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Deformation behaviour of self-expanding magnesium stents based on auxetic chiral lattices

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Abstract

Current stenting solutions commonly employ metal alloys and are permanent. This fact has the consequence of diverse long term risks for the patients, e.g. Restenosis, late-term stent Thrombosis, etc. One possible solution to attenuate these problems is the use of polymer or metallic based bioabsorbable stents that tend to be degraded by corrosion and completely eliminated after their scaffolding duties are fulfilled. Additionally, there is a need to find new ways of deploying these devices. A route to fulfill this goal, can be the design of stents that eliminate the necessity of balloon expansion and are able to self-expand by their own deformation mechanism, for example by possessing auxetic behavior. The objective of this study is the modeling of a stent that reveals auxetic behavior and is composed by a biodegradable material (AZ91D Magnesium alloy), to embrace both recent tendencies on stenting designs. It is shown that the defined stent modeling is able to expand when stretched (auxetic behavior) and reveals a deformation mechanism that may be interesting for further development. In conclusion, the combination of both biodegradable and auxetic characteristics shown in this study may be a future step in the evolution of these medical devices.

Keywords: stent; biodegradable; auxetic; elasto-plastic; finite element.

1. Introduction

Coronary stents are medical devices that may be defined as scaffolds with a round tubular geometry, typically adopted to treat coronary heart disease [1] such as atherosclerosis [2], and to re-establish vascular lumen, regular blood flow [3] and prevent early arterial recoil [4]. This device is deployed within a coronary artery and expanded, generally by the inflation of a balloon that applies a plastic deformation in the stent [5], to open and support the vessel [6].

Commonly, the deployed stents are permanent and composed by metal alloys such as stainless steel (316L), cobalt-chromium (CoCr) [2] or nitinol (NiTi) [7]. These materials have the advantage of possessing enhanced mechanical strength and support severe elastic and plastic deformation [1] when compared with common light alloys (additionally, NiTi also presents shape memory characteristics [7]). However, given the permanent character of the stents that use the referred materials, there is an associated risk of restenosis [4], rise of late and very-late stent thrombosis [8], demand of anti-platelet therapy and long-term patient health risks [2].

Reducing these risks is possible by the adoption of bioabsorbable stents. This type of devices has attracted attention given their ability to provide temporary scaffolding [9]. They represent the ideal stent,

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providing a gradual loss of mass and mechanical strength, while the arterial vessel recovers. After a projected time span, it is fully degraded and disappears, allowing the original tissue to find a new equilibrium [6].

Bioabsorbable stents may be produced using polymers or metals, although both types present lower mechanical properties when compared with permanent stents. Moreover, polymer based stents may cause adverse reactions and even lower mechanical properties, when compared to metal based bioabsorbable stents [10].

Absorbable metallic based stents are generally composed by Iron or Magnesium alloys, and are a newly emerging cardiovascular technology [2]. They are considered promising candidates and the next evolutionary step concerning this kind of medical devices [1], given their good combination of mechanical, corrosion, production [11] and biocompatibility characteristics [6]. Generally, Magnesium alloys based reabsorbable stents are produced by laser cutting a thin-walled tube into a desired scaffolding pattern, followed by annealing, polishing and cleaning [10]. Given that these alloys are susceptible to galvanic corrosion, they are degraded and their non-toxic (above 2.5-3.5 mmol/l [12]) release is excreted in the urine [10].

Additionally to these considerations related to the selection and evolution of stents in terms of base material, there are also recent advances on the development of these devices with alternative deployment techniques, such as auxetic stents [13]. Given the definition of auxetic behavior (bodies that expand/contract in tension/compression, i.e. possess a negative Poisson's ratio [14]), this kind of devices are expanded and accommodated in the vessel walls by being stretched. This fact may allow the drop of use of the classic inflating balloon and consequently the interruption of blood flow during deployment. They are also believed to prevent some common problems, such as foreshortening and stent migration within the vessel [15].

This paper presents an early study that intends to develop a new type of stent that is able to gather most of the recent advances in the field, i.e. a device that is able to self-expand without the classic balloon inflation approach and reduced foreshortening. In terms of auxetic geometry, it was explored the use of chiral lattices given their low value of Poisson's ratio (near -1) [16] and thus allowing an improved ability to self-expand. Additionally, the presented design hypothesis, is also composed by the Magnesium alloy AZ91D. It has been shown that this alloy, when subjected to Chandler-Loop experiments to simulate blood flow corrosion, has a relatively improved performance [17], when compared with other common Magnesium alloys. The proposed stent was virtually expanded and, using finite element analysis, its overall deformation behavior and expansion mechanism were characterized to determine if this is a viable solution for further exploration.

2. Computational Modeling

Numerical simulations have been performed to study the deformation behavior of a modeled auxetic stent, based on chiral lattices, and to characterize the expansion of this kind of device. The chiral geometry involved the construction and testing of a computer model based stent, recurring to finite element analysis, developed within the framework of COMSOL Multiphysics.

2.1. Finite Element Analysis

The definition of the modeled stent deformation behavior was performed considering a static elasto-plastic isotropic hardening material, according to most current approaches [5,18]. It is assumed that the model is linear in terms of finite elastic deformation and non-linear isotropic hardening in the plastic domain. The von Mises stress ($\sigma_{vonMises}$) is determined by Eq. 1.

$$F_y = \sigma_{vonMises} - \sigma_{ys} \qquad (1)$$

This stress results from the Yield function (F_y) associated to a solid with the described theory by the incremental plastic stress (σ_{ys}). It is originated by the sum of the initial yield stress (σ_{ys0}) and the instant hardening of the material determined by the hardening stress (σ_h) induced by plastic strain (ε_p) (Eq. 2). The referred stress and strain to be used on the numerical simulations are based on the performed tensile tests.

$$\sigma_{ys} = \sigma_{ys0} + \sigma_h(\varepsilon_p) \qquad (2)$$

2.2. Stent Geometrical Modeling

The modeling of the studied stent is based on chiral lattices, allowing that its original planar (2D) plate form is bent in a tube shape to obtain the final stent Fig.1). The model stent is characterized by an aspect ratio (D/L) of 4, whose struts are composed by a square cross-section with a thickness (t) of L/160.

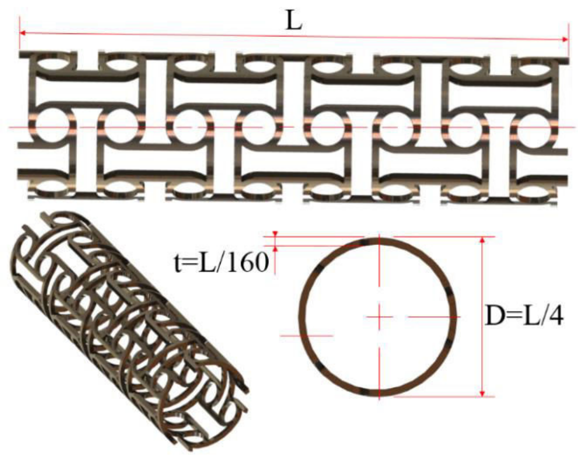

Fig. 1. Auxetic stent modelling with proportional size relationship.

2.3. Material characterization

In order to generate input values for the material properties, necessary as input data for the referred numerical simulations, the selected Magnesium alloy was processed and subjected to mechanical testing.

AZ91 D alloy was melted and held inside a crucible at 700 ºC during 15 minutes for homogenization while protected by CO_2 + 0.5% SF_6 atmosphere to prevent the oxidation. The molten alloy was then allowed to cool until 680 ºC and poured in the steel die (pre-heated to 250 ºC). To characterize the static mechanical behavior of the AZ91D alloy, specimens were machined from the as-cast samples according EN 10002-1:2004 with gauge length L_0 of 50 mm and cross section diameter d_0 of 8 mm. Tensile tests were carried out at room temperature on a INSTRON - Model 8874 testing machine using 1 mm/min strain rate, to obtain stress-strain (Fig. 2) behavior of the AZ91D alloy.

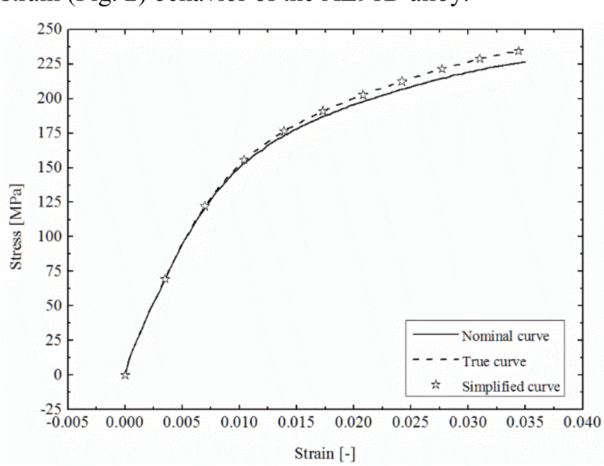

Fig. 2. AZ91D Stress-strain behaviour.

By the execution of the referred tensile test, the Cauchy stress-strain (respectively, σ and ε) behavior of the casted AZ91D alloy was determined. There was also calculated the Hencky stress-strain (respectively, σ_T and ε_T) behavior, recurring to the Eqs. 3 and 4 [19], to generate the material related data that is necessary to perform the elasto-plastic finite element simulation. However, the Hencky stress-strain relation, represented as a continuous function, implies an elevated amount of computing time, thus a simplified curve based on the referred function was determined to reduce simulation processing time.

$$\sigma_T = \sigma(1+\varepsilon) \qquad (3)$$

$$\varepsilon_T = \ln(1+\varepsilon) \qquad (4)$$

2.4. Boundary conditions

In order to characterize the deformation behavior of the stent modeling (initially in free body) and its capability to expand within a vessel, there were imposed two collinear and directionally opposite deformations (ΔL/2). This deformation was increased until the values of Von Mises stress exceeded the material Ultimate Tensile Strength. While the stent was stretched, the diameter deformation (ΔD) was monitored to determine the stent expansion (Fig. 3).

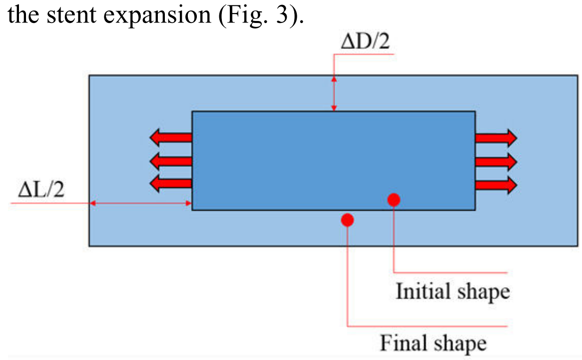

Fig. 3. Stent deformation and expansion.

2.5. Determination of the Poisson's ratio

To characterize the deformation behavior of the modelled stent, particularly its expansion, there were determined the values of Poisson's ratio of this device as it is stretched. As the axial deformation (ΔL) is applied to the stent, given its auxetic behavior, it starts to increase its cross-section (ΔD). Relating these values with the original dimensions in terms of length (L) and diameter (D), there can be determined the values of axial (ε_L) and diameter (ε_D) strains. The values of the

Poisson's ratio (ν) were calculated simply by the use of its classic formulation (Eq. 5).

$$\nu = -{}^{\varepsilon_D}/_{\varepsilon_L} \qquad (5)$$

3. Results and discussion

By the use of finite element analysis, a modeling of a stent based on quiral geometries, had its deformation behavior simulated to determine its expansion mechanism. The radial strain was monitored to determine if the device reveals auxetic behavior.

It may be observed in Fig. 4 that, when the device is stretched, there is an overall expansion. The physical meaning of this fact is that the modelled stent possesses a negative Poisson's ratio, thus auxetic behavior. In the same figure, there can be observed some stages of the expansion of the stent (in terms of axial strain), with the consequent value of von Mises stress.

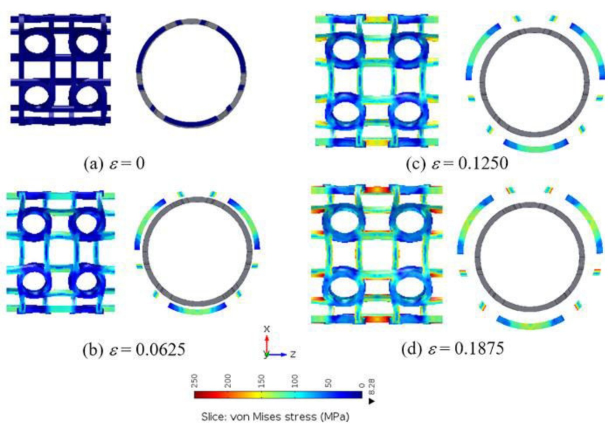

Fig. 4. Simulated expansion of the modelled stent.

According to Fig. 5, there is a linear behavior between the axial strain (resultant from the stent stretching) and the radial strain (ε_r). This linear bidimensional strain dependence and by the use of Eq. 5, imply that the modelled stent has an overall Poisson's ratio of -0.65. This value is not dependent on the progression of stress and strain that the plastic deformation implies, given that the represented regression is almost a perfect fit to a linear function.

Interpreting Fig. 5, it may be also observed that the adopted design is able to support an axial deformation of 17%, and that this stretch value generates a 12% expansion in terms of radial dimension. The main source for these values of maximum stress is the stress concentration in the rib/center connection in the chiral cells, where the stent is most likely to fail by fracture.

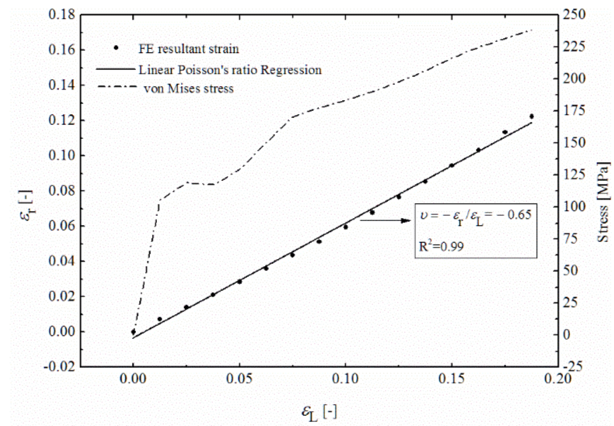

Fig. 5. Axial and radial strain dependence and von Mises stress values.

4. Conclusions

This study presents a modeling of a self-expanding stent based on chiral lattices, resulting in a device that possesses a negative Poisson's ratio (i.e. auxetic behavior). This fact allows new possibilities in terms of deployment approaches, for instance, using the stent itself to generate expansion instead of the classic balloon inflation. Additionally, this modeling considers the use of recent advances in terms of stenting material technology, the use of Magnesium alloys (AZ91D) as a biodegradable base material.

It is shown that the modelled stent has an overall negative Poisson's ratio and is able to expand by itself as it is stretched. The value of axial strain that the device is able to withstand is relatively low (17%) and this fact generates low values of maximum radial expansion (12%). This fact may be altered by the introduction of base material processing (enhancing mechanical properties), geometry optimization (reduction of stress concentrations) and initially crimping the stent.

Given that the suggestions represent simple tasks and that the adopted design is able to accomplish the established objectives, it may be concluded that the studied design may be an interesting study opportunity. In future studies and with further development on this field, it may be a viable solution to solve problems related with the risks of stenting, mainly permanent time effects and deployment issues.

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