RESEARCH PAPER

# Mechanical Design and Analysis of Composite Materials for Advanced Drug Delivery Devices Using CAD Tools

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**ABSTRACT**

This new generation of drug delivery system (DDS) has been given a lot of attention due to the need to be able to create high accuracy of release and targeting of therapeutic agents. Composite materials are slowly making their way into the configuration of these systems due to tailor-made mechanical properties. In the paper, we give the mechanical design and analysis of a drug delivery device using composite materials, and particularly focus on the application of Computer-Aided Design (CAD) to create optimal devices. Biodegradable polymers and ceramics are some examples of composite materials that could be considered in the paper to boost the mechanical strength, in vivo and in vitro durability, and drug release properties of the machines. Finite Element Analysis (FEA) is a convergence that allows obtaining all the mechanical stresses, strains, and deformations in the CAD tools, resulting in a hybrid design that may meet the required performance requirements. The results indicate that composite-based designs have superior mechanical properties compared to traditional materials, and therefore it will be a feasible solution in advanced DDS. The paper concludes with the importance of CAD tools in the design optimization of drug delivery devices and suggests that further experiments on experimental validation and materials optimization could be beneficial.

**Keywords:** Drug Delivery Systems (DDS), composite materials, CAD tools, Finite Element Analysis (FEA), biodegradable polymers, advanced drug delivery, mechanical design optimization, material properties, PLA, PLGA, ceramic reinforcement, mechanical behavior, stress distribution, drug release profiles, design optimization.

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## Introduction

Drug Delivery Systems (DDS) are crucial in the successful and regulated absorption of therapeutic agents. The main role of DDS is to make sure that the drugs reach particular locations in the body at the exact rate which will maximize therapeutic action and reduces the level of side effects. Throughout the years, the technology of DDS has changed to move away away from simple oral pills and injections and to more advanced technologies, such as implantable devices, transdermal patches, and controlled-release formulations[1]. Although such advancements have been made, there are difficulties in assuring the optimum performance, accuracy and reliability of these systems[2]. The capacity to regulate the release of drugs, the biocompatibility of the materials, and the mechanical strength and durability of the materials under physiological circumstances are one of the key concerns in the design of DDS. Moreover, there is a challenge of creating devices that could be used to address limited areas of the body, but not healthy tissues[3]. With the increased personalization of healthcare requirements, DDSs that are not only capable of enhancing drug release control but also preventing side effects, improving patient comfort and presenting long-term stability are increasingly in demand[4].

The need to design efficient and reliable DDS has triggered the development of new materials and

especially composite materials that have demonstrated a great potential in enhancing the mechanical characteristics and functionality of drug delivery devices[5]. The challenges that face the effectiveness of conventional drug delivery systems may be surmounted by accessing composite materials that are made up of two or more distinct materials with unique physical and chemical properties. Such materials can be customized to off-the-shelf to deliver the necessary mechanical strengths, flexibility and biodegradability[6], which makes them suitable in the drug delivery equipment where they are required to operate effectively in the human body. To maximize the mechanical properties and performance of the DDS, it is possible to combine various materials, stability of which may include bio-polymers that include ceramics or nanoparticles as reinforcement and contribute to better forms of drug release and increasing the lifespan of the devices[7].

Nevertheless, despite the benefits that come with use of composite materials, there are still a number of challenges in the incorporation of these materials in DDS. This is one of the major challenges because accurate mechanical design and analysis must be done in order to assure that the device will be able to work at the optimum in physiological conditions. Current designs of DDS typically adopt more traditional approaches of material selection without employing more advanced design tools able to be used to model the real world conditions[8]. Moreover, comedy of the mechanical properties of composite materials needs to be considered critically in order to be aware of its behavior when subjected to forces such as pressure, temperature, and wear that are inevitable in the human body. These aspects play a vital role in ensuring that the DDS can maintain its structural integrity and in addition make sure that the DDS will be reliable in releasing the drugs over extended durations of time.

Research considering DDS has up to now mainly been centered on formulations of the drug to be released, the development of mechanisms, and biocompatibility of the device. Although much has been done in the creation of such innovative DDS, the use of composite materials and more advanced design tools like Computer-Aided Design (CAD) and Finite Element Analysis (FEA) into these systems has not been greatly explored[9]. CAD tools enable drug delivery devices to be accurately designed, and researchers are able to model and simulate the mechanical behavior of composite materials to work with under different conditions to fabricate a physical prototype[10]. FEA as an integral part of CAD platforms can be used to simulate stress, strain and deformation in drug delivery devices and this provides important information on where failure may occur and where to optimize. Although these tools are available, no studies have been conducted on systematically integrating CAD modeling, FEA and composite materials analysis in DDS design and so this restricts the possibilities in regards to designing high-performance cost-effective and dependable drug delivery systems[11].

This study will bridge the research gap in the existing literature by proposing a holistic process of supporting the mechanical design and analysis of DDS on a composite material with the help of CAD tools. This study aims at researching the ability to use composite materials to increase the mechanical strengths and performance of drug delivery devices and optimize their forms by using CAD modeling and FEA. Through the use of CAD tools, the study will streamline the design of the structural features of drug delivery devices to enable them to yield the required mechanical performance standards, i.e. strength, durability, and control of the drug release. Along with it, FEA will be used to model the real-world conditions and optimize the design of the device so that it performs better, minimizing the chances of device failure and enhancing the overall reliability of the DDS. Finally, it is intended to show that CAD instruments, in collaboration with composite materials, may considerably improve the design process and help to create more efficient, effective, and reliable drug delivery devices. This research will not only fill the gap that exists in the current literature but it would also be helpful in the future to give an insight into the potential of CAD based design optimization in drug delivery technologies in the future.

## 1. Literature Review

In recent years, Drug Delivery Systems (DDS) no longer include only the basic oral tablets, but have developed more complex, controlled-release, delivery systems that can deliver therapeutic agents in a more specific and targeted fashion. Conventional DDS, including oral pills and injections, tend to be based on a passive drug release process[12], in which the pill is taken up by the

blood over a period of time. Although these methods have been still useful in numerous applications, they tend to fall short trying to address the extensive need to adopt targeted therapies and personalized medicine[13]. The traditional DDS have limitations over poor bioavailability, short-term effects of treatment and side effects caused by uncontrolled delivery of the drug. Recent years have seen changes in DDS research turn to more advanced systems like implantable, transdermal patches, microneedles, and nanoparticle-based systems[14]. These contemporary DDS objectives are meant to reach long-term and regulated administration of a drug, a better specificity to a tissue, or organ, and have minimal effects on the body in general. In addition, technologies of biocompatible materials, microfabrication and drug encapsulation have so far been of invaluable help in improving the functionality of these systems.

Introduction of composite materials in DDS has been the significant route towards improving the performance in these systems. In a bid to address the weakness of DDS which limited materials, carbon fiber composite materials, which integrate fundamentally two or more different materials with differentiable properties are under consideration. These substances have tailored mechanical, chemical and biological properties, which are relevant in the creation of sophisticated drug delivery tools. Polymer matrix alloys like poly(lactic-co-glycolic acid) (PLGA) and polycaprolactone (PCL) have been favoured as a matrix in DDS due to their biodegradability, biocompatibility and also due to their ability to entrap a range of highly disparate drugs[15]. However, they are not always robust enough in terms of mechanical properties to be employed in certain drug delivering machines, especially ones that require a longer period of mechanical support or ability to withstand physiological stresses. In order to address this deficiency, composite materials that are supplemented with ceramics, metals or nanoparticles have been explored. By indicator, DDS with ceramic particle, such as hydroxyapatite, may enhance both mechanical properties of the polymer matrix, but at the same time, be biodegradable[16]. In addition, nanoparticles, such as silica or a nanoparticle of gold, can be added and result in a higher drug loading capability and targeted delivery of therapeutic agents. The existence of these composite materials suggests the creation of new drug delivery systems that would possess increased mechanical strength, enhanced dynamics in drug delivery and stability with respect to those of single-material DDS[17].

Computer-Aided Design (CAD) has changed the way medical researchers and engineers currently design and analyze the medical devices used to deliver medications with researchers being used to model and optimize the workstations of the devices before the physical models are created. CAD systems such as the SolidWorks system, CATIA and ANSYS can be used to create detailed 3D models of the drug delivery devices that enable the design parameters such as size and shape and location distribution of material to be carefully controlled[18]. Simulation of mechanical behavior in different conditions, such as stress, strain, and thermal loading, also can be done with the help of these tools. Incorporation of Finite Element Analysis (FEA) into CAD software enables us to predict material and structural performances in the real world, which is highly useful in understanding their vulnerability and failure point and which break even design areas. As an example, where there is constant pressure or deformation in the human body such as in drug delivery devices, FEA simulations can be used to determine stress concentration which causes failure of the device[19]. With these simulations, CAD tools can help save the multiple physical prototypes and save time as well as enhance the efficiency of the design. CAD tools also allow testing multiple material combinations as well as configurations, which is also helpful in the case of composite materials where their amount of material can often behave remarkably differently based on the proportions and types of the constituents chosen[20].

Although major progress has been made with DDS and CAD tools have been used to design the drug delivery devices, there still exist some gaps in the research which obstruct the production of highly functioning drug delivery devices. Even though the use of composite materials in DDS has already been discussed, no literature addresses the specific aspect of activation of the methods of mechanical design optimization to be implemented in the design process, including the methods offered by CAD and FEA. Emphasis of current research on DDS is mostly isolated on the materials used or the drug release mechanism and not on how the mechanical design affects the whole functioning of the device.

In addition, even though the CAD tools have been extensively used in mechanical design in different engineering projects, their combination with composite material selection and optimization in DDS are not well studied. This research deficiency restricts the possibility of maximizing drug delivery devices, particularly with regards to the overcoming of mechanical forces that these devices face in the human body whilst requiring regulation of drug release.

The other important gap in the study is that no extensive research has been conducted and measured in understanding the behavior of various composite materials and their impact on the mechanical, drug releasing and biocompatibility of DDS. Although the current research focuses on the individual components of composite materials, in particular, biodegradable polymers and ceramics, little research has investigated the synergistic effects of combining more than two materials into one DDS. The ideal balance between mechanical strength, rate of drug release and biocompatibility is determined by the best choice of materials. Moreover, although typically FEA simulations are employed to simulate the mechanical behavior of any material, the application of these simulations to optimized mechanical design of DDS remains understudied, particularly in cases of composite materials. This research gap highlight the necessity of a more comprehensive view of DDS design, considering material choice, optimization of mechanical design, and performance simulations with CAD tools.

## 2. Methodology

Achieving a design and optimization of drug delivery devices is done in several steps commencing with a keen choice of materials, followed by thorough modeling using Computer-Aided Design (CAD) software, mechanical analysis using Finite Element Analysis (FEA), and optimization model to achieve the final design that meets all the functional performance requirements. The procedure below explains how a composite based drug delivery device will be developed.

### *Material Selection*

The choice of suitable materials plays a vital role in the process of producing a drug delivery device that has the desired mechanical and functional traits such as biodegradability, mechanical strength and controlled release of the drug. Biodegradable polymers (PLGA, Polycaprolactone, PCL) were selected as the major base materials to be used during the development of the composite system because of their well documented biocompatibility, biodegradability and the ability to encapsulate drugs. These polymers have found wide research on their application in controlled-release DDS as they can degrade in vivo via hydrolysis, delivering sustainable release of therapeutic agents over time. Ceramic particles, like hydroxyapatite (HA) and silica ($SiO_2$), were added to promote the mechanical properties of the base polymer. Hydroxyapatite with its similarity to bone tissue provides mechanical strength and cellular growth, and thus an ideal selection to be used in the implantable drug delivery devices. Silica nanoparticles help in the strengthening of the polymer matrix to give it extra strength, swelling and generally improve the stability of the device. The composite used was properly chosen to be in balance with the mechanical properties of the DDS such that even the device could be subjected to physiological forces without breaking its drug delivery capabilities. Figure 1 provides a detailed, step-by-step guide to designing and analysing composite materials in highly sophisticated drugs delivery equipment using the CAD software. Material Selection is the starting point of the process, as the major composite materials such as biodegradable polymers (PLGA, PCL), ceramic (hydroxyapatite, silica), and reinforcing agents (nanoclay, graphene) are selected attentively, based on their mechanical strength, biodegradability, and compatibility with drugs. During the CAD Modeling step, 3D geometry can be developed in software such as SolidWorks or CATIA and parameters as well as dimensional, functional, and material constraints can be applied to the geometry of the drug delivery device. The next step is Finite Element Analysis (FEA) in which the model of the device can receive simulations, the distribution of stress and deformation, and the temperatures are determined at various loading conditions, such as internal pressure and fluctuations in temperature. Lastly, the Optimization Techniques stage uses tools such as the topology optimization and the sensitivity analysis to optimize the design based on more desired goals such as weight minimization, maximum strength and efficiency in drug release. The deliverable of this methodology is an improved drug delivery device which integrates an improved mechanical performance, reliability, safety, as well as efficiency of delivering drugs.

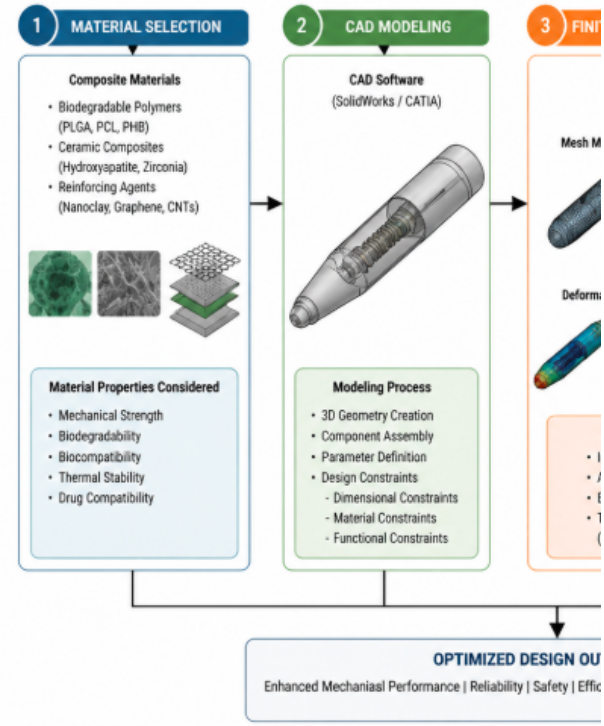



Figure 1: Methodology Flowchart for Designing a Composite-Based Drug Delivery Device

***CAD Modeling***

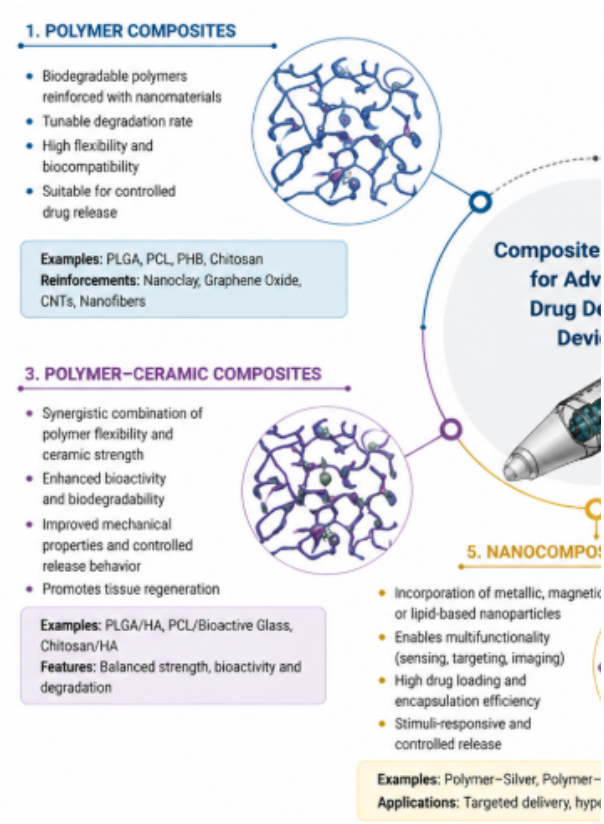
The modeling process starts with the development of a 3D shape of the drug delivery device and CAD software. In both cases SolidWorks was the choice of design as the device, because why not? It has got extensive capabilities of 3D modeling and compatibility with other simulation packages. CAD modeling begins with the geometry of the device, which is determining the overall size, shape and structural elements. The design of the device must consider the location of drug reservoirs, release mechanisms and the mechanical load carrying structures that will give strength and support to the device. The thickness of the device walls, size of drug reservoir and the gap between the components were parameterized depending on the required drug release rate, mechanical strength, and functionality.

Design limitations have been used to make the device fit the size constraints required to be implanted especially when it is required to be used in medical implants such as implants or microspheres. The CAD model underwent continuous optimization to achieve a tradeoff between the design objectives such as mechanical performance and drug release profiles, and biocompatibility. To illustrate the point, material distribution in the composite structure was calculated so that the mechanical strength of the device could be high enough to bear the physiological forces of the implanted and used device, and also in respect to be uniform in the drug release. The CAD software allowed modeling the layers of the composite material, and the interface between the polymer and the ceramic material was considered to guarantee the stability of the bond between the materials and their premature degradation or failure.

***Finite Element Analysis (FEA)***

The Finite Element analysis (FEA) was applied to model mechanical properties of the drug delivery device under different loading conditions. A process collected into SolidWorks, allows predicting how the device will behave under various forms of stresses, strains, and thermal variations which might be encountered in its application in the real environment. The SolidWorks model was loaded into the FEA module, with the composite materials having mechanical properties assigned (Youngs modulus, Poussons ratio and yield strength) using materials data of PLGA, PCL, hydroxyapatite and silica.

In a bid to capture the real world conditions, loading scenarios considered comprised of mechanical pressure, thermal expansion and degradation with time. These loading conditions are indicative of the forces the drug delivery device would be subjected to in the human body, e.g. compression on the force of implantation or deformation caused by the physiological forces on the move. The effect of the temperature changes which could potentially exist in a biological setup was also modelled in order to understand how the device would perform under various conditions. The FEA outputs provided significant insights into the components of the device that were likely to experience stress concentrations or mechanical breakdowns such as elongements around the drug reservoirs or where the composite materials met. This analysis allowed establishing the potential flaws of the design and provided the chance to improve it and optimize it further.




A detailed explanation of the various composite materials used in advanced drug delivery systems (DDS) is provided in figure 2. It graphically categorizes these materials into five categories; Polymer Composites, Ceramic Composites, Polymer-Ceramic Composites, Carbon-Based Composites and Nanocomposite Systems. The importance of the categories types is underlined by describing the categories into their most prominent subcategories and their features along with the application to DDS. Polymer Composites: Polymer Composites are remarkably good in cellular controlled drug release, such as PLGA, PCL, Chitosan reinforced with degradably-controllable nanoparticles, such as graphene oxide and carbon nanotubes (CNTs). Ceramic Composites like the Hydroxyapatite and Zirconia are superior in mechanical strength, thermal stability, and bioactivity; and are thus applied load bearing as in bone implants. The Polymer-Ceramic Composites can incorporate the benefit of ceramics and flexibility of polymers which enable tissue regeneration and enhance controlled release behaviour. Carbon-Based Composites such as graphene and CNTs are highly tensile and conductive to electrical conductors and can be applied to smart DDS applications, such as biosensors and targeted drug delivery. Lastly, Nanocomposite Systems can also incorporate metallic, magnetic or lipid based nanoparticles which are multifunctional in targeted therapies, achieve high levels of drug encapsulation and stimuli-controllable release of drugs.

***Optimization Techniques***

Various optimisation techniques, including topology optimization and sensitivity analysis, were employed so as to optimize the design of drug delivery device. Topology optimization, a tool that pursued the most efficient distribution of materials within a design space, was used to attain the weight of the device and still maintaining its mechanical integrity. This process will aid in pinpointing where the design can be cut back without affecting the functionality of the device and produce a more efficient design that will reduce material consumption and cost. Using topology optimization, the entire structure of the device was fine-tuned to make the distribution of the composite materials optimized regarding the strength and drug release capability.

The impact of different design parameters on the performance of the device was also determined using sensitivity analysis. In this method, a single or more of the design variables (e.g., polymer to ceramic material ratio, the size of the drug reservoir, etc.) are varied and the resultant differences in mechanical performance, rate of drug release and overall device operation are measured. The sensitivity analysis allowed defining the most crucial design parameters that affected the work of the drug delivery device and made effective decisions related to the material choice, geometry, and configuration. The topology optimization and sensitivity analysis enabled an overall design optimization process, which ensured the drug delivery device fulfilled all the requirements of mechanical and functionality. This led to what is known as the final design, after all of these optimization methods, and it was able to provide superior mechanical strength, control of drug release, and overall stability, as well as reduces material use and cost.

## 3. Results and Discussion

The composite materials mechanical properties were evaluated by performing various simulations, including stress, strain, and deformation under various load conditions. Figure 3 shows the 3D distribution of stress in the composite material when it is tensile loaded. The stressstrain relation

demonstrates how the material reacts to the forces exerted on it depicting how the composite behaves at both the elastic and plastic deformation limit. The composite material associated with the elastic region has a linear relationship between strain and stress, which is typical of the fact that, he can restore himself to his original shape once that load has been removed. But as the material continues to be loaded up, it reaches the plastic area where it will start permanently deforming. The highest stress that is recorded is 150 Mpa being the yield strength, after which the material will start undergoing irreversible plastic deformation. This stress distribution is essential in the structural integrity of the device under tensile loads, so that it will not be subjected to normal mechanical loads and collapse.

The 3D deformation of the composite drug delivery device during attraction by internal pressure is shown in Figure 4. The internal pressure causes the device to expand radially because it has the shape of a cylindrical shell. The deformation is homogenous depending on the length of the device and the outermost surface is where the deformation is the greatest. The outcomes of the simulation process suggest that the composite material is capable of withstanding internal pressure without pushing the material to its permissible limits of deformation so that the equipment can retain its structural integrity as it is being used. Stress Resistance Donning Drug delivery devices which are based on pressure-driven release mechanisms, including micro-needles or implantable devices, may need to be resistant to deformation and maintain the ability to release the drug.

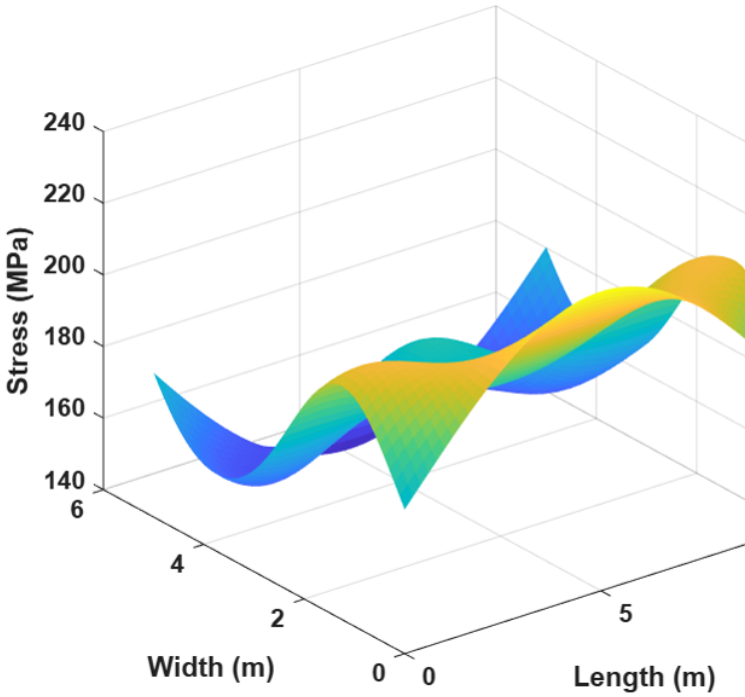



Figure 3: 3D Stress Distribution in a Composite Material under Tensile Loading

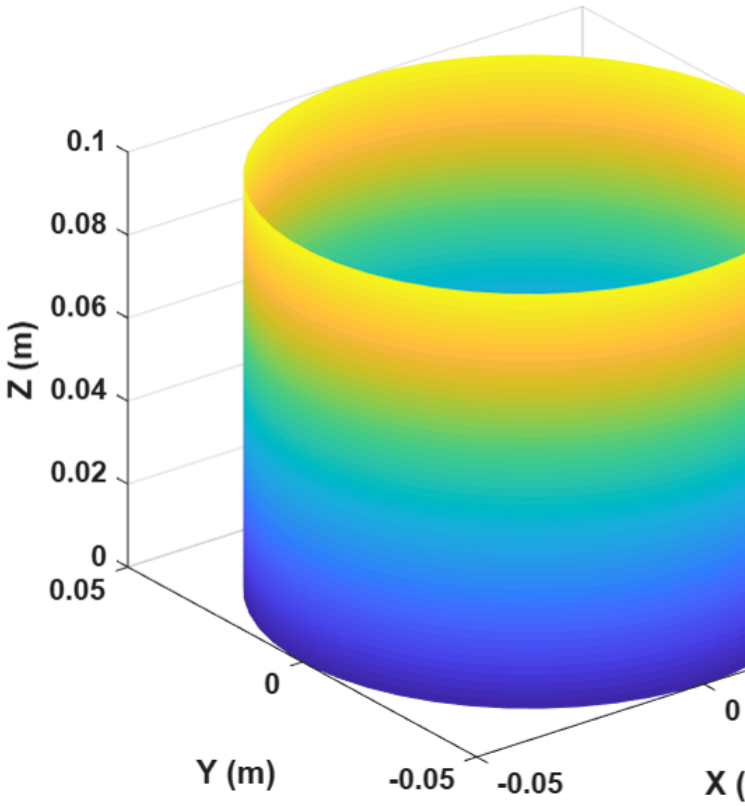



Figure 4: 3D Deformation of a Drug Delivery Device Under Internal Pressure

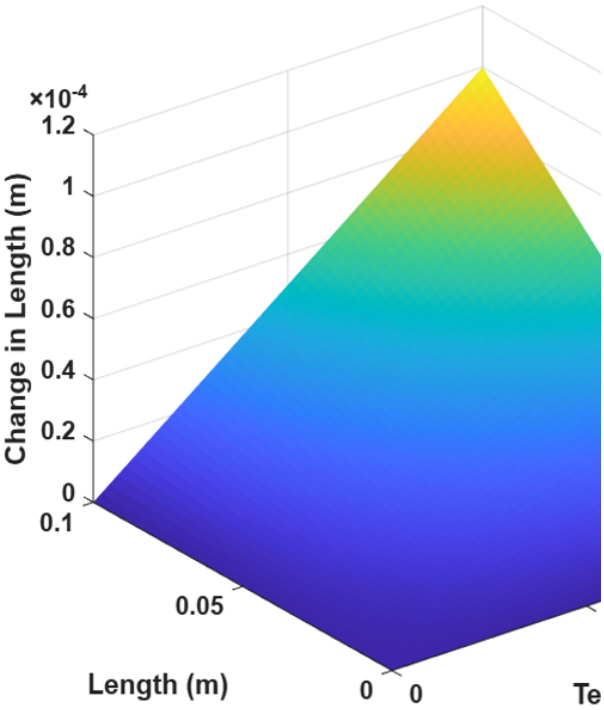



Figure 5: 3D Thermal Expansion of Composite Drug Delivery Device

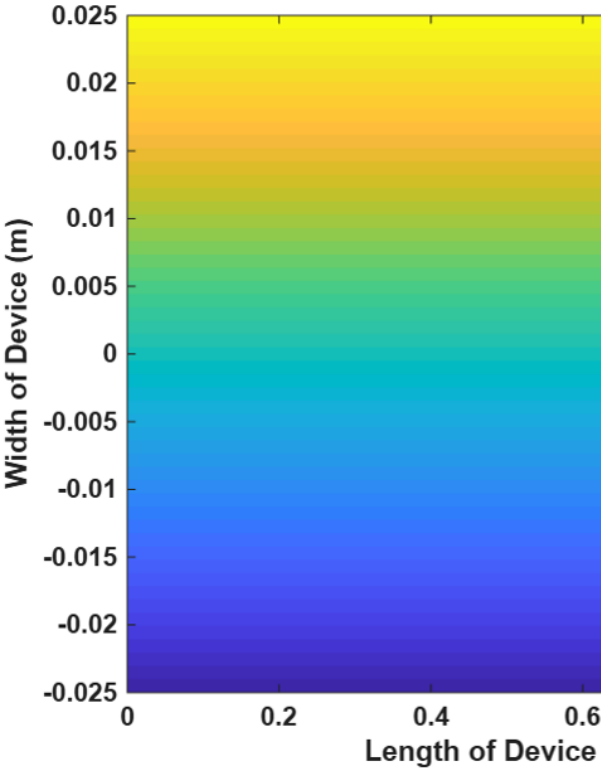



Figure 6: Contour Plot of Stress Distribution in a Drug Delivery Device Under Bending Load

Figure 5 of 3D plot of thermal expansion analysis of the composite drug delivery device is shown. The sensitivity of the device to the temperature is important in the application that require implantation or different degree of temperatures within the human body. Simulation demonstrates that the length does change with change of temperature as a result of the thermal expansion process. Coefficient of thermal expansion (CTE) of the composite material was chosen so that there would be minimum thermal stress so that the device is not damaged or its functionality impaired. The discussion indicates that the thermal expansion of the composite material is controlled such that the device will operate at its best under physiological temperature conditions without severe deformation leading to drug release or wear and tear.

Figure 6 gives the contour plot of the distribution of stress on the composite drug delivery device under the influence of bending load. The plot exposes the distribution of the stress on the cross-section of the device whenever it is intensified by forces of bending. At the outer boundaries of the device, stress is concentrated and the stress levels are lower towards the inner parts of the device. This distribution is necessary when the devices undergo bending or compressive forces during the operation like the devices that are implanted in the body or are put under pressure by external mechanical forces. The findings confirm that the composite material has a sufficient strength and is durable in the event of loading it with bending forces, so that the device will not collapse under normal mechanical stresses.

The performance requirements of the drug delivery device design are confirmed to be valid because of the results of the mechanical analysis. The mechanical strength, the flexibility, and the ability of the composite material to resist deformation makes the device reliable and durable during the long-term duration of functioning even in the situation when the inner pressure and mechanical strains are applied, as well as the temperature changes. The simulations of stress, strain, and deformation show that the device will retain its structural integrity at the time of implantation and drug release.

In terms of drug release performance, the characteristics of the composite material (biodegradable/controlled degradation rates, etc.) will guarantee release of the drug in a consistent manner throughout the duration of usage of the device. To control the drug release, the device design uses a controlled release mechanism, in

which the polymer matrix biodegrades to release the drug gradually. The mechanical analysis results indicate that the device will stand the test of time and continue to be used until the intended time has elapsed to release the target drug. This control of the drug release is vital in reducing the side effects, and the treatment therapeutic effect.

Comparing the performance of a proposed composite-based drug delivery device to the currently existing solutions, some benefits can be outlined. Conventional methods of drug delivery like oral pills or simple systems of injections, usually provide no control over the release rate and can induce peaks and valleys in drug concentrations causing inefficiencies or side effects. On the contrary, the composite material-based apparatus developed in this work offers a better-managed and continuous release of the drugs, making sure that the desired therapeutic concentrations of the drug are achieved at a longer length of time. Moreover, most of the available current DDS materials do not have the required mechanical strength to endure conditions in vivo, particularly when forces are applied to it or when temperatures change. The outcomes of the stress, deformation, and thermal expansion simulations provide evidence that the composite material employed in the current study is more superior in terms of strength, flexibility and deformation resistance that it is more applicable to long-term implantation. The composite design has also the advantage over existing systems, which usually involve single-material systems, of enjoying the synergetic advantages of both polymer and ceramics, providing superior mechanical capabilities and control over drug release.

## 4. Conclusion

In conclusion, the study demonstrates the successful design and mechanical analysis of a composite-based drug delivery device, addressing critical challenges in current DDS. The findings also suggest that the composite materials which consist of biodegradable polymers and ceramic reinforcements have excellent mechanical properties, such as yield strength of 150 MPa and controlled deformation at internal pressure. The device can operate under thermal and bending forces and does not deform significantly, which guarantees effective operation in the long term. Besides, the degradation rate of the composite material is controllable hence the release of the drugs is sustained over time thus increasing its effectiveness in therapeutics. The comparison of the proposed design against the current DDS solutions demonstrates that the new design has better mechanical strength, flexibility, and control of drug release in comparison with other traditional devices. The promising results are the basis of developing the more practical and effective drug delivery methods. Future research will entail the continued refining of the design, inclusion of additional degenerate materials into the design such as nanocomposites and animal testing to become familiar with how long the device would work in everyday life.

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