Electrodes for transcutaneous (surface) electrical stimulation

Thierry Keller and Andreas Kuhn

Abstract—In therapeutic and functional applications transcutaneous electrical stimulation (TES) is still the most frequently applied technique for muscle and nerve activation despite the huge efforts made to improve implantable technologies. Stimulation electrodes play the important role in interfacing the tissue with the stimulation unit. Between the electrode and the excitable tissue there are a number of obstacles in form of tissue resistivities and permittivities that can only be circumvented by magnetic fields but not by electric fields and currents. However, the generation of magnetic fields needed for the activation of excitable tissues in the human body requires large and bulky equipment.

TES devices on the other hand can be built cheap, small and light weight. The weak part in TES is the electrode that cannot be brought close enough to the excitable tissue and has to fulfill a number of requirements to be able to act as efficient as possible.

The present review article summarizes the most important factors that influence efficient TES, presents and discusses currently used electrode materials, designs and configurations, and points out findings that have been obtained through modeling, simulation and testing.

Index Terms—High impedance electrode-skin interface, Homogeneous current density, Stimulation electrodes, Transcutaneous electrical stimulation.

I. INTRODUCTION

TRANSCUTANEOUS electrical stimulation (TES) is a technique frequently used in physical therapy or in socalled neuroprostheses to activate excitable tissue in the human body from the skin surface. Electrodes are placed on the skin at locations where the underlying tissue is intended to be activated. Electrical current is injected through at least one pair of electrodes and generates a potential gradient in the underlying tissue. The potential gradient depolarizes excitable tissue under the electrodes that serve as cathode. Above a certain threshold potential excitable tissue is activated.

Many applications use this mechanism for either unspecific or more specific activation of nerve cells, skin

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receptors, other sensory organs or motor units. Examples of such applications are:

- Therapeutic electrical nerve stimulation (TENS), which aims at activation of unspecific sensory nerves;
- Reflex stimulation, which activates distinct afferent nerves like the peroneal nerve for dropped foot stimulation or the pudendal nerve stimulation against bladder incontinence;
- Muscle activation, either direct motor unit activation when muscles are denervated or via motor nerves, against muscle atrophy or multi-site activations for generating more complex limb movements like walking or hand grasp;
- Direct current (DC) stimulation used in intophoresis (diffusion of medication) or electroporation
- Quasi-DC stimulation for galvanic vestibular stimulation;
- Defibrillation for sinoatrial node reactivation.

For all these applications specific types of electrodes, electrode sizes, and electrode configurations are used. This review article will shortly introduce the structures and characteristics of the tissues important to TES. Most important for the sensation of TES is the skin layer with its inhomogeneities. However, for the activation of deeper structures, e.g. motor axons or muscle fibers, the fat and muscle tissues have a significant influence on activation levels and activation selectivity. Besides the different tissue properties the stimulation principle (resistive or capacitive stimulation) influences the design of stimulation electrodes. For inductive stimulation (magnetic stimulation) coils instead of electrodes are used but will not be discussed here. Other design aspects are electrode sizes, shapes and configurations of multiple electrodes. All design aspects have a great influence on the comfort and performance of TES electrodes.

II. SKIN AND ELECTRODE-SKIN INTERFACE MODELS

A. Skin anatomy

For the characterization of the electrode-skin interface we first should have a look at the skin and its layered structure. The skin consists of the epidermis and the dermis, see Fig. 1. It has a variable thickness from less than a millimeter at the eyelid up to more than a centimeter at the palm or foot. Some skin is hairy, some regions are especially sensitive, e.g. face and finger tips, and some are not (back, foot soles).

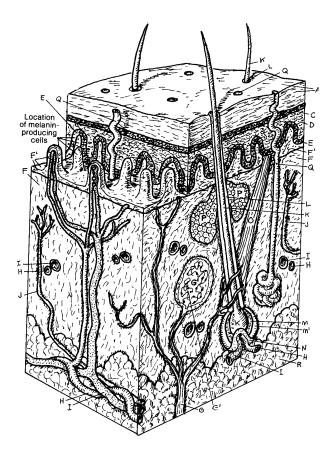


Fig. 1. Anatomical drawing from skin layers. Epidermis: A) Stratum Corneum; B) Stratum Lucidum; C) Stratum Granulosum; D) Stratum Spinosum; E) Stratum Basale (germinating layer). Dermis: F) Connective Tissue; G) Nerve; H)Artery; I) Vein; J) Limphatic Vessel. Hair: K) Shaft; L) Follicle; M) Bulb; Q) Sweat Gland; R) Superficial Fascia;. Figure originates from [1].

B. Epidermis

The epidermis has a layered structure. The outer layer, the stratum corneum (SC), consists of a lipid-corneocyte matrix crossed by appendages like sweat glands or hair follicles. The SC has the highest resistance of about $10^5 \,\Omega \text{cm}^2$ and a capacitance of ~ $0.03 \,\mu\text{F/cm}^2$ [2] when small currents are applied. However, through electroporation, a high increase in permeability of the cell membrane caused by an externally applied electrical field, the skin impedance drops significantly. The lipid matrix has about 70-100 lipidcorneocyte bilayers [3, 4]. Electroporation occurs when the voltage drop across each bilayer of about 300-400 mV is applied, which is a voltage drop through the SC of about 30 V [2]. Lower voltage drops are too small for electroporation [5]. Inner layers of the epidermis have gradually lower impedances as they come closer to the stratum basale, the germinating layer where all epidermal cells arise. A fine meshed vascular network lies deep to the avascular epidermisin, the dermal cones and serves as nutrition source. The outer the layers the more they are dehydrated, keratinize and peel off with sweat or bath. For the epidermis brick structured models are used [6]. An example of such a brick model is depicted in Fig. 2. There are two main pathways: The lipid-corneocyte matrix pathway as described above and the appendageal pathway. The latter is often model using cylindrical tubes filled with an electrolyte that cross the SC.

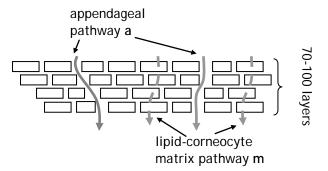


Fig. 2. The stratum corneum (SC) is often modeled as a layered brick model. The impedance of the SC consists mostly of dried out keratin layers with very high impedance. Appendages cross the skin and are preferred pathways for electrical current [7].

C. Dermis

The dermis is full of bundles of fibrous connective tissue, blood and lympic vessels, sensory receptors and related nerves and glands. The electric impedance of the dermis is much lower than the much dryer epidermis. It is modeled either as equipotential area (when the epidermis is modeled in more detail) or as homogeneous volume conductor with a resistivity of about the fat layer. In simplified models the epidermis and dermis are modeled as skin layer using a single volume conductor (e.g. conductivity $\rho=300 \Omega m$; permittivity $\epsilon r=6000$).

D. Lumped skin model

For modeling purposes the skin layer comprising both the matrix and appendageal pathways can be modeled with lumped resistors and capacitors as depicted in Fig. 3. In a simplified version the two pathways are not differentiated, what is debatable from a physical point of view and has been extensively studied [2, 7].

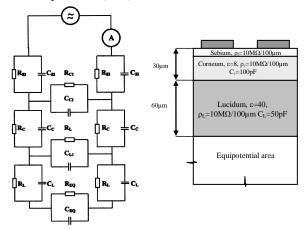


Fig. 3. Model of human skin: R_{el} , C_{el} = electrode impedance; R_C , C_C = sebium impedance; R_L , C_L = lucidum impedance; R_{EQ} , C_{EQ} = equipotential impedance (adapted from [2])

Nevertheless, this simplified lumped model Fig. 4a is most commonly used as electrode-skin interface model for stimulation and biopotential electrodes. In the case of biopotential electrodes a voltage source is added in series to model the half cell potential that occurs when a metal electrode is in contact with a electrolyte. This potential is also present at the interface of TES electrodes, however does not play an active role.

III. EFFECTS OF SKIN PARAMETERS

A. Non-linearity of skin resistance

For low currents in the μA range (when the applied voltage is lower than 1 V) the voltage-current dependence, hence the impedance, is linear in accordance to measured values [8]. For higher currents the skin impedance is a non-linear function of the current density. The non-linear skin resistivities were measured by Dorgen et. al. for current densities up to 5 mA/cm² [9]. For large electrodes (e.g. 5×5 cm2) such current densities are sufficient. However, when using smaller electrodes (e.g., on array electrodes) higher current densities can be required. We performed experimental measurements on human volunteers in order to obtain skin resistivities also at higher current densities (up to 15 mA/cm²). In vivo, the skin resistivity cannot directly be measured. A way to obtain the skin resistivity is using an equivalent network model, which is tuned to give the measured current-voltage response [10, 11]. Such a network model (see Fig. 4a) consists of a capacitor C_s in parallel with a resistor R_s representing the skin and a series resistor R_c for the plain resistive part (fat, muscle). Polarization voltage V_{Pol} (not depicted) can be neglected in surface electrical stimulation [9].

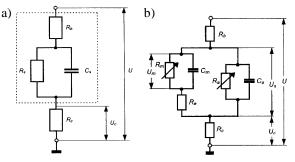


Fig. 4. a) Simplified lumped skin model; b) Slightly more complex model shows the two pathways. R_b = bulk (equipotential) impedance; R_m , C_m = matrix impedance; R_e = epidermis impedance; R_a , C_a = appendagal impedance; R_c = electrode impedance.

B. Skin and electrode inhomogeneities

Skin and electrode inhomogeneities have a great influence on the current density distribution. Both affect stimulation efficiency and comfort. As such, the design of electrodes is crucial for effective and comfortable stimulation [12]. Localized high current densities can cause discomfort or even skin burns [13]. Such high current densities can have different origins:

- Inhomogeneities of the resistance in the electrode material can cause locally high current densities and worsen stimulation comfort. The size of such inhomogeneities is usually a couple of millimeters [14].
- Current densities are higher at the edges of electrodes (see edge effects) [15].
- The skin layer has a complex structure with local inhomogeneities that lead to resistance changes [16, 17], which cause locally higher or lower current densities. Different sizes of inhomogeneities were identified: Small inhomogeneities from pores and sweat glands which have a size of 50 to 100 µm [2, 7]; larger inhomogeneities that are due to different water content

and due to different skin structures have a size of a couple of millimeters [18].

It is hypothesized that high resistance electrodes can improve the homogeneity underneath surface electrodes. Panescu et al. [17] presented a 2D finite element (FE) model with millimeter sized skin inhomogeneities to analyze this hypothesis. They showed that high resistivity electrodes can improve the distribution of the current density underneath surface electrodes. Sha et al. [19] integrated a one pore sized (μ m) skin inhomogeneity in a 2D axis-symmetric FE model. They also found that higher electrode resistivities can reduce high current densities peaks produced by the skin inhomogeneities. In the following a more detailed 3D FE model is presented that allowed us to investigate large (mm) and small (μ m) inhomogeneities in the skin and also inhomogeneities in the electrode [20].

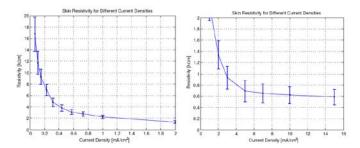
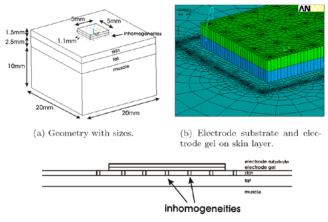


Fig. 5. Non-linear behavior of skin resistivity versus the current density measured experimentally on 7 human volunteers. Two charts are provided for visual clarity where the left one shows the skin resistivity for moderate densities and the right one for high current densities [20].

C. Small Skin Inhomogeneities (Pores, Glands)

Fig. 6 shows the geometry that was used to model small inhomogeneities within the skin structure.



(c) Schematic drawing of inhomogeneities in the skin layer.

Fig. 6. Geometry and mesh of the model used in [20] to analyze small inhomogeneities.

An array of small channels through the skin representing pores and glands (identified as black dots in Fig. 6a) were placed under the electrode surface with a density of 100 per cm² and diameters of 50 or 100 μ m (common values for a human forearm). A small electrode of 0.5×0.5 cm² was modeled because larger areas significantly increased the number of finite elements in the FE model. The tissue properties are given in Table 1 and the skin inhomogeneity (e.g. pore) had a resistivity of 1.4 Ω m[19]. A current of 5mA was applied between the stimulation electrodes and the plane underneath the volume representing muscle.

		Min	Standard	Max
Electrode interface	$\rho [\Omega m]$	1	300	10000
	ε_r	1	1	2000000
Skin	$\rho [\Omega m]$	500	700	6000
	ε_r	1000	6000	30000
Fat	$\rho [\Omega m]$	10	33	600
	ε_r	1500	25000	50000
Muscle	$\rho [\Omega m]$	2	3	5
(axial)	ε_r	100000	120000	2500000
Muscle	$\rho [\Omega m]$	6	9	15
(radial)	ε_r	33000	40000	830000
Cortical bone	$\rho [\Omega m]$	40	50	60
	ε_r	2400	3000	3600
Bone Marrow	$\rho [\Omega m]$	10	12.5	15
	ε_r	8000	10000	12000

Table 1. Resistivities and relative permittivities of different tissues. Columns "Min" and "Max" are extreme permittivity values from [18, 24-26]. The column "Standard" contains properties used in an FE model that was verified with experimental measurements [27].

D. Large Inhomogeneities (Water Content, Structure)

Larger inhomogeneities in electrode and skin were investigated using the same models for small and large inhomogeneities with slightly changed geometry. The inhomogeneities in the electrode and the skin were assumed to have a factor of 10 lower resistivity than the surrounding electrode gel resistivity or skin resistivity [17]. Either skin inhomogeneities or electrode inhomogeneities were modeled, but the combined effects were not investigated. The inhomogeneities had a diameter of either 0.2 cm or 1 cm [4, 17].

Detailed results from extensive simulations using the above models for small and large inhomogeneities have been published in [20]. Following conclusions could be made:

- The high current densities at the edge of surface electrodes compared to the center of the electrodes resulting from edge effects can be reduced by using a higher electrode gel resistivity.
- Locally high current densities occurring from large skin inhomogeneities can be decreased with high resistive electrodes. Compared to standard hydrogel electrodes $(300\Omega m)$ a high resistive electrode $(70k\Omega m)$ decreased the current density by 50% at the skin-fat interface. These results compare well with [17] where a more even current density distribution was predicted. However, for small skin inhomogeneities (e.g. pores), where much higher peak current densities are present, there was only a small improvement of 3% at the skin-fat interface. These simulation results are in agreement with an experimental study that showed only marginal comfort improvements when using high resistance electrodes [28] or gels [29].

In another study Sha et al. [19] predicted in a simulation study that for small inhomogeneities (pores) the current density distribution can be improved using high resistance electrodes, which could not be reproduced with the presented model. We found current densities inside the inhomogeneities increase deeper within the skin layer. This effect is more prominent in a 3D model as shown in [20] compared to the 2D model presented in [19]. In a 3D model the current can enter the pore from all sides, whereas the 2D case has only two boundary lines where the current can flow from the skin into the pore.

- Inhomogeneities in high resistivity electrodes cause locally high current densities. This effect increases for higher electrode gel resistivities. Therefore, electrode inhomogeneities should be avoided in the production process of high resistivity electrodes.
- The electrode gel resistivity should not be chosen too high. There is a trade-off between a more homogeneous current distribution due to a higher electrode gel resistivity and an unequal current distribution due to inhomogeneities in the electrode material. In general electrodes with smaller inhomogeneities in the electrode material can have a higher resistance.
- Our results indicated that that using electrode gel resistivities that are above the values of the skin resistivity ($\rho_{gel} > 700\Omega m$) should be favored. Lower gel resistivities always resulted in a less homogeneous current distribution. Significantly higher resistivities do not improve homogeneity much further and will only cause high voltages at the stimulation electrodes.

Besides inhomogeneities the influence of the edge effects on the localized current densities was investigated. The potential and the current density distribution were calculated using static FE model.

E. Electrode Edge Effects

Electrode edge effects play a significant role in the electrode design for defibrillation. High currents in the Ampere region cause skin damage mainly at the electrode edges because the current density there is higher than in the center [21].

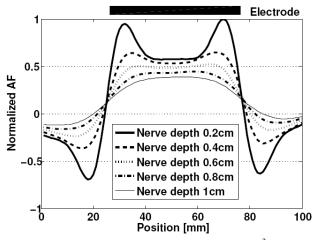


Fig. 7. AF at different depths underneath a $5 \times 5 \text{ cm}^2$ cathode ($\rho_{gel} = 300\Omega m$). Edge effects are largest for superficial nerves.

For TES applications electrode edge effects are less dangerous, however they have been studied intensively. Experimental setups were used to investigate skin damage cause by edge effects [13] and more complex installations were used to directly measure the potential distribution underneath the electrodes [22, 23]. Besides hazardous effects the influence of the electrode edge effects on nerve activation is of interest. It can be investigated using a volume conductor model for the calculations of the electrical potentials and the activation function (AF) that is basically the 2^{nd} spatial derivative of the potential distribution [15]. The AF depicted in Fig. 7 was calculated underneath the cathode at typical depths from the fat-muscle interface between 0.1 cm and 2.5 cm. These are depths where motor nerves can be expected in human arms.

The tissue and electrode impedance has a great influence on how the edge effects affect nerve activation. The edge effects are shown for an electrode 3×3 cm² size for electrode gel resistivities between 1 Ω m and 10k Ω m.

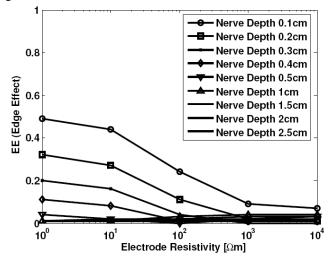


Fig. 8. Edge Effects for different electrode gel resistivities and nerve depths using a 3×3 cm² electrode. The edge effects decrease for larger electrode gel resistivities and deeper nerves.

IV. NON-POLARIZABLE / POLARIZABLE ELECTRODES

A. Resistive stimulation

Through electrolytic contact of the skin with a conductive (non-polarizable) electrode excitable tissue is stimulated through pathways with direct current flow. The current passes freely across the interface. At the metal-electrolyte junction the electric current is transformed into ionic current. Since the electrode-electrolyte interface and predominantly the electrolyte-skin interface have a high impedance not only ionic currents but also displacement (capacitive) currents are generated. These displacement currents are dominant in these interfaces and also in the skin layer. In the electrolyte reversible and non-reversible chemical reactions take place (mainly Redox reactions). Details about the occurring processes, which are more important for toxicity reasons in implantable electrodes than in surface electrodes can be found in [30] or in [31]. For TES especially important is a good electrode-skin contact, such that no high current density peaks can occur because of a small contact area. Conductive contact gels or liquids containing few ions, like tap water are recommended [32], preferably with high impedance between the electrode and the skin.[29].

B. Capacitive stimulation

Although stimulation of excitable tissues is traditionally done with electrodes that are in contact with an electrolyte, pure capacitive stimulation can be done with polarizable electrodes that have no direct skin contact. A capacitor skin surface electrode has a relatively uniform current distribution and promises to stimulate motor nerves with the least skin sensation. A Glass tube with a metal coating inside the tube has been proposed [33]. A high voltage of up to 60 kV could deliver 40 mA currents with a pulse duration of about 70 μ s. Muscle twitches and tetanic contractions could be produced with little skin sensation. This could even be improved by using a gauze pad moistened with tap water to make the electrode-skin contact (here the dielectric constant) more uniform.

In our own experiments we reproduced the above described results. As dielectric insulation layer we used a thin PE-Foil, normally used to write on for overhead projection. A simple circuitry for the generation of the stimulation pulses was used (see Fig. 9). The increase of the high voltage above 2-3 kV caused a light flash discharge what resulted in a current flow through the upper limb and the 100 k Ω resistor. The higher the voltage, the faster the light flashes were produced and increased the stimulation frequency. In comparison to state of the art hydrogel electrodes we could not observe a huge difference. Muscle twitches were smooth and tetanic contraction was strong such that most sensation came from the contraction of the muscles (muscle ache feeling) and the stretching of the tendons.

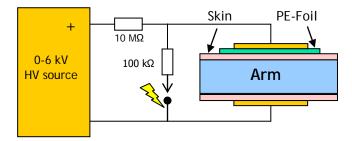


Fig. 9. Simple setup for capacitive stimulation through stimulation polarizable electrodes.

Capacitive stimulation would be a preferred way of activating muscle nerves and fibers, when the inherent danger of high voltage breakdowns of the dielectric material can be eliminated. Goal of future research could be the development of improved and ultra-thin dielectric foils, such that the high stimulation voltage can be lowered.

V. REQUIREMENTS FOR ELECTRODES

Requirements for conductive stimulation electrodes are fairly simple: They should provide the optimal performance with the least pain, not cause permanent skin damage (burns) or irritation. For neuromuscular stimulation optimal performance is effective muscle activation at the desired location. For TENS applications many sensory organs and afferent nerves should be activated without producing lot of discomfort. This second requirement can be achieved with electrode designs that do not allow currents to enter deep into the tissues as for example proposed by [6].

A. Electrode-skin contact

Good skin contact allows the electrode to interface the

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skin on the largest area possible. In microscopic images it is obvious that the skin has a very uneven surface with mountains, valleys with loose keratin layers that are breaking off etc. Liquid or sticky gel-type interfaces are used with most success to increase the contact area. Other materials as e.g. conductive hotmelts showed good results, too [20]. A secondary effect of sticky electrodes is that they removably fix the electrode to the skin.

B. Homogeneous current density

The current density should preferably be homogenous over the entire electrode. However, a gradually lower current density towards the electrode edges will in addition help to reduce edge effects. This can be achieved as e.g. done in latest designs of hydrogel electrodes by adding a current redistribution layer in a sandwich between two hydrogel layers.

C. High impedance

When the electrode or the interface gel is the dominant impedance skin inhomogeneities like the SC layer thickness, partial abraded skin, and more importantly appendages like sweat ducts and hair follicles have theoretically less influence. However, sweat ducts if not dried out are filled with good conducting salty liquid that collects the current from the surroundings and can cause a stinging sensation and pain.

VI. ELECTRODE MATERIALS

A. Metal plate electrodes covered by fabric tissue

In the early days of electrical stimulation metal plates covered with fabric tissue were used as stimulation electrodes. The metal plate has to be made from a biocompatible material. Often stainless steel or silver/silver



chloride electrodes are used. The fabric tissue can be cotton but is often a polymer textile material that has a certain degree of elasticity and doesn't wear out fast. Spongy material have also been used and recommended

[32]. The fabric is made conductive with water or electrode gel. It equally distributes the current over the skin in order to prevent skin burns. Care has to be taken that the electrode does not dry out. In the best case (if completely dry) such a dried out electrode isolates the metal plate from the skin. But while drying out, unequally distributed electrical fields under the electrodes may cause severe skin burns. The electrodes need to be fixed to the skin with elastic straps or have to be built into a garment or cast as it is the case, for example, with the Bioness (formerly Ness Handmaster) neuroprostheses [34].

B. Carbon electrodes

Before self-adhesive hydrogel electrode existed carbon loaded silicone electrodes replaced fabric covered metal plate electrodes in many TES applications. The handling and application of TES got simpler mainly because the danger of skin burns through directly contact of the skin with the metal electrode couldn't occur anymore. In addition, the carbon rubber has a much higher resistance than metal, which prevents high current concentrations in small areas. Carbon rubber electrodes were mainly used in the 1980's (e.g. in



[35, 36] or [37]). However, for special applications like iontophoreses they are still used because of their chemical stability. Important is also the fact that hydrogel electrodes are not stable at temperatures over 40°C and over long time periods; therefore storage and handling in Middle

Eastern countries is costly and difficult. In these regions carbon rubber electrodes still are preferred. Carbon rubber electrodes need gel or water as skin interface material when the currents are higher than 10 mA. For low current applications like TENS gel is recommended but not required.

C. Self adhesive hydrogel electrodes

Self-adhesive electrodes for transcutaneous stimulation use a gel to contact a conductive member with the subject's skin. The electrode is built in a multi-layer configuration as shown in Fig. 10, consisting of multiple layers of hydrogel. The skin interface layer includes an electrically conductive



gel with relatively low peel strength for removably contacting the subject's skin. It has a wet feeling and can be removed relatively easily from the skin. The conductive gel is made from co-polymers derived from

polymerization, e.g. of acrylic acid and N-vinylpyrrolidone. A second hydrogel layer connects the substrate (a low resistive material like carbon rubber or a wire mesh) with the skin hydrogel layer. This second conductive gel layer has a relatively high peel strength that provides very good adhesion to the substrate.

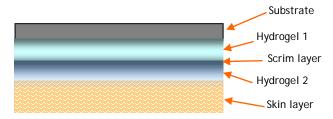


Fig. 10. Self-adhesive hydrogel stimulation electrodes are manufactured in a multi-layer configuration.

As material for the substrate conductive fabric, carbon film, or other conductive materials are used. A wiring cable connects the electric stimulator to the self-adhesive electrode substrate.



Fig. 11. The specially designed electrode Ultrastim from Axelgaard Mfg. Co., Inc. can be placed individually on the garment. It is connected to the stimulator with a connector pad.

Between the two hydrogel layers a scrim layer can be introduced. This scrim layer is introduced to prevent slippage of the two hydrogel layers and can also serve to strengthen the multi-layer substrate. A new type of selfadhesive electrode uses a scrim layer to redistribute the stimulation current that it receives from a metal connector pin on a garment (see Fig. 11). Therefore the electrode can be positioned more freely on the garment. The second hydrogel layer delivers the stimulation current obtained from the metal pin to a scrim layer made from a good conductive carbon film. The scrim layer homogeneously redistributes the stimulation current and provides it via a first selfadhesive hydrogel layer to the skin. Except for special applications almost exclusively self-adhesive hydrogel electrodes are used in TES.

D. Textile electrodes

Textile electrodes are up to now mainly developed for the recording and monitoring of biosignals. We developed embroidered multi-channel TES electrodes that consisted of multiple fabric layers [38]. The fabric layer facing the skin held embroidered electrode pads made of plasma coated metallized yarn. Because of the thin metal coating (<25nm coating particles obtained with a plasma process) the yarn kept its textile properties and could be embroidered. Silver coatings proved to be most stable and survived 30 washings. A second layer contained the embroidered electrode wiring made from the same materials and was designed such that no short circuits were produced between the pads when stitched together. The multi-channel stimulation electrodes were integrated in a glove-like garment.



Fig. 12. Prototype of a multi-channel textile neuroprosthesis: Multi-layer structure comprises electrodes placed for finger and wrist articulation.

For low currents (<8 mA) the textile electrode could directly contact the skin. But for higher currents a skin contacting material, e.g. hydrogel or new skin interface material made from a biocompatible hotmelt blended with

carbon nanotubes. The use of carbon nanotubes instead of carbon black was necessary because of the high impedance we wanted to achieve with keeping the material homogeneity within 10%.

This skin interface layer had a higher impedance than the skin. Thus skin inhomogeneities were no longer dominant in determining the path of electrical current flow into the body. A second big advantage of the high impedance skin interface was the possibility to cover multiple electrode pads without impacting the current distribution formed by them. Between pads a high impedance skin interfacing layer did not produce shortcuts as it would be the case with a low impedance material. This significantly simplifies the manufacturing process of multi-channel electrode arrays.

Stimulation comfort tests showed the same results as state of the art hydrogel electrodes [20].

VII. ELECTRODE SIZE

Electrode sizes are selected depending on the size of the targeted muscles or as described below according to the thickness of the fat layer. Large muscle groups like the knee extensors (quadriceps) are either stimulated with 10cm×5cm single electrodes or with several 5cm×5cm electrodes that are located over the four different muscle heads. For the stimulation of denervated muscles even larger electrodes are recommended to prevent too high current densities and risk of skin burns [39]. On the other hand smaller electrodes are used when reflexes are elicited at afferent nerves, e.g. for the flexion reflex.

Array electrodes are also composed of multiple small electrode elements which can be individually activated to form a virtual electrode of arbitrary size and location [40]. However, there are no guidelines on how small the individual elements should be in order to achieve comfortable stimulation of deep nerves. Elements that are too small might not be effective on persons with thick fat layers because the large current spread within the fat layer prevents the current to reach the motor nerves laying deeper [41]. With FE modeling and simulations we could find an optimal electrode pad size of 0.8cm×0.8cm for the proximal arm when the fat thickness is less than 1cm.

VIII. ELECTRODE CONFIGURATIONS

A. Single (pair of) electrodes

In a classical setup for TES one or more pairs of electrodes (mainly self-adhesive hydrogel electrodes) are placed on the muscle bellies of the targeted muscle groups. A good reference with many illustrations of electrode positions for placing the electrodes can be found in [35]. Most TENS and transcutaneous FES systems use this type of electrode configuration. The cathode needs to be more carefully placed over the motor point of the targeted muscle. Illustrations of motor points, these are regions where muscles are most likely to be activated, can be found in [42]. The anode also called indifferent electrode can be place at any location, preferably not over or close to a motor nerve. The reason for it is that TES uses in most applications charge balanced stimulation. This is current flow in both directions (from cathode to anode and vice versa). Like that 42

the charge compensating pulse would also generate an AP, this time at the anode. This is prevented in several ways: Either this charge compensating pulse has an amplitude below motor threshold, or the pulse duration is so short that no AP is generated, or as mentioned before the electrodes are far enough away from a motor nerve.

B. Array electrodes

Almost 30 years ago array electrodes were used in a neuroprosthesis for the upper extremities [36] and to quantify wrist torque and movement directions [43]. However, the system was far to complex to find a broader application. A 1D array of surface electrodes was also used to indicate to as a cognitive help to know which function is stimulated [44] by a system with implantable electrodes. Only a few years ago array electrodes were reconsidered for TES applications, this time to distribute the stimulation current to multiple electrodes [38, 45].

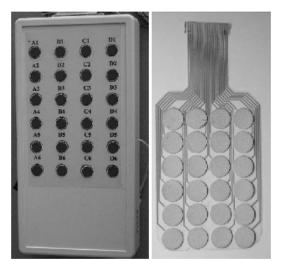


Fig. 13. Actitrode is a 24-field electrode array including the electrode and controller box [45].

The goal of these systems was to enable repositioning of the stimulated area without need to change the physical electrode location. A 64 channel TES system that allowed real-time switching of the number of active electrodes (depolarizing current) was presented in [38]. The system enabled an improved control of the spatial and temporal distribution of electrical current fields and showed improved specific finger articulations.

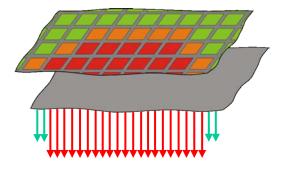


Fig. 14. On array electrodes dynamically changing activation fields with homogenous or inhomogeneous current distributions can be composed. Skin interface layer establishes good contact.

The new technology delivered the stimulation current in any arbitrary composition of timing, amplitude and location over the skin surface into the human body. This makes it possible to automate the electrode positioning for neuroprosthetic applications and enables to generate more precise limb movements. It allowed stimulating motor and sensory nerves more selectively, which can lead to new therapeutic interventions. Another advantage of the multichannel TES system is the significantly simplified donning and doffing compared to state of the art multi-channel systems. All needed electrodes (embedded in a garment) can be positioned at once by putting on the garment. The positions of the 'virtual electrodes' are restored by the software.

The array technology is a versatile approach that can dynamically change the size and position of the active region of a stimulation electrode. This approach shortens the timeconsuming procedure of finding optimal electrode positions and sizes. However, it was unclear how the gaps between the array elements and the resistivity of the interface layer (gel resistivity) influence activation. Furthermore, it was unclear how big the losses are when cathode and anode are placed on the same array connected by the gel layer. A combined FE and nerve model was employed to clarify what gel resistivities and gap sizes should be used [20]. A modeling approach was favored over experiments because it has the advantage that specific influences and parameter ranges can be investigated. With experiments only the number of different configurations that can be investigated would be very limited.

The simulation results with gap sizes between 1mm and 5mm indicated that low resistivities lead to a large spread of the current within the gel layer when a gel layer covers the entire array (Fig. 14). As a consequence the area where the current enters the skin is larger than the area of a single array element. The advantage of the large spread is that the activation is more uniform and that gaps have less influence. However, the selectivity is reduced.

On the other hand the results showed that a too high gel resistivity dramatically reduced activation underneath the gaps of the array because the current flows perpendicular down into the muscle and does not reach nerves located directly underneath the gaps (see Fig. 17). As a consequence for high gel resistivities the activation is non-uniform but selective. For these reasons the gel resistivity is an important design parameter that has to be properly chosen depending on the gap sizes of the constructed array electrode in order to achieve a good tradeoff between uniformity and selectivity of the activation.

For automatic identification algorithms that find optimal stimulation regions [38] it is important that all locations underneath the electrodes experience similar activations. Therefore, it can be important to produce a uniform current distribution underneath the array. The simulation results where cathode and anode were on the same gel layer (see Fig. 13) showed that the gel resistivity should be at least $50\Omega m$ and the cathode-anode distances should be above 19mm in order to keep losses below 2mA.

In conclusion, for a good trade-off we suggest, based on the simulation results, that gap sizes should be smaller than 3mm in order to have losses below 2mA. For 3mm gap sizes the preferred gel resistivity was ~1500 Ω m, for 2mm gap sizes ~3000 Ω m, and for 1mm gap sizes ~4500 Ω m.

IX. ELECTRODE PERFORMANCE

A. Stimulation efficiency

When stimulating with current regulated TES systems the generated muscle force of single electrodes is mainly limited by the stimulation comfort the electrode produces. The applied current defines muscle contraction. When pain impedes a further increase of the stimulation current no higher forces or torques can be produced.

We investigated how the choice of electrode materials influences the comfort and the nerve activation during TES. Experimental measurements were performed to identify motor thresholds and pain thresholds for different electrode materials on the forearm of 10 human volunteers. We measured all excitatory levels according to a standard procedure used in [12]. The tested materials were Hydrogel (200 Ω m), Hotmelt (400 Ω m), and Carbon Rubber (5 Ω m).

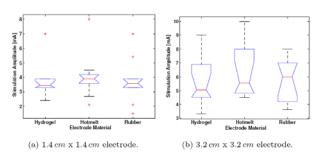


Fig. 15. Measured motor thresholds using different electrode materials and electrode sizes.

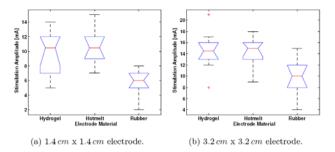


Fig. 16. Measured pain thresholds using different electrode materials and electrode sizes.

Motor thresholds did not significantly change for the different electrode materials (see Figs. 15 and 16). Stimulation comfort (pain threshold), however, was largely influenced by the choice of the electrode material over a wide range of current densities. We could conclude that new electrodes can be designed with the focus on optimizing the stimulation comfort without compromising stimulation magnitude. Two limitations regarding this conclusion have to be considered:

• The voltage that has to be applied to the electrode in order to maintain a constant current increases when the electrode resistivity is increased. Lower voltages are preferred due to the reduced power consumption and for safety reasons.

These results are only valid for single electrodes where the electrode substrate has the same size as the electrode gel. For larger gel layers, as for example shown in Fig. 14 where array electrodes are used that have a substrate smaller than the gel layer, the current can spread within the gel layer. Then the interface layer helps to shortcut stimulation currents such that nerves in a certain depth cannot be reached. There is also a reduction of the stimulation efficiency when the fat layer is thick and the electrodes are placed too close together.

B. Stimulation selectivity

In the upper extremities, specifically for stimulating hand functions, the electrode size has an influence on selective activation of the multiple muscles bundled closely together. More selective activation of the different muscles can be achieved using smaller electrodes. Small electrodes are used for example in array electrodes which were proposed to improve efficacy of TES systems [45]. Limiting factor is the applied current density.

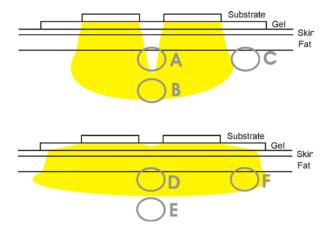


Fig. 17. Depicts qualitatively the influence of different gel resistivities on the spreading of the current (grey area). The upper sketch shows the spread for a high gel resistivity (e.g., $10k\Omega m$) and the lower sketch for a low gel resistivity (e.g., $1\Omega m$).

C. Stimulation comfort

Small electrodes produce high current densities already with moderate stimulation amplitudes, which may be uncomfortable, indeed painful, and can limit the effectiveness of TES [46]. However, not only the current density influences the perceived comfort during TES but also the area where the electrode is active and the stimulation parameters [35, 47]. McNeal [48] investigated the comfort of two electrode sizes $(4.5 \times 4.5 \text{ cm}^2 \text{ and } 6 \times 6 \text{ cm}^2)$ cm^{2}) on the quadriceps and the hamstrings. For generating the same muscle force output the human volunteers preferred larger electrodes. More different electrode sizes were investigated by Alon [12]. Excitatory levels (sensory-, motor-, pain-, and maximal tolerable threshold) were experimentally investigated for four different square electrode sizes with edge lengths 6.3 cm, 4.5 cm, 3 cm, and 1.5 cm on the gastrocnemius. The two largest electrodes $(6.3 \times 6.3 \text{ cm}^2 \text{ and } 4.5 \times 4.5 \text{ cm}^2)$ were significantly more comfortable and produced the highest force, when compared to the smaller electrodes. Hence, the 4.5×4.5 cm² electrode was the size of choice because the 6.3×6.3 cm² electrode could not further improve comfort and force. Lyons [47] compared the two largest electrode sizes $(4.5 \times 4.5 \text{ cm}^2 \text{ and}$ 6.3×6.3 cm²) used by Alon [12] and showed that on the gastrocnemius the smaller $4.5 \times 4.5 \text{ cm}^2$ electrode was significantly more comfortable compared to the 6.3×6.3 cm² electrode. Verhoeven [49] compared the generated pain of $0.6 \times 0.6 \text{ cm}^2$ electrodes with the generated pain of $3.6 \times 3.6 \text{ cm}^2$ electrodes when stimulating the tibial nerve for conduction studies. They found that pain could be reduced the larger electrode $(3.6 \times 3.6 \text{ cm}^2)$ with without compromising H- or M-waves. These studies show that differently sized electrodes were most comfortable on different subjects and on different body parts. However, what causes certain electrode sizes to be more comfortable than others and why from a certain size on larger electrodes become more painful was not conclusively analyzed up to now. This remains to be investigated in future research.

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