Part 7. Appendices

7.1. Summary of Questions Asked of Each Cochlear Implant Team Carrying out Clinical Work

1. What is the size of the team and of support services?
2. How are patients selected for implanatation, with particular regard to diagnosis, testing, motivation and cognitive assessment?
3. What is the nature of the implant? Where is it implanted? What materials are used? Unipolar or bipolar stimulation? What is the link or connecting system? What form does the driving and coding system take? And what is the cost of development and manufacture?
4. What form does the surgery take, how long does it last and what facilities are required?
5. What surgical problems are encountered and is there any morbidity or rejection?
6. What systems failures are encountered?
7. What testing and training procedures are used for rehabilitation and what time is spent on this?
8. What are the results of implantation with particular regard to duration of use, psychological well-being, environmental awareness, alarm detection, sound localization, lip-reading skills and speech production?
9. How do implantation results compare with gains from high-level aids or vibrotactile devices?
10. Have there been any problems with the use of the implant, such as background noise disturbance?
11. How many patients are likely to benefit from cochlear implantation?
12. Is cochlear implantation a 'clinically valuable rehabilitative tool'?
13. With multichannel electrodes, what are the differences in threshold obtained between electrodes, and what is the variation in threshold over time?

7.2. The Place of Transtympanic Electrocochleography and Promontory Stimulation in Patient Selection

7.2.1. E.R.A. Responses

In theory, it should be possible to localize the level of a lesion in sensori-neural hearing loss (i.e. cochlear, neural, brain-stem or cortical) by employing the different E.R.A. responses, i.e. transtympanic ECochG,

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brain stem and cortical evoked responses. In practice, for cochlear implantation, the technique would be used to confirm objectively that the lesion was cochlear (sensory).

7.2.2. Promontory Stimulation

Following ECochG examination, with the transtympanic electrode still in position, the inner ear is stimulated electrically with alternating current. A forehead electrode acts as the ground. Sine waves of 30, 60, 90 and 120 Hz at peak-to-peak voltages of 0·3 to 1·2 V, in 0·3 V steps, are delivered. Pain is often elicited at about 1·2 V. The patient is asked if he perceives an auditory sensation. A vibro-tactile sensation is considered as a negative response. Eventually it is hoped to make use of brain-stem responses to this promontory stimulation in order to evaluate the population of surviving neurones.

With promontory stimulation, post-lingually deafened patients have little difficulty in identifying an auditory sensation. The pre-lingually deaf do not give a reliable description of their sensations. Provided there is a positive response to the promontory testing, the Los Angeles Group consider this evidence of sufficient neuronal survival to proceed to single channel implantation, and to date all patients have met this criterion; if there had been no response to the test the prospective implant candidate would have been excluded.

At the Lake Tahoe meeting, promontory testing was discussed with Dr. Derald Brackmann. He now has experience of some 600 tested ears. Patients with normal hearing do not respond to the stimulus and there is a direct relationship between the percentage of ears responding and the average pure tone threshold loss up to about 100 dB ISO; the greater the hearing loss, the higher the percentage of positive responses. We had previously discussed this phenomenon with the Los Angeles and San Francisco groups and suggested that normal subjects might not 'hear' the promontory electrical stimulus because of masking by background noise. This hypothesis will have to be tested.

It is possible that direct stimulation of the round window membrane will result in a higher percentage of positive responses than simple promontory stimulation in patients with total sensory deafness. This is discussed in Appendix 7.7.

7.3. **Brief Summary of Pittsburgh Study** (Bilger *et al.*, 1977)

1. Carried out on 13 subjects implanted in Los Angeles and San Francisco. The implants were well tolerated, although both subjects whose leads were routed via the subcutaneous external canal had evidence of chronic otitis externa, and one subject appeared to be extruding a ground electrode through the tympanic membrane.

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2. Activation of the prostheses disrupted the postural stability of subjects, particularly when their eyes were closed, although few complained of disequilibrium. (Most subjects had successfully adapted to their loss of vestibular function caused by the pathology of their condition).

3. Although subjects could not understand speech with their prostheses,

(a) They were aware of sounds throughout the range of frequencies tested (100 Hz–8 kHz) at intensity levels likely to occur in the environment.

(b) Some of the subjects did score significantly higher on tests of lip-reading (words and sentences: test set consisting of four alternatives) with prostheses activated than with the prostheses not activated. (The improvement in score was about 10 per cent averaged over all subjects and conditions).

(c) Some of the subjects (5/13) had significantly higher scores on tests of identification of common environmental sounds (test set of 4 alternatives) with their prosthesis activated than when they were not.

(d) Some of the subjects (3/13) performed better with their prostheses activated than without, in spondee recognition tests (set of 16 alternatives).

(e) The articulation of some of the subjects (4/13) was judged to be significantly better with the prostheses activated than without. Those whose speech was totally unintelligible were not helped.

(f) Most of the subjects with their prostheses activated could discriminate intensity differences as well as normal subjects.

(g) Most subjects could discriminate differences in frequency below 250 Hz.

(h) Subjects could discriminate sounds differing in temporal cues, e.g. duration, rhythm, tone vs. narrow band noise.

4. 11 of the subjects found their prostheses to be of value: 8 in terms of communication; 3 in terms of the awareness of sound in the environment.

5. All of the subjects found noise bothersome.

7.4. Walt Disney Hearing Rehabilitation Research Centre Rehabilitation Programme

7.4.1. Rehabilitation of the Cochlear Implant Recipient Involves Five Major Areas

Evaluation prior to surgery
Hearing aid training programme
Post-surgical care and direction
Three-month training programme with cochlear implant
Post-programme and follow-up evaluations.

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7.4.2. Evaluation Prior to Surgery (Approximately 15 Hours of Testing for Research Purposes)

Information is needed as to how the recipient is functioning in his daily life at the present time. The life style, over-all communication ability, and motivation for change/self-improvement are the major concerns. Our staff includes speech pathologists, audiologists, and psychologists who have formulated a battery of tests including:

Psychological battery
Speech evaluation
Speech-reading
English skills and other communication modes
Audiologic battery
Fitting of hearing aid

Included in this evaluation battery are interviews with family members and employers whenever possible, and meetings with other implant users. One critical factor affecting the benefit which the recipient receives from the implant and this programme is a realistic concept of what to expect and what will be asked of him.

7.4.3. Hearing Aid Training Programme Prior to Surgery (Approximately 50 Hours)

(See cochlear implant training description).

7.4.4. Post-Surgical Care and Direction (2 Month Healing Period)

Aside from the necessary medical post-surgical care, the recipient at this time is instructed in the care of the stimulator unit and fitted for the unit after healing is completed. An additional group meeting and family conferences are scheduled to prepare for the training programme.

7.4.5. Three-Month Training Programme with Cochlear Implant (Approximately 50 Hours)

This training period involves individual therapy, group meetings, programmed instruction, home practice work, and counselling as does the hearing aid training programme. Individual therapy consists of:

Speech therapy
Auditory training
Speech reading practice
Counselling

Group meetings are initiated with other implant users to offer discussion of mutual problems, interests, and feelings. Family counselling is critical at this point. Groups of concerned family members and friends discuss adjustment aspects of the cochlear implant and its user, and how it affects the total family unit.

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This training period is essentially a re-learning procedure. The recipient is encouraged to adjust his life style to take best advantage of a prosthetic device. Consistent, beneficial use of the stimulator is influenced by developing or re-developing a critical listening ability, relaxed use of the device, and non-competitive progress toward utilization, on an increasingly unconscious level, of the environmental noise and voice cues that now reach the recipient.

7.4.6. Post-Programme and Follow-up Evaluation

Continuing group meetings
Anuual post testing
Medical check

7.5. Ethical Guidelines Adopted at the First International Conference on Electrical Stimulation of the Acoustic Nerve for Profound Sensori-Neural Deafness in Man

At the end of the First International Conference on Electrical Stimulation of the Acoustic Nerve as a Treatment for Profound Sensori-neural Deafness in Man, held in San Francisco in 1974, certain 'guidelines' for patient selection were suggested and accepted (Merzenich *et al.*, 1974). These were as follows:

1. Children will not be implanted.
2. Adults will be eligible if:

(a) There is no demonstrable hearing or speech intelligibility in either ear with any presently available amplification device or apparatus.
(b) The patient is available on a regular basis for two years, for study and retraining at least two hours per week.
(c) The patient is psychologically stable and is strongly motivated to utilize an implant by virtue of economic or other factors.

In addition there should be a 'cooling off' period between a decision that the patient is qualified and the actual procedure.

3. In cases of ototoxic or traumatic deafness, a minimum of two years should elapse after the medication or injury, to allow every chance for spontaneous recovery.

7.6. Participants in Weekend Symposium, Lake Tahoe, October 22nd and 23rd 1977

Otologists

Mr. John Ballantyne, F.R.C.S.	(London)
Dr. Derald E. Brackmann, M.D.	(Los Angeles)
Dr. Robin Michelson, M.D.	(San Francisco)
Mr. Andrew W. Morrison, F.R.C.S.	(London)
Dr. Mansfield F. W. Smith, M.D.	(Stanford)

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Neurophysiologists

Dr. Edward F. Evans, M.B., Ph.D.	(Keele)
Dr. Theodore J. Glattke, Ph.D.	(Tucson)
Dr. Michael M. Merzenich, Ph.D.	(San Francisco)

Engineering

Dr. Mel Barts, Ph.D.	(Los Angeles)
Dr. William McFarland, Ph.D.	(Stanford)
Dr. Mark White, Ph.D.	(San Francisco)

Rehabilitation

Miss Janna Lang, Ph.D.	(Stanford)

7.7. Additional Information on Cochlear Implantation Obtained at the "Third International Course of Oto-Neuro-Surgery", with Comments

One of us (AWM) attended the above course in Grenoble, France, from 13th to 16th March, 1978.

7.7.1. Utah Project

Dr. D. Brackmann reported that the two recently implanted patients (see p. 63) had now been subjected to an initial study. In both patients all the intracochlear electrodes and the promontory electrodes were functioning. 'Place' pitch percepts had been convincingly demonstrated. Compared with the scala tympani electrodes, the promontory electrodes required about twice the current strength to reach threshold. In discussion Dr. William House indicated that, many years ago, their group had investigated the possibility of promontory electrode stimulation in two patients, but the method had been abandoned because of the proximity of the hearing and pain thresholds obtained in these two patients. (Conversely, we understand that the Douek group in London have encountered no problems with pain thresholds from extra-cochlear stimulation at the round window).

Dr. Brackmann also reported that one of the two recently implanted patients, who had normal vestibular function pre-operatively, had been re-investigated from this viewpoint and there had been no significant change in vestibular function in the implanted ear.

7.7.2. Implantation Programme of Drs. C. H. Chouard, P. Macleod and Associates in Paris

Much additional information was obtained on patient selection and experience, surgical technique, electrodes, stimulation parameters, transmission link systems and rehabilitation.

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Patient selection

This topic was covered mainly by Dr. A. Morgon, of Lyon. Patients should have bilateral total or subtotal hearing loss; they should be emotionally stable, properly motivated and willing and able to participate in the rehabilitation programme. Lip-reading skills should be assessed pre-operatively. Dr. Chouard did not think that patients should be "bullied" into excessively prolonged psychological assessment.

In adults, acute stimulation experiments were carried out under local anaesthesia. After tympanotomy, an electrode was placed on the round window membrane. Stimulation was with rectangular waves, of 300 μs duration, from 30 to 500 Hz. Discrimination of frequency differences was possible below 300 Hz. Approximately 85 per cent of totally deaf adults obtained auditory percepts to this form of stimulation.

Children with congenital or acquired hearing loss are not excluded. In co-operative adolescents, the round window stimulation is carried out as in adults. In younger children or in the absence of co-operation, brain-stem and 'far field' potentials are recorded during round window stimulation, under general anaesthesia. Of 70 'deaf and dumb' children and adolescents, positive responses were obtained in 55.

Dr. Chouard thought that, to obtain the most reliable information on neuronal survival, test stimulation should be carried out at the round window. In his view, very few neurones were required for multichannel stimulation to be effective (although it is not clear to us on what grounds this supposition was based). The amplitude of the brain stem responses to electrical stimulation might be directly related to the number of responding neurones.

Implantation experience

In the early 1970's, Dr. Chouard carried out experimental implants in four patients. The first was a man with total loss of inner ear function and facial paralysis following a head injury. The results were encouraging.

Between 1973 and 1975, he implanted a further 22 patients with multichannel devices, five to eight channels being employed. A dual approach to the cochlea was used (via middle cranial fossa and mastoidectomy). In each case the transmission link system used was a percutaneous Teflon plug. One patient accidently tore off the plug, while in *all the other 21*, the plugs became dangerously loose and were removed by Dr. Chouard, after intervals of 12–20 months, the wires being left in a subcutaneous position. In a few of these patients, some of the wires are visible and accessible through the skin. These electrodes still respond to stimulation with unchanged thresholds. Since subcutaneous connectors were used, it will be possible to employ a newly-developed transcutaneous transmission link system; twenty patients are awaiting revision surgery and the supply of external electronics packages. One major obstacle is the cost

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of this package—50,000 F. for the 8 channel device. None of these 20 patients can afford the device, though Dr. Chouard is attempting to raise funds to assist them.

In the early stages of his experience, Dr. Chouard implanted six patients with total deafness associated with chronic ear disease. Post-operative infection resulted in the loss of some of the leads in 3 of these 6 patients. It was not clear (or ascertained) how many of these six belonged to the early experimental group of four patients.

In the past 18 months, two of the 22 patients were *supplied* with prototypes of the new external package and transcutaneous link system; and ten further new implants (8-channel) have been carried out, these patients purchasing their external devices. No information was obtained as to whether or not there were surgical/hospital charges. Therefore 12 patients, including 3 juveniles (aged 9, 14 and 17 years), have functioning implants.

Surgical considerations

A cine film of the Chouard implantation programme was presented, with commentary in French. The surgical technique (which could be understood but was incomplete) formed part of this film. The skin flap is a large inverted U, based on the zygoma and mastoid bone and more or less outlining the temporalis muscle. Fascia is removed for subsequent repair. A radical mastoidectomy is performed, with removal of the incus and head of malleus. The tensor tympani tendon is divided and the muscle removed—together with its bony canal—to gain access to the superior parts of the cochlear coils. The middle fossa dura is then elevated, and the greater superficial petrosal nerve is used as a landmark to the most superior part of the first cochlear coil. The next part of the film was shown as a cine version of a black and white TV monitor and could not be clearly seen. It consisted of insertion of the 'middle fossa' electrode.

Surgery then returned to the promontory. Multiple openings (probably seven) into the cochlea were effected with 1–2 mm diamond burrs. These fenestrations followed the spiral of the cochlea and appeared to be several millimeters apart. Sheets of silastic (somewhat larger than the fenestrae) were advanced into each cochlear 'hole', followed by the electrodes which were also advanced at an angle. The electrodes were fixed with one or two drops of 'Histoacryl' tissue adhesive, which could be seen entering the cochlea. Each separate electrode was identified by a (colour or number) code attached to its connector. The subcutaneous coil with its 8 electrodes (and ground) was then placed (though the method of fixation was not obvious) in a 2 cm diameter circular gutter in the mastoid/occipital bone. Connection was made between the 8 electrodes and the subcutaneous coil via individual subcutaneous connectors, the interior of each of which was filled at the time of connection with liquid silicone rubber. The leads were

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left lying under the large skin flaps. The placement of the ground electrode was not shown.

Wound closure was not demonstrated, but Dr. Chouard indicated that the mastoidectomy cavity was obliterated with bone paté and that the external canal was also obliterated.

No surgical complications have been encountered. Surgery takes about 8 hours.

Electrodes

The electrodes are of 0·0025″ platinum:iridium (90:10), insulated with 0·0025″ extruded Teflon. 1 mm of insulation is removed from the intracochlear tips, which are not flamed. These electrodes are imported from the U.S.A. (from the same suppliers as to the Utah project). The subcutaneous connectors are fabricated from silastic. No insulation problems have been encountered and, in each of the 12 subjects with working devices, all electrodes are functioning. No information was obtained on insulation of the subcutaneous package.

Stimulation parameters

This information was supplied by the neurophysiologist, Dr. P. Macleod. With each electrode, the frequency is fixed at 500 Hz and the amplitude is fixed at 5 V. The duration of each pulse is varied, between 60 and 150 μ seconds. The DC component is blocked by capacitors, i.e. there is no nett charge transfer.

Transmission link system and coding

Information and power are transmitted to a subcutaneously implanted package by radio-frequency induction between an external transmitter coil and a receiver coil implanted under the skin.

The earlier subcutaneous coil (2 cm diameter) was flat. The latest models are saucer-shaped, to fit the convexity of the occipital/mastoid bones of the skull. The external coil has a diameter of about 3 cm. It is attached to the retroauricular part of a spectacle frame. Positioning is *not* critical, i.e. the external loop can be moved about 2 to 3 cm off-centre (from the implanted coil) before there is a sudden loss of signal.

Power is obtained from the external source through the coil (by rectifying the 2 MHz signal received). The threshold and dynamic range of individual electrodes are specified by the corresponding pulse duration. The address of the electrode to be stimulated, and the duration of its pulse, are digitally coded, through the same coil, using a multiplex system. The implanted circuitry is a 16-place decoder normally used to drive multi-segment L.E.D. (light emitting diode) indicators.

For the strategy of stimulation, the 'vocoder' principle (see p. 9) has been employed, from April 1978, using 8 channels or 12 channels.

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The electrodes are placed about 2 mm apart in the cochlea and are intended to cover those areas which cover the frequency range 0·2 to 4 kHz. Each channel of the 12 channel 'vocoder' covers approximately $\frac{1}{3}$ of an octave. The signals are phased to stimulate the basal to the more apical electrodes in sequence, within about 1 ms. Eventually it is hoped to use a longer delay time than this. A compression system is built into the external electronic package.

The external package for the 8 channel device is sizeable (about the size of a small attaché case) and is powered by ordinary domestic batteries. It is worn in a canvas (or similar) bag supported by a shoulder strap. The newest package for the 12 channel implant will be about half this size and will cost the patient 63,000 F.

It is hoped, eventually, to incorporate a directional microphone which the patient may use for conversation in noisy backgrounds.

On the question of the adequacy of isolation of the individual electrodes in the cochlea, both Dr. Macleod and Dr. Chouard admitted that the silastic sheeting was a rather crude type of insulation, and they agreed that the problem of providing a sufficient number of *isolated* compartments had not been solved.

Rehabilitation and results

It was reported that, of the 12 working multichannel implants, all electrodes in all patients were functioning. No psychophysical data were given, though it was stated that thresholds varied during the first 5 months but were static thereafter. Dr. Macleod indicated that patients received 'very distorted' sound signals. Dr. Chouard said that the patients heard sounds which were "quite different" from their prior hearing experience, yet he insisted that with his multichannel system they could recognize "speech". He thought that children, in particular, obtained "benefit at once". One of the implanted children has now graduated from a school for the deaf to a normally hearing school environment.

Rehabilitation was covered briefly by Dr. Morgon and by Dr. Chouard. It embranced three main topics, viz. (1) auditory rehabilitation (the learning of word lists and the psychophysical evaluation); (2) lip-reading instruction and monitoring of progress; and (3) speech production and its evaluation. To assist in the latter, voice analysis (by sonagraph) is employed. The sonagrams help both the patient and the speech therapist. Examples were demonstrated, comparing both pre- and post-implant performance with that of normal subjects.

The auditory rehabilitation is prolonged. Patients start by learning to repeat (without lip-reading) from a closed list of 10 words. Within a month, they can discriminate words from closed lists of 20 words. By 6 months, they have 'learned' to discriminate from lists of 100 words.

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Dr. Chouard claimed that most implanted patients could, with practice, score 80 per cent on these word lists without lip-reading.

Patients used their implants up to 16 hours a day.

Future outlook

The 12 channel system is now ready for use. Dr. Chouard intends to start implanting patients with this system in April 1978, and he hopes to operate on 2 to 3 patients a month. Two electrodes will be implanted via the middle fossa and the remainder through the promontory. The 'First International Course on Multichannel Cochlear Implant' will be given in Paris from September 20th to 25th 1978. Among the instructors will be Professors Pialoux, Chouard, Macleod and Charachon, and Dr. Morgon, from France, with participation by Professors Engström, Spoendlin and Clark, and Drs. Schindler, Merzenich, William House and Michelson.

Dr. Chouard indicated that full details of their implantation programme and results would be made known at this course.

Comments

Some aspects of the Chouard programme incorporate useful ideas: for example, the attempt to quantify the pre-operative brain-stem responses to round window stimulation, and to relate them to the likely surviving neuronal population; the use of sonagrams to assess improvements in voice production after implantation; the planned auditory rehabilitation (as used in the management of profoundly deaf children); the proposal to use directional microphones; the transcutaneous link, utilizing a multiplex system; and the use of subcutaneous connectors (*individual* to each electrode), to minimize the risk of leakage that would cause short-circuiting between electrodes.

The fact that there are apparently no problems about implanting juveniles and children in France means that, in time, information should become available which, at present, cannot be obtained elsewhere.

In theory, something of the order of 10 channels would appear to be the minimum requirement for minimal speech intelligibility. It remains to be seen if the Chouard technique can achieve this. Indeed, at present, no scientific or recorded evidence *has been presented* to indicate that his multichannel systems result in greater information transfer than can be achieved with single channel systems. Detailed observations on the psychophysical responses await publication.

A number of criticisms can be made of the surgical technique. Obliteration of the external meatus could result in the formation of inclusion dermoids and cholesteatomas; or, in some cases, the obliteration could break down and cause infection. The compartmentalization of the cochlea with silastic sheeting seems certain to cause local damage to the cochlear partition, and possibly in some areas damage to all the cochlear duct

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structures. From experience elsewhere, this will result in secondary neuronal degeneration which will continue over many months. Nevertheless the encouraging claim has been made that, despite this almost inevitable trauma, all electrodes in all the recent patients can still evoke a response to stimulation (for periods up to 18 months). However, the fact that (in the Chouard patients) thresholds took much longer (5 months) to stabilize than those in most of the centres in the U.S.A., could suggest that neuronal degeneration was occurring. The use of tissue glues, leaking into the cochlea, must add to the tissue damage. The use of the middle fossa approach, while certainly giving access to the more apical part of the tonotopically important region of the cochlea, greatly increases the length of the operation and must involve a slight risk to the facial nerve.

Failure of *all* the first 22 or so implants, due to the unfortunate choice of Teflon for the percutaneous connector plug, merits some comment. Had the technique been tried out on experimental animals, or even if the materials had been assessed in a *small* number of volunteer patients in the first instance, then this tragedy could have been avoided. Implantation between 1973 and 1975 must have been at the rate of approximately one a month, and with the 8 channel device (between 1975 and 1977) at one every two months. It is now proposed to use the 12 channel devices at the rate of 2 to 3 a month. One hopes there will be no further problems with hardware.

It can be argued that there is no objection to wealthy patients purchasing their own implants and accompanying electronics. A case, however, could be made for raising funds to assist less well-off patients *before* they are included in the programme.

(Since this paper was completed, Chouard (1978) has published further information on his implantation programme).

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