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Aspects Regarding Conceiving and Fabrication of Some Aneurismal Intracranian Clips

Florentina Livia GHIGA[1], Emil BUDESCU[2], Eugen Merticaru[2]

Summary

The accidents provoked by break of the cerebral aneurisms represent, nowadays, approximately 10 % from the total of the vascular cerebral accidents. Treatment against a sacular aneurism consists in total exclusion of blood circulation, by using a micro-surgical clip or by embolysation with spirals through vascular catheterism. The paper presents the problem of designing and fabrication of micro-surgical clips.

Introduction

Intracranian arterial aneurisms are sacular or spindle-shaped dilatations of the arterial wall, occurred in points where there exist structural defects of the elastic tunic, due to the pressure exerted by the cerebral circulation [4]. They appear as vascular malformations (figure 1), often located at the basis of brain. An aneurism presents, structurally, an area of smaller dimensions called packet, through the aneurism is inserted onto the bearing blood vessel, and the aneurismal sack, with very thin walls, at whose level usually occur the breaks. Dimensionally, aneurisms have varied dimensions amd may be classified as: very small aneurisms (smaller than 2 mm), small aneurisms (2–6 mm), medium aneurisms (6–15 mm), big aneurisms (15–25 mm) and giant aneurisms (25–60 mm), and the aneurismal packet may be vary small (1–3 mm) or big (4–10 mm). Between the two forms of aneurisms, sacular and spindle-shaped, more frequently are the sacular ones, their incidence being about 66–90 % from the total of aneurisms.

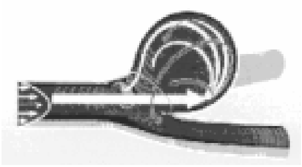

Figure 1: Arterial aneurism

Now, the treatamen for aneurisms consists in total exclusion from the blood circulation by using a micro-surgical clip or by embolysation with spirals through vascular catheterism. Micro-surgical clipping implies disection under surgical microscope and application of a clip onto the aneurismal packet (figure 2), aiming to integrally exclude form circulation the aneurism and keeping the bearing blood vessel. Sometimes, in the case of aneurisms with wide neck, polilobate aneurisms and giant aneurisms, there are necessary many clips for a single aneurism.

Figure 2: Aneurismal clip

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[1] Physical Education and Sports Faculty, "Alexandru Ioan Cuza" University, Iasi

[2] Laboratory of Biomechanics, Technical University "Gh. Asachi" Iaşi, Romania

Efficiency of clipping the arterial aneurisms depends on many factors, such as: factors regarding the patient, factors regarding the used surgical technique and factors regarding the aneurismal clips (mechanical and bio-compatibility of these).

Clipping an aneurism is considered, in general, a method with very good results, in spite of ocasional reports about sliding or breaking of the clips. Chosing the suitable clip for every aneurism is a matter of surgical experience, knowledge and supply with as much as performant clips.

The paper presents the problem of designing two aneurismal clips, of type Mc Fadden, respectively one with spring with simple spiral, and the second with spring in double spiral, each variant in more type-dimensoins and made of two different materials. Using the finite elements analysis (FEA), there could be selected those types of aneurismal clips which fulfil the condition of realizing a given pinching force, having at the same time, the smallest possible dimensions among the given variants.

Elements of design of an aneurismal clip

The auto-static clips, used for intracranian aneurisms, have into their construction a spring which ensures their re-opening and re-positioning without altering the wall of blood vessel, ensures a predetermined closing pressure, are applied and re-positioned easyly, using applicators especially made for each type of clip.

Constructively, there can be distinguished the following component parts of an auto-static clip: the spring of the clip, the arms, with interior active facets,the tip and the articulation (figure 3).

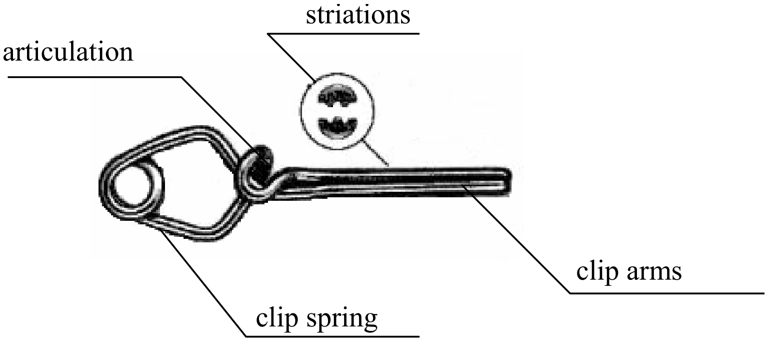

Figure 3: Constructive elements of a clip

The spring of clip ensures the auto-static properties and a part of the manevrability. The closing force is transmited to the arms, which, through the active facets, come in contact with the aneurismal packet and determine closing of the packet and interruption of blood flow from the bearing vessel toward the aneurismal sack.

Clips must have proper closing force, to prevent sliding on the aneurismal packet, but, at the same time, it has to be enough small, so that to prevent injury of the tissue of vascular wall, and the clip can be easyly applied [1, 4]. Closing an opening of the clip with the help of the applicator has to be easy and lack of resistance. For the closing force there have been considered two extreme values, namely: 0.8 and 5.0 N.

The aneurismal clips has to be conceived to fulfil three main criteria :

- they have to be able to generate enough closing force to obliterate the aneurismal lumen, in spite of vessels' pulsations;
- they have to be made from a resisting material, that the cerebral tissue can tolerate well;
- they have not be affected by the magnetic fields or by RMN.

Resistance at sliding of a clip depends on certain factors such as: the pressure exerted by clip, thickness and the striations on the clip arms, blood pressure, the caliber and consistency of blood vessels.

The two variants of clips Mc Fadden analyzed in this paper are represented in figure 4.

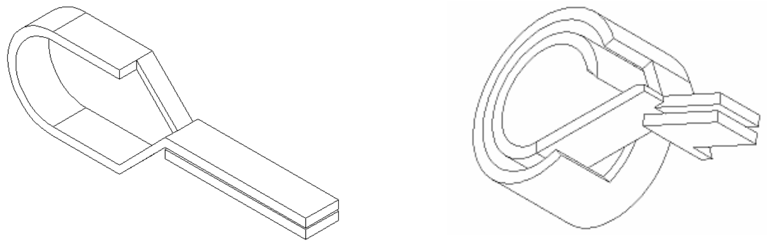

Figure 4: Variants of aneurismal clips: a – simple spiral, b – double spiral

In the case of first variant of clip, the spring was conceived as coming from a circle arc, prolonged with two right segments, and the dimensions considered for the entire clip are:

- thickness of the half-finished clip, g: 0.2, 0.3, 0.5 and 1.0 mm;
- width of the half-finished clip: 2.0 mm;
- diameter of circle arc: 5.5 mm;
- length of clip spring, L_1: 4.0, 6.0 and 8.0 mm;
- length of clip arms, L_2: 8.5 mm;
- distance between clip arms, s, in work position: 0.05 mm.

Taking into account the different values for the thickness of half-finished clip and the length of clip spring, there resulted 12 type-dimensions for the clip of type simple spiral. Constructive schematic representation of this clip is given in figure 5.

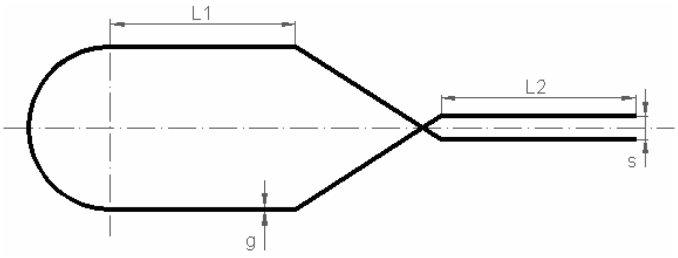

Figure 5: Constructive variant of a clip with simple spiral spring

In the case of the second variant of clip, the spring comes from a spiral type Archimedes, for which only two coilings were considered. The analyzed type-dimensions resulted from the following data:

- thickness of the half-finished clip, g: 0.2, 0.3, 0.5 and 1.0 mm;
- width of the half-finished clip: 4.0 mm;
- length of the clip arms, L: 8.5 mm;
- distance between clip arms, s, in work position: 0.05 mm.

Constructive representation of the clip with double spiral spring is given in figure 6.

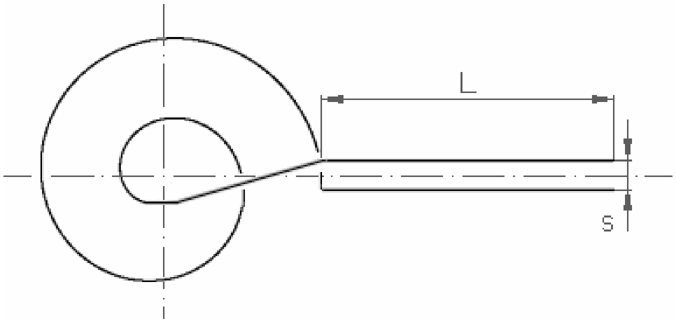

Figure 6: Constructive variant of a clip with double spiral spring

Dimensionally, taking into account only the variation of thickness of the half-finished, there resulted four type-dimensions for this variant of clip.

For both variants of aneurismal clips there have been chosen two materials that are respecting the conditions of biocompatibility and non-interference with magnetic fields or RMN, these being: stainless steel AISI 316 (CrNiMo or CrNiMn) and titan (Ti). The main physical-mechanical characteristics of these two materials are presented in table 1.

Analysis of geometrical models

The 16 type-dimension geometrical models obtained were analyzed using the method of finite elements (FEM), watching the state of stress and deformation in

Table 1: Physical-mechanical properties

Material	**Stainless steel** AISI 316 **(Cr Ni Mo, Cr Ni Mn)**	**Titan** **(Ti)**
Volume mass	8027,3 kg/m^3	4500 kg/m^3
Modulus of elasticity E	1,931 $\times$ 10^{11} Pa	1,098 $\times$ 10^{10} Pa
Coefficient of Poisson υ	0,3	0,313
Elasticity limit σ_y	310,3 MPa	300 MPa
Strength stress σ_r	620,5 MPa	500 MPa
Specific heat	418 Nm/kgK	544 Nm/kgK
Thermal conductivity	46,7 W/mK	7,44 W/mK
Thermal coefficient of diffusion	1,13 $\times$ 10^{-5}	9,34 $\times$ 10^{-6}

material. For that, there were considered the support conditions (embeding type) and loading conditions (a concentrated force or distributed on a given surface), depending on the aspects specific to each variant of clip.

Thus, for the clip with simple spiral spring, due to a symmetry axis, the point of intersection between this symmetry axis and the circle arc of the clip has no displacement, so that this point may be considered as being embeded (rigid fixed); at the same time, for loading, there have been taken into account both concentrated force and distributed force, as represented in figure 7.

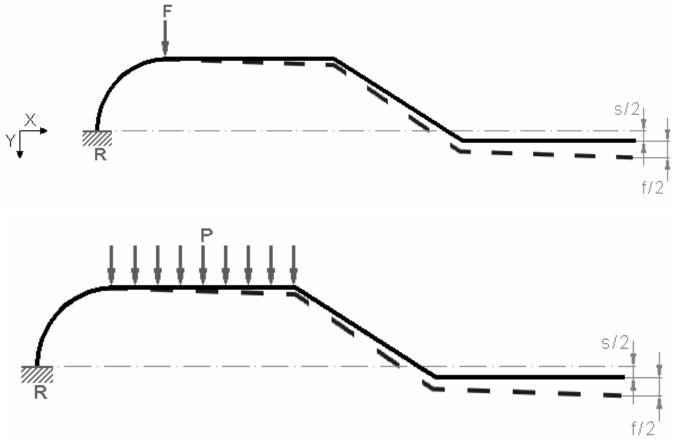

Figure 7: Scheme of analysis for the clip with simple spiral spring

The 12 dimensional variants of the clip with simple spiral spring are multiplied by two, because of the two analyzed materials, and then it is multiplied by four, corresponding to the two extreme values of load of type concentrated force and distrubiuted force. Therefore, it yields a number of 96 of numerical teste performed for the variant of aneurismal clip with simple spiral spring. For each test there is calculated the half-deflection along “Y” axis (displacement along “Y” axis of the clip arm) and the maximum value of the equivalent stress von Mises.

For the clip with double spiral spring, there have been considered that by using the applicator, during applying the clip onto the aneurismal packet, the support, of embeding type, is done at the side opposed to load, of type distributed force (pressure), as can be seen in figure 8.

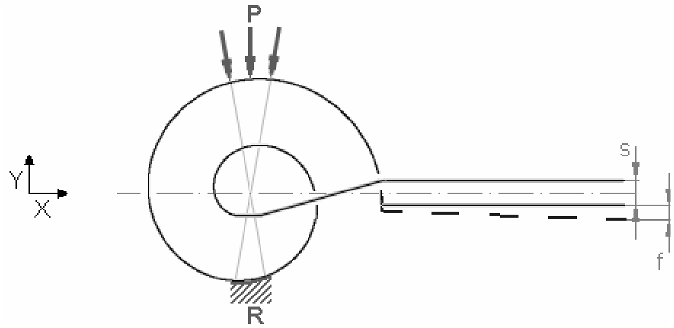

Figure 8: Scheme of analysis for the clip with double spiral spring

The number of numerical tests applied to the clip with double spiral spring is 16, being obtained by multiplying the four dimensional variants with the the two types of materials and with two extreme values of load, of type pressure. Like with the other variant of aneurismal clip, with the help of numerical tests there are determined the deflection (arms opening), as being the displacement along "Y" axis and the maximum value of equivalent stress von Mises.

Validation of a numerical test assumes to simultaneously fulfil two conditions: realizing an imposed force or pressure of griping and a maximum opening of the arms (medical condition) and to not exceed the limit values of elasticity and strength of the material under given load (mechanical condition).

Results and interpretation

The results of the performed analysis for the 112 numerical tests (96 for the clip with simple spiral spring and 16 for the clip with double spiral spring) are presented in table 2.

For simplicity of notations, for the clip with simple spiral spring, instead of L_1 there have

been done the notation L in table 2. The numerical values following after "L" or "g" represent the length of the active linear part of the spring and respectively the thickness of the flat bar of the half-finished clip, in milimeters.

Aanalyzing the results there can be observed that as the thickness of the flat bar of the clip increases, the deflection and the equivalent stress von Mises decrease,

Table 2: Numerical results obtained through FEM analysis
f max – maximum deflection, σ_v max – maximum equivalent stress von Mises
colors code: $\sigma_v \max > \sigma_y$, $\sigma_v \max > \sigma_r$ and maximum deflection of clip arms > 5 mm

Clip	**Simple L4 g0,2 STEEL**	**Simple L4 g0,2 TITAN**
Concentrated force	f max = 0,1748 mm	f max = 0,288 mm
F = 0,8 N	σ_v max = 59,4 MPa	σ_v max = 55,9 MPa
Concentrated force	f max = 1,092 mm	f max = 1,796 mm
F = 5 N	σ_v max = 371 MPa	σ_v max = 350 MPa
Pressure	f max = 0,576 mm	f max = 1,006 mm
P = 1×10^5 Pa	σ_v max = 102 MPa	σ_v max = 99,8 MPa
Pressure	f max = 3,64 mm	f max = 6,30 mm
P = $6{,}25 \times 10^5$ Pa	σ_v max = 638 MPa	σ_v max = 624 MPa

Clip	**Simple L4 g0,3 STEEL**	**Simple L4 g0,3 TITAN**
Concentrated force	f max = 0,1172 mm	f max = 0,206 mm
F = 0,8 N	σ_v max = 40,4 MPa	σ_v max = 40,4 MPa
Concentrated force	f max = 0,732 mm	f max = 1,288 mm
F = 5 N	σ_v max = 252 MPa	σ_v max = 253 MPa
Pressure	f max = 0,346 mm	f max = 0,604 mm
P = 1×10^5 Pa	σ_v max = 87,6 MPa	σ_v max = 87,4 MPa
Pressure	f max = 2,16 mm	f max = 3,78 mm
P = $6{,}25 \times 10^5$Pa	σ_v max = 548 MPa	σ_v max = 546 MPa

Clip	**Simple L4 g0,5 STEEL**	**Simple L4 g0,5 TITAN**
Concentrated force	f max = 0,0384 mm	f max = 0,0674 mm
F = 0,8 N	σ_v max = 19,7 MPa	σ_v max = 20,1 MPa
Concentrated force	f max = 0,240 mm	f max = 0,422 mm
F = 5 N	σ_v max = 123 MPa	σ_v max = 124 MPa
Pressure	f max = 0,1012 mm	f max = 0,1774 mm
P = 1×10^5 Pa	σ_v max = 36,9 MPa	σ_v max = 36,7 MPa
Pressure	f max = 0,632 mm	f max = 1,110 mm
P = $6{,}25 \times 10^5$ Pa	σ_v max = 230 MPa	σ_v max = 229 MPa

Clip	**Simple L4 g1,0 STEEL**	**Simple L4 g1,0 TITAN**
Concentrated force	f max = 0,00386 mm	f max = 0,00674 mm
F = 0,8 N	σ_v max = 5,22 MPa	σ_v max = 5,10 MPa
Concentrated force	f max = 0,0242 mm	f max = 0,0422 mm
F = 5 N	σ_v max = 32,7 MPa	σ_v max = 31,9 MPa
Pressure	f max = 0,01112 mm	f max = 0,01942 mm
P = 1×10^5 Pa	σ_v max = 9,30 MPa	σ_v max = 9,23 MPa
Pressure	f max = 0,0694 mm	f max = 0,1214 mm
P = $6{,}25 \times 10^5$ Pa	σ_v max = 58,2 MPa	σ_v max = 57,7 MPa

Tab. 2 (continuation)

Clip	**Simple L6 g0,2 STEEL**	**Simple L6 g0,2 TITAN**
Concentrated force	f max = 0,242 mm	f max = 0,424 mm
F = 0,8 N	σ_v max = 61,1 MPa	σ_v max = 61,7 MPa
Concentrated force	f max = 1,508 mm	f max = 2,64 mm
F = 5 N	σ_v max = 381 MPa	σ_v max = 385 MPa
Pressure	f max = 1,298 mm	f max = 2,28 mm
P = 0,67 × 10^5 Pa	σ_v max = 169 MPa	σ_v max = 168 MPa
Pressure	f max = 8,08 mm	f max = 14,14 mm
P = 4,17 × 10^5 Pa	σ_v max = 1050 MPa	σ_v max = 1050 MPa

Clip	**Simple L6 g0,3 STEEL**	**Simple L6 g0,3 TITAN**
Concentrated force	f max = 0,1288 mm	f max = 0,228 mm
F = 0,8 N	σ_v max = 42,4 MPa	σ_v max = 42,7 MPa
Concentrated force	f max = 0,806 mm	f max = 1,422 mm
F = 5 N	σ_v max = 265 MPa	σ_v max = 267 MPa
Pressure	f max = 0,572 mm	f max = 1,000 mm
P = 0,67 × 10^5 Pa	σ_v max = 120 MPa	σ_v max = 120 MPa
Pressure	f max = 3,56 mm	f max = 6,22 mm
P = 4,17 × 10^5 Pa	σ_v max = 748 MPa	σ_v max = 746 MPa

Clip	**Simple L6 g0,5 STEEL**	**Simple L6 g0,5 TITAN**
Concentrated force	f max = 0,0428 mm	f max = 0,0754 mm
F = 0,8 N	σ_v max = 19,4 MPa	σ_v max = 19,5 MPa
Concentrated force	f max = 0,268 mm	f max = 0,472 mm
F = 5 N	σ_v max = 121 MPa	σ_v max = 122 MPa
Pressure	f max = 0,1616 mm	f max = 0,284 mm
P = 0,67 × 10^5 Pa	σ_v max = 46,4 MPa	σ_v max = 46,1 MPa
Pressure	f max = 1,006 mm	f max = 1,762 mm
P = 4,17 × 10^5 Pa	σ_v max = 289 MPa	σ_v max = 287 MPa

Clip	**Simple L6 g1,0 STEEL**	**Simple L6 g1,0 TITAN**
Concentrated force	f max = 0,00424 mm	f max = 0,0074 mm
F = 0,8 N	σ_v max = 5,36 MPa	σ_v max = 5,33 MPa
Concentrated force	f max = 0,0266 mm	f max = 0,0462 mm
F = 5 N	σ_v max = 33,5 MPa	σ_v max = 33,3 MPa
Pressure	f max = 0,01798 mm	f max = 0,0314 mm
P = 0,67 × 10^5 Pa	σ_v max = 12,7 MPa	σ_v max = 12,5 Mpa
Pressure	f max = 0,1118 mm	f max = 0,1954 mm
P = 4,17 × 10^5 Pa	σ_v max = 79,1 MPa	σ_v max = 77,7 MPa

Tab. 2 (continuation)

Clip	**Simple L8 g0,2 STEEL**	**Simple L8 g0,2 TITAN**
Concentrated force	f max = 0,206 mm	f max = 0,360 mm
F = 0,8 N	σ_v max = 57,2 MPa	σ_v max = 55,9 MPa
Concentrated force	f max = 1,288 mm	f max = 2,26 mm
F = 5 N	σ_v max = 357 MPa	σ_v max = 350 MPa
Pressure	f max = 1,778 mm	f max = 3,12 mm
P = 0,5 × 10^5 Pa	σ_v max = 183 MPa	σ_v max = 182 MPa
Pressure	f max = 11,12 mm	f max = 19,46 mm
P = 3,125 × 10^5 Pa	σ_v max = 1150 MPa	σ_v max = 1140 MPa

Clip	**Simple L8 g0,3 STEEL**	**Simple L8 g0,3 TITAN**
Concentrated force	f max = 0,224 mm	f max = 0,390 mm
F = 0,8 N	σ_v max = 61,2 MPa	σ_v max = 57,5 MPa
Concentrated force	f max = 1,380 mm	f max = 2,44 mm
F = 5 N	σ_v max = 383 MPa	σ_v max = 359 MPa
Pressure	f max = 1,086 mm	f max = 1,902 mm
P = 0,5 × 10^5 Pa	σ_v max = 170 MPa	σ_v max = 169 MPa
Pressure	f max = 6,78 mm	f max = 11,88 mm
P = 3,125 × 10^5 Pa	σ_v max = 1060 MPa	σ_v max = 1060 MPa

Clip	**Simple L8 g0,5 STEEL**	**Simple L8 g0,5 TITAN**
Concentrated force	f max = 0,0476 mm	f max = 0,0834 mm
F = 0,8 N	σ_v max = 19,3 MPa	σ_v max = 19,8 MPa
Concentrated force	f max = 0,298 mm	f max = 0,520 mm
F = 5 N	σ_v max = 121 MPa	σ_v max = 124 MPa
Pressure	f max = 0,240 mm	f max = 0,420 mm
P = 0,5 × 10^5 Pa	σ_v max = 54,6 MPa	σ_v max = 54,3 MPa
Pressure	f max = 1,494 mm	f max = 2,62 mm
P = 3,125 × 10^5 Pa	σ_v max = 341 MPa	σ_v max = 339 MPa

Clip	**Simple L8 g1,0 STEEL**	**Simple L8 g1,0 TITAN**
Concentrated force	f max = 0,0048 mm	f max = 0,00836 mm
F = 0,8 N	σ_v max = 5,47 MPa	σ_v max = 5,83 MPa
Concentrated force	f max = 0,0300 mm	f max = 0,0522 mm
F = 5 N	σ_v max = 34,1 MPa	σ_v max = 36,4 MPa
Pressure	f max = 0,0274 mm	f max = 0,0480 mm
P = 0,5 × 10^5 Pa	σ_v max = 15,2 MPa	σ_v max = 150 MPa
Pressure	f max = 0,1714 mm	f max = 0,300 mm
P = 3,125 × 10^5 Pa	σ_v max = 94,9 MPa	σ_v max = 93,8 MPa

Tab. 2 (continuation)

Clip	**Double g0,2 STEEL**	**Double g0,2 TITAN**
Pressure	f max = 3,40 mm	f max = 5,78 mm
P = 5,7 × 10^5 Pa	σ_v max = 550 MPa	σ_v max = 551 MPa
Pressure	f max = 20,4 mm	f max = 37,4 mm
P = 35,62 × 10^5 Pa	σ_v max = 3440 MPa	σ_v max = 3440 MPa

Clip	**Double g0,3 STEEL**	**Double g0,3 TITAN**
Pressure	f max = 0,986 mm	f max = 1,87 mm
P = 5,7 × 10ˆ5 Pa	σ_v max = 249 MPa	σ_v max = 250 MPa
Pressure	f max = 6,12 mm	f max = 11,6 mm
P = 35,62 × 10ˆ5 Pa	σ_v max = 1560 MPa	σ_v max = 1560 MPa

Clip	**Double g0,5 STEEL**	**Double g0,5 TITAN**
Pressure	f max = 0,204 mm	f max = 0,357 mm
P = 5,7 x10^5 Pa	σ_v max = 90,6 MPa	σ_v max = 90,6 MPa
Pressure	f max = 1,29 mm	f max = 2,21 mm
P = 35,62 x10^5 Pa	σ_v max = 566 MPa	σ_v max = 566 MPa

Clip	**Double g1,0 STEEL**	**Double g1,0 TITAN**
Pressure	f max = 0,0187 mm	f max = 0,0340 mm
P = 5,7 × 10^5 Pa	σ_v max = 21,5 MPa	σ_v max = 21,5 MPa
Pressure	f max = 0,121 mm	f max = 0,208 mm
P = 35,62 × 10^5 Pa	σ_v max = 134 MPa	σ_v max = 135 MPa

but in change, the length of the linear active part of the simple spring does not influence in a definite way the deflection and the stress von Mises. The results confirm the fact that titan is more elastic at effort than stainless steel.

Among the aneurismal clips with simple spiral spring, eight of them have a value of deflection bigger than 5 mm when there is applied a load of type pressure; the variants of clip in this situation are: L4 g0.2 (titan), L6 g0.2 (steel and titan), L6 g0.3 (titan), L8 g0.2 (steel and titan) and L8 g0.3 (steel and titan). Unfortunately, for the all eight variants of clip there are exceeded the values of strength stress, therefore they must be eliminated. However, there could be kept five variants of clip for which the deflection is a little bit bigger than 5 mm and the maximum stress von Mises is smaller than the strength stress of material; the five variants are:

- L4 g0.2 (titan), f_{max} = 5,04 mm,
- L6 g0.2 (titan), f_{max} = 5,08 mm,
- L8 g0.2 (steel), f_{max} = 5,34 mm,
- L8 g0.2 (titan), f_{max} = 6,22 mm,
- L8 g0.3 (titan), f_{max} = 5,34 mm.

From the analysis of the results obtained for the clip with double spiral spring, there can be observed that four variants perform a deflection bigger than 5 mm, but in change there are exceeded, in this case, the values of strength stress of material. For the others four variants of this type of clip, there are obtained small values of the deflection of arms, and they can not be used from medical point of view. There can be concluded that this type of aneurismal clip is not functional, being necessary different conditions regarding the support and the surface on which the load acts, or being necessary to conceibe another geometry starting from theoretical spiral of Archimedes.

Conclusions

Conceveing and analyzing some models of aneurismal clips using the computer is the first step, compulsory, for fabrication of these products. Numerical simulation and analysis, using finite element method, allow to "visualise" the real behavior of the material and the geometry of the possible intracranian aneurismal clip, being an "interface" between engineer and neurosurgeon. The values obtained through simulation are enough close to the real data, they offering informations absolutely necessary for experimental tests "in vitro".

As a sequel of analysis of 112 numerical tests for the 32 variants of aneurismal clip, only 5 variants respected the imposed conditions, these being of the type clip with simple spiral spring. No variant of aneurismal clip with double spiral spring did not respected the imposed conditions, being not employable practically.

From technological point of view, the flat bars with bigger thickness are more advantageous, but in change, as the thickness increases, the deflection decreases, the clpi becoming not employable. Using numerical simulation, there can be found the optimal value of the thickness for satisfying the imposed citeria.

Validation of new geometrical shapes of aneurismal clips may be done, firstly, only with the help of simulation and analysis, by numerical testing.

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