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A Comprehensive Study on Design Trends and Future Scope of Implantable Drug Delivery Systems

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Abstract

Implantable Drug Delivery System (IDDS) emerges as an achievement in healthcare that promises to optimize the therapeutic properties of drug and reduce the risks in life threatening disorders like cancer, ischemic heart attack, brain stroke, aids. The design of an implantable drug delivery system that has been made viable by the convergence of a controller for decision making and a drug delivery mechanism that delivers drug at the site of action has been discussed. This paper presents a first of its kind survey on the need for an implantable drug delivery system along with the research projects being carried out in the area of control design and drug delivery mechanisms. The advantages of IDDS are detailed with the challenges and design constraints that are faced while designing these systems. With IDDS, the patient compliance and quality of life can be enhanced considerably. This paper also investigates the possible future research scope and applications of IDDS such as for chronic disorders that need to be regularly monitored and timely treated.

Keywords*: Implantable Drug Delivery, Molecular Communication, Multilayer Perceptron, Proportional Integrator Derivative Controller, Ultrasound Cavitation*

1. Introduction

There are many acute disorders that may seriously affect the functioning of human body. These diseases are silent killers that grow eventually over a period of time in human body. Patients suffering from these diseases need regular consultation, dosage and medical tests to avoid risks. Hence, there is a need of early detection and continuous monitoring with required drug delivery for the patients. Therefore, to curb the problems of regular monitoring, heavy dosages and patient compliance implantable medical devices have been designed and more research work is going in this area to design implantable for other serious disorders. Implantable medical devices are placed inside or on the surface of the body for delivering medication, monitoring body functions or providing support to organs [1]. Incorporating drug delivery into medical implants is of significant additional benefit. The convergence between implantable devices and devices which deliver drugs as their primary action is increasing [2], resulting in a complete implantable drug delivery system (IDDS). The complete implantable drug delivery system with all the constituents is shown in Figure 1 [3]

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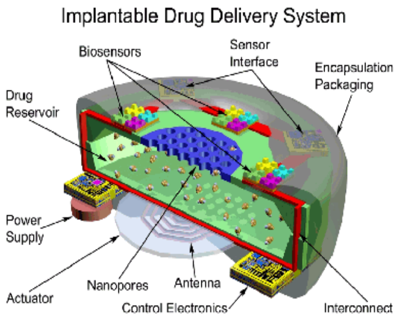

Figure 1. Implantable Drug Delivery System [3]

IDDS develops as a technology for controlled release of therapeutic substances according to the requirement of the patient and injection of the drug at the required site in the patient body. The amount of drug is decided by a control system that does all the decision making for the patient and drug delivery at targeted site is accomplished by a particular delivery mechanism. IDDS thus enables the introduction of drugs in the body and improves system's efficiency and ensures safety by controlling the injection rate and drug concentration in the body. Therefore, IDDS administers the drug locally and does not affect the whole body. Automatic controllers in IDDS increase the accuracy, reliability and regulate the physiological parameters like respiratory control, drug infusion, and body temperature and dialysis mechanism. An intelligent control system with the ability of automatically adjusting the concentration of drug by regulating all the key physiological parameters of human body is desirable.

Many control system designs have been proposed and implemented using proportional integrator, proportional differentiator, neural networks, and fuzzy logic [13-15]. The drug delivery component of IDDS is used to deliver the decided concentration of drug by controller from the drug reservoirs to the patient body. Many delivery mechanisms are designed and investigated. These methods include targeted drug delivery using Microrobot, drug delivery by focused ultrasound in case of central nervous system diseases, drug delivery by micropumps mechanism [19,23,26].

The two main constituents of an implantable drug delivery system *i.e.* Control System Design and Drug Delivery Mechanism are investigated in this paper and can be represented as shown in Figure 2

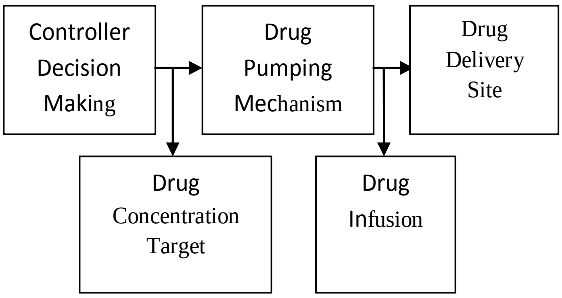

Figure 2. Block Diagram of an Implantable Drug Delivery System

The paper is organized as follows: section 2 describes the need for an implantable drug delivery system along with the research work done in the field of control system and drug delivery in section 3. Section 4 explores the advantages of an implantable drug delivery system followed by section 5 which presents the various ongoing research projects on IDDS. Later, in section 6, challenges and design constraints in the design of an IDDS are investigated. Finally section 7 concludes this paper along with the future research issues in section 8

2. Need of Implantable Drug Delivery System

Drugs used to be administered orally, as liquid or in powder form. New dosage forms were introduced to overcome problems that resulted due to the conventional forms of drug administration. As time progressed, need for drug delivery systems that could maintain sustained rate of release of drug at specific location grew. Moreover, there was a requirement of automatic control of drug concentration and adjustment according to patient need. Therefore, IDDS have been designed and to control and optimize the therapeutic properties of drug making them more safe, effective and reliable. Complex IDDS are implantable medical devices with both control mechanism and drug pump, where the drug is controlled by a controller that regulates the flow rate in relation with the setting operated by the physician [4] Patients suffering from acute disorders require intensive care with constant monitoring and that too by experienced medical personnel. For such cases, administrations of drugs keep patient vital physiological parameters within desirable limits. Thus, the rate of infusion of drug becomes critical parameter for those cases and requires constant attention and adjustment.

Manual control results in more consumption of time and can be more tedious. To avoid risks, a need exists for such systems that can automatically administer drug concentration using an intelligent control strategy and decision making. Automation due to the latest advance technologies provides a realistic mean for curbing increasing costs of healthcare [5]. Implantable drug delivery devices enable site specific drug administration thus, reducing significantly the doses that can minimize potential side effects of the drug to other healthy organs and tissues. Moreover, implantable drug delivery devices allow sustained release of drug. Most important advantage of implantable drug delivery devices is patient compliance as treatment procedure associated with IDDD is less burdensome for patients than injections or pills [6]. The amount of drug dosage, frequency and interval of delivering drugs that would be impractical for professional administration can be well programmed by these devices [4,7].

3. Implantable Drug Delivery System Techniques

The literature survey in this paper is divided into two parts viz., the research work done on designing controller system for implant and drug delivery mechanism. Various control strategies are designed using neural networks, fuzzy logic, and proportional integral controller as mentioned in the literature survey. Drug delivery strategies like designing drug vehicles, micropumps, and modeling drug delivery as communication channel are also discussed in the survey.

3.1. Control System Designs

A computer aided system for drug delivery with control system employing neural networks using adaptive predictive control has been presented in [8]. The system predicts the future responses of patients to drug infusions and calculates the optimal input drug concentration. The system also controls the arterial blood pressure in case of disturbance like bleeding. Computers detected acute response changes and prevents risks by referring to the history of patients’ responses. In future, more research based on this paper can be done to make design modifications in the system to achieve quick searching in computer for optimal inputs keeping in consideration the sensitivity of patient. Also, system can be designed for achieving multiple drug injection. Design of control system for the determination of drug dosage for patients with hypothyroidism is presented in paper [9]. The design is based on two multilayer Perceptron neural networks.

Authors in [10] present the investigation of a drug delivery system for blood pressure monitoring and regulation using multilayer Perceptron. The paper is based on Proportional Integrator Derivative-Neural Network controller to regulate the mean arterial pressure by infusing Sodium Nitroprusside. The authors have presented a linear and discrete time model of mean arterial pressure of a patient after taking drug. Future research work can be done in making system more intelligent by taking all the physical and emotional conditions of the patient for decision making that lead to the increase in mean arterial pressure. Non-linear discrete time model can also be designed for the system. Similarly, target control infusion, based on proportional integral derivative controller is achieved in paper [11].

Adaptive control scheme for post-surgical blood pressure regulation is proposed in [12]. The adaptive modeling and control scheme is based on generalized fuzzy neural network. Automation of drug delivery has been done by infusing drug for regulation of mean arterial pressure. The non-linearity of system is modeled by generalized fuzzy neural network technique. The future study is required to investigate robustness of proposed fuzzy-neural network control strategy.

Proportional Integrator controller is proposed for monitoring and regulating arterial blood pressure for a long time in [14]. It is based on a single input single output controller to produce a set of controlling parameters for regulating physiological conditions. Based on the present study, control system with multiple inputs multiple outputs can be designed and tested for establishing patients' safety. An adaptive Proportional Integrator controller is proposed in [15] with an algorithm for estimating time delay for blood pressure regulation in hypertension patients.

3.2. Drug Delivery Mechanisms

A system on chip with integrated drug reservoirs and active circuit for drug release is presented in [15]. The microbubbles generated by electrolysis force to open drug reservoirs in order to release the drug. The present study has not considered the need to avoid the mixing of drug and water during electrolysis process. Moreover, no strategy has been discussed for reducing the continuous power supply.

The work in [16], discusses the design of swimming micro robot that is injected inside the human body for controlled drug delivery. The system can be investigated for patients' safety. The architecture of a Touch communication model based on Transient Microbot for targeted drug delivery is proposed in [17]. Various parameters associated with Transient Microbot like delay, angle of arrival, path loss, delay spectrum are investigated for information exchange.

The modeling of drug delivery as nano communication paradigm based on Transient Microbot system is discussed in [18]. It also presents the simulation tools for describing the transient characteristics of microbots with transmitting and receiving processes as well. A case study is presented for breast cancer treatment to elaborate nano communication model based on Transient Microbot System. The present study has not considered the effect of Microbots on the immune system of the patient as it is a foreign concept for the human body.

In [19], the modeling of drug delivery system as a molecular communication paradigm where drug particles are information carriers that are transported from injection site to the drug release site is presented. The cardio-vascular network and the blood velocity profile are modeled as communication channel. Based on the present research work in this paper, in future research can be done in the area for investigating the safety issues of molecular communication for human beings. Moreover, optimization can be done for achieving highly targeted drug delivery.

The paper [20], proposes anti-cancer drug delivery across the physiological barriers by ultrasound cavitation. The paper presents the achievement of complete regression of tumor cells based on ultrasound enhanced drug delivery. The future work based on this paper can be done in the area to explore the parameters deciding the extent of opening blood brain barrier depending on drug molecule. Moreover, the effects of ultrasound radiations on healthy tissues need to be considered to ensure safety.

The work in [21] is based on focused ultrasound technique for drug delivery through blood brain barrier. The paper investigated delivery of drug through the ultrasound induced blood brain barriers in mice. Authors in [22] proposed a mathematical framework for achieving optimal infusion of drug to the brain. The paper introduces methodology for predicting optimal treatment volumes and penetration range of drugs in central nervous system.

In [23] the design of an implantable micro pump for drug delivery is presented. The simulation and mechanical analysis of proposed micro pump is done. The micro pump dimensions have been determined for the purpose of fabrication and reducing the cost of fabrication. Further optimization in the design parameters can be done. Electrostatic mechanism is used in [24] for designing and simulating micro machined pump.

4. Advantages of an Implantable Drug Delivery System

IDDS modulates the drug infusion safely and precisely minimizing the disruptions for treatment and diagnostics, while simultaneously optimizing drug delivery [4]. As analyzed from the survey, IDDS enhances the efficacy of the system with respect to dosage concentration, also the drug concentration is administered at desirable rate and there is reduced need for follow up care [5,8]. IDDS will prove beneficial for conditions such as brain tumors, chronic pain syndrome, infectious diseases, and cardiac disorders [6]. These unique advantages of Targeted delivery, controlled and sustained drug release rate, minimal monitoring, adaptive with patients' response, better patient compliance, shorter hospitalizations, enhanced drug efficacy, reduced toxicity, less side effects, lower healthcare costs [25], compactness and controllability allow the development of IDDS to become reality [7].

5. Current Research Projects on IDDS

The recently, IDDS has gained a lot of research interest from various disciplines. A list of some research projects on IDDS currently being carried out for different applications is given in table 1.

6. Design Challenges of an IDDS

Several challenges that are faced while designing an IDDS are effective drug deliver strategy, operating time [26-27], drug reservoir size and loading volume [28], biocompatibility [29], location of implant [30] Drug concentration decision making based on the physiological needs of a patient and temporary or permanent mental and physical states of patient is difficult to achieve as human body is very complex and non-linearity in responses is also high. Risks include designing malfunctions that can cause over or under infusion of drug. Moreover, another important issue is drug reservoir size as it is impractical to increase the device size to accommodate a large reservoir. Device needs to be as small as possible so as not to cause any side effects to other tissues surrounding the implant [28]. Refillable drug reservoirs need to be designed keeping in consideration sensitivity of the patient as refilling procedure may hurt sensitive parts of body [31]. IDDS needs to be long time operable for the treatment of chronic disorders to provide constant pulsatile drug delivery profile. Miniaturization of actuator design needs to be done that will allow larger drug reservoir without increasing volume of the device [6,32]. Another most important challenge to overcome is biocompatibility with the human body. Immune system should respond well to the implant and also stability of system needs to be ensured at implant site. Risks such as inflammation, allergies, mechanical instability needs to be overcome in such a manner that it does not make whole design complex [33]. Drug delivery pumps needs to be engineered to allow injection of drug at targeted site without interruption or failure keeping in consideration sensitivity of the patient.

Table 1. Current Research Projects on Implantable Drug Delivery Systems

Project Name	Research Area
SLAP-HIV [34]	Development and testing of an implantable drug delivery system for protection of high-risk individuals from HIV infection for up to a year at a time. The project is funded by the NIH's National Institute of Allergy and Infectious Diseases (NIAID).
IMPACT [35]	Developing new approaches for the treatment of cancer using implanted smart sensors on silicon, fabricated in the University's Scottish Microelectronics Centre. The project is funded by an EPSRC Program Grant.
Implantable Micro Drug Delivery System [36]	To develop an implantable drug delivery device which can be controlled remotely and can provide the drug on-demand for several years without replacement. The project is funded by KAUST.
LOC4BIO [37]	Development of a new generation of Lab-on-Chip devices, integrating various micro fabricated components. The project is funded by EU.
Nano-Channel Delivery System (nDS) [38]	Development of an implantable device for delivering therapeutic drugs at a rate directed by remote control. The project is funded by The Center for the Advancement of Science in Space (CASIS) at Florida's Kennedy Space Center.
Min-ePump [39]	Developing an implantable, wirelessly controlled, rapid dosing drug delivery system for small animal research. The project is funded by National Institutes of Health.
NANOHEDONISM [40]	Development of a Photo-triggered On-demand basis Drug Delivery System for Chronic Pain. The project is funded by ERC.
Drug Delivery Device for AMD [41]	Development of a Drug Delivery Micro-device for Age-related Macular Degeneration. It has been awarded by NSF EAGER grant.
BRIDGE [42]	Developing an implantable drug-delivery device for ovarian cancer to be implanted in the peritoneal cavity to release chemotherapy drugs over a long period of time. The project is funded by MIT and DF/HCC.

7. Future Scope

Great focus is on designing micro devices and nano devices for disease treatment like wirelessly controlled micro robots that can penetrate deep in the body and serve as drug vectors. For providing multiple drugs for a particular application, designs that can easily provide precise drug dosages from one or more than one reservoir without complex pumping and flow mechanism are required. System can be designed for dispensing drugs from different reservoirs according to required drug flow rates, allowing for variable dosing to meet particular circumstances like time of day, physical activity level, mental state. Many of the new drugs that are continuously being developed are formulated from proteins and peptides that are difficult to administer when taken orally. New forms of sustained release drug delivery designs will make it possible to deliver such drugs at constant rate over a long period of time. It is hoped that development of efficient and new IDDS will reduce drug therapy cost with increased patient compliance [33].

Moreover, IDDS benefits go beyond patient convenience and quality of life. The current urgent need is to develop system designs for targeted therapy of chronic disorders. Increasing complicated system requirements can be met with efficient engineered solutions that can enhance the accuracy and versatility of devices, while simultaneously reducing risks. In the future, wide range of application areas will make IDDS an integral part of health care development. However, realization of IDDS needs to overcome the challenges as discussed in this paper.

8. Conclusion

An intelligent control design with an efficient drug delivery mechanism essentially constitutes an implantable drug delivery system. IDDS provides controlled, sustained and individualized drug delivery profile which is an attractive approach to most of the medical conditions. The controlled release, site specific delivery, reduced toxicity, reduced side effects, increased convenience, better patient compliance, shorter hospitalizations are the characteristics of IDDS that may create many new and exciting application areas for healthcare.

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