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Wireless communication with implanted medical devices using the conductive properties of the body

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Abstract

Many medical devices that are implanted in the body use wires or wireless radiofrequency telemetry to communicate with circuitry outside the body. However, the wires are a common source of surgical complications, including breakage, infection and electrical noise. In addition, radiofrequency telemetry requires large amounts of power and results in low-efficiency transmission through biological tissue. As an alternative, the conductive properties of the body can be used to enable wireless communication with implanted devices. In this article, several methods of intrabody communication are described and compared. In addition to reducing the complications that occur with current implantable medical devices, intrabody communication can enable novel types of miniature devices for research and clinical applications.

Keywords

biotelemetry; cardiac implants; implantable device; intrabody communication; neural implants; remote monitoring; wireless

Implantable devices for physiological monitoring are used widely by clinicians and researchers to monitor health and to study normal and abnormal body functions. These devices can relay important signals (e.g., electrocardiogram, glucose level and blood pressure) from implanted sensors to external equipment to be analyzed or to guide treatment. Implantable devices can also be used to record neural signals in brain–machine interfaces to control prostheses [1] or paralyzed limbs [2].

Communication with implanted devices is usually accomplished with a wired connection or with wireless radiofrequency (RF) telemetry. However, wires can break, become infected or introduce noise in the recording through movement artifacts or by antenna effects.

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Complications with wires are frequently reported with deep brain stimulation devices [3] and with pacemakers and implantable cardioverter-defibrillators [4].

Wireless RF telemetry has been used in several implantable medical devices to avoid the complications of wired implants [5,6]. However, wireless RF telemetry requires significant power and suffers from poor transmission through biological tissue. RF telemetry also needs a relatively large antenna, which limits how small the implantable devices can be and prevents implantation in organs such as the brain, heart and spinal cord without causing significant damage. Other methods of wireless communication have been investigated to communicate with implants, including optical [7] and ultrasound [8]. However, these methods also have low-efficiency transmission through the body and would be difficult to miniaturize.

Intrabody communication is a recently developed alternative method of wireless communication, which uses the conductive properties of the body to transmit signals. This article will explain the major developments and the theory of intrabody communication, describe challenges to putting the technology into practice, and discuss how intrabody communication can be used as the basis for a novel class of wireless implantable medical devices.

Historical development

The first report of intrabody communication was in 1995 by Zimmerman *et al.* [9], where a small signal (~50 pA) was transmitted through the body and detected at a receiving electrode. In this system, a single transmitting and a single receiving electrode were placed near the skin without touching it, capacitively coupled to the body. Another set of electrodes at the transmitter and receiver were also oriented away from the body and were capactively coupled to the environmental ground, serving as the signal's return path (Figure 1A).

This type of telemetry, called capacitive intrabody communication, has primarily been used for surface-based communication with both the transmitter and receiver electrodes placed on or near the skin. The major limitation of this transmission method is its reliance on capacitive connections to both the body and ground and thus has not been used for communicating with implanted devices. Several applications of capacitive intrabody communication have been developed for transmitting data to consumer electronic devices [10,11].

The second type of intrabody communication, galvanic, was first reported in 1997 by Handa *et al.* [12]. A small alternating current flowed from transmitting electrodes on the chest, through the body, and was detected by receiving electrodes on the wrist. The transmitting and receiving electrodes were in direct contact with the body, resulting in galvanic coupling (Figure 1B). A major advantage of this technology was its very small power requirement, only 8 μW. In addition, because no ground connection was required, this type of telemetry could be used with implanted devices.

Galvanic intrabody communication has been studied for a range of medical applications including communicating with implanted and surface-mounted devices. This article will focus on galvanic communication; interested readers can find a recent review of capacitive intrabody communication in [13].

Implant-to-surface communication

In implant-to-surface communication, galvanic coupling is used to send signals from an implanted device to electrodes on the skin. This allows for easy placement and repositioning of the skin electrodes to improve the quality of signal reception. However, because the signal has to travel through the skin, which is less conductive than many of the tissues inside the body, more signal attenuation occurs.

Human cadaver testing

Lindsey *et al.* tested a method of galvanic communication between an implanted device and surface electrodes to monitor and transmit information about anterior cruciate ligament graft tension after surgery [14]. Two platinum electrodes (each 0.38 mm in diameter, separated by 2.5 mm) were used to inject current into the leg of a human cadaver. Electromyography (EMG) electrodes on the surface of the leg were able to detect the transmitted signals. The signals tested were sine waves with frequencies of 2–160 kHz and currents of 1–3 mA, resulting in a minimum signal attenuation of 37 dB. The attenuation increased with smaller currents, with longer distance to the surface electrodes, and with decreased inter-electrode separation of the surface EMG electrodes. In addition, the signal attenuation was sensitive to the placement of the surface electrodes in relation to the joint line. Because standard EMG electrodes were used to receive the signal, they could be easily repositioned to improve the quality of signal reception. However, the signal attenuation remained very high (37–50 dB), making signal transmission with high signal-to-noise ratios difficult.

Anesthetized animal testing

A more efficient implant-to-surface communication system was developed by Sun *et al.* and tested in saline and an anesthetized pig (Figure 1C) [15]. The implanted transmitter was integrated in an ‘x-antenna’, where the electrodes were integrated in two parabola-like surfaces that altered the current flow. The insulated sections of the x-antenna caused the current to flow in larger paths around the antenna and allowed for more current to be detected at the receiver electrodes. In a saline test, signal delivery using the x-antenna was found to only require 1% of the power of a traditional electrode pair. However, the diameter of the x-antenna was 9 mm, and the transmitter was designed to be implanted on the surface of the brain in between the dura and the cortex, with the signal detected by needle electrodes in the scalp. This system would be too large to be implanted inside the brain without causing significant damage.

Implant-to-implant communication

In implant-to-implant communication, signals are transmitted from the implanted device to receiver electrodes also implanted inside the body. The implanted receiver can then be connected to equipment outside the body using a short wire or with wireless RF telemetry. In this way, less power is needed to transmit to the implanted receiver electrodes than to electrodes on the skin. However, the implanted receiver electrodes cannot be as easily repositioned as skin-mounted receiver electrodes.

Tissue analog testing

A system for implant-to-implant communication was developed by Wegmueller *et al.* and tested in a muscle-tissue analog (Figure 1D) [16]. The two electrodes of the transmitter galvanically coupled an alternating-current signal into the body. The signal was then detected by two receiver electrodes. Signals with frequencies of 100–500 kHz were used in order to avoid common neural frequencies, and less than 1 μA of current was used. Two different designs for the transmitting and receiving electrodes were tested: pairs of exposed copper cylinders (10 mm in length and 4 mm in diameter) and exposed copper circles (4 mm in diameter). The electrode sites were spaced 50 mm apart for both the transmitter and receiver. The copper cylinder electrodes could transmit sinusoidal signals with a loss of approximately 32 dB over 5 cm, and the copper circle electrodes had a loss of 47 dB over 5 cm. However, the electrodes were large and significant signal loss was found with any misalignment between the transmitter and receiver electrodes. The large signal losses were caused by the four-electrode design; most of the transmitted current returned to the transmitter and did not reach the receiver.

Anesthetized animal testing

A two-electrode system was developed by Al-Ashmouny *et al.* and tested in an anesthetized rat (Figure 1e) [17]. The system used two electrodes in contact with the tissue, one for the transmitter and one for the receiver. Both electrodes were made from 50-μm diameter platinum–iridium wire. The transmitter, an insulated complementary metal–oxide–semiconductor chip less than 1 mm^3 in volume, was implanted in the rat's brain and transmitted alternating-current signals to the receiver electrode, which was also implanted in the brain. Because the transmitter's circuit ground was insulated from the tissue, the path for current returning to the transmitter had higher impedance than the path through the brain to the receiver. Thus, there was a high-efficiency transfer of the signal to the recording site. Care was taken to use a charge-balanced alternating-current signal in order to avoid charge buildup or tissue damage at the electrode. Using this setup, an encoded neural signal was faithfully transmitted through brain tissue with approximately 20 dB of signal loss. A simultaneous microelectrode recording showed no obvious disruption in activity during signal transmission in the anesthetized rat's brain. The two-electrode setup of this system allowed for high efficiency transmission of the signal, but made the system vulnerable to extra current sinks in the system. If a low impedance path to ground was present, such as contact between the body and a circuit ground or a grounded water pipe, the signal would be lost.

Surface-to-surface communication

Galvanic coupling can also be used to communicate between devices mounted on the skin. Surface-to-surface communication allows for quick and easy positioning of electrodes, fewer constraints on the size and power demands of the transmitting devices, and avoids surgical implantation. However, because the sensors are on the skin, they may be far from the sources of the signals that are being measured and can result in weak, distorted or indirect physiological measurements compared with implanted sensors. Nevertheless, these surface-to-surface signals can be combined with signals from implanted devices to create a network of sensors across and inside the body.

Human testing

Because of the convenience and noninvasiveness of surface-to-surface systems, they can easily be tested in humans. Many laboratories have successfully used galvanic intrabody communication to transmit data between electrodes attached to the skin [12,18–20].

Challenges

Power

One of the most difficult challenges for implanted device technologies to overcome is in providing implants with sufficient power to record and transmit signals. However, there has been great progress in understanding how to design miniature low-power circuits for biological applications [21]. The most common method of powering larger implants such as pacemakers and deep brain stimulation devices is via batteries. However, batteries are difficult to miniaturize and remain the size-limiting component of many implants. In addition, the lifetime of batteries limits the useful life of potential implants. Battery replacement for implantable devices often requires an additional surgery and can cause many complications. Alternatively, rechargeable batteries allow for longer useful lifetimes but need an additional means of delivering power to recharge, such as RF approaches, which suffer from low-efficiency power transfer and require relatively large, aligned antennas.

Other non-RF methods to wirelessly power implanted devices have been proposed but are only in very early stages of development and will require many advances before they are practical. Witricity, which uses magnetic resonance coupling, allows for highly efficient energy transfer but requires large coils [22,23]. Ultrasound energy can be used to deliver power to implanted devices, but the efficiency of power delivery is very small, approximately 0.06% [24]. Energy scavenging [25] and optical energy [7] have also started to be investigated but currently produce too little energy to reliably power implantable devices.

Another approach is to design the implants as passive devices, not requiring any onboard power source. In this approach, the implant acts like a radiofrequency identification (RFID)-type device and modulates the signal generated by an external source. The signal then detected outside of the brain includes the information transmitted by the implant. The interrogating signal can be generated by radiative RF signals like a traditional RFID device [26,27] or using volume conduction [28]. This approach would allow for the greatest degree of miniaturization since no battery is required. However, early prototypes have used inductors, which are difficult to miniaturize.

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Insertion

For a miniature implantable device, alternative approaches to positioning the implant within the body are necessary. The easiest way to insert an implant is by injecting it with a hypodermic needle. This technique is commonly used for implanting RFID tags into the bodies of livestock for identification [29]. For implantation in the brain, the hard needle protects the implant from the forces encountered when penetrating through dura and brain tissue. However, the volume of brain tissue displaced is larger than if the implant were moved alone. In addition, the positive pressure from the syringe may cause damage to tissue. An alternative to a hypodermic needle is to use a vacuum-based tool, similar to the vacuum pickup tools used in placing microelectronic components. In this setup, the implant is held to the tip of a hollow tube by vacuum. Once inserted to the desired depth, the vacuum is released and the tool is retracted, leaving the implant in place.

Another approach to inserting implants is using magnetic guidance, originally developed to guide catheters within the brain [30] and for drug delivery of nanoparticles [31]. In magnetic guidance, several large external superconducting magnets control the movement of permanent magnets integrated in the implant. This system allows for control in three dimensions and for easy repositioning of the implant. Nonlinear trajectories can even be used to avoid sensitive regions of the brain, which would be impossible in a traditional linear stereotactic approach. However, the implant must be magnetically sensitive, and a complex purpose-built system is required to control the magnetic implant. Another potential concern is unintentional movement of the magnetic implant after implantation due to magnetic forces in the environment or from MRI.

Dissolvable silk films, which have recently been used to create a mesh for electrodes placed conformably on the brain surface [32], could also potentially be used in implanting miniature wireless devices. Silk films dissolve over time, leaving the implant completely unconnected to any wires or fibers. The silk structure attached to the implant can also be used to move or extract the implant during the first few days or weeks before the fibers dissolve. However, the mechanical properties of silk films require further investigation and testing.

Safety

Another important challenge is to minimize the body’s response to the implant. Upon recognizing a foreign implant, the body mounts a complex response that occurs on both short and long time scales [33,34]. This response can adversely affect both the function of the implant and, more importantly, the health of the tissue. Many approaches have been attempted to minimize the tissue response that could also be applied to wireless implantable devices, including careful selection of biocompatible materials and coatings [35] and localized drug delivery [36].

It is also important to minimize the effects of intrabody communication on the body, including localized heating caused by power dissipation and unintended stimulation. To avoid the localized heating that can occur with RF telemetry, intrabody communication should use a low-frequency carrier wave, ideally below a few MHz. Also, to minimize any unintended stimulation, the frequency of the carrier wave should be above physiologically important frequencies, at least approximately 100 kHz. This range of frequencies between the two bounds also has the advantage of having good-quality transmission in biological tissue [37–39] and is the frequency range of the tests described in this article. Nevertheless, even at this middle frequency, care must be taken to observe that the specific energy absorption rate and the current density are below the values set in international guidelines [40]. Because intrabody communication is a new technology, potential tissue heating and unintended stimulation should be closely monitored in future experiments, even if the transmission is within accepted international standards.

Expert commentary & five-year view

Several approaches to communicating with implanted medical devices using the body as the transmission channel have been proposed and tested. Each of these methods offers some insight in how such a communication system can be realized. Intrabody communication offers several advantages over wires and RF wireless telemetry for communicating with implanted devices. However, intrabody communication is a new technology and several challenges, especially improving power delivery and thoroughly evaluating safety, need to be addressed before it is implanted in humans and used for routine clinical applications such as physiological monitoring.

In the near future, the likeliest users of intrabody communication will be biomedical research laboratories that will investigate the capabilities of the technology and develop applications for small animal studies, where miniature implantable sensors are vital for many research questions. Further in the future, a novel form of physiological monitoring can be envisioned, where multiple ultra miniature implants are injected into various locations in the body. These implants can be interrogated using an RFID-type telemetry system. By making each implant sensitive only to a specific frequency range, the implants can be made individually addressable and be used in a body-wide network. Such a system of implantable devices would allow for flexible positioning options without the restrictions and problems of wires and could enable access to tissues sensitive to movement such as the heart and spinal cord.

One especially exciting potential future application is a network of injectable, miniature wireless neural implants (Figure 2). By being wireless and miniature, they would allow researchers to have complete freedom in selecting the locations of neural recording sites. Since most neurological diseases affect multiple brain regions, being able to monitor neural activity and observe intra-region communication is likely to be important to our understanding of dysfunction. For example, multiple injectable neural recording implants in and around the focus of seizure activity would be beneficial in surgical planning or monitoring for epilepsy patients.

Because of the body's conductive properties, it can be used as a communication channel to transmit power or information to or from an implant. By eliminating wires, miniature devices can be implanted in multiple structures without restrictions in their positions or be implanted in fragile structures, such as the heart or spinal cord, that would be damaged with moving wires. In addition, the miniature devices could simplify surgical procedures and would help minimize the surgical complications common in implants that use wired connections. Low-power, ultra-miniature implantable devices that use intrabody communication have the potential to enable many exciting applications in the future for both biomedical researchers and clinicians.

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Key issues

- Implantable medical devices are important tools for researchers and clinicians, but the wires connecting the implants to external circuitry are common sources of complications (e.g., wire breakage, infection, tissue damage and electrical noise).
- Wireless radiofrequency telemetry is also being used for communicating with implants, but its transmission efficiency is very low through biological tissues, and it has large power demands. In addition, the antennas are too large to fully implant in structures such as the brain and heart without causing significant damage.
- Intrabody communication, which uses the body as a conductor, allows for a miniaturizable and power-efficient means of wirelessly communicating with implants.
- Shaping the current flow through the body with high- and low-impedance paths improves the efficiency of signal transmission.
- Issues such as safety, insertion methods, tissue response and power are important practical considerations in the development of implantable, wireless neural devices.

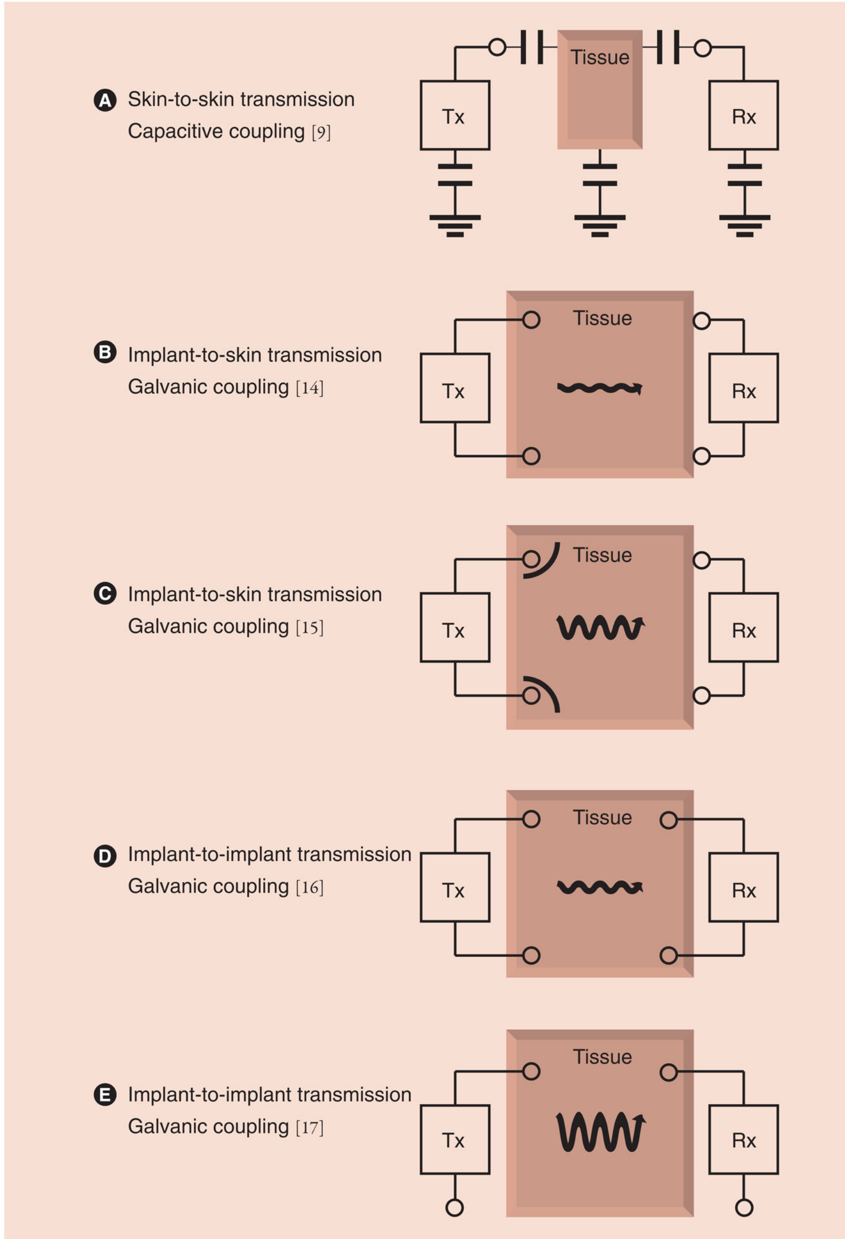

Figure 1. Five types of intrabody communication

(A) Signal is transmitted from a Tx to a Rx, both located on the skin, with the body capacitively coupled to the Tx and Rx electrodes. The Tx and Rx are also capacitively coupled to the ground, but capacitance between the body and ground reduces the efficiency of signal transmission. **(B)** Signal is transmitted from a Tx implanted in the tissue to a Rx on the skin. The Tx and Rx electrodes are galvanically coupled to the tissue. Most of the current passes between the two Tx electrodes, but sufficient signal transmits across the tissue to be detected by the Rx. **(C)** Using x-antennas to shape the current path, creating a higher impedance path between the Tx electrodes, stronger signal is detected at the Rx than without x-antennas. **(D)** Signals are detected by an implanted Rx, which reduces signal attenuation and power demands compared with skin-mounted Rx electrodes. **(E)** By using only one Tx electrode and one Rx electrode galvanically coupled to the tissue, the path between Tx electrodes has higher impedance than the path to the Rx, resulting in less signal attenuation. High-frequency, charge-balanced, alternating-current signals prevent charge build up.

Rx: Receiver Tx: Transmitter.

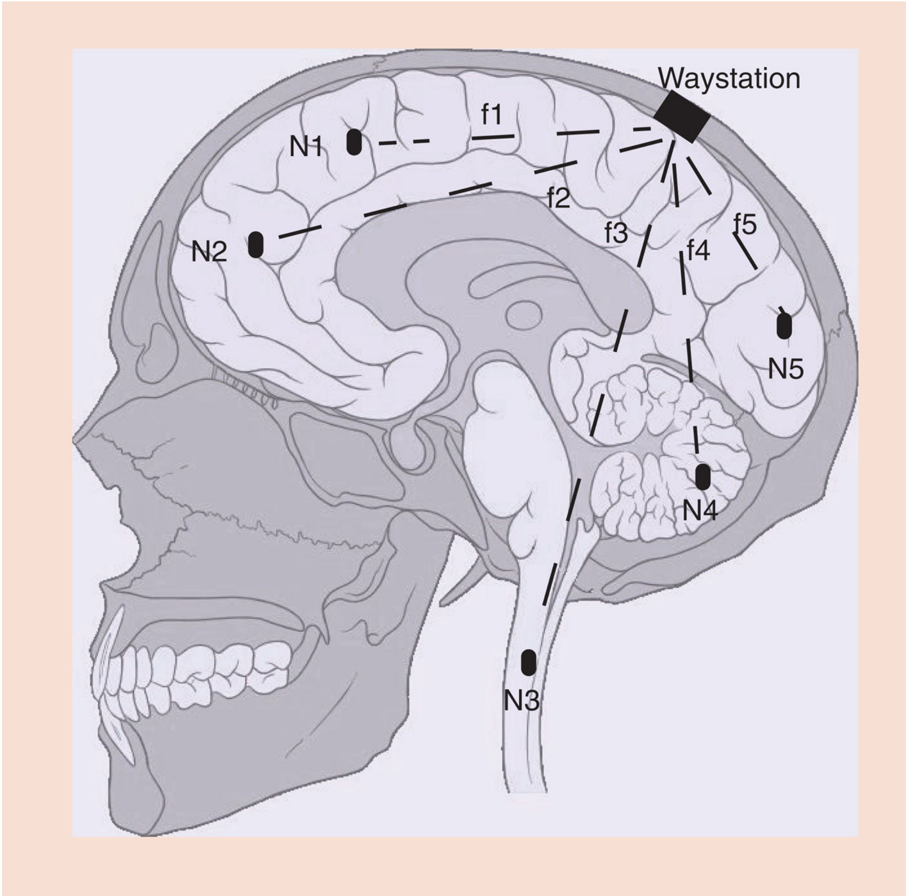

Figure 2. A possible future vision for wireless, miniature implantable devices for neurological monitoring applications, different from any currently available technologies

Several implants (N1–N5) are injected into the brain and spinal cord. The implants are tuned to specific frequencies (f1–f5) and thus are individually addressable. The receiver, the waystation, allows for communication between multiple implants and external devices, and, because it is implanted, it improves the transmission efficiency. This technology could enable the development of novel tools for neuroscience research and clinical care.

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