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UCSF Cochlear Implant Device

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The UCSF Cochlear Implant Research Group has been working on the development of a cochlear implant for more than a decade. Over that time, a series of device generations have been successively applied in a small number of patients. Our strategy has been to progressively define the "optimum" device configuration, with each element of the device (especially the sound processor-stimulator) subject to change in each application. In the most recent period, the implantable parts of the implant (electrode, connector, receiver, cables) have been optimized, and a design acceptable for wide application in the profoundly deaf defined. The relative efficacy of a channel vocoder-based coding device coupled to the UCSF electrode array in patients believed to have good nerve survival has been demonstrated in experiments in which different device models have been evaluated in the same patients. Patient performances with that device, as "optimized" to its present state, and when applied in patients believed to have good auditory nerve survival, approaches the theoretical optimum. Therefore, for the first time, we are prepared to carry a device with a fixed configuration into a full-scale clinical trial. A collaborative agreement has been established with Storz Medical Instruments, who are now constructing implant devices for this trial.

In this report, I shall review basic design features of the UCSF device and shall briefly outline research that has led to definition of its "optimal" form. Some directions for future development that have been undertaken by the UCSF group shall also be outlined.

Basic Features of the UCSF Cochlear Implant

The basic elements of the UCSF cochlear implant are illustrated diagramatically in Figure 1. A photograph of the implantable section of a present-generation device is shown in Figure 2. The 16-electrode intracochlear insert (4, 6, 9, 10) is designed for insertion 23 - 25 mm into the scala tympani. It is designed for either bipolar or monopolar or common ground plane operation (i.e., the efficacy of any of these electronics-to-electrode coupling configurations can be evaluated with its use). It has special mechanical features which allow for non-traumatic insertion to these cochlear distances, and which allow for accurate, positive placement of electrode contacts re the inner surfaces of the scala. Its 8 bipolar electrode pairs are "optimally" designed and positioned for effecting control of discrete auditory nerve sectors, as determined in directed physiological electrode mapping studies (6, 7, 11, 14). Electrode pairs are two millimeters apart, center to center. The biocompatibility of these electrodes has been demonstrated (2, 13, 14) and the safe limits of electrical stimulation with these electrodes has been studied (3, 15).

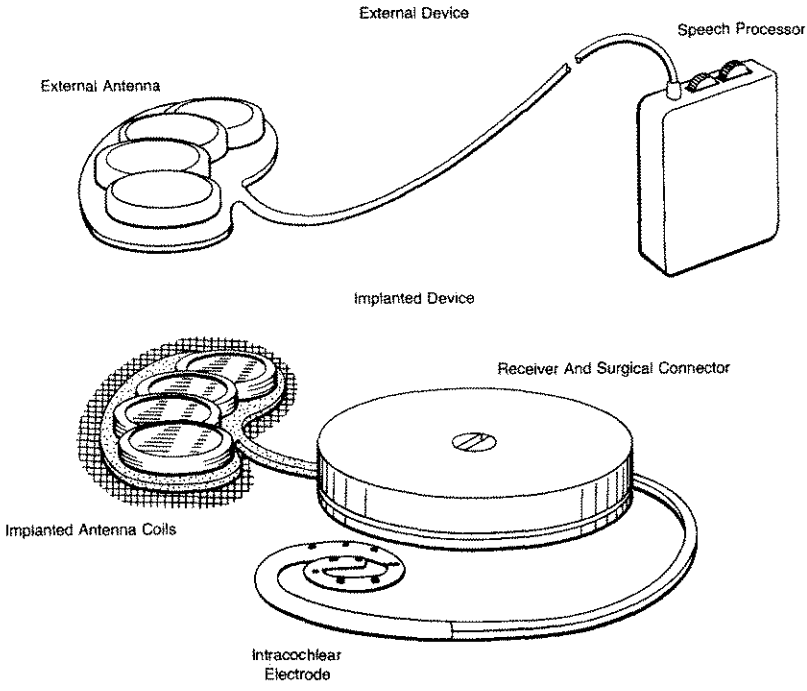

Figure 1: University of California at San Francisco (UCSF) cochlear implant device components.

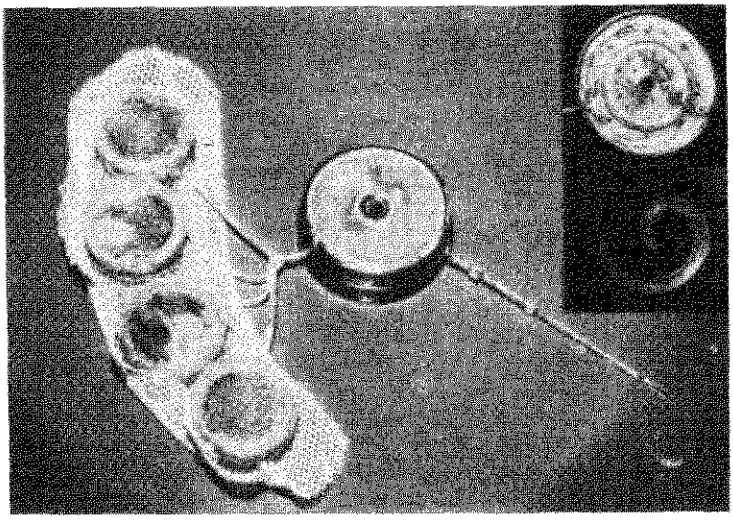

Figure 2: Implantable components of the UCSF cochlear implant prosthesis. Upper inset: opened connector base, with connector pads for the electrode array (center) and receiving coil (periphery) visible. Lower inset: 16-electrode scala tympani array.

The electrode is manufactured as a single unit with a connector pad which is one element of an implantable connector (4, 6, 9, 10). This connector (Figures 1, 2) is a rubber-under-pressure clamp. When closed, interface pressures far exceed osmotic pressures, thereby assuring their permanent sealing against fluid leaks. Connector pads are constructed of dacron-reinforced silicon rubber. The closing pressure is about 200 ATM. Connector performance has been nearly perfect, in bench testing and in practice.

This implantable connector provides a means of: a) replacing defective receiving electronics without disturbing a functioning intracochlear electrode; b) upgrading receiving electronics, when superior device generations are manufactured; and c) establishing a transcutaneous link to the electrode array with a temporary percutaneous cable or connector, by which psychophysical studies can be conducted without imposition of any of the limits of a telemetry system.

A percutaneous cable is used temporarily during a period of 3-4 months, in patients in our experimental series (4, 9, 10). This percutaneous cable is coupled into the implantable connector by its own connector pad. It is routed over the calvarium, to exit from a location on the opposite mastoid. The cable is about the diameter of small percutaneous cannulae used in other medical applications; the exit site is treated and maintained in the same way. Thousands of such vascular or peritoneal cannulae have been chronically implanted in humans, and the rules for their safe maintenance are well established.

At the end of our 3-4 month experimental period (part of which is dedicated to defining the optimal implantable device for each successive patient under study), the connector is opened and the percutaneous cable pad removed; the cable is removed and discarded; and a permanent receiving system is clamped onto the connector base.

The receiving electronics are enclosed within a welded titanium capsule mounted on the connector (4, 6, 9, 10; see Figures 1, 2). Independent receiving coils for four parallel RF detectors are satellited to the connector; within it, they have their own connector pad. Receiving electronics are coupled in the connector to both receiving coils and the electrode array. In permanent devices, the four channels are coupled bipolarly (i.e., to off-radial electrode pairs); and channels are completely independent of each other. Electronics are mounted in a hybrid form on a metallized ceramic substrate within the receiver capsule.

There are several advantages and disadvantages of this simple telemetry system. The device is simple, with few active components and in its hybrid form should have good survival characteristics. Telemetry channels have bandpasses extending from about 100 Hz to more than 10 kHz. Thus, almost any reasonable signal (in terms of electrical stimulation) can be passed across any given electrode channel. The device allows for simultaneous operation, with bipolar coupling, of a number of electrode channels. It is the only telemetry system now being applied with this feature. That performance feature is crucial for optimal driving with a multichannel implant. Finally, device output levels should result in effective and safe driving of all candidate patients with surviving intracochlear ganglion cells.

Among its disadvantages: the foreign body and external antennae are large; and present 4-channel devices appear to be channel limited.

Implementation of a Vocoder-Based Nerve Array Response Simulation Model

The UCSF cochlear implant is designed to implement a multichannel nerve array response simulation model (5, 8, 11). The design of this model reflects both what is required for simulation of the normal neural patterns of representation of speech sounds, and a consideration of the performance characteristics of optimized, implanted electrode channels.

Implementation of this model requires (8, 10): a) discrete control of nerve array sectors 1 1/2 - 2 mm in length with individual stimulation channels of the stimulating electrode array; with those channels spanning the cochlear zone of representation of the speech frequency range; and with limited effective channel interaction; b) appropriate speech processing in a channel vocoder; c) appropriate temporal representation of information at each stimulation site; and d) compression circuitry to effect appropriate dynamic range adjustment.

Of course, there are a number of obvious general requirements for any cochlear implant system of this type. Electrodes must be implantable for these long intracochlear distances (spanning the speech frequency range) without inducing trauma that might damage the organ of Corti or bony endosteum of the inner ear. The implant must be constructed of biocompatible materials, and its presence in the inner ear must not by itself generate degeneration of the auditory nerve. Applied and operationally required electrical stimuli must not induce damage. The inner ear with an implanted electrode array must survive a middle ear infection. Electronic failures must be correctable without a requirement for reimplantation of a long intracochlear electrode. Devices must be upgradable, especially in the instance (as with most cochlear implant devices) that the telemetry device limits transmittable information. To determine the optimum form of implant coders, they must be studied in a model that imposes no critical limitations of this nature. Transmission electronics must be reliable. Failed transmission electronics must be replaceable.

The UCSF Implant Research Group has addressed all of these questions; and nearly all have been positively resolved (4, 6, 9, 10).

The basic elements of a sound processor-stimulator used for implementation of a multiple channel nerve array response simulation model are illustrated diagramatically in Figure 3. If such a device could effect control of a series of discrete sectors of the auditory nerve array (there generating, site by site, appropriate temporal patterns of stimulation) a device of this class might be expected to operate like a channel vocoder of the same channel number (5, 8, 11). In fact, the most apical (lowest frequency) implant channel operates like a baseband channel of a baseband vocoder. That is, speech information across the lowest frequency range (below 800 - 900 Hz) fed to an apical location is represented reasonably faithfully by a single channel. In a baseband vocoder, full speech intelligibility is achieved with 6-8 channel devices (1). At present, our models and wearable clinically applicable devices have had four or fewer operating channels. Studies with these devices indicate, however, that performance with these devices approach the theoretical optimal, in patients believed to have good nerve survival.

Thus, for example: a) In studies of M. Ochs and M. White, high levels of performance have been recorded in multiple item consonant and vowel confusion matrix series (about 65-75% of items correct, with nearly all errors a misidentification of the most confuseable items). b) Very significant levels of recognition based upon second formant recognition

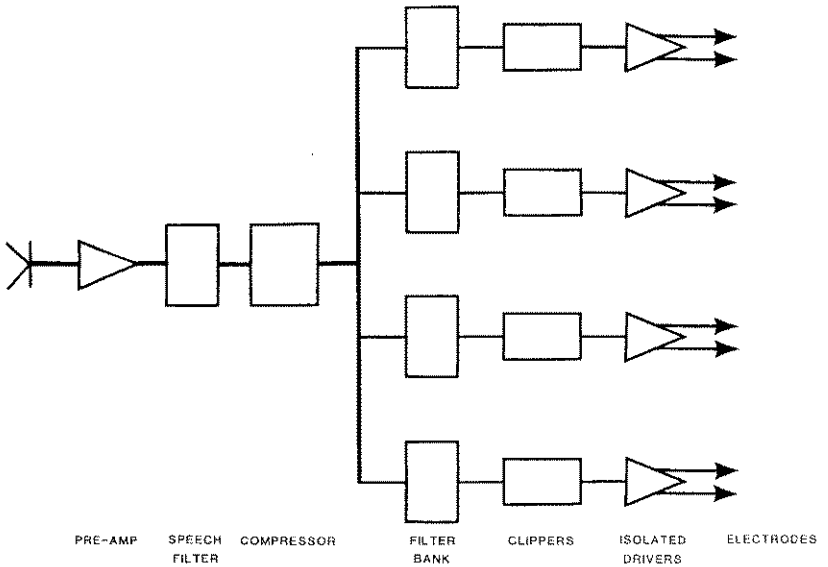

Figure 3: Basic configuration of the UCSF channel vocoder-based (nerve array response simulation) sound processor-stimulator.

have been recorded. In fact, when the second formants of contrast pairs of either natural or synthetic vowels are devolved across different electrode channels, they are correctly identified almost without error. On the other hand, performance is near chance when the second formants of contrast pairs are represented on the same sound processing (electrode) channel.

A simple demonstration of this latter result is shown in Figure 4. In this representative experiment from the studies of Ochs and White, steady state vowels have been synthetically generated, with the first formant and third and fourth formants constant and represented on the most apical and most basal electrode channels, respectively. The center frequency of F2 is variable, and extends across the frequency range of two central channels. In such a case, the patient invariably identified the vowel heard as one of two (the correct) vowels. That is, open recognition was almost invariably correct. Moreover, a categorical change in vowel identity occured as F2 shifted from one channel to the other.

Such results demonstrate the basis for superior MAC battery test results in these devices as compared to single channel devices. With a "frequency balanced" single channel device model (meant to simulate the Austrian device), for example, consonant and vowel confusion matrix results revealed frequent gross errors, and second formant recognition was near chance levels. Comparative tests also indicate substantially higher performance of bipolarly coupled, as compared to monopolarly coupled, devices of the same channel number. That is, best results were dependent on bipolar, simultaneous multichannel device operation.

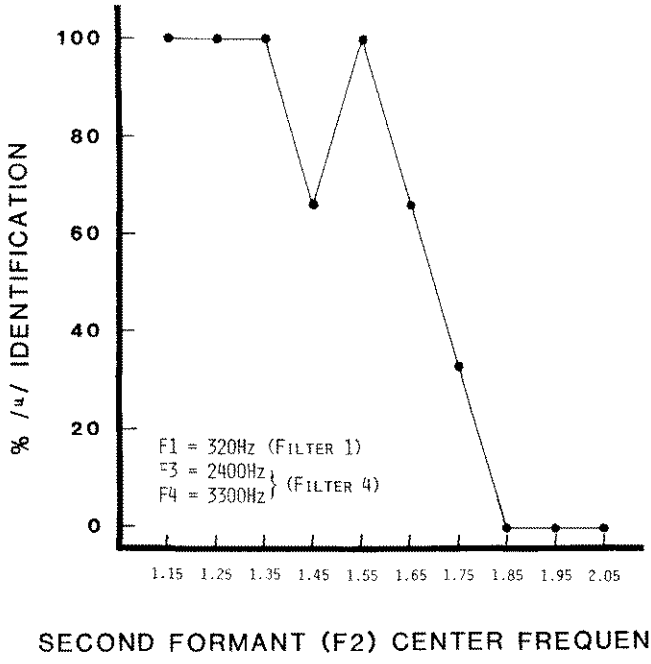

Figure 4: Recognition of synthetic steady state vowels as F2 center frequency is systematically shifted across two sound processor channels. A categorical shift in recognition in this and other similar tests (with different vowels) occurs near the common high and low break points (1.45 kHz) of these two adjacent band pass filters. The outputs of these filters drive bipolar electrode pairs exciting restricted nerve array sectors. In this series, stimuli were presented in random sequence. There were three repetitions of each item.

Overall, results with optimally fitted devices of this type approach those obtainable with baseband vocoders of the same channel number in normal hearing subjects.

It should be noted that this very optimistic picture applies to two patients studied by the UCSF group that were believed to have good auditory nerve survival (as judged by monopolar and bipolar thresholds and channel interaction measures). In two other patients, by these same criteria, nerve survival was believed to be poor - as was performance with this class of speech processor. In the most intensively studied of these patients, multichannel devices were strongly preferred over single channel devices, but objectively measureable benefits were small, and no very significant open speech recognition was recorded. Channel interactions are great in such patients, and the distortions generated thereby are often annoying.

Thus, while we feel we are approaching the optimal device design of a multichannel system for patients with good nerve survival, we are likely far from the optimum for patients with poor nerve survival.

Further Device Development

We now feel that we have a multichannel device model suitable for initiating a large-scale clinical trial. That clinical series is being initiated with the collaboration of Storz Medical Instruments, who are now maufacturing the UCSF device, and with the collaboration of implant research and application groups at other institutions. At the same time, we are working on further device development, pursuing a number of further basic research and development objectives. They include (6): a) External sound processor-stimulator model devices tested with the percutaneous cable have been extended to six (soon to eight) channels. b) A ceramic encapsulation strategy for receiving electronics is being developed. In this upgrade, a smaller receiving coil structure shall be brought inside a moderately larger electronics capsule. c) Receiving electronics models are being extended to eight channels. d) Studies are being conducted to define strategies by which these devices might be safely applied in children. Major problems being addressed include protection of the implanted inner ear from chronic middle ear infections; and accommodation, in these devices, of the length changes in the paths of electrode cables consequent from head growth. e) Dimensions of cable pathway lengths and their variability have been studied in children as a function of age, as another adjunct to the eventual implantation of children with multichannel devices. f) Strategies for coating electrode surfaces with iridium oxide are being developed. Iridium oxide surfaced electrodes have greater charge carrying capacity and such electrodes can be operated at lower voltage levels (12). That feature simplifies the application of controlled current transmission systems, and there are wider safe limits of operation of such devices. g) Two computer-based systems are being constructed that would allow for evaluation of almost any imagineable coding scheme on the same implant patient, given a temporary transcutaneous link via our electrode cable. One is a real-time microprocessor-based model of our next generation of cochlear implant sound processors. The second is a powerful nonreal-time model being developed by a collaborative team at the Research Triangle Institute in North Carolina. h) Finally, we are evaluating a strategy by which a more permanent, direct percutaneous link might be employed in experimental subjects.

We believe that simulation-based devices of the form applied in our models to date shall probably consistently provide high levels of speech recognition in patients with good nerve survival. Further optimization of these devices, which are now principally channel limited, would appear to be straightforward, and shall probably not require substantial invention. On the other hand, this device is not very satisfactory in patients with poor nerve survival. Future research must provide a basis for distinguishing members of these two very different candidate populations prior to implantation; and must be directed toward defining the optimum form of a speech processor-stimulator in this latter, more difficult patient group.

Acknowledgements

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References

1. Flanagan, J.L. (1972) Speech Analysis, Synthesis and Perception. Springer-Verlag. Berlin.

2. Leake-Jones, P.A., and Rebscher, S.J. (1983) Cochlear pathology with chronically implanted scala tympani electrodes. In: Cochlear Prostheses: An International Symposium. Parkins, C.W., and Anderson, S.W. (eds.) Ann. N.Y. Acad. Sci. 405:203-223.

3. Leake-Jones, P.A., Walsh, S.M., and Merzenich, M.M. (1981) Cochlear pathology following chronic intracochlear stimulation. Ann. Otol. 90 (Suppl. 82) 6-8.

4. Loeb, G.E., Byers, C.L., Rebscher, S.J., Casey, D.E., Fong, M.M., Schindler, R.A., Gray, R.F., and Merzenich, M.M. (1983) Design and fabrication of an experimental cochlear prosthesis. Med. & Biol. Eng. & Comput. 21:241-254.

5. Merzenich, M.M. (1983) Coding of sound in a cochlear prosthesis: Some theoretical and practical considerations. In: Cochlear Prostheses: An International Smposium. Parkins, C.W., and Anderson, S.W. (eds.) Ann. N.Y. Acad. Sci. 405:502-508.

6. Merzenich, M.M., and colleagues (1978-1984) Progress Reports 1-9. Development of multichannel electrodes for an auditory prosthesis. NIH Contract NO1-NS-7-2367. Neuroprosthesis Contract Program, NINCDS, NIH, Washington 1978-1980. Progress Reports 1-8. Development of multichannel electrodes for an auditory prosthesis. NIH Contract NO1-NS-0-2337. Neuroprosthesis Contract Program, NINCDS, NIH, Washington 1980-1983. Progress Reports 1-3. Scala Tympani Electrode Arrays. NIH Contract NO1-NS-3-2353. Neuroprosthesis Contract Program, NINCDS, NIH Washington 1983-1984.

7. Merzenich, M.M., and White, M. (1977) Cochlear implants: The interface problem. In: Functional Electrical Stimulation. Hambrecht, F.T., and Reswick, J.B. (eds.) Marcel Dekker, New York.

8. Merzenich, M.M., and White, M. (1980) Coding considerations in design of cochlear prostheses. Ann. Otol. 89:84-87.

9. Merzenich, M.M., Byers, C.L., White, M., and Vivion, M.C. (1980) Cochlear implant prostheses: Strategies and progress. Ann. Biomed. Eng. IEEE 8:361-368.

10. Merzenich, M.M., Rebscher, S.J., Loeb, G.E., Byers, C.L., and Schindler, R.A. (1984) The UCSF cochlear implant project. State of development. Adv. Audiol. 2:119-144.

11. Merzenich, M.M., White, M., and Vivion, M.C. (1979) Some considerations of multichannel electrical stimulation of the auditory nerve in the profoundly deaf: Interfacing electrode arrays with the auditory nerve array. Acta Otolaryngol. 87:196-203.

12. Robblee, L.S., Lefko, J.L., and Brummer, S.B. (in press) Activated iridium, an electrode suitable for reversible charge injection into saline solutions. J. Electrochem. Soc.

13. Schindler, R.A., and Merzenich, M.M. (1974) Chronic intracochlear electrode implantation: Cochlear pathology and acoustic nerve survival. Ann. Otol. 83:202-213.

14. Schindler, R.A., Merzenich, M.M., White, M., and Bjorkroth, B. (1977) Multielectrode intracochlear implants. Arch. Otolaryngol. 103:691-699.

15. Walsh, S.M., and Leake-Jones, P.A. (1982) Chronic electrical stimulation of the auditory nerve in cat: Physiological and histological results. Hearing Res. 7:281-304.