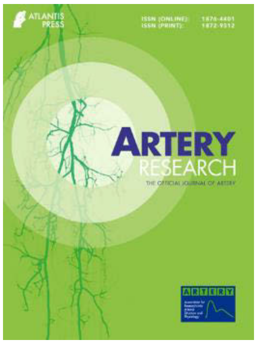

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A numerical study on the application of the functionally graded bioabsorbable materials in the stent design

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Optimization;
Plasticity

Abstract *Background:* Angioplasty with stenting is one of the primary treatment for coronary artery disease, hence, performance of the stent is deemed important. Bioabsorbable stents are the new generation of stents. Bioabsorbable magnesium alloys are a promising solution for adverse effects of long-term usage of stents. While their corrosion mechanics and biocompatibility have extensively been studied, there are no studies on application of functionally graded materials (FGM) on reduction of dogboning in bioabsorbable stents.
Methods: The objective of this study was at reducing the dogboning via the application of the FGM. A combination of the finite element (FE) method and optimization algorithm were employed to analyse/optimize the mechanical behaviour of bioabsorbable stents. Proposed FGM, in this study, was a combination of AZ80 and WE43 magnesium alloys. Dogboning of the FGM stent was chosen as objective function to be minimized and heterogeneous index was chosen as control variable in the optimization algorithm.
Results: The results revealed that the optimum FGM stent with heterogeneous index of 1.4625 has lower dogboning (63%) compared to that of the uniform stents made of AZ89 or WE43 magnesium alloy.
Conclusions: Furthermore, the results suggested that the plastic material properties have higher impact on the mechanical behaviour of the stent in comparison to the elastic material properties.

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Introduction

Currently, one of best treatments for coronary artery disease is angioplasty with stenting.[1] While there have been tremendous improvements in the coronary stent design, still there are several scientific and technological challenges to overcome in the field.[2] Namely complications associated with long term use of stent[3] and its non-uniform deformation in form of dogboning[4,5] are two of the most challenging areas that still remain. One of the best solutions for the problems associated with long term use of stent is material degradation.[3] Now bioabsorbable stents can degrade completely in body after the necessary scaffolding is over. This can improve arterial remodeling and help in case of need for second angioplasty procedure. Bioabsorbable stents are usually made of either polymers or magnesium alloy. They allow the use of stent in same site. Furthermore, these type of stents can be used in anatomically complex areas where the usage of conventional stents is not viable or in infant patients, where stent is placed in a growing vessel. Bioabsorbable stents can address issues, such as controlling the local drug delivery, in-stent restenosis, late stent thrombosis, and stent fatigue fracture.[3,6] While degradation of bioabsorbable stents has many benefits, they need to have good mechanical behavior in order to limit undesirable deformation, such as dogboning and foreshortening which can induce injury to the arterial wall.

Generally, bioabsorbable materials should have sufficient strength, worthy degradation rate according to the application and biocompatibility.[3,6] Magnesium alloys are new kind of bioabsorbable materials with suitable mechanical properties. Furthermore, magnesium fourth most abundant cation in the human body and is essential for the body. In addition, magnesium alloys have good degradation rates, which makes them suitable materials for use in the biomedical devices as a bioabsorbable material.[6] Therefore, with suitable mechanical properties, biocompatibility, and degradation rate magnesium alloys are among the most common materials to be used to make bioabsorbable stents.[3,6]

In coronary artery angioplasty with stenting, a balloon with a stent inserts into the diseased artery, when it reaches the diseased cite, balloon inflates and its inflation expands the stent, then the balloon is removed.[7–9] However, because of the plastic deformation that occurred in the stent it remains expanded to function as a scaffold to keep the artery open.[10] The plaque or the artery can be damaged during stent deployment. Due to the symmetric design of stents, stresses at later sides of stent are higher compared to its middle.[11] This effect causes the lateral sides of stent to expand more than its middle, hence, dogboning occurs which can induce injury in the arterial wall. Furthermore, longitudinal recoil of stent can cause friction between the artery and stent, which again can cause injury to the arterial wall.[12] To prevent these adverse effects, understanding of this mechanical process is deemed needed.

Functionally graded materials (FGMs) are one of the new types of materials with a growing application in many fields, including the biomedical science. In the FGM, the composition and/or the structure gradually change over the volume, resulting in corresponding changes in the properties of the material.[13,14] Therefore, this type of material can have the advantages of composites with extra control over its mechanical properties and avoid the main disadvantages of composites, such as delamination. FGMs were first introduced in 1972[13,14] and since then their applications have grown from their early application in aerospace to other fields.[13] Due to the gradual alterations in the properties of the FGMs over their volume, their compositions and structures can be tailored to achieve a certain property or design purpose, whereas avoiding the main disadvantages of composite materials. While FGMs have been used in other fields, such as aerospace sciences for a while, their application has grown in biomedical engineering.[13] FGMs has shown a great promise in dental implant[15] and orthopedic prosthesis design.[16,17] Recent studies have shown their potential application in the stent design.[5]

As one of the important inventions in cardiovascular medicine, stent is an extensively studied device. Use of this device was first purposed in 1964,[18] but it was until 1986 that a coronary stent was implanted in a patient.[19] Ever since numerous studies tried to improve its design.[4,5,20–24] One of the main goals of many of these studies was to enhance the deformation of stent in deployment process in order to reduce adverse effects, such as dogboning. To do so, knowledge of the mechanical behavior of the stent is needed. As finite element (FE) method is a well-known method in the computational biomechanics, several studies have used this method to investigate the mechanical behavior of different stent designing to reduce the dogboning of stent.[5,21,22] Most of these studies did so by altering the geometrical features of stent[4,22,24] as FGMs are promising new type of materials in biomedical engineering.[5,13,15,17] The general idea of structural gradients first was advanced for composites and polymeric materials in 1972.[13,14] Due to their earlier mentioned advantages over conventional stents, bioabsorbable stents have gained a lot of attentions.[13] Recently, it has been shown that a FGM metallic stent can reduce dogboning in comparison to a uniform metallic stent.[5] This suggests the question that whether or not this could be applied to bioabsorbable stents.

While both stent design and bioabsorbable stents have been extensively studied, to date there is no study on the application of the FGM materials in bioabsorbable stent design. Furthermore, while degradation rate and biocompatibility of bioabsorbable stent have improved,[6] their undesirable deformation still may have adverse effects. This study aimed at investigating the mechanical performance of parabolic FGM bioabsorbable stents made of bioabsorbable magnesium alloys. In the current research, FE method and optimization algorithm were employed to simulate and optimize FGM bioabsorbable stents. The goal was to find the optimum material design for the FGM bioabsorbable stents to minimize the dogboning. To do so, the FE method was used to calculate the deformation and mechanical response of the bioabsorbable stents during stent deployment. Thereafter, optimization method was used to find the optimum heterogeneous index, corresponding to the best gradual change of the FGM composition that can minimize the dogboning effect. It should be noted that as the degradation plays no role in the initial deformation and dogboning of the stent, it was not included in this study.

Method

A three-dimensional (3D) numerical simulation of an idealized balloon expandable Palmaz-Schatz stent was developed to predict the mechanical response of bioabsorbable stent during deployment. Due to the symmetric nature of Palmaz-Schatz stent, 1/24 of the geometry was used in this study. The length, unexpanded inner radius, and thickness of the stent were 9.86 mm, 0.70 mm, and 0.05 mm, respectively. The model was built, meshed, and solved in a commercial FE software, namely COMSOL Multiphysics (COMSOL Inc, Proprietary EULA, Burlington, MA, the United States). 3845 s order tetrahedral elements were used to mesh the entire geometry as displayed in Fig. 1.

Bioabsorbable magnesium alloys were modeled using elasto-plastic theory. AZ80 and WE43, as two bioabsorbable magnesium alloys were used as components of the FGM in this study.[3,6,25] While these two alloys have similar elastic modulus, they have different tangent modulus and their mechanical properties are listed in Table 1. The FGM was a combination of these two materials, where the FGM stent material combination starts as magnesium alloy AZ80 at one end, and gradually changes to complete the WE43 in the middle of the stent. Eventually changes back to the AZ80 at the other end. The changes in the material properties of the FGM stent over it length is corresponding to change in its composition which is described by equation (1). Where f is an arbitrary material property, D is the distance from the middle, l is the length of the stent, and n is the heterogeneous index. Large plastic strain theory was used to account for the large plastic deformation of the bioabsorbable stent.

$$f(l)=(f_{out}-f_{in})\left[\frac{D}{l}\right]^{n}+f_{in} \tag{1}$$

By taking the advantage of symmetrical conditions, computation time and cost can significantly be reduced. Therefore, symmetrical boundary conditions were imposed on the nodes of the stent in the planes of symmetry where all the nodes perpendicular to y-axis were not allowed to move in y-direction and all the nodes perpendicular to x-axis were not allowed to move in x-direction. Balloon was modeled as a pressure, imposed on inner surface of the stent. Furthermore, to allow the stent to deform and expand freely, no constrains were applied to two ends of stent. The simulation was continued until stent expanded to a maximum of 2 mm radius.

Figure 1 The meshed geometry of stent. Only 1/24 of the stent was simulated due to the symmetry of the model.

Table 1 Mechanical properties of magnesium alloys used in this study.

	E (GPa)	ρ (kg/m^3)	ν	S_y (MPa)	E_t (MPa)
AZ80	45	1740	0.3	230	941
WE43	45	1740	0.3	161	703

In this study optimization method was used to find the optimum heterogeneous index which can minimize the dogboning. Dogboning is a result of the non-uniform expansion of the stent, where usually its distal end is expanded more than its center and it is defined by equation (2).

$$dogboning=\frac{r_{load}^{distal}-r_{load}^{central}}{r_{load}^{distal}} \tag{2}$$

where r is the distance from the center of the stent.

The optimization problem was to find the value of the control variables that minimizes/maximizes the objective function, subjects to a number of constraints. The constraints collectively define a set, the feasible set, of permissible values for the control variables. The bound optimization by quadratic approximation (BOBYQA) algorithm for optimization was used in this study. BOBYQA is an iterative algorithm to find a minimum/maximum of an objective function. BOBYQA is a derivative free algorithm to solve bound constrained optimization problems. This algorithm uses a trust region method that forms quadratic models by interpolation. This method iteratively approximates the objective function by a quadratic model which is valid in a region around the current iterate.[26] In order to solve the optimization problem, a control variable and an objective function are needed. Dogboning was chosen as the objective function. Furthermore, heterogeneous index of FGMs was selected to be the control variable. Heterogeneous index was set to be between 0.10 and 5 in all cases. Moreover, the initial guess for the optimum heterogeneous index was 1, which would make gradient of the material to be linear. The number of interpolation conditions was fixed to $2n+1$, where n is the number of control variables.

While most studies tend to attempt to improve the dogboning of stents, other undesirable deformation can have adverse effect on this treatment. Foreshortening is the longitudinal recoil of stent and can be described by equation (3).

$$foreshortening=\frac{L-l}{L} \tag{3}$$

where L and l are unloaded and load lengths of the stent, respectively.

Results

In this study an iterative was used to minimize the maximum dogboning of the purposed stent. Figure 2 shows the maximum dogboning versus the optimization iteration. These are corresponding to changes of the heterogeneous index at each iteration as presented in Fig. 3. These results show that maximum dogboning was reduced to 18.6% at the heterogeneous index of 1.4625, from the maximum dogboning of 20% at heterogeneous index of 1.

The goal of this study was to reduce the dogboning of bioabsorbable stents using the FGM materials. The dogboning of the optimum FGM stent found earlier to stents made of uniform AZ80 (50.40%) and WE43 (51.31%) magnesium alloys as illustrated in Fig. 4. Not only the maximum dogboning of the FGM stent was significantly lower than that of the stents made of uniform materials, but its dogboning during stenting process also remained lower than that of the other two at all times. Furthermore, variation of foreshortening of the optimum FGM bioabsorbable stent and both uniform magnesium alloy stents are displayed in Fig. 5.

Discussion

While the research in regard of the bioabsorbable stent is mostly focused on improving its biocompatibility and degradation rate, undesirable deformations, such as high dogboning can still induce damage to the arterial wall.[3,6] Therefore, this study was focused on this aspect of bioabsorbable stents rather their degradation. Furthermore, while there have been extensive research to find newly improved materials to employ in bioabsorbable stents, still there are few viable options.[3] Amongst them magnesium alloys are one of the most popular options.[6]

In the current research, it took 33 iteration for optimization algorithm to find the optimum heterogeneous index of 1.4625. While maximum dogboning of optimum stent was not much lower than the initial guess, it did reduce from 20.00% for heterogeneous of 1—18.60% in the optimum case. Furthermore, results of this study showed that the optimum FGM bioabsorbable stents have significantly lower dogboning in comparison to the uniform ones. Maximum dogboning of the optimum FGM stent was 63% lower than the maximum dogboning of the uniform stents as depicted in Fig. 6.

The dogboning, as a non-uniform deformation, is a result of a non-uniform stress in stent, where stress of lateral areas of stent is higher than its middle section. This imbalance causes lateral sides of stent to expand faster and further than its middle, causing the adverse effect commonly called dogboning. As stated in our previous study, this event can be neglected by using stiffer materials for lateral sides of the stent.[5,27] Using controlled higher stiffness for lateral sides of stent balances the difference in stress and causes a suitably uniform deformation. FGMs are perfect materials for this purpose. Unfortunately, suitable materials to use in the stent are scare, and amongst them very few are bioabsorbable.[3] This hinders us to design a good FGM for purpose of this study, as differences in the mechanical properties and most importantly stiffness of composing materials of FGM is what makes this method work. While there are different magnesium alloys used in the bioabsorbable stent design, their mechanical properties are usually similar. AZ80 and WE43 as two magnesium alloys used in this study have similar elastic properties, but their plastic mechanical behavior is different. The reason that FGM stent made of these two materials works in this method was due to large plastic strains of stent. A stent needs to undergo large plastic strains to be able to expand from the small diameter of narrowed blood vessel to its full diameter and retain its form after balloon is removed. This makes plastic mechanical behavior of the stent very important. While plastic mechanical properties of stent play important roles in its performance, initially when the stress is lower, deformation of the stent is controlled by its elastic properties, which in this case makes the stent to

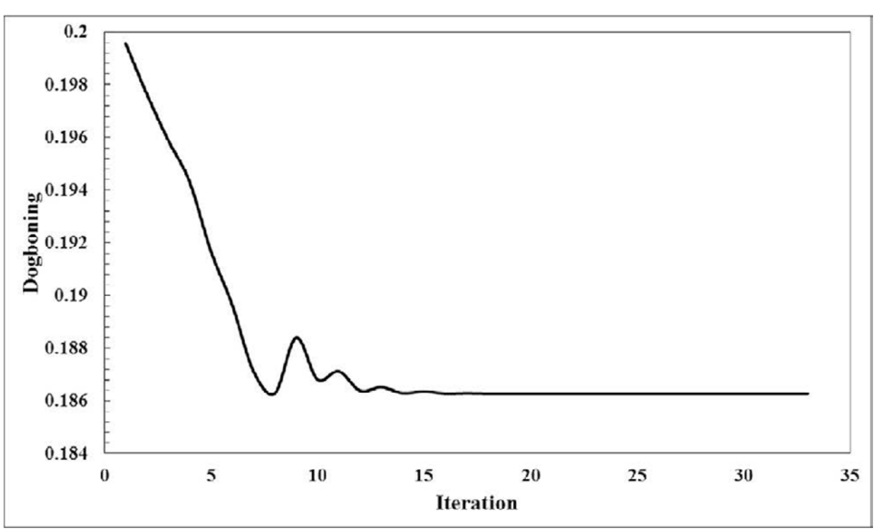

Figure 2 Dogboning of the stent versus the simulation iterations. The proposed algorithm optimized the maximum dogboning value of stent by controlling the heterogeneous index within the described limits.

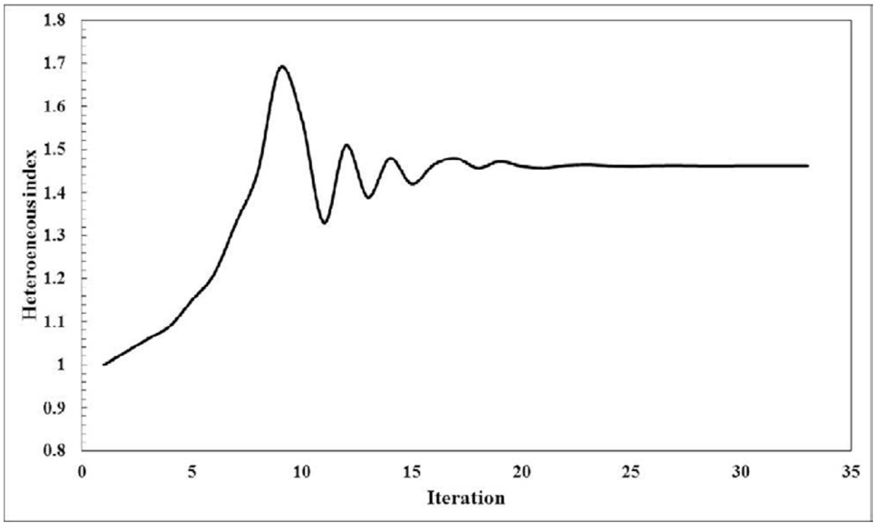

Figure 3 The heterogeneous index versus the simulation iterations. The proposed algorithm optimized the heterogeneous index value of stent within the described limits.

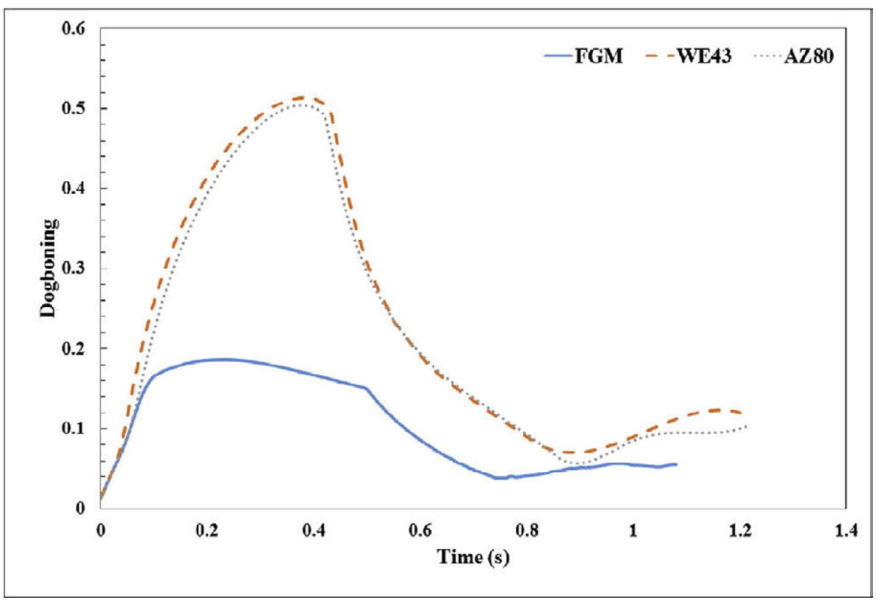

Figure 4 A comparative variation of the dogboning among different stents versus the simulation time.

perform like a uniform material at lower stresses. While only shortly at the start of loading, stress is lower than yielding stress, but this event prevents stent from benefiting of the negative dogboning that have been reported for metallic FGM stents. Both uniform bioabsorbable stents and FGM bioabsorbable stents at their maximum respective dogboning are indicated in Fig. 7. Moreover, foreshortening of the optimum FGM stent was similar to the uniform stents.

While the objective of this study was to find an alternative bioabsorbable material with improved deformation using FGMs, inclusion of material degradation in simulation could be helpful in some ways. This exclusion was mainly due to short duration of simulation which was about 1s. Yet limited the degradation, considering changes of material properties corresponding to material degradation, can increase accuracy of the model. Secondly, compositional gradients of material could possibly be used to manipulate its degradation rate. For example, we can take advantage of this by using two bioabsorbable materials with different degradation rates as composing materials of the FGM. Therefore, it might be possible to tailor a specific degradation rate in any place inside the material volume as long as this new degradation rate is between the degradation rates of the composing materials. While this can be possible but future studies are needed to assess the viability of this method. Furthermore, while the Palmaz-Schatz geometry is a viable stent geometry, there are other geometrical models that have shown better mechanical performance compared to the Palmaz-Schatz.[28] While using other

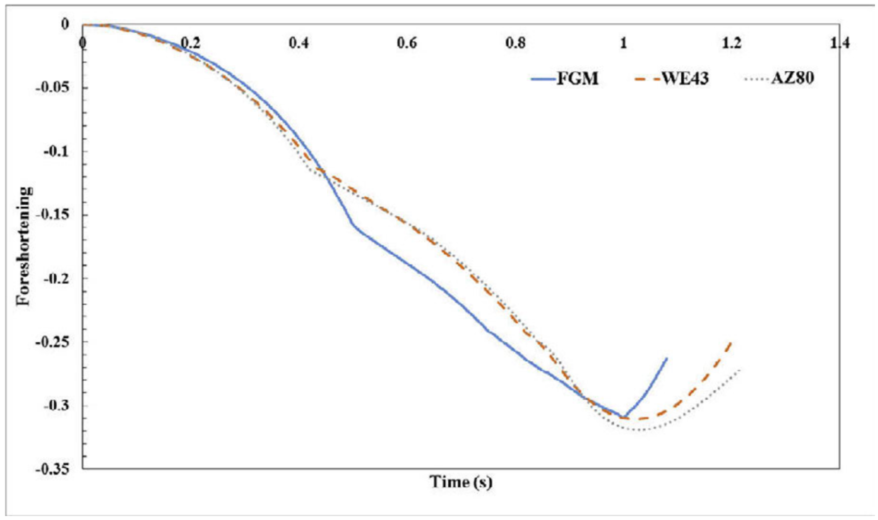

Figure 5 A comparative variation of the foreshortening among different stents versus the simulation time.

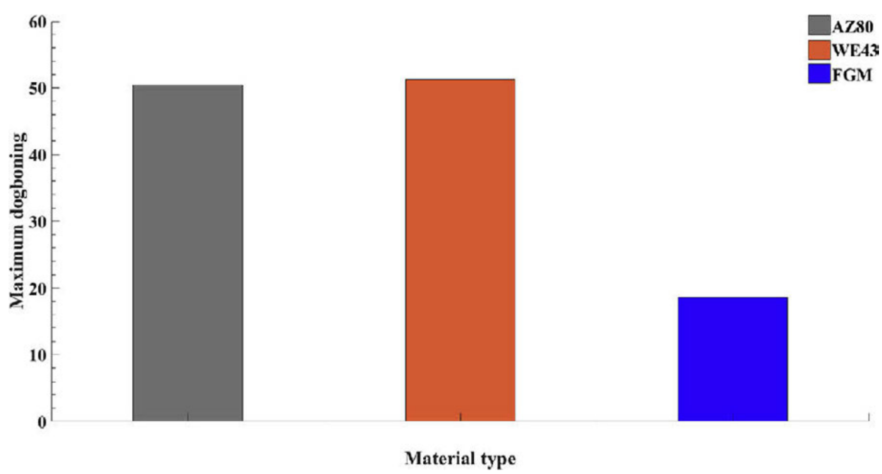

Figure 6 A comparative bar graph representation of the maximum dogboning versus the material types of the stents.

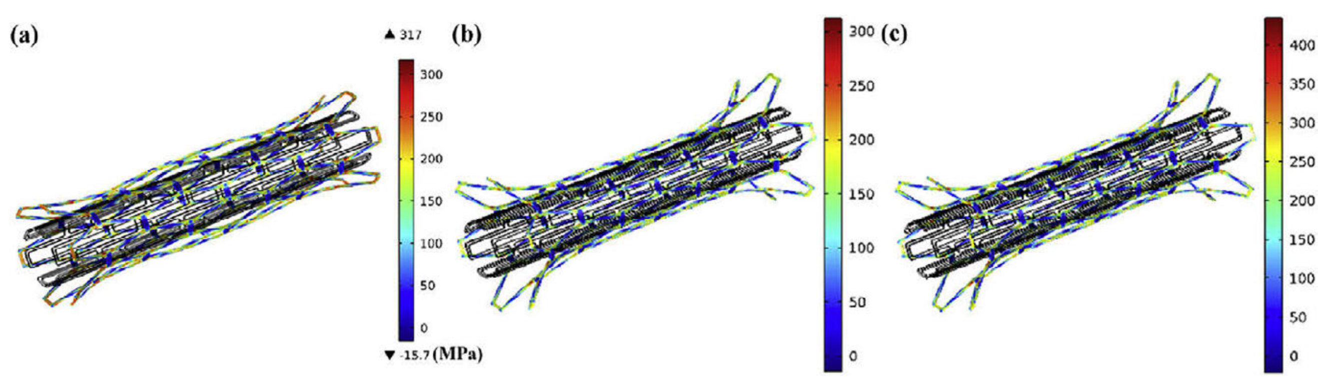

Figure 7 The **(a)** FGM stent showed more uniform deformation compared to the **(b)** WE43 or **(c)** AZ80 magnesium alloy stents. Stresses in here are reported in MPa.

geometrical models might be able to further enhance the mechanical behavior of the FGM bioabsorbable stent, the goal of this study was to compare the mechanical behavior of the FGM bioabsorbable stents with uniform ones and determine whether or not, using this new type of material can reduce the dogboning. Moreover, in the current research balloon was modeled as a pressure and blood vessel was not included in the model.[29–36] In addition, as the degradation plays no role in the initial deformation and dogboning of the stent, it has not been considered in this study which might be a limitation of this work. Overall, while this study has several limitations, those were mostly done in order simplify the model and reduce the computation time and cost. While adding those details can enhance the model and improve its accuracy in future studies, we believe that these simplifications do not hinder the ability of model to predict the mechanical behavior of stent.

Conclusions

Deployment process of FGM stent made of bioabsorbable materials was modeled in this study. This model was solved using FE method. Furthermore, BOBYQA optimization method was employed to find the optimum heterogeneous index for the FGM, which can minimize the maximum dogboning of the stent. Results of the current research suggest that using the FGM can significantly reduce dogboning of bioabsorbable stents. Furthermore, results of this study shows the importance of plastic mechanical properties of stent.

Conflicts of interest

None declared.

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