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Inner ear implants for experimental electrical stimulation of auditory nerve arrays

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Electrode arrays chronically implanted in the inner ear are gaining increased use for experimental studies of the auditory nervous system, as well as for studies related to development of improved auditory prostheses. Commercially available electrode arrays are designed for human use and thus may be unsuitable for experimental studies, particularly in small animals. This paper describes a simple, inexpensive method for making custom electrode arrays in a variety of configurations, suitable for animals ranging from small rodents to non-human primates.

Introduction

Electrical stimulation of the auditory nerve has been used to study the functional properties of the auditory system since the 1930s (Andreev et al., 1934; Hallpike and Hartridge, 1937; Stevens and Jones, 1939; Woolsey and Walzl, 1942). The experiments, however, involved either placement of single electrodes in the ear canal or visually guided placement of electrodes on the nerve array in a dissected cochlea. The development of electrode arrays that could be chronically implanted in the inner ear was driven by the clinical development of the cochlear prosthesis which grew out of the experiment of Djourno et al. (1957) with a single-wire implant in a profoundly deaf patient. This experiment inspired the development of a clinical program in Los Angeles (Doyle et al., 1964; House

and Urban, 1973) which, by 1985, had led to implantation of FDA-approved single-channel devices in over 700 patients (Hopkinson et al., 1986).

The concept of a multielectrode device which could differentially activate subpopulations of auditory nerve fibers was first tested by Simmons (1966) who placed multiple wires in the auditory nerve root in the modiolus. Only a few patients to date have been implanted with these devices, partly due to concerns about mechanical damage to the nerve, but the concept, using much smaller electrodes, is still under development (White, 1985; Anderson 1988).

Scala tympani electrodes housed in a silicone rubber carrier were first implemented by Michelson (1971), who molded the carrier to the scala tympani so that the electrodes would lie close to the auditory-nerve peripheral processes. This allowed placement of electrodes along the systematic array of nerve fibers which naturally occurs along the length of the spiraling cochlear scalae (Merzenich et al., 1974). The initial use of a molded carrier was soon abandoned due to con-

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cerns about mechanical damage, and replaced by a smaller diameter implant (Sutton et al., 1980). This has now developed into 3 basic designs, all using electrodes held in place by a tubular silicone-rubber carrier. The arrays can be spherical or hemispherical electrodes arranged longitudinally along one or more sides of the carrier (Pfungst et al., 1979; Hochmair-Desoyer et al., 1983); electrodes arranged radially along a spiraling carrier (Loeb et al., 1983; Merzenich, 1985) or banded electrodes circling the carrier (Patrick et al., 1985).

The continuing experimental use of electrical stimulation for studying the auditory nervous system has been aided by these developments in that experiments in chronically as well as acutely implanted preparations are now routine. Examples include electrophysiological studies of the responses of auditory nerve fibers to electrical stimulation (Hartmann et al., 1984; Javel et al., 1987; Parkins and Colombo, 1987), studies of the representation and processing of this information at higher levels of the auditory pathway (Clopton and Glass, 1984; Ryan et al., 1986), and psychophysical studies of the functional properties of electrical stimulation (Pfungst et al., 1985).

Commercially manufactured electrode arrays are expensive and, because they are designed for human cochleas, they are often too large for some experimental animal preparations. Furthermore, they do not allow the flexibility in design required for some experimental protocols. We describe here an inexpensive technique for making custom multielectrode arrays for chronic implantation in the scala tympani of the cochlea. The arrays can be as small as 0.2 mm in diameter and still retain mechanical stability.

Materials and Methods

The implants described in this paper consist of platinum-iridium (Pt-Ir) electrodes arranged on the outer surface of a flexible solid silicone rubber carrier. The electrodes can be of two types: (1) spherical electrodes which can be arranged along one or more sides of the carrier, or (2) banded electrodes created by wrapping Pt-Ir wire around the carrier. These types may also be combined on

the same carrier. The carrier is made by filling a polyethylene mold with silicone rubber. After the rubber is cured, a thermo demolding process is used to remove the mold.

The spherical electrodes (which we call Type I) are flamed Pt-Ir balls. The banded electrodes (called Type II) are formed by wrapping Pt-Ir wire around the silicone carrier. When the diameter of the banded electrode is less than 0.3 mm, the Pt-Ir wire is flattened before being wrapped because the flattened wire is easier to wrap around the tubing and has a larger surface area. These electrodes are called Type III.

Fabrication procedure

Soft mold formation. The mold is made of polyethylene tubing (Clay Adams, Parsippany, NJ). For implant diameters under 0.6 mm, 1.6764 mm i.d. \times 2.413 mm o.d. tubing gives the best result. The tubing is held 10 cm above a Bunsen burner, heated, and pulled. This results in a small tapered polyethylene tube (Fig. 1a). The inside diameter of the tube can be made as small as 0.1 mm. If a flattened side is desired (Fig. 1b), the tubing can be flattened on a glass plate placed on a 120°C hot plate. To prevent the tubing from sticking to the plate, the glass is rubbed with several drops of Dow Corning 360 Silastic thinner (Dow Corning Co., Midland, Michigan) before being heated. The flattened shape of the tubing will be preserved after the pulling procedure. After the tube is shaped, the preferred portion of the tubing, usually 1.5–2.5 cm in length, is cut off.

Electrode preparation. Stimulating sites and inter-connecting cable are fabricated from

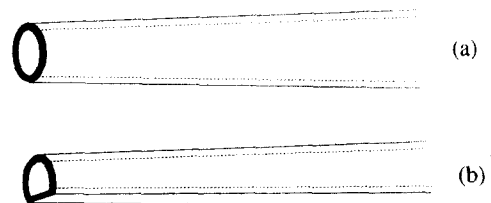


Fig. 1. Polyethylene soft molds: (a) round mold, and (b) flat-sided mold. The polyethylene tubing is heated above a Bunsen burner, and pulled to form the tapered mold. The flat side is produced by pressing the mold against a heated glass plate before pulling.

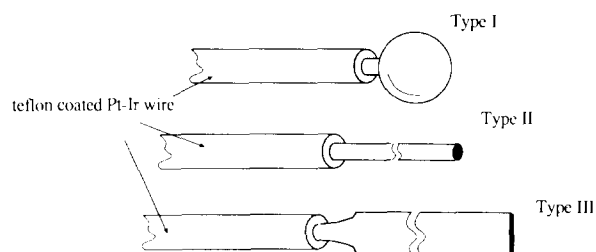


Fig. 2. Electrode wire preparation. Type I is formed by flaming the Pt-Ir wire with a microtorch. Type II is a bared wire. Type III is a bared, flattened wire.

Teflon-coated 90% Pt-10% Ir wires. Wires, manufactured by Medwire Co. (Mount Vernon, NY) can be prepared in 3 different ways depending on the desired implant type and size (Fig. 2). For spherical (Type I) electrodes, 1T (0.0254 mm diameter) Teflon-coated wire is flamed with a microtorch to form a small ball at the tip. The microtorch is made with a No. 18 syringe needle. The natural gas and oxygen ratio to the microtorch is adjusted to give a focused flame so that the spherical electrode can be formed without burning off too much of the Teflon coating from the wire leading to the sphere. The size of the sphere can be controlled by adjusting the length of the wire to be flamed. The diameter can easily be controlled between 0.1-0.5 mm. For banded electrodes (Type II), the Teflon coating is peeled off with a pair of No. 5 fine tweezers to expose 3 cm of wire which will be wrapped on the Silastic carrier to form the band. For Type III electrodes the exposed wire is flattened with a stainless steel roller.

Wire insertion. The mold is placed on a micro-ruler printed on a glass plate and observed under a dissecting microscope. Small holes are punched at desired positions manually with a very fine needle made from a 0.5 mm diameter wire sharpened to a fine tip (a tungsten microelectrode can be used), and the Teflon-coated wires are fed into the mold through these holes. For the Type I electrodes, the balls should be pulled all the way to the mold, and half of the ball should be embedded in the mold (Fig. 3a). For Type II and Type III electrodes, the wire should be inserted enough so that the uninsulated portion of the wire left inside the mold is minimal (Fig. 3b, c). For

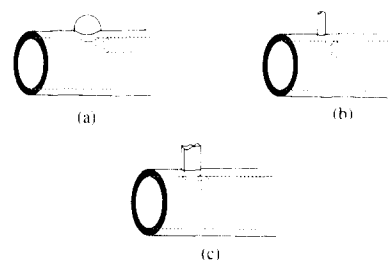


Fig. 3. Wire insertion. a: For Type I electrodes, the wire is pulled enough so that part of the spherical site is embedded in the polyethylene mold. b: Type II wire insertion. c: for Type III electrodes, the flattened surface of the wire is parallel to the long axis of the mold.

Type III electrodes, the flattened surface of the wire should be parallel to the long axis of the mold (Fig. 3c).

Silicone rubber preparation and injection. The electrode carrier is made of silicone rubber. Dow Corning 382 Silastic elastomer* is mixed with Dow Corning catalyst M (Stannous Octoate). The amount of the catalyst should be no more than 0.25% by weight so that more than 30 min are allowed before the Silastic cures. Also, with larger amounts of catalyst, the resulting compound will be weaker mechanically and may not be biocompatible. The viscosity of the Silastic elastomer can be controlled by adding Dow Corning 360 Silastic thinner. However, excess Silastic thinner may cause air bubbles. The apparatus for injecting Silastic into the mold is a pulled-glass pipet. The mixed Silastic is sucked into the pipet by a vacuum pump. The pipet is inserted into the larger end of the mold, and the Silastic is injected into the mold by pumping air into the glass pipet. Several hours are required for complete curing of the Silastic.

Thermo demolding. This is the critical step of the fabrication process. A simple custom-built vise is used to hold and manipulate the mold (Fig. 4). The small end of the mold which extends beyond the electrodes is held in the vise. A fine tip soldering iron is held close to the large end of the mold. When the mold is heated, it turns soft, shrinks in

* Medical grade 382 Silastic paste has been discontinued by Dow Corning. Medical grade MDX4-4210 Silastic paste, which requires longer curing time at room temperature, may be used as a replacement.

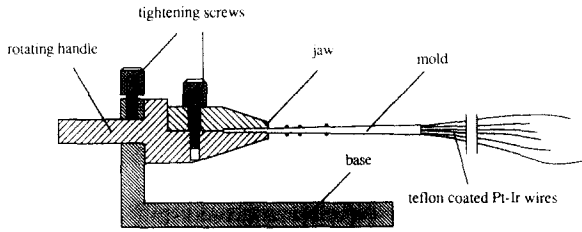


Fig. 4. Vise for implant demolding. The rotating handle allows the implant to be rotated after small pieces of the mold have been pulled off one side.

length and expands in diameter. A pair of fine forceps is used to tear and peel the mold, piece by piece, off the large end for 5–10 mm. Then the exposed large end of the implant is held by the vise. The small end of the mold is heated with the soldering iron, and peeled off piece by piece. This process has to be started from the end of the mold, and performed on a small portion at a time. Care must be taken not to tear off the polyethylene tubing until it is completely softened by the heat.

Electrode site formation. For the Type I electrodes, the ball should be pushed down to the Silastic rod surface. A very small amount of Silastic elastomer, to cover the exposed wire (Fig. 5a), may be applied using a fine needle. The implant can be heated in an oven at 100–130 °C to speed curing. For the Type II electrodes, first the wire is cut to form a sharp tip, then the wire is wrapped around the Silastic rod for 3–5 turns. Next, the end of the wire is inserted through the Silastic carrier, pulled “tightly” and cut. The cut end of

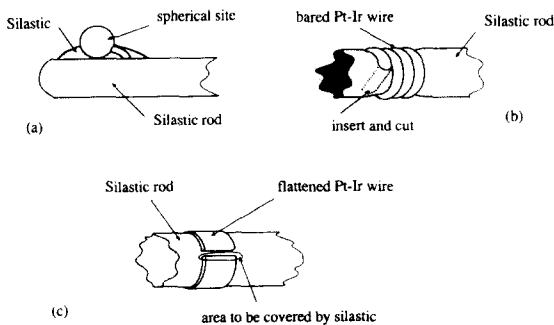


Fig. 5. Electrodes mounted on silicone rubber carriers. a: Type I electrode. b: Type II electrode. c: Type III electrode.

the wire will recess back into the silicone rubber carrier (Fig. 5b). For the Type III electrodes, the metal ribbon is wrapped on the Silastic carrier just one turn and then cut. The end of the ribbon can be buried in a small drop of uncured Silastic applied with a fine needle (Fig. 5c), and the implant can be baked to cure. The front end of the Silastic carrier can be cut to the desired length. A drop of uncured Silastic is applied on the cut end to form a smooth tip.

Cable formation. The connecting wires are threaded through Dow Corning Silastic tubing of desired length and diameter. The most commonly used sizes are 1.65 mm o.d. and 1.20 mm o.d. Tubing diameter should be selected according to the number of the wires which will pass through it.

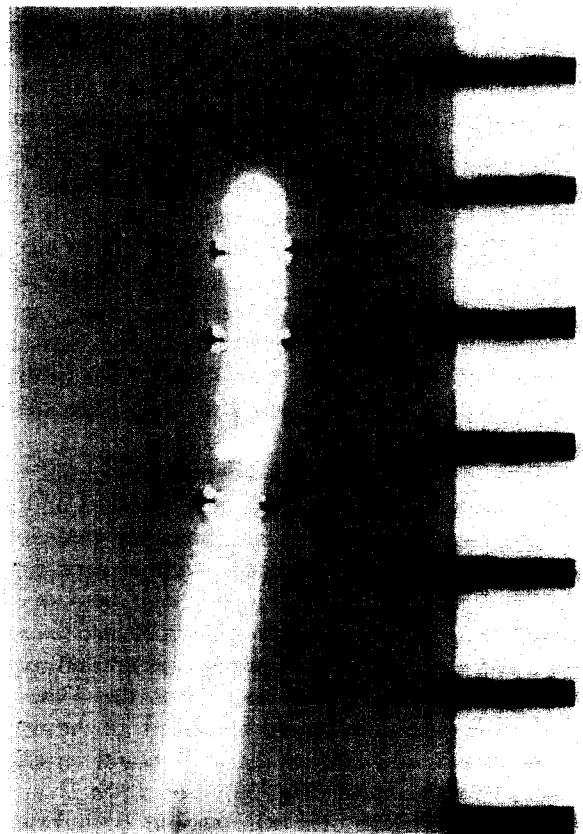


Fig. 6. A double sided 6-channel Type I implant. Scale = 1 mm.

Silastic is injected into the tubing by the method described above, and left to cure. The whole implant is thus finished.

Type I, II and III electrodes can also be combined on the same implant to meet different experimental purposes. We have successfully fabricated double-sided 6-electrode Type I, and 6-electrode Type II implants for monkeys, and 8-electrode Type III implants for guinea pigs. Fig. 6 shows a finished double-sided Type I implant.

Electrical Characteristics

In vitro impedance tests

Electrode impedances at different frequencies were measured in a normal saline solution. A 3-electrode system was used. In order to compare with the in vivo test results, the counter electrode and reference electrode were bared Pt-Ir wires with surface areas hundreds of times larger than the active electrode. A sinusoidal current of 10 μ A p-p was delivered to the active and counter electrodes, and the voltage between the active electrode and the reference electrode was measured at frequencies from 10 Hz to 5 kHz. It was found that the impedance vs frequency curves of Type I, II, and III electrodes were quite similar except in absolute magnitude. Fig. 7 shows the impedances of typical Type I, II and III electrodes. The impedances decreased as a function of frequency, as

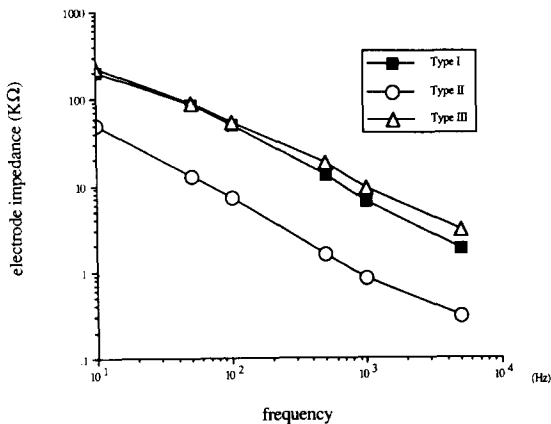


Fig. 7. Electrode impedances of 3 electrode types, measured at 10 μ A p-p in saline.

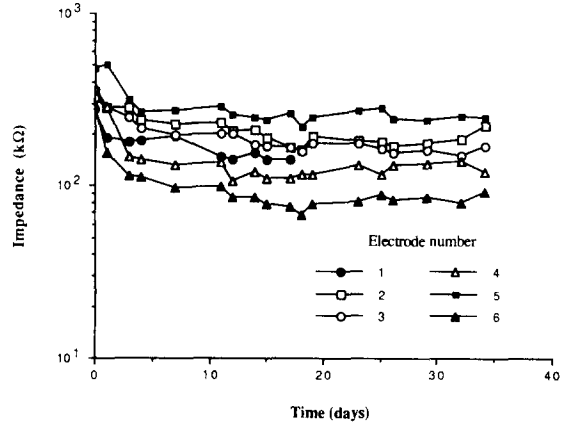


Fig. 8. Soak test results. The impedance was measured in a standard saline solution with a two-electrode-system at 1 kHz 1 μ A p-p. The reference electrode was a 0.18 mm bared Pt-Ir alloy wire of 40 mm in length.

expected due to the capacitive characteristics of the electrode-electrolyte interface. When the frequency exceeded 5 kHz, the impedances approached constant resistive values.

A long-term soak study was done using a double-sided Type I implant. The implant was immersed in saline solution for over 30 days. A two electrode system was used for monopolar impedance measurement with a bared Pt-Ir wire used as a reference electrode. Bipolar impedance was measured between electrode pairs. The impedance was measured with a 1 kHz, 1 μ A p-p sinusoidal current source. Both monopolar and bipolar impedances stabilized after 24 h of soaking, and showed good stability over a 30-day period. The monopolar impedances are illustrated in Fig. 8.

In vivo impedance tests

Type I and Type II electrodes have been implanted for chronic electrical stimulation in behaviorally trained monkeys. The Type III electrode has only been used for acute studies. The electrode impedance in vivo drifts during the first few weeks post implantation with ranges varying from animal to animal, and then stabilizes. Our records on 6 implanted animals show, with one exception, that the impedances decrease and stabilize at lower values. This result is similar to the in vitro soak study result, except that the stabilization process takes much longer.

TABLE I
DIMENSIONS AND "REAL SURFACE AREAS" OF SAMPLE TYPE I, II, AND III ELECTRODES

	Electrode type		
	Type I	Type II	Type III
Electrode dimensions (mm)	ball dia. = 0.12	band dia. = 0.6 band width = 0.15	band dia. = 0.35 band width = 0.07
Effective area (mm ²)	0.233	1.495	0.365

Effective electrode area measurement

The electrode surface roughness varies for different types of electrodes due to the fabrication process. Estimating the effective electrode area is a key requirement for safe use of the electrodes. Based on the fact that the charge density necessary for hydride formation (HF) is precisely defined for cathodic-first charge injection, the effective area can be estimated by the total HF charge during a pulse test (Brummer and Turner 1977a). A 3 electrode system was used for the pulse tests. The stimulating electrodes were subjected to charge balanced cathodic-first current pulses, and the voltage data were collected by a Modular Instruments Incorporated (MI²) data acquisition system with a sampling frequency of 100 kHz. The measurement was repeated 200 times. Effective areas for samples of the 3 types of electrodes were calculated from the data and are listed in Table I. Note that the electrode dimensions for Type I and Type II electrodes can be varied depending on the requirements of the experiment. Diameters for Type I electrodes typically range from 0.12 mm to 0.25 mm.

Discussion

Our method for fabrication of implantable multielectrode arrays can support a variety of laboratory experiments requiring specific implant geometries and electrode configurations. These implants have demonstrated good mechanical and

electrical stability over many months of chronic electrical stimulation. We have examined two implants which were removed from the cochlea after several months of implantation and found that they retained their original configuration, despite the mechanical stresses encountered during the insertion and removal. This stability was not typical of earlier designs in which Silastic tubing was used as the carrier, even if the tubing was filled with Silastic after electrode insertion.

Fabrication procedures using hard reusable molds may be valuable for production in bulk, but the initial cost of the mold is high due to the fine machining required. Probably the most economical technique for mass production would involve thin film technology, but these techniques are still under development (White, 1985; Van der Puije et al., 1987). Especially difficult tasks are thin film fabrication of flexible arrays with appropriate mechanical characteristics for insertion into the delicate structures of the cochlea, and the biological compatibility and stability required for chronic implantation in the body. Also under development are multielectrode arrays which can be implanted outside the scala tympani (Pfungst et al., in press; Anderson et al., 1988). For experimental purposes where low cost and design flexibility are required and production volume is low, hand production techniques such as described here are, at this time, preferred.

In making electrode arrays for chronic implantation in the cochlea, the potential of damage to the cochlea and auditory nerve must always be considered. One variable which is related to the potential for physical damage is the size of the array (length and diameter). Another is electrode geometry. The small spherical electrodes may have advantages for localizing current, but have the potential for creating more physical insertion trauma than the banded electrodes. Also, with implants of the dimensions described here, charge densities at the electrodes can be high which may result in the release of gases or other toxic materials. This is especially a risk with the Type I electrodes and particularly if the electrode array is made for small cochleas. In Table I we give typical "real surface areas" of the 3 electrode types. These values can be measured for any electrode array

using the method described by Brummer and Turner (1977a). Given these values, one can determine the damage limits for electrical stimulation based on gassing or other criteria (Brummer and Turner, 1977b; Miller et al., 1983). One must then consider the relationship of these values to the desired operating range (Pfungst et al., 1980) to determine if the electrode size is adequate.

We note two limitations of the techniques described here: (1) since the mold is thermo demolding, only cold-curing Silastic can be used; (2) when the number of stimulation sites exceeds ten, wire insertion becomes difficult.

Given these constraints and those imposed by considerations of safety to the implanted tissues, we find this technique the most useful and economical we have encountered for experimental multichannel electrical stimulation of the auditory nerve.

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