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# A feasibility study of subcutaneous electronic devices for real-time biological monitoring

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**Abstract:**

With the rising prevalence of chronic diseases, medical monitoring has become increasingly important. As medical technology rapidly advances, implantable subcutaneous monitoring devices are being widely adopted to enhance medical convenience. In recent years, the technology for these devices has also seen significant development. Subcutaneous continuous glucose monitoring has been proven feasible and is now used in ICUs. Subcutaneous needle electrodes in the throat have also been proven feasible, and recently, implantable electronic temperature chips have been introduced. Most subcutaneous electrodes have shown good monitoring effects, and the technology has been proven viable. However, implantable subcutaneous electronic devices still face issues such as short lifespan, low comfort, susceptibility to electromagnetic interference, and some ethical concerns. The demand for improvements in implantable subcutaneous electronic devices from both patients and healthcare providers continues to increase. According to scientific and medical exploration, solutions to these problems mainly include: 1. Using rechargeable batteries to power subcutaneous electrodes, employing wireless charging technology to extend battery life and reduce the frequency of battery replacement. 2. Developing biodegradable materials for use in capacitors to avoid frequent surgical removal and replacement. Adjusting the internal structure of silicon for use in flexible electrodes, which can be implanted in the body to reduce rejection reactions and improve patient comfort. 3. Improving the design of mobile communication devices to add thin steel plates or use magnetic shielding phone cases to prevent electromagnetic waves from interfering with the device. 4. Establishing regulations to standardize their management and use.

**Keywords:** Implantable subcutaneous electronic device, Monitoring, Electrodes.

# 1. Introduction

In recent years, the incidence of chronic diseases has continued to rise, with an increasing number of patients requiring hospitalization for chronic conditions and needing continuous monitoring. For example, according to studies, about 828 million adults globally were diagnosed with diabates, reflecting an increase of 630 million since 1990[1]. These patients need constant blood glucose monitoring, which has driven the application of biosensing electronic devices. Traditional monitoring methods and equipment can cause significant errors and place a heavy burden on patients. In recent years, subcutaneous electrode implants have rapidly become popular. As society continues to age, some elderly individuals with mobility issues do not want to frequently be hospitalized or travel between home and the hospital; they prefer home treatment. Therefore, the importance of subcutaneous electrodes for them is self-evident. Subcutaneous electrodes play a crucial role in monitoring various indicators and vital signs. However, as their use increases, some technical shortcomings of current subcutaneous electronic monitoring devices have gradually become apparent. Implantable subcutaneous electronic monitoring devices also raise ethical issues related to patient privacy, prompting societal reflection. Additionally, patients are increasingly considering comfort and cost. This has forced the medical and scientific communities to jointly develop more accurate, comfortable, and relatively affordable subcutaneous electrodes. The emergence of new technologies such as soft electrodes provides a technical foundation for this. This study will focus on the current use of implantable subcutaneous electronic devices, their shortcomings, and technical challenges, and propose improvement measures.

# 2. The usage status of subcutaneous implantable monitoring systems

## 2.1 The current clinical use of electrodes (probes)

Currently, the technology of subcutaneous probes has significantly improved, which is evident in clinical monitoring of patients, especially critical patients. This article first introduces the subcutaneous monitoring techniques that have been proven feasible. Firstly, subcutaneous needle electrodes in the anterior neck have been proven feasible in small incision surgeries. Parathyroid surgery is an important method for treating hyperparathyroidism, characterized by small incisions and aesthetic benefits, but intraoperative nerve monitoring is crucial. To overcome the limitations of surface electrodes on tracheal intubation, the Shenzhen Hospital of Peking University conducted trials of this technique on some patients with hyperparathyroidism between 2018 and 2019. A total of 20 patients were involved, undergoing general anesthesia with tracheal intubation. While using traditional surface electrodes on the tracheal tube, subcutaneous needle electrodes were also tried. Two double-needle electrodes were inserted into the subcutaneous tissue on the surface of the thyroid cartilage plate, powered on with a current intensity of 3.0mA, threshold of 100μA, and frequency of 10Hz for intraoperative monitoring. All 20 patients successfully completed the surgery. During the procedure, the positions and courses of the recurrent laryngeal nerves were effectively recorded, allowing medical staff to avoid the recurrent laryngeal nerves during surgery and efficiently remove the tumor. The amplitude of the electromyographic signal was also smaller than that of the tracheal tube. In terms of cost, the cost of the anterior neck subcutaneous probe is only one-fourth of the surface electrode on the tracheal tube. Overall, the technology is basically feasible. However, based on the current clinical trial results, there are still deficiencies in the understanding of anterior neck subcutaneous needle electrodes: firstly, the number of clinical trial cases is small, and the conclusions may have limitations. Secondly, other factors affecting the current intensity of the recurrent laryngeal nerve have not been explored[2].

Secondly, subcutaneous continuous glucose monitoring has also been proven feasible in ICUs and was put into use in the United States during the COVID-19 pandemic in 2020, under the promotion of the U.S. Food and Drug Administration. Accurate blood glucose monitoring is crucial for patient treatment, while cost control is also a major concern. The subcutaneous continuous monitoring system consists of three parts: a sensor, a transmitter, and a receiver. In the experiment, the hospital divided patients into two groups: an experimental group and a control group. The control group used traditional capillary blood glucose monitoring and arterial continuous glucose monitoring, while the experimental group used this technology. In the experimental group, the sensor was implanted subcutaneously on the arm or abdomen. The glucose oxidase in the sensor reacts with glucose in the tissue fluid, generating an electrical signal, which is then processed to convert into glucose concentration. The experiment ended when the patients in the experimental group were transferred out of the ICU, died, or the monitoring duration reached seven days. After the experiment, the monitoring results were compared with those of the control group. Among the 55 subjects in the experimental group, only six patients had petechiae, accounting for 10.89%, and none had ecchymosis. In contrast, among the patients in

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the control group who used capillary blood glucose monitoring, 63.64% had petechiae, and none had ecchymosis. The incidence of petechiae in patients using continuous arterial glucose monitoring was 0%, but the incidence of ecchymosis was 38.18%. The above comparison proves its safety and lower discomfort. Additionally, this technology is more cost-effective compared to continuous arterial glucose monitoring and more accurate than capillary glucose monitoring[3].

Thirdly, subcutaneous electronic temperature chip technology has also made significant technological breakthroughs in recent years. Shenzhen Yingmijia Electronic Tag Co., Ltd. has developed a subcutaneous implantable electronic temperature chip. Its shape is capsule-like and it can connect to smartphones or other electronic communication devices via Bluetooth. It charges wirelessly. This product successfully applied for a patent in 2023[4].

### 2.2 Materials

Regarding the materials of subcutaneous monitoring systems, their current status can be discussed from two aspects. The first is human adaptability. With the increasing popularity of subcutaneously implanted electronic medical devices, human adaptability has become a topic of significant concern. As foreign objects, subcutaneous implantation systems are more likely to trigger rejection reactions in the body. Currently, most devices do not cause significant rejection reactions, but some still do. This is a major issue that needs to be addressed. The second aspect is the biodegradability of the materials. With current technology, the lifespan of most rechargeable subcutaneous electrodes is between 5-10 years, while non-rechargeable ones have an even shorter lifespan. Once their lifespan is over, replacement requires surgery to remove the old electrodes and implant new ones, which often causes great inconvenience and mental burden for patients. The battery part is the component most likely to trigger rejection reactions due to its larger size and rigidity. Additionally, it contains heavy metals and toxic electrolytes, which cannot be degraded by the body once their lifespan is over[5]. Therefore, although implantable electronic devices have become widespread in medicine, there is still significant room for improvement in their material usage, especially in reducing rejection reactions and enhancing the biodegradability of the materials.

### 2.3 Battery life and charging methods

The battery life of subcutaneous electrodes is also a significant issue to consider. Currently, the batteries used in subcutaneous medical devices are typically lithium batteries, some of which can be recharged, while others need to be removed and replaced once their power is depleted. Therefore, the development and popularization of rechargeable subcutaneous electrodes are extremely important. For charging methods, wireless charging is the best option. In recent years, several technologies for wireless charging have been developed. The first method involves energy conversion for charging. Energy conversion devices can transform external energy and human kinetic energy into electrical energy[6], as shown in the figure 1 below. Currently, radiofrequency waves are the most common form of external energy used clinically, but research on light and ultrasound is rapidly advancing. Among these, near-infrared two-window (NIR-II) light is particularly emphasized for its ability to deliver high-power density energy to deep tissues. Sunlight or LEDs transmit infrared light to subcutaneous photovoltaic cells, and reflectors are used to enhance the efficiency of light transmission[7]. The second type is near electric field.The principle of this technology is the capacitive effect between electrodes for energy transfer. This technology enables wireless power supply, efficiently transmitting electricity to implants. By modeling the power chain, the optimal frequency for power supply is identified. This technology has been tested on deceased primates, achieving a peak efficiency higher than 50%. Subsequent studies on bending deformation have demonstrated its flexibility and deformability, indicating its reliability for practical clinical applications[5].

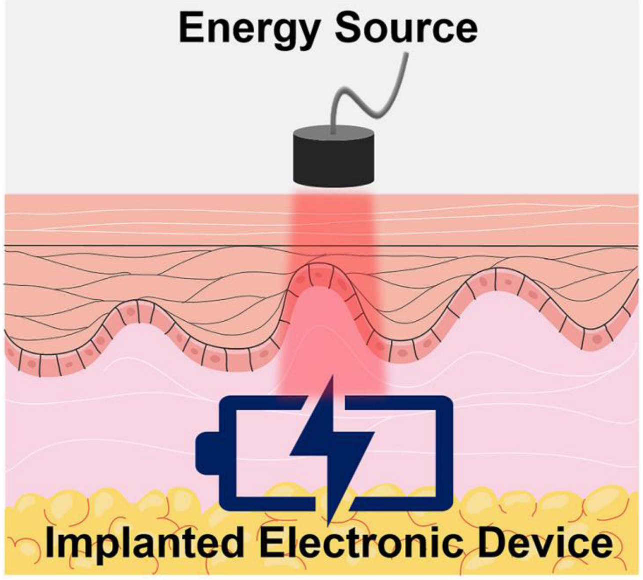


**Fig. 1 The RF wave charging coupling technology**

### 2.4 Sensors

The signal transmission of subcutaneously implantable electronic devices has two methods. One is the connection between the detector and the external control device through wires, with signals transmitted via the wires. The other is wireless transmission, where the sensor emits signals. Wire technology is already quite mature, while the development of sensors remains a widely discussed topic in the medical and scientific communities. Electrochemical sensors are already quite common in clinical settings, for example, in continuous glucose monitoring[8]. The more common monitoring methods mainly include liquid chromatography and gas chromatography. The technology of detection through enzymes has been proven feasible, but there is still a gap before it can be widely applied in clinical settings.

### 2.5 Interference resistance

Implantable electronic devices are mostly made of metal, which, as conductors, are susceptible to magnetic field interference, especially given the widespread use of mobile communication devices such as smartphones today. With the advancement of technology, the magnetic fields of modern smartphones and other communication devices are continuously decreasing, reducing their impact on subcutaneous electronic devices, particularly under the supervision of trained professionals. However, electromagnetic wave interference can still occur under certain uncontrolled conditions. To investigate the actual situation under current technological conditions, a team from the University Hospital of Münster conducted relevant experiments. In the experiment, two phones were used: an iPhone 14 and a Google Pixel 8 Pro. The subcutaneous device chosen was an implantable cardiac electronic device. The iPhone 14 uses magnetic fields for wireless charging, so it has magnets attached inside.Two methods were used to block the signal: placing the phone in a case compatible with 'Magsafe' or inserting a steel plate into the back of the phone case. In the experiment, 16 implantable cardiac devices were implanted under the skin of isolated pig chest specimens. Two phones were placed on top of the implant locations, and the cardiac devices were affected by the magnetic field. When the iPhone 14 was placed in a 'Magsafe'-compatible case (which can block the magnetic field), six devices were still affected, while none of the Google Pixel 8 Pro devices caused any interference. In the experiment using the steel plate, neither the iPhone 14 nor the Google Pixel 8 Pro caused any magnetic interference[9]. The comprehensive experimental results show that using thin steel plates for magnetic shielding is an effective method to mitigate the impact of the magnetic field on equipment[10].

### 2.6 Other problems

With the widespread use of subcutaneous electronic medical devices, how to handle these devices when patients die has become a challenge for forensic experts responsible for handling the bodies. Although there are many guidelines on the use of these devices, there are no clear opinions or regulations on how to handle them after the patient's death, which also brings certain technical challenges and conflicts of interest. Analyzing the information recorded by these devices, such as implantable cardiac devices (CIEDs), can help infer the patient's condition and cause of death at the time of death. However, in some cases, CIEDs have experienced data loss after the patient's death, making it difficult to determine the true cause of death during autopsies of sudden death victims, thus increasing the difficulty of the autopsy. If the implantation team is involved in retrieving monitoring data at this time, it may also lead to conflicts of interest with the forensic team. Further research has found that analyzing device data immediately after the patient's death is crucial for investigating the cause of death.

## 3. The summary of the problems and the solutions

In this study, subcutaneous implantable electronic devices have become widespread. From a technical perspective, they are feasible for monitoring indicators, but they still face issues related to safety. Therefore, the solutions are as follows:

Firstly, the needle-shaped electrode is small, has no sharp edges, and is unlikely to cause rejection reactions, making it worth promoting in clinical settings.

Secondly, there is significant room for improvement in the use of materials. First, it is essential to ensure their biocompatibility to avoid rejection reactions. Electrodes can be categorized into rigid electrodes and flexible electrodes. Currently, research and development of flexible electrodes are relatively lacking, so while enhancing the technology of rigid electrodes, attention should also be given to the development of flexible electrodes. Flexible electrodes, due to their excellent deformation capabilities, are less likely to cause rejection reactions when implanted in soft or fragile parts of the body. Single-crystal silicon is a material worth considering, especially for use in softer or more fragile tissue areas. Although silicon is currently mainly used in rigid electrodes, through geometric engineering, optimizing its dimensions at the micrometer and nanometer levels can overcome silicon's inherent rigidity. Additionally, thinning bulk silicon down to nanoscale thickness can enhance its flexibility, and creating silicon

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nanowires can further increase its deformation capability[11], then apply it to flexible electrodes, thereby reducing the rejection reaction after electrode implantation in the body. The zinc-ion battery in figure 2 is also an ideal choice.Secondly, accelerate the research and development of water-soluble materials for use in batteries, allowing the human body to absorb them. Currently, widely studied and used water-soluble metals include Mg, Zn, W, Fe, Mo, and their alloys, with their hydrolysis chemical equations being[12]:

$$Mg+2H_2O\text{¡ú}Mg(OH)_2+H_2 \quad (1)$$

$$Zn+2H_2O\text{¡ú}Zn(OH)_2+H_2 \quad (2)$$

$$2W+3O_2+2H_2O\text{¡ú}2H_2WO_4 \quad (3)$$

$$2Mo+3O_2+2H_2O\text{¡ú}2H_2MoO_4 \quad (4)$$

Thirdly, develop wireless charging technology to avoid frequent battery replacements and implants.

Fourthly, Develop phone cases with metal shielding features for patients with subcutaneous electronic devices to prevent mobile phone electromagnetic waves from interfering with the devices.

Fifthly, Improve the guidelines for the use of subcutaneous implantable electronic devices, including the handling and data analysis of the device after the patient's death. Clearly define how forensic experts and the implantation team should divide responsibilities and establish the boundaries of their rights to avoid conflicts.

Lastly, Utilize the regulatory mechanism of competitive hydrogen bonds, leverage the solubility regeneration process of natural polymers, and introduce non-solvents to establish a competitive hydrogen bond system[13], which improves the flexibility of the electrodes and their contact with the skin.

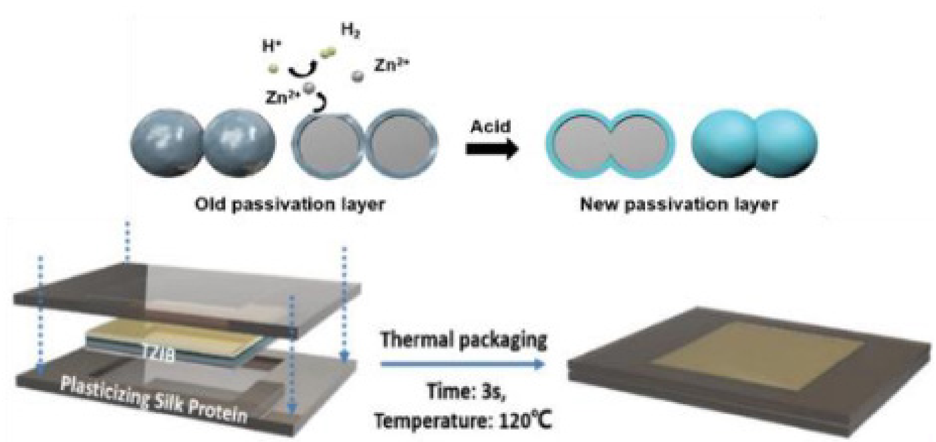


**Fig. 2 degradable zinc-ion battery**

## 4. Conclusion

In summary, subcutaneous electrode implants have now entered a large-scale clinical application phase. They are particularly used in surgical settings or ICUs and other special or dangerous situations. Their accuracy is generally high. Some subcutaneous devices can already connect to mobile phones and other communication devices via Bluetooth, making operation convenient and allowing for real-time adjustment and control. With current technology levels, the human body can adapt to most subcutaneous electrodes. Patients' overall experience is good, but there is still significant room for improvement. Charging methods need further exploration, and the capacity and battery life of the electrodes still need to be enhanced. Mobile phones and other communication devices may still affect the accuracy of subcutaneous electrodes. Currently, almost all electrodes cannot degrade within the body, and frequent surgical removal and implantation are also important factors affecting patient experience. The monitoring methods of sensors are relatively single, mainly electrochemical sensors. Additionally, some emerging products like laryngeal subcutaneous needle electrodes, although feasible and successfully applied in clinical settings, have relatively few clinical applications, limited case numbers, and are not fully understood. However, overall, the development potential of implantable subcutaneous electronic devices is great, and their application prospects are broad. Considering the current shortcomings, future improvements should focus on several aspects. Firstly, the development of flexible electrodes should be actively promoted to better adapt to the internal body environment and reduce rejection reactions. Water-soluble capacitors should also be put into use as soon as possible so that they can be absorbed by the human body, reducing the frequency of surgical implantation and removal, and improving comfort. The design of mobile communication devices should also pay attention to electromagnetic field shielding. The detection methods of sensors need to be further diversified. Additionally, new charging methods such as near-field coupling technology should be applied to clinical use as early as possible to improve the convenience of charging. Finally, the clinical application scale of new electrodes, such as the subcutaneous needle electrode in the throat area, should be strengthened to fully understand the characteristics of these electrodes, standardize their use, and achieve optimal usage efficiency and monitoring effects.

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