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Wearable Neural Prostheses

Restoration of Sensory-Motor Function by Transcutaneous Electrical Stimulation

Motor and sensory functions can be partly restored using electrical stimulation (ES). ES can be delivered through different interfaces (Figure 1) such as implanted electrodes (epineural or intramuscular electrodes) or transcutaneous electrodes [1]. It is important to point out that this is a schematic classification and that the invasiveness/selectivity ratio can be modified by changing the structure of the electrodes. For example, as shown in this article, the selectivity of the surface electrodes can be increased by using electrode arrays, and the same applies to other types of electrodes (e.g., tripolar and multichannel cuffs).

In this article, we focus on the least invasive interface: transcutaneous ES (TES), i.e., the use of surface electrodes as an interface between the stimulator and sensory-motor systems. TES is delivered by a burst of short electrical charge pulses applied between pairs of electrodes positioned on the skin. Monophasic or charge-balanced biphasic (symmetric or asymmetric) stimulation pulses can be delivered. The latter ones have the advantage to provide contraction force while minimizing tissue damage [2].

The controlled voltage applied at the electrodes generates a current between the anode and cathode, thereby changing the relative concentration of ions (e.g., potassium and sodium), resulting in hyperpolarization and depolarization of excitable cellular membranes. The ES activates the sensory-motor systems by generating action potentials of the efferent fibers (motor neurons), resulting in contraction of the muscle that is innervated by the motor neurons, or afferent fibers, resulting in reflex activity of one or more muscles and activation of higher centers within the central nervous system. In principle, it is possible to directly activate the muscle fibers, but the excitation thresholds (charge amount) are significantly higher (>100×) compared with the thresholds when activating neural tissues. It is very difficult to generate muscle forces required to produce functional movement with direct stimulation of muscles. Thus, most ES applications target the neural tissues entering the muscle groups [3] to produce a functional contraction.

During volitional movement, the motor neuron asynchronously activates the muscle fibers. The activation of the nerve motor units is controlled via synaptic activation and follows a well-specified order, allowing fine control of contraction from low to tetanic level. The mechanism of ES-generated contraction is different: the electrical field activates the larger (alpha) nerve fibers first (and smaller fibers close to the electrode) synchronously. This not only prevents fine control of muscle force but also increases the rate of fatigue.

ES has been suggested for use as an orthosis or a muscle trainer. More recently, ES has been suggested as a therapeutic modality [4] and sensory augmentation [5]. To achieve effective restoration of functions, it is crucial to develop ES systems able to selectively activate the sensory or motor systems. At the same time, ES systems have to be simple for daily application in the clinical and home environment.

Surface electrodes are noninvasive and easy to reconfigure for different functional modalities. However, they provide selective activation only for muscles close to the surface. They also generate discomfort, since skin receptors are also activated. Inhomogeneities in the current distribution at the electrode–skin interface can also lead to increased discomfort. Despite these limitations, transcutaneous electrodes are by far least invasive and are therefore regularly used for therapeutic applications of ES [6].

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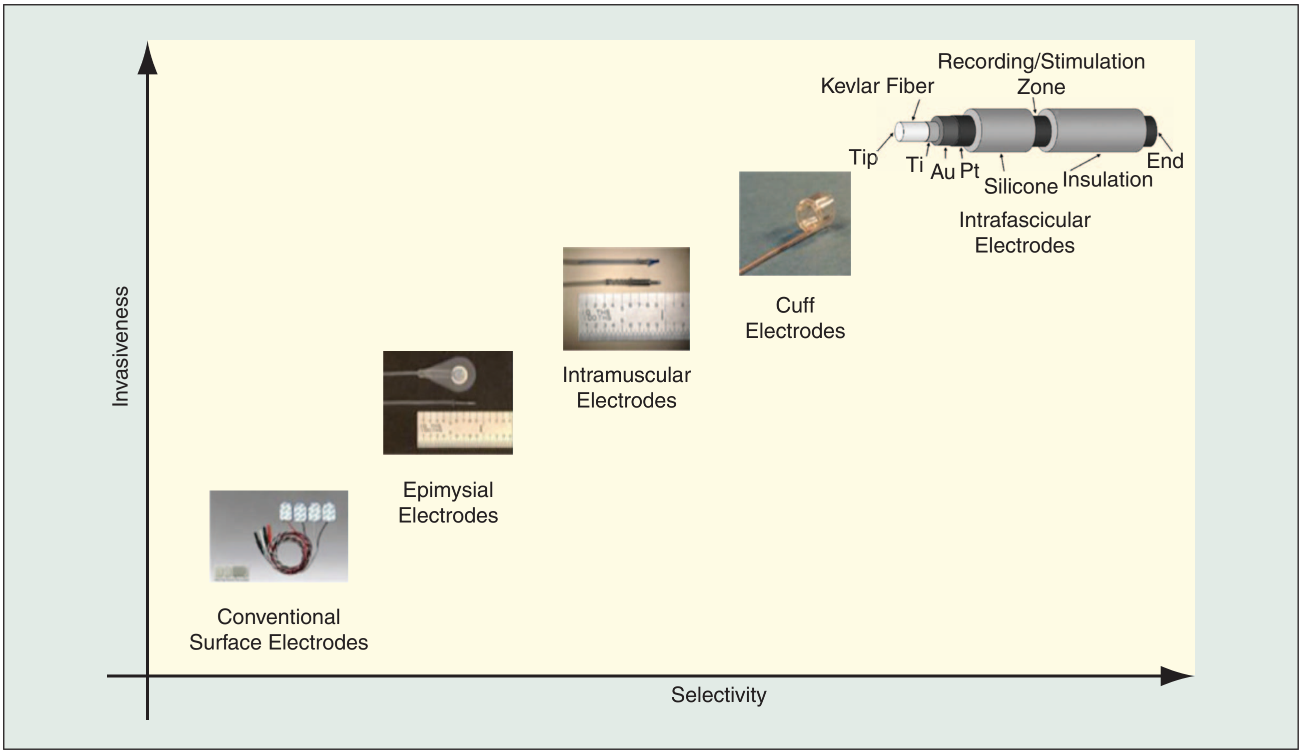

Fig. 1. The different types of electrodes applied to interface peripheral nerves classified regarding invasiveness and selectivity.

Since 1970, TES has been suggested for the restoration of hand grasp in individuals with cervical spinal cord lesions [7]. The human hand is a dexterous organ that can be used to perform many different grasp and prehension types and are used for activities of daily living (see Figure 2) [8]. The grasping function is achieved through a synergistic activity of many muscles, all innervated by the radial, median, and ulnar nerves branching to various muscles and sensory systems in the forearm, as shown in Table 1.

The pattern of muscle activity that occurs during grasping depends upon the type of grasp required, the size and mass of the object to be manipulated, and the procedure that is to be performed. An example in the animal study of monkeys shows a variety of muscle activations.

This article summarizes the evolution of TES approaches to restore grasping and describes the advantages of current and limitations and possible future applications.

First Generation of Wearable ES Devices for Hand Grasp Restoration

A neuroprosthesis (NP) can be considered as a multichannel ES system that is used to restore functional movements of muscles after damage to the nervous system. Various NPs for grasp restoration based on TES have demonstrated clinical benefits; these include the Bioness H200 (formerly Ness Handmaster) [9] and Bionic Glove [10] (see Figure 3).

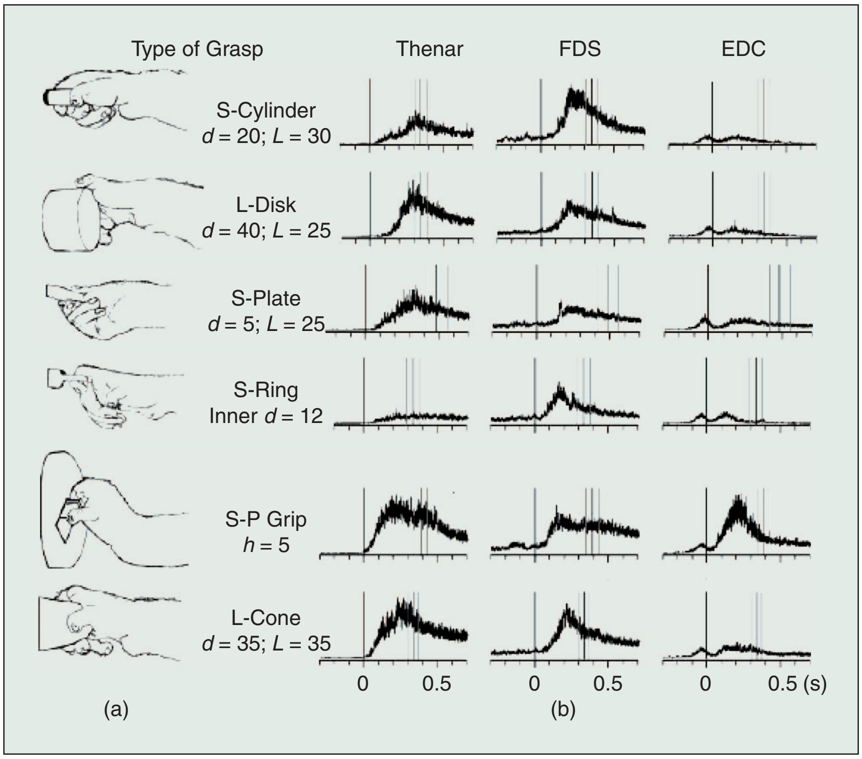

Fig. 2. (a) An example of muscular activities during grasping recorded with intramuscular electrodes. The vertical lines in (b) show the time of grasping, and 0 indicates the time at rest just before the beginning of grasping. FDS: flexor digitorum superficialis m.; EDC: extensor digitorium communis m. Modified from (8) and reprinted with permission.

> **The selectivity of the surface electrodes can be increased by using electrode arrays, and the same applies to other types of electrodes.**

The H200 NP uses textile electrode patches that are positioned appropriately during the setup. The patches are housed in the plastic wrist splint that is customized to fit the size of the forearm and hand. The plastic splint locks the wrist in position; therefore, the wrist flexion and extension are eliminated although the wrist flexors and extensors are activated in parallel with finger flexors and extensors. The operation of the H200 is preprogrammed to allow exercise, palmar and lateral grasps with electrodes over the thenar muscles, finger flexors, finger extensors, and carpal tunnel (anode). The Bionic Glove uses modified self-adhesive electrodes with metal studs mounted on the rear to connect with wire mesh embedded into the inner side of the garment (glove). The system uses three cathodes over the thenar muscles, finger extensors and flexors, and one anode over the carpal tunnel. The Bionic Glove operates as a tenodesis grasp enhancer, and it can be used only by patients with sufficient wrist control. Both NPs were designed for the use in tetraplegic patients but both found more recent application in the neurorehabilitation of stroke patients. Based on the experiences and findings from clinical trials with the H200 and Bionic Glove, the UNA FET and Compex Motion stimulator have been developed and used in several studies for therapy of stroke and spinal cord-injured patients [4].

All the systems share the same problems: somewhat limited muscle selectivity, increased rate of muscle fatigue, and complexity in application due to the problems with positioning of the electrodes.

Second Generation of Wearable ES Devices for Grasping Restoration

Electrode Array Technology

Although transcutaneous electrode positions for selective activation of superficial muscles can be determined on an individual basis, it is a time-consuming and error-prone process [11]. Furthermore, the electrode positions are dependent upon the relative orientation of the underlying muscles with respect to the skin surface; for example, supination and pronation can cause up to 4 cm of movement of the optimal electrode positions for finger flexors. Similarly, contraction of the underlying muscles can also cause relative displacements of the electrode positions. The lack of selectivity when using TES electrodes is especially important when designing NP for the upper arm, which typically uses multiple fixed electrode positions. Consequently, assessment tools are required to evaluate the degree of selective finger activation that can be achieved using TES.

One solution to improve the selective activation of the finger muscles is to dynamically switch the ES between an array of small transcutaneous electrodes positioned over the portion of the forearm, where the major forearm nerves are branching to individual muscles (see Figure 4).

The technique was first used to map wrist torques and finger forces from single and multiple transcutaneous electrodes mounted in an annular ring [14]. More recently, transcutaneous electrode arrays have been used to improve functional grasping [12]. The arrays have been fabricated from flexible straps with isolated

Table 1. List of muscles used to obtain upper limb and hand movements, related spinal segment, and peripheral nerves.

Muscle	C6	C7	C8	T1	Nerve
Ext. carpi radialis longus (C6)	X	X	-	-	Median
Pronator teres	X	X	-	-	Median
Flexor carpi radialis (C7)	X	X	-	-	Median
Ext. carpi radialis brevis	X	X	X	-	Radial
Anconeus	-	X	X	-	Radial
Triceps brachii (C7)	X	X	X	-	Radial
Ext. digitorum (C7)	-	X	X	-	Radial
Ext. digiti V.	-	X	X	-	Radial
Ext. indicis	-	X	X	-	Radial
Ext. carpi ulnaris	-	X	X	-	Radial
Abductor pollicis longus	-	X	X	-	Radial
Ext. pollicis brevis	-	X	X	-	Radial
Ext. pollicis longus	-	X	X	-	Radial
Flexor carpi ulnaris	-	X	X	-	Ulnar
Flexor digitorum superficialis (C8)	-	X	X	X	Median
Flexor digitorum profundus (C8)	-	X	X	X	Median and ulnar
Flexor pollicis longus	-	-	X	X	Median
Pronator quadratus	-	-	X	X	Median
Abductor pollicis brevis	-	-	X	X	Median
Flexor pollicis brevis	-	-	X	X	Median
Opponens pollicis	-	-	X	X	Median
Adductor pollicis	-	-	X	X	Ulnar
Adductor digiti V.	-	-	X	X	Ulnar
Flexor digiti V.	-	-	X	X	Ulnar
Opponens digiti V.	-	-	X	X	Ulnar
Lumbricals	-	-	X	X	Median and ulnar
Interossei (T1)	-	-	X	X	Ulnar

TES has been suggested for the restoration of hand grasp in individuals with cervical spinal cord lesions.

conductive rubber patches [14], flexible PCBs with individual electrolyte-soaked pads [13], as well as novel, embroidered electrode structures [15]. In this approach, the analysis of the desired characteristics of the electrode array according to the specific application is particularly important. This can be achieved by using finite element model simulations. Specifically, the influence of electrode configurations, pad sizes, and electrode material properties on muscle activation for a variation of tissue properties and nerve–electrode distances have been analyzed [16], [17].

After the development of the electrode array, the main issue is to develop a method to select the optimal electrode location and stimulation parameters. A promising automatic algorithm to achieve this goal has been recently developed [18]. Seven angles (proximal interphalangeal and metacarpal phalangeal index and ring finger joint rotations, wrist extension/flexion and ulnar/radial rotation, and pronation/supination of the forearm) were recorded while stimulating the different channels. The optimal electrode location was determined as a combination of pads that led to fingers, wrist, and forearm rotations being similar to the trajectories of healthy individuals when grasping.

Embroidered Electrode Technology

The use of embroidered electrode technology can also improve muscle selectivity and practicability of this approach. Multiple sets of embroidered electrodes can be combined into a single garment, which can be used to restore hand grasp. New materials and techniques allow seamless integration of multiple surface TES electrodes into textile garments or clothing. These techniques enable the implementation of new TES systems based on a multichannel stimulation approach, which allows us to perform real-time spatial and temporal variations of the electrical current density on the skin surface and in deeper tissue layers. Dynamic real-time adjustments of the electrode size and location for multiple regions in a single garment can be made possible. This new approach can produce better muscle selectivity and improved muscle activation patterns compared with state-of-art TES systems, which operate with predetermined electrode positions. The combination of full textile integration and the new multichannel TES approach increases the ease of use, stimulation, and wear comfort of TES and enables a variety of new applications for the medical and consumer market.

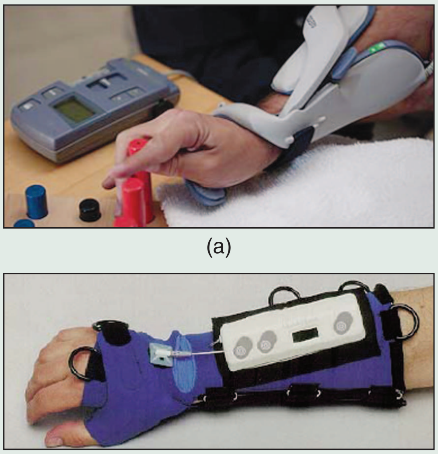

Fig. 3. The (a) HandMaster (9) and (b) Bionic Glove (10).

Possible Future Developments

The use of wearable electrode arrays can significantly improve the usability of NP for functional restoration. A combination of well-defined spatial distribution of the current densities with the innovative approach of routing the stimulation current toward deeper muscles, as proposed by Prochazka and colleagues [19], can enable more complex functions for a natural variety of grasps. This later technique uses minimally invasive passive implants that redirect the current delivered by a TES system to muscles that cannot be directly reached by TES.

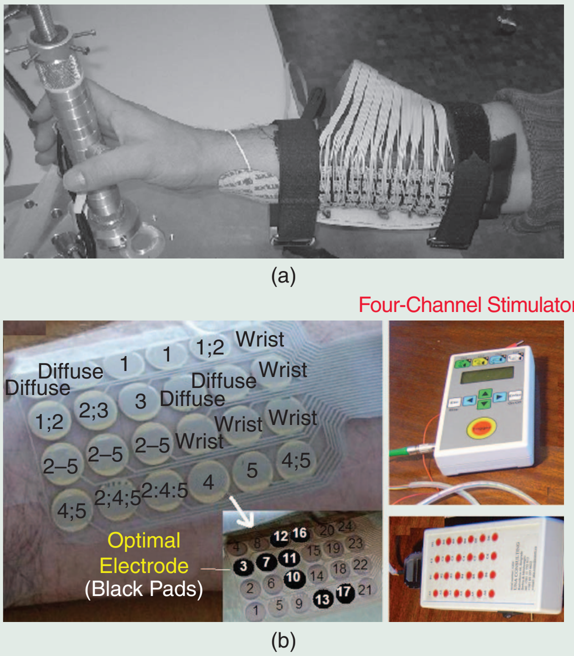

Fig. 4. Two electrode arrays developed by the authors. The system developed at (a) ETH Zurich (12) and (b) the University of Belgrade (13).

Inhomogeneities in the current distribution at the electrode–skin interface can also lead to increased discomfort.

Wearable array electrodes can also open up new possibilities for new hybrid applications. For example, it could be possible to combine surface NP for grasping function restoration with passive or active mechatronic devices for the restoration or assistance of upper limb functions [20]. In fact, a robotic system for hand function restoration is quite difficult to be developed for the intrinsic complexity of hand movements, while NP cannot be built in a practical manner to control or assist upper arm movements. Individual limitations of robotic- and NP-based therapies can be eliminated by combining the two modalities. Immediate advantages include promotion of normal muscle activation, the possibility for practice of normal patterns earlier during rehabilitation, reduced requirements on physical therapist support, and hand activation.

At the same time, the development of the targeted muscle reinnervation demonstrated that it might be possible to integrate into the NP the sensory feedback to the patient. In particular, it has been shown that sensory feedback can improve performance and contribute to cortical reorganization [21]. Moreover, Kuiken et al. have shown that after targeted muscular reinnervation it is possible to restore sensations related to touch [22] (see Figure 5).

Wearable TES systems can also be used to deliver sensory feedback to amputees. Specific shapes of garments can be used for specific applications.

In summary, wearable ES systems (i.e., NP with surface electrodes) are becoming an important element in the treatment of patients in the acute and subacute phase of paralysis caused by the central nervous system lesion. The integration of smart textiles and automatic lifelike control is bridging the gap of nonpracticality for use in clinical and home environment. The surface NPs are not likely to become an orthosis for tetraplegic patients, and the use of implantable interfaces in this patient population is much appreciated, but the methods developed for selective stimulation and intelligent control are applicable to these systems.

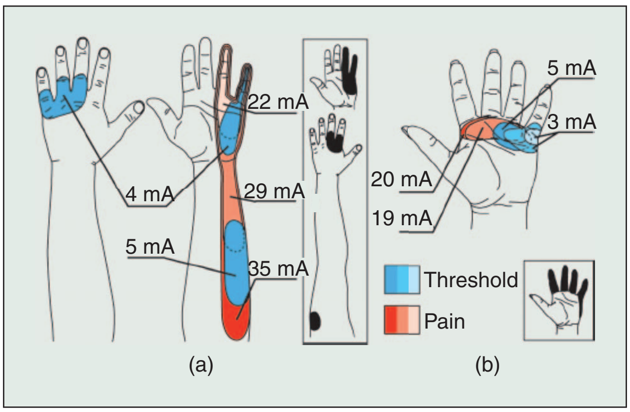

Fig. 5. Projected sensations elicited by ES for two patients (a) and (b) (22).

Silvestro Micera received his university degree (laurea) in electrical engineering from the University of Pisa in 1996. During 1999, he was a visiting student at Aalborg University. He received his Ph.D. degree in biomedical engineering from Scuola Superiore Sant'Anna in 2000. From 2000 to 2009, he was an assistant professor of biorobotics at Scuola Superiore Sant'Anna, where he is now the head of the Neural Engineering Group. In 2007, he was a visiting scientist at Massachusetts Institute of Technology, Cambridge, with a Fulbright Scholarship. Since 2008, he has been the head of the NP Control Group and an adjunct assistant professor at the Institute for Automation, Swiss Federal Institute of Technology, Zurich, CH. In 2009, he was the recipient of the Early Career Achievement Award of the IEEE Engineering in Medicine and Biology Society. He is the author of several scientific papers and international patents. He served as a guest editor of several biomedical engineering journals. He is currently an associate editor of *IEEE Transactions on Biomedical Engineering* and *IEEE Transactions on Neural Systems and Rehabilitation Engineering*. He is also a member of the editorial board of *Journal of Neuroengineering and Rehabilitation* and deputy editor-in-chief of *IEEE Engineering in Medicine and Biology Magazine*. His research interests include the development of hybrid neuroprosthetic systems (interfacing the central and peripheral nervous systems with artificial systems) and mechatronic and robotic systems for function and assessment restoration in disabled and elderly persons.

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