INTERNATIONAL SEVEN JOURNAL
OF MULTIDISCIPLINARY
ISSN: 2764-9547

Relationship between accommodation of the stent and triple stent in aortic anomaly and length change

Relação entre a acomodação do stent e triplo stent na anomalia da aorta e a mudança do comprimento

DOI: 10.56238/isevmjv1n2-002
Receiving the originals: 01/03/2023
Acceptance for publication: 21/03/2023

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ISSN: 2764-9547

ABSTRACT
Among aneurysm treatments, endovascular treatment of the abdominal aorta with stents is the most widely applied alternative today. The aim of this study is to determine a mathematical algorithm that allows defining an equation to predict the final length after stent catheter release in the implantation of one stent or three stents (triple stent). To establish the mathematical equation, a self-expandable Lumini® nitinol stent, manufactured by Braile® Biomédica (Brazil), inserted in a tube of known diameter, was used. To obtain the equation, measurements of the dimensional variation of the cells were performed from the insertion diameter to the zone of free expansion of the stent, where the cells would be in their geometric shape of recovery 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 predetermining the change of extension for each stent applied in the treatment, depending on the diameter in which it will be inserted.

Key-words: Biomechanics, stent, triple stent, aneurysm.

1 INTRODUCTION

Nowadays, in order to reduce 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 to develop new materials, prostheses [4-5], medical instruments [6] and technologies to improve the standard of living of patients who need these devices.

In recent years, thoracic aortic aneurysms are a life-threatening disease. The improvement of materials and techniques of endovascular treatment has made possible the successful repair of aortic aneurysms using stenting, endoprosthesis, which, implanted in the aorta, allows the exclusion of the aneurysm and revascularization of the arteries [7]. According to the literature, visceral artery aneurysms and visceral artery aneurysms can be defined as aneurysms affecting 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 arteries and can be life-threatening conditions with a high incidence of rupture and hemorrhage [8].

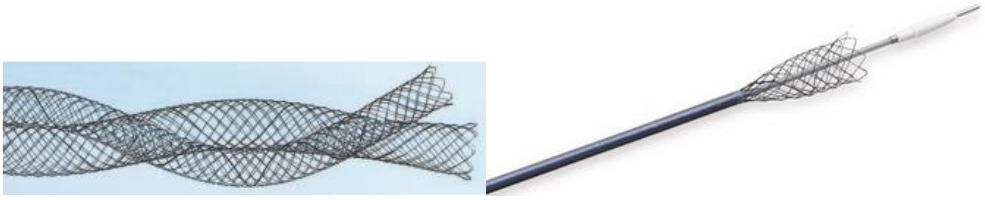
The aorta is considered the main artery of the human body and has the function of carrying blood from the heart to the organs [9]. Aneurysm is when an artery wall dilation occurs, that is, a permanent variation of at least 50% more than the normal diameter caused by several causes [10]. This vascular problem is the cause of the greatest mortality and recurs more in men than in women, especially after the age of 50. In Brazil, about 4% of the population suffers from the problem, and in people over 60 years old, the percentage increases to 6%. It is a serious disease, easily detectable. When treated on time and correctly, it presents good results, with a 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 a pulsatile mass on 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 endoprostheses through the implantation of the stent via endovascular route or resulting in a breakthrough in vascular surgery [11]. The stent is a metallic structure, covered with a film of expanded polytetrafluoroethylene (PTFEe). The architecture of stents is composed of rings that can be either individually mounted or sequentially accumulated in a repeating pattern. The individual rings can be simply attached to each other, similar to the Gianturco (Cook) stent. Stents can be made of materials such as 304 SS, 316 L SS, tantalum, elgiloy (SS), platinum, cobalt alloy, and nitinol [8]. Dyet&Schurmann [9], cite that 316 L series stainless steel stents show good biofunctionality. Nitinol is a nickel-titanium alloy with thermal memory properties, which allows it to be compacted tightly inside a delivery system when cooled, to expand rapidly and reacquire its pre-designated shape and size after release from its delivery system into the bloodstream. In addition, it has great elasticity and resistance to fracture. Nitinol is the acronym for Nickel-Titanium Naval Ordinance Laboratories, whose metal alloy was initially developed for military purposes [9]. In 1985, a prototype endoprosthesis consisting of continuous mesh expandable by 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 endoprostheses. 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 an adjustable guide inside. Once placed in the appropriate endoluminal position, this guide was removed, allowing the self-expansion of the endoprosthesis, adapting even to tortuous arteries.

Figure 1 - Stainless stent with adjustable guide [12].



Nowadays, abdominal aortic aneurysm can be considered the third leading cause of sudden death, especially in men over 65 years of age. As an aggravating factor, it is a disease of difficult identification, 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, ruptured abdominal aortic aneurysm (AAA) is almost always fatal. Moreover, despite significant advances in intensive care unit management and surgical techniques, mortality after repair of ruptured AAA 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 which is compressed into a delivery sheath through the lumen of an access vessel, usually the common femoral artery. After implantation, the graft expands, contacting the aortic wall and iliac vessels to exclude the aneurysmal sac of the aorta from aortic blood flow and pressure. Surgical outcomes can be improved with endovascular aneurysm repair (EVAR). Today the application of aortic stenting in emergency circumstances presents many challenges. A growing number of institutions have initiated endovascular repair protocols for ruptured AAA 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, likely 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 dilatation of the abdominal aorta, it is relatively common with the 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 come to the hospital for treatment, between 30 and 50 percent die in the hospital [16, 17].

When compared to open aneurysm repair, EVAR is significant 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 view the artery, the surgeon threads the stent into the aorta up to the aneurysm. The stent is then expanded inside the aorta and secured in place to form a stable channel for blood flow. This stent stiffens 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. The latest generation stents show encouraging short- and medium-term results, but a thorough analysis of their long-term performance is needed [20, 21].

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

Short- and mid-term clinical outcomes have improved significantly over the past 20 years and the number of patients who qualify for EVAR has increased dramatically. Late failure 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 continued comparison with previous devices and the historically proven open surgical repair. [30]. Stents are manufactured from stainless steel (316L), cobalt-chromium(Co-Cr) and platinum-iridium alloys (Pt-Ir), tantalum

(Ta) or nitinol (Ni-Ti) and in recent years coated stents, DES and biodegradable stents (BDS) are being manufactured [31]. An overview of stent technology in the treatment of aneurysms, has trends of new developments in their manufacturing technologies [32].

The importance of new studies of the possibilities of obtaining results that facilitate more viable solutions for patients who wait in long lines to have this medical alternative to face this type of disease in states like 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, mainly in men over 65 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 stenting is still much higher compared to open surgery.

Thus, the objective of this work was to obtain a tool that assists the medical procedure by predicting the change of the stent length 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. This information is necessary for the physicians to have an answer before implanting the result in relation to covering the entire abnormality of the artery.

2 MATERIALS AND METHODS

A Nitinol Lumini® stent from Braile® Biomédica, with dimensions: diameter (ø) 37.68 mm and length (L) 149.96 mm, was used as a model for the study. The stent cells were defined by the basic characteristics of length (X) and height (Y), which were measured 5 times each using a Mitutoyo Profile Projector PJ-A3000, with 0.001 mm resolution and 10X magnification lenses (see Figures 2 and 3). The measurement results were tabulated and statistically processed and evaluated using Microsoft Excel® software.

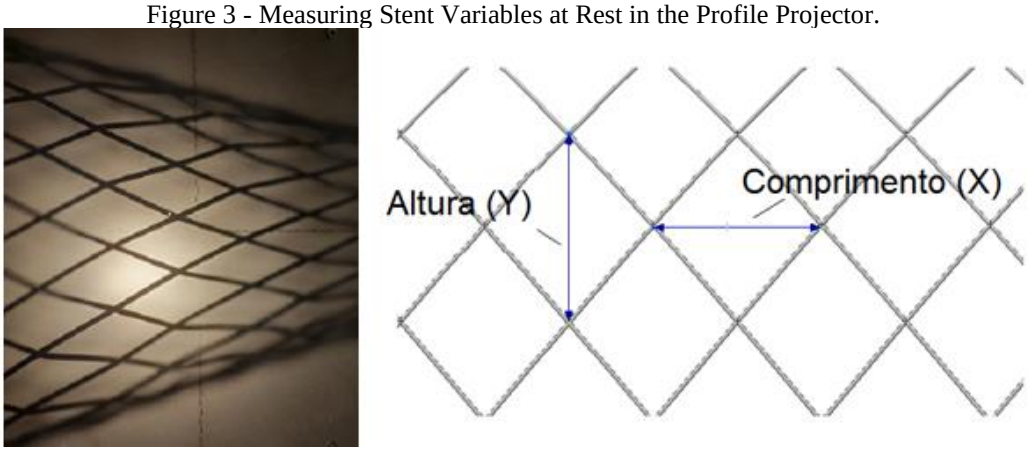
In surgical treatments with stent implantation, it is important to know how the stent length will change. As a tool for success, a mathematical equation to predict this length can be obtained. Due to the irregular geometry of the aneutistma, there is a variation in the stent diameter between the insertion part and the recovery zone, which defines the variation in length in relation to the cells. That is, in each cell of the test stent, the length and height parameters were defined, considering the spatial orientation of the cells, to obtain the final stent length as a function of these parameters. For the study, two different diameters were selected from the insertion zone to the

recovery zone, the measurements were performed in the radial (height Y) and longitudinal (length X) cells, as seen in Figure 2.

Figure 2 - Setup of the experiment for measuring X and Y, with the Mitutoyo PJ-A3000 Profile Projector

To define the mathematical equation, using a test tube with a diameter of 10 mm, where the stent is introduced to simulate the behavior of the stent in the alteria and thus opter a relation of the variation of the X and Y parameters in the insertion zone, in the transition zone and in the zone of its normal condition, at rest and without deformation, simulating the theoretical application condition. To evaluate the behavior of the cells, a profile projector was used where 5 measurements of each cell (Figure 2) were taken in predetermined positions (Figure 3 and 4).

Figure 3 - Measuring Stent Variables at Rest in the Profile Projector.



3 RESULTS AND DISCUSSION

From the measurements of length X and height Y, the corresponding mean value for each variable is determined as an individual parameter, together with the standard deviation. The data obtained are presented in Table 1. Table 2 shows the mean height and length measurements of the

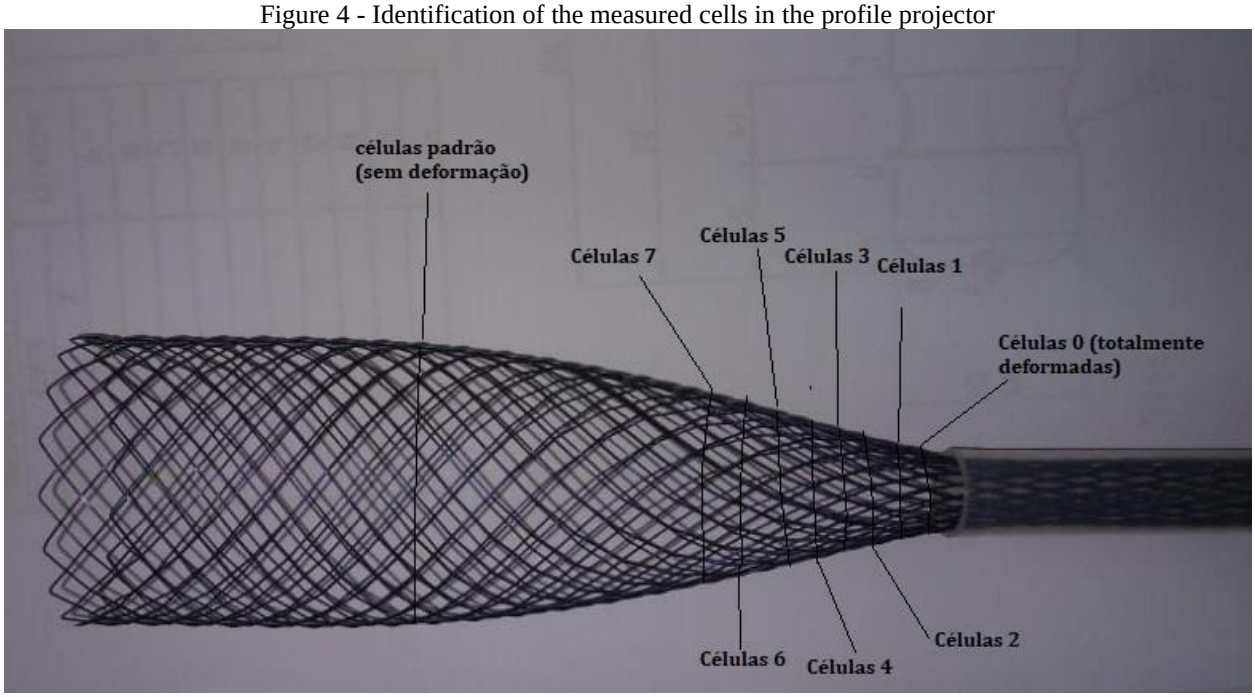
cells from no deformation in the stent physical memory recovery stage to the maximum deformation stage (inside the 10mm tube). The standard deviation (σ) and the coefficient of variation (cv) were calculated in order to verify the divergence and stability between measurements.

From the evaluation of the coefficient of variation values (cv) that are less than 15%, it shows that the optimum data are considered normal and consistent for statistical analysis. With the tabulated data, a graph (Figure 5) of Length *versus* Height is generated and a function that defines the behavior of the cells through these parameters.

The dotted line is the curve given by the equation x = f(y) resulting in a polynomial equation of order 3 for estimating the value of cell length X:

$$X = -0.0093y^3 + 0.116y^2 - 0.989y + 9.5792 \quad (1)$$

Figure 4 - Identification of the measured cells in the profile projector



INTERNATIONAL SEVEN JOURNAL
OF MULTIDISCIPLINARY
ISSN: 2764-9547

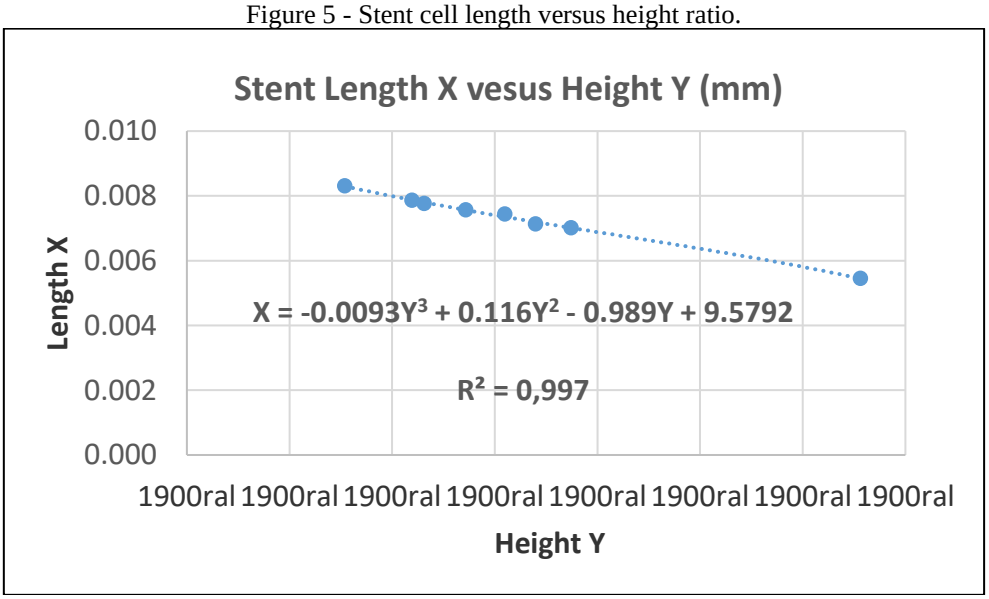
Table 1 - Measured values for the cells (length X and height Y) according to stent orientation (Figure 3).

Cell 01		Cell 02		Cell 03		Cell 04	
X	Y	X	Y	X	Y	X	Y
8,173	1,517	7,880	2,423	7,717	2,190	7,580	2,818
8,259	1,623	7,816	2,086	7,847	2,271	7,404	2,677
8,446	1,516	7,878	2,048	7,889	2,443	7,400	2,678
8,211	1,522	7,833	2,432	7,741	2,378	7,762	2,675
8,472	1,510	7,897	1,975	7,614	2,277	7,688	2,740
Cell 05		**Cell 06**		**Cell 07**		**Standard cell**	
X	Y	X	Y	X	Y	X	Y
7,716	2,980	6,886	3,330	6,973	3,728	5,609	6,611
7,274	3,054	6,906	3,297	6,999	3,627	5,666	6,525
7,458	3,274	7,198	3,367	6,796	3,760	5,335	6,531
7,397	3,083	7,396	3,488	7,060	3,744	5,237	6,621
7,377	3,087	7,303	3,501	7,225	3,858	5,421	6,510

Table 2 - Values in mm of the variables mean length $\dot{X}$ and mean height $\dot{Y}$, according to stent orientation, σ_x and σ_y the standard deviation and the coefficient of variation(cv).

Cell	$\dot{X}_n$	σ_x	CV_x	$\dot{Y}_n$	σ_y	CV_y
1	8,312	0,053	1%	1,537	0,131	9%
2	7,860	0,217	3%	2,192	0,034	2%
3	7,761	0,099	1%	2,311	0,109	5%
4	7,566	0,062	1%	2,717	0,163	6%
5	7,444	0,108	1%	3,095	0,165	5%
6	7,137	0,092	1%	3,396	0,231	7%
7	7,010	0,082	1%	3,743	0,154	4%
Standard	5,453	0,149	3%	6,560	0,156	2%

Figure 5 - Stent cell length versus height ratio.



The resulting equation as a 3rd degree polynomial has more precision than a linear function and fewer inflections than higher order polynomials. After obtaining the deformation formula for each cell, the goal is to establish the relationship with the total stent deformation.

As a next step, it is necessary to define two more parameters: number of cells on the axis Y ($\mathbf{N_{y)}}$ e number of cells on the axis X ($\mathbf{N_x}$). Considering that the stent is now "opened" in such a way as to transform its cylindrical geometry into a rectangle contained in a circular plane of the space R^2.

Being:

$\mathbf{N_y}$: is the sum of their heights, responsible for forming the diameter of the stent covering the perimeter of the resulting circle.

$\mathbf{N_x}$: is the sum of their lengths responsible for forming the stent length.

Both parameters are fixed for this stent model, being:

$$\boldsymbol{N_y} = 18 \text{e} \boldsymbol{N_x} = 27{,}5$$

We now define the relationship of the heights and the number of cells (Ny) to the stent diameter using the siguente relationship:

$$d = \frac{N_y \,.\, Y}{\pi} \, (2)$$

Manipulating Equation 2 and isolating Ẏ**in order** to apply this value to the function generated in Figure 6 to obtain the unit length of the cells, we have

$$Y = \frac{\pi \,.\, d}{N_y} \, (3)$$

With the above values and equation 3, we have the value of Y to insert into equation 1 and obtain X. Next we can calculate the final length that the stent would have from the relationship:

$$\mathrm{L} = \mathrm{N_X} \,.\, \mathrm{Xo} \, (4)$$

Being:

L is the final stent length to be considered in the patient intervention.

Using the Lumini® stent in question (diameter 37.58 mm and length 149.96 mm), one can estimate its length under certain conditions of application. By estimating the intervention diameters of the aneurysm (ø) 10.0 and (ø) 37.5 mm at intervals of 2.5 mm, we have the estimate shown in Table 3.

Table 3 - Values of the final length of the L Stent as a function of the intervention diameter (values in mm).

Ø	X	Y	L
37,50	5,468	6,545	150,37
35,00	5,746	6,109	158,03
32,50	6,004	5,672	165,12
30,00	6,246	5,236	171,77
27,50	6,476	4,800	178,10
25,00	6,700	4,363	184,24
22,50	6,921	3,927	190,33
20,00	7,145	3,491	196,48
17,50	7,376	3,054	202,83
15,00	7,618	2,618	209,50
12,50	7,877	2,182	216,62
10,00	8,157	1,745	224,32

5 CONCLUSION

Through this work, it was found that it is possible, with the processing of the data regarding the variables height and length of the deformed cells and the behavior of the relation of the parameters from the insertion point to the stent resting zone, to generate a curve that allows the deduction of a mathematical equation that makes it possible to relate the variation of the height and length of the cells, which allows the predetermination of the change in length for the stent in the axial axis, with the facility of being applicable to different diameters, as long as the stent responds to this type of geometry.

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