Injectable Stimulators Based on Rectification of High Frequency Current Bursts: Power Efficiency of 2 mm Thick Prototypes

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***Abstract*—To overcome the miniaturization bottleneck imposed by existing power generation/transfer technologies for implantable stimulators, we have proposed a heterodox electrical stimulation method based on local rectification of high frequency (≥ 1 MHz) current bursts delivered through superficial electrodes. We have reported 2 mm thick addressable injectable stimulators, made of off-the-shelf components, that operate according to this principle. Since a significant amount of high frequency power is wasted by Joule heating, the method exhibits poor energy efficiency. In here we have performed a numerical case study in which the presence of the above implant prototypes is simulated in an anatomically realistic leg model. The results from this study indicate that, despite low power transfer efficiency (~ 0.05%), the power consumed by the external high frequency current generator is low enough (< 4 W) to grant the use of small portable batteries.**

I. Introduction

EXISTING power generation/transfer technologies for electronic implants either require stiff and bulky parts (e.g. coils and batteries) or result in systems that are not capable of producing the current magnitudes that would be required for neuromuscular stimulation. This hampers progress in the field of motor neuroprosthetics. Recently [1], we have *in vivo* demonstrated injectable microstimulators (Fig. 1) based on a heterodox electrical stimulation method: the implants act as rectifiers of innocuous high frequency (HF) current bursts (≥ 1 MHz) supplied to the tissues by galvanic coupling using superficial electrodes. Thereby, low frequency (LF) currents capable of stimulating excitable tissues are generated locally through the implants. Since the method avoids the use of batteries, coils or any bulky part for power, very thin implants can be accomplished.

To the best of our knowledge, the demonstrated devices (Fig. 1) are the first injectable and addressable implants powered only by galvanic coupling.

A significant drawback of the proposed stimulation method is that a considerable amount of HF power is wasted in tissue due to Joule heating without being transformed into LF current for stimulation. In here we present a numerical analysis to evaluate if, despite these losses, a portable external system that delivers enough HF current for stimulation would be feasible.

L. Becerra-Fajardo's research is supported by a PRC fellowship from the Universitat Pompeu Fabra.

A. Ivorra's research was supported by a Marie Curie grant (IRG 256376) from the European Commission.

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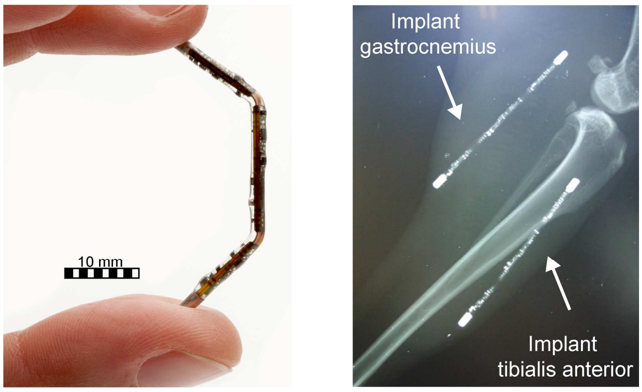

Fig. 1. Addressable neuromuscular stimulator reported in [1]. The X-ray image shows two implants in a rabbit leg. Much thinner and more flexible versions are conceivable by embedding all circuitry in a single integrated circuit.

II. Methods

To perform the numerical analysis, we customized a high-resolution anatomical model from a 34 year old male which was developed for electromagnetic studies [2]. It consists of three regions: bone tissue, muscle tissue and "other tissues". This last region corresponds to the skin, subcutaneous adipose tissue and fat. The three regions were decimated and converted into solid geometries. The resulting geometries were imported into a finite element method (FEM) software package (COMSOL Multiphysics 4.4) for performing electrical simulations using the 'Electric Currents' application mode. Two superficial electrodes were modeled around the generated limb (Fig. 2) and two 2 mm thick dummy implants were modeled inside the tibialis anterior (TA) and gastrocnemius (GA) muscles. The dummy implants simply consist in an insulating tube (length = 41 mm, Ø = 2 mm) with two metallic cylinders at opposite ends (length = 3.8 mm, Ø = 2 mm). The software automatically generated a mesh of 407,300 tetrahedral elements. The dielectric properties of the simulated materials are reported in Table I. In the case of "other tissues", a weighted average between those reported for fat, skin and subcutaneous adipose tissue was selected [3].

A parametric analysis was performed in which the amplitude of the external voltage was increased from 0 to 100 V at 10 V steps. The implant electrodes were defined as voltage probes, and the resulting electric potential was exported to another numerical computing software (Matlab, by Mathworks, Inc) for further analysis.

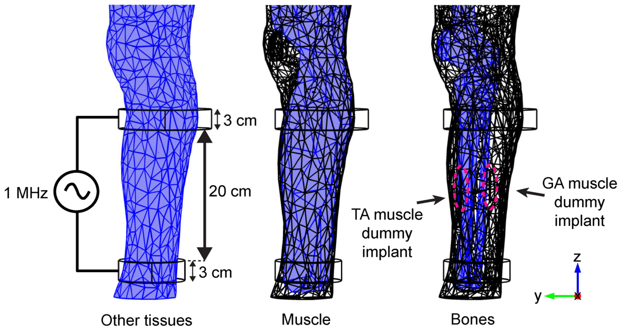

Fig. 2. Leg model, corresponding to a male adult, used in the simulations. Two external electrodes are modeled around the limb, and two dummy implants are modeled in the tibialis anterior (TA) and gastrocnemius (GA) muscles.

The power applied by the external system is calculated using the resulting current delivered by the external electrodes. This power depends on the rate of *Initialization* stages and that of *Stimulation bursts* as defined in the communication protocol reported in [4].

TABLE I
DIELECTRIC PROPERTIES OF MATERIALS @ 1 MHZ

Material	Conductivity σ (S/m)	Relative permittivity
Bone (cortical) [5]	0.024	150
Muscle [5]	0.50	1800
Other tissues [5]	0.049	280
Electrodes	1×10^{4}	1
Insulating tube	1×10^{-4}	12

III. RESULTS

Fig. 3-a shows the voltage amplitude across the implants electrodes with respect to the amplitude applied by the external electrodes. A minimum voltage amplitude of 7.35 V across the dummy implant electrodes is required for implant operation [1]. This, according to the simulation, corresponds to 57 V and 68 V applied by the external system to activate the GA and TA implants respectively. Fig. 4 shows the electric potential amplitude in the cross sectional area of the implants deployed into the TA and GA muscles when 70 V are applied by the external system.

If the implants were to be used as sensing devices, only an *Initialization* (85 ms) stage would be required each second. Then, the average HF power consumption of the external system would be 2.2 W (A= 70 V). If the implants were to be used for continuous stimulation, assuming that the system had to be initialized each second, the power would range between 2.7 and 4 W depending on the frequency of stimulation (Fig. 3-b).

For each stimulation burst, the implants deliver a biphasic current pulse with an amplitude of about 2 mA through an impedance of about 500 Ω (muscle tissue impedance across the implant electrodes). Hence the instantaneous power delivered by the implants is about 2 mW. At a stimulation frequency of 100 Hz, assuming that the implants are required to stimulate continuously (A= 70 V), the required HF power would be 3.7 W (Fig. 3-b), which implies an efficiency of 0.05%.

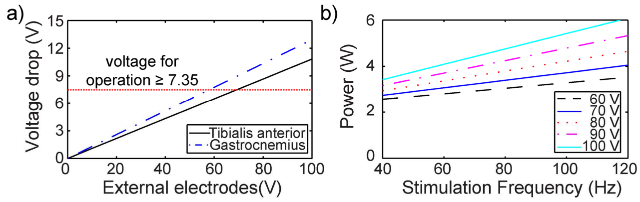

Fig. 3. Parametric simulation results. a) Voltage amplitude across implant electrodes. b) Power consumption of the external system when the implants are used for continuous stimulation, modeling different input voltages and stimulation frequencies (i.e. bursts frequency).

IV. DISCUSSION

Despite it was simulated an extreme and almost implausible scenario – implants must continuously apply stimulation pulses at 100 Hz – this study indicates that the power drawn by the external generator would be below 4 W. This indicates that, although the method exhibits a very poor energy efficiency, it will be possible to use existing rechargeable portable batteries (> 100 Wh/kg) in the external generator in charge of delivering the HF current to drive the network of microstimulators. Thus, not only the implants can be minimally invasive but also the external systems can be comfortable as they may consist in a small electronic unit wired to superficial electrodes, which may be embedded in a garment using conductive textiles [4].

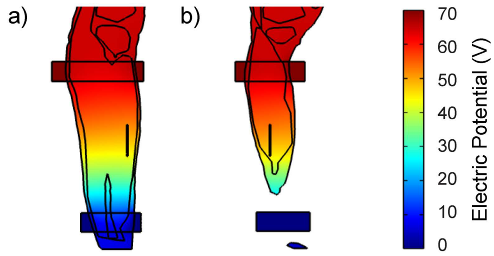

Fig. 4. Electric potential at yz planes where the implants are deployed when 70 V are applied by the external system. a) Plane through implant at tibialis anterior and b) gastrocnemius muscles.

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