14 Implantable Myoelectric Sensors for Prosthetic Control

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While prosthetic technology has been continuously advancing over the last decades, the bottleneck of translation into intuitive and natural prosthetic control has been the functional interface between user and prosthesis. Currently used surface electrodes entail various shortcomings, ranging from low selectivity to frequent signal instability. Most of these limitations can be overcome by implantation of myoelectric sensors, thereby moving them closer to the biological signal source. Different implantable solutions for prosthetic interfacing have been developed and tested in animal as well as human studies. This chapter will give a short overview of the current limitations and go on to present promising implantable solutions as well as a future outlook.

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Current Solutions and Their Shortcomings

While there have been major advances in prosthetic technology and amputation surgery in the last decades, the basic mechanisms of myoelectric signal pickup have remained largely unchanged since its first use roughly 60 years ago [20]. Currently, the control of myoelectric prosthetic devices is achieved via transcutaneous detection of EMG signals using surface electrodes. These are placed in the socket of the device and positioned on the skin over the corresponding muscle. Surface EMG (sEMG) activity can thus be registered and used as control input for prosthetic movements, employing either direct approaches or signal processing algorithms such as pattern recognition or regression. Transcutaneous signal transmission bears several well-known limitations, which negatively influence reliability and overall performance of prosthetic devices, increasing frustration and device abandonment rates among users [4]. An important factor to consider is the amount of tissue between electrode and muscle, comprising mostly skin and fat, which decreases EMG signal amplitude and promotes signal crosstalk between recording sites [8]. Particularly in overweight patients, this leads to a significant decrease in EMG quality, limiting sensitivity and selectivity of each electrode and constraining the number and quality of available sites for myoelectric control. Furthermore, changes of skin electrode position are unavoidable during movement of the stump, especially when lifting heavy objects, or after donning and doffing the device. Other factors which contribute to signal instability are variability of stump size, relative movement of the muscle with respect to the electrode and changes in electrode impedance due to sweating. Given the low signal intensity, higher threshold values need to be used to discriminate between volitional EMG signals and background noise or artefacts. This results in the need for stronger muscular contractions, limiting the accuracy of proportional myoelectric control and promoting fatigue.

The shortcomings of surface electrodes become particularly apparent in patients who have received targeted muscle reinnervation surgery to increase the number of myosignals [18]. Since up to six independent muscle signals have to be registered within the limited surface area of a residual limb, electrode placement becomes increasingly difficult and time-consuming. Crosstalk between signals and incorrect placement of the electrodes often limits control performance and adds to the frustration of patient and prosthetist during the process of prosthetic rehabilitation. Finally, research on the use of cognitive nerve transfers for muscle reinnervation in amputees has shown that the resulting biosignals offer a complex array of compacted information within a relatively small space [5]. In order to fully harvest this potential, high-fidelity signal transmission is necessary (see section "Future Outlook") [3].

While improving efferent control is a major focus in prosthetic research, the inclusion of sensory feedback to close the loop is another important goal which has so far remained elusive in clinical practice. Due to the lack of touch and proprioception, the user needs to rely on visual feedback to guide prosthetic control, which is slow, unintuitive and impedes natural use as well as device embodiment. The strong predominance of afferent fibres within the human brachial plexus, of a factor of approximately 10:1 in relation to motor fibres, underlines the great importance of sensory perceptions for effective interaction with our surroundings [6]. The next chapter will go into further detail regarding the complex topic of sensory feedback.

Developing Implantable Interfaces

Research and clinical experience over the last years have suggested that the necessary way forward to attain more reliable and selective myoelectric control is implantation of EMG sensors. Implantable electrodes can either be directly attached to the surface of a muscle (epimysial) or placed within the muscle belly (intramuscular). This approach largely eliminates the limitations associated with sEMG pickup, while offering the possibility to access a higher number of independent signals [13]. Close proximity to the signal source greatly increases the amplitude of the biosignal, removes crosstalk and effectively prevents changes in impedance and signal quality. Furthermore, implanted electrodes can also be used to stimulate nerves which are cognitively related to the lost hand. In combination with pressure sensors incorporated into prosthetic fingers, this approach can be used to elicit sensory feedback when grasping objects.

However, while these are promising perspectives, development of an implantable medical device comes with its own challenges. First of all, any long-term implant should be designed without the need for percutaneous leads, which are susceptible to infection and may cause additional harm through dislodging, while also being psychologically unacceptable for most patients [19]. Data transmission and powering of the implant must therefore be achieved wirelessly, e.g. using radiofrequency or light-related transmission. Further considerations that need to be addressed when developing an implant for clinical use are biocompatibility of all materials used, chemical and mechanical stability, injury during implantation and chronic functionality. Before moving into human application, these factors need to be evaluated thoroughly in animal models, generally moving from biocompatibility studies in small animals to long-term functionality studies in large animals [1]. Materials used for the implant surface should be well-known and inert, such as silicone, titanium or ceramic for the casing and platin-iridium or steel for the electrode contacts. Any areas with risk of implant failure or wire breakage, such as connections between the central implant and a cable, need to receive special attention during the design process. Once material tests and animal experiments are conducted and confirm device stability and chronic functionality, human studies can be planned, which involves an extensive regulatory process and rigorous documentation. A limited number of implantable systems to improve prosthetic interfacing have been developed and tested so far, none of which have yet become commercially available.

Overview of Implantable Systems

IMES

The IMES (“Implantable MyoElectric Sensors”) system is one of the few which has been chronically tested in humans. Originally it was developed by the Alfred Mann Foundation in the US. The IMES are small implants (16 mm long and 2.5 mm in diameter) with a ceramic housing of cylindrical shape and metal end caps acting as electrodes for recording intramuscular EMG [15]. Up to six individual sensors can be placed in different muscles, in order to wirelessly transmit EMG data to the prosthesis. Data transmission as well as power supply of the sensors is achieved through a circumferential external coil, which has to be integrated into the prosthetic socket (see Fig. 14.1). Recently, the first long-term implantation of IMES in conjunction with TMR in above-elbow amputees has been reported, demonstrating that the intramuscular sensors can chronically register and transmit EMG after selective nerve transfers for establishing natural prosthetic control [17]. The results over a period of more than 2.5 years showed substantial functional improvements compared to standard surface EMG control without any events of disconnection or malfunction of the system. Due to the intramuscular placement, signals are independent from the position of the prosthesis and are therefore not subject to disturbances during postural changes or after donning and doffing. For the same reason, these signals can be detected early after nerve transfer surgery, which leads to a significant decrease in rehabilitation time. The fact that these sensors individually transmit signals without a central transmission unit close to the surface allows a certain freedom of wireless placement. However, the distance that needs to be covered requires energy supply which cannot be integrated into the prosthesis. Patients therefore need to wear an additional external belt-worn device, which is generally perceived as bothersome by its users. Another drawback is that the current IMES system is not compatible with metal implants at the stump region. Thus, surgical procedures such as angulation osteotomy or osseointegration cannot

Fig. 14.1 A patient using the IMES system to handle a light bulb. An X-ray of the stump is shown, which includes the individual sensors of the system as well as the circumferential coil which is embedded into the prosthetic socket. The coil is used for wireless communication with the implanted sensors and also provides power supply. The purple circle highlights an illustration of an intramuscular sensor. (© Aron Cserveny for Oskar Aszmann)

be currently combined with the implantable system. Additionally, as the coil has to be placed circumferentially around the stump, short above-elbow amputations or shoulder disarticulations cannot be treated with this system. Finally, the IMES sensors are unidirectional and cannot serve as an afferent signal interface.

eOPRA/OHMG

Osseointegration has emerged as an increasingly accepted approach to improve the mechanical connection between stump and prosthesis after limb amputation. Through an intramedullary titanium implant which is connected to a transcutaneous abutment, a direct and durable link between skeleton and prosthetic device is achieved. Conventional sockets are thus not necessary, and full range of motion can be maintained in the proximal joints. The OPRA (Integrum, Sweden) system was the first of this kind, having been developed by Prof. Rickard Brånemark. More recently, the eOPRA (also referred to as osseointegrated human-machine gateway, OHMG) was presented, which harnesses the transcutaneous port of the osseointegrated implant to establish a connection to permanently implanted neuromuscular electrodes. Wires are tunnelled through the implant, so that the eOPRA neither requires telemetry nor implanted active electronic components (see Fig. 14.2). However, it relies on connectors between the wires and the electrodes, which may increase the risk of implant failure due to fluid intrusion or wire breakage. Epimysial electrodes

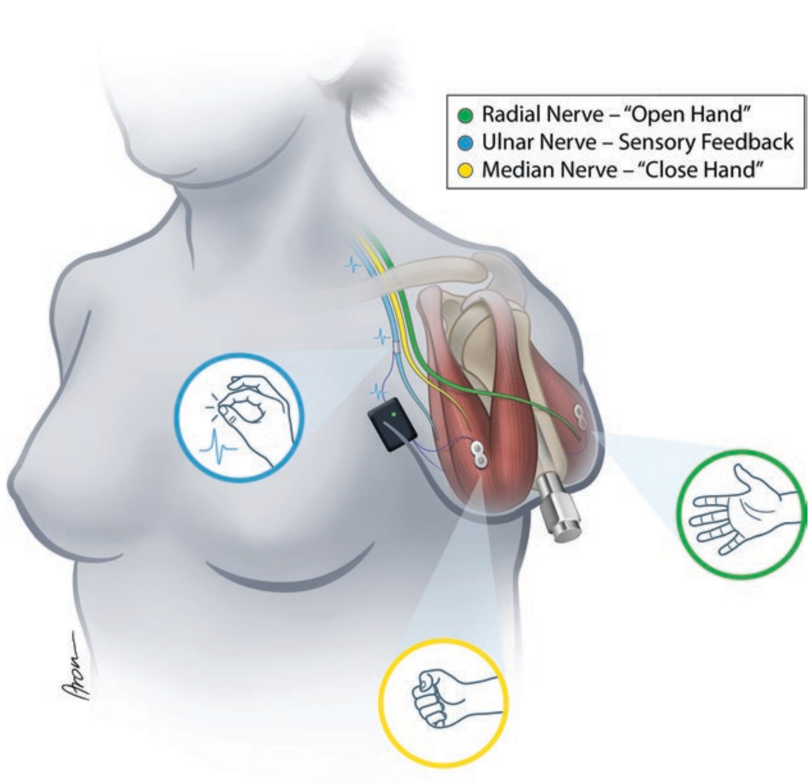

Fig. 14.2 The eOPRA combines the use of an osseointegrated titanium implant for prosthesis attachment with implanted neuromuscular electrodes for bidirectional functional interfacing. The electrode wires are tunnelled through the transcutaneous titanium implant, thus no telemetry is needed. The figure shows two epimysial electrodes placed on reinnervated muscles in a transhumeral amputee, as well as the respective cognitive signals for prosthetic control. A cuff electrode is placed around the ulnar nerve for sensory feedback. (© Aron Cserveny for Oskar Aszmann)

are used for recording EMG signals, and nerve cuff electrodes are employed for sensory feedback, effectively closing the loop of upper limb prosthetic control. The prosthetic device can thus be connected to the patient's bone, nerves and muscles. The eOPRA has been used in human studies on four transhumeral amputees for up to 7 years, demonstrating chronic functionality and functional benefits for patients in daily life [14]. In two of the patients which also underwent targeted muscle reinnervation, the first EMG signals could be registered as early as 1 month after surgery through the epimysial electrodes. Similar to the results of the IMES study, this facilitates an accelerated rehabilitation protocol after TMR. For further details, please see Chap. 6. Advantages compared to the IMES system include implementation without the need for a socket and inclusion of a feedback mechanism. However, similarly to the IMES, adequate stump length is necessary for the osseointegration, and glenohumeral amputees are therefore not suitable. Also, while chronic sensory feedback through nerve stimulation presents an important step forward, this approach is currently not able to restore natural touch perception. The sensations elicited through peripheral nerve stimulation are frequently described by patients as electrical, vibratory or twitching [16].

Flat Coil Technology with Central Implant

In order to offer implantable solutions which are applicable at all levels of amputation, including glenohumeral amputees, different design approaches need to be chosen. Instead of a circumferential coil, as is used in the IMES system, a flat coil technology can be implemented in order to establish a wireless communication and power supply link. This approach has been frequently used in other biomedical devices, such as cochlear or retinal implants, and allows for flexible positioning within the body. Two such systems have been developed to detect EMG signals for prosthetic control.

The MyoPlant was developed in a cooperation between academic and industry partners [9]. It consists of a central implant connected to four to eight epimysial electrodes. These record EMG signals, which are then transmitted by the central unit to the prosthesis via radiofrequency transmission. Power to the implant is also supplied wirelessly, using a transcutaneous inductive link from an external battery. A major advantage of this fully implantable flat coil design is that placement of the central unit during surgery is flexible and can thus accommodate various anatomical requirements. Regarding a potential clinical application in glenohumeral amputees, the MyoPlant system can be placed just below the clavicle over the pectoral muscle, to provide a safe and durable link for transcutaneous signal transmission (see Fig. 14.3). So far, the MyoPlant has been tested extensively in several preclinical studies, where its long-term stability was assessed

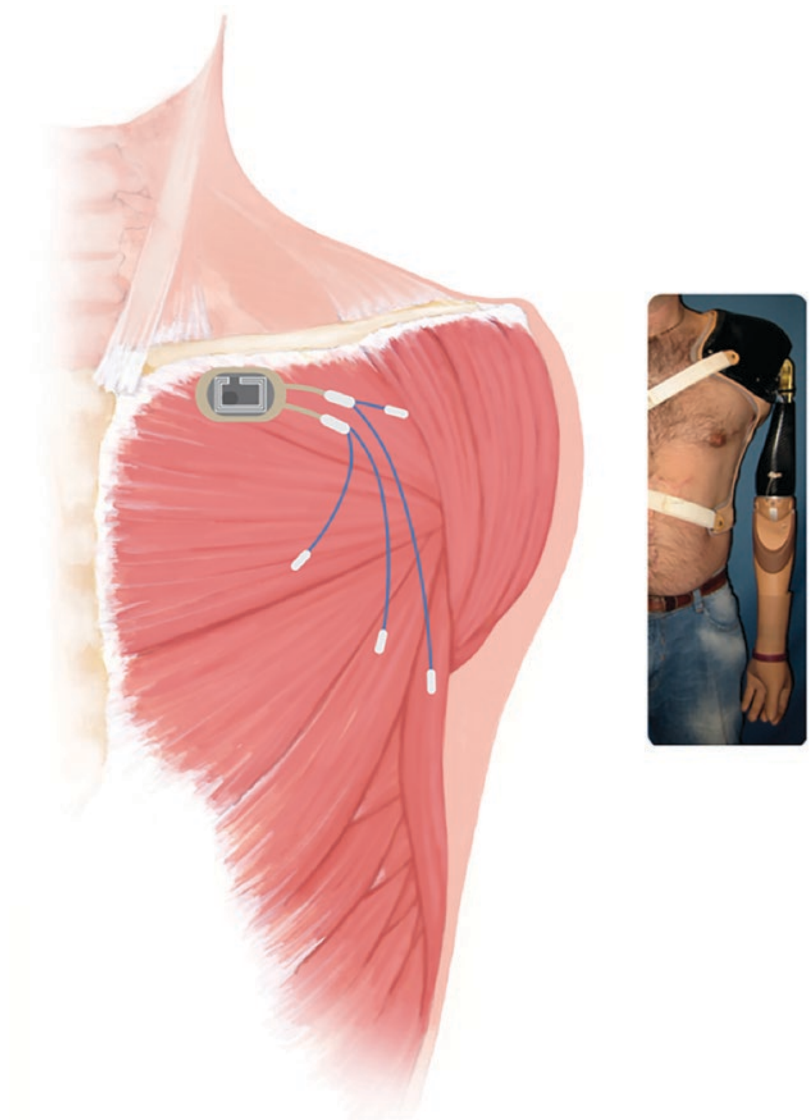

Fig. 14.3 Possible human application of the MyoPlant system. The central unit is placed identically to cardiac pacemakers and the electrodes are implanted epimysial to the targeted muscles. In this scenario, the electrodes receive signals from three separate pectoralis parts and the latissimus dorsi muscle after TMR surgery before being transmitted by the central unit wirelessly to the prosthesis. The system can be equipped with up to eight electrodes to increase the number of muscle signals. (Figure reprinted with permission from Wolters Kluwer [2])

in rats, sheep and rhesus monkeys [2, 10]. Chronic implantation in large animals demonstrated its reliable ability to record EMG data with low crosstalk between agonist and antagonist muscles. A drawback of the MyoPlant system is that it relies on connectors between central unit and electrodes, which represents a predilection site for wire breakage. Also, sensory feedback is not featured in the current design.

The MIRA ("Myoelectric Implantable Recording Array") is a similar solution, which was developed by Ripple Neuro Inc. (Utah, USA). Its central unit is connected to eight silicone leads, each of which carries four electrode contacts (see Fig. 14.4). The leads are placed intramuscularly, in order to gather EMG information from different locations within each muscle. A polypropylene anchor is placed at the end of each intramuscular lead, which ensures fixation within the muscle. In total, the MIRA can record myosignals from 32 individual channels. The central unit is placed directly under the skin and transmits the gathered data to an externally aligned transceiver disc via infrared communication. Power supply is provided through inductive coupling. Similar in its basic design to the MyoPlant, it can also be placed in various anatomic locations and does not require a defined stump length. Also, it offers the advantage of being one complete unit, while the MyoPlant requires assembly of different components via damage-prone connectors. The MIRA has been tested extensively regarding material safety and biocompatibility. Large-animal studies have been performed in dogs and sheep for up to 2 years, demonstrating its ability to chronically transmit stable and highly selective EMG signals from individual muscles (unpublished data). First in human testing is currently being planned. A drawback of the current system is that it does not include sensory feedback. However, the next generation of the MIRA is being designed to include the option for bidirectional transmission. Also, given its high number of channels, the MIRA may be used together with advanced control algorithms, which are able to determine the firing pattern of individual spinal motor units from the activity of reinnervated muscles (see below).

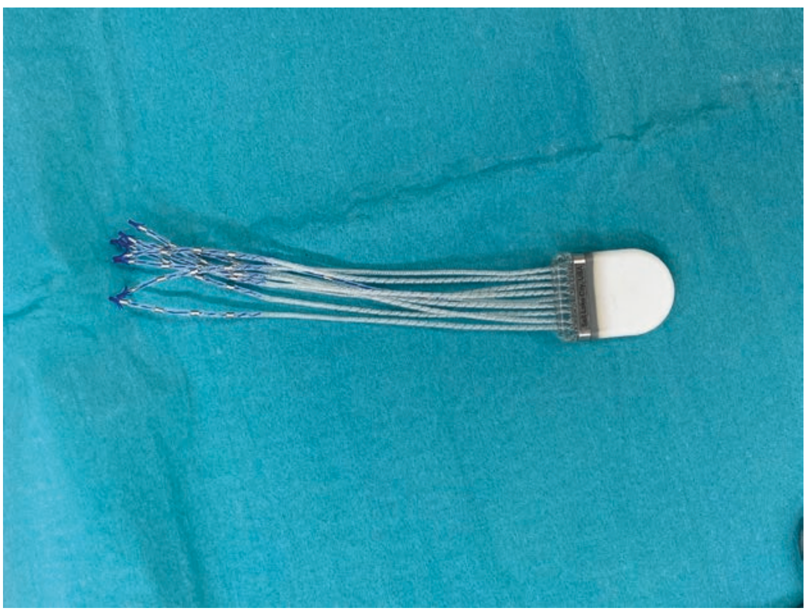

Fig. 14.4 The MIRA implant (Ripple Neuro Inc., Utah, USA) consists of a ceramic-encased central unit which is connected to eight intramuscular silicone leads. Each of the leads carries four steel electrode contacts as well as an anchor for intramuscular fixation. The central unit gathers the EMG signals and sends them to an external transceiver via infrared transmission

Future Outlook: Implantable High-Density EMG Electrodes

With the technological advances described above, an important step forward has been made towards implantation of EMG-triggered systems in clinical practice. This improves signal acquisition and reduces disadvantages of surface EMG as mentioned before. However, most of the systems described only offer between four and eight individual signals, which translates into a maximum of four intuitive degrees of freedom. While these systems lead to a more natural control of prosthetic devices which requires less effort by the user, patients will still be limited to a low number of individual movements, far from replacing the numerous intricate motions of the human hand.

As described in previous chapters, TMR provides additional axonal input to each reinnervated muscle, since highly capable nerves such as the median or the ulnar are used to drive cognitively simple muscles such as the biceps or the triceps. Research has shown, that high-density electrode grids placed over such muscles can be combined with advanced decoding algorithms in order to estimate the actual neural drive of the motor nerve used for reinnervation [5]. So far, this represents the only existing option to access the activity of individual motor neurons and is therefore a major milestone towards highly advanced and natural prosthetic control. Such high-density interfaces, however, still face the well-known problems of superficial electrodes. Therefore, implantation of these multichannel systems will allow to fully harvest the potential of motor unit decoding [7]. The concept of motor unit identification using different implantable muscle electrodes has so far been validated in the acute setting, in animal as well as human subjects [11, 12]. Current studies are ongoing to further develop this approach, evaluating its full potential and biosafety during long-term implantation of high-density electrode grids, after which translation into human subjects will be conducted. In its final application, this implantable system also aims to include natural sensory feedback, through mechanical stimulation of reinnervated dermal matrices. Through a combination of muscle reinnervation and dermal matrix implantation, a cognitive representation of the missing hand will be created within the stump. Together with advanced implanted electronic systems as well as specific mathematical decoding algorithms, this approach aims to create a truly natural substitution of the lost limb (see Fig. 14.5).

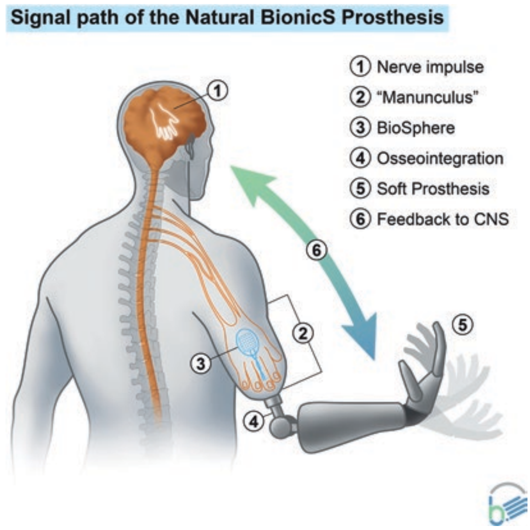

Fig. 14.5 A schematic illustration of truly natural bionic limb replacement, representing the goal of our current research efforts. The neural impulses (1) directed to the missing hand travel from the brain to the "manunculus" within the stump (2). The manunculus describes a surgical concept, which aims to recreate the cognitive representation of the missing hand, employing a combination of targeted nerve transfers and dermal matrix transplantation. In a biosphere (3), which consists of different afferent as well as efferent electrodes, the biological signals are acquired and sent to the prosthetic device, which is attached to the stump via osseointegration (4). Soft robotic hands (5) will be used, which have recently been developed in order to more closely mimic the natural characteristics of the human hand. Sensors within the device send feedback impulses through the biosphere back to the brain (6), in order to close the loop of prosthetic control and promote natural use as well as device embodiment. (© Aron Cserveny for Oskar Aszmann)

Conclusion

The use of implantable EMG sensors enables the extraction and transmission of selective, high-quality myosignals, without crosstalk or other signal disturbances. While the risk of infection and additional surgery needs to be considered, implantable devices nonetheless represent a major improvement compared to current surface electrodes. Both the IMES and the eOPRA have been used in combination with selective nerve transfers in above-elbow amputees, leading to long-term intuitive and dexterous control of robotic arms. Due to the placement of sensors close to the muscle, EMG signals can be detected early after nerve transfer surgery with significant decrease in rehabilitation time. The MyoPlant and the MIRA have so far only been tested preclinically but offer the advantage of flexible placement during surgery and can thus be used in glenohumeral amputees as well. The use of implantable sensors will have an impact on the surgical procedure of TMR, since these sensors can record from deep and small muscles which may thus become new targets for nerve transfers. Future systems should aim to combine the benefits of implantable high-density electrode grids with solutions for natural sensory feedback, in order to close the loop and promote intuitive prosthetic use as well as device embodiment.

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