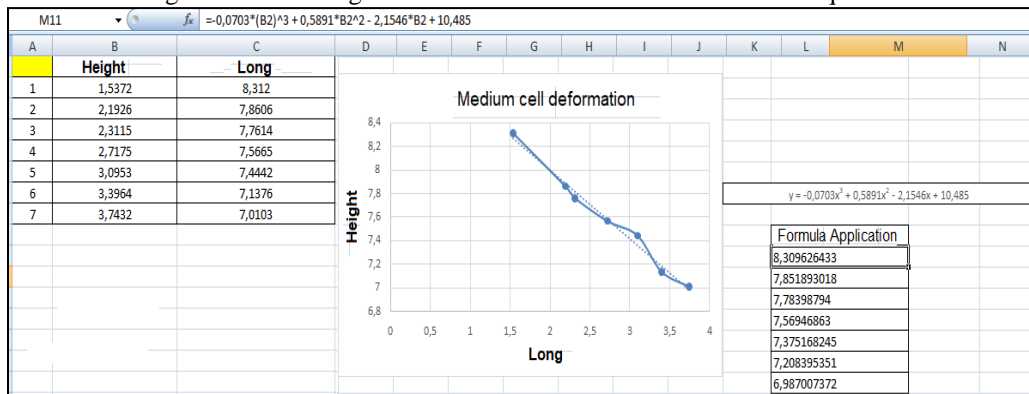
$$\text{Equation 1: } d = \frac{N_y \cdot \dot{Y}}{\pi} = \frac{18 \cdot 6,56}{3,14} = 37,58 \text{ mm}$$

The value of 37.58 mm, is the value that corresponds with the actual diameter of the stent in the recovery state of the nitinol memory after it is recovered from the deformation to be inserted into the 10 mm tube..

The variation of stent length for one insertion diameter depends on the data in table 3.

As a criterion of the evaluation of the adherence of the formula, it applies to test mode, equation 1 with the data obtained and the calculated values are very similar to the means of the measured values. Figure 2.

Figure 4. Processing of data for octention of the mathematical equation



$$\text{Equation 2: } L = -0.0703 \cdot (B2)^3 + 0.5891 \cdot B2^2 - 2.1546 \cdot B2 + 10.485$$

With the results and the definition of the mathematical equation, it is possible to estimate the change in the linear length of the stent as a result of the variation of the insertion diameter that depends on the aneurysm.

Considering (B2), our variation relation of the deformed cells in the axial axis, substituting in equation 1, sé defines:

$$\text{Equation 2: } d = \frac{N_y \cdot B2}{\pi}$$



Isolating B2

$$\text{Equation 3: } B_2 = \frac{d \cdot \pi}{N_y}$$

$$B_2 = \frac{10\text{mm} \cdot 3,14}{18} = 1,75\text{mm}$$

When we apply this value to the equation

$$L = -0.0703 \cdot (B_2)^3 + 0.5891 \cdot B_2^2 - 2.1546 \cdot B_2 + 10.485$$

$$L = 5,14\text{mm}$$

Then with the L value, if you can predetermine the total length of the stent, example for a diameter of 10 mm the result will be:

$$\text{Equation 5: } L_f = L \cdot N_x$$

$$L_f = 5.67 \cdot 27.5$$

$$L_f = 156\text{mm}$$

2.1 CASE STUDY

To analyze the results of the study stage, it was decided to complement the research with a case study with a patient who was going to be added to the triple stent implantation procedure

Selection of the abdominal aortic artery, with two and three lateral branches - patient tomography and used Osirix Lite software.

Figure 5: Tomography in a patient, case study

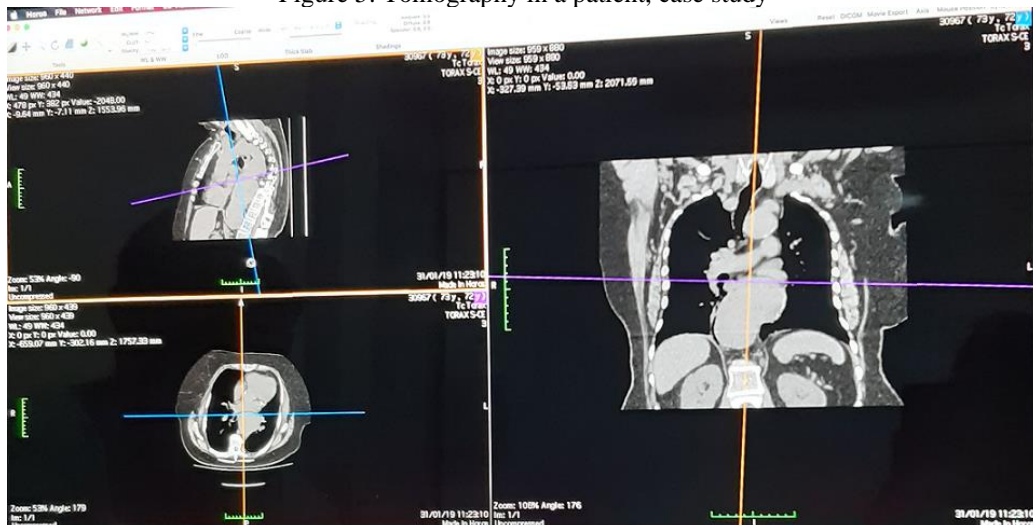




Figure 6: Definition of measurement plans

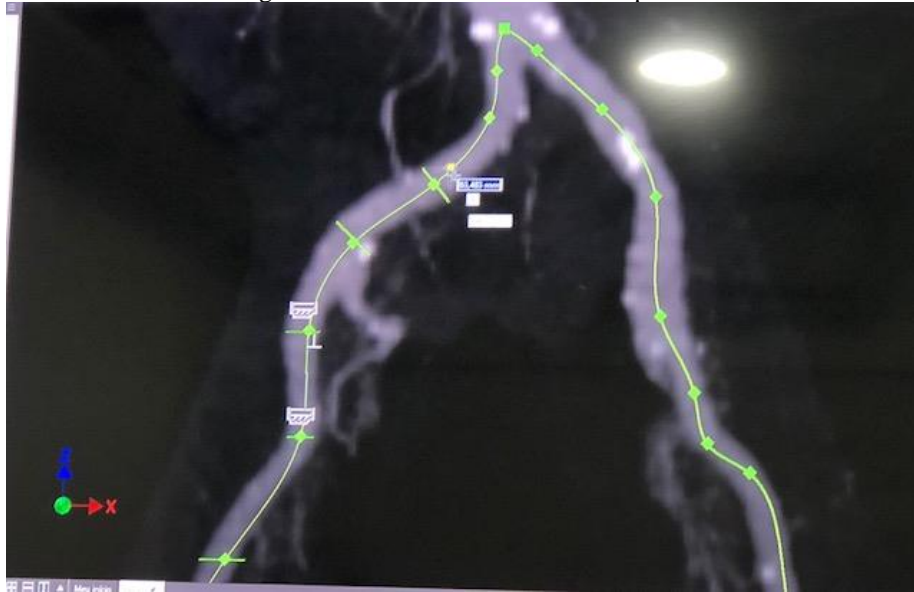


Figure 7: Measurement of the diameter of the artery in the plane

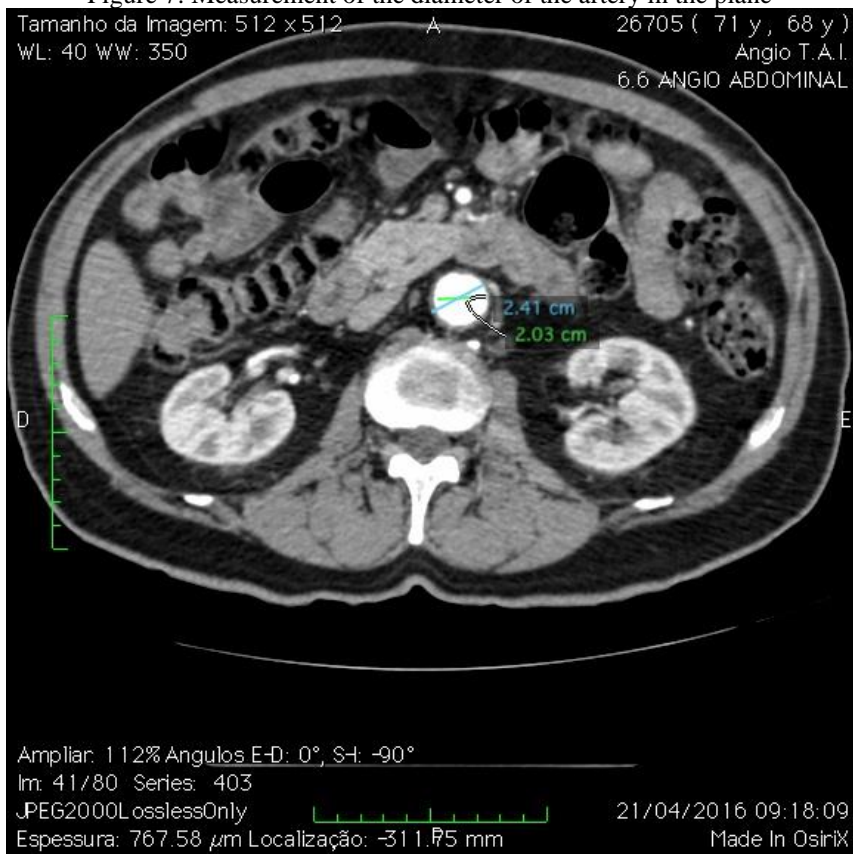




Figure 12: Triple Stent accommodated in the artery model.



3 CONCLUSION

The way of the work was found that it is possible with the processing of the data in relation to the variables height and length of the deformed cells and the behavior of the relation of the parameters from the point of insertion to the rest zone of the stent and with the images resulting from the cuts in the tomography, to generate a curve that allows deducing a mathematical equation that makes it possible to relate the variation of the height and the length of the cells that allows to relate the variation of the height and the length of the cells that allows predetermine the change of length for the stent on the axial axis, with the ease of being applicable for different diameters, provided that the stent responds to this type of geometry.



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