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Design and fabrication of an experimental cochlear prosthesis

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Abstract—*The technical and safety requirements for intracochlear electrical stimulation to restore hearing in the profoundly deaf are reviewed. A system has been implanted in human subjects which comprises a 16-contact flexible electrode array, radio receiver/stimulator and surgical disconnect which permits changing from percutaneous cable to transcutaneous telemetry. The design, fabrication, and mechanical and electrical testing of each of the components are discussed in detail. Major improvements over previous systems include controlled introduction of anisotropic flexing properties in the electrode array to facilitate insertion and optimal contact orientation, enlarged and stabilised contact surface area and the development of a new connector technology which combines high density, high reliability, biocompatibility and ease of operation during surgery.*

Keywords—*Auditory prosthesis, Cochlear prosthesis, Connectors, Deafness, Electrical stimulation, Electrode arrays*

1 Introduction

THE DEVICES described here were designed and built to satisfy the technical requirements of experiments in volunteer subjects with total sensory deafness. Previous attempts here and elsewhere to provide discrete, multichannel stimulation of the auditory nerve in deaf patients have indicated the need for a system capable of better temporal and spatial control of stimulus delivery. The system described here is not intended for routine clinical use. However, it incorporates many novel solutions to design problems which can be expected to recur in both experimental and clinical multichannel neural prostheses. In particular, it addresses the problems of replacing failed or obsolete implanted components as subassemblies to minimise surgical trauma.

2 State-of-the-art

Attempts to produce a functional auditory prosthesis are currently underway in many centres around the world (HOUSE, 1976; CHOUARD and MACLEOD, 1976; EDDINGTON *et al.*, 1978; SIMMONS *et al.*, 1979; FOURCIN *et al.*, 1979; HOCHMAIR *et al.*, 1980; MERZENICH *et al.*, 1980; MICHELSON and SCHINDLER, 1981; CLARK *et al.*, 1981; SPILLMANN *et al.*, 1982.) Most of these projects share the goal of using electrical stimulation of auditory nerve fibres to produce auditory sensations which will be perceived as familiar enough that they can be used for speech reception without additional cues and with minimal training. Both information theory and empirical experience with single-channel stimulation suggest that high levels of speech intelligibility will probably require multiple (at least 4–8) neural information channels (BILGER, 1977; BALLANTYNE *et al.*, 1978; WHITE, 1978; KIANG *et al.*, 1979; MERZENICH *et al.*, 1979*b*). It has generally been assumed that the nervous system has a better chance of being able to use such information if the channels are independent and the perceptions produced combine linearly (MERZENICH *et al.*, 1979*b*).

Achieving such conditions with a multielectrode stimulation array requires consideration of the physical separations among electrodes and the activatable neural structures, the threshold and dynamic range of the neurons and the physical spread of stimulation current (RANCK, 1975; BLACK *et al.*, 1981; LOEB *et al.*, in press). These considerations plus surgical accessibility and minimisation of tissue damage have led most groups to pursue intracochlear (usually *scala tympani*) electrode arrays. There, separate electrode contacts can be spaced out longitudinally over intervals greater than the distance between a given electrode site and its excitable target, which increases the chances for activation of independent populations of nerve fibres by each channel of information.

The possible one-to-one correspondence between a position (base to apex in the *scala*) and the pitch of the perception that stimulation of this site might evoke

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(based on the place pitch theory) was also a factor in the design of the first intracochlear devices. If such a correspondence could, in fact, be demonstrated, it might permit a very simple encoding scheme for the information based on the frequency channel vocoder, with which there is already considerable psychophysical experience (FLANAGAN, 1972).

The limited experience to date indicates that the pitch perceptions achieved with the first generation electrode arrays are acoustically complex sounds only generally correlated in pitch with the characteristic frequency normally associated with a given *scala tympani* locus and influenced complexly by electrical stimulation parameters such as pulse duration, frequency, and amplitude as well as electrode configuration and orientation (MERZENICH, 1973; EDDINGTON *et al.*, 1978; TONG *et al.*, 1979; MICHELSON, 1980). This suggests two possibilities: either the electrode arrays were not adequately selective in activating discrete populations of neurons from each electrode site, and/or the auditory nervous system is sensitive to finer grain spatiotemporal details of neuronal activity patterns than simply the general location and intensity of that activity. Distinguishing between these possibilities (and coping with either) necessitated the development of a physically improved multielectrode array capable of being precisely and safely positioned, activated, and monitored in the patient.

This is not to say that a relatively simple frequency channel vocoder strategy might not provide high levels of speech intelligibility. But directed psychophysical studies are required to determine its optimum form, and those studies require use of an electrode array into which excitation of the nerve array is well understood and highly controllable.

3 Technical requirements

3.1 *Electrode contact surface area*

One of the most important factors contributing to damage of tissue and corrosion of the electrodes themselves during the passage of balanced biphasic electric current is the charge density per phase, expressed here in microcoulombs per square centimetre of apparent geometric surface area (BRUMMER and TURNER, 1977; see LOEB *et al.*, 1982, for review). It is still not clear what the safe limit of charge density is in the cochlea. However, the desire to achieve highly localised stimulation over a wide range of stimulus frequencies and amplitudes suggests that electrode contacts may often be operating near such limits, necessitating designs which make optimum use of the limited space available.

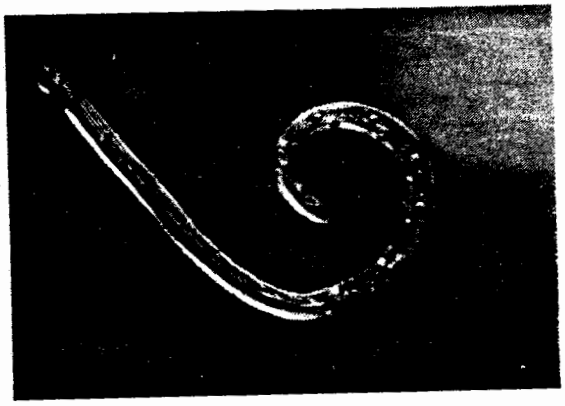
In a multiple electrode cochlear array, it is sometimes desirable to drive at least some electrode pairs in parallel from a single signal source. The efficacy of a stimulus is a function of the actual currents it induces in the tissue rather than its driving voltage. In a parallel configuration, the partition of the current from a voltage or current source into the various electrode pairs is a function of their individual impedances. Electrode contacts which are unnecessarily small are subject to impedance fluctuations through manufacturing tolerances and corrosive and biologically reactive phenomena resulting from high charge density in use.

3.2 *Electrode configuration and orientation*

Previous studies have indicated that isolated pairs of bipolar intracochlear electrodes provide very good auditory nerve selectivity (most localised stimulation) when oriented radially in the *scala tympani* (MERZENICH and WHITE, 1977). For such pairs, the threshold is strongly influenced by the mediolateral positioning and spacing of the electrodes with respect to the *habenula perforata*, through which the spiral ganglion cell dendrites approach the organ of Corti (see Fig. 1*d*). We have identified a pair position which appears to give relatively low and relatively uniform thresholds for cases in which the spiral ganglion cell dendrites are intact and for cases where they are degenerated. (In these cases the stimulation current must activate the spiral ganglion cell bodies themselves in the medial part of the bony wall.) This is important because dendrite loss in profoundly deaf patients is unpredictable, ranging from insignificant to patchy to total. To maintain close apposition between the electrode contacts and the desired position on the wall of the *scala tympani*, a semi-space-filling' electrode array was constructed which fits snugly within the spiralling cavity.

Earlier intracochlear devices were moulded in dies produced from casts of the *scala tympani*. This has been discontinued because of difficulty in achieving reliable atraumatic insertion unless the arrays were relatively undersized and loose fitting. In particular, such electrodes had difficulty passing a small constriction which we have noted on some of these castings at a distance of about 16 mm from the round window (see Fig. 1). This elevation of the scalar floor apparently marks the passage of the facial nerve through the adjacent bone. The smooth, round cross-section device described below positions the contacts well, restricts perilymphatic flow less, and facilitates an insertion strategy which involves rotating the electrode after it is partway into the *scala* (SCHINLDER *et al.*, 1981).

Previously fabricated intracochlear multielectrodes moulded in casting-based dies rotated significantly upon insertion (MERZENICH *et al.*, 1979*a*; O'REILLY, 1981) when tested. Fortunately, the shifting between the original electrode position (as moulded into the device) and their final orientation (with respect to cochlear structures) was constant and reproducible for each electrode and apparently primarily a function of the mechanical characteristics of the lead wire bundle within the insert. Thus one requirement of the redesigned fabrication process was that it must facilitate reproducible stacking of these wires and



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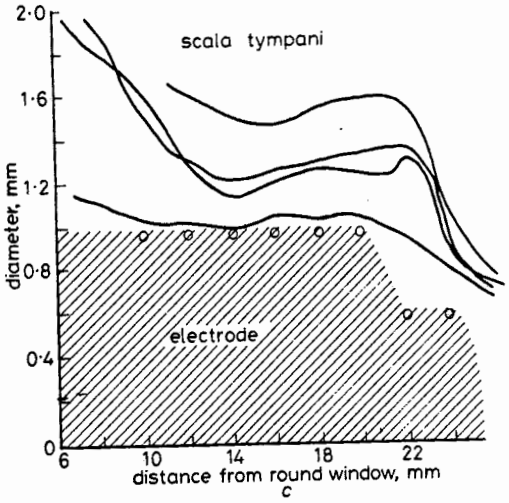

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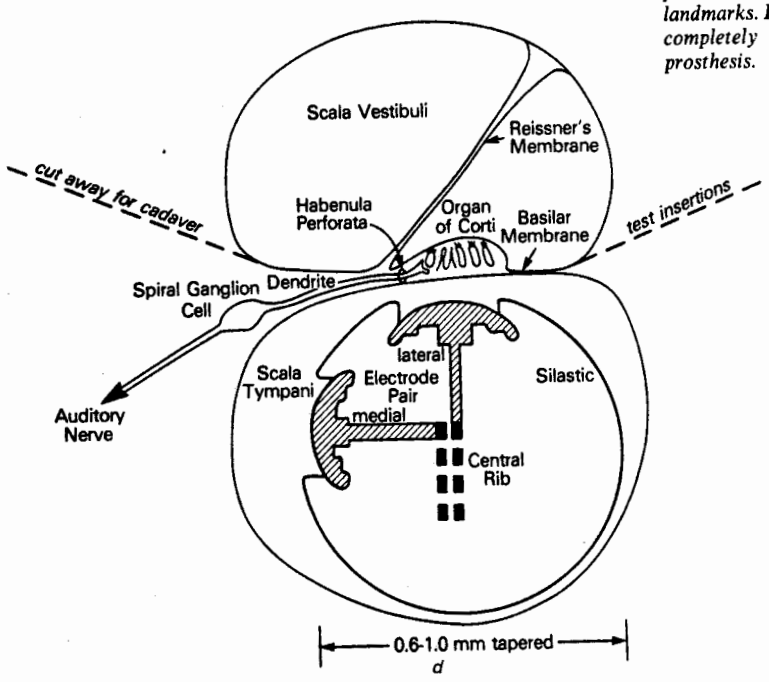
Fig. 1 *(a) 16-contact electrode array showing longitudinal arrangement of eight pairs (only lateral contacts facing upward are visible) and central rib of lead wires visible through the transparent Silastic carrier. (b) Electrode array inserted into a cadaver temporal bone, view looking down through basilar membrane into the* scala tympani *after the* scala vestibuli *has been dissected away. The broken circle indicates approximate original position of the round window, here enlarged in the manner employed during surgical insertion. (c) The graph shows the minimum diameter of the* scala tympani *against distance from the round window for Woods metal castings from four adult cadaver temporal bones, along with the relative dimensions of the uncoiled, cylindrical electrode array. (d) Cross-section schematic showing the relative positions of electrode contacts and cochlear landmarks. Hair cells shown in the Organ of Corti are completely absent in deaf candidates for this prosthesis.*



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reorientation of electrode contacts to correct for rotational shifts.

From a consideration of the orderly pattern of representation of sound frequency along the human basilar membrane, it was apparent that sound frequencies required for normal speech perception could be spanned by an electrode array which was inserted to a distance of about 24 mm (BEKESY, 1960; FLANAGAN, 1972). The initial designs have comprised eight bipolar pairs of electrodes spaced every 2 mm over the interval 10–24 mm from the round window entrance point, as shown in Fig. 1. An eight-channel frequency vocoder with centre frequencies spanning this range would synthesise speech with a relatively high level of intelligibility (see FLANAGAN, 1972).

3.3 *Control of electrical stimulation*

The present uncertainty regarding the relationships between electrical stimulation parameters, the perceptions they produce and optimal speech encoding strategies to make use of such perceptions forces us to entertain a very wide variety of experiments in these patients. The consequences of manipulating electrode configuration, current waveform (100–6000 Hz), and interelectrode interactions such as the effects of phasing must all be understood to design adequate and feasible prostheses. Information on the *in vivo* condition and performance of the electrodes over time postimplantation is also needed. It was decided that these requirements were impractical to fulfil with telemetered systems, and that, at least for some significant postoperative period, they would necessitate the use of hardwired, percutaneous access to each electrode contact individually and simultaneously.

Eventually, for general clinical use, such prostheses must be chronically implanted without percutaneous connectors. Factors such as those cited above appear to affect the overall speech perception performance of such prostheses in ways which are not obviously predictable from the individual perceptions reported during controlled parametric testing. Furthermore, factors such as number of channels, bandwidth, waveform control, and dynamic range are extremely important and tend to interact competitively in the design of telemetry equipment. Therefore, this system was developed for use with various hardwired and computer simulated paradigms of speech presentation, so that important factors could be identified and bounds placed on them. Owing to unpredictable differences between patients, some form of direct access testing of each implant may be necessary before an optimal configuration for telemetered activation can be established, particularly given the limitations of both current telemetry equipment and clinical experience.

3.4 *Adaptation and learning with constant use*

There is some evidence that previously implanted patients have progressed over time in their abilities to make effective use of their prostheses. This probably resulted from

(*a*) their learning to interpret their perceptions correctly (e.g. correlating them with lip reading)

(*b*) from the iterative process of adjusting and optimising their stimulation equipment to account for individual differences

(*c*) from changes in the reactivated (and long dormant) central auditory nervous system

(*d*) possibly from postoperative changes in the electrical milieu of the cochlea

(*e*) also, patients' subjective preferences for certain options in their stimulation parameters were not always correlated with their actual performance over time.

Therefore, it was deemed important that the experimental device be capable of being used in some stable and well understood configuration on an essentially continuous basis by the patient, particularly during a 3–4 month period of intensive parametric testing immediately after the implantation of the device.

4 Human factors requirements

4.1 *Intraoperative safety*

The basilar membrane separating the *scala tympani* from the *scala media* is a delicate structure whose integrity is required for the continued survival of the spiral ganglion cells comprising the auditory nerve. The insertion of a long, delicate, flexible array into a tightly coiled structure via a deeply located access port (the round window) presents a difficult problem. A relatively straight electrode form meets resistance and is easily pushed up through the basilar membrane as it is pushed against the curved outer wall of the *scala tympani*. Coiled electrode inserts have to undergo significant bending and manipulation to initiate entrance into the *scala tympani*. They must be robust enough to be straightened without damage while retaining a 'memory' of the curvature of the cochlear spiral. Given that memory, resistance to insertion is greatly reduced and the final position of the individual contacts is highly reproducible (O'REILLY, 1981).

4.2 *Postoperative safety*

The use of percutaneous breaches of the barrier layer of the skin for extended periods has been a much studied but generally unsatisfactorily resolved problem (KADEFORS *et al.*, 1970; LEE *et al.*, 1970; AL-NAKEEB *et al.*, 1972; GIBBONS *et al.*, 1972; MOONEY *et al.*, 1974; FERNIE *et al.*, 1977; GROSSE-SIESTRUP *et al.*, 1979). This is particularly so when the percutaneous device is continuous with a foreign body which is left chronically implanted even after the percutaneous parts are removed, since once infection occurs around foreign bodies, they provide protected niches for

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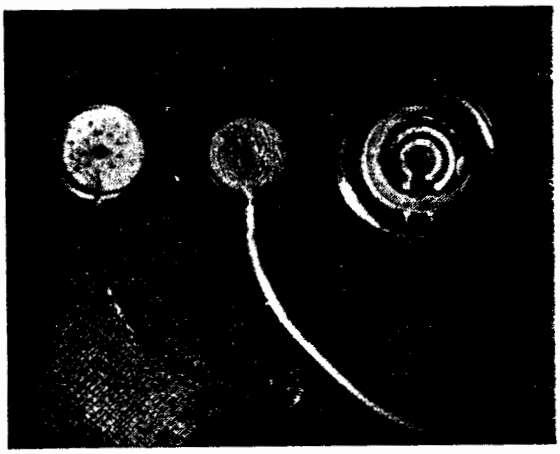
bacteria. In reviewing clinical and animal literature, it became apparent that there are three time frames for percutaneous devices, each with distinct pathophysiological mechanisms. For the acute postoperative period of about 1 week, the exit point may be treated as a sterile site, subject to careful bandaging and aseptic techniques. For the period from 1 week to about 3–5 months, a mechanically stable



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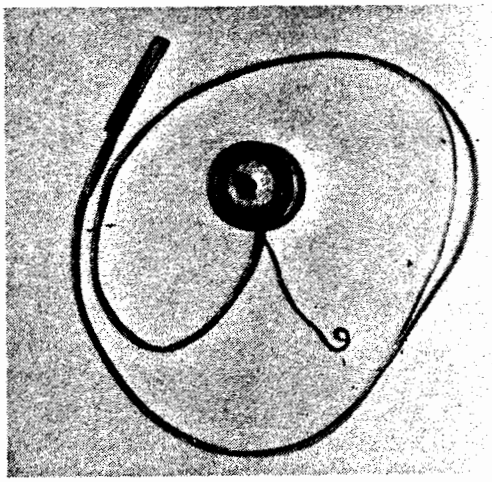

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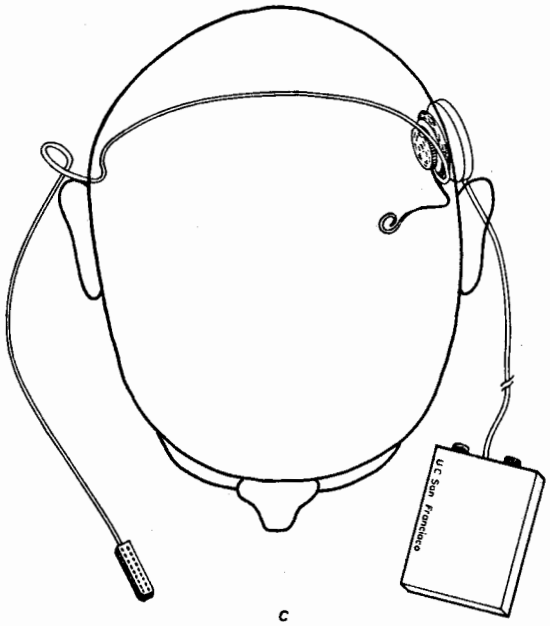

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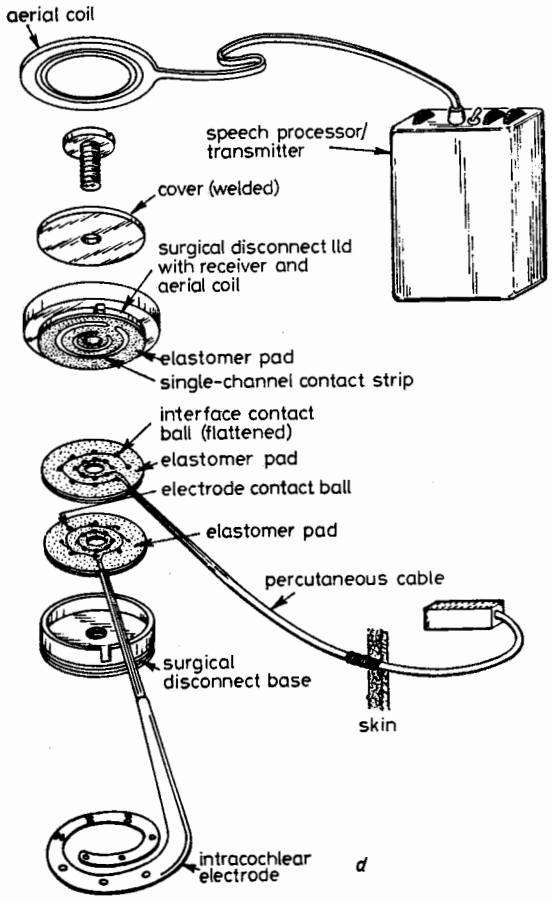

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Fig. 2 *(a) Opened assembly with disconnect base and electrode array on the left, percutaneous interface pad in the centre, and bottom view of the single-channel receiver showing platinum foil buss bars. (b) Fully assembled surgical disconnect with radio receiver lid, percutaneous cable and spiral-shaped intracochlear electrode. (c) Physical positioning of devices in a patient, with percutaneous cable exiting behind ear contralateral to the site of fixation of the surgical disconnect/receiver and electrode array. (d) Exploded view of entire system including external components (transmitter and aerial coil) and implanted assembly*

and biocompatible device is capable of forming a reasonably adherent junction with the healing skin and subcutaneous connective tissue, which can exclude infection. Beyond this period, the invagination of epithelium along the inner device surfaces plus the accumulation of keratinous debris provide the nidus for chronic infection (see KADEFORS, 1970). In view of the above, it was decided to employ a percutaneous connection limited to not more than four months, during which time care and observation of the exit point could be professionally supervised. This required achieving a mechanically stable exit point and isolating the permanently implanted parts of the system from the possibility of ascending sinus track infection.

4.3 *Prosthetic utility*

Simple but useful single-channel auditory prostheses are now available for providing at least temporal cue information in deaf patients (HOUSE, 1976; BILGER, 1977). Furthermore, it would appear unlikely that any device, once implanted in the cochlea, could be safely and effectively removed and replaced with another device. Therefore, patients participating in this series of experiments must have a reasonable expectation of emerging from it with a permanently functional device at least equal to the present state-of-the-art. Furthermore, these volunteers should be able to enjoy the fruits of the research to which they have contributed. We have therefore adopted the strategy of having an internal connector system which permits the surgeon to replace the internal electronic parts (radio receiver and stimulator) without dislodging the electrode array. Thus

(*a*) the percutaneous cable can be replaced by a functional single-channel radio receiver system

(*b*) this receiver can be replaced in the future when better, presumably multichannel, receivers are available

(*c*) a failed receiver can be replaced in a minor surgical procedure.

Because of the uncertain and possibly prolonged functional lifespan required for these r.f. tuned receiver devices, most of the electronic circuitry must be protected by hermetic encapsulation (see DONALDSON, 1976).

5 System design

Fig. 2 shows the physical relationship among the various components of the experimental system. It is centred around a novel connector system which provides maximum flexibility in the conduct of the experiments with only minor surgical intervention required to achieve the necessary reconfiguration from percutaneous to telemetered operation.

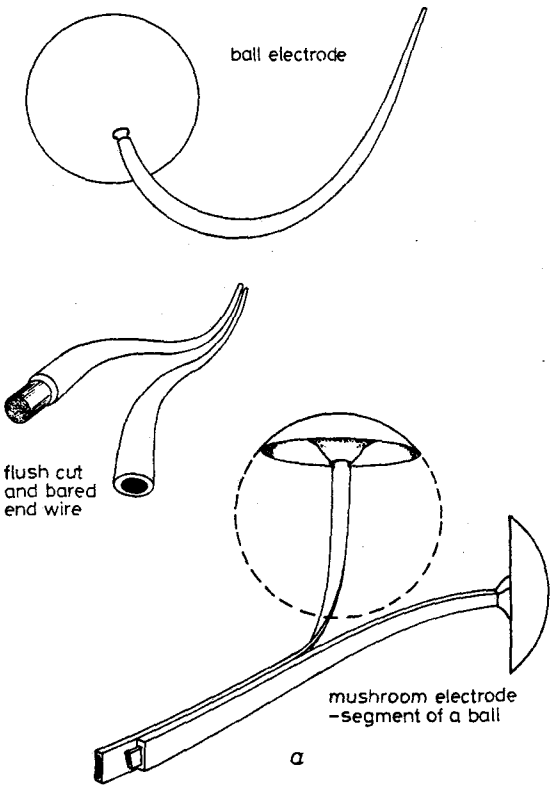
The electrode array is moulded in a single operation to form both the intracochlear contact portion and the disconnect contact pad. The conductors are platinum/iridium (90:10) alloy which are physically continuous with the contacts at either end. This eliminates welds as potential failure points. The silicone elastomer moulding compound forms the biocompatible space-filling electrode carrier, the flexible binder and mechanical protection of the individually insulated leads, as well as a pressure gasket which provides electrical isolation between contacts in the surgical disconnect.

The surgical disconnect uses the principles of mechanical pressure and gasket sealing. The base and lid are machined from a rigid, biocompatible titanium alloy (6% Al, 4% V; see LAING *et al.*, 1967). An axial tensioning screw allows them to function as a clamp, applying uniform pressure upon the silicone pads which carry the metal contacts.

The percutaneous connector system mates with the electrodes via a multiwire cable which terminates in an interface pad similar to that of the interface pad of the electrode array and against which it is compressed.

The disconnect lid is hollow and contains the telemetry receiver circuit. In the single-channel system illustrated in Fig. 2, hermetic feedthroughs in the side walls connect to the aerial coil, which is moulded in epoxy outside the metal can. (In a 3-channel system currently under construction, a multicoil aerial assembly is satellited on a short cable with its own pressure disconnect assembly.) Two similar feedthroughs direct the electrically floating output to the bottom surface of the lid (actually the inside of the disconnect). There, output lines are formed by buss strips of platinum/iridium foil on silicone elastomer carriers. When the percutaneous interface pad is in place, two contacts on its top surface pick up the receiver output and their leads convey it through the percutaneous cable, along with the 16 leads which mate with the electrode contacts. At the exteriorised portion of the percutaneous cable the electrodes can be individually stimulated and monitored, or a jumper connector can be attached which selects the desired electrode(s) to receive the output of the implanted stimulator. This jumper system allows the patient to be sent home with any desired electrode configuration operating in a normal telemetered mode without directly attached cables.

When the percutaneous connector is to be removed, the surgical disconnect is opened and the percutaneous connector pad slipped out. The cable is removed by subcutaneously pulling it outward through the exit point (to avoid contamination) after cutting off the pad. The receiver can be simply repositioned over the electrode array pad so that its output is now directly connected to the electrodes via the buss bar. Alternatively, a new buss bar pad may be interposed to rearrange the output configuration, if tests have suggested that this be done. The entire receiver may be replaced in a minor surgical procedure as more sophisticated receivers become available.



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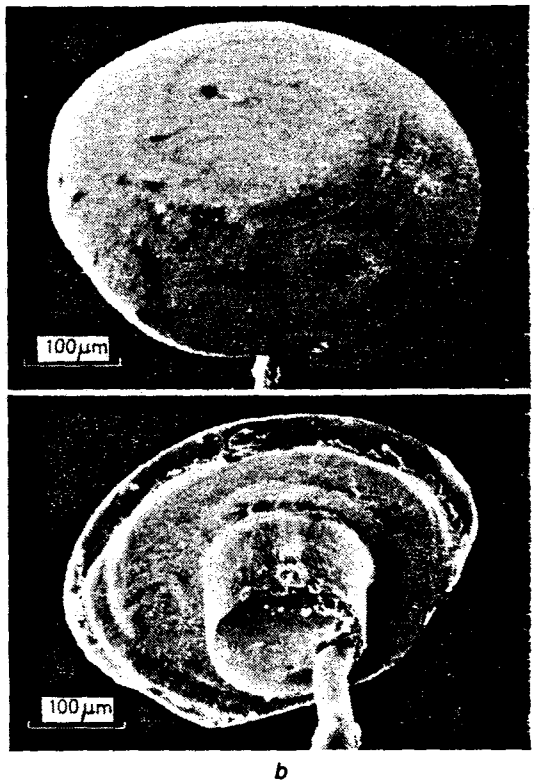

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The external parts of the system include a pocket-size sound processor and transmitter box plus a transmitter aerial coil. The transmitter coil is small, light, and flexible, since when in use it must be positioned on the skin directly over the receiver coil, which is affixed to the mastoid bone. The sound processor box contains the usual components of a high-quality hearing aid (microphone, batteries, patient controls for tone and volume) plus the radio-frequency generator and a set of internally adjustable compressors and filters which are set during clinical testing sessions to optimise speech intelligibility.

6 Component fabrication

6.1 *Electrode contacts*

The fine diameter wires comprising the individual electrode leads require expansion of their dimensions at the point where a low-impedance contact with the body fluids is required. Only noble metals which resist electrolytic corrosion are permissible, and junctions between dissimilar metals must be avoided (see LOUCKS *et al.*, 1959; LOEB *et al.*, 1982). Fig. 3*a* shows two previous approaches to this problem: scraping the insulation near the end or melting the end into a ball. The former produces only limited surface area improvements and is difficult to control reproducibly.

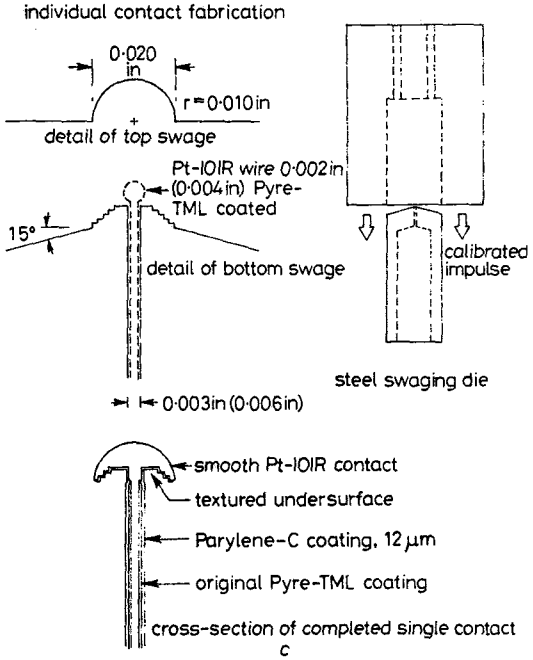

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Fig. 3 *(a) Approximately scale views of various electrode contact configurations and their contact areas. (b) Scanning electron microscopic view of the actual mushroom electrodes fabricated (as shown in (c)) by cold-forming a melted ball in a shaped pair of swages. The finished shape is Parylene coated over the lead wire and back surface of the mushroom for electrical insulation*

The latter occupies a large internal volume for the surface area obtained, interfering with the close spacing of the contacts and the collection of the apically-coursing leads into a central rib (see below). The mushroom shape illustrated can be precisely reproduced by cold-forming a melted ball in a hardened steel swaging die, as shown in Fig. 3*c*. The exact size and shape are determined by the machined shapes of the swages, the volume of the melted ball (which depends on the length of wire passed into the microtorch flame), and the force of the forming blow. The scanning electron photomicrograph in Fig. 3*b* shows a typical product with a smooth, convex electrode surface and contoured undersurface, which is designed to optimise its adhesion to the silicone rubber moulding compound which forms the array.

It is important that there is no electrical shunting between the leads of the electrode array. Therefore each mushroom electrode is overcoated with a 3 μm coating of Parylene-C (applied by Viking Technology, Inc., Santa Clara, California, USA; see LOEB *et al.*, 1977). The contact surface is masked by affixing it to a sticky gelatin surface, and the vapour deposited polymer covers the contoured back of the mushroom, the stem portion where the original wire insulation of Pyre-TML is partially degraded by the heat of the torch, and the remainder of the lead in case pinholes or cracks have developed during handling.

6.2 *Electrode array assembly*

Sixteen contacts must be assembled into an array which has the form of a 24 mm long spiral tapering from 1 mm to 0·6 mm diameter. The basic strategy is to position and fix the contacts on the walls of a split mould which has the desired spiral form, route the leads within the cavity, and injection mould the assembly in one operation.

The tapered spiral mould shown in Fig. 4 is formed by coining the shape into a roughed-out brass split mould. The blank shape is formed by turning a steel rod to the appropriate diameters and bending it into the spiral shape, then hardening. After coining, two sets of holes are drilled along the longitudinal axis of the spiral in the bottom mould half. One set (0·1 mm diameter) accommodates removable tungsten rods for holding the electrode leads in the central rib arrangement. The other holes (0·3 mm diameter) are located at the desired electrode locations, to be used as described below. The brass is nickel plated to provide an inert surface.

During loading of the electrodes, the entire mould is placed on a hot plate to keep it at 200–300°F. At this temperature, the Silastic moulding compound MDX4-4210 (Dow Corning Corp.), which normally has a pot life of several hours at room temperature, can be cured almost instantly, so that small amounts can be applied through a pressure dispenser to tack wires and electrodes in place (Portionaire, Glenmarc Mfg., Inc., Northbrook, Illinois, USA).

Secure anchoring of the electrodes greatly facilitates the positioning of the leads in the mould. It has also been found that it is important to keep the electrode contact surface protected during the moulding process. This provides clean, reproducible, stable surface areas with a minimum of hand finishing. Once silicone rubber cures in contact with the metal surface, there appears to be a recurrent tendency for the material to migrate over the surface and increase the electrode impedance.

Just prior to loading the mould, a 0·3 mm diameter tungsten rod is inserted into the hole located at each

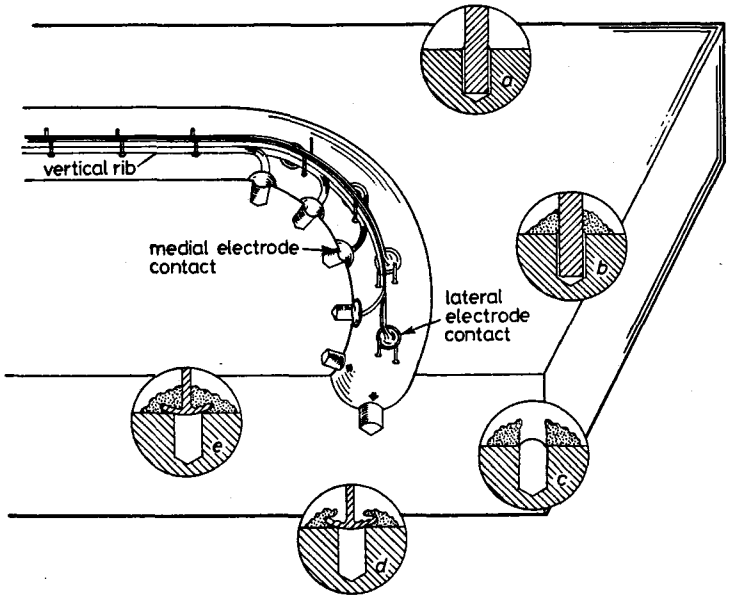

Fig. 4 *Schematic view of the electrode array mould and features for positioning the individual contacts on the outer surface and the leads in the central rib. See text for details of fabrication and use. Inserts (a)–(e) show the sequence of steps for anchoring mushroom-shaped electrode contacts to the walls of the spiral mould*

electrode position. The silicone elastomer is applied around the base of each rod and allowed to harden. The rods are then pulled out leaving the cup-shaped silicone rubber cavities shown in Fig. 4.

Each mushroom-shaped electrode contact is pushed into its cavity and secured by additional elastomer applied over its back surface. Its lead is then routed between the guide pins to form a central wire rib. The electrodes are loaded serially from base to apex, with occasional elastomer dabs to tack the leads in place. The tungsten rods are removed prior to the final injection moulding step described below, which incorporates all the applied elastomer into the final seamless product.

The surgical handling properties of the electrode are governed by the structure of the central rib formed by the lead-out wires. There tends to be a progressive decrease in the stiffness of this rib apically, where there are fewer leads present. When first introduced surgically at the large diameter region of the *scala tympani* basally, previous versions of this array had a tendency for the tip to curl upward and out of the plane of the cochlear spiral, fracturing the basilar membrane. This has been largely eliminated by the use of flattened wires (California Fine Wire, Grover City, CA, USA) with staggered dimensions, as shown in Fig. 5. The rib formed by stacking these leads carefully into the vertical axis of the array has an anisotropic and longitudinally consistent stiffness which permits the array to flex smoothly but only in the desired direction (in the plane of the spiral). The relative orientations of the electrodes and the tungsten rib positioning rods can be used to fabricate reproducible arrays which, when inserted, have all of the lateral electrodes lying directly under the *habenula perforata*, i.e. their previously noted 'ideal' locations.

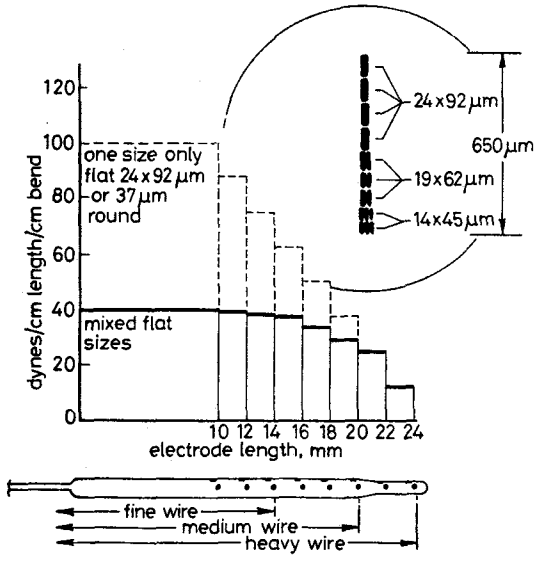

Fig. 5 *Structural analysis of central rib structure (shown in cross-section in insert). A selection of different sizes of flat wire permits a relatively homogeneous flexing property along the length of the electrode array, which is strongly anisotropic. The view at the bottom is schematic for electrode positions in a straightened out spiral electrode*

6.3 *Surgical disconnect pad assembly*

Each of the 16 electrode leads is cut to a predetermined length and has a 0·5 mm diameter ball melted onto the end opposite its mushroom electrode. At the end of the mould cavity opposite the spiral, a circular expansion 14 mm in diameter is fitted with 16 shallow depressions which accommodate these balls. They are tacked into these depressions and covered over by a dense weave nylon mesh (CMN-37, Small Parts, Inc., Miami, FL 33138, USA) which is incorporated into and provides mechanical stability for the Silastic moulding compound (Fig. 6). The dense mesh side is used against the titanium bottom of the pressure disconnect assembly and prevents the balls from shorting to the case. The electrode array and its connector pad are simultaneously moulded in one step, avoiding junctions and seams in the conductive pathways, the individual wire jacketing insulation, or the supporting matrix.

The interface pad of the percutaneous cable requires two layers of contacts: 16 facing down to interface with each of the 16 electrode leads and two facing up to pick up the feedthroughs from the receiver, which is hermetically sealed into the lid of the connector assembly. Fig. 6*b* details their structure, with two layers of Dacron mesh used to provide both lateral and vertical stability. Note that the percutaneous cable contacts which interface with the ball-shaped electrode contacts are somewhat larger and have been flattened by pressing them in a micrometer, which avoids the problem of two round surfaces sliding over each other.

The cable itself is made up of 18 stranded conductors, each comprising seven strands of 40 μm diameter Pt-10IR wire in a Teflon jacket (Cooner Wire Co., Chatsworth, CA 93433, USA). The stranded wire melts well into the required ball. The wires are pulled into a Silastic tube which is sealed at the ends with Silastic moulding compound MDX4-4210 and becomes continuous with the matrix of the disconnect pad itself. At the external end, the leads are coded by their position as moulded into a narrow Silastic carrier, and they are soldered postoperatively to a modified IC dual-inline socket. A narrow profile is required during surgery because the percutaneous cable is passed subcutaneously over the cranial vertex and exits at the opposite mastoid region. A small sleeve of Dacron felt is affixed to the cable just subcutaneously to improve the tissue anchoring, in the manner of chronic parenteral feeding tubes (see HALL, 1967; WITT *et al.*, 1980).

The receiver outputs exit from the bottom surface of the connector cover via platinum feedthroughs hermetically sealed into the can with ceramic seals. In addition to being picked up by the percutaneous cable,

these outputs need to be bussed directly to a suitable configuration of electrodes when the percutaneous cable and its interface pad are removed. The feedthroughs are machined so that they project exactly 0·25 mm below the can. The desired conductor pattern is engraved into platinum foil supported on a temporary substrate. This pattern is transferred to the bottom of the can in a Silastic moulding operation in which the can and the substrate form the top and bottom of a mould cavity. After dissolving away the temporary substrate, the bottom of the can appears as in Fig. 2*a* (right in photograph), shown along with the percutaneous pad (centre) and the electrode array with its pad in the titanium base of the disconnect assembly.

When assembled and compressed by tightening a titanium screw through the receiver lid into the base, there are no voids in the connector assembly. The side walls of the base prevent any lateral motion of the pads and the minimally compressible Silastic compound quickly reaches a high, uniform pressure which excludes fluid from the connection points. Pressure sensitive transducers have been incorporated into test pads and have indicated that 0·74 cm kg of screw torque produces pressures of 200 psi. This same

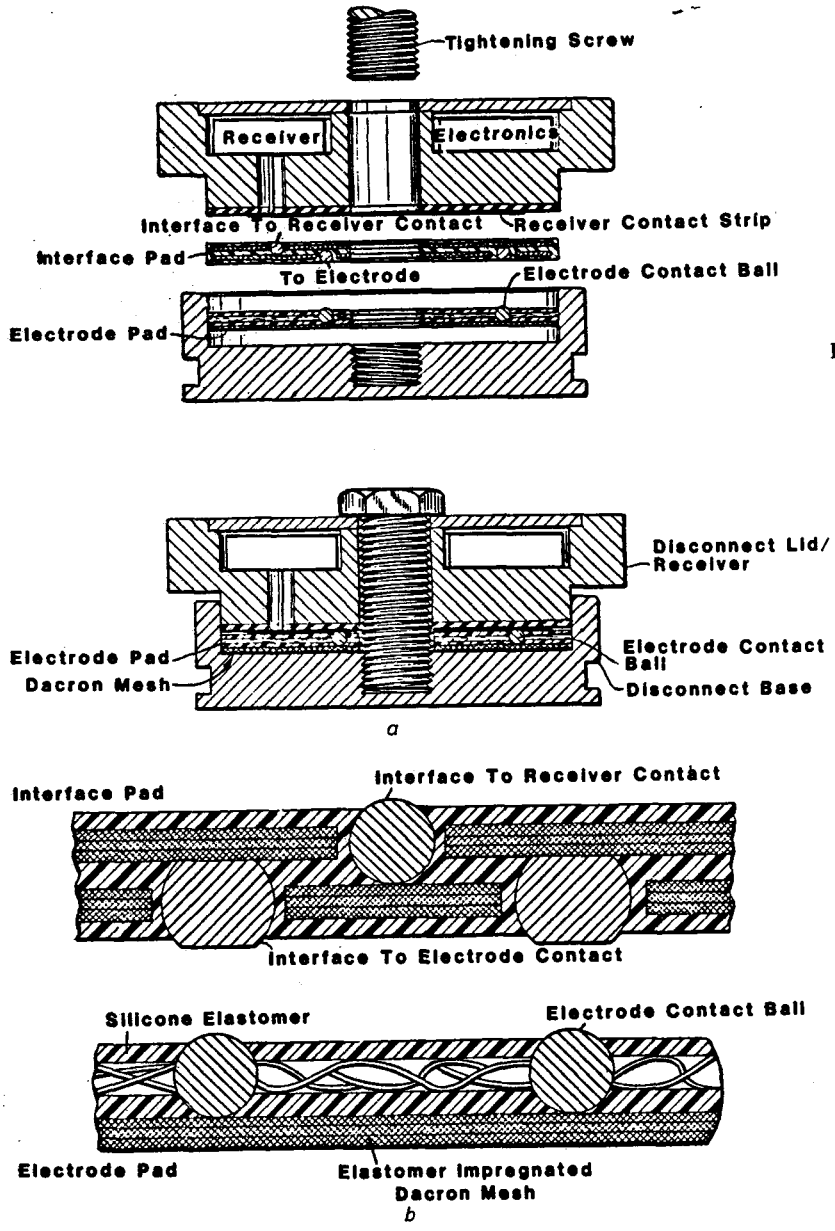

Fig. 6 *(a) Cross-sectional views of the surgical disconnect assembly configured for use with a percutaneous disconnect cable. The interface pad can be removed to establish direct telemetric links between receiver contact strips and electrode contact balls. Outer diameter = 18 mm, height = 7 mm. (b) Structural detail of the connection pads and metal contacts for the percutaneous interface cable and the electrode array. Note that the interface pad has two sets of connector balls—a round upper set for contact with the Yat platinum foil buss bars on the bottom of the receiver and a flattened lower set for contact with the round balls from the electrode array pad. Both pads include 'densely' woven nylon fabric to prevent vertical migration of the balls through the silicone elastomer when clamped under pressure in the disconnect assembly. Ball diameter = 0·5 mm*

pressure guarantees good electrical contact between the opposing balls and foils.

6.4 *Receiver and connector case*

The bottom half of the connector is a metal shell which is permanently affixed to the mastoid bone and which supports and contains the connector pads of the electrode array and percutaneous cable. It is turned from the titanium alloy and includes a circumferential groove and vertical flutes in the outer wall to facilitate anchoring with methacrylate, as shown in Fig. 7. Various anchoring schemes have been tested in cadaver bones to be certain that they will withstand the screw torque needed to open and close the connector assembly. A special trephine creates a circular cavity in the mastoid cortex to a fixed depth. The boney floor is perforated with a dental burr in several places to allow methacrylate to penetrate. At surgery, the outside surface of the connector base is painted with liquid methacrylate and positioned in this excavated recess as the polymer sets.

The top half of the connector is similarly turned from titanium alloy and fitted with a keying pin to assure its proper alignment with the base. The cavity in which the receiver components lie is toroidal shaped because of the central post which accommodates the draw-down screw. In addition to the two platinum and ceramic feedthroughs in the floor, there are two similar feedthroughs through the sidewalls which connect with the aerial coil. After the components are loaded, a titanium lid is welded in place and the unit is helium leak tested. The receiver coil must be outside and some distance from the can to reduce electromagnetic shielding. It is welded to the feedthroughs and potted in place using Hysol epoxy resin on the glass-beaded outside surface of the titanium can (resin C8-W795 plus hardener H-W796 cured per Hysol Bulletin E3-211).

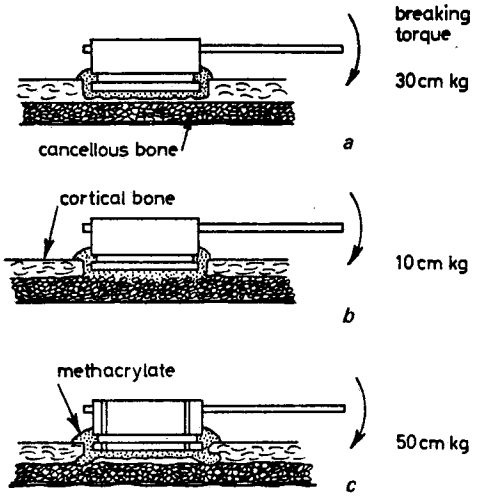

Fig. 7 *Various schemes for surgically fixing the base of the surgical disconnect to the bone of the mastoid process, and test results from assemblies so fixed in cadaver mastoid bones. (a) Base fixed entirely to shallow depression in cancellous bone of the mastoid cortex using methylmethacrylate. (b) Recess in mastoid extended through the cortex into the medullary bone over the entire floor before setting the base into methylmethacrylate. (c) Method currently in use with the base fixed primarily to the cancellous floor of the trephined recess with distributed dental burr holes allowing penetration of some methylmethacrylate into medullary spaces*

7 Test results

Each of the components has been extensively tested *in vitro* and *in vivo*.

Test connector assemblies have survived over 10 months of saline soak with no significant resistance between mating contacts (typically less than 15 Ω) or interlead leakage (typically greater than 2 MΩ resistance between leads). After four months of subcutaneous implantation in a cat, there was no difficulty opening, separating and reconnecting the pads. Tests revealed that even when closed *in situ* with fluid covering the contact surfaces, the fluid was forced out, leaving secure and well isolated connections.

The contact impedances against frequency of a test array in saline are shown in Fig. 8*a*, both before (unconditioned) and after (conditioned) passage of typical levels of current employed by the prosthesis (100 μA at 300 Hz). The conditioned state impedances are stable with use and low enough that the full dynamic range of perceptual loudness should be achievable with a maximum driving voltage of less than 5 V. This greatly simplifies the design of the receiver and driving circuits, particularly for various multichannel configurations.

Even with the present moulding techniques, there is some tendency for the contact impedance measured initially with low signals (0·1 μA at 1 kHz) to be much higher than that achieved after passage of stimulation-level currents for a few minutes. As shown in Fig. 8*b*, these contacts tended to maintain low and stable impedances even after several months of daily prosthetic use in our two patients. To minimise this initial 'conditioning' effect, each contact is routinely tested in saline after autoclaving and before implantation by applying a −9 V d.c. level against remote earth and observing it visually. The resulting electrolysis bubbles clean the surface, presumably removing silicone oils and metal oxides, and provide a sensitive test of continuity and insulation integrity as well (LOEB *et al.*, 1977).

Electrode arrays fabricated in this manner have been used for repeated test insertions in both preserved and fresh cadaver temporal bones. The surgical technique for implantation has been described elsewhere (SCHINDLER *et al.*, 1981). These electrodes can be inserted to their design depth of 24 mm with an acceptably low probability of damaging the basilar membrane. The orientations of the electrode contacts with respect to the *habenula* are uniform along the

array and reproducible through multiple insertions (see Fig. 1). In the two patients in whom these electrodes have been implanted to date, the electrodes slid into the *scala tympani* without significant neurophysiological and psychophysical experiments over extended periods of time in disabled human subjects without compromising either their safety or their eventual rehabilitation. The system described

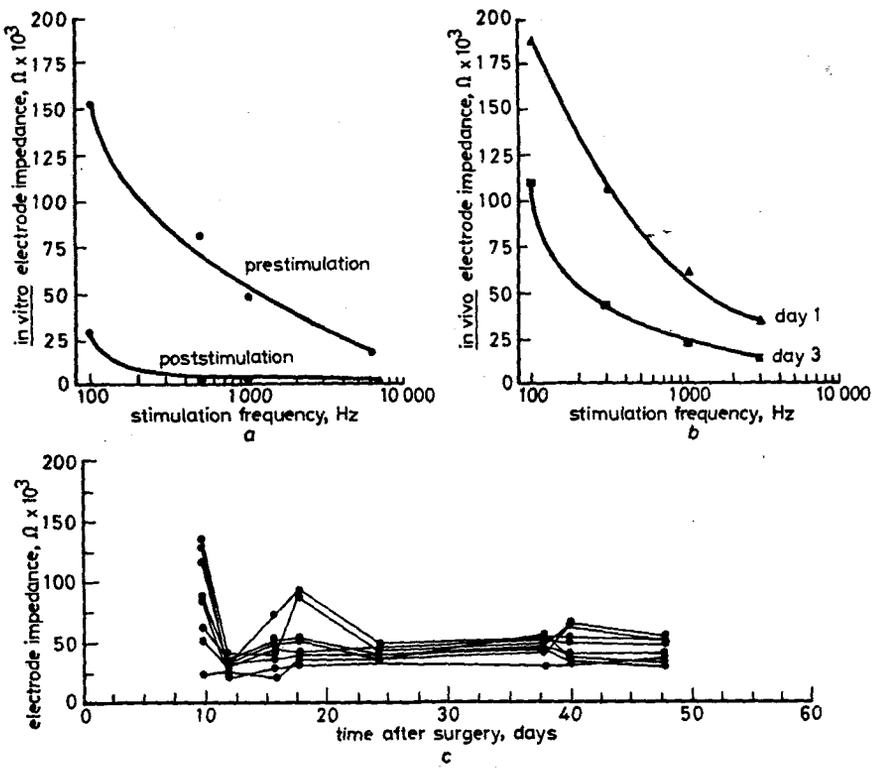

Fig. 8 *Mean values of electrode impedance against frequency of low current a.c. test signal (0·1 μA), for eight adjacent bipolar pairs of contacts in a 16-contact array designed and built as described here. See Section 7 for a description of the conditioning effect, seen as impedance change following stimulation both (a)* in vitro *(saline bath) and (b)* in vivo. *Pt.: C.B.; test day: 1 and 3; test current: 1 μA. (c) Impedance of the same bipolar electrode pairs over time postimplantation in a cochlear prosthesis patient using the device about 8 h a day at comfortable hearing levels. Stimulation frequency:* 1000 *Hz, test current: 1 μA, Pt.: C.B.*

resistance to a depth of about 25 mm. The surgeon was confident that the insertion was atraumatic. The perceptual thresholds obtained postoperatively at each electrode contact were reasonably low and relatively uniform and stable over time, consistent with proper positioning and minimal surgical trauma. Details of the psychophysical testing will be reported separately.

8 Conclusions

Sophisticated neural prosthetic devices such as the cochlear prosthesis pose unique problems in their development and clinical application. Because of the complex nature of their interaction with the nervous system, it is unlikely that researchers will be able to establish designs or predict results from animal experimentation alone. Thus we need to develop a methodology which will facilitate highly complex achieves these objectives for the current generation of intracochlear auditory prostheses.

Problems such as those encountered here required consideration of the application as a whole and innovative solutions rather than the *ad hoc* adaptation of available technology. This, in turn, demanded close collaboration among the engineers, clinicians, and basic scientists who contributed to this undertaking. Neural prosthetics is a new field, with limited mutual understanding and little common language to facilitate this interaction. We hope that this presentation will be useful to others in this field and that it will encourage similarly 'systems oriented' approaches to mutual problems.

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