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IMPLANTABLE SILICONE ELECTRODE FOR MEASUREMENT OF MUSCLE ACTIVITY: RESULTS OF FIRST IN VIVO EVALUATION

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Abstract: *An implantable silicone electrode for acquisition of the electromyogram (EMG) was developed and tested on the musculus gluteus superficialis of fourteen rats for a period of eight weeks. A simple and low invasive procedure for electrode implantation was developed and achieved reliable and reproducible positioning of the electrodes. All electrodes stayed mechanically intact over implantation period. Electrode impedance decreased from implantation to explantation and no electrical failures of electrodes were observed.*

Keywords: *implantable electrode, implantation procedure, electrode impedance, encapsulation tissue*

Introduction

State of the art prosthetic hands offer an increasing number of degrees of freedom, sometimes even the movement of individual fingers. However there is still the challenge of providing an intuitive control for this functionality. One approach to overcome this problem is to use intracorporal signals [1]. In transcarpal amputees who are still able to control the muscles in their forearm, or in amputees who underwent targeted muscle reinnervation [2], a high number of independent, intuitively controlled signals could be obtained by means of implanted electrodes recording EMG directly on the muscles.

The work presented here is part of the development of a fully implantable EMG recording system for control of upper limb prosthetic devices [3], [4].

Methods

The developed implantable silicone electrode (Figure 1) is based on monopolar stimulation electrodes that have proven good long term stability [5]. A silicone carrier is built from two layers of PTFE reinforced silicone sheets (NA 501-1, Nagor) stuck together with silicone (MED 4011, NuSil). It carries two contact disks that were laser welded to single stranded, PTFE isolated cables (MP35N, Heraeus). The cables were coiled and tubed in a silicone tube (Silastic Rx 50, Dow Corning). A first design had smooth platinum-iridium (Pt/Ir 90/10) contact discs with an area of 3.1 mm^2, whereas the second design had contact surfaces of 7.1 mm^2 made from stainless steel (SS).

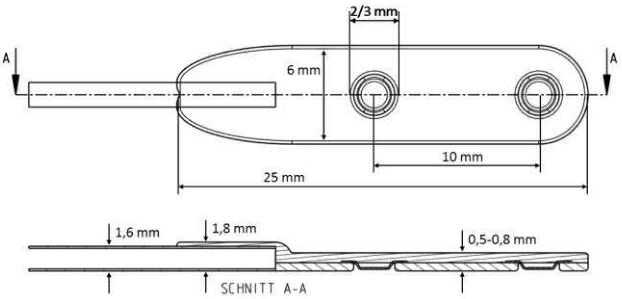

Figure 1: Schematic drawing of the developed silicone electrode for subepimysial implantation.

The steps of the implantation procedure are shown in Figure 2. An incision is made at the intended position of the transition between electrode and cable. This incision is only slightly wider than the electrode and is extended past the epimysium down to the superficial muscle fibres. An arterial clamp is used to form a pocket which starts at the incision and has the size of the electrode. The electrode is then inserted into the pocket with a pair of forceps. For fixation of the electrode only one suture is made around the cable where it passes into the electrode using a non-absorbable filament.

To test stability and biocompatibility of the electrodes as well as the implantation procedure and its ability of properly fixating the electrodes, electrodes were implanted in 14 Sprague Dawley Rats for eight weeks. Both electrode designs were implanted in each rat, one on each musculus gluteus superficialis. Cables were rooted over

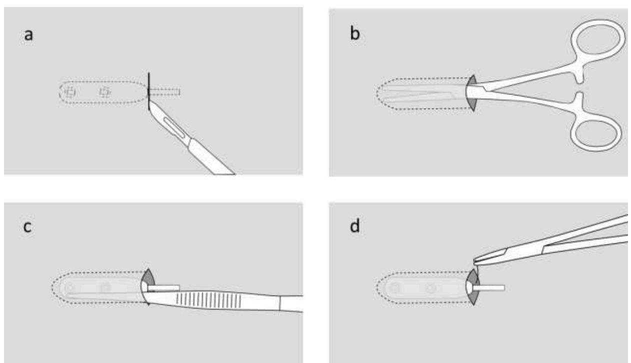

Figure 2: Implantation procedure for subepimysial placement and fixation of the developed silicone electrode.

the hip joint, to achieve mechanical loading of the leads, and then subcutaneously to the neck where they were fixed in place. After implantation and before explantation the position of the electrodes was marked on the skin and documented on pictures that were compared afterwards. Intraoperative impedance measurements were carried out with a custom built impedance measurement system [6]. The system applied a current of 1 μA_{RMS} consisting of a linear combination of 21 frequencies from 1 Hz to 10 kHz between the two contacts of each electrode. The resulting voltage was measured and decomposed into the induced frequencies by FFT, which allowed the calculation of the impedance at each frequency separately.

During explantation electrodes were excised with the connective tissue formed around them. These tissue samples are intended for later histological analysis.

Results

The handling of electrodes during implantation was good and allowed a precise placement with little tissue damage in combination with the developed implantation procedure. Eight weeks after implantation all electrodes and cables were covered by a layer of connective tissue that provided secure positioning. No signs of tissue damage or inflammation were visible. All electrodes and cables were mechanically intact and electrodes were still positioned at the gluteus superficialis. One electrode was turned 90° around its long axis and visual inspection indicated that a thicker capsule of connective tissue was formed around it. Two of the fourteen SS electrodes showed signs of corrosion in the region of the welding points which was not observed on the Pt/Ir electrodes.

Electrode impedances measured directly after implantation and just before explantation are presented in Figure 3. No electrode breaks were observed at any time. The magnitude of the impedance decreased over the whole frequency range for both contact materials over the first eight weeks after implantation. This decrease is smallest for Pt/Ir contacts at high frequencies.

Discussion

The developed silicone electrodes demonstrated good stability and the procedure for their subepimysial implantation achieved reliable positioning while causing little tissue damage. The corrosion observed at two SS electrodes is expected to be caused by modification of material properties due to excessive heating during welding. Based on their mechanical durability the developed silicone electrodes will be tested in further animal experiments, finally aiming at clinical testing in the human. Further testing will increase mechanical loads on the implanted components and allow for measurement of EMG during voluntary muscle contractions. Also the implantation procedure will be refined for further experiments.

The presented animal trial includes a second group of rats, which will be implanted for twelve weeks. Histological analysis of connective tissue samples of both groups will show if there is on-going formation of connective

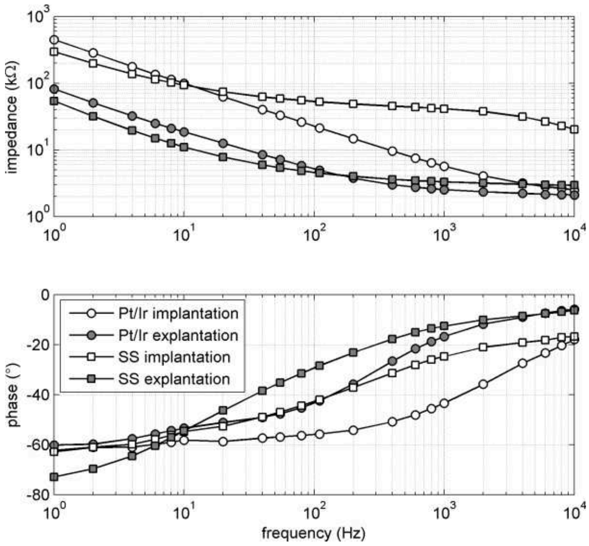

Figure 3: Bode plot of impedance measured during implantation and explantation of platinum-iridium (Pt/Ir) and stainless steel (SS) electrodes.

tissue around electrodes even after eight weeks of implantation or if incorporation can be expected to be stable as observed for other electrodes implanted at the same position [6]. Results from histologic analysis will be related to the impedance measurements.

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