BIOMEDICAL ENGINEERING AND
INSTRUMENTATION
FUNCTIONAL ELECTRICAL STIMULATION
(1977) VOL. 3, 321-340

COCHLEAR IMPLANT
The Interface Problem

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INTRODUCTION

The principal objective in development of auditory nerve stimulation prosthetic devices is to restore hearing of intelligible speech in profoundly deaf subjects with significant survival of the auditory nerve. Numerous studies in prosthesis-related physiological and psychophysical research [1-10] and studies in the speech sciences [11] have revealed that if intelligible speech can be encoded by a nerve stimulation device, a series of independent stimulation channels shall undoubtedly be required. Hope for development of useful devices lies with the fact that the number of channels required is not necessarily very large. High discrimination scores can be obtained with voice coders with an output delivered via as few as six or eight information channels, in normal hearing subjects [11,12]. If six or eight or more sectors of the auditory nerve array can be independently electrically excited in an appropriate way, it might thereby be possible to encode speech in profoundly deaf individuals.

Obviously, for effective stimulation with a multichannel cochlear prosthesis , a series of fundamental problems involved in interfacing multi-electrode arrays with the auditory nerve must be favorably resolved. Consideration of these interface problems together constitutes an analysis of the feasibility of development and application of multi-electrode arrays potentially capable of restoring (at least to some extent) hearing of intelligible speech in profoundly deaf individuals.

Most of these interface considerations are obvious. Long, safely implantable multi-electrode arrays must be fabricated and tested in animals. Elements of these multi-electrode arrays must excite predetermined, restricted sectors of the auditory nerve array in an appropriate way. Interelectrode interactions must be determined, and compensated for. Long-dormant cochlear ganglion cells must survive long term implantation of multi-electrode arrays. They must also survive long term stimulation at current levels required for establishing an acceptable dynamic range of loudness at each stimulus channel. Before any significant population of patients can be implanted, a versatile transcutaneous multi-electrode driving system must be developed. The design configuration of a sound processor which provides maximum speech discrimination for a given multi-electrode array must be defined. Given this information, a wearable sound processor-transmitter must be fabricated. Finally, it would be highly desirable to be able to objectively define excitation patterns and to estimate numbers of surviving nerve fibers in given implanted patients. Such information is crucial for interpretation of psychophysical results derived from multichannel stimulation in profoundly deaf subjects.

We shall summarize results of research directed toward resolution of these fundamental problems inherent to the development of multi-electrode cochlear prosthetic devices. Experiments conducted to this time indicate that such devices are feasible to build, and point to an obvious path for their development and initial application.

SUMMARY OF RESULTS

1. *It is possible to excite a series of discrete, predetermined sectors of the auditory nerve array, with stimulation with a multi-electrode array implanted within the scala tympani.* Stimulation excitation patterns have now been defined for more than 30 long-implanted intracochlear electrode arrays, using a single-unit mapping technique. The method takes advantage of the binaural cochleotopic organization of a large portion of the central nucleus on the inferior colliculus [13]. Within that region, neurons are excited with

stimulation at corresponding points along the basilar membrane of both cochleas. Thus, by defining the "best frequency" of an isolated neuron to sound stimulation delivered to the normal ipsilateral ear, the location along the basilar partition from which this neuron derives its input in the electrode-implanted ear is defined. Given the spectacular cochleotopic organization of the central nucleus of the cat, it is thus relatively easy to map the spatial pattern of excitation for any given implanted electrode array, by determining best frequencies for ipsilateral sound stimulation and thresholds for contralateral electrical stimulation for a long, continuous series of cochlear basilar membrane locations.

Excitation patterns evoked by representative electrodes are shown in Figure 1. The low-frequency side of the excitation

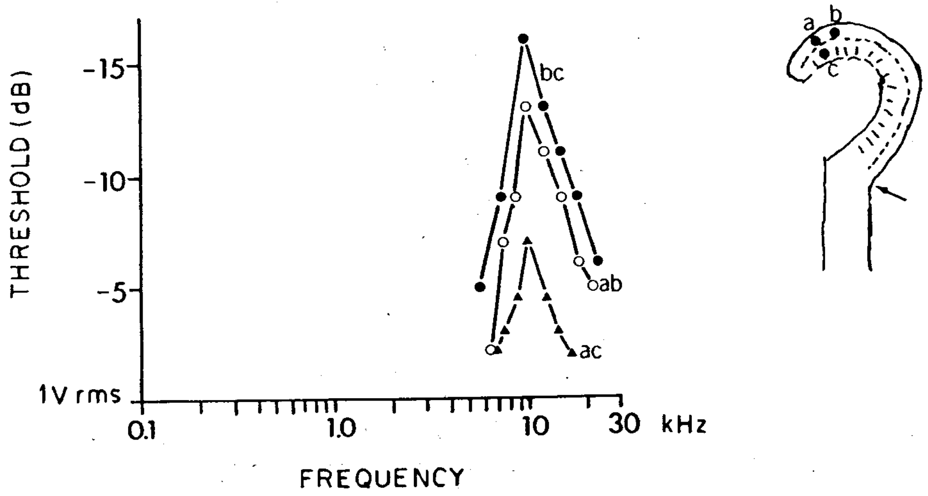


FIG. 1 Response patterns for closely spaced, bipolar scala tympani electrodes. The series of curves was derived from study of an implanted electrode triad (schematically drawn at the right). The triad was positioned at approximately the 10 kHz location within the cochlea. Each curve represents the pattern of response generated by a different electrode combination of the triad. Inter-electrode spacing was approximately 400 µ for ac; 800 µ for ab; and 1000 µ for cb. The curves were derived as described in the text.

"place-profile" is shown for bipolar electrode pairs in Figure 2. For bipolar electrode pairs judged to be "properly" positioned (the leftmost 12 curves, Figure 2) excitation threshold changed as a function of basilar membrane location by about 10 to 25 decibels/octave (or about 10 to 30 decibels/3mm sector of the basilar partition).

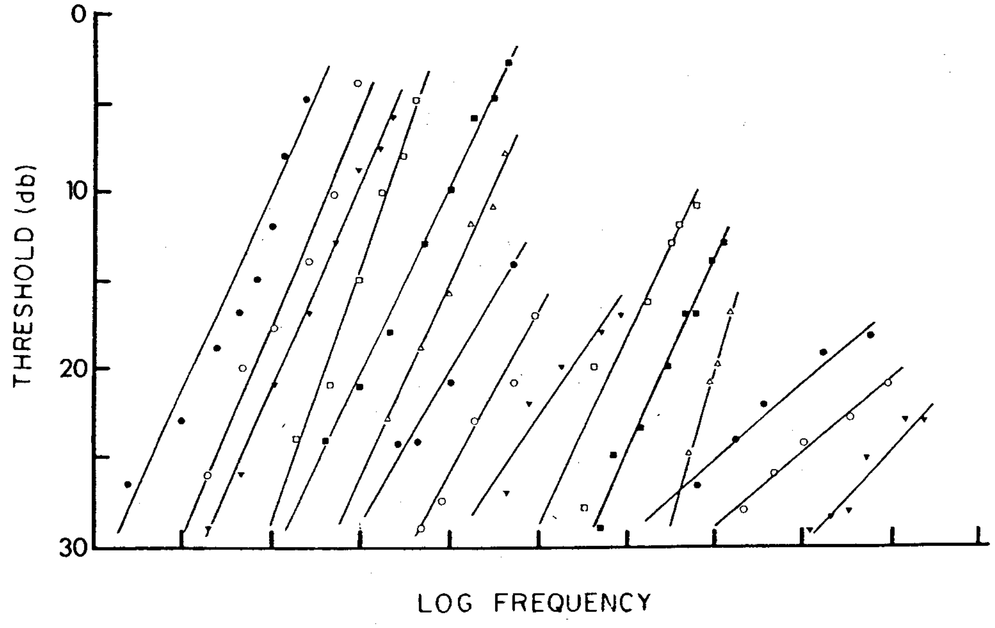


FIG. 2 Threshold plotted as a function of represented cochlear frequency, for the low frequency side of the restricted excitation region of 12 well-positioned intracochlear bipolar electrodes (leftmost 12 curves) and 3 mispositioned intracochlear electrode pairs (rightmost 3 curves; see text). Results are representative of all derived bipolar electrode maps. Rightmost 3 curves are very similar to those defined for several studied bipolar electrodes introduced directly into the center of the scala in the basal cochlea. Interelectrode spacing varied from about 400 to about 1200 microns for illustrated examples. Divisions along the abscissa are octaves (or approx. 3 mm sectors of the basilar partition of the cat).

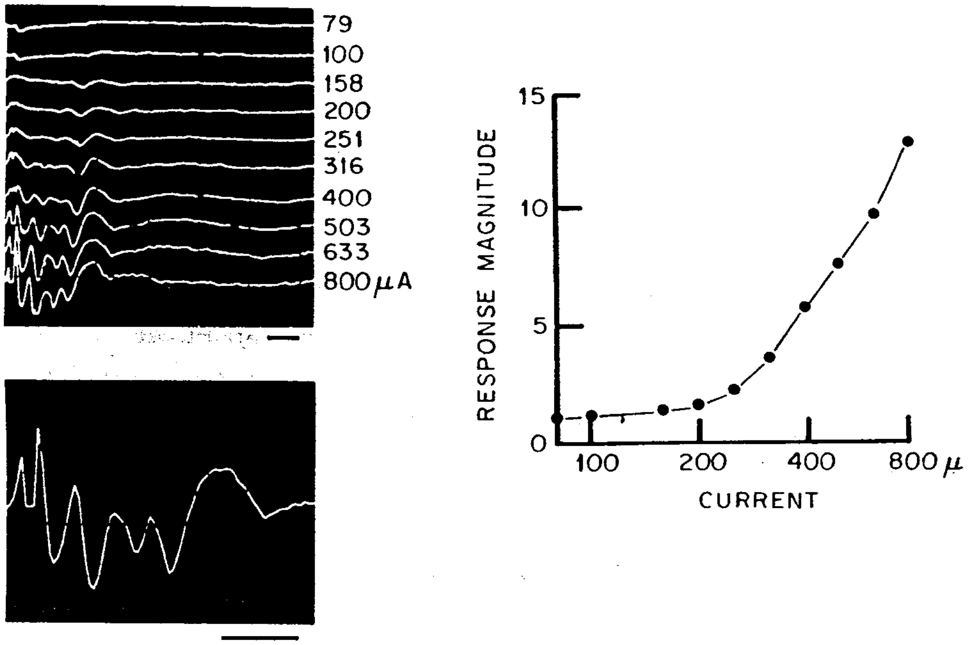


FIG. 3 Derivation of intensity function, using recording of brain-stem auditory potentials ("far-field" potentials). Responses averaged for 5000 trials are shown in each trace at the left. Stimulation current levels are shown at the right of each averaged response. Stimuli were 100 μsec biphasic pulses. Bars at the bottom of these response series are 1 msec in duration. Response magnitude (derived through use of cross-correlation technique) is plotted as a function of stimulus current level at the right. Far-field potential recording has been employed extensively in deriving basic information about multi-electrode performance, and in monitoring the physiological status of the auditory nerve array in long-implanted cats.

If bipolar electrodes are positioned far medial or lateral to the region of the basilar partition (rightmost three curves, Figure 2), or if they are inserted into the center of the scala tympani, excitation profiles are not as sharp. If the basilar membrane is perforated at the time of implantation, excitation with bipolar electrodes in the region of the perforation is inexplicably very broad. Three such electrode pairs have now been studied (an example is shown in Figure 4, lower).

2. *A noninvasive method has been developed by which excitation patterns produced by intracochlear arrays can be estimated.* Recording of "far-field potentials" [14,15] has been extensively employed

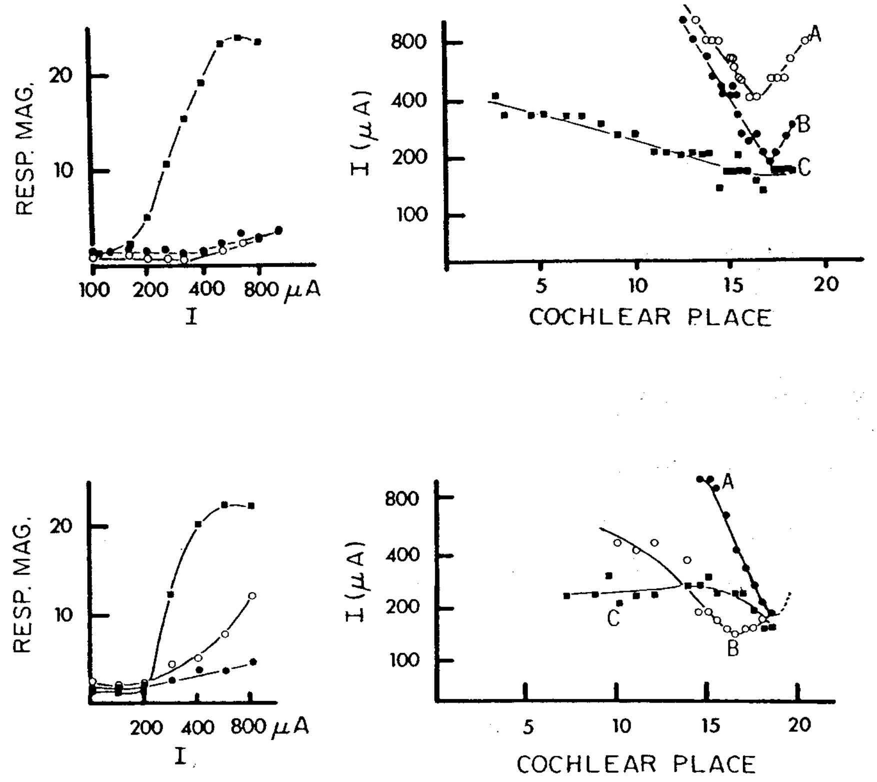


FIG. 4 On the left: Magnitudes of far-field potentials plotted as a function of stimulus level, from experiments conducted in two different implanted cats (upper and lower graphs). On the right: Excitation threshold current as a function of cochlear place, derived in an inferior colliculus electrode mapping study. In the experiment represented by the upper graphs, electrodes whose responses are represented by curves A and B were bipolar, with interelectrode separations of 2000 microns. Curve C was derived with "monopolar" stimulation; i.e., with stimulation between one of the electrodes in the "A" bipolar pair and a ground wire in the middle ear. In the lower graphs, curve A was derived with a normal bipolar electrode; curve B was derived with a bipolar electrode in a region in which the basilar membrane was perforated (see text); curve C was derived with stimulation with a "monopolar" electrode. These and many other such studies reveal that the growth of magnitude of brainstem auditory potentials reflects in a simple way the increase in number of fibers in the auditory nerve array stimulated, as a function of stimulus current level.

in studies of the characteristics of implanted electrodes. Studies of these brainstem auditory potentials provide a convenient non-invasive method for assessing electrode function (Figure 3). Such studies have now been conducted with many implanted electrodes. One observation from these results is that the growth of magnitude of these potentials is a monotonic function of the number of fibers excited which is a function of stimulus level (as determined by colliculus unit mapping studies). Thus, for given intracochlear electrode element locations, excitation patterns can be estimated by simply deriving response magnitude functions. Examples are illustrated in Figure 4. Such information can be of great significance in objectively interpreting function of implanted human multi-electrode arrays.

3. *With "monopolar" excitation within the scala tympani (second lead in the middle ear, or elsewhere on the head), very broad excitation of the nerve is effected.* Discrete excitation of restricted sectors of the auditory nerve array can probably not be generated with "monopolar" scala tympani stimulation. Excitation patterns for monopolar electrodes many millimeters apart, or with very different contact surface areas can be virtually identical. Maximum excitation is not necessarily realized in the region of the nerve array nearest the electrode site. The entire auditory nerve is commonly excited at current levels 10-15 decibels above thresholds (see Figure 5). These results suggest that the favored current path is *via* the auditory nerve trunk.

4. *Ganglion cells survive long term implantation of intracochlear electrodes, in prior-normal and in neomycin-deafened cats.* The cochleas of approximately 30 implanted cats have now been examined. Results have been obtained from study of cats implanted for periods up to more than two-and-a-half years, and are summarized elsewhere [16-18]. Important results include: a) In cats with normally implanted electrode arrays, counts of ganglion cells reveal that few or none are lost as a consequence of long term intra-cochlear implantation. b) Any surviving hair cells in the region of the implant are lost as a consequence of intracochlear implantation; at least most supporting cells survive the implant procedure, as do many

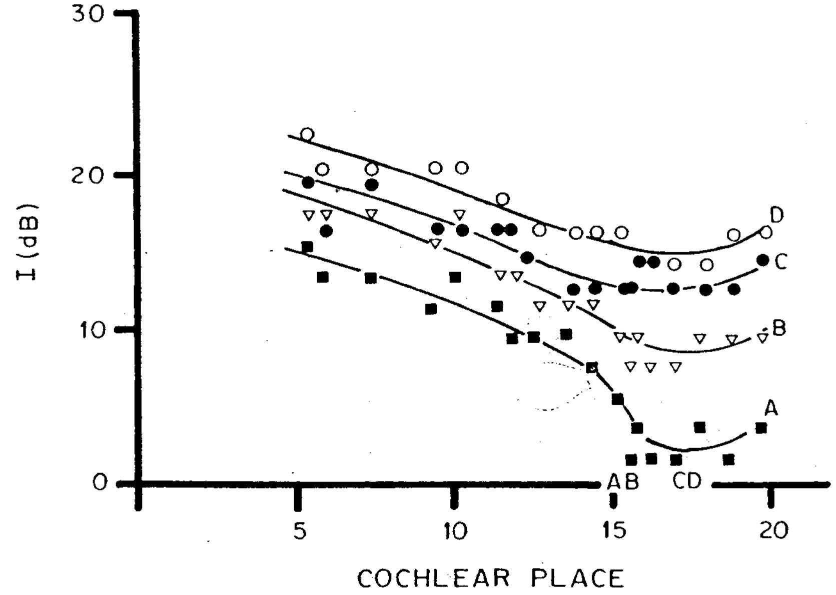
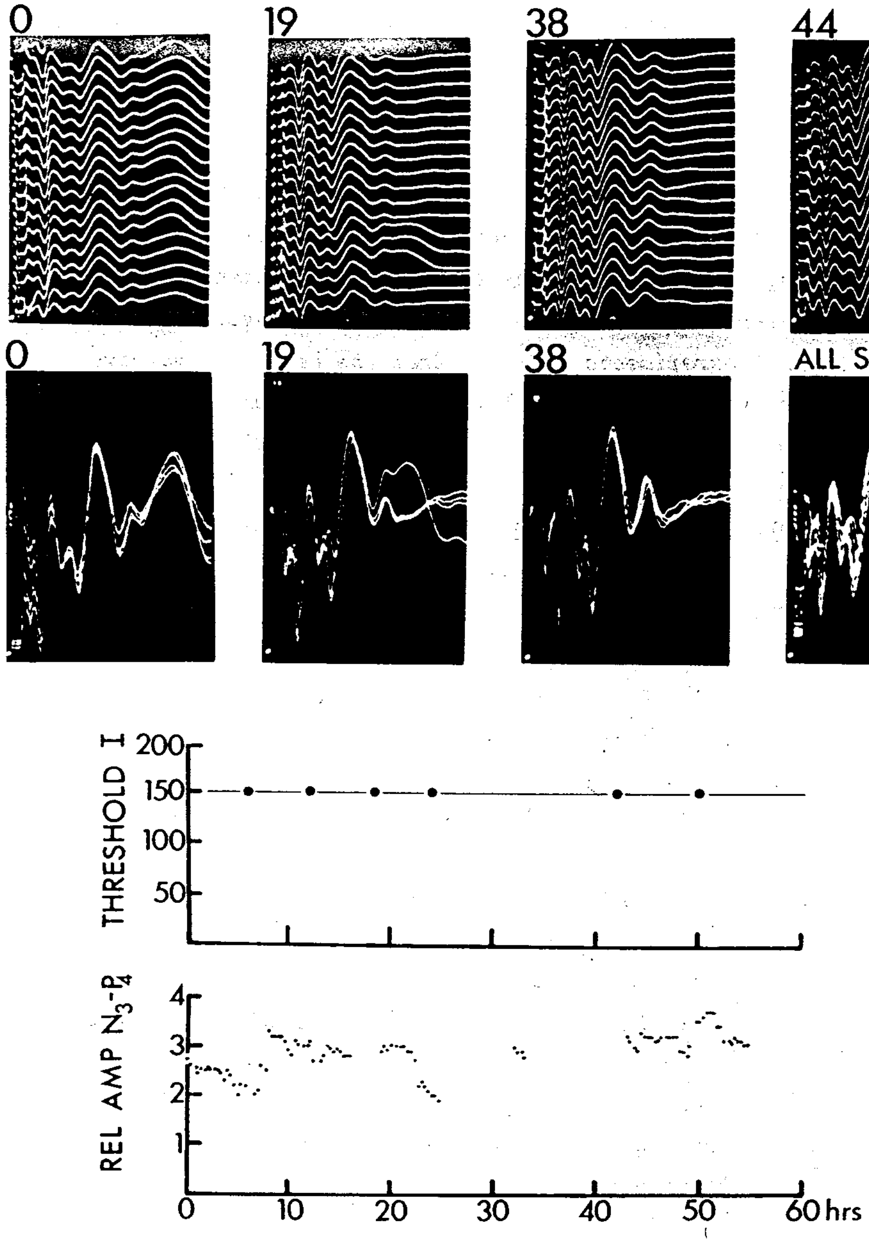


FIG. 5 Excitation patterns derived from study of four typical "monopolar" scala tympani electrodes. The approximate sites of the intracochlear electrodes are indicated by the letters along the abscissa. Excitation with such electrodes has invariably been observed to be very broad, regardless of electrode size or location within the scala tympani. Site of maximum excitation does not necessarily correspond with intracochlear electrode location.

FIG. 6 (Right) Representative case from study of functional histopathological consequences of heavy continuous stimulation. In this example the stimulation level was 1 mamp. Each series at the top represents far-field responses recorded over a six-hour period. Each trace represents the average response for 12,000 stimuli (10 biphasic 100 µsec pulses/sec for 20 minutes). The number at the top of each series is the time from onset of continuous stimulation of the first stimulus in that six-hour series, in hours. In the traces in the middle, the 2nd, 6th, 11th and 16th traces from response series above are shown superimposed. The thresholds for far-field responses were derived at six-hour intervals, and were found to be constant (upper graph). The amplitude of a given wave in the far-field potential response series varied significantly through the duration of stimulation, but showed no overall decline during more than 50 hours of continuous stimulation. Examination of this cochlea (with the cat sacrificed three weeks after overstimulation) revealed no loss of ganglion cells resulting from this continuous heavy stimulation. This current level (1 mamp) is probably a realistic upper limit for operational multichannel prostheses with acceptable dynamic ranges.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hair cells apical to the multi-electrode implant. c) Unmyelinated processes of spiral ganglion cells that survive the pathological insult causing deafness also survive long term implantation of intracochlear electrode arrays. d) Areolar connective tissue rapidly envelopes the implanted electrode insert. e) Degenerative changes in the stria vascularis and spiral ligament in the region of the insert are commonly observed. f) Severe nerve degeneration is observed as a consequence of perforation of the basilar membrane, or following damage to the bony endosteum. In both instances, nerve fiber loss is strictly limited to the region of damage.

5. *Initial experiments indicate that the nerve can survive heavy, continuous stimulation at current levels required for operation of multichannel prosthetic devices.* Many more experiments must be conducted. The general experimental approach employed in these studies is reviewed in Figure 6. The responses to continuous, heavy electrical stimulation are continuously monitored, and threshold measured at frequent intervals. At the end of this overstimulation exposure, animals survived for approximately three weeks; their cochleas were then perfused, and the auditory nerve examined in detail. No damage to auditory nerve fibers has yet been observed consequent from heavy stimulation in these studies, and charge and current levels used have probably exceeded those required for operation of multichannel cochlear implants. There is an electrically-induced change in the connective tissue above the electrode, consequent from heavy, long-term stimulation. The exact nature of this induced change is now being studied. It may account for a 2-3 week period of changing electrode impedance and stimulus threshold in patients implanted with single-channel prosthetic devices [19].

6. *Spiral ganglion cells remained electrically excitable through long periods of dormancy, in all studied deaf cats.* Moreover, although the spontaneous activity of neurons in auditory nuclei is greatly reduced in bilaterally deafened animals, evoked unit responses cannot be readily distinguished from those observed in cats with one normal ear, in studies of neurons in short-survival cases.

7. *In tested multielectrode arrays, interelectrode interactions are an important consideration.* Excitation patterns generated by stimulation with bipolar electrodes were broader than those estimated for bipolar electrodes in a homogeneous medium (which the cochlea obviously is not). This suggested at an early stage of this study that neural elements excited electrically by scala tympani excitation are, effectively, not immediately adjacent to stimulating electrodes; or alternatively, that there is an impedance barrier (e.g., that might be effected by the connective tissue layer overlying the electrode array and the nerve array). Results of extensive studies of interelectrode interactions were consistent with these observations. There is no question that interactions between adjacent electrodes do occur, and are unavoidable if stimulation of nearby channels is temporally coincident (Figures 7,8). In fact, when two adjacent bipolar electrodes are stimulated simultaneously, the threshold for excitation in the region <u>between</u> two electrode pairs can actually be lower than that observed with excitation of either bipolar electrode pair stimulated alone, presumably because of field interaction.

Interelectrode interactions can be circumvented by appropriate sequencing of excitation to prevent simultaneous activation of adjacent electrodes (Figure 9). However, interactions might well be taken advantage of in stimulus coding; current experiments are being directed toward defining whether or not this might be accomplished.

8. *The actual site of electrical stimulation of spiral ganglion cells has not yet been determined.* Spatial mapping data have suggested that it might be myelinated nerve that is excited by electrical stimulation within the scala tympani. Similarly, strength-duration curves suggest that the myelinated processes of the nerve might be excited with bipolar stimulation at threshold (Figure 10) [20].

9. *Some basic design parameters of transcutaneous electrode driving devices have been defined in these studies.* This information has been given to the Stanford research group led by Dr. Robert White, who have developed (and are improving) a multichannel transcutaneous driver [21-23]. Other critical design parameters must be obtained in psychophysical studies in implanted deaf patients.

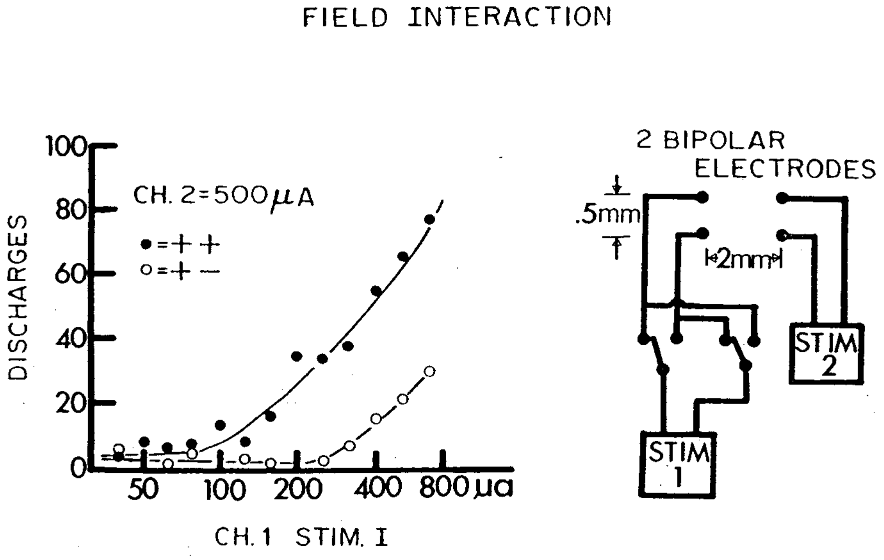

FIG. 7 Illustrating one class of experiments employed to study interelectrode interaction along multichannel intracochlear arrays. The basic conditions of the experiment are indicated schematically, at the right. Differences in responses of a neuron as a function of stimulus level when simultaneous biphasic pulses have the same phase (current adding; filled circles), as compared with when their phases are opposite (current subtracting; open circles) provide a measure of the extent of field interaction. This studied neuron derived its input from the cochlear partition in the region between two adjacent bipolar electrodes. Thresholds derived for single channel bipolar stimulation of either polarity were approximately equal.

10. *No evidence of vestibular nerve or vestibular sensory epithelium excitation can be seen with bipolar electrical stimulation within the scala tympani.* Stimulation at levels above those required for operation of multielectrode nerve stimulation devices (and at the 5 mamp limit of our stimulators) with bipolar stimulation elements do not lead to excitation of the vestibular or facial nerves. With monopolar stimulation, facial nerve or direct muscle excitation is commonly observed, at the top of the predicted, required dynamic range of stimulation of such devices.

11. *Methods have been developed for manufacturing multielectrode wire arrays believed to be suitable for limited testing in human patients.* The procedure involves the following stages: a) A low

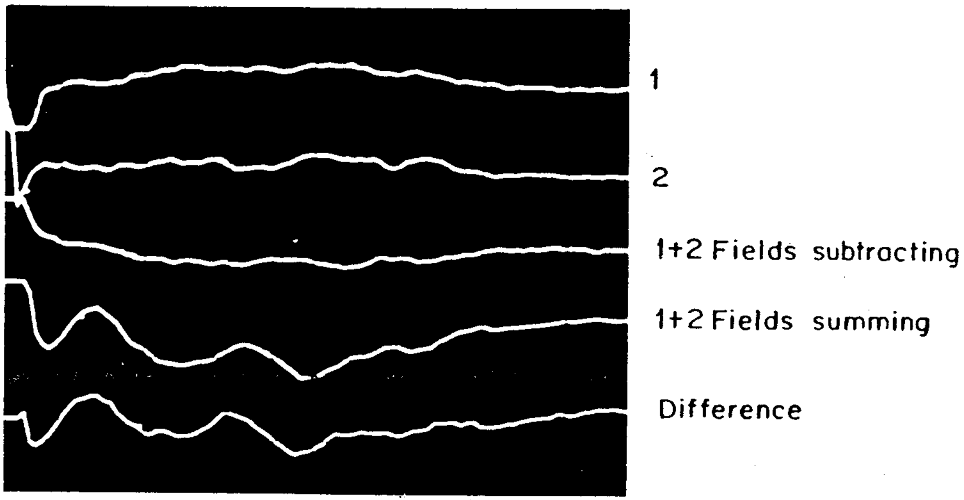

FIG. 8 Interelectrode interaction, as revealed in far-field potential recording. Electrodes 1 and 2 are bipolar pairs approximately 2 mm apart. In this series both were being stimulated at current levels near (just at) threshold. The response to stimulation of "channel" 1 alone (2000 trials) shown by the 1st trace, and of "channel" 2 by the 2nd trace. With stimuli delivered simultaneously out of phase, fields subtract, and the response in the 3rd trace (below threshold) was derived. With stimuli delivered simultaneously in phase, the fields sum and a strong response is seen (4th trace). The difference (5th trace) is a measure of the extent of interelectrode interaction. Study of units in the inferior colliculus has revealed that activity like that arising from simultaneous inphase stimulation of adjacent bipolar pairs (trace 4) is centered in the region between the two electrode pairs.

melting point Woods metal is used to produce a precision cast of the scala tympani in a fresh cochlea. b) The cast is plated with a thin coat of copper. c) The lower side of the plated cast (away from the basilar partition) is cut away, and the Wood's metal removed. d) Positioning holes (100 microns in diameter) are introduced at future electrode contact surface locations with pivot drills. e) After ultrasonic cleaning, the inner surface of the die is plated with an ultrathin layer of hard chrome. f) An array of insulated electrode wires is positioned in the locating holes, and the die filled with medical grade Silastic*. When the Silastic cures, the multielectrode

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*Silastic is a trademark of Dow Corning.

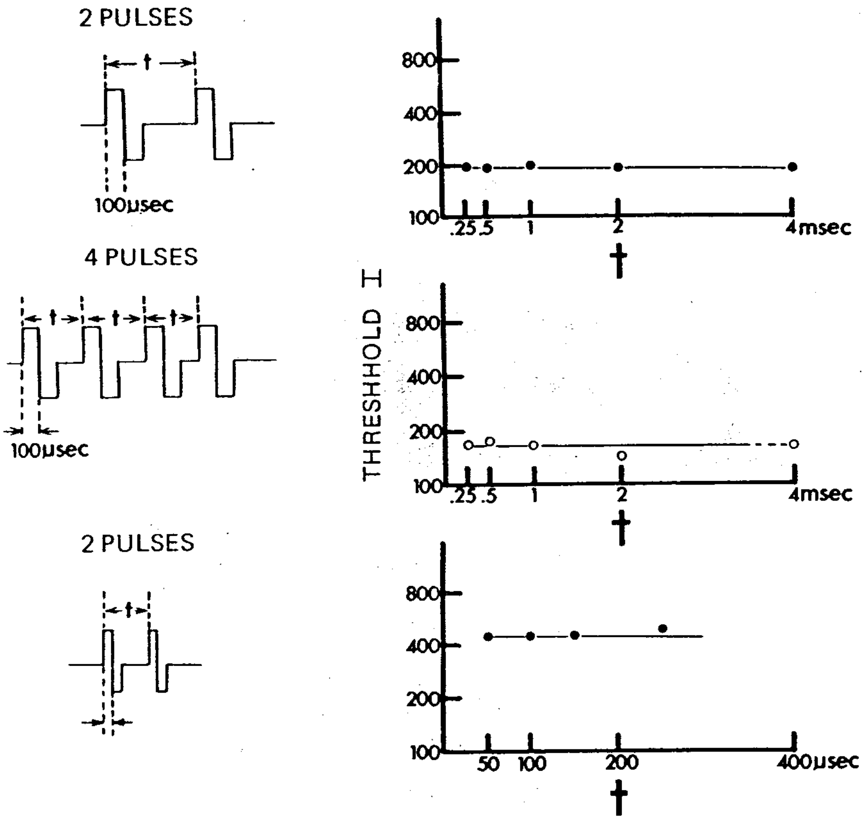

FIG. 9 Inter-electrode interactions can be circumvented by appropriate sequencing of stimuli. The basic experiment is shown schematically for each graph, at the left. Unit threshold is plotted as a function of interpulse interval for each stimulus condition, at the right. These and much similar data reveal that stimuli presented as little as 75 μsec apart in one channel cannot alter the threshold of excitation of an adjacent channel.

implant is withdrawn from the mold, and the electrode contact surfaces finished with special purpose tools.

Such electrode arrays designed for implantation 20-23 mm into the human scala tympani have been constructed and tested for feasibility of implantation in cadaver material. From such studies, and with modification of the mechanical properties of these long arrays with use of a central vertical rib, long implantable multielectrode

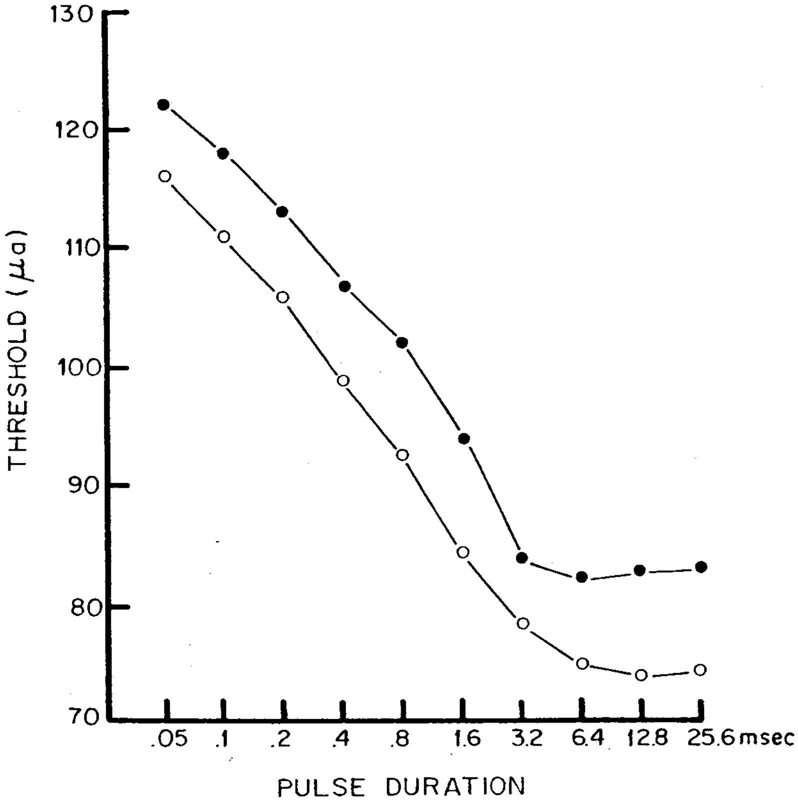

FIG. 10 Strength-duration curve for electrically stimulated auditory neurons derived from determination of threshold as a function of pulse duration, for two neurons within the central nucleus of the inferior colliculus. All strength-duration data derived (for different electrodes, in different cats) were similar to those shown.

arrays have been constructed that can probably be safely implanted in a small number of patients. Tests of these long implanted multielectrode arrays are ongoing.

12. *A versatile computer-controlled multichannel sound processing system, and an ultrasafe, versatile multichannel stimulator have been developed.* Definition of the optimum speech processing format for gaining maximum intelligibility with stimulation with a given kind of multielectrode array requires utilization of such a system, employed in an extensive series of psychophysical experiments conducted in

implanted patients. In these experiments, the consequences of changing design parameters of processor models can be systematically evaluated. Processed speech materials are being produced, with use of three basic classes of speech-processor models. One models the excitation of the auditory nerve array by normal sound. That is, the multichannel array effects spatially and temporally patterned input that is the closest possible facsimile to that generated by normal sound in a normal cochlea. The second model is based on a voice excited channel vocoder. In the third model perceptually important information is delivered so that the processing employs the best information-bearing modes of stimulation.

DISCUSSION

Cochlear implants offer the prospect for re-establishment of direct hearing of speech for a significant population of the profoundly deaf [9,24,25]. Final favorable resolution of the above-stated interface problems are obviously required before any multichannel electrical stimulation device capable of delivering information required for encoding intelligible speech (if that is, indeed possible) can be constructed and applied. Although consideration of these problems is still not complete, *all evidence indicates that useful multichannel electrical stimulation prosthetic devices can be constructed,* and safely applied to profoundly deaf subjects with surviving auditory nerve. That is:

1. It is possible to excite a series of sectors of the auditory nerve array with bipolar elements of an implanted scala tympani multielectrode array. Electrode pairs must be appropriately positioned. Discrete excitation has not been effected with use of "monopolar" scala tympani stimulation. Experiments directed toward determining if it might be possible to use a common intracochlear ground (simplifying the design of electrode driving electronics) are still under way.
2. Interelectrode interactions occur when nearby channels are simultaneously stimulated. They can be circumvented by appropriate sequencing of stimuli. Interactions could conceivably be taken advantage of to shift the stimulus focus between adjacent bipolar electrode pairs.

3. The long multielectrode arrays required for multichannel stimulation of the auditory nerve array in man have been constructed. Studies indicate that they can be safely inserted in the small number of patients required for determining the efficacy of these devices.
4. The auditory nerve in deaf animals (and probably in implanted deaf patients [7,26]) survives implantation of long indwelling multielectrode arrays. Preliminary experiments in deaf animals indicate that the auditory nerve survives continuous electrical stimulation, at levels above those required for re-establishment of an acceptable dynamic range of loudness for each electrode pair. Adequate excitation of the nerve can probably be effected at "safe" charge and current densities determined for platinum electrodes [27].
5. A versatile multielectrode driving system has been constructed, and is being tested in animals.
6. Systems for psychophysical definition of the optimal format for speech processing are now being prepared for use with implanted patients. Such an analysis system is absolutely required for defining the design configuration of the wearable processor-transmitter required for this prosthetic device.
7. Methods employing recording of far-field (brainstem) auditory potentials are being developed for defining excitation patterns and numbers of surviving nerve fibers stimulated by elements of multielectrode arrays in implanted patients. Such measurements are crucial to interpretation of the function of these devices in individual implanted patients.

Taken collectively, results of these studies (along with results of psychophysical studies on deaf patients implanted with single channel nerve stimulation devices) indicate that multichannel devices potentially capable of delivering information necessary and sufficient for the hearing of intelligible speech by profoundly deaf subjects with good auditory nerve survival are feasible to build. Such devices must be tested in a small, intensively studied population of profoundly deaf patients with high probability of nerve survival, in the immediate future. From such a study, in which proper attention is paid to the optimization of the processor-transmitter and in which objective determination of numbers of surviving nerve fibers and evoked stimulation patterns are defined in individual patients, an accurate evaluation of the potential wider application of these devices as aids for the profoundly deaf can be efficiently realized.

ACKNOWLEDGEMENTS

The authors would like to acknowledge the participation of Robin Michelson, Robert Schindler, David Schindler, Birgitta Bjorkroth and Patricia Leake in some of these described studies. P. Kent Taylor and Patricia Clepper provided important technical assistance. Aspects of this work conducted in the Coleman Laboratory were supported by the Coleman Memorial Fund, Hearing Research, Inc., and NIH grant NS-11804.

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