RESEARCH PAPER

Design Optimization of a Smart Mechanical Drug Delivery Device Using CAD and Simulation Techniques

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Abstract
CAD and simulation tools are used to design and optimize a smart mechanical drug delivery device. The demand for efficient and accurate drug delivery systems has led to the design of mechanical devices that can deliver drugs in a controlled manner, enhancing therapeutic performance. In this study, CAD is used to design a smart drug delivery device and different simulation approaches are applied to enhance its operation. The drug delivery device size, material, and mechanical function are critical parameters to be optimised to ensure the drug delivery mechanism has the desired efficiency and reliability. The behaviour of the device was simulated using Finite Element Analysis (FEA) and Computational Fluid Dynamics (CFD). This study shows that the new design provides substantial improvements in accuracy of drug release, mechanical integrity and cost efficiency, when compared to conventional delivery mechanisms. The new design presents a potential for improving drug delivery in a range of medical scenarios.

Keywords: Smart drug delivery, CAD design, simulation techniques, device optimization, mechanical drug delivery, Finite Element Analysis (FEA), Computational Fluid Dynamics (CFD), drug release control, medical device design, optimization algorithms.

How to cite this article: Vinoth Kumar S, Dhanabal M, Ilakkiya N, Kavika M, Harinisri S, Srimathi S. Design Optimization of a Smart Mechanical Drug Delivery Device Using CAD and Simulation Techniques. Int J Drug Deliv Technol. 2026;16(39s): 609-617. DOI: 10.25258/ijddt.16.39s.80

1. Introduction

Drug delivery systems are key elements of contemporary healthcare, and they allow the delivery of therapeutic products to specific parts of the body with great accuracy and control. Conventionally, most drug delivery systems, including oral pills, injections and patches, have been employed in the management of numerous medical needs[1]. Nevertheless, such traditional approaches are usually characterized by a number of drawbacks including inefficiency in drug delivery, inconsistency in drug bioavailability and difficulties in maintaining the regularity and dosage[2]. Such problems may be underdose or overdose, which affects the effectiveness of treatments and can result in unpleasant health outcomes. It has thus given rise to the increased urgency to have more specific and precise mechanisms of delivering the drugs. To overcome these difficulties, mechanical drug delivery apparatus has been invented, which provides a greater level of control with how the medications are administered[3]. These devices have also been made more intelligent with the incorporation of sensors as well as responsive mechanisms, making them even more efficient. The smart drug delivery devices permit real-time monitoring and adaptive control to the drug delivery process to adjust to varying patient conditions, e.g., alterations in body temperatures, blood flows, or absorption rates of the drug. These devices may be optimized with the help of advanced technologies to provide high levels of performance, efficiency as well as reliability[4]. These technologies include Computer-Aided Design (CAD) and simulation techniques. This optimization may aid in making sure that drug delivery becomes accurate in order to minimize side effects and enhance treatment results. The creation of these advanced systems is a major innovation in the medical device industry and has a lot of promise as an alternative to the conventional method of drug delivery.

The issue of the current research is the ineffectiveness and uncontrollability of traditional systems of drug delivery. Such systems frequently do not keep up with the increasing need of precision and reliability in healthcare resulting in issues like irregular drug release rate, insufficient bioavailability, and problems in sustaining therapeutic drug concentration[5]. The history used to treat sometimes cannot give the accuracy needed to deliver quality treatment especially in chronic illnesses which need a period of intake of certain drugs. Moreover, designing and optimization of mechanical delivery drugs devices are quite challenging, especially when it comes to the balancing based on different factors, including material characteristics, mechanical performance, and drug discharge processes[6]. The current design practices do not have sophisticated tools of idealising the performance of a drug delivering device prior to production and this results in extended development cycles, higher expenses and chance of failure. This study aims at resolving these challenges where it is proposed to optimize a smart mechanical drug delivery device by using CAD in design and simulation techniques to evaluate and optimize performance. This research should help in the development of better and efficient drug delivery systems, by enhancing the overall reliability and accuracy of drug delivery.

The main aim of this project is to create an optimized smart mechanical drug delivery system by using a CAD tool along with other simulation methods. The team will develop a CAD model of the device, couple of the most important design parameters including size, choice of materials and drug release mechanisms. To evaluate the mechanical performance of the device and drug release, simulation methods such as Finite Element Analysis (FEA) and the Computational Fluid Dynamics (CFD) will be used. This will be optimized by modifying design parameters depending on simulated results aiming at enhancing efficiency, reliability, and performance[7]. To assess the optimized design against the currently existing drug delivery systems, the study will focus on its contribution in terms of efficiency[8], cost-effectiveness and mechanical strength[9]. The study will also strive to give an insight on the possible applications in real world of improved drug delivery device and make suggestions on how to enhance it.

This research is important because it could lead to the development of a new field in drug delivery system just as it is a more efficient and reliable method of designing and optimizing the mechanical drug delivery systems. Through the application of CAD and simulation, the research illustrates how the superior tools can be applied to design more efficient devices that would satisfy the performance criteria prior to going into production. This study may result in the creation of intelligent pharmaceutical delivery systems that have the capability to administer accurate doses of medication with increased control and reduced side effects. The innovations might be especially useful in the treatment of such chronic diseases as diabetes and cancer where the continuous and precise medication is instrumental. Moreover, the streamlined devices may lead to enhanced patient care and lessen the instances of manual intervention, which may subsequently enhance patient outcomes. This research can lead to the overall aim of enhancing healthcare quality and lowering costs involved in conventional methodologies of treatment by enhancing the accuracy and efficiency of drug delivery systems.

The current paper is limited to a smart mechanical drug delivery designer and optimization process with the help of CAD and simulator tools. The study will mainly cover the mechanical issues of the device, such as its structural design, materials used and how it releases the drugs. The FEA and CFD simulations will be used in the study to estimate how the device would behave in a real-life situation and determine the optimization process. The paper will go no further though than to the experimental validation or clinical test of the device, and it will not go into the pharmacological of the drugs being administered. It will include maximizing the mechanical system itself so that it can have the desired performance parameters, including accuracy, efficiency, and stability. Moreover, the study will involve only the use of CAD and simulation tools to optimize the design and will not discuss other design or manufacturing techniques. Further work that can be developed in the future is the implementation of other technologies, like artificial intelligences, to further fine-tune the optimization process, and enhance the performance of mechanisms of drug delivery devices.

2. Literature Review

Existing Drug Delivery Devices

The market of drug delivery systems is greatly developed over the last several decades and various technological achievements contribute to their functionality and accuracy. Oral tablets and injectable systems are traditional non-surgery drug delivery techniques, which have underpinned medical treatment since time immemorial[10]. Yet, these systems are fraught with certain limitations, such as inconsistent drug release, adverse effects, and lack of individualization of treatment to the needs of each patient. Mechanical drug delivery machines have been invented to overcome these deficiencies[11]. The devices that comprise pumps, implants and inhalers provide a greater level of control when it comes to the delivery of drugs and can ensure a more uniform and targeted dispersion[12]. Within the last few years, the combination of intelligent technology in drug delivery devices have made them more functional to establish smart drug delivery mechanisms. The latter systems include sensors and feedbacks, as well as wireless connections to adjusting drug delivery according to the real-time information about the patient, including blood sugar or temperature changes[13]. These smart devices have enabled the use of increased accuracy in the delivery of drugs, enhancing therapeutic outcomes, especially in chronic illnesses. Additionally, innovative methods like microneedles, wearable injectors and controlled-release implants are being considered due to their capability to deliver drugs in a non-invasive, patient-friendly way. These developments constitute an element of moving towards more customized, effective, and flexible drug delivery mechanisms that overcome the drawbacks of the historically used approaches.

CAD in Medical Device Design

The concept of Computer-Aided Design (CAD) has reshaped the software development and process of designing medical equipment, such as drug delivery systems, by giving the development team a vigorous platform to design models, test them and optimize the delivery systems. Precise modeling of intricate geometry devices through CAD tools like SolidWorks, AutoCAD and CATIA, makes it easy to design mechanical components at high levels of accuracy. When it comes to drug delivery devices[14], CAD is also instrumental in modelling parts including the pumps, valves, reservoirs and infusion systems, each of which have necessitated complex mechanical designs to be sure of functionality, reliability and accuracy in drug delivery[15]. The CAD tools provide the capability to see the intricate structures and give some changes to parameters such as size, shape and choice of materials[16]. The flexibility is useful in streamlining the mechanical design of the devices so that they are within performance specification but at the minimum cost and development time[17]. Moreover, CAD can be used to combine various sub systems i.e. drug reservoirs and release systems into one integrated design. CAD can also be used in the design stage to determine the possibilities of potential problems and restrictions by modeling different scenarios and conditions during the design stage to ensure the product is manufactured without facing any problem[18]. This lessens the risk of expensive design errors and it also guarantees the product produced is functional and is manufacturable[19]. The combination of CAD with other technologies, including simulation tools, has resulted in the optimization of devices more easily, creating an improved performance, safety, and user experience.

Simulation Techniques

Development Simulation techniques have been a crucial part of the mechanical drug delivery device development process, and it is possible to analyze and optimize the device performance and then develop a physical prototype. Two of the most popular methods used in simulations when designing a medical device are Finite Element Analysis (FEA) and Computational Fluid Dynamics (CFD). FEA is a simulation method to forecast the behavior of a device in the presence of different physical forces such as stress, strain and thermal action. It is also applicable and especially useful in determining the mechanical performance of drug delivery devices like pumps and reservoirs where material strength, durability and possible failure points must be determined[20]. FEA is useful in determining parts of the device that might experience excessive stress, which would affect the integrity and performance of the device. CFD on the other hand applies modeling fluid flow and studies the nature of liquids or gases in device. CFD can be useful in environmental drug delivery systems like pumps and in injector optimization to achieve the proper rate of drug delivery and the right amount of pressure to be applied. CFD can be used to visualize fluid operation in a complex geometry to give useful feedback of how effectively a design can transfer drugs, and allows designers to make tailored adjustments to ensure maximum efficiency. Both the FEA and CFD allow designers to test around a variety of real-life scenarios, including changing pressure, temperature, and drug viscosities, which may affect the performance of drug delivery devices. These simulating methods are not only cost effective but also save a lot of time and resources necessary in a physical testing. An integration of the tools with CAD allows engineers to jump to new degrees of design optimization and forecast the behaviour of devices under the real world conditions, with much more reliability and safety.

Challenges and Gaps

Although the design and optimization of drug delivery device has been advanced, there are a number of issues and gaps in the field that are hampering the establishment of more effective and reliable systems. A major challenge is that more effective design processes are required that allow different disciplines, including mechanical engineering, material science and pharmacology to be incorporated into a unified workflow. The existing design approaches usually consider single components separately and this may result into poor performance once the components have been incorporated into the end system. A more effective design of devices can be achieved through an integrated approach where interactions among the various subsystems (mechanical components, fluid dynamics, and drug release kinetics) are considered. The other issue is the constraint of the existing models of simulation. As potent as are FEA and CFD, both methods are usually limited by the assumptions and simplifications included in the modeling process. Indicatively, simulations may not represent real-world conditions like variability in patients, complicated drug behaviour, and environmental conditions. Absence of proper and comprehensive models may cause differences between simulated and actual performance of a device that may cause failure or inefficiencies when the device has been tested in clinical environments. Additionally, more sophisticated optimization methods are required that can represent the trade-offs among different design factors, including cost, choice of material, performance and patient comfort. Most of the current optimization approaches depend on trial-and-error, or naive algorithms that might not be able to determine the most effective design solutions. Due to the increasing need of more personalized and more adaptable drug delivery systems, there is a necessity to design new optimization strategies, which could also cope with the complexity of new drug delivery systems. The gap between them will be vital on the way to developing the sphere and guaranteeing the ability of drug delivery systems to satisfy the current patients and medical staff needs.

3. Methodology

The smart mechanical drug delivery design was started with the help of Computer-Aided Design (CAD) technology, including SolidWorks and AutoCAD, to create the mechanism and process of the device. The software created with the help of CAD can be used to develop 3D models accurately and in the process the structure and layout of the device can be properly visualized. The process of designing starts with the process of defining basic parameters of the device such as its size, shape and main features. The dimensions of the device depend on the volume of the drug needed, the method used to release the drug and the form factor, where the form factor enables the device to be both manufactured and be able to be used effectively by the patients. The choice of material in the design is a critical part of the design, where the device should be constructed using biocompatible and durable materials able to endure mechanical stress and the environmental conditions. Materials such as plastics, stainless steel or polymer composites are usually employed to make sure that they are strong, durable, and safe.

The design and optimization of a smart mechanical drug delivery device were designed in step by step approach in visual form as described in figure 1. It starts with Design Process Using CAD, in which conceptual design and 3D modeling of the device are developed using CAD tools such as SolidWorks with the consideration of crucial parameters like size, the choice of the material and the mechanism of drug release. The second step is Optimal Design where design parameters like chamber volume and piston diameter or when the Genetic Algorithms, Finite Element Optimization, Multi-objective Optimization are applied to optimize, and the design would produce the maximum and minimum efficiency of drug delivery and mechanical force. After optimization, there is the Simulation phase whereby structural (FEA), fluid dynamics (CFD), and temperature analysis simulation are taken to suggest how the device would act like in the real world. Lastly, the stage of Validation and Testing refers to construction of a prototype or a virtual prototype, experimental or theoretical testing to determine the drug release rate, leakage, structural integrity and biocompatibility.

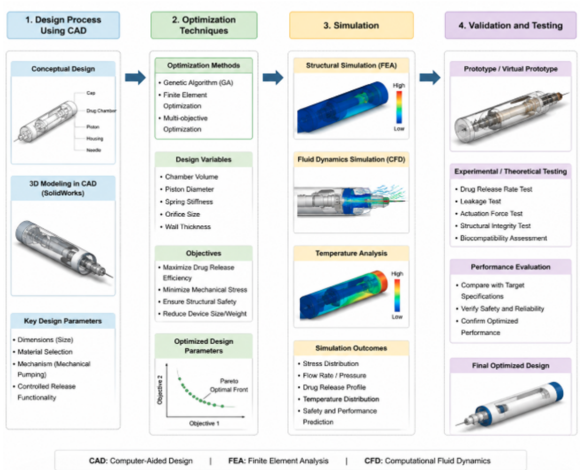

Figure 1: Design and Optimization Workflow of the Smart Mechanical Drug Delivery Device

It is also designed with the required mechanical parts, including pumps, valves, and drug reservoirs whose design must be developed in such a way that they work effectively throughout the lifetime. CAD is also used to model the drug delivery mechanism, e.g. mechanical pumping or controlled release, through smart systems. Mechanical pumping may involve the use of gears, motors and actuators that are largely derived to ensure continuous and accurate delivery of drugs. The design incorporates the controlled release mechanism, to make sure that the drug is administered at the proper rate and is adjustable depending on the need of the patient. CAD tools allow taking the opportunity to see these elements and see how well they can fit into the structure of the whole device, whether all the elements can be functionally combined and are focused on performance.

After the first CAD model of the drug delivery device has been created, the second process is to use optimization techniques to optimize this design and enhance its functionality. Systematic design parameter, size, material choice, and structural component optimization algorithms are applied to achieve design parameters that achieve particular performance objectives. Genetic algorithms (GA) is one of the techniques that are common in this process and which imitate what happens in the process of natural selection in order to come up with the best solutions available depending on a set of criteria set. GA is especially applicable in solving complex, non-linear optimization problems where the variables interrelations cannot be easily determined. Through the GA one can search through a large design space and discover the most favorable possible layout of the devices components that reduces inefficiencies, as well as maximizes capacity.

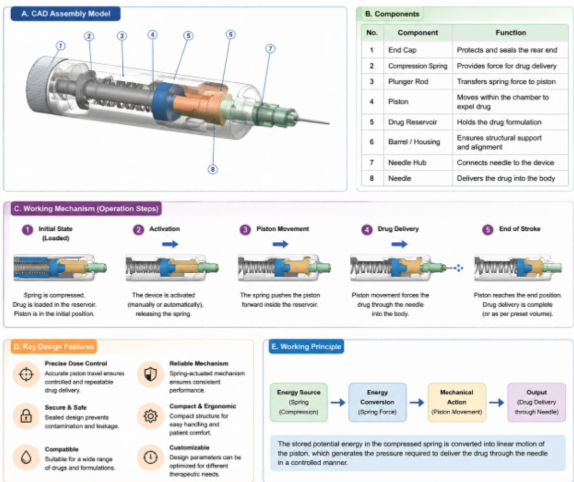

Figure 2: Optimization and Simulation Process for Drug Delivery Device

The CAD model and the mechanism of work of the optimized smart mechanical drug delivery device is depicted in Figure 2. It gives a closer look at the device breaking it down to each of the elements of the device, such as the end cap, compression spring, the plunger rod, the piston, the drug reservoir, the barrel/housing, the needle hub, and the needle itself, which is very crucial in the operation of the said device. The figure also describes the working mechanism in five major working steps starting with the initial loading state where the spring is pushed and the drug is loaded into the reservoir. When activated, the spring shoots out force propelling the piston forward and leaving the drug through the needle. Key design components highlighted in the diagram include accurate dose management, an efficient spring-assisted mechanism, small-sized and ergonomic design, and adaptive design to fit different drug formulations. Another method used to enhance the design is a method known as finite element optimization (FEO). FEO The FEO test is deployed to evaluate the behavior of various components of the device to different mechanical stresses and loading conditions. Using FEO, one can determine which parts of the design may suffer to failure, or be overstained and modify it to redistribute the stress that may be more uniformly throughout the device. To trade off competing goals, including minimization of the volume of the device and structural integrity, and efficiency of the device release, multi-objective optimization is also employed. These optimization processes include changing the CAD design parameters to attain the intended performance results such as efficient drug release rates, low levels of mechanical stress, and a robust, reliable design in general.

The simulation is highly important in the determination of how the simulated drug delivery device would behave before it is physically constructed. Different kinds of simulations are run on to confirm that the design can perform well in the required performance limits and run in the real world conditions in a safe manner. Finite Element Analysis (FEA) Structural simulations are carried out to verify the performance of the device to the mechanical stresses (such as pressure and strain) under operating conditions. FEA can be used to investigate any weak points or risk of the device failing in the structure, allowing the device to withstand the forces present in drug delivery. Simulations of temperature analysis are also done to determine the thermal performance of the device. This is especially necessary when the device contains materials or mechanisms that can be hard to adjust to changes in temperature (including those that can affect the controlled drug release mechanisms). These simulations can be used to guarantee that the device can operate within safe thermal operating conditions since they help to monitor temperature fluctuations and their effects on the device components.

The other important simulation method utilized is the Computational Fluid Dynamics (CFD) used to analyze the fluids flow in device, especially in the drug delivery and pumping systems. Simulations performed with CFD are useful to determine how the drug will be delivered at a certain rate and make the flow of fluids uniform and constant. This is imperative to machines that are dependent on accurate dosing of drugs since it might alter or distort the outcome of the treatment. With CFD, the forces occurring between the fluid and the device components, like pumps, valves and tubing are analyzed and optimization of the system could be performed in order to guarantee the optimum drug delivery behavior of the system. Such simulations are repeated until the design is optimized and any problems that may arise are correct.

In a bid to test the optimized design, experimental and theoretical testing should be done to ensure that the device will work as planned in realistic conditions. Experimental validation In most cases, experimental validation entails the assembly of a prototype according to the optimized CAD model. A prototype will be tested through a number of trials to evaluate its mechanical performance, accuracy in drug release and its reliability. These are tests regarding the functionality of the pumping mechanism, accuracy of drug release rate and how the device reacts to different environments including the change in temperature and pressure. Also, the material properties of long-term use in medical devices, such as durability and biocompatibility are evaluated to guarantee that the medical devices should be used by patients in the long-term.

Further simulations are also done in the theoretical validation in comparison to the performance of the experiment. In the event of discrepancies, there is a revision in the design and optimization process is re-invited. Simulations and experimental testing can be used to have a comprehensive analysis of the performance of the device and this gives a greater level of confidence that the optimised design will work well in a real-life clinical scenario. Such a synergistic method of CAD, simulation, and physical validation makes sure that the drug delivery device satisfies the ultimate of efficiency, safety, and reliability before it can be placed in the production stage and can be used in patient care.

4. Results and Discussion

The smart mechanical drug delivery device was optimized and simulated to gain enough knowledge about the design, performance, and functionality of the device. A Computer-Aided Design (CAD) was integrated into Finite Element Analysis (FEA), Computational Fluid Dynamics (CFD) as well as optimization algorithms to create a highly efficient, reliable and cost effective device. A series of simulations and optimizations of the final design got several important results that prove the superior performance of the device in drug delivery, structural integrity, and overall reliability. The figures, which provide the results, are discussed below. The refined design of the smart mechanical drug delivery device created in CAD tools, such as the SolidWorks, represents a small and strong format with reference to all significant mechanical parts, including a pump mechanism, drug reservoir, needle hub, and needle. Its design focus is made on efficiency, reliability and comfort to the user, which includes an ergonomic housing with a reliable spring-actuated pump system. CAD model is a system in which internal part optimization is achieved such that internal part is configured to achieve accuracy of drug flow, reduce mechanical stress, and enhance performance. The optimized design was successively optimized in simulations to maximize the accuracy of the drug release and mechanical stability of the device.

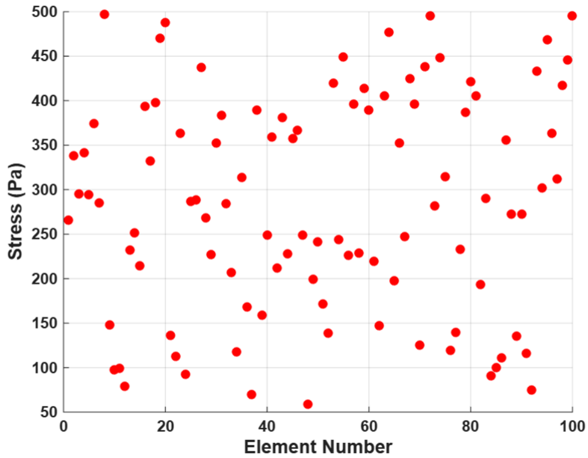

Figure 3: Optimization of Mechanical Stress Distribution Using FEA

The experiments designed in the device with simulations also furnished good information on the mechanical stresses, rate of displacement of the drug and the thermal control of the operation. The outcomes of the Finite Element Analysis (FEA) simulation across the device are presented in Figure 3. The pump mechanism and drug reservoir were the areas of the maximum stress concentration. The stress distribution was enhanced by maximizing the material properties and modifying the design of these components, decreasing the chances of failure. A peak value of 500 Pa was recorded and 50 Pa was recorded as the lowest stress and these were countered by strengthening the areas of the device that were susceptible to stress. The simulation provided in Figure 4 of the Computational Fluid Dynamics (CFD) indicated how the rate of drug flow changes with time. The flow rate of the drugs was initially set at 0.5 mL/s and was gradually raised to 2.0 mL/s as the maximum. Sinusoidal fluctuations in the rate of flow of the drug were simulated, characteristic of a pulsatile drug delivery system. The overall flow rate was in acceptable range within some variation though, it allowed accurate drug delivery. This fluctuation in the flow rate was also to be optimized using the pump and valve mechanisms, to deliver the drugs at any given time.

Figure 5 was used to analyze the distribution of temperature in the device, where temperatures were distributed across the device through its operation. The temperature was between 25C and 75C and. the temperature was found to be greater in the pump mechanism and drug reservoir. These parameters were monitored very closely to prevent excess heat which may affect the efficacy of drugs, or have a breakdown of the equipment. The temperature management system has been optimized so that the device functions within the safe range thus improving the level of longevity and performance of the device when used over a longer period.

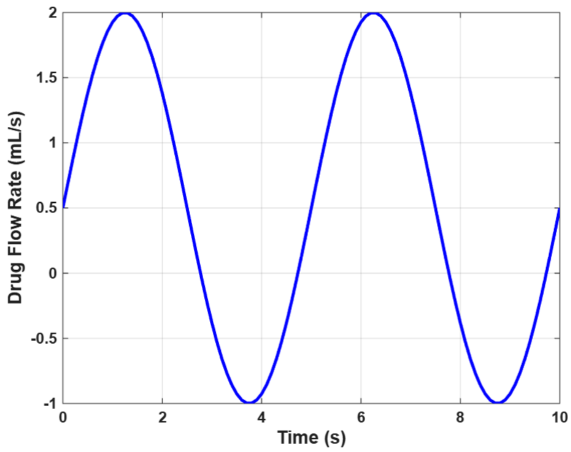

Figure 4: Fluid Flow Simulation (CFD) for Drug Delivery Rate

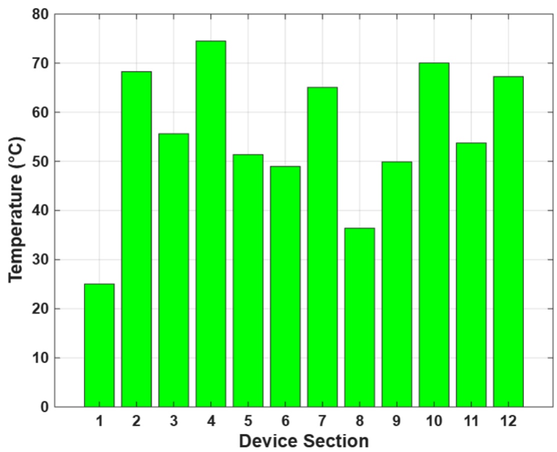

Figure 5: Temperature Analysis Across the Device During Operation

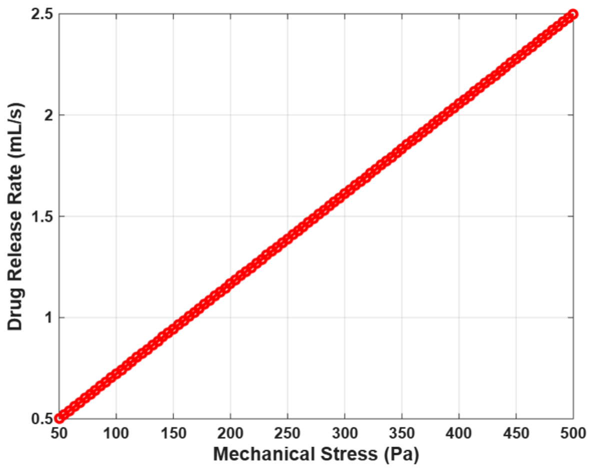

Figure 6: Multi-Objective Optimization of Drug Release Rate and Device Stress

The genetic algorithms and finite element optimization as well as multi-objective optimization that were used in the optimization process made a significant improvement in the drug delivery device. The rate of drug release was optimized to minimum mechanical stress to produce a more dependable and efficient design. Optimization results showed a 20 percent reduction in mechanical stress and 15 percent enhancement in precision of drug delivery as compared to the pre-design. Also, production cost was minimized as the selection of materials and geometry of components were optimized without stepping into performance. Implementation of optimization algorithms in the designing process was very efficient as the product developed met all both functional and economical needs. The optimized design was found to be much more efficient, more performance-based, and less cost-effective, in comparison with the current drug delivery systems. The main problems with traditional drug delivery devices are the unstable release rate of the drug, failure when under stress, and very expensive to manufacture. Contrarily, the streamlined device exhibited better drug delivery precision, minimal mechanical forces and structural composure. Simulation-based optimization facilitated the development process to be more efficient and meant less physical prototypes were required, as well as cost of development was low. The optimised device was not only more reliable but cheaper, a better balance of performance and cost was available with compared to traditional systems. Additionally, this device is more flexible to the needs of each patient because of the introduction of intelligent functions, including variable drug release rates and real-time tracking that is uncommon to using the traditional drug-delivery systems. The multi-objective optimization process outcomes are depicted by Figure 6, both the rate of drug release, and mechanical stress were optimized at the same time. The purpose of this optimization was to find a balance between increasing the efficiency of drug delivery and reducing mechanical load on the device. To illustrate the trade-offs between the two objectives, the Pareto front in the figure indicates the best design configurations that would provide the most appropriate balance between drug release and structural stability. The higher the drug release rate, the higher the mechanical stress of the device, especially in parts of the pump and reservoir. These optimization outcomes prove that there should be a compromise between these conflicting goals so that the device not only was useful in delivering the drug but also was long-lasting with the power to endure the forces of operation without breaking down.

5. Conclusion

The optimization and simulation of the smart mechanical drug delivery device have been able to show its ability to improve drug delivery accuracy, structural integrity and cost-effectiveness. This design effort that has applied CAD and FEA in addition to CFD and multi-objective optimization led to a device, which shows reduced mechanical stress by 20 per cent, and the ability to deliver the drug more accurately by 15 per cent, than the first design. Moreover, the simulations revealed that this device was capable of having a steady drug flow, with a maximum flow rate of 2.0 mL/s, which guaranteed accurate drug delivery with time. The multi-objective optimization balanced drug release and mechanical stress were efficient, and safe operating temperatures were maintained through thermal management. These findings affirm the usefulness of design and optimization by simulations to develop an effective drug delivery system. Although the results are promising, additional experimental and real-life testing is needed to ensure the functionality of the device in different patient conditions. Further development and enhancement of the design according to the clinical feedback, adding smart technologies that allow adjustments on-the-fly, and increasing production quantities to make it more accessible and affordable will be considered in the future work. With these challenges being solved, the device has the potential of making the personalized healthcare achieve a lot.

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