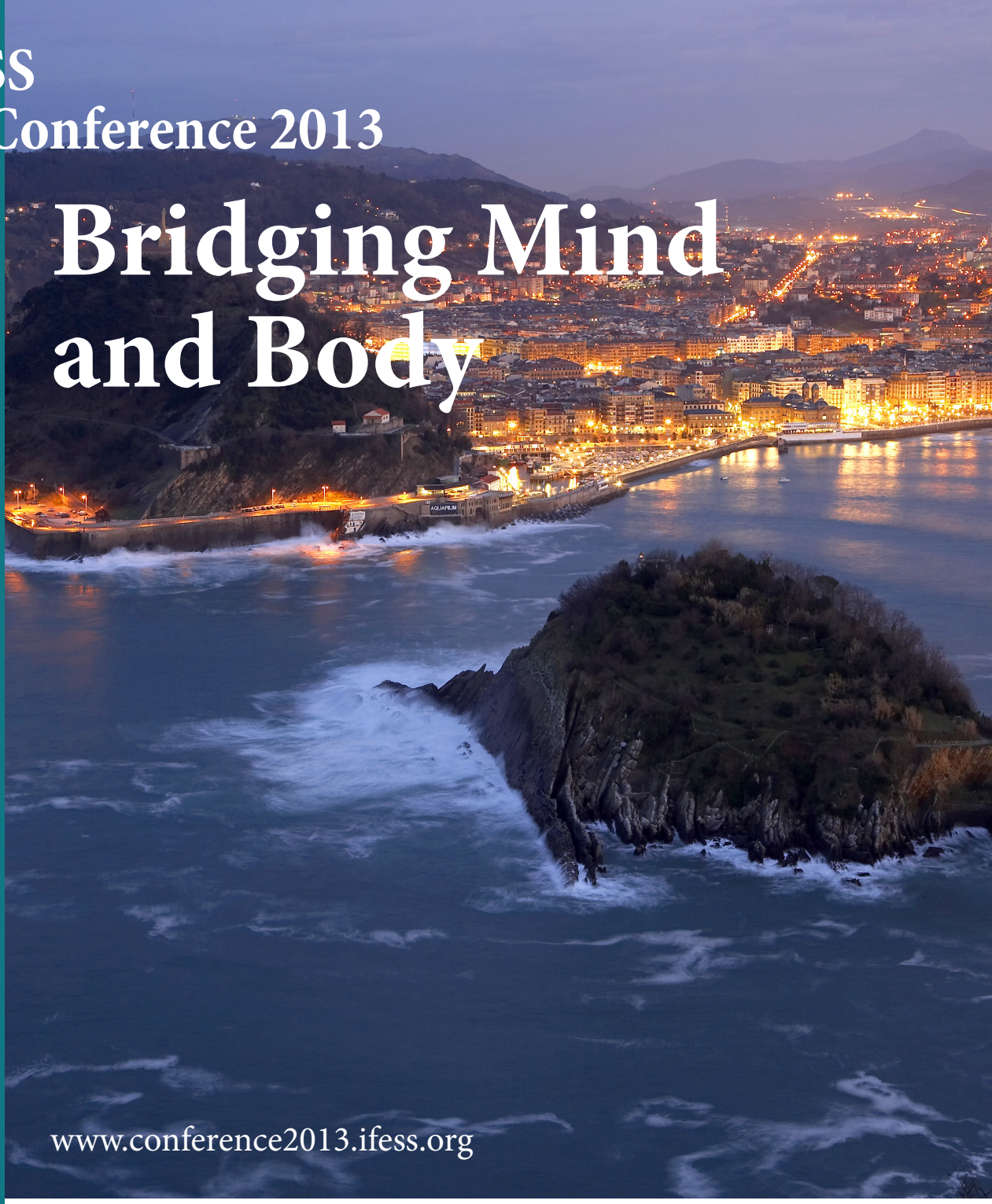
18th IFESS Annual Conference 2013

Bridging Mind and Body



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Wireless Microstimulators Based on Electronic Rectification of Epidermically Applied Currents: Safety and Portability Analysis

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***Abstract*— Miniaturization of implantable medical electronic devices is currently compromised by the available means for electrically powering them. Most common energy supply techniques for implants – batteries and inductive couplers – comprise bulky parts which, in most cases, are significantly larger than the circuitry they feed. For overcoming such miniaturization bottleneck in the case of implants for electrical stimulation, we recently proposed and demonstrated a method in which the implants operate as rectifiers of bursts of high frequency (HF) current supplied by remote electrodes. In this way, low frequency currents capable of performing stimulation of excitable tissues are generated locally around the implants whereas the auxiliary high frequency currents only cause innocuous heating. This approach has the potential to reduce the diameter of the implants to one-tenth the diameter of current microstimulators and, more importantly, to allow that most of the implants' volume consists of flexible materials. Implants based on the proposed method may look like short pieces of flexible thread. With currently available microelectronic techniques, diameters down to 200 µm are easily conceivable. The numerical study presented here, in which a hypothetical but plausible clinical scenario for paralysis is analyzed, shows that the auxiliary high frequency (1 MHz) currents will be indeed safe according to safety standards and that portable systems based on portable batteries will be feasible.**

I. Introduction

Implantation of most electrical stimulation systems for therapeutics requires complex surgeries which hamper their use in pathologies for which less invasive treatment alternatives exist; even if these alternatives are suboptimal. For instance, among those cases it could be cited pain management by means of electrical neuromodulation. Nevertheless, probably the most crucial limitation of previously developed systems based on central stimulation units is that they are not adequate for applications in which a large number of sites must be individually stimulated over large and mobile body parts; thus hindering solutions for patients suffering paralysis due to spinal cord injury or other neurological disorders. In this kind of scenarios, besides the complexity of the implantation process, another significant drawback of centralized stimulation systems is manifested: these systems require long leads running from the active electronics to the stimulation electrodes. These leads are subjected to great mechanical stress and, as a consequence, are prone to failure. In fact, not only the leads suffer from mechanical stress but also the tissues through which the leads go through or to which the electrodes are anchored.

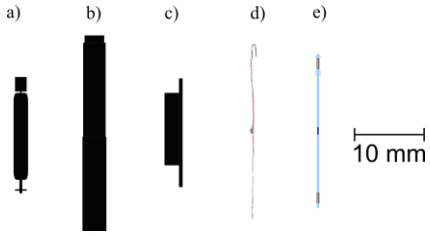

Fig. 1. Relative sizes of microstimulators. Silhouettes a, b and c correspond to existing microstimulators based on inductive coupling [1, 2]. Picture d corresponds to the single diode proof-of-concept functional implant presented in [3]. Diagram e shows a possible implementation for implants based on the method proposed here.

A solution to the above challenges could consist in developing a network of addressable single-channel wireless microstimulators which would be implanted by means of simple procedures, such as injection, and which would be activated in coordinated patterns by an external automated controller. In fact, such solution was proposed and tried in the past [1, 2]. Among the developed systems following such paradigm it is convenient to highlight the BION systems, which are in use for treating some pathologies [1]. These previous efforts, however, did not achieve full success as the developed implants were stiff and too large (Fig. 1). In other words, these developed systems were still too invasive. Further miniaturization was impeded in previous designs due to the use of inductive coupling for power because this method implies that the implant must contain a multiple-turn rigid coil. The coil is required for transforming the externally generated magnetic field into an electric current and, in order to establish an effective inductive link, it is required that the coil has a minimum diameter. For generating currents in the order of those required for neuromuscular stimulation, it is extremely hard to conceive inductive implantable devices with diameters significantly below 1 mm.

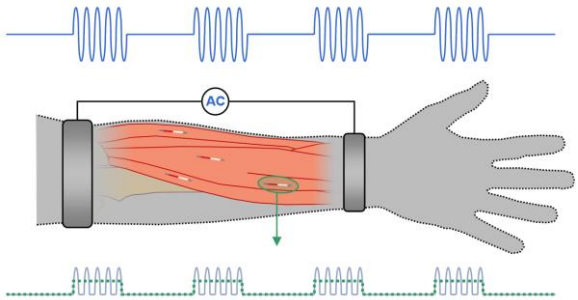

Fig. 2. Proposed technology is based on externally applying an inert HF current which is rectified by the implants into LF currents capable of stimulation.

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In [4] we proposed and *in vivo* demonstrated an alternative method for performing electrical stimulation by using electronic implants: the implanted devices rectify bursts of innocuous high frequency currents supplied to the tissue of interest by remote electrodes so that DC or low frequency (LF) currents are generated locally through the implants and these resultant currents are capable of performing stimulation of local excitable tissues without disturbing neighbor tissues. This idea is schematically illustrated in Figure 2. In comparison to inductive coupling – or to electrochemical batteries – this method offers an unprecedented level of miniaturization as all necessary components can be integrated in a single integrated circuit (IC). Only two peripheral electrodes are required for picking-up the high frequency (HF) currents and for performing stimulation. In principle, those two electrodes could be monolithically integrated within the IC. Nevertheless, since the proposed method requires a minimum voltage gradient to operate, in most applications it will be necessary that both electrodes are quite separated (from some millimeters to a very few centimeters) and, consequently, we propose not to monolithically integrate both electrodes in the IC, but to place them at some distance from it, so that most of the length of the implant can be flexible (Figures 1 and 3). The implants may mostly look like short pieces of flexible and stretchable thread. Because of such feature, and because of their intended functionality, we coined the name "Electronic Axons" (eAXONs) for these implants. Aiming towards ultrathin eAXONs (diameter < 0.5 mm), we contemplate making use of recent developments for stretchable electrodes and connections [5].

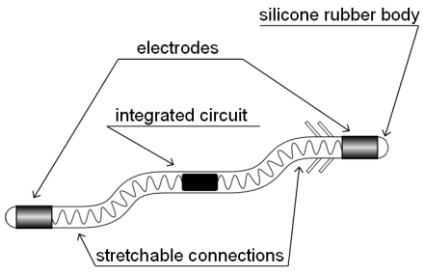

Fig. 3. Diagram of a feasible implementation for the eAXONs (not to scale). eAXONs diameters down to 200 μm are easily conceivable.

In contrast to the cumbersome external coils employed in inductive systems, the proposed method will work with thin epidermal electrodes. Those electrodes can be shaped as cosmetically appealing garments (Fig. 4) using materials for textile electrodes, particularly due to the fact that those materials exhibit low contact impedance at HF.

In its simplest version, eAXON circuitry consists in a single diode. For most clinical scenarios, however, "smarter" rectifiers will be required. First, such smart rectifier has to be capable of switching the LF current polarity so that bipolar current pulses can be generated for preventing electrochemical damage to tissues and electrodes. In addition, it has to be programmable so that current pulse amplitude and width can be controlled independently from the external HF excitation. And finally, it has to be addressable to enable multisite stimulation with different current pulse patterns and timings. A proof-of-concept of this "smart" rectifier is presented in [6].

As discussed in [4], a drawback of the proposed method is its poor energy efficiency: a very significant amount of HF power is lost as heat flowing through tissues without being transformed into LF current used for stimulation.

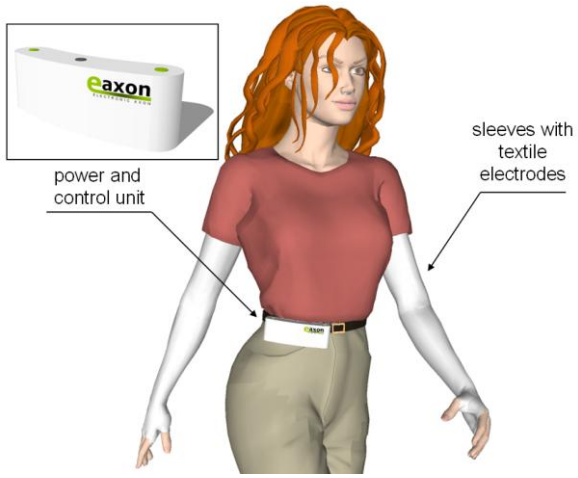

Fig. 4. Thanks to textile electrodes, this is how an arm neuroprosthesis based on the proposed technology could look like externally.

Nevertheless, it must be pointed out that energy efficiency, by itself, is not a crucial feature for neuroprosthetics provided it does not compromise safety and portability of the systems.

The main goal of the numerical study presented here is to prove, in a plausible application scenario, that safe and portable systems are feasible with the proposed method, despite its poor energy efficiency. In particular, the analyzed hypothetical clinical scenario would correspond to a neuroprosthetic system intended to activate forearm muscles which deliver motion to hand fingers through long tendons. It will be shown that the required auxiliary current of 1 MHz can be applied safely and is low enough as to be delivered for hours with portable batteries.

II. Analysis Considerations

A. IEEE Standard for Safety

The "IEEE Standard for Safety Levels with Respect to Human Exposure to Radio Frequency Electromagnetic Fields, 3 kHz to 300 GHz", C95.1-2005, defines two sets of safety thresholds for an applied electric field at 1 MHz according to the two consequences of applying HF currents through human tissues that must be avoided:

1. For avoiding unsought electrical stimulation, the "basic restriction" for "action level" is $|E| < 2.1\ V_{RMS}/cm$ for any tissue (averaging time for RMS measurement is 0.2 s). For "persons in controlled environments" the "basic restriction" is $|E| < 6.3\ V_{RMS}/cm$ for any tissue.

2. For avoiding overheating effects, the "basic restriction" for "action level" is Specific Absorption Rate (SAR) < 2 W/kg for localized exposure which translates to approximately $|E| < 0.6\ V_{RMS}/cm$ (assumptions: $\sigma = 0.5$ S/m and tissue density = 1000 kg/m^3). The "basic restriction" for "persons in controlled environments" is SAR < 10 W/kg.

Note that for avoiding unsought electrical stimulation the frequency of the HF auxiliary current is critical: as frequency increases, the electric field threshold will increase. In fact, this is a key component of the proposed method: HF electric fields will not cause any stimulation whereas the LF electric fields resulting from rectifying those HF fields at the implants, despite a lower magnitude, will perform local stimulation. As it will be shown, 1 MHz is high enough for avoiding unsought electrical stimulation. At the same time, 1 MHz is low enough as to being easily rectified with standard electronic technologies.

Heating, on the other hand, is quite independent of frequency as tissue conductivity is relatively constant in the band from 1 kHz to 100 MHz. Hence no benefit will be obtained in terms of heating by increasing the frequency.

According to the IEEE standard, the "basic restriction" for "action level" refers to exposure restrictions that incorporate large enough safety factors as to be adequate for general public. That is, it would correspond to exposure restrictions adequate to ordinary commercial equipment and appliances. In case of "persons in controlled environments" the exposure restrictions are less stringent but they also incorporate safety margins. The IEEE standard introduction states that there is no measurable risk associated with exposures below this upper tier; the lower tier (i.e. "action level") has been included in order to add an additional safety factor for recognizing public concerns and in order to support the process of harmonization with other standards (e.g. NCRP recommendations, ICNIRP guidelines [7]). Therefore, since medical systems may exceed basic safety thresholds defined by regulations if therapeutically justified, "basic restriction" levels for "persons in controlled environments" can be considered as adequate thresholds for the method proposed here. Nevertheless, as it will be shown, it is even possible to meet the lower tier thresholds with the proposed method.

B. Portable batteries

The proposed method requires the generation of short bursts (a few hundreds of microseconds), at moderate rates (<50 bursts/s), of high-voltage (10 to 500 V) and high-current (a few amperes) modulated HF signals (1 MHz) to be applied to the skin electrodes. Such specifications are not trivially met but are perfectly feasible with standard technologies. In particular, two features facilitate to a great extent their feasibility: first, since bursts rather than continuous signals are applied, it is possible to use intermediate capacitors whose charge at high-voltage (provided a DC-DC converter) is replenished in the intervals between bursts and, second, since 1 MHz is high enough for avoiding unsought electrical stimulation, quite standard high-power components will suffice. We anticipate that portable electronics will be feasible. The question to be posed here is whether it will be possible to power these electronics with portable batteries so that portable systems are realizable. Assuming that energy efficiencies of about 80% or higher are achieved in switched-mode power supplies, it can be concluded that portable systems will be realizable if average power consumptions are in the order, or below, tens of watts as existing portable batteries have charge capacities of some tens of watts-hour.

C. eAXONs requirements

In order to generate LF pulses of about 10 V peak-to-peak, which is a voltage magnitude typically used in stimulation, eAXONs will require about 16 V of HF voltage amplitude between their two electrodes. If a length of 3 cm is assumed for eAXONs, this would imply that a peak HF electric field of 5.3 V/cm would be required in the direction defined by the eAXON axis (RMS value 3.74 V/cm). If applied continuously, a HF field of 3.74 V_{RMS}/cm would dangerously heat tissues. In the eAXONs case, however, the HF electric field is to be applied as very short bursts. A worst case scenario would require bursts of 250 μs at a repetition rate of 50 bursts per second for generating LF pulses of about 200 μs (some μs will be required for communication purposes) at a repetition rate of 50 pulses per second. Hence the maximum required time fraction in which HF current will be applied is 0.0125 s/s which scales the RMS value by a 0.112 factor. Therefore, in this extreme case, the equivalent RMS value for the HF electric field, in the direction defined by the eAXON axis, would be 0.42 V_{RMS}/cm, which is a completely safe magnitude according to the IEEE standard for safety. The goal of the numerical study presented here is to show that the restrictions of the standard are also met in a plausible scenario in which the electric field is not uniform and not perfectly aligned with the eAXONs axes.

III. NUMERICAL MODEL

The implemented numerical model would correspond to a hypothetical neuroprosthetic system intended to activate forearm muscles which deliver motion to hand fingers (loosely resembling Fig. 2). The eAXONs would be implanted longitudinally in the forearm segment comprised by two band electrodes.

The model geometry is depicted in Fig 5.a. Two band electrodes (5 cm length) are tied around a conically shaped forearm (30 cm length, 9 cm larger diameter, 6 cm smaller diameter) at a separation distance of 15 cm. The forearm contains two parallel bones (1.5 cm diameter) and an outer layer of skin and fat. The bulk of the forearm consists of muscle tissue.

Dielectric properties for tissues at 1 MHz have been obtained from (http://niremf.ifac.cnr.it/tissprop/) which corresponds to a parametric model developed by Gabriel and colleagues [8]. In the particular case of the skin/fat layer, an intermediate value between those reported for fat and wet skin was selected.

Material	Conductivity [S/m]	Relative permittivity
Electrodes	1×10^7	1
Muscle	0.5	1800
Bone (cortical)	0.025	150
Skin/fat	0.1	30

Table 1. Dielectric properties (conductivity, σ, and relative permittivity, ε) of materials employed in the model at 1 MHz.

A 1 MHz signal of 200 V is applied between the upper and the lower electrode. The contact impedance between the electrodes and the forearm surface is not made uniform but higher towards the edges as to minimize the edge effect [9].

The model is solved by means of a Finite Element Method (FEM) software platform (COMSOL Multiphysics, COMSOL AB, Stockholm, Sweden). In particular, the 'Electric Currents' application mode was selected for this model. A mesh of 61580 tetrahedral elements was generated automatically by COMSOL in order to obtain the solution for the potential distribution at 1 MHz.

IV. Results and Discussion

Results from the numerical model are displayed in Fig. 5. The electric field component parallel to the eAXONs axes is larger than 6 V/cm in the region comprised by the two band electrodes and, therefore, the eAXONs within this region will be capable of generating large enough pulses for electrical stimulation of forearm motor points. On the other hand, the electric field RMS value (scaled by the 0.112 factor because of the time fraction during which HF are effectively applied) does not reach magnitudes larger than 1.2 V/cm and the SAR value – which is proportional to the square of the local electric field magnitude and to the local conductivity – does not surpasses 2 W/kg. Therefore, the auxiliary 1 MHz current is completely safe according to the IEEE standard, both for avoiding unsought stimulation and for preventing overheating. The "basic restrictions" for "action level" are met. This implies that an extra safety margin exists before reaching the upper tier thresholds that would be acceptable in a medical system. Note that the pulse protocol modeled here – pulses of 200 μs at a rate of 50 pulses per second – represents an extreme scenario.

Peak current flowing through the electrodes is 1.1 A. Hence, peak power consumption is 220 W. This peak is only reached during the bursts, which represent 0.0125 s/s, and, consequently, average power consumption is only 2.75 W which can be supplied for hours with existing rechargeable portable batteries.

Finally, it is worth noting that requirements were met by properly selecting the length of the implants: longer implants will require lower electric fields and, therefore, will lessen the requirements.

V. Conclusion

In the numerical study presented here, which corresponds to a hypothetical neuroprosthetic system intended to activate forearm muscles, it is possible to provide a large enough electric field for operation of the microstimulators based on the proposed method and, at the same time, safety restrictions are met concerning the required auxiliary current at 1 MHz. In fact, safety margins are large enough as to think that the method will be applicable in a large variety of clinical scenarios. In addition, the obtained average power consumption (2.75 W) indicates that portable systems based on rechargeable portable batteries will be feasible.

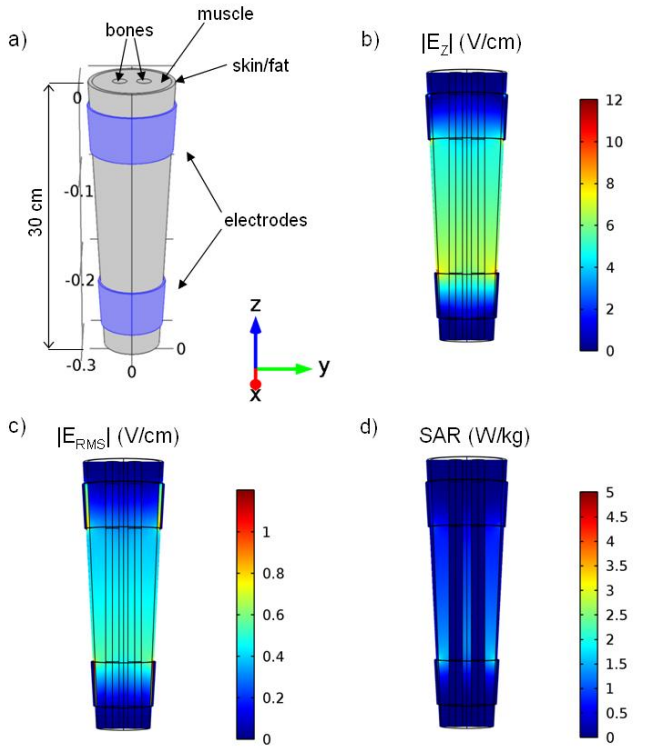

Fig. 5. Model geometry and results. Electric field component parallel to eAXONs is large enough to power them and, at the same time, safety requirements are met.

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