Advanced Implantable Devices and Data Analysis Techniques for Peripheral Nerve Injury Treatment: Challenges and Innovations

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Abstract. Peripheral nerve injuries (PNIs) present significant clinical challenges, affecting communication between the central nervous system and peripheral organs, thereby impacting patients' quality of life. These injuries, often due to traumas like crushing, compression, and penetrating wounds, lead to chronic disabilities and substantial healthcare costs. Timely intervention and personalized therapeutic approaches are essential to restore neural functionality. Traditional treatments, despite their availability, have limitations such as side effects and variable outcomes. Recent research has focused on developing advanced, often implantable, devices to provide more effective and less invasive solutions. However, integrating these technologies into clinical practice is complex, involving challenges related to biocompatibility, hermeticity, power management, and data security. This article examines the intricacies of implanted device technology, highlighting the need for advanced data analysis techniques to enhance their efficacy. It explores signal analysis methods for classification, including preprocessing, data augmentation, and machine learning strategies. The article also reviews power strategies for implantable devices, such as batteries, energy harvesting, and radio frequency, alongside other methods like inductive, capacitive, and magnetic resonance coupling, which are also used for wireless communication. Additionally, the evolution of integrated circuits and coating materials is discussed, emphasizing their role in improving device performance and longevity. This comprehensive review aims to provide a guide for overcoming the current challenges in PNI treatment through technological innovation.

Keywords: Data transmission, ENG data analysis, Implantable device, Wireless Powering.

1 Introduction

Peripheral nerve injuries (PNIs) are complex clinical challenges that significantly impact neural communication and quality of life, often caused by traumas like crushing, compression, and penetrating wounds. These injuries lead to chronic disabilities and high healthcare costs. When a peripheral nerve axon is damaged, Wallerian degeneration occurs, disrupting neural communication and exacerbating dysfunction. Mechanical injury can cause a wide array of neuropathies, such as axonal fragmentation and compression neuropathy. The former disrupts the continuity of nerve fibers [1] and impairs the transport of essential molecules and signals. In the latter case, prolonged compression results in reduced blood flow and ischemic neuropathy [2], in which insufficient oxygen supply causes demyelination (loss of the protective myelin sheath) and axonal degeneration. Nerve compression may also trigger an inflammatory response [2], leading to demyelination and axonal damage. Timely intervention is crucial, but the severity of injuries requires personalized treatment. Traditional treatments, including drugs, physiotherapy, electrical stimulation, and surgery, have limitations such as side effects and variable outcomes. Recent research focuses on advanced, often implantable, devices for more effective and less invasive treatment [3]. However, integrating these devices into clinical practice faces challenges like biocompatibility, structural design, power management, wireless communication, data security, and regulatory compliance [4].

Paper organization: The following sections focus on the problems, the novel methods and technologies used to implement implanted devices for peripheral nerve injury treatment. Section II focuses on data handling and classification tchniques, section III on powering and data communication, section IV on chip design.

2 Signal analysis for classification

A potential solution to these injuries is to create a digital bypass over the damaged section of the nerve [5, 6]. Signals passing through the nerve would be recorded before the damaged area, then classified to reproduce the correct stimuli after the damaged section. In this framing of the problem correctly classifying the different signals is of paramount importance. To extract the characteristics of the Electroneurography (ENG) signal, multiple analysis steps are needed. Through preprocessing, data balancing and data augmentation we obtain a complete dataset that can be used to train a machine learning (ML) or deep learning (DL) model of choice (Figure 1) [5, 6, 7]. Important aspects to take into consideration when creating a model are temporal constraints if targeted to a real time application and computational constraints when dealing with embedded devices [6].

2.1 Preprocessing

Preprocessing is essential to extract the relevant features for classification. Usually, a band-pass filter is used to attenuate noise below 800 Hz, originating from muscles, and above 2500 Hz, to minimize other sources of noise [5, 6, 7, 8]. This band pass improves the signal-to-noise ratio (SNR) given that most ENG signal power has been observed to be in the range between 1000 and 2500 Hz [5]. The Discrete Wavelet Transform (DWT) [9] can be employed for further noise reduction. This method decomposes a signal into various frequency components and achieves both time and frequency localization in a concise representation, thereby reducing noise [9]. Signals may also be compressed and reconstructed using Autoencoders, this process diminishes noise by retaining only the vital features of the signal [10]. Compared to the Wavelet approach, in a synthetic environment, autoencoders have demonstrated a noise removal efficiency with a 4 dB improvement in SNR [10]. To enhance the signal quality, feature extraction algorithms such as the Running Observation Window (ROW) [11] or Velocity Selective Recording (VSR) [12] can be implemented. Finally, down-sampling up to 5 kHz can be applied to reduce data dimensionality without altering the classification outcomes, as evidenced in [5, 6]. Given the complexity of the task and the limited size of Electroneurographic (ENG) signal datasets, which may include imbalance among different stimuli, data augmentation techniques like noise addition, overlapping windows, and Generative Adversarial Networks (GANs) [13, 14] can be used. To address class imbalance, methods such as random oversampling or random undersampling [14,15] are employed.

2.2 Machine learning classifiers

In the realm of machine learning, classifiers such as Random Forest (RF) [16], Linear Discriminant Analysis (LDA) [7], and Support Vector Machines (SVM) [17] are frequently used for ENG signal classification. While these models provide interpretability, they might lack the complexity needed to capture detailed patterns. RF, which constructs multiple decision trees and integrates their predictions, has achieved up to 85% accuracy in classifying vagal nerve signals in pigs across six test subjects under four different stimuli using 500 ms windows for classification, as reported in [16]. LDA classifies signals by maximizing the separation between classes in a feature

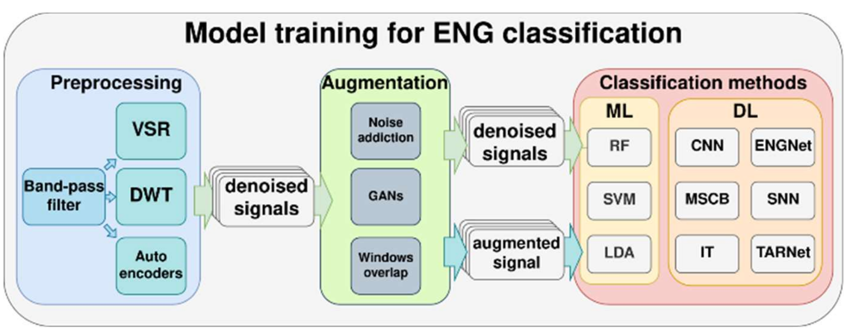

Fig. 1. A simplified pipeline to obtain a classifier model. The data undergoes preprocessing and augmentation before being used to train and test classifiers.

space derived from a linear combination of inputs and has been used to classify ENG signals under ten different stimuli (such as proprioception, nociception, and touch) with accuracies ranging from 40% to 70% using 500 ms windows [7]. SVM, which categorizes elements by identifying separating hyperplanes in an enhanced feature space, were used to classify ENG signals from rats under three different stimuli, achieving an average accuracy of 75% to 84% [17].

2.3 Deep learning classifiers

Deep learning models, including Convolutional Neural Networks (CNNs) [5], Multi-Scale Convolution Block (MSCB) [18], InceptionTime (IT) [6, 18], Transformers (TARNet) [18], Electroneurographic Network (ENGNet) [6], and Spiking Neural Network (SNN) [5], offer a more profound level of classification compared to traditional machine learning methods. Nonetheless these models may encounter challenges due to limited data and computational constraints [14]. For instance, a similar implementation of a CNN achieved accuracy rates between 80.2% and 86.4% on a ten-class classification task involving rat ENG signals [17]. MSCB [18], a variation of CNN that uses multiple kernel sizes for convolution, captures a wide range of information from the input signal, acting as diverse filters SNN (Figure 2). It achieved 93.6% accuracy in classifying three classes of signal using 50 ms windows. IT [6, 18] consists of multiple blocks, each featuring a convolutional reduction layer, a convolutional layer with various-sized kernels, and a max pooling layer, achieving accuracies from 78.5% to 98.1% for four-class classification using 100 ms windows [6] (dataset presented in [17]). ENGNet [6], which comprises three main blocks — temporal convolution for selecting temporal information, spatial convolution for channel selection, and a combination of features to resolve classification problems—

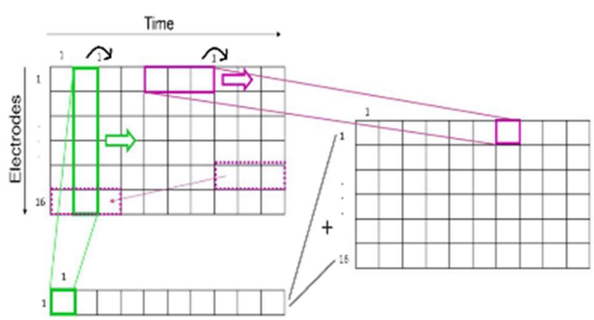

Fig. 2. Scheme of the convolutional approach from [5]. The signal is represented by a matrix, where each row corresponds to the signal coming from a different recording channel. Then one-dimensional convolutions are applied either on the temporal or on the spatial axis.

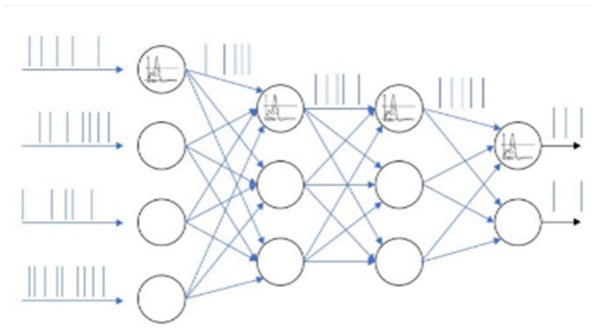

Fig. 3. A schematic representation of a SNN [5]: Information is transmitted through spike trains, represented as binary sequences. Each neuron is modeled with an internal state variable, such as the membrane potential, which is updated at every time step based on the spatiotemporal summation of incoming signals.

Table. 1. Comparison of Machine Learning Methods.

	Machine Learning Algorithm		
Method	***RF***	***SVM***	***LDA***
Accuracy	●○○	●●○	●○○
Interpretability	●○○	●○○	●●○
Speed	●●○	●●○	●●●

has demonstrated accuracies between 82.5% and 96.5% using 100 ms windows with the same dataset as IT. SNN (Figure 3), as presented in [5] is a third-generation network model that employs an activation function designed to mimic human neural activity, has reached accuracies from 80.2% to 86.4%. TARNet [18], a classifier based on an attention mechanism that selectively weights and integrates information from different parts of the input sequence, achieved a 72.1% accuracy over three classes using 50 ms signal windows [18]. Currently most of the deep learning networks are convolutional and between them ENGNet has proven to be one of the most effective neural network models for classifying ENG signals. A summary of the Neural Network performance is presented in Table 1 and Table 2.

Table. 2. Comparison of Deep Learning Methods.

Method	Deep Learning Architectures		
	Convolutional (CNN, MSCB, ENGNet, IT)	***Trasformer Based (TARNet)***	***Spiking Neural Networks (SNN)***
Accuracy	●●●	●●○	●○○
Interpretability	●○○	○○○	●○○
Speed	●○○	●○○	●○○

3 Powering and data communication

Powering and communication are two key aspects of Implantable Medical Devices (IMDs). These devices rely on efficient power sources and reliable data transfer methods to ensure proper functionality and patient safety. For wireless communication, as reported in [19], the Bluetooth Low Energy (BLE) 5 protocol is used to optimize wireless communication in implantable medical devices, due to its low power consumption and compatibility with compact devices. BLE 5 operates in the 2.4 GHz Industrial, Scientific and Medical band with dynamic channel allocation to minimize interference, achieving a theoretical throughput of 1.366 Mbps, sufficient for real-time data transmission. Tests confirm stable communication up to 50 cm and in the presence of biological tissues, with an increased packet error rate in higher Body Mass Index scenarios. Regarding powering, there are various methods that allow to transfer power to the IMDs, including batteries, energy harvesting and radio frequency. At the end of the section, Table 3 is presented, where a summary of the discussion is provided.

3.1 Batteries

The development of batteries for implantable biomedical devices focuses on enhancing performance, safety, and longevity, with advancements in lithium-based, lithium-polymer, and solid-state batteries offering high energy density and improved biocompatibility. Challenges such as potential leakage, biocompatible packaging, and manufacturing costs persist, particularly for devices with high power demands like Implantable Cardioverter-Defibrillators, which use lithium-manganese dioxide and lithium-silver vanadium oxide batteries [20, 21]. Improving battery life is essential to reduce the need for frequent surgical replacements and associated risks, benefiting both patients and healthcare systems [22].

3.2 Energy harvesting

Energy harvesting for IMDs utilizes human motion, thermal gradients, infrared radiation, and solar energy to generate power. Techniques include piezoelectric materials, electrostatic and magnetic induction generators for kinetic energy, thermoelectric generators for thermal energy, and photodiode arrays for infrared radiation. These methods aim to reduce the need for battery replacements and improve device longevity [23, 24].

3.3 Radio frequency

Radio Frequency (RF) Power Transfer utilizes electromagnetic waves to transmit energy from an external transmitter to an implanted receiver. It's suitable for longer distances, ideal for low-power devices needing continuous operation. However, careful control is necessary to prevent tissue damage and ensure compliance with regulatory standards [25]. Other methods valid both for the powering and the communication aspects include inductive coupling, capacitive coupling, magnetic resonance coupling and ultrasound (Figure 4).

3.4 Inductive Coupling

Inductive Power Transfer (IPT) is a near-field wireless power transfer (WPT) technique that utilizes magnetic induction to transfer electrical energy between two coils. The IPT system operates by applying an alternating current to the primary coil in the energy transmitter, which generates a varying magnetic field. This magnetic field induces a current in the secondary coil, which can then be used for charging a wireless device or storage system. This system relies on mutual inductance, where one coil is placed outside the body and the other is integrated into the implanted device.

The mutual inductance M between the coils can be computed using the formula:

$$M = k\sqrt{L_1 L_2} \tag{1}$$

where k is the coupling coefficient, L1 and L2 are the inductances of the primary and secondary coils, respectively. Inductive coupling has several advantages, including a simple topology, ease of implementation, and high-power transfer efficiency over short distances. It is widely used in powering devices such as cochlear implants, neurostimulators and cardiac pacemakers [26]. However, IPT also has limitations. It requires precise alignment between the coils, and its efficiency decreases with increasing distance, making it unsuitable for portable applications. In addition to powering, inductive coupling is also utilized in telecommunication systems for implanted devices. It features a typical throughput ranging from several hundred kilobits per second (kbps) to 1 Megabit per second (Mbps) [27], making it suitable for both short and long-term applications [26].

3.5 Capacitive coupling

Capacitive coupling is an efficient technique for data and power transfer in short-range wireless communications for implanted devices. This methodology relies on two parallel plates acting as capacitors: one attached to the skin and the other implanted and connected to the device. The skin acts as a dielectric separator, facilitating the coupling.

Energy transmission occurs via displacement current Id, described by the equation:

$$I_d = \varepsilon_r \cdot \varepsilon_0 \cdot \frac{dE}{dt} \cdot A \tag{2}$$

where E is the electric field intensity, A is the area of the plate, ε_r and ε_0 are the relative permittivity and free space permittivity respectively, t denotes time. To optimize efficiency, the displacement current must be increased by reducing the distance between the plates and increasing the excitation voltage. Capacitive coupling is advantageous due to its low cost and minimal parasitic current loss. It is used to power implanted microstimulators, deep brain stimulators, and neurostimulation devices. The throughput ranges from 100 kbps to 1 Mbps [28, 29]. However, it has some limitations, such as the increase in tissue temperature around the plates and the absorption of the electric field by the tissues [29]. Despite these limitations, capacitive coupling can be effectively used in retinal implants to transfer power and data to microelectrodes on the retina, helping restore vision [30].

3.6 Magnetic resonance coupling

Magnetic Resonance Coupling (MRC) is an advanced technique used for both wireless power transfer and telecommunication in implantable biomedical devices. This method employs strong coupling between resonant coils, operating at the same resonant frequency, to efficiently transfer power wirelessly [31].

The fundamental frequency for these systems can be determined using the formula:

$$\omega = \frac{1}{\sqrt{C_1 L_1}} = \frac{1}{\sqrt{C_2 L_2}} \tag{3}$$

where L1 and L2 are the inductances, and C1 and C2 are the capacitances of the primary and secondary coils, respectively. To optimize power transmission and minimize losses due to weak coupling, the inductance of the coils should be adjusted by adding parallel or series capacitances. This ensures that the resonant frequency of the coils matches, thereby maintaining strong coupling. One of the key advantages of MRC is its immunity to environmental factors, allowing it to transfer energy through free space with minimal efficiency loss. This makes it suitable for devices like ventricular assist devices [32] and other long-term implants [33], where consistent and reliable power transfer is essential. The strong coupling achieved by resonant coils can extend transmission distances to meters [34], making it a robust solution for various biomedical applications. In addition to powering, MRC is also used for telecommunication in implantable devices. It leverages the same principles of resonant coupling to achieve high data transfer rates. The throughput of MRC systems is typically well above 1 Mbps [35], which is adequate for most biomedical applications requiring high-speed data transmission.

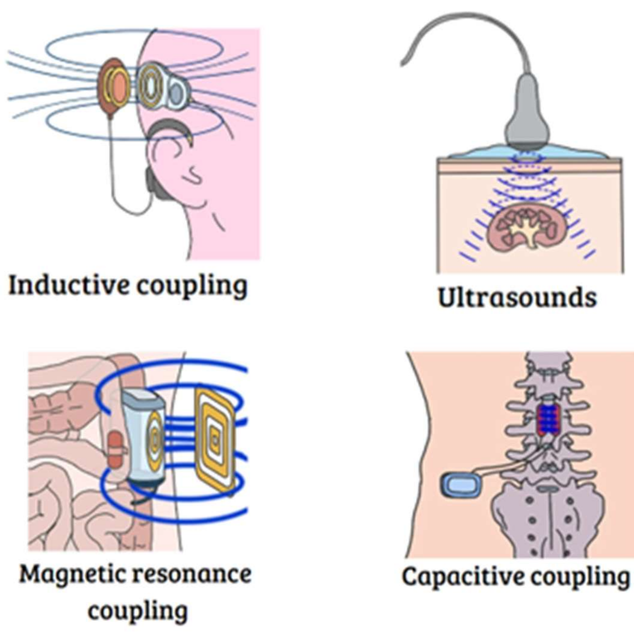

Fig. 4. Powering and communication systems.

Table. 3. Powering and Communication Methods

	RF	***IPT***	***Cap. coupling***	***MRC***	***Ultra-sound***
Data rate	Depends on power	Up to 1Mbps	Up to 1Mbps	Above 1Mbps	0.1-1Mbps
Range	●●●	●○○	●○○	●●○	●●●
Cost (lower is better)	●●○	●●○	●○○	●●○	●●●
Efficiency	●●●	●●●	●●○	●●●	●●●
Complexity (lower is better)	●●○	●○○	●●○	●●○	●●●

3.7 Ultrasound

Ultrasound refers to sound pressure with frequencies above the human hearing limit, commonly over 20 kHz. A newer application is ultrasonic power transfer (UPT), which uses ultrasonic frequencies to transmit energy wirelessly. This process involves a transmitter converting electrical energy into ultrasonic waves and a receiver converting those waves back into electrical energy. UPT systems can transfer power over long distances with a relatively small size due to the short wavelength and low operating frequency. Ultrasound-based power transfer is efficient due to low attenuation in biological tissues but requires precise alignment and must avoid causing mechanical damage [36]. Ultrasound telecommunication systems are generally used in advanced telemetry systems, deep tissue implants, and pacemakers [37]. These systems typically achieve an experimental throughput of 0.1 to 1 Mbps [36], but under optimal conditions they can reach several Mbps. However, ultrasound telecommunication systems in implanted devices are generally high cost [31].

4 Integrated circuits and coating

The development of integrated circuits (ICs) from their inception to the present day has enabled more sophisticated, reliable, and compact medical devices. This progression has profoundly influenced the design, functionality, and application of medical devices, which often rely on ICs for data acquisition, signal processing and wireless communication. These functions are critical in advanced medical devices such as

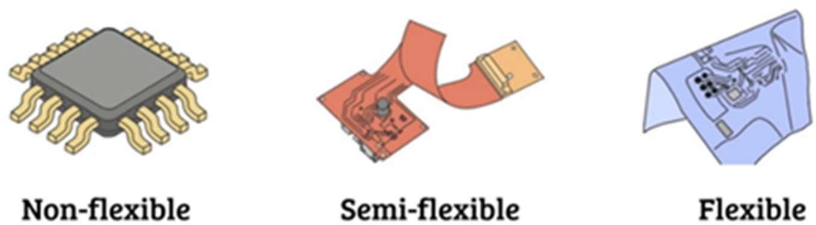

Fig. 5. Different types of Ics.

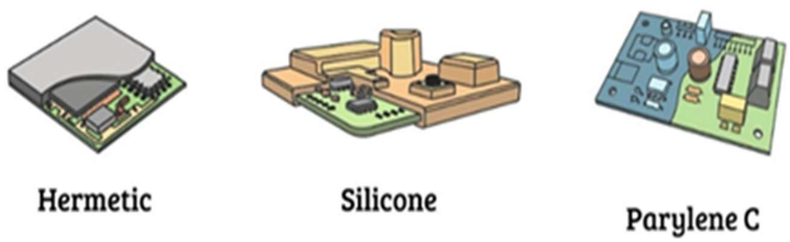

Fig. 6. Different materials for encapsulation.

pacemakers, neurostimulators and insulin pumps, enhancing diagnostic and therapeutic capabilities [38]. The historical evolution of chip technology in medical devices is marked by three stages: non-flexible, semi-flexible, and flexible chips. In the early days, spanning from the 1960s to the 1980s, medical devices utilized non-flexible chips made from rigid silicon and encased in robust metal or ceramic packages. This period saw the introduction of early pacemakers and large diagnostic equipment, which benefited from hermetic sealing techniques, ensuring long-term stability and reliability [39]. The 90s marked the transition to semi-flexible chips, which balanced the rigidity of traditional silicon chips with the flexibility needed for wearable medical devices. These chips improved the comfort and durability of devices like fitness trackers and heart rate monitors, making them essential tools for health monitoring [40]. Finally, the advent of flexible electronics in the 2000s represented a significant milestone. Modern flexible chips, integrated into soft, stretchable materials, allowed for seamless integration with the human body. These chips are now used in wearable health monitors, implantable sensors and flexible diagnostic devices, benefiting from advancements in flexible substrates like polyimide, parylene, and liquid crystal polymers (Figure 5) [41]. Additionally, the miniaturization trend has enabled the development of lab-on-a-chip (LOC) technologies, which integrate multiple laboratory functions onto a single chip for biomedical applications, thus revolutionizing diagnostic tools [42]. Beyond advancements in chip materials, it is essential to consider the methods of protecting and ensuring the longevity of these components in medical devices. The encapsulation of ICs plays a crucial role in guaranteeing their durability and reliability, especially in the harsh biological environment inside the human body. Chronic implantation of devices within the human body often leads to the formation of fibrotic capsules around the device. This fibrotic response can affect the functionality of the implant by creating a barrier to electrical signals and drug delivery [43, 43]. The encapsulation materials used must, therefore, not only protect the ICs from moisture and corrosion but also minimize the body's immune response to prolong the device's effective operational life. Traditional hermetic packaging methods involve creating airtight seals around electronic components. While effective in preventing moisture and gas ingress, these packages are rigid and bulky, limiting the miniaturization and flexibility of devices. By addressing the challenges associated with size, weight, and cost, hermetic packaging remains a cornerstone of reliable medical device design, contributing significantly to the advancement of medical technology and patient care [39, 44]. Silicones, especially silicon-containing polymers like polydimethylsiloxane (PDMS), are integral to the encapsulation of medical device implants due to their distinctive properties, including biocompatibility, hydrophobicity, low surface tension, and exceptional chemical and thermal stability. Silicone encapsulation enhances device performance and biocompatibility by providing a protective barrier that integrates well with biological tissues [45]. In the realm of medical implants, the ability to form a biocompatible and durable encapsulation layer is paramount for the device's long-term success. Moreover, silicones' hydrophobic nature helps to create a moisture-resistant barrier, crucial for implants exposed to body fluids. This property, combined with their chemical inertness, ensures that implants remain unaffected by the body's internal environment [45]. Recent advancements in the encapsulation and packaging of ICs have significantly enhanced the reliability and performance of electronic devices. Encapsulation materials such as epoxy resins, silicone rubbers, and thermosetting polymers are crucial for protecting ICs from environmental factors including moisture, thermal stress, and mechanical damage [46]. Emerging encapsulation materials, including inorganic coatings like aluminum oxide and hafnium oxide, as well as organic polymers like polyimide and parylene, offer promising alternatives. These materials provide excellent barrier properties, mechanical strength, and biocompatibility, making them suitable for long-term use in microfabricated implants. Advanced characterization techniques and accelerated testing methods are employed to assess the performance and longevity of these materials, ensuring they meet the stringent requirements of modern biomedical devices [41]. Continuous innovation in IC encapsulation and packaging technologies is essential for the safe and stable operation of implantable medical devices, which are expected to function reliably within the human body for several decades. By leveraging the unique properties of advanced materials, medical devices can achieve higher performance standards, improve patient outcomes, and contribute significantly to the advancement of biomedical engineering (Figure 6) [46].

5 Conclusions

This review has explored recent advancements in implantable device technology for peripheral nerve injury treatment, focusing on signal classification, powering, communication methods, and integrated circuit encapsulation. The complex nature of PNIs demands robust solutions that can overcome traditional treatment limitations, offering more reliable and minimally invasive options. Through advanced signal analysis techniques and machine learning, more accurate and responsive neural interfaces can be achieved, creating potential for real-time, personalized interventions. Furthermore, powering and communication strategies such as energy harvesting, inductive and capacitive coupling, and magnetic resonance coupling provide sustainable energy solutions while minimizing surgical interventions. The development of flexible and biocompatible ICs and encapsulation materials marks a significant step forward, enhancing device stability and integration within biological environments. However, translating these innovations into clinical practice poses substantial challenges, including regulatory hurdles, biocompatibility concerns, and the need for optimized data security. By addressing these issues through continued research and development, the biomedical field can significantly improve patient outcomes and quality of life. The integration of advanced materials, efficient power management, and sophisticated data processing will be crucial for the next generation of PNI treatments, paving the way for innovative therapeutic approaches that harness the full potential of implanted device technology.

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