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TOPOLOGY OPTIMIZATION OF THE STENTS CELLS PLANE MODEL WITH MAXIMUM HARDENING AND FLEXIBILITY

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ABSTRACT

Stents for angioplasty have been extensively used in the treatment of cardiovascular diseases; they should be flexible during the implant procedure and stiff after the implant. The design criteria depend on the stent material distribution. The objective of this work is to apply topology optimization as a mechanical design tool in order to provide the best material distribution of a stent. In this context, the flexibility and hardening are formulated in different objective functions to be maximized. The idea of the procedure is to compute the sensibility of each element from the design space by using the finite element method. Subsequently, the calculated sensibility is used to update the stent material distribution. The updating of the stent topology is based on the optimality criteria by computing the Lagrangian multiplier from the volume constraint. The optimization subroutines have been implemented in Matlab® 6.5. The computation of the plastic and elastic strain energy to be used in the calculation of sensibility are extracted from software ANSYS® 6.0 and Matlab® 6.5. The results illustrate the topology of the optimized stent cell.

INTRODUCTION

The heart diseases have been one of the greatest causes of death among adults around the world. In most cases, the problem arises when the coronary arteries, the arteries that supply blood to the heart muscle, get blocked due to accumulation of certain substances such as cholesterol [1]. In the past, most of cardiovascular diseases were treatable through a by-pass surgery. Nowadays, a surgery free catheter-based procedure has been extensively used to unblock the blocked artery. In this procedure, a thin tube called stent is placed in the region of the unblocked artery to prevent closure.

There are many criteria to be considered in the stent design [2-4]. The major role of a stent is to prevent restenosis, which is the re-closure of the unblocked artery. Due to this, the stent should be sufficiently stiff in order to avoid any artery diameter reduction after the implant. On the other hand, the stent should be also flexible during the implant procedure. If the stent is not flexible, it could not track the catheter during the navigation inside the blood vessel.

NOMENCLATURE

A = gradient of objective
C(x) = compliance
D = gradient of f
E = Young's Modulus
f = volume fraction
F = force vector
K = stiffness matrix
L = stent length
m = move limit
p = penalization power
t = stent thickness
U = displacement
V = total volume
V(x) = stent volume
w = stent width
W = hardening work
x = relative density

Greek Symbols

ε = strain
λ = Lagrangian multiplier
σ = yield stress

Subscripts

0 = solid material
1 = applied load
2 = measured load
b = buckling
f = flattening
p = plastic range
t = tangent

Superscripts

j = index iteration
T = transpose

The material and the geometry of stents are the parameters that control explicitly their flexibility and stiffness. The influence of these parameters on the design criteria of stents has been studied in several works published in the literature [2-5]. In these applications, nonlinear finite elements models or experimental techniques are usually used in order to simulate the response of a stent. Subsequently, the stent designer creates a geometrical model based on the analysis of the response that was simulated. The intuition and experience are the tools that the designer uses to create the optimized stent geometry. However, there is no information concerning the application of the numerical optimization techniques to the design of stents.

Topological Optimization is one of optimal structural design tools that may be used for improving the stent geometry. The idea of the procedure is to solve the inverse problem of obtaining the best material distribution of a structure with specific properties [6]. For linear problems, the procedure has been usually applied for the maximization of stiffness and flexibility [6-8]. Recently, topology optimization has also been used for the optimization of structures subjected to plastic strain [9-10]. Then, this technique may be also applied to the definition of the stent material distribution.

The main objective of this work is to employ topological optimization as a geometrical design tool of stents made of stainless steel 316L. The hardening of the stent structure after the implant and its flexibility during the implant procedure will be optimized separately by using different objective functions. A Bilinear Isotropic Hardening model will be used as the constitutive law for the stainless steel 316L. A description of the main models used in the analysis of stents and the formulation of the topology optimization problem will be shown in this work. The discussion of the obtained results and the final conclusions are described at the end of paper.

MODELS AND DEFINITION OF STENTS

What are Stents

A stent may be defined as any device with circular section used to reinforce the internal wall of a vessel [5]. Figure (1) illustrates a Computer Aided Design model of a stent. As can be seen, its structure is formed by a repetitive geometrical pattern, known as cells [3]. After the implant, the stent diameter is usually two to four times larger than the original one [2]. In this phase, the stent external surface contacts the internal surface of the vessel wall. The importance of this contact between stent and vessel is to prevent restenosis after the implant.

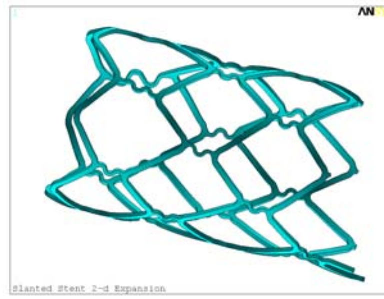

Fig. 1. Three-dimensional stent [3].

The stents design conception depends on the material used in their manufacture. In most cases, metallic stents either are made of stainless steel or are manufactured from a NiTi alloy (Nitinol). Nitinol stents are super-elastic, self-expanding and adapt better to the artery wall anatomy. Stainless steel stents are subjected to plastic strain. In this case, an expandable balloon placed at the end of catheter inflates and deforms plastically the stent [4]. In this work, it will be emphasized only the design characteristics of stainless steel stents.

Models of Stents

After the implant, the stent will be subjected to a distributed compressive load, which is applied by the artery wall. In practice, this load will change depending on the artery anatomy shape [4]. In this situation, there will be tension, torsion and bending components in the cylindrical three-dimensional stent model shown in fig. (1). Nonlinear finite elements analysis provides the stress and strain distributions of these highly complex loading components [3-4].

It can be demonstrated that the order of magnitude of the stent bending component is usually much larger than the others load components [4]. The major effects of this component are buckling and flattening of the stent circular cross section. Consider the plane model of one cell shown in the Fig. (2). A firstorder approximation of the buckling stiffness for a load applied in the plane of the stent cell can be given by [4]:

$$K_b \propto \frac{Ew^3 t}{L^3} \qquad (1)$$

and, similarly, the stent flattening stiffness, K_f, for a normal loading applied to the cell can be approximated by:

$$K_f \propto \frac{Et^3 w}{L^3} \qquad (2)$$

where E is the Young's Modulus of the material, t is the tube thickness, w is the stent cell width and L the cell length in the longitudinal direction. Equation (1) illustrates that the contribution of t in the stent buckling stiffness, K_b, is negligible when compared to the parameters w and L. This proves that the K_b depends on the geometrical parameters of the cell model shown in the Fig. (2). The stent thickness t, which is normal to the cell plane does not contribute effectively in the calculation of K_b [4].

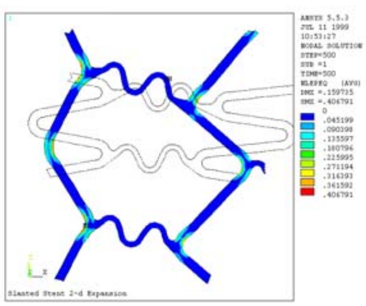

Fig. 2. Plane model of the stent cell [3].

Equation (2) shows that the stent thickness has a major role in the calculation of the flattening stiffness. The importance of the geometry of the stent cell plane model in the derivation of K_f is negligible [4]. However, this design problem will not be studied in this work. Note that the Eqs. (1) and (2) are only good approximations of the stent stiffness within the linear elastic range. For cells with more complicated geometry, subjected to plastic strain, K_f and K_b should be estimated using the finite element method [4-5].

TOPOLOGICAL OPTIMIZATION OF THE STENT CELL PLANE MODEL

Formulation of the Problem with Maximum Hardening

The stent should be stiff after the implant procedure. Physically, the topology of an ideally stiff stent has minimal strain energy. It means that the stent should not deform once implanted in the artery. Mathematically, this topology optimization problem is defined by [6]:

$$\text{Minimize:} \quad C(x) = U^T K U \qquad (3)$$

$$\text{Subjected to:} \quad \frac{V(x)}{V} = f \qquad (4)$$

$$KU = F \qquad (5)$$

$$0 \le x_{min} \le x \le 1 \qquad (6)$$

where C(x) represents compliance or elastic strain energy of the structure. The variable K denotes the global stiffness matrix of the finite element model, U is the displacement vector and F the load vector applied to the structure. During the optimization, the user selects the optimal topology volume V(x). This parameter divided by the design space volume, V, defines the optimal topology volume fraction, f. The relative density of the structure finite elements, x, is the design variable of this optimization problem.

This formulation would be valid if the stent was only subjected to elastic strains. During the expansion of the balloon, the stent is subjected to an outward internal pressure in the radial direction. This radial pressure increases the stent diameter and generates plastic strain regions in all cells. The role of these plastic strain regions is to avoid restenosis of the blood vessel after the implant.

This state of irreversible strain is provided by the hardening of the stainless steel stent [11]. The larger the hardening, the larger will be the stresses needed to deform plastically the stent material. Indeed, the stent hardening improves its ability of reinforcement of the artery wall after the implant.

In this situation, it is convenient to maximize the hardening work of the stent, W, during the expansion of the balloon. Therefore, instead of the Eq. (3), the objective function to be maximized will be given by:

$$W = \int_V \varepsilon_p^T E_p \varepsilon_p dV \tag{7}$$

and the Eq. (7) also represents the plastic strain energy of the stent after the implant. The variable ε_p is the plastic strain field in the stent material due to the expansion procedure. The Plastic Modulus, E_p, is defined by:

$$E_p = \frac{E_t E}{E - E_t} \tag{8}$$

where E_t denotes the Tangent Modulus obtained from a Bilinear Isotropic Hardening model [9]. In this constitutive law model, the elastic and plastic ranges are approximated by the Tangent Modulus, E_t, and the Young's Modulus, E, respectively.

The numerical implementation of topology optimization procedure defined by the Eq. (8) subjected to constraints (4), (5) and (6) requires that a material interpolation law be used. In this work, it will be used the power-law approach [6]. For the Bilinear Isotropic Hardening model, the material properties and relative density, x, of each finite element are modeled by [12]:

$$E = (x)^p E_0 \tag{9}$$

$$E_t = (x)^p E_{t0} \tag{10}$$

$$\sigma = (x)^p \sigma_0 \tag{11}$$

where σ is the yield stress of the elastic-plastic material. The parameter p is the penalty power usually equals to 3 (three) [6]. The subscript 0 (zero) represents the constant properties of the solid material with relative density equals to 1.

Formulation of the Problem with Maximum Flexibility

The flexibility of the stent during the implant procedure should also be incorporated in the formulation of the topology optimization problem [2-4]. For this purpose, consider the elastic solid body in static equilibrium shown in Fig. (3), subjected to two loads, F_1 and F_2. The load F_1 produces a displacement field U_1 and, analogously, the load F_2 generates a displacement U_2 in the elastic solid. In this context, the load F_1 has magnitude $|F_1|$ but, the load F_2 is a unit dummy force. A definition of flexibility can be given by [7-8]:

$$C(x) = U_1^T K U_2 \tag{12}$$

This equation is also known as mutual mean compliance. The equation (12) represents a measure of the deformation of the structure in the direction of the unit dummy load, F_2, when the load F_1 is applied [7]. In this sense, deformation in the direction of the load F_2 due to load F_1 is interpreted as the flexibility of the structure. Therefore, a highly flexible structure has a large value of the mutual mean compliance.

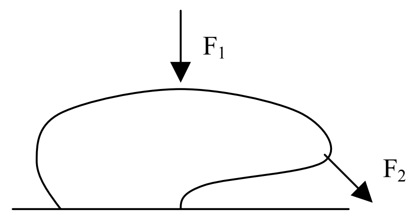

Fig. 3. Concept of flexibility of an elastic body.

The problem of the maximization of the flexibility of a stent is not as simple as the minimization of Eq. (3). If no limit is imposed during the maximization of the Eq. (12), the structure will deform indefinitely when the load F_1 is applied. In this situation, mutual mean compliance will be close to infinity. One way to deal with this ill-conditioned problem is not let the structure to deform indefinitely. For this, the stiffness represented in the Eq. (3) should be considered simultaneously in the formulation of the structural flexibility. The optimization problem now will be [8]:

$$\text{Minimize:} \quad -\frac{U_1^T K U_2}{U^T K U} \tag{13}$$

$$\text{Subjected to:} \quad \frac{V(x)}{V} = f \tag{14}$$

$$K U_1 = F_1 \tag{15}$$

$$K U_2 = F_2 \tag{16}$$

$$K_1 U = F \tag{17}$$

$$0 \le x_{min} \le x \le 1 \tag{18}$$

where the constraints (15) and (16) are respectively the equilibrium equations of the finite elements model of the structure due to two loads, F_1 and F_2, used in the calculation of $U_1^TKU_2$. The solution of the Eq. (17) provides the displacement field U to be used in the computation of strain energy U^TKU. For the calculation of U_1 and U_2, it is used the same finite elements model and boundary conditions, subjected to two different loads cases, F_1 and F_2. In the derivation of U, the stiffness matrix K_1 is not the same once the boundary conditions may be modified.

This formulation will be adopted in this work as a topological design model of the stent cell flexibility. Once again, the power-law approach will be used for the modeling of the material properties. The flexibility of the stent will be defined for the elastic range. In this case, the Young's Modulus defined in the Eq. (9) will be the only material property to be considered.

NUMERICAL IMPLEMENTATION OF THE PROCEDURE

The stent volume fraction is the only active constraint of both formulations above described. Furthermore, the maximization of hardening and the maximization of the flexibility have a large number of design variables. These design variables are the relative density of each finite element from design space. For problems of this nature, the optimality criteria method is the optimizer more eficient and simpler to obtain the optimal solution [6-8]. Therefore, it will be used in this work in order to provide the stent cell optimal topology.

The optimality criteria method is based on the Kuhn-Tucker conditions applied to Lagrangian of the objective function and constraints [6]. For both formulations, maximization of the hardening and flexibility, it can be demonstrated that [6,9]:

$$A + \lambda D = 0 \qquad (19)$$

is the minimum of both optimization problems. This is the solution from design space where the derivative of the Lagrangian with respect to the relative density, x, vanishes [6,9]. In particular, for each problem, the parameter A represents the gradient of the objective function defined in the Eq. (7) or (13). The parameter D denotes the derivative of active volume constraint, written as:

$$V(x(\lambda)) - fV = 0 \qquad (20)$$

The value of the Lagrangian multiplier λ given by the solution of the Eq. (20) provides the minimum of the optimization problem stated in the Eq. (7) or (13). This concept will be used in this work in order to derivate an updating scheme of the stent cell topology. Equation (19) multiplied by –1 denotes the gradient of both constrained formulations. Geometrically, Eq. (19) represents the steepest descent direction in the design space. In this context, an updating scheme of the relative density will be defined by [7]:

$$x^{j+1} = x^j - \left(A^j + \lambda^j D^j\right) \qquad (21)$$

The Eq. (21) is a commonly used representation of most numerical optimization algorithms [13]. Although Eq. (21) is the simplest way of updating the design variables, it is enough efficiency in the topology optimization field [7]. The index j denotes the number of iteration used in the updating of the relative density. Unfortunately, Eq. (21) does not guarantee a stable convergence since abrupt changes may occur in the formation of the topology. In order to stabilize the formation of the topology, the following procedure was used in this work [6]:

$$\max(0.001, x^j - m) \le x^{j+1} \le \min(1, x^j + m) \qquad (22)$$

where m represents a limit value of the change of relative density. The role of this parameter is to avoid the formation of discontinuities in the topology during the optimization [6]. The choice of the value of this parameter depends on the behaviour of objective function to be optimized. In Eq. (22), 0.001 and 1 are respectively the minimum and maximum values which the relative density can assume (side constraints).

The Fig. (4) illustrates the steps of the topology optimization algorithm to be used in the problem of the flexibility or hardening. Initially, all finite elements from design space have relative density equal to volume fraction chosen by the user. For the maximization problem of the flexibility, the nodal displacement fields U_1, U_2 and U are obtained by solving the equilibrium equations (15), (16) and (17). These displacements will be extracted from a subroutine implemented in the Matlab® 6.5 [6]. For the hardening problem, it will be used the finite element software ANSYS® 6.0 in order to extract the plastic strain field of the stent design space. Subsequently, the objective function sensibility is calculated and filtered [6]. Finally, the Lagrangian multiplier λ from volume constraint is determined using a bi-sectioning algorithm and the topology of stent cell is updated according to Eq. (22). The subroutines of filtering, optimization and updating of the stent cell topology have been implemented in Matlab® 6.5 [6].

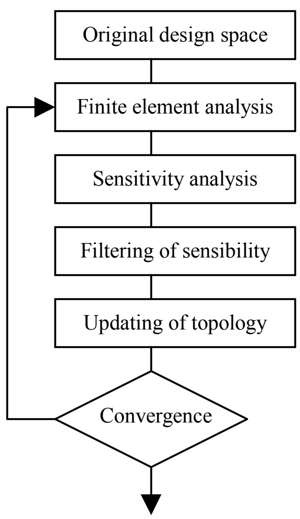

Fig. 4. Flowchart of the optimization algorithm.

STRUCTURAL MODEL FOR THE STENT CELL TOPOLOGY OPTIMIZATION

It has been shown in Fig. (2) a plane model for the stent cell that simulates the expansion process due to pressure applied by a balloon [3]. This figure compares the cell shape before and after the expansion. The stent cell shown in this figure has two symmetrical legs in the vertical direction . It can be seen some regions in these legs where the stress level exceeds the yield stress. The hardening of these plastic strain regions provides the capacity to support the vessel wall after the implant.

The two symmetrical legs shown in the Fig. (2) are linked by two curved structures in the longitudinal direction [3]. The major role of these curved linkage elements is to improve the flexibility of the stent. A flexible linkage element should absorb a large amount of elastic deflection energy. A better tradeoff between the flexibility and stiffness of the stent cell depends on the combination of the legs geometry with the linkage elements [2-4].

This design conception will be used in this work to create the optimal topology of the stent cell by considering each criteria separately. For the stent hardening problem, the Fig. (5) illustrates the design space and the boundary conditions that simulate the balloon expansion [3]. Because of the symmetry of the stent cell, it will only be considered the half of its design space. Most of commercial stents have a volume fraction equal or smaller than 20% of the original design space volume [2]. This same value will be used in this work to avoid the stent recrossability.

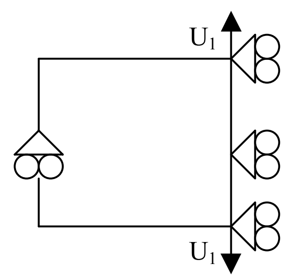

Fig. 5. Model for the stent hardening.

Table 1. Physical properties of the stent [2].

Property	Magnitude
Young's Modulus	190GPa
Tangent Modulus	1300MPa
Yield Stress	250MPa
Poisson's ration	0.3
Stent cell length	0.5mm
Stent cell high	0.4mm

Table (1) shows the geometrical parameters as well as the material properties to be used for this problem [3]. The displacement U_1 applied to the botton and upper right corner of the design space is equal to 0.15mm. This load simulates the effect of the stent cell expansion during the implant. Nonlinear finite element analysis from software ANSYS® 6.0 simulates this expansion process several times during the optimization.

The physical model for the maximization of the flexibility of the stent cell is shown in the Fig. (6). The length and the high of this design space are respectively, 0.30 mm and 0.20 mm. For this case, the only material property to be used is the Young's Modulus from Table (1). The vertical load F_1 simulates the catheter movement effect during the stent navigation into the vessel. The dummy load F_2 is the desirable direction of the stent flexibility. It is applied at the middle of the bottom edge of the design space shown in the Fig. (6). Moreover, the flexible stent cell should maintain its shape when subjected to deflection caused by the load F_1 [8]. Then, the cell stiffness should also be maximized due to the compressive load F [8].

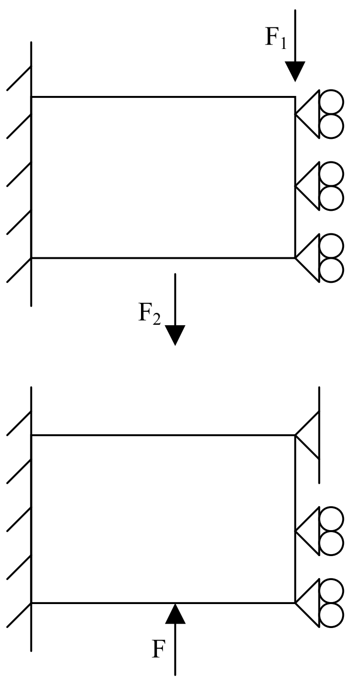

Fig. 6. Model for the stent flexibility.

ANALYSIS OF THE RESULTS

Figure (7) shows the optimal topology of the stent cell with maximum hardening. A mesh of 24 by 20 solid finite elements with 4 (four) nodes in plane stress state was used for the discretization of the stent cell design space. For this situation, the objective to be maximized is defined in the Eq. (7) subjected to constraints (4), (5) and (6). The procedure has converged with 146 iterations by employing a limit m equals to 0.05. This value of move limit, 0.05, has been selected based on the observation of the convergence of the stent cell topology. The topology shown in the Fig. (7) has an error equals to 0.3% between two steps of solution.

The topology optimization procedure with maximum hardening distributed material in the regions of plastic strain of the stent cell. It is observed in Fig. (7), the presence of material connecting the application point of the displacements U_1 to the middle of the left edge that is supported only in the vertical direction. Furthermore, there is material in the right edge of the stent cell optimal topology. The presence of this right edge does not allow any displacement in the horizontal direction. The combination of these two material distribution patterns shown in the Fig. (7) maximizes the stent cell hardening.

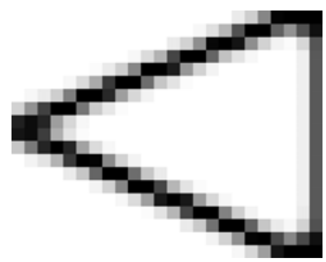

Fig. 7. Cell topology with maximum hardening.

The optimal topology of the stent cell with maximum flexibility and stiffness is shown in Fig. (8). For this problem, it was used a mesh of 30X20 solid finite elements of 4 (four) nodes in plane stress state. This topology converged with 3397 iterations by using a limit m equals to 0.0005. The limit m chosen for this situation is considerably less than the value of m used in the last situation (0.05). Due to sudden behaviour of the flexibility in the objective function (13), it was necessary to use a minor value of m in order to prevent a divergence in the solution process [8].

The topology with maximum stiffness and flexibility illustrated in the Fig. (8) is more complex than the topology shown in Fig. (7). In this situation, there is more material in the region of the application point of the load F. The role of this local material distribution is to improve the stiffness of the stent cell. On the other hand, there is material connecting the point of the load F_2 with the left edge. It can be seen the presence of a hinge, close to left edge. Indeed, this topology pattern improves the flexibility of stent cell without damaging the stiffness of the topology.

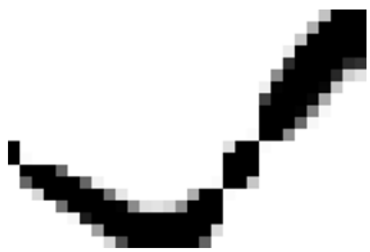

Fig. 8. Cell topology with maximum flexibility.

The optimal topology of the stent cell is the combination of the stiff and flexible topologies shown in the Figs. (7) and (8). The geometries shown in these figures can be manufactured by using the laser cutting process [5]. The flexible linkage elements of commercial stents shown in the Fig. (2) do not have hinges [2]. However, these hinges improve the flexibility of the cell in the direction of the load F_2.

CONCLUSIONS

A methodology for the optimal topology design of the stent cell plane model was proposed in this work. The stent cell topology with maximum hardening and flexibility were computed and studied separately. These topology patterns were generated based on the design conception of a stent. For the case that considers only the hardening, the procedure distributed material where the plastic strain fields were larger. In the situation involving the flexibility and stiffness, the methodology have emphasized both design criteria. Then, it has been proved that this technique can serve as a stent cell design tool.

Another stent cell design conception is to consider hardening and flexibility in a unique topology optimization problem. The stent cell optimal topology that incorporates these design criteria simultaneously should be different when compared to the topologies shown in this work. In the future, others boundary conditions as well as the hardening added to flexibility will also be considered in the stent cell topology optimization problem.

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