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Review Article

Biocompatibility Concerns and An Innovations in Implantable Medical Devices

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ABSTRACT

Implantable medical devices have been used for biological science research, medical diagnosis and prognosis, therapeutic uses, and the assessment of in vivo physiological data in humans and animal models. Novel biomaterials combined with micro/nanotechnology advancements have significantly improved biocompatibility, sensitivity, longevity, and dependability in recently developed low-cost, small devices. In order to offer point-of-care and personalized medication, close-loop systems with sensing and treatment capabilities have also been developed. However, whether power can be continually and adequately supplied for the system's overall operation remains one of the issues. Due to the growing demand for electricity for wireless, this problem is becoming more and more important. connectivity between implanted devices and mobile health (m-Health), the future healthcare infrastructure. In order to highlight the use and significance of several possible power sources, this review paper introduces and discusses energy transfer and harvesting techniques in implantable medical devices. This review delves into the intricate realm of biocompatibility testing, covering chemical, mechanical, and biological characterization as well as other aspects of biocompatibility, including definitions, illustrative examples, and real-world contexts.

INTRODUCTION

A medical device is defined as *implantable* if it is either partly or totally introduced, surgically or medically, into the human body and is intended to remain there after the procedure. Jiang and Zhou have described that 8% to 10% of the population in America and 5% to 6% of people in industrialized countries have experienced an implantable medical device for rebuilding body functions, achieving a better quality of life, or expanding longevity.[4] The term “biocompatibility” is formed from two roots: life and compatibility. Biocompatibility relates to how living hosts interact with their environment. Life is living, while harmony is a functioning balance.

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Biocompatibility is establishing an environment or product compatible with humans.[1] The definition above also refers to “a specific application”, which means that biocompatibility is contextual. For example, a biomaterial may be biocompatible in bone but not in blood and vice versa, or it may be biocompatible for short-time use in a specific tissue, but not in a long-term application in the same tissue.[2] In latest scenario Ultrasonic device shave attracted growing interest in recent years due to their comparative efficiency, compactness and immunity to electromagnetic radiation. Nonetheless, inductive power transmission across the body tissue is currently the only viable solution to deliver sufficient power to various kinds of IMDs with miniaturized

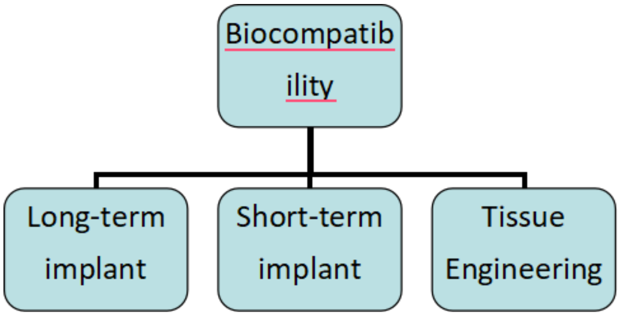

Figure 2: Evolutionary steps in heart valve implant technology.

HISTORY

Although the field of medical implants has been around for many centuries, it has developed over the last six to eight decades thanks in large part to advancements in metallurgy and materials science, electronics and instrumentation, and knowledge of the biochemical and immunological interactions of materials with the human body. Despite being less than a century old, medical implant technology has advanced significantly, helping millions of people by easing their suffering and improving their quality of life [5]. Implantable medical systems or devices have advanced during the last 60 years thanks to advancements in science and engineering, particularly in the fields of microelectronics, biotechnology, and materials. Medical professionals have made commendable efforts to enhance patients' quality of life with a variety of medical devices, including the implantable cardiac defibrillator, cochlear implant, implanted bladder stimulator, and implantable wireless pressure sensor, from Zoll's first report on electrical heart stimulation in 1952 to the first commercialized wireless blood pressure measurement system introduced by Cardiomems in 2010. These implanted medical devices were created to either activate physiological organs or detect a physiological response in vivo.[4]

WORK RATIONALITY

Through surgery or other medical procedures, implantable medical devices are inserted into the human body. Artificial joints, breast implants, cochlear implants, intraocular lenses, pacemakers, and other cardiac implants or prostheses are some of the most widely used devices.

AIM

The main goal of implanted medical devices is to support or restore normal bodily processes by being temporarily or permanently inserted into the human body to diagnose, monitor, or treat medical disorders. [6]

Objectives

1. Replace or restore lost physiological functions, such as cochlear implants, artificial joints, or heart valves.[7]
2. Offer long-term therapeutic effects, such as regulating body processes (such as insulin pumps for diabetes) or managing heart rhythm (such as pacemakers and implanted cardioverter defibrillators) [8]
3. Constantly track physiological factors, such as implanted blood pressure monitors or neurostimulators, and provide real-time data for diagnosis or continuous treatment.[8]

4. Reduce the everyday burden of managing chronic diseases by sustaining organ function or automatically administering medication to improve patient adherence to treatment regimens.[7]
5. Treat complicated or difficult-to-treat medical diseases that are not amenable to external devices or medications, frequently supporting minimally invasive or individualized medical practices.[6]

6. Use biocompatible materials and minimally invasive techniques to implant the device to reduce discomfort, infection risk, and the need for repeated surgeries.[8]
7. Implantable Medical Device Goals Among the main goals are:restoring lost or compromised function (e.g., neurostimulators, cardiac pacemakers) [6]

8. Constant, dependable physiological monitoring or therapeutic administration (e.g., insulin pumps, implanted sensors) [7]
9. Improving patient outcomes by encouraging long-term therapy adherence, being simple to use, and being minimally invasive [5]

WORK PLAN

Neuro-electronic interface and nano-bio-robotics are made possible by the amazing advancements in integration density and dynamic power dissipation that can result from the design and manufacture of implanted circuits using nanoscale and molecular-scale technologies.[10,11] There are still issues with current biomedical nanotechnologies, including poorer dependability, comparatively high standby power consumption, and electron leakage because of inadequate insulating.[11]

Aggressive cleaning techniques applied to the devices before implantation may further weaken the organic layers and adhesives, and the trend toward compact, light, and flexible electronics may compromise the mechanical robustness of the implant.[12]

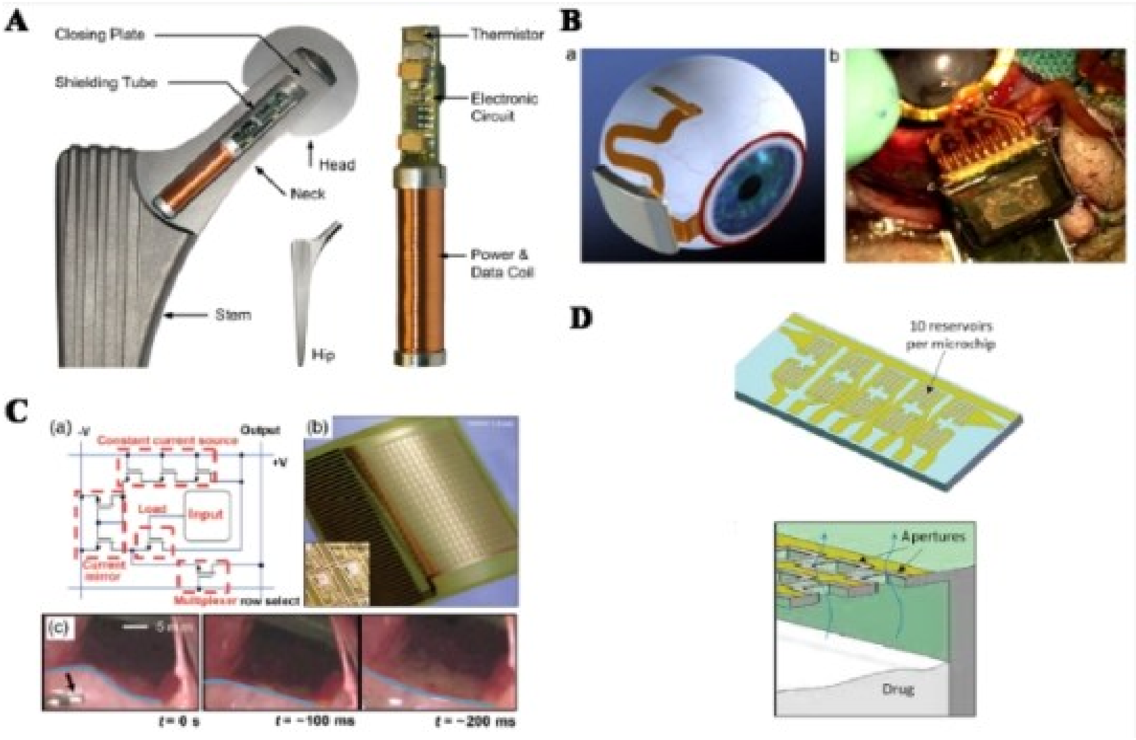

Fig :- (A) Cross-section of a model of the modified hip implant with a metal head. The temperature telemetry with thermistor, electronic circuit and power/data coil are placed inside the neck of the implant.[13] Fig :- (B) Retinal prosthesis.[13] Fig :-(C) An active, flexible device for cardiac electrophysiological mapping.[14] Fig :-(D) The implantable microchip-based human parathyroid hormone drug delivery.

The power transfer efficiency has been shown to depend on the distance over which the magnetic field is transmitted, i.e., the distance between the internal and external coils, the device geometry, and the diameter of the coils [19]. The chosen transmission frequency is dependent upon the properties of the living tissues that separate the indwelling module from the external component; specifically, the frequency-dependent attenuation caused by Foucault currents generated within the host tissues varies according to the type of tissue [20]. The voltage is then rectified and smoothed to fit the indwelling electronic circuitry.

There have also been reports of less traditional energy harvesting techniques that use the energy generated by the physiological environment or natural body motion for internal charge; a few examples are shown in Fig.

Table 1. Dielectric properties of tissues [1].

Tissue Type	**Relative Permittivity ε_r ($\times 10^3$)**	**Conductivity**
Bone	0.28	0.0144
Liver	9.8–14	0.15–0.16
Spleen	3.3	0.62
Blood	2.7–4.0	0.55–0.68
Kidney	10.9–12.5	0.24–0.25

Retina	4.75	0.52
Bone (cancellous)	0.47	0.09
Bone (cortical)	0.23	0.02
Bone (marrow)	0.11	0.003
Cartilage	2.57	0.18
Skeletal muscle	14.4–27.3	0.38–0.65
Fat	0.09	0.02
Cerebrospinal fluid	0.1	2
Brain (grey matter)	3.8	0.17
Brain (white matter)	1.9–3.4	

based on computational research. This suggests that low-power brain-machine interfaces could be powered by this energy source. It was demonstrated that glucose biofuel cells with laccase and glucose oxidase mechanically integrated into a conductive pure carbon nanotube matrix could reach a greater power density of up to 1.3 mW cm−2 and an open circuit voltage of 0.95 V [23].

Under physiological settings of pH 7 and 5 × 10−3 mol−1 glucose, the devices maintained stability for a month while delivering 1 mW cm−2 power density. By providing an open circuit voltage of 1.8 V with a maximum, two of these cells connected in series showed the ability to power implanted biomedical devices that typically require at least an operational voltage of 0.5–0.6 V. and maximum power of 3.25Mw The power consumption of a cytochrome P450-based molecular biosensor for drug sensing with temperature and pH monitoring was reported to be 48 μW, of which 32 μW were required for molecular detection, 2.5 μW for pH measurement, and 1.4 μW for temperature sensor control under 12 μW for multiplexing and measurement reading [24].

Enzymatic biofuel cells function far poorer in vivo, despite promising results from in vitro studies. For instance, an intravenous implanted glucose/dioxygen hybrid enzyme-Pt micro-biofuel cell showed excellent electrocatalytic performance in vitro (at 4.7 × 10−3 mol−1glucose, pH 7.2) with a maximum output power of 0.2 mW cm−2 at 0.25V and an open circuit voltage of 0.4 V [25].

The modulations listed above make up about 10% of the carrier frequency. The modulation method selected will also depend on the data transfer requirements of the implant; implants with modest data rate requirements will utilize lower frequencies, while those requiring continuous, high volume data transmission will use higher frequencies. The choice of modulation technique will also be influenced by the system's constraints, such as power or bandwidth availability. Modulations can enhance the quality of the signal when applied correctly. increase the capacity of communication channels, improve signal quality, enable accurate data transfer despite noise and other interference, and strengthen patient-related data security. The three forms of communication channels are additive white Gaussian noise (AWGN), fading, and band-limited [27].

A micrograph of one prototype shows the metal layers of the anode (central electrode) and cathode contact (outer ring) patterned on a silicon wafer, along with a likely location for implantation within the subarachnoid space, demonstrating the ability of an implantable glucose fuel cell to extract power from cerebrospinal fluid [21]. (B) A photovoltaic-powered, energy-autonomous CMOS implanted sensor [28]

An anatomically sized chip that harnesses the energy of the electrochemical potential in the guinea pig's cochlea powers a wireless transmitter: (a) a potential site for implantation in the mammalian ear; (b) a cross-section of a typical cochlear half-turn showing the endolymphatic space (yellow) encircled by tight junctions (red), the stria vascularis (green), and hair cells (blue), which are in contact with primary auditory neurons (orange) [29]

A VIEW OF THE FUTURE

Diagnostic electronics, such as endoscopic capsules, only stay in the patient's body for a brief period of time, and the doctor at the clinic usually keeps an eye on the patient throughout the process. Implantable electronics systems that are meant to stay in the patient's body for years, such as implantable cardiovascular devices, are reviewed periodically, with follow-up appointments interspersed with long stretches of time during which the doctor is not informed about the patient's health or the implantable system's performance. Additionally, the indwelling device's working parameters don't change between follow-up appointments, which might not accurately represent the patient's needs and clinical condition.

However, there are numerous plans to produce intelligent cardiac implanted sensors inthefuture. A novel class of cardiovascular implant medical devices (IMD) with the ability to detect artery occlusion, flow, and pressure is gaining popularity. Wireless hemodynamic data collection with remote home monitoring may allow for early intervention, illness prevention, reduced medical expenses, and improved patient quality of life. A interdisciplinary strategy that integrates engineering studies with cardiovascular research has enhanced the development of implantable biosensors for cardiovascular diseases. Implantable biosensors' real-time monitoring capabilities may allow for point-of-care diagnosis and early intervention for more specialized medical care.

Smartstents and grafts will transform healthcare procedures because to their remote diagnostic and therapeutic capabilities. One sensing technique is to measure the increase in critical electrical properties caused by cellular material buildup within an IMD. The employment of specifically designed sensors with integrated telemetry circuit technology enables this decentralized approach to healthcare. For example, Bussooa et al. have shown that by producing a controlled electromediated form of cell death, biosensors can be used as both therapeutic and diagnostic instruments. Stereolithography (SLA) is one of the several high-resolution 3D printing techniques that have been developed. These printing processes have enabled the creation of biocompatible, flexible, and tiny conductive nanomaterials in complicated shapes. Jordan et al. (2020), for instance, employed aerosol jet deposition to produce

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Summary

The development, operation, and prospects for the future of implanted medical devices (IMDs)—instruments intended to diagnose, track, and treat a variety of medical diseases from within the human body—are covered in this review paper. It emphasizes how biomaterials and micro/nanotechnology have been combined to create more compact, effective, and biocompatible devices that can be used for both sensing and treatment.

The article highlights the ongoing advancements in biocompatibility, materials science, and power management systems while tracing the development of IMDs from early cardiac pacemakers to sophisticated wireless biosensors. Energy transfer and harvesting techniques, like inductive coupling, ultrasonic transmission, and biofuel cells that use human motion or glucose to produce electricity, are given a lot of attention.

Studies on energy management strategies, wireless communication, and device packaging are included in the literature review, which also highlights developments in mechanical and electrical performance as well as biocompatibility testing. The paper also covers the use of modulation techniques in secure data transfer, as well as wireless telemetry for communication and recharging.

Smart, biocompatible, and miniature implants with remote communication and real-time monitoring capabilities are emerging trends. Intelligent cardiovascular implants, 3D-printed biosensors, and drug delivery systems powered by nanotechnology are examples of future directions that aim to provide effective and individualized healthcare.

To sum up, implantable medical devices have revolutionized modern medicine by improving patient outcomes through targeted therapy, ongoing monitoring, and integration with digital and mobile health technologies.

CONCLUSION

Modern healthcare has been transformed by implantable medical devices, which provide patients better quality of life, focused therapy, and ongoing monitoring. These devices are now safer, more effective, and have a longer lifespan thanks to the integration of wireless communication systems, sophisticated biomaterials, and micro/nanotechnology. Despite significant advancements, issues including long-term biocompatibility, dependable power supply, and miniaturization are still being investigated. These constraints are anticipated to be solved by upcoming developments in nanotechnology, 3D printing, and bioenergy harvesting, resulting in the next generation of intelligent, self-powered, and patient-specific implanted systems. In the end, these developments will open the door to more individualized, effective, and long-lasting healthcare solutions.

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