18polar Hybrid Cuff Electrodes for Stimulation of Peripheral Nerves

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Abstract - For restoration of neuro-muscular functions in disabled people, cuff type electrodes have been used for several 10 years. A lot of experiences were collected using 12polar electrodes, which consisted of silicone tubes, carrying 4 stimulation tripoles, each tripole orientated longitudinally to the nerve. The tripoles were at 0°, 90°, 180°, and 270° position around the nerve. It is obvious that the success of fascicle selective stimulation strongly depends on the position of the tripoles relatively to the nerve and its inner fascicles. It appears to be nearly impossible to selectively excite only the aimed few in a compound of about 40 fascicles of e.g. a radial nerve using a "traditional" 12polar cuff electrode. Higher numbers of stimulation sites seem to be recommendable. Here, we describe the development of a new cuff electrode with 6 tripoles.

Keywords: multipolar cuff electrode, FES, peripheral nerve, thin-film, silicone

1. Introduction

Most cuff electrodes are manufactured using well known silicone materials in combination with platinum foils, welded to stainless steel wires [1]. These devices are hand-crafted and strongly limited in channels. Their major drawback are the costs, that rise proportional to the number of stimulation sites due to the additional fabrication effort. Each stimulation site is connected to an insulated lead somehow embedded in the cuff. The more channels it has the more rigid is the whole cuff. The major advantages of the traditional silicone technology are reliability, well know body reactions, and the softness of the material (in case of thin sheets).

![Fig. 1: Arrangement of electrodes around the radial nerve of a 60 kg pig (photomontage). Left: "traditional" 4-tripoles, right: new 6-tripoles configuration.](image)

A different technology is not yet established in clinical use but also investigated since over 10 years: cuff electrodes made of flexible, micromachined thin-film substrates [2]. Micromachining enables one to fabricate cuff electrodes with high numbers of stimulation sites, having it's own integrated interconnection lines. These devices are highly reproducible in shape and electrical and mechanical properties. Because of the batch processing procedure, they are cheap despite their high possible number of channels. Unfortunately, they are stiff compared to silicone cuffs and because of the costs that increase proportionally to the area, a single devices claims on a wafer, thin-film cuffs are restricted to small sized nerves.

![Fig. 2: Fabrication process of a hybrid cuff electrode (former 12polar layout of PI scaffold).](image)

Our approach was to combine the advantages of both technologies to a hybrid device, assembling traditional self-spiraling silicone cuffs and a micromachined thin-film structures based on a polyimide (PI) substrates (Fig. 2).

2. Materials and Methods

a) Fabrication process of hybrid cuff electrodes

The micromachining procedure of the PI is illustrated in Fig. 3. First, a 5 µm thick layer of polyimide resin (Pyralin 2611, DuPont, Bad Homburg, Germany) was spun onto a silicon wafer which served as a support structure during the whole process (Fig. 3a). After curing the PI at 350°C, under N2-atmosphere, the metallization for the connection pads and integrated interconnection lines (30 nm titanium, 300 nm gold) was sputtered on and patterned in lift-off technique (Fig. 3b, c). In the same way, the electrode metallization (300 nm platinum) was deposited and patterned (Fig. 3d, e). A second layer of PI was spun on (5 µm) and cured; an aluminum etching mask was deposited (Fig. 3f, e). A second layer of PI was spun on (5 µm) and cured; an aluminum etching mask was deposited (Fig. 3f). Reactive Ion Etching (RIE in an STS 320 reactor at 13.56 MHz,
120 W, oxygen plasma) was used to open the electrode sites and connection pads and to separate the single devices by etching the outer shapes down to the support wafer (Fig. 3g, h).

a) Spinning on polyimide (PI) on silicon wafer.

b) Spinning on resist, developing, depositing metal for interconnection lines and pads.

c) Lift-off.

d) Spinning on resist, developing; depositing metal for electrode sites.

e) Lift-off.

f) Spinning on PI, depositing etching mask.

g) Reactive Ion Etching (RIE) of PI.

h) Removing etching mask.

i) Separation from silicon wafer.

Fig. 3: Micromachining of polyimide microelectrodes.

Subsequently, the thin-film devices were separated from the wafer (Fig. 3i). To finally achieve the three dimensional shape (more exact: 2½ dimensional), the thin-film structures were put inside a tube-like mounting fixture, which inner diameter is similar to the outer diameter of the nerve, the structure is made for, and tempered 3 hours at 350°C. After this, the structures stayed in the new shape without mechanical stress. Silicone cuffs were manufactured by gluing (silicone adhesive MED-2000, NuSil, Carpinteria, California) one silicone rubber sheet (thickness 0.05ʺ, Specialty Silicone, Paso Robles, California) to another which was stretched to a defined extent. We temporarily applied 1.5 N/mm by rolling a cylinder on the sheets to squeeze out excessive glue. After curing of the adhesive (2 hours), the tension of the pre-stretched sheet rolled the "sandwich" to a spiral. Subsequently, the thin-film structure was glued (Primer: SP-120, Adhesive: MED-2000, NuSil) inside the silicone spiral.

Fig. 4: Layout of thin-film structure before three dimensional shaping. Dimensions are explained in Tab. 1. Integrated interconnection lines are not shown in respect to clarity.

b) Layout of Microstructure

The most important demand on the thin-film microstructure was to use as less PI as possible to ensure, that the mechanical properties of the silicone cuff dominate. That led to the design of Fig. 4: 18 stimulation sites (platinum, Ø=500 µm) and a connector pad are arranged on a scaffold-like substrate. The classical tripolar configuration was chosen to keep spreading current at minimum: one cathode between two anodes (longitudinally). The two anodes of each tripole were short-circuited. To ensure a symmetric current flow, different lengths of integrated interconnection lines were compensated by their width, respectively.

<table>
<thead>
<tr>
<th>Ø cuff</th>
<th>4 mm</th>
<th>6 mm</th>
<th>8 mm</th>
</tr>
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<tbody>
<tr>
<td>a</td>
<td>12.517 mm</td>
<td>18.279 mm</td>
<td>24.034 mm</td>
</tr>
<tr>
<td>b</td>
<td>25.4 mm</td>
<td>25.4 mm</td>
<td>25.4 mm</td>
</tr>
<tr>
<td>c</td>
<td>3.0 mm</td>
<td>3.0 mm</td>
<td>3.0 mm</td>
</tr>
<tr>
<td>d</td>
<td>1.047 mm</td>
<td>1.571 mm</td>
<td>2.094 mm</td>
</tr>
</tbody>
</table>

Tab. 1: Dimensions referring to Fig. 4.
c) Interconnection Technique

One of the most critical points was a reliable interconnection of flexible thin-film substrates and robust medical grade cables. An adapter was made by screen printing platinum leads and pads on an Al$_2$O$_3$ substrate (substrate thickness: 600 µm; printing paste: LPA 88-11, Heraeus, Germany; screen printer: M2, EKRA, Kirchheim, Germany).

![Image of adapter](image1.png)

Fig. 5: Adapting PI thin-film to medical grade cable using a patterned ceramic. Left: µFlex, right: welding.

One end of the adapter [Fig. 5] size: 3.7 · 11.6 mm$^2$ was designed to ball-bond the PI thin-film on, using µFlex interconnection technique [3], the other for parallel gap welding [4] of Elgiloy wires. Both, materials and applied technologies, used for manufacturing this adapter, are non-cytotoxic. (Bonder: KS 4524 digital, Giessen Electronics, Germany; welding: McGregor DC 1000 / thin-line Weld head model 68, Weld-Equip, München, Germany.)

d) Implantable Multichannel Cable

The cables were made of 12 helical wound wires, embedded in a silicone hose (HM Medical Engineering, Binzen, Germany). The wires (MP-DFT, used in pacemaker industry) were made of Elgiloy with an inner core of silver which reduced the impedance of the wire. The outer diameter of each wire was 150 µm, including a 20 µm insulation layer. The total outer diameter of the cable was 2.7 mm, the length was 95 cm.

c) Functional Testing

The cuff electrodes were functionally tested in 0.9 % saline solution at room temperature using a custom made computer controlled impedance spectrometer based on a three electrode setup (potentiostat, platinum counter electrode and Ag/AgCl reference). The voltage amplitude was 100 mV, sine wave excitation.

3. Results

We fabricated 18polar spiral hybrid cuff electrodes for selective stimulation of large and medium sized peripheral nerves. The cuffs had an inner diameter of 4, 6, and 8 mm and because of their ability to self-size, they were suitable for nerve trunks in the range of 4 to 10 mm diameter. The length of a silicone cuff was 8 mm.

![Image of cuff electrodes](image2.png)

Fig. 6: Relationship of stretching extent (s) of first silicone sheet and resulting diameter (d) of self-spiraling cuff.

By gluing the PI substrates to the inner side of the silicone spiral, the PI was smoothly embedded in silicone adhesive. No sharp edges could be found [Fig. 7] and the PI/silicone adhesion was good. The total thickness of the cuff electrodes including two layers of adhesive, thin-film, and two silicone rubber sheets was about 350 µm.

![Image of PI in silicone adhesive](image3.png)

Fig. 7: Embedding of PI in silicone adhesive by gluing the thin-film to the inner site of the silicone cuff (scheme and photo).

The electrical impedance of a single platinum electrode with an area of 0.196 mm$^2$ was 2.5 kΩ at 1 kHz [Fig. 8]. We developed a method for interfacing thin-film substrates to medical grade cables using patterned Al$_2$O$_3$ substrates adapters and two different interconnection techniques. An implantable 12 channel cable was developed in cooperation with a German enterprise that is suitable to provide a connection between a hybrid cuff electrode and an implantable stimulator. This cable had an ohmic impedance of about 25 Ω/m per channel.
and was very flexible. It was possible to weld the wires to the ceramic adapter. Ball-bonding of the thin-film caused no problems.

Unfortunately, parallel gap welding of the wires to the ceramic adapter was proved as very delicate. The whole device (cuff and cable) was robust and easy to handle/to implant. The small longitudinal dimension of the cuff (possible length: 7 to 20 mm) offers surgeons a wide range of implantation sites. The great length of the cable enables one to bridge long distances between the implantation sites of cuff and stimulator/telemetry. However, the advantages of 18polar cuff electrodes compared to 12polar cuffs have to be verified in animal experiments (aimed model: large "arm" nerves of pig.  

Fig. 8: Ohmic impedance of platinum dot electrode versus frequency.

4. Discussion

Fabrication of the PI thin-film substrates on silicone support wafers worked well, highly reproducible and precise. The results of long term pulse test will show, whether the electrode metallization has to be thickened by electroplating or not. The applied method of making self-spiraling silicone cuffs was sufficiently reproducible and appeared to be suitable.

Using silicone adhesive to join the PI structure to the silicone cuffs was a good choice not at least because of the smooth embedding of sharp PI edges. Especially this point was criticized in literature [5]. The implantable 12 channel cable was very durable and flexible.

5. Conclusion

We established a process for fabrication of multipolar hybrid cuff electrodes. A new concept for adapting thin-film structures to heavy duty medical grade cables was presented. Implantable 12 channel silicone cables were developed and manufactured. Further investigation have to be done to bring the new technologies to clinical relevance.

References


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