ESCHER TESSELLATION FOR DESIGN OF SLOTTED TUBE VASCULAR STENT

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Abstract: *An intravascular stent is a tubular structure intended for permanent implant in native or graft vasculature. The stent is designed to provide mechanical radial support after deployment. This support is meant to enhance vessel patency over the life of the device.*

In this work an approach for designing the geometry and construction of slotted-tube balloon-extendable stent, produced by Nd^{3+}:YAG laser cutting from stainless steel 316L tube is proposed.

3D model of the stent, produced by ISMA Ltd, Sofia, is prepared by using SolidWorks. FEM analysis of the stent is performed and the mechanical properties are compared with variety of commercial stents.

Keywords: VASCULAR STENT, LASER CUTTING, PICOSECOND LASER, NEODYM LASER, 3D CAD SOFTWARE, FEM ANALYSIS

1. Introduction

A vascular stent is an implant for keeping the lumen of an anatomic vessel. The bare metal stents (BMS) are mostly produced from a tube with appropriate diameter and wall thickness using a nano- or picosecond solid state (Nd^{3+}:YAG) or fiber laser (wavelength 1,064 μm or 532 nm by second harmonic generation). The laser cutting is performed following a specific topology, thus forming the construction of the stent struts.

There are many types of stent construction. Depending on the connecting bridges, they are classified as “open” and “closed” type. A close type stent is such a stent, all struts of which are connected trough a bridge.

Considering the form of the bridge, stents can be classified as Palmaz-Schatz (PS), type with straight bridges, [1], shown in ***Fig. 1.***, S- or V- shaped stents (***Fig. 2***, ***Fig. 3***.).

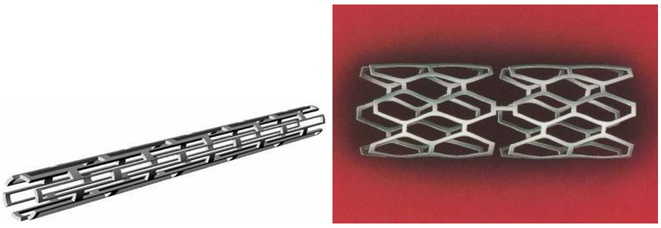

Fig. 1. *Palmaz-Schatz stent*

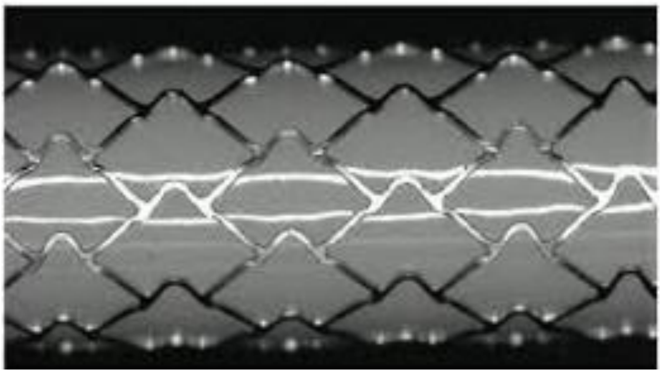

Fig. 2. *V-Shaped stent*

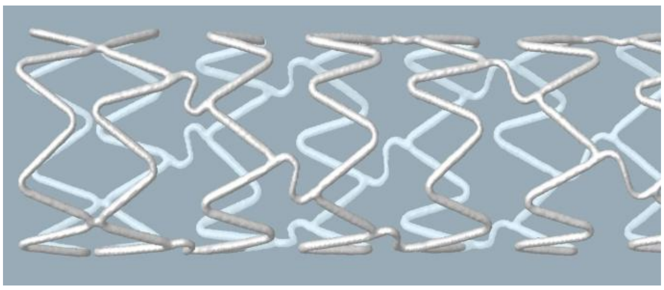

Fig. 3. *S-shaped stent*

The laser cutting requires the laser to follow the topology of the stent struts. This fabrication process needs a 3D CAD/CAM software and, correspondingly, a derived complex CNC program for cutting a rotating cylindrical surface.

The mostly used lasers are ultrashort pulse lasers in the nano- and picosecond range. This ensures that the energy, deposited by the laser, cannot diffuse in the bulk material due to the very short interaction time. All the heat remains in the laser spot, the material is overheated, which follows to rapid evaporation or even sublimation of material in this zone.

Using a second harmonic generation, i. e. the half wavelength, a small laser spot size can be achieved – in order from app. 60 μm to several micrometers - with very precise circle form, because of the smaller Airy spot.

The advantages of this technology are:

Non-contact process;
No clamping of the detail;
Small spot size (narrow kerf);
High cutting speed;
Laser cutting can be used with almost materials;
Quiet and cheap process.

Both aspects – lack of extended thermal zone and thin kerf – make the production of slotted tube stents by laser cutting very perspective.

After the stent is positioned on the right place, the stent is inflated with an expandable balloon, folded in the lumen of the stent, The plastic deformations in the stent are responsible for keeping the proper desired lumen.

In this work an approach for design of open and close type stent is proposed, by using only one closed polyline, acting as a stencil, which is translated along the tube axis and in circumferential direction, forming the struts in Escher’s way of tessellation of “birds and fisches”, thus simplifying the process of CNC programming of laser cutting.

2. Design of the geometry of stent struts

2.1. Stencile form

The proposed design for slotted tube stent is based on the rolled-out geometry in the x-y plane. The x-direction is along the tube axis, the y-direction is the rolled-out cylindrical circumferential direction.

Geometrically, an open and closed-cell stent is an assembly of a number of Repeated Unit Cells (RUC, in terms of [2]) and exhibits a periodicity in both longitudinal and circumferential directions.

The stent under design has a length of L, diameter d and circumference $W = \pi d$. In addition, the model of the stent consists of N RUCs along the x-direction and M RUCs in circumferential direction. A “clipping region”, which is a rectangle with dimensions $2l = L/N$ and $2w = W/M$, is introduced, which contains the polyline.

The topology of the struts is based on the following rules:

The form of the struts can be obtained by translation of a closed polyline, hereinafter called “stencil.

Every strut consists of two parallel straight lines tangent to circular arcs with common centers and radii r and $R = r + \Delta$, where Δ is the size of the strut.

The stencil consists of consecutive small and big arcs, connected by straight lines, as shown in ***Fig. 4***.

The left down quadrant is translated by l and w to a new position in the first quadrant. The graphical primitives in the upper left quadrant translation are translated distances by l and $-w$ to a new position in the right bottom quadrant.

The new arc must have a radius, which is Δ larger then original, if the original arc is small, and Δ smaller then original, if the original arc is big. A symmetry about the line, connecting both centers is needed.

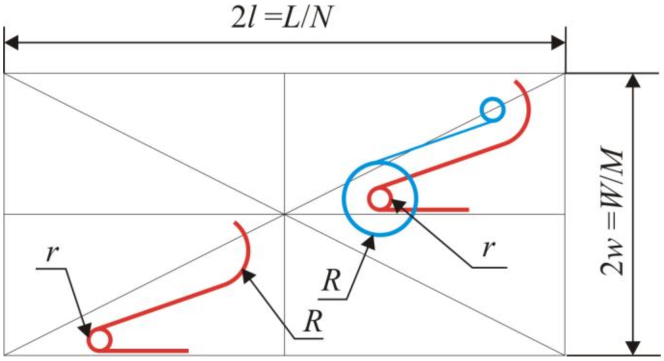

Fig. 4. *Shaping the contour of the stencil*

The same is guilty for translation in the y-direction.

The small radius depends on the kerf size. Typical dimension of the struts is 150 μm, but it can vary with respect of the material, desired mechanical properties and usage purposes.

Forming the left bottom part, we can receive the outlines of the right upper part of the shape. In the same way one can draw the upper left and bottom right part, as well as central top an bottom center contour.

Repeating the shape in $2l$ up and bottom, w and l distance, struts with constant brightness can be achieved.

An example for a shape form, designed by this method, is shown on ***Fig. 5***.

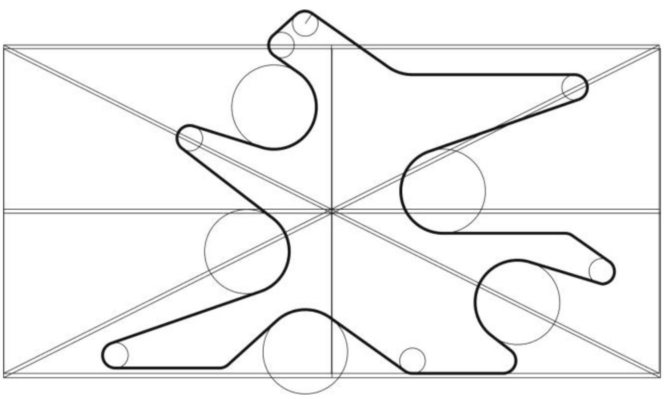

Fig. 5. *The stencil form*

To achieve the whole design of the stent the stencil must be initially repeatedly copied M-times by a step of 2w in circumferential direction. Afterwards, the stencil must be translated by ±w and ±l and then repeatedly multiplied M-times by 2w in circumferential direction.

The final Escher tessellation is shown in ***Fig. 6***.

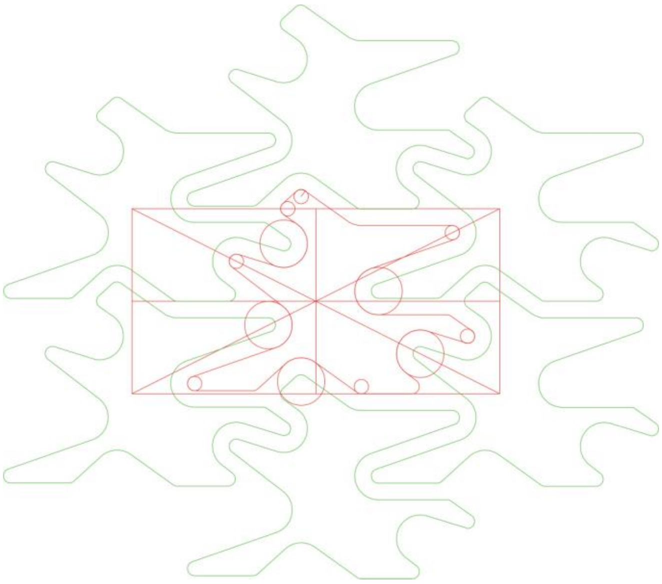

Fig. 6. *Tessellation and struts*

2.2. ISMA stent

Using this approach, the firma ISMA Ltd, Sofia, Bulgaria, has developed a new stent with an original and unique stencil form depicted in ***Fig. 7*** ([3]-[5]) . This stent will be called hereinafter “ISMA stent”. ***Fig. 7*** shows the rolled-out ISMA stent.

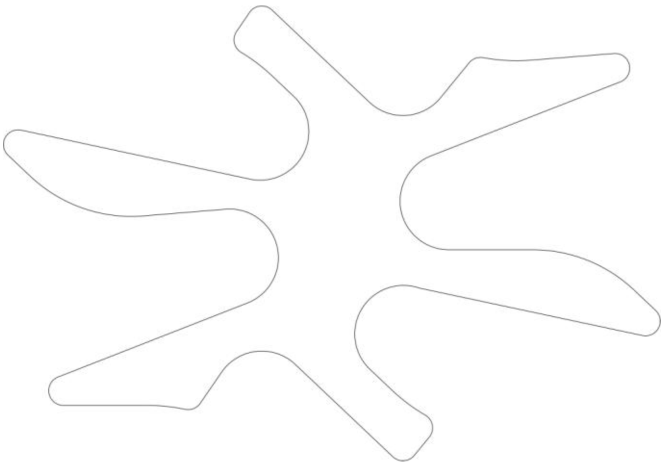

Fig. 7. *Shape of ISMA stent stencil*

Planar rolled-out geometry of the ISMA stent is shown in ***Fig. 8***.

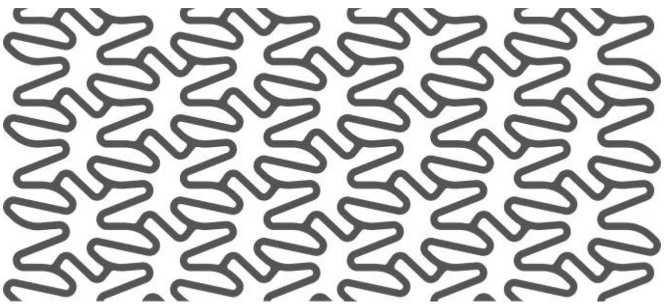

Fig. 8. *Rolled-out ISMA stent*

The planar drawing of the rolled-out stent is imported in SolidWorks and wrapped around the outer cylindrical tube surface. Then, using the build-in operation “Deboss” the stencil regions are removed, so that only the struts remains (***Fig. 9***).

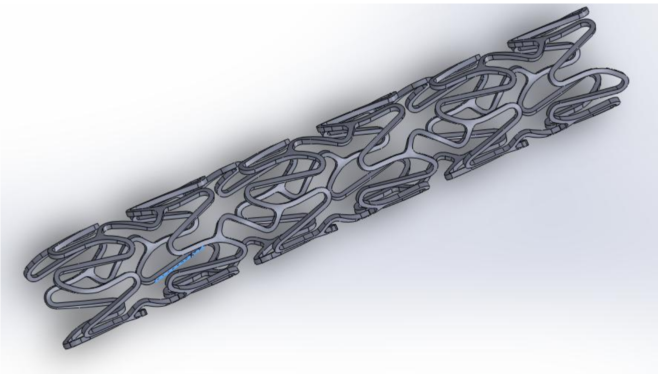

Fig. 9. *3D model of the ISMA stent*

3. Comparative FEM analysis

Three characteristics of a PS and an ISMA stents are calculated and compared: recoil (RR), foreshortening (FS) and the dogboning (DB).

The stents have a length of 8 mm for PS and 10 mm for ISMA, and an initial diameter of 1.37 mm and 1.6 mm (ghosh paper). The struts have a size of 0,1, mm for PS and 0,1 mm for ISMA.

Both stents are presumed to be fabricated from stainless steel Grade 316L. Mechanical parameters of this steel are listed in Table 1.

Table 1. *Mechanical properties of stainless steel Grade 316L ([1])*

Metal	Elastic modulus GPa	Ultimate tensile strength MPa	Pois-son's ratio	Yield strength MPa	Isotropic hardening modulus, GPa	Density kg/m^3
316L	193	550	0,3	300	2	7850

COMSOL Multiphysics 3.5, Structural mechanics module, stress-strain setting, is used for numerical simulation.

The balloon extension is simulated by a pressure, applied normally to the strut internal surface. Parametric solver is used, so that the normal pressure is increased from 0 to a maximal load of 0,3 MPa and backwards. At this stage the final shape and mechanical parameters of the stent are obtained.

Computed parameters are listed in Table 2.

Table 2. *Computed parameters of PS and ISMA stens*

Parameter Stent	Diameter, mm	RR, %	FS, %	DB, %
Palmaz-Schatz	3.0	3.1	7.1	7.1
ISMA	3.0	3	1.7	-26.3

The data for the computed parameters are taken from [1] for the PS stent and [3] and [5] for ISMA stent, correspondingly.

From Table 2 it can be seen, that the final lumen diameter and recoil for the PS and ISMA stents are the same.

ISMA stent is more resistible against axial prolongation. The ISMA stent preserves the same length (FS = 1,7%) after inflation under pressure of up to 0,3 MPa while the length of a PS stent becomes essential shorter (FS = 7,1%). In our opinion, it is a result of the more complex geometry of the stent. The element A depicted in ***Fig. 8*** and ***Fig. 11***, experiences longitudinal strain which leads practically to a conservation of the length of an ISMA stent.

The dogboning rate is calculated as follows:

$$DB = \frac{d_{distal} - d_{proximal}}{d_{proximal}} \quad (1)$$

The most important advantage of the ISMA stent over the PS is its negative dogboning. The ISMA stents show usually negative dogboning because forces in the distal regions are exerted, which prevents from becoming more deformed at the ends of the stent comparing to the middle. In this way, in our opinion, the ends of the ISMA stents reveal a slightly smaller diameter than in the middle.

Unlike ISMA stents, the standard PS stents usually reveal positive dogboning ([1]), thus many research papers are dedicated to optimization of such stents in terms of their connecting bridges ([6]).

This property of the ISMA stents are very important for the practical usage. The warped edges of the struts of the PS strat can injure the vessel tissue and induce a inflammable response, resulting in thrombosis and restenosis.

The ISMA stent, due to its native specific stencil and strut form, has a slightly larger diameter in the middle region. This is an advantage because of reduced risk of restenosis, as well as it can be positioned in such a way, that the middle region is placed where the embarrassment is, so the desired lumen is achieved on the right place..

Another very important parameter, which is in a relation with the durability and the life time of the device, are the critical stresses in the stent.

The results are expressed in terms of von Mises stress and they are shown in ***Table 3***.

Table 3. *von Mises stresses*

№	Type of stent	Maximal von Mises stress, MPa
1	Palmaz – Schatz (from [1])	939
2	ISMA (from[4])	400

From the ***Table 3*** it can be seen that the maximal von Mises stress is deeply lower than the ultimate tensile strength (UTS) for the stainless steel grade 316L (650 MPa, see ***Table 1***) for an ISMA stent in contrast to the PS stent, which maximal von Mises stress exceeds the UTS. It can be assumed that the ISMA stent presumes longer life time and durability of the device.

The distribution of the critical stresses for both stents – PS and ISMA, are shown in ***Fig. 10*** and ***Fig. 11***, respectively.

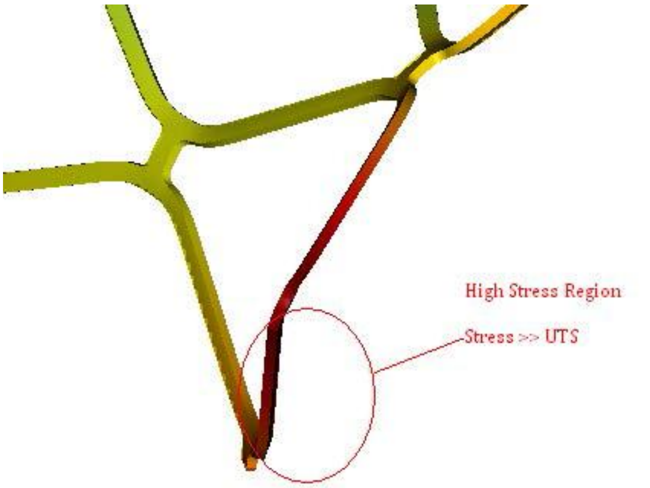

Fig. 10. *von Mises stresses in PS stent*

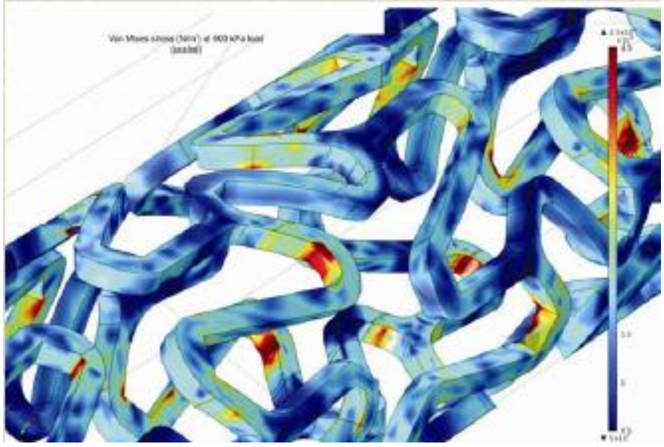

***Fig. 11**. von Mises stresses in an ISMA stent*

Conclusions

An approach for designing of open and closed cell stents is proposed. This approach is based on translation of a closed polyline, called a "stencil", consisting of straight lines and circular arcs. This tessellation like Escher's pictures builds in a native way struts with parallel walls and coaxial arc walls. An algorithm for obtaining such stencil is presented.

A real stent, designed by this approach and produced by the Firma ISMA EOOD, Sofia, Bulgaria, is 3D modeled and its mechanical parameters after balloon inflation are FEA calculated. The analysis shows very good parameters, comparable or even better than conventional Palmaz-Schatz stent, presented in FEA COMSOL Conference 2011.

The approach suggested is very useful for preparing of a CNC program for laser cutting of a tubular stent due to following reasons:

In the general case, the coordinates of every single line or arc, which constitute a part of the strut geometry, must be taken from the 3D model. Thus the CNC program becomes very long with unavoidable errors.

Using the approach suggested, one needs only a relatively short program for only one closed polyline - stencil. Following the stencil, the laser removes the material and the strut remains natively without any additional operation. In the next step, the program needs only a translation of the origin point of the stencil. In this way the length of the program is reduced approximately 1/2*N*M times.

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