OPTIMALNE KARAKTERISTIKE NITINOLSKOG STENTA PRI DEJSTVU ARTERIJSKIH SILA

OPTIMAL CHARACTERISTICS OF A SELF-EXPANDING NITINOL STENT UNDER THE ACTION OF ARTERIAL FORCES

Milovan PAUNIC[1], Miroslav JOVANOVIC[2], Vladimir CERNICIN[3]

[1]*Innovation Center, Faculty of Mechanical Engineering, Belgrade, Serbia*
[2]*The Faculty of Civil Aviation, Megatrend University, Belgrade, Serbia*
[3]*Faculty of Mechanical Engineering, University of Belgrade, Belgrade, Serbia*

Apstrakt. *Nitinol je materijal koji je široko poznat zbog svog memorijskog svojstva. Njegova osobina super-elastičnosti je od velikog značaja u slučaju implatabilnih sistema gde je učestalo stanje cikličnih promena opterećenja. Ateroskleroza je bolest modernog doba i podrazumeva suženje krvnog suda na mestu sakupljanja krvnog plaka. Ukoliko se ovo stanje ne tretira na odgovarajući način, posledice mogu biti ozbiljne. Zbog toga je od velikog značaja izučavanje optimalnih karakteristika stenta i stanja u krvnim sudovima.*
Samo-šireći nitonolski stent se u porastu koristi za tretiranje arterijskih suženja. U radu će biti analiziran uticaj radijalnih sila u zavisnosti od odnosa prečnika stenta i krvnog suda kao i veličine aterosklerotičnog plaka. Uticaj radijalnih sila ima direktnu vezu sa pojavom restenoze koju treba sprečiti. Zahvaljujući analizi, dobijene su informacije o optimalnom odnosu dijametra stenta i dijametra krvnog suda kao i preporučen odnos debljine zida stenta kako bi deformacije na kraju zamornog ciklusa bile zadovoljavajuće.
Ključne reči*: samoekspandirajući stent; nitinol; radijalne sile; restenoza.*

Abstract. *Nitinol is a material widely known because of its super-elasticity characteristic which is important in cyclic load area. Atherosclerosis is a disease of the modern age that involves blood vessels narrowing. If this condition is not properly treated, the consequences can be serious. Therefore, it is of great importance to study the optimal characteristics of the stent and the hemodynamic condition in the blood vessels.*
Self-expanding nitinol stents have been often used to treat arterial narrowing. This paper will analyze the influence of the ratio between the stent diameter and the blood vessel diameter and their correlation with radial forces in the case of atherosclerotic plaque or fibrous cap. Also, this paper will analyze recommended stent thickness to ensure satisfactory deformations at the end of the fatigue cycle.
Keywords*: self-expanding stent; nitinol; radial forces; restenosis.*

1. INTRODUCTION

A stent is an implantable system in the form of a mesh tube that is inserted into a blood vessel to prevent further problems caused by the local narrowing of the blood vessel. The stent is designed to allow normal blood flow through the constricted blood vessel. In this paper, attention will be focused on the self-expanding type of stent. Self-expanding stents are made of super-elastic alloys with the ability to change shapes (smart materials), such as e.g. nitinol, while the other types of the balloon-expandable stents are usually made of stainless steel or cobalt-chrome alloy.

In case when a stent is inserted into the blood vessel at the place of frequent bending (extremities), the probability of fracture increases. For that reason, balloon-expanding stents are not appropriate, as plastic deformation may occur again. In this case, the main feature of the nitinol stent comes to the fore, because after removal of the catheter, it changes shape to its initial value without plastic deformation, which is not the case with a balloon-expanding stent. The nitinol stent is suitable for placement at the frequent bending places as it will return to its initial position after deformation due to limb flexion.

The placement of nitinol stent[1] involves the use of the catheter to position the stent in the blood vessel and then the catheter is pulled out while the stent extends independently and remains positioned at the desired location. The potential problem can occur in the improper procedure of the stent placement or in stent dimensions. It is extremely important for the stent to be of the right size relative to the blood vessel to avoid restenosis.

Recently, a lot of papers described optimization of biodegradable stents that would require support for some period of time until the plaque is fully regulated.[2,3] This approach is convenient because it ensures that no restenosis occurs.

In many cases, stent fractures occur within the first year after implementation. This is due to in vivo cyclical influences. Therefore, cyclic fatigue testing of a self-expanding nitinol stent is of great importance. Stent characteristics will be tested using Abaqus software and a curve will be determined so that the recommended stent characteristics can be used for future research on stent geometry optimization.

This paper will discuss the self-expanding stent, the analysis of the influence of local forces, and the recommended basic geometric characteristics.

2. MECHANICAL CHARACTERISTICS OF NITINOL AND BLOOD VESSEL

The nitinol stent has certain advantages over other materials, which will be discussed below. Nitinol was discovered in 1959 by William J. Buehler while working at the U.S. Navy. The term Nitinol comes from the initial letters of nickel (Ni), titanium (Ti), and the Naval Ordnance Laboratory – Nol.[4] Buehler concluded that nitinol has excellent fatigue resistance as well as shape memory when the temperature changes. [5]

Nitinol has unique characteristics due to its crystalline structure, which undergoes phase changes during mechanical or temperature changes. Nitinol has the ability to change shape and maintain its original form.

In the paper,[6] the behavior of nitinol alloy modeled by different kinetic laws is presented. Figure 1 shows the mechanical characteristics of nitinol, and its super-elasticity as well, as the material is able to return to its original form even after major deformations.

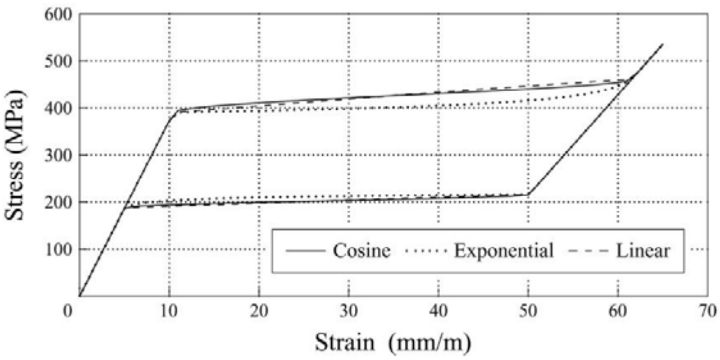

Figure 1. Stress-strain diagram of nitinol material

The nitinol characteristics required for the simulation are Young's modulus of elasticity and the Poisson's ratio. It can be inferred that Jang's modulus of elasticity for nitinol is E = 40 GPa.[7] Nitinol has the ability to return to its initial state after 8% deformation and its Poisson's ratio is μ = 0.32.[8] From the paper,[9] it can be inferred that the yield stress is 30,000 psi or about 200 MPa. The material density is 6.45 g/cm^3.

The characteristics of a blood vessel are of great importance as they directly affect the radial forces in the stent. Each heartbeat causes a pressure variation that leads to the expansion and contraction of the diameter of the blood vessel. This paper studies a variation of pressure from 50 mmHg to 150 mmHg[10] as well as its impact on the diameter change or deformation of the arterial wall, which has an indirect effect on the fatigue of the stent material.

The Poisson ratio of the arterial wall is in the range of 0.3-0.4[11] for the deformation zone of interest to us–a zone that will not cause restenosis and will be discussed below.

In the paper,[12] the influence of radial forces on the occurrence of restenosis was examined. Three radial forces (low - 3.4 N, high - 16.4 N and ultra-high - 19.4 N) were used. Blood vessel diameter was measured before placement, after placement and one more time, 30 days later. After 30 days, it was observed that there was a significant thickening of the blood vessel and increased proliferation of the arterial wall cells with an increase of radial force value. The results showed that the optimal force by which the stent acts on the blood vessel depends on the geometry, structure and mechanical characteristics of the blood vessel where the stent is placed. In order to ensure the optimal condition, it was concluded that the stent should not act on the blood vessel with a higher load than the one marking the end of the transition zone which approximately equals 90% of the deformation. [12]

Young's modulus of elasticity for the zone of large deformation varies in the range of 2-6 MPa.[10] For the deformation zone below 90%, which is our zone of interest, it can be concluded that the modulus of elasticity is in the range from approximately 0.2-0.3 MPa to up to 0.6 MPa for a higher deformation zone, which can be seen on Figure 2.

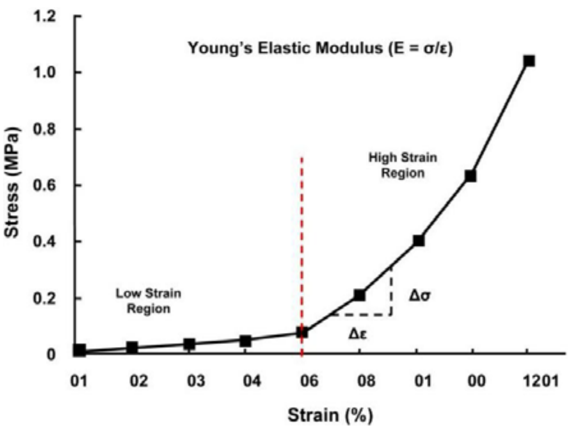

Figure 2. Stress-strain diagram of the typical artery [10]

In most blood vessels, the region of the low modulus of elasticity has a linear behavior until about 50-60% deformation is reached. At this point, a change to the higher modulus of elasticity occurs.

3. HEMODYNAMIC INFLUENCE AND RECOMMENDED RATIO Rs_{max}/R_k

The basic function of the stent is to extend the blood vessel to its normal diameter. Changing the velocity profile due to different cross-sections can cause thrombosis.[13] The longitudinal section of the blood vessel at the constriction place is represented in Figure 3. The figure shows the change in velocity gradient at the spot of the blood vessel constriction (*ESS* - endothelial shear stress, *μ*-viscosity, *dv/dy* velocity gradient).

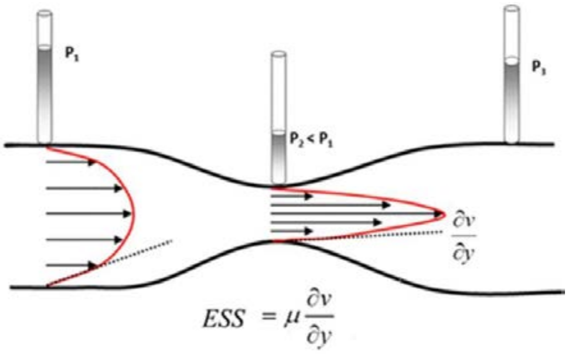

Figure 3. The change in velocity gradient at the area of blood vessel narrowing [13]

The higher the velocity gradient is, the higher is the shear stress, which directly provokes the occurrence of thrombosis. Therefore, in these conditions, it is extremely important to restore normal blood flow as soon as possible by widening the cross-section to avoid further complications.

The impact of restenosis and other unfavorable cardiac events is directly related to a decrease in the stent diameter and an increase in its length.[14]

A larger increase in diameter causes the greater flow increase, but in that case, attention should be paid to the degree of deformation of the blood vessel, which increases the probability of restenosis. In the case of a small cross-section in the constriction area, the probability of thrombosis increases, while an excessively larger diameter increases the possibility of restenosis. For that reason, there is the tendency of finding the optimal diameter that will minimize both unfavorable events.

Figure 4 presents the longitudinal section of the blood vessel after stent placement and it shows that the largest diameter of the blood vessel is at the location of the highest amount of plaque. Right there, the radial force is at its maximum as the blood vessel wall is most deformed. The plaque is symbolically represented by yellow color.

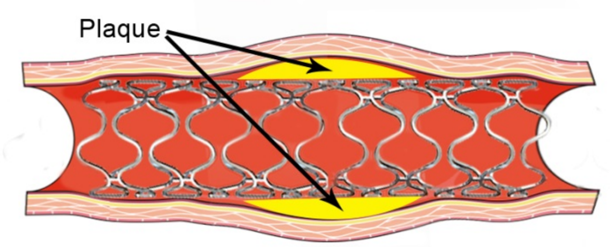

Figure 4. Longitudinal section of the blood vessel in the stent placement area

In order to successfully position the stent, the inside diameter of the blood vessel (R_k) should be in a proper ratio with the outer diameter of the stent (Rs_{max}). That ratio has direct impact on the probability of the restenosis. Figure 5 presents a stress-strain diagram in cases of different plaque types. It is important to emphasize that these characteristics may vary. Still, the averaged value can be considered as relevant. In our case, plaque will be included in the calculation as a fibrous cap.

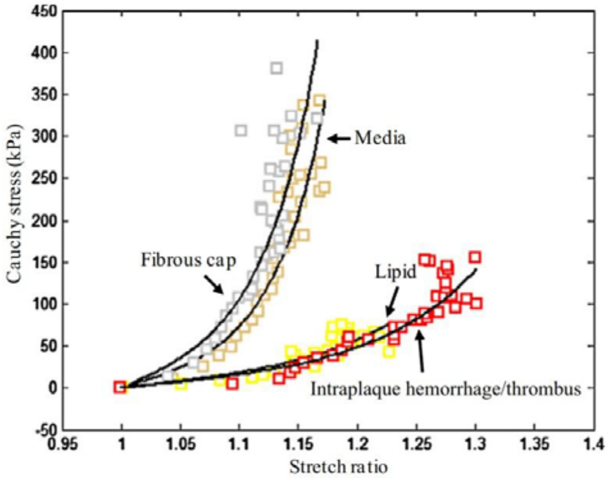

Figure 5. Stress-strain diagram of the different plaque types [15]

The recommended stent diameter can be obtained by an indirect approach - based on maximum deformations of the vessel wall that does not induce restenosis (90%). In order to achieve a higher safety factor, the limiting deformation of the blood vessel should be considered around 80%. Blood vessel deformation depends on plaque size, stent size, and variable pressure.

It can be seen from Figure 2 that the deformation of the blood vessel is around 200 KPa at 80%, so we will take that value as the case of working conditions. If it is assumed that the stent deformations at working conditions are very small (Figure 1), a limit line of recommendation of the ratio R_{smax} / R_k can be obtained, depending on the occupancy of the cross-sectional area of the blood vessel by the fibrosis cap (Figure 6). The deformation of the fibrous cap under the same working conditions of 200 KPa is about 15%, which is shown in Figure 5.

Estimation of the recommended size of the stent is made based on the size of the maximum narrowing of the blood vessel, because at that point the blood vessel will be most deformed (Figure 4) and the reaction force will have the most intense effect on the stent.

Figure 6 presents a schematic representation of the blood vessel cross-section before narrowing, at narrowing, and after stent placement. P_b is the surface area before narrowing and P_s is the area at the point of narrowing, where blood flows. Since P_p is a plaque surface, the bond between these surfaces is $P_b = P_s + P_p$. Figure 6c shows the significant deformation of the blood vessel after stent implementation. The stent surface is P_{st} while the plaque surface is compressed and has a new value (Pp_{akt}).

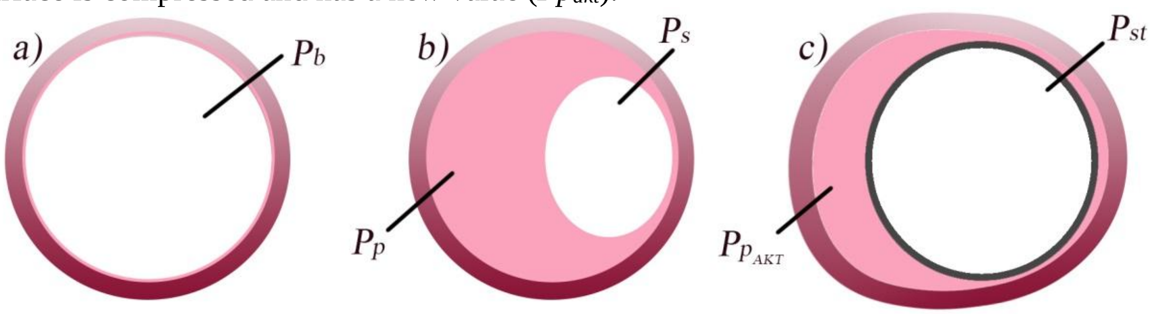

Figure 6. Cross-section: a) before narrowing, b) at narrowing, and c) after stent placement

Figure 6c shows that $P_{max} = P_{st} + Pp_{akt}$. The exact value of P_b is determined by the size of the cross-section at the moment of the systolic pressure action when the blood vessel is most stressed. It varies from one case to another but approximately goes from 120 mmHg to 160 mmHg, and the deviation for different cases is only 5%: at 120 mmHg the deformation is 20%, and the deformation at 160 mmHg is about 25%.[16]

All it takes to obtain the desired data is to know P_b and P_s for the particular case, that can be easily obtained from the velocity profiles. If we assume that e.g. P_b = 5 mm^2 and P_s = 2 mm^2, the example below can be explained in the following way. The deformation of the blood vessel wall is about 20%-25% due to the fact that the size of the cross-section is widened due to the effect of the systolic pressure. Therefore, we must correct the allowed deformation in the form $P_{max}=(P_b*1.8)/1.25$. At the stress of 200 KPa, $Pp_{akt} = Pp*0.85$ as the deformation is 15% (Figure 5). Based on the information above, Table 1 can be formed. A specific value is obtained for the maximum recommended radius of Rs_{max} stent.

Table 1. An overview of the calculation steps in the case of P_b=5 mm^2 and P_s=2 mm^2

P_b [mm^2]	R_k [mm]	P_{max} [mm^2]	P_s [mm^2]	P_p [mm^2]	Pp_{akt} [mm^2]	P [%]	Ps_{max} [mm^2]	Rs_{max} [mm]	Rs_{max}/R_k
5.0	1.26	7.2	2.0	73.44	2.4	60	4.8	1.236	0.981

Analogous to the previous case, the same approach can be applied for different plaque size values expressed as a percentage ($P=P_p/P_b*100$) to obtain a graph of the dependence of Rs_{max} / R_k in the case of a fibrous plug. In the previous case, the plaque size was 40%, while values in the range of 20-80% plaque size will be indicated in Figure 7. In this case, the following graph is obtained to estimate the max allowed radius of the stent at which restenosis is minimized:

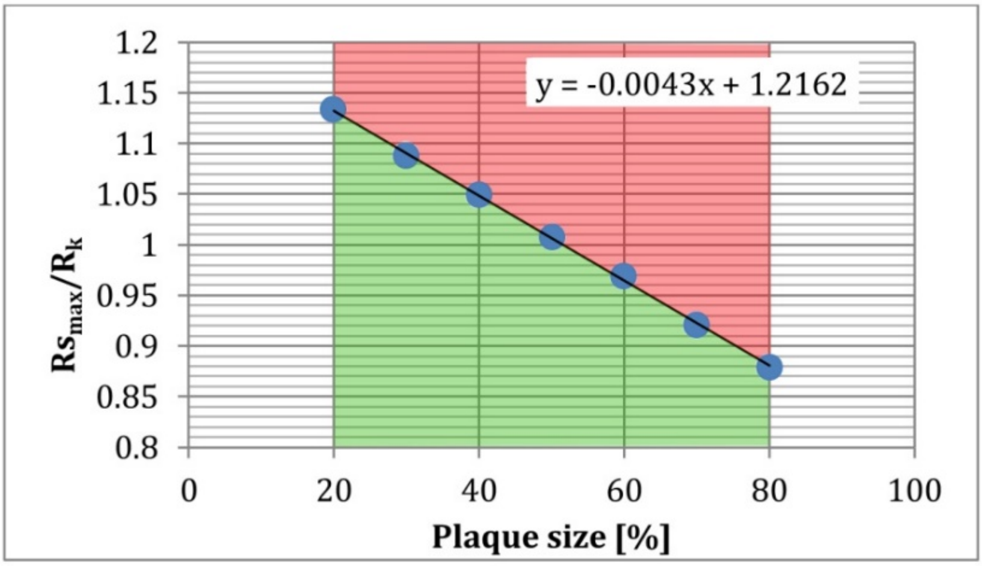

Figure 7. Recommended ratio Rs_{max}/R_k at which restenosis is minimized

The regression line represents the case of the end of the transition zone (80% of the vessel deformation to minimize the probability of restenosis). The linear function $y=-0.0043x+1.2162$ describes the above-mentioned dependence. The zone below the line represents a “safe zone” where the occurrence of restenosis is minimal. Oppositely, the zone above the line represents the zone of the high possibility of restenosis. Using the previous function, it is possible to easily determine the maximum recommended radius of the stent (from the aspect of minimizing restenosis) if we know the values of the cross-sectional area of the blood vessel before narrowing P_b and at the point of narrowing P_s.

4. COMPUTER SIMULATION OF FATIGUE UNDER WORKING CONDITIONS

After the function describing the recommended stent radius is determined, it is necessary to obtain information on the recommended thickness *(t)* of the stent since it is the first parameter that affects the performance of the implant in working conditions, immediately after its surface geometry. Working conditions were evaluated at the place of the largest deformations of the blood vessel–at the spot of the largest narrowing. The mechanical characteristics of nitinol are taken from Figure 2. It is important because it directly affects the fatigue of the material due to the cyclic loading caused by the change in pressure.

If we assume that the pressure changes the value from 150 mmHg ≈ 20 KPa to 50 mmHg ≈ 6 KPa, we get that the pressure oscillation is 14 KPa. Therefore, if the Rs_{max}/R_k ratio is in the "safe zone" or below the regression curve (Figure 7), lower loads will be obtained under working conditions (e.g. 160 KPa instead of 200 KPa). If a deviation of 14 KPa is applied, the value of the variable pressure ranges from 160 KPa to 146 KPa.

Finite element analysis was done using Abaqus software. The stent was modeled as a tube to completely exclude the factor of surface geometry, and all attention was directed to the analysis of the thickness value impact. The real working conditions were replaced by a radial load of 160-146 KPa. The simulation was performed at 10^5 cycles which can be considered as a sufficient number of cycles for the relevant estimation since 10^5 cycles belong to the "high cycle" region of the fatigue curve.[17]

Figure 8a shows the effect of radial forces relative to the stent cross-section. Figure 8b shows the boundary conditions in which a fixed node is represented by a red circle, for better visibility.

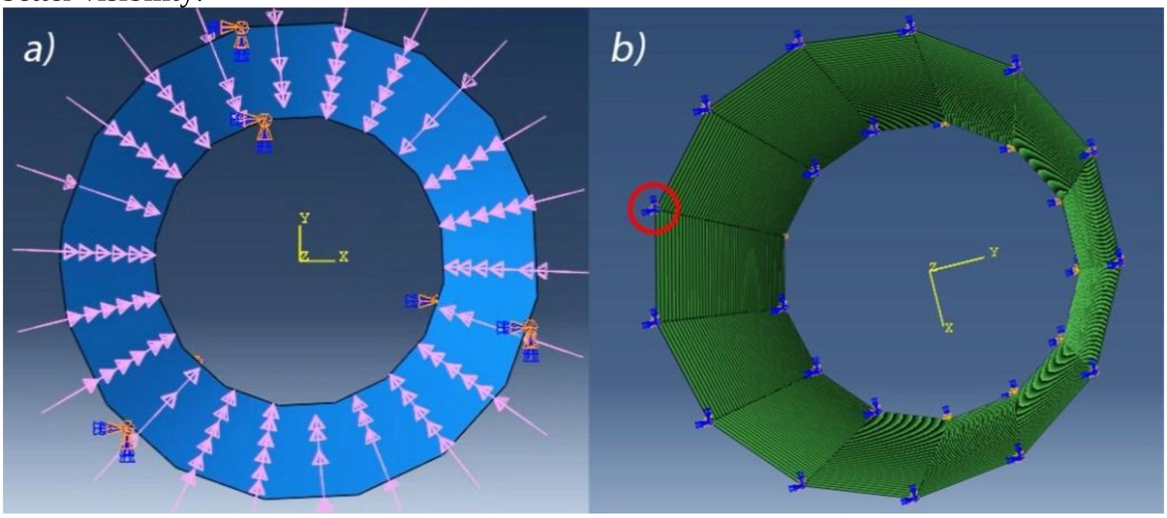

Figure 8. Radial force action and boundary conditions in Abaqus software

Maximum deformation values are in the central area, where the largest plaque surface is situated, which was previously presented in Figure 4. Stent has sufficient length to provide uniform deformation distribution in the central part, which represents the zone of interest. The deformation readings are in the central part of the stent. The stent diameter was used in the form $D_{st}= 2R_{st}$. There are a total of 4 simulations for 4.9mm stent diameter with different values of the D_{st}/t ratio. Although the deformation values are small, by their mutual comparison we can approximate the influence of different stent thicknesses on the implant lifetime. Figure 9 shows a correlation between strain and thickness as a function of the D_{st}/t ratio.

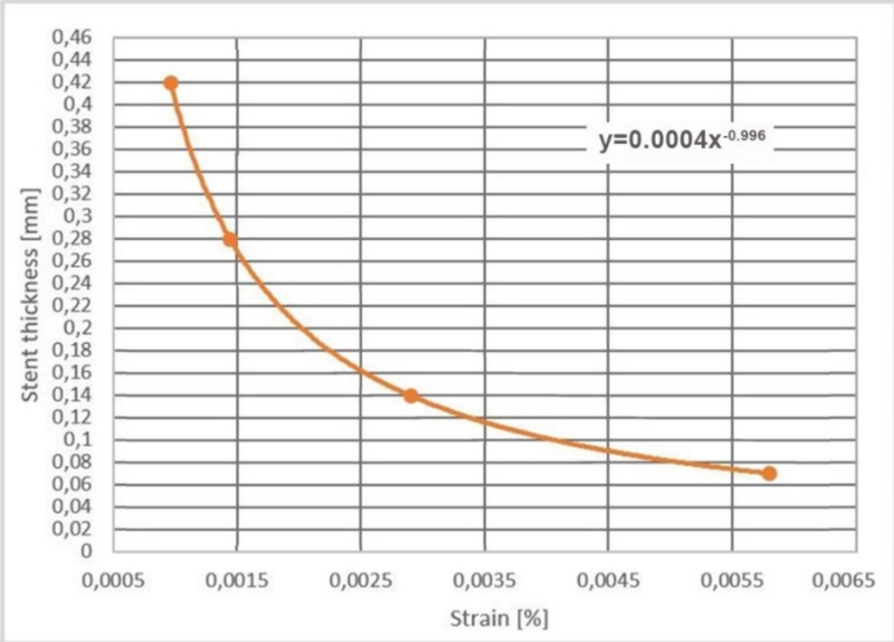

Figure 9. Strain-thickness diagram after the fatigue period

The orange line represents a diameter of 4.9 mm and is formed by 4 points representing a thickness of 0.3 mm, 0.2 mm, 0.1 mm and 0.05 mm (from left to right). Considering that the surface geometry factor was excluded from the calculation because the intention of this paper was to analyze solely the effect of stent thickness on the fatigue characteristics, we can conclude that minor deformations lead to a longer implant lifetime. If the value of the stent thickness t increases from the minimum to the highest value, the change is exponential and can be represented by equation $y=0.004x^{-0.996}$. The increase of t will reduce the deformation, but it should be kept in mind that the excessive thickness of the stent wall can affect the appearance of thrombosis. By using Figure 9, it is possible to quickly determine the correction of the implant lifetime and stent thickness value.

5. CONCLUSION

The application of a stent is vital in conditions of a significant amount of plaque. Stent placement carries certain consequences due to local hemodynamic forces and loads, such as restenosis and thrombosis. The focus of this paper was to obtain the equation of curve that minimized the probability of restenosis, relative to plaque size. Attention was also focused on numerical simulation in Abaqus at variable radial load for 10^5 cycles–“high cycle” region of the fatigue curve. The displacements were read and the values of deformations in the center of the stent were obtained. Using these values, a graph was formed, showing how much the change in stent thickness would affect the change in strain and the length of the stent lifetime.

The previously formed graphs helped obtain the maximal value of the stent radius Rs_{max} (to minimize restenosis) related to blood vessel radius R_k and plaque size (Fig. 7), as well as the relation between the change in stent thickness and fatigue characteristics of the implant (Fig. 9). The simulation excludes the factor of the surface geometry and focuses solely on the thickness t and its effect on the implant lifetime, under the assumption that the implant lifetime is directly correlated with the strain.

To complete the analysis of the recommended diameter and thickness of the stent wall, further testing could be directed towards the examination of the effect of coatings as well as the improvement of the geometric characteristics of the stent surface on fatigue.

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