Fabrication and test of robust spherical epimysial electrodes for lower limb stimulation

Klaus Peter Koch, Christian Leinenbach, Thomas Stieglitz
Fraunhofer Institute of Biomedical Engineering
Ensheimer Str. 48, D-66386 St. Ingbert, Germany
E-mail: kochk@ibmt.fhg.de

Abstract

Robust epimysial electrodes were fabricated for a neural prostheses to stimulate muscles in lower limb, to stand up and walk.

For the fabrication of epimysial electrodes, we used pacemaker leads, medical grade silicone and medical grade platinum for the electrode itself. To fixate the electrode at the muscle and to increase the stability, a polypropylene mesh was shed with silicone around the platinum electrode. The platinum electrode itself was mould into a spherical form to increase the surface.

Electrodes have been characterised in vitro with pulse-test of 10 million pulses in physiologic saline solution (0,9% NaCl) and the same number of pulses in tissue culture medium have been applied. As reference, impedance spectroscopy was made before and after pulse testing in both liquids. Implantations have been performed in animals. The Electrodes have been sutured on the motor points and stimulation thresholds have been determined after acute and chronic implantation.

Keywords: Epimysial electrode, FES, Implant,

1. Introduction

Despite all microminiaturization trends, there is a need of robust electrodes that deliver high currents for the electrical stimulation of large muscles in lower limbs. Epimysial electrodes were already used by other groups to restore stand-up and walk movements in clinical studies [1]. Histological investigation of explanted (upper limp) electrodes indicated only moderate tissue reactions [2]. Unfortunately, this type of electrodes was not commercially available without buying a whole prosthetic system. In this paper, we present the development and test of own epimysial electrodes using standard components to facilitate the approval to clinical investigation. Eight of our electrodes were implanted in a human subject within the SUAW project (see acknowledgement).

2. Materials and Methods

Design and Fabrication

We designed an epimysial electrode for stimulating big muscles of the lower limb for functional electrical stimulation for stand up and walk. Electrodes in this area were mechanically stressed. One reason for the mechanical stress is that the patient sits and lies on the area where the electrodes are implanted. One further reason for mechanical stress is the large movement of cables over the hip joint and the movements regarding the contraction of the muscles. Another point to be considered is the difficulty to implant a system for lower limb functional electrical stimulation, because many electrodes on different paces have to be implanted. Thus we decided to construct a robust electrode which is easy to handle. For a fast development of the electrode, we chose approved materials from clinical distributors (Table 1).

Description	Type	Distributor	Location
Platinum	Medical quality	W.C. Heraeus	Hanau, Germany
stainless steel	316L	W.C. Heraeus	Hanau, Germany
silicone capsulation	MED 4211	Polytec	Waldbronn, Germany
silicone glue	MED 1137	Polytec	Waldbronn, Germany
silicone colour	R-1008-X	Polytec	Waldbronn, Germany
Implantable polypropylen mesh	SurgiMesh® REF 41515p	Resorba Clinicare GmbH	Nürnberg, Germany
Cable with connector	Unipolar IS-connector with cable	Dr. Osypka GmbH	Grenzach-Wyhlen, Germany
suture	Ethibond 3-0 RB-1	Ethicon GmbH	Norderstedt, Germany

Table 1: Components and material for epimysial electrodes.

To have a low impedance of the electrode and a good contact, we chose a spherical form for the electrical active surface of the electrode. We calculated the surface A as a function of the radius r and the height h of the lens as shown in Fig. 1 to

$$A = \pi * (r^2 + h^2).$$

As material for the stimulation part of the electrode we used round disks of platinum with medical quality and pressed them into spherical form with a margin around the spherical part. The lens is fixed by a polypropylen mesh around that margin. We put the platinum lens though a hole in the middle of the round polypropylen mesh.

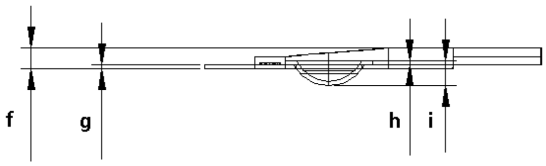

Fig. 1: Schematic of epimysial electrode (side view).

To insulate the backside of the electrode and fixation we used a silicone encapsulation. For stabilisation of the silicone encapsulation and as an opportunity to fix the electrode on the muscle, an implantable polypropylen mesh was incompletely moulded into the silicone as shown in Fig. 2. At first, we cut a round piece of polypropylen mesh and moulded the middle part with the shape of the final electrode with silicon. Afterwards, we punched a hole into the middle of the mesh. This hole is the opening for the electric active part of the lenses.

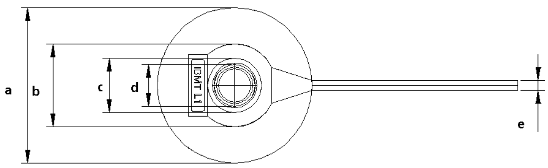

Fig. 2: Schematic of epimysial electrode (top view).

To contact the electrode to the implant electronics located in the patient's chest, we used a long cable. We chose a standard connector from the cardiology, a unipolar IS-1 connector (EN 50 077 standard, 1993), to be able to replace electrodes easily. Furthermore, we used a cable from the cardiology with an IS-1 connector on one side. This cable includes 4 helices of MP35N with a diameter of 0.81 mm. It was insulated by a silicone tube.

Each single strand of the cable was welded at the platinum lens by parallel gap welding [3]. We used the welder DC1000 from Mac Gregor (GB) with molybdenum electrodes type EU2030 M. One welding electrode was placed on the platinum lens and the second welding electrode was placed on the strand of the cable. We used double pulse voltage controlled welding parameters for a good temperature distribution. Additionally, we used an inert gas atmosphere of helium during the welding process.

For strain-relief of the cable, we fixed surgical suture in the polypropylen mesh with knots around the cable. Thereby, mechanical stress at the welding points were avoided.

We included little plates of stainless steel with notches made by a laser for x-raying. The notches were made with a line width of 0.15 mm.

Concerning the transparency of the silicone mould, we used this identity plate to control the front end of the electrode during the operation. Additionally, we put three colour identification codes near the connector. The same colour codes were placed on the stimulator implant. Hereby, electrode assignment during the surgical procedure was easy.

To finish the manufacturing of the electrode the identification plate were glue on the polypropylen mesh with medical silicon glue. The cable with the lens was put on the mesh and fixed with the suture at the helix of the cable and with glue between the margin of the lens and the mesh. Additional the backside of the lens was glued to have a better contact to the encapsulation. Then the whole backside was moulded with silicone. In reference to Fig. 1 and Fig. 2 all dimensions are listed in Table 2.

Dimension	Description	Length
a	Mesh diameter	30 mm
b	Silicone diameter	16 mm
c	Platinum diameter	10.5 mm
d	Lens diameter	8 mm
e	Cable diameter	2 mm
f	Thickness of silicone encapsulation	2.5 mm
g	Thickness of mesh	0.5 mm
h	Thickness of platinum	0.5 mm
i	Radius of lens	2.5 mm

Table 2: Dimensions of electrode components.

Finally the electrodes were sterilised with an ethylene-oxide sterilisation and packaged by HM-Medical Engineering, Binzen, Germany (Fig. 5). The validation of the sterilisation was also done by HM-Medical Engineering. The whole silicone manufacturing was done in a Class 100 clean room atmosphere.

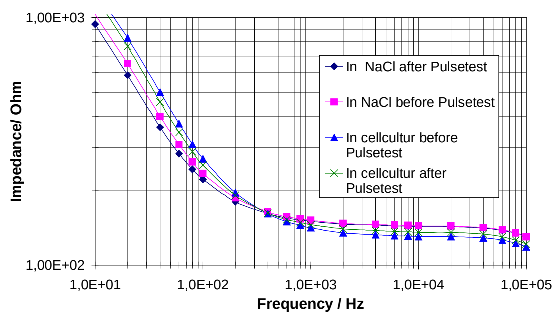

Fig. 3: Impedance spectra of epimysial electrodes.

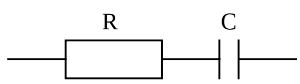

Fig. 4: Equivalent circuit of epimysial electrode.

In vitro Test

For the in vitro test we used two different mediums to test the electrodes. At first, we used a standard physiological saline solution (0.9% NaCl); the second test was in cell culture medium. The cell culture medium includes 89% Eagle Medium from Dulbecco's Mod, 10% Foetal Bovine Serum from Life Technologie and 1% Penicillin-Streptomycin with 10mg Streptomycin in 0,9% NaCl. Measurements were performed under sterile conditions. At first, we measured the impedance of the electrodes as a spectrum. We used a computer controlled measurement system with an IEEE-Bus. This system controlled a HP 3245A programmable source as a sinus current source and an EG&G 5302 lock-in amplifier for voltage and phase measurements (Fig. 6). During the impedance spectroscopy, we used a current of 0.5 mA in the frequency range from 10 Hz to 100 kHz. We took five measurement points per decade and an average of ten values per frequency.

Fig. 5: Photograph of electrode.

Pulse tests were performed under the same conditions as in the final implant. For the pulse tests, we also used a computer controlled system managing the measurement and data acquisition. As current source we used the HP 3245A with a bi-phasic rectangular pulse (Fig. 7). The parameters were selected to a pulse width of 1.2 ms, a current amplitude of 5 mA, a frequency of 20 Hz and 10^6 pulses. To avoid DC components, we used a 10 µF capacitance in serial to the electrode. To measure the voltage at the electrode, we used a HP3458A Digital-Multi-Meter. After the pulse-test we measured the impedance-spectroscopy again to have a control if changes have proceeded.

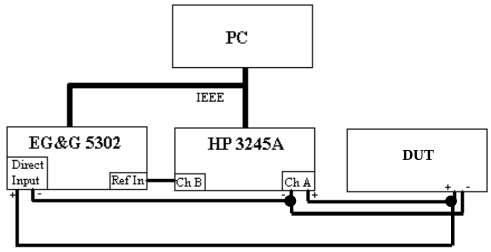

Fig. 6: Measurement setup for electrode impedance spectroscopy.

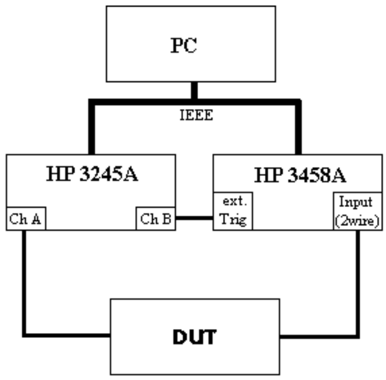

Fig. 7: Measurement setup for electrode pulse-test with current generator (HP3245A) and digital Multimeter (HP3458A); DUT: device under test.

In vivo Tests

Different in vivo tests were made to check the function of the electrodes. The functionality and the biocompatibility of the materials' combination and the form of electrode were tested. For the acute tests, we made a motorpoint mapping on the muscles, fixed the electrodes with suture and made a pulse-test at the muscles with excitation threshold and impedance of the electrode. We used a biphasic rectangular pulse and exponential charge compensation with different pulsewidths, frequencies and amplitudes. We made the same test during the implantation and during explantation. Long term tests were made in a monkey for 21days and pigs for 27 days. Each animal was tested with 2 active electrodes.

3. Results

It was shown that the letters on the tag for electrode identification were easily to read on a X-ray picture. Also the electrical surface was increased of a factor of 1.39 by the special form of the electrode.

During the in vitro pulse-tests the maximum change of the impedance was 10 % after 10 million pulses. in physiological saline solution as well as in cell culture medium (Fig. 3). No significant change in the impedance of the electrode was observed after the 10 million pulses with a charge of 6µC per pulse (Fig. 8).

Test	**R / Ω**	**C / µF**
Impedance in NaCl before pulse test	146.6	12.9
Pulse test in NaCl	126.2	17,03
Impedance in NaCl after pulsetest	146.1	14,4
Impedance in cell culture medium before pulse test	133.5	10.0
Pulse test in cell culture medium	126.6	13.8
Impedance in cell culture medium after pulse test	138	10.7
In pig acute stimulation	550	6
In pig stimulation after 27 days	300	5.5

Table 3: Parameters of electrode equivalent circuit.

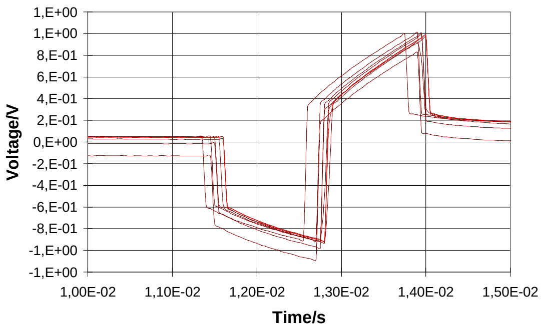

Fig. 8: Voltage response of current pulses with pulse width of 1.2 ms and amplitude of 5 mA.

The equivalent circuit of the electrode was modelled to a resistor-capacitor series circuit (Fig. 4). Variations between saline solutions and cell culture medium were very low and were caused by different conductivity of the media (Table 3).

4. Conclusions

Using clinical approved materials and components, we fabricated robust, spherical shaped epimysial electrodes. When properly placed near the motor point, stimulation was performed at relatively low current levels.

References

[1] Rudi Kobetic, Roland J. Triolo, James P. Uhlir, Carole Bieri, Michael Wibowo, Gordie Polando, E. Bayron Masolais, John A. Davis, Jr., Kathleen A. Ferguson, and Mukut Sharma, (1999) Implanted Functional Electrical Stimulation System for Mobility in Paraplegia: A Follow-Up Case Report, IEEE Transaction on Rehabilitation Engineering, Vol.7, 4:390-398.

[2] June M. Akers, P. Hunter Peckham, Michael W. Keith, and Katharine Merritt, (1997) Tissue Response to Chronically Stimulated Implanted Epimysial and Intramuscular Electrodes, IEEE Transactions on Rehabilitation Engineering, Vol.5, 7:207-220.

[3] Johnson DR, Knutson, RE, (1976) Parallel Gap Welding to Thick-Film Metallization, IEEE Transactions on Parts, Hybrids and Packaging, PHP-12, 3:187-194.

Acknowledgement: This work was funded by a grant of the European Union (Biomed II Programme, BMH4-CT965-1501) within the SUAW project. We would like to thank all project partners for their contributions during the development and testing time.