International Journal of Research Publication and Reviews

Journal homepage: www.ijrpr.com ISSN 2582-7421

Biodegradable Polymeric Stents: A Focused Review on Materials and Clinical Studies

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ABSTRACT:

Coronary artery disease (CAD), characterized by plaque accumulation in coronary arteries, often necessitates intervention to restore blood flow, with stenting being the current standard. While conventional stents have evolved from bare metal to drug-eluting designs, concerns persist regarding their permanent presence, especially in specific cases. This paper reviews the progress of biodegradable metal stents, focusing on magnesium, iron, and zinc alloys designed to degrade without causing toxicity. The project detailed in the same context involves modifying and analyzing two biodegradable stent designs using SolidWorks and ANSYS, followed by Design Expert for optimization through Response Surface Methodology. The iterative approach showcases improvements in stress distribution, strain, and deformation characteristics, demonstrating promise for enhanced stent performance. Furthermore, the review emphasizes the next-generation potential of bioresorbable stents (BRSs) to address long-term complications associated with permanent metallic stents. The mechanical performance of polymeric BRSs is critically assessed through experimental and computational studies, highlighting the need for further research to understand and control their mechanical behavior as they degrade within the human body.

Key words: Von Mises Stress, stress intensity, maximum principle stress, and total deformation Response Surface Methodology (RSM)

I. INTRODUCTION

Atherosclerosis is one of the cardiovascular diseases. Its pathological mechanism is that fat or lipid substances are deposited on the arterial wall under the influence of various cardiovascular risk factors. These depositions form a large number of plaques, leading to arterial wall thickening, causing a vascular blockage, and affecting blood flowing .Severe atherosclerosis can also cause coronary artery disease, stroke, peripheral artery disease, or kidney problems. At present, the most common and effective treatment method in the world is Percutaneous Coronary Intervention (PCI). PCI is to unblock and restore blood by placing a vascular stent on the stenosis and hardening of the artery for expansion. PCI is minimally invasive and highly effective. In the treatment of PCI, the stent is a tiny tubular structure and used to expand the vessel wall and expand the vascular lumen to prevent the artery wall from recoiling and restore the cardiovascular obstructed by atherosclerosis.

Therefore, the vascular stent, as the sophisticated medical device for clinical treatment, should have ideal functions and mechanical properties: (1) high elasticity to realize the curling and re-expansion of the stent in the blood vessel; (2) high strength and fatigue resistance to withstand the periodic physiological load of arteries; (3) good biocompatibility to reduce the incidence of thrombosis and vascular restenosis and alleviate implant rejection in the body.

In addition, there are other properties. In addition to these features mentioned, 13 different properties of ideal stent were listed in the review article of Liu et al. which provides a great help for the design of vascular stents. And Liu et al. also pointed out that there were no perfect stents. The current clinical application of vascular stents, after decades of development, has the corresponding therapeutic function and mechanical properties. Manufacturing technology and surgical technology are gradually becoming mature. What's more, the arterial blockage after interventional therapy has been significantly reduced. However, each stent still has its own advantages and drawbacks inevitably. A stent cannot cover all ideal properties, and usually offers several good proper- ties.

II. DESIGN

3D Modeling: SolidWorks allows users to create complex 3D models using a variety of sketching, surfacing, and solid modeling tools. It supports both parametric and direct modeling approaches, enabling efficient design iterations and modifications. Assembly Design: SolidWorks facilitates the assembly of multiple components by providing features such as mates, constraints, and smart components. It enables users to simulate the movement and interactions of the assembled parts . Simulation and Analysis: SolidWorks offers integrated simulation capabilities to evaluate the structural integrity, thermal behavior , and fluid flow characteristics of designs. It includes tools for finite element analysis (FEA), computational fluid dynamics (CFD), and motion analysis. Visualization and Rendering: SolidWorks enables users to create realistic renderings and visualizations of their designs. It supports various materials, textures, lighting effects, and camera settings to create compelling images and animations. Drawing and Documentation: SolidWorks includes tools for generating detailed engineering drawings, including dimensions, annotations, and views. It automates the creation of Bill of Materials (BOMs) and facilitates the generation of documentation for manufacturing and assembly processes. Collaboration and Integration: SolidWorks provides features for collaboration, allowing multiple users to work on the same design concurrently. It also integrates with other software and file formats, enabling interoperability with other CAD systems and supporting data exchange. Add-ons and Extensions: SolidWorks offers a range of add-ons and extensions, such as SolidWorks Simulation, SolidWorks Electrical, SolidWorks CAM, and more, to extend its functionality and cater to specific industry needs.

Table 1 Design parameters

Software used	**Solid works**
Material	316 L Stainless Steel
Length	15mm
Diameter	3mm
Youngs Modulus	200Gpa
Density	0.29 lbm/in^3
Thermal conductivity	16.3 w/mk

Design 1

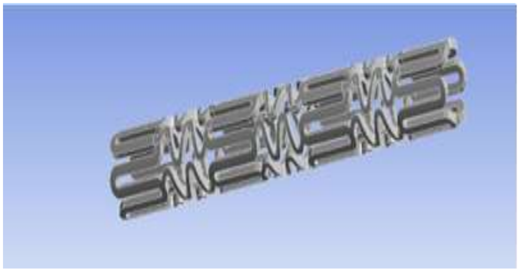


Figure 1 stent 3D model 1 using solidworks

Design 2

Figure 2 stent 3D model 2 using solidworks

III. RESULTS AND DISCUSSION

EQUIVALENT STRESS

Von Mises stress is a widely used measure of stress in engineering applications, and it can be calculated using the finite element analysis capabilities of ANSYS software. ANSYS utilizes the principles of the finite element method to model and simulate the behavior of complex structures under various loading conditions. When analyzing stress in ANSYS, the von Mises stress is a scalar quantity derived from the tensorial stress components at each point within the model. It provides a measure of the equivalent stress experienced by a material, taking into account both the magnitude and distribution of the stress components. By visualizing the von Mises stress results, engineers can identify critical areas where the material may be prone to failure or deformation, allowing them to optimize designs and make informed decisions to ensure structural integrity and performance.

Figure 3 Equivalent von mises stress of stent design 1

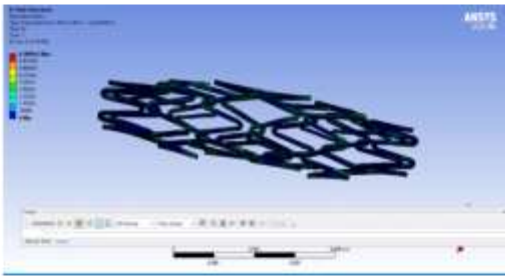


Figure 4 Equivalent von mises stress of stent design 2

EQUIVALENT ELASTIC STRAIN

Equivalent elastic strain, also known as von Mises strain, is a measure of the deformation experienced by a material under mechanical loading conditions, and it can be analyzed using ANSYS software. ANSYS employs the finite element method to simulate the behavior of structures and calculate the strain distribution within them. When evaluating equivalent elastic strain, ANSYS considers the strain components at each point in the model and combines them using the von Mises criterion. This criterion determines the effective strain experienced by the material, taking into account both the magnitude and direction of the individual strain components. By visualizing the equivalent elastic strain results, engineers can identify areas of high strain and potential failure, enabling them to optimize designs, assess material performance, and ensure the structural integrity of their designs.

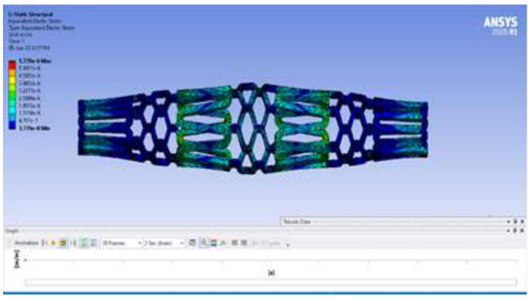


Figure 5 Equivalent von mises strain of stent design 1

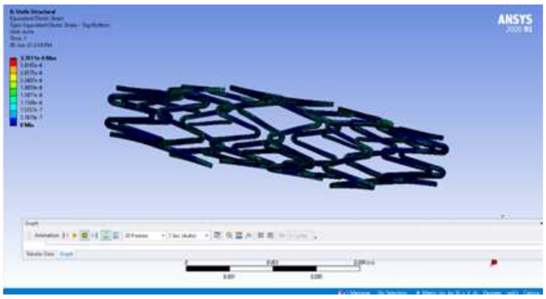


Figure 6 Equivalent von mises strain of stent design 2

TOTAL DEFORMATION

Total deformation is a critical aspect of structural analysis that can be calculated using ANSYS software. ANSYS employs the finite element method to simulate the behavior of complex structures under various loading conditions. When analyzing total deformation, ANSYS considers the displacement and deformation of each element within the model. By solving the system of equations derived from the finite element analysis, ANSYS computes the displacement and deformation at each node of the model. The total deformation represents the cumulative effect of these displacements and deformations. By visualizing the total deformation results, engineers can gain insights into the overall structural response, identify areas of excessive deformation, and assess the potential for failure or performance issues. This information aids in optimizing designs, evaluating structural integrity, and making informed decisions to ensure the safety and reliability of the analyzed structures.

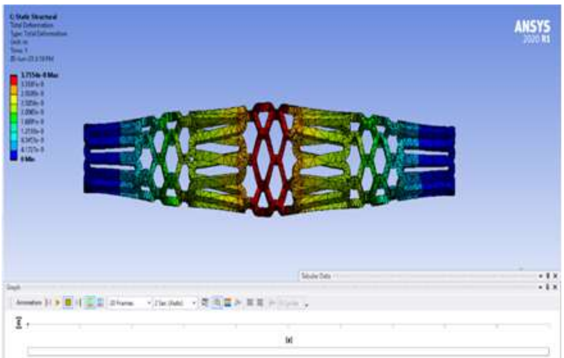


Figure 7 Total deformation of stent design 1

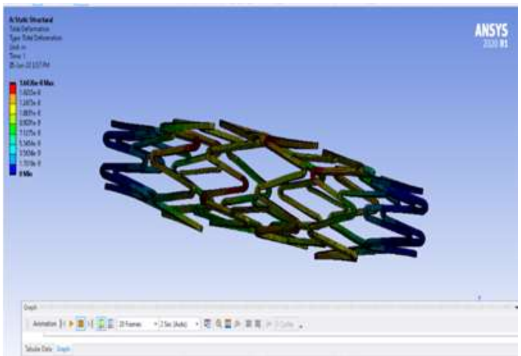


Figure 8 Total deformation of stent design 2

ANALYSIS OF VARIANCE (ANOVA TABLE)

Design Expert software is a powerful tool for conducting Analysis of Variance (ANOVA) in experimental design. It provides researchers and analysts with a comprehensive platform to efficiently analyze and interpret the variation observed in their data. The software allows users to input their experimental design, including factors, levels, and responses, and performs ANOVA calculations to determine the significance of these factors and their interactions. Design Expert's intuitive interface enables users to visualize the results through graphical representations such as main effects plots, interaction plots, and contour plots, aiding in the identification of influential factors and optimal parameter settings. With its robust statistical capabilities and user-friendly features, Design Expert software streamlines the ANOVA process, facilitating the identification of significant factors and supporting informed decision-making in experimental design.

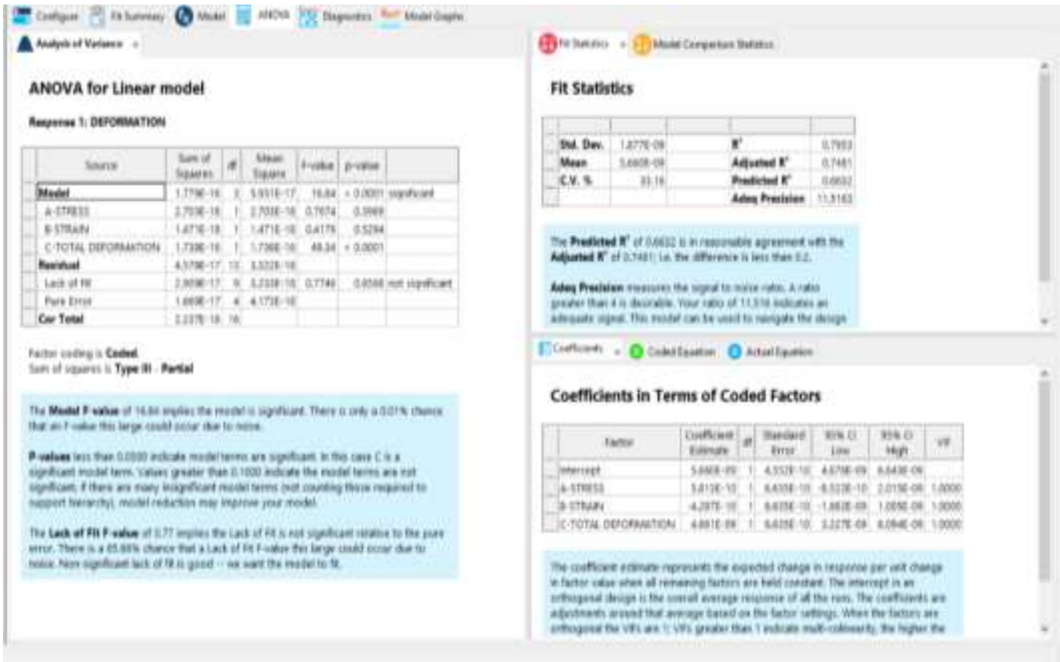


Figure 9 ANOVA table for stent design 1

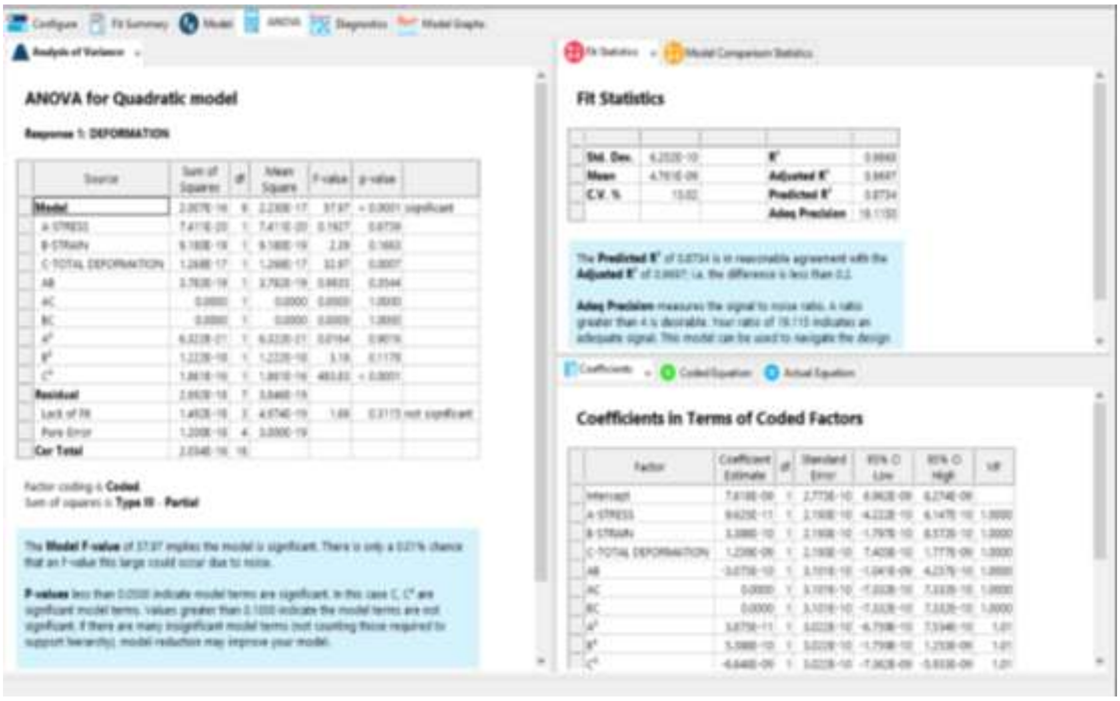


Figure 10 ANOVA table for stent design 2

The actual graph as shown in fig 6.2 describe the expected outcome of a normal plot of residuals for a stent design with a deformation of 9.801E-9 in Design Expert software. In this case, the normal plot of residuals would exhibit a similar behavior to the one described earlier. The plot would show the distribution of residuals with their quantiles, and a straight line would indicate a normal distribution. If the residuals closely follow the straight line, it would suggest that the model assumptions are met and that the stent design with a deformation of 9.801E-9 is statistically acceptable. However, if the residuals significantly deviate from the line, it would indicate potential lack of fit or other issues with the model, requiring further investigation and possible refinement of the stent design parameters.

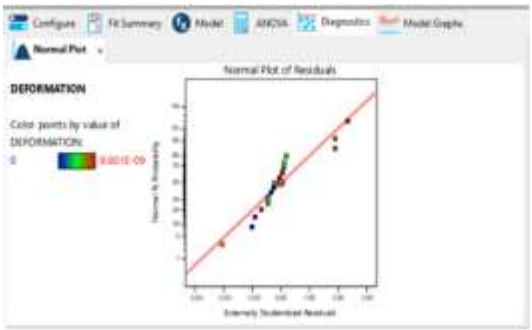


Figure 11 Normal plot of Residuals for stent design 1

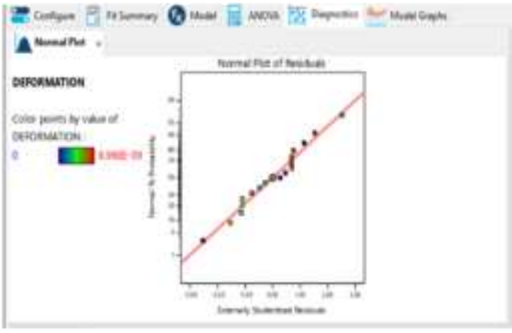
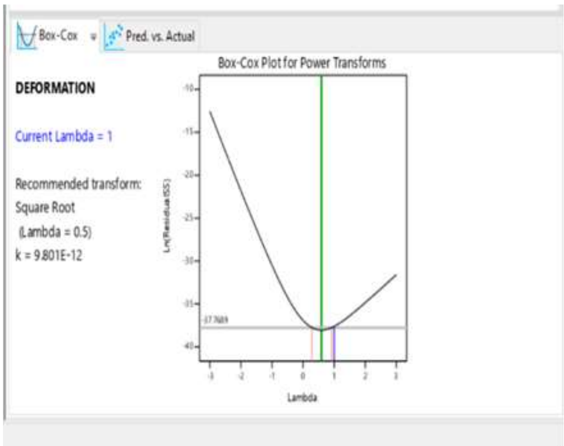


Figure 12 Normal plot of Residuals for stent design 2

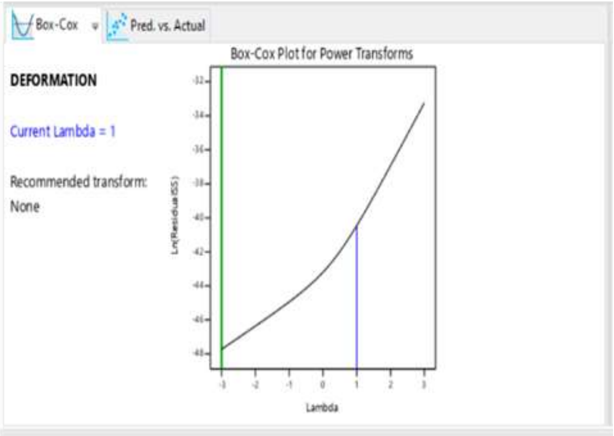
Stent design dataset with lambda = 1 and K = 9.801e-12 as shown in figure 6.5 the Box-Cox plot would show different lambda values and their associated goodness-of-fit measures. The goal is to identify the lambda value that yields the most desirable distributional properties or variance homogeneity for the stent design data. By examining the plot, you can identify the optimal lambda value, which would be used to transform the data accordingly for further analysis or modeling.



Current Lambda = 1

Recommended transform:
Square Root
(Lambda = 0.5)
k = 9.801E-12

Figure 13 Box-Cox plot for power transforms for stent design1



Current Lambda = 1

Recommended transform:
None

Figure 14 Box-Cox plot for power transforms for stent design 2

IV. CONCLUSION

Comparing the two design results, it is evident that the second design result performs better in terms of accuracy, adjusted R², and signal-to-noise ratio compared to the first design result.

In the first design result, the Predicted R² and Adjusted R² values are 0.6632 and 0.7481, respectively. While these values indicate a moderate level of explanatory power, they are lower than the corresponding values in the second design result. The second design result has a higher Predicted R² of 0.8734 and a higher Adjusted R² of 0.9697. This suggests that the second model explains a greater proportion of the variability in the response variable and has better predictive capabilities.

Moreover, the second design result has a higher Adeq Precision value of 19.115, indicating a stronger signal-to-noise ratio compared to the Adeq Precision value of 11.516 in the first design result. This suggests that the second model has less noise and provides more reliable predictions.

Based on these comparisons, it can be concluded that the second design result is more favorable for your project. It demonstrates higher accuracy, better adjustment for predictors, and a stronger signal-to-noise ratio. Therefore, the second model is likely to be more reliable and suitable for navigating the design space in your project compared to the first model.

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