Part 2. Centres visited

2.1. Walt Disney Hearing Rehabilitation Research Center, Los Angeles, California. (Monday and Tuesday 17 and 18 October, 1977)

2.1.1. Strategy

This group, led by Dr. William House, has implanted electrodes entirely within the scala tympani of the cochlea. Their first implants, in the 1960's, were almost entirely multi-channel (5 monopolar electrodes) and were aimed at answering two questions: would such cochlear prostheses be practicable for patients to use; and would such implantation lead to further damage to the inner ear, and electrical stimulation lead to damage to the nervous system?

Although the multichannel implants were able, in at least one patient, to evoke percepts whose 'pitch' was related to the place of stimulation, the multielectrode system did not help in producing 'meaningful' sound patterns in each of a variety of coding systems tried, and eventually became inoperable because of electrical shunting between the electrodes. From extensive studies on a highly motivated, sophisticated and articulate subject, the team decided that multichannel systems in the current state of development did not offer advantages over single channel systems which were easier to construct and insert. Since the early 1970's, therefore, they have concentrated on exploiting the limited usefulness of single channel implants—a single wire in the scala tympani stimulated with reference to a subcutaneous 'ground' wire. This decision had the singular advantage that a 'take-home' stimulation unit could be given to the patients, and this has been a key feature of the group's strategy.

The current emphasis, therefore, is on intensive rehabilitation of their group of implanted patients (now totalling 22) to optimize the usefulness of the limited information imparted by a single channel system.

As far as the first of the original questions is concerned, the team are comparing the performance of the implanted patients, in various acoustic situations, after training with their implants, with their preoperative performance with high-level bone or air conduction aids. Since the emphasis has been on rehabilitative training and psychological evaluation, no systematic psychophysical investigations have been performed. On the second question, no adverse effects of electrical stimulation on the nervous system have been observed in 40 'ear-years' of stimulation, including one patient who has used his implants for 16 hours per day for seven years. With respect to local damage arising from the implant, while the same

https://doi.org/10.1017/S0022215100085005 Published online by Cambridge University Press

patient has had 4 successful implantations, temporal bone studies on one of the earliest implanted patients did show fibrous, bone-like tissue reaction although the 'luetic' aetiology complicates interpretation (see p. 88).

2.1.2. Staffing and Facilities

The Walt Disney Hearing Rehabilitation Research Center (HRRC) is a non-profit corporation affiliated with the Ear Research Institute of Los Angeles, in which it is situated. The facilities available to the implant team include laboratories for temporal bone dissection; scanning and transmission electron microscopy for examination of the long-term effects of implantation on electrode materials; electrocochleography and brain-stem electrophysiology for preoperative assessment. Surgical facilities (with closed circuit colour television) are available in the adjacent St Vincent's Hospital. Patient evaluation has been conducted in the related Otologic Medical Group. Laboratories for audiological and psycho-physical testing and for the making of surface preparations of cochleas, were being established. No animal facilities existed, although they hoped to establish links with U.C.L.A.

The implant team, consisted of the following:

Dr. William House, otologist (voluntary, director)

Mrs. Norma Norton, speech and hearing therapist (in charge of rehabilitation)

Audiologist

Engineer (manager of programme)

2 Psychologists, for cognitive and emotional testing and for supportive psychotherapy.

In addition, an engineer (Mr. Jack Urban) has given much time free to the programme, and contracted work has been placed with another engineer for the development of radio-frequency transcutaneous electronic links.

2.1.3. Funding

The HRRC currently obtains its funds from the Ear Research Institute, i.e.: from the private sector.

No charge is made to the patients.

Each implant unit currently costs about $800 to construct, including electrodes and the body-worn control unit.

The estimated costs of surgery and rehabilitation amounted to approximately $8000, equivalent to those for middle ear prosthetic surgery, including preoperative evaluation and post-operative hearing aid fitments and rehabilitation.

https://doi.org/10.1017/S0022215100085005 Published online by Cambridge University Press

2.1.4. Patient Selection

Since 1961, Dr. House has implanted 22 patients, with single-channel electrodes. Of these, 11 currently using their implants have been studied by Dr. Bilger's team in Pittsburgh (Bilger *et al.*, 1977), and we saw 5 of them.

Of these 22 patients, the deafness was due to otosclerosis in 7; to ototoxic drugs in 5; to meningitis in 2; to unknown causes in 8 (see Table 6.1.).

Eighteen of the subjects had been deafened after the acquisition of language, and 4 were pre-lingually deaf; of these four, 2 were born deaf and 2 acquired deafness in early childhood.

Their ages ranged from 23 to 64 years, at the time of selection for their implants.

The Walt Disney Center will not accept for implantation any patient with chronic debilitating general disease, active ear infection or disabling vertigo; and tinnitus, although not an absolute contra-indication, may preclude some patients from consideration if it is felt that it may adversely influence motivation or co-operation.

Radiologically, there should be no abnormality of either internal auditory canal or bony cochlea.

Audiological assessment is of the utmost importance. The potential implantee should be profoundly deaf in both ears, the hearing loss by pure tone audiometry exceeding 95 dB in the better hearing ear at all frequencies from 250 Hz to 8 kHz; there should be no response to electro-cochleography (See Appendix 7.2.). Since for surgical reasons a normal middle ear is desirable, then ideally clinical assessment (including tympanometry) should show no gross abnormality.

Using a very powerful body-worn hearing aid (either the patient's own or one lent by the centre), the prospective patient should have no speech reception threshold in either ear for spondees, tested in sets of 10 words. If he scores anything at all with a hearing aid, he is excluded from the implant programme, but binaural aids have not been used in such tests. In the future, vibrotactile devices will also be tested.

In order to determine whether or not some (at least) of the central nervous pathways remain intact, electrical stimulation of the promontory should be carried out, and other appropriate tests when available.

There should be no disabling vertigo and tests of vestibular function should include caloric stimulation and electronystagmography (ENG).

Although existing tests leave much to be desired, attempts have been made to assess the linguistic and communicative skills of the subjects, with particular reference to vocabulary, lip-reading (speech-reading) and the patient's own voice and speech.

When testing for innate intellectual ability, it is important that non-verbal (performance) tests should be used as well as verbal tests, and

https://doi.org/10.1017/S0022215100085005 Published online by Cambridge University Press

ideally the subject should be of above-average intelligence. There should be no psychotic traits, and no evidence of organic brain damage. The patient should be emotionally stable and well adjusted to his handicap, and his motivation and expectations must be realistic.

He *must* be made to understand that he is *not* going to hear normal speech, and that the additional auditory cues which he will hear will be minimal. Confirmation of this understanding is obtained by questionnaire.

An assessment of the patient's degree of social adjustment is made by a "quantifiable social adjustment scale interview", and the 'loner' should be eliminated. Support from family and friends is essential, frequent regular journeys must not be precluded by distance or financial constraints, and the subject must be prepared to adjust his life style to fit the rehabilitation programme.

Patients are told that they are experimental subjects.

At the end of all interviews, and cognitive and emotional testing, a staff conference is held on each patient. No patient is recommended for implantation without a full staff consensus, and a patient can withdraw at any time.

This also gives opportunity for prospective implantees to meet already implanted patients and their families.

It is vitally important that the limitations of a single-channel implant should be carefully explained to any patient who is contemplating it.

Of all those patients who enquire about an implant, about 99 per cent are rejected, on otological or audiological grounds (e.g. because the loss is not severe enough); and of those accepted at the first 'screen', 20 per cent are rejected as unsuitable on psychological or rehabilitative grounds.

At present, the most satisfactory patient is one who wants 'simply to hear', and patients awaiting implantation are encouraged to meet others already implanted (and their families).

Dr. House believes that the greatest potential benefit of cochlear implants is to be found in children born deaf, but there is at present a substantial emotional opposition to this in the United States. Furthermore, the laws of 'informed consent' are such that a child implanted at an early age, even with the permission of his parents, would be entitled to sue the physician at any time after coming of age (at 18 years), if some totally unexpected complication were to occur.

2.1.5. Electrodes

The earliest electrodes used by the group were gold and silver wires, the latter insulated with Pyre ML.

The multichannel systems consisted of 5: 0·004″ diameter silver wires insulated with Pyre ML, with tips exposed at 5 mm intervals, inserted 22 mm into the scala tympani via the round window. The reference electrode was a single silver wire introduced via the oval window into the scala vestibuli.

https://doi.org/10.1017/S0022215100085005 Published online by Cambridge University Press

The subsequent single channel system employed an active electrode, introduced into the scala tympani through the round window, consisting of 0·005″ diameter platinum: iridium wire (90:10) terminating in a ball of about twice the diameter of the wire. The reference electrode was made of the same material and was placed subcutaneously, in the middle ear or in the Eustachian tube. The wires were insulated, except for the terminal 18 mm of the active electrode and 4 cm of the reference electrode, by Pyre ML. Subsequently, the insulation was changed to epoxy with a silicone rubber overcoat.

Inter-electrode resistances are of the order of 7–10 k Ohms. The current strengths employed are of the order of hundreds of μA. Constant current stimulation is not used.

2.1.6. Transmission Link Systems

The multichannel systems were connected to a teflon-embedded multi-way connector screwed to the mastoid. To keep the contacts clean during showering, etc., a teflon cap covered the connector. Direct electrical connection was made to a control unit designed to deliver a variety of electrical wave shapes. In the course of extensive testing on one patient (CG) it was concluded that amplitude modulation of a 16 kHz carrier with speech waveforms produced better results within the limited dynamic range for electrical stimulation, than direct stimulation with the speech waveforms. This conclusion appears to have been based on an unfavourable comparison between a direct analogue system without adequate compression facilities and the 16 kHz modulation system equipped with A.G.C. 'compression'.

Thereafter, the 16 kHz modulation system has been employed. It seems likely that the success of this system is due to non-linear operation of the driving amplifier, as established in the Pittsburgh Report (Bilger *et al*, 1977) and/or rectification at the electrode: tissue interface. Thus, the former produced "a train of biphasic pulses" (Bilger *et al.*, 1977) and the latter could produce demodulation of the carrier, thereby introducing analogue stimulation with the original speech waveform. In this respect, it is of significance that some of their patients performed better with the modulation unbalanced.

Because of tissue reaction to the teflon connector, subsequent transmission link systems have been transcutaneous, utilizing low-frequency inductive or radio-frequency (r.f.) transmission.

The low-frequency inductive system consists of an implanted coil of the platinum electrode wire, insulated with epoxy, and wound on a ferrite core of about 1 cm diameter, the whole coated with epoxy and silicone rubber. It is driven by a transmitter coil held over the receiver by means of a head band or spectacle frame. The alignment of the transmitter and receiver coils is extremely crucial: deviation of a few millimeters introduces

https://doi.org/10.1017/S0022215100085005 Published online by Cambridge University Press

substantial attenuation of the signal. Some patients find this a considerable nuisance, the device requiring manual location and even compression of the tissues overlying the receiver to optimize the signal under difficult listening conditions. (One patient produced tissue necrosis by exerting excessive pressure with a head scarf; another glued her transmitter coil over her receiver with carpet glue!).

The body-worn unit consists of an electret microphone amplifier, modulator, 16 kHz carrier oscillator, output amplifier, and batteries enclosed in a metal box worn usually under the clothes. The output amplitude was set by an external control which could be adjusted by the patient, although the patients rarely did so. Internal controls set the sensitivity of the microphone amplifier, the level and frequency of the carrier, and the depth and symmetry (balance) of the modulation. These settings were often optimized by the patients themselves.

The most recent 4 subjects were implanted with frequency modulation-radio frequency (r.f.) receivers in an attempt to obviate the necessity for precise alignment of transmitter and receiver occasioned by the low-frequency induction system. These were developed at a cost of $75,000. An unfortunate conjunction of failure of Pyre ML insulation and design of the implanted integrated circuit package led to the failure of each of these systems. The r.f. system has accordingly been abandoned for the present.

Interestingly, no disturbing interference is experienced with any of these systems. Only interference from an airport radio control and a computer has been reported. The only electrical problems encountered have been blocking, in response to acoustic overload, although the patients wearing the abortive r.f. units had complained of "flashes across the head" with overload.

2.1.7. Systems Failures

Five out of 20 implanted direct connection and inductive transcutaneous systems have failed, 4 on one patient. Of the more recent F.M.: r.f. transcutaneous devices, all 4 failed.

Of 22 implanted patients, 9 are currently using the implants for several hours per day; 2 are using their devices for less than 2 hours per day; 6 are awaiting delivery of external control units, and 4 await removal of the failed F.M.: r.f. packages. One is deceased from unrelated causes (see Table 6.2.).

The reasons for the failures have been: rejection of implanted Teflon connector; breakage of electrode wires; and breakdown of Pyre ML insulation (a suspected defective batch of wire coating in the 4 FM: r.f. transcutaneous devices).

https://doi.org/10.1017/S0022215100085005 Published online by Cambridge University Press

2.1.8. Surgical Considerations

Surgical Approach

A colour video-tape recording of implantation of an otosclerotic patient with subtotal deafness was presented.

Surgery takes 1 to 2 hours and should be within the capability of a competent, suitably-trained otological surgeon.

Surgery, under general anaesthesia, starts by passing a needle through the centre of a dummy induction coil sited about $\frac{1}{2}''$ behind the upper end of the pinna. The needle marks the bone. The skin incision is anterior to this, to avoid a scar over the coil. After elevation of the periosteum, a circle of temporalis muscle is excised to enable the coil to lie subcutaneously.

A hand trephine is used to define a gutter in the squamous temporal bone, above the roof of the external auditory canal, to accommodate the induction coil, and the bone central to this gutter is drilled out to a depth of about 2 mm. Two anteriorly—and two posteriorly—placed holes are drilled through the bone to accommodate anchoring sutures. The approach to the round window is by cortical mastoidectomy with opening of the facial recess, having identified the facial nerve and posterior semicircular canal. A lateral tympanotomy, as in the standard combined approach to the middle ear, is not utilized. The ossicular chain is not disturbed. A groove is drilled from the trephine area into the mastoid cavity to take the wires.

Promontory bone is drilled to expose the round window membrane. Haemostasis is secured. A hole is made in the membrane and enlarged with hooks to enter the scale tympani. In the film the electrode assembly was then tested with a resistance meter. This in situ testing has now been abandoned.

Braided merseline sutures are passed through the calvarial drill holes, and the induction coil is anchored by the two sutures. The reference (or ground) wire is passed through the attic to lie free in the Eustachian tube. (Early in the series there were problems with the ground electrode in the temporalis muscle, in an inveterate gum-chewer!). The active electrode is then directed into the scala tympani, allowing the peripheral bony wall to effect the curvature, until the insulation is just inside the scala tympani. The round window niche and facial recess are plugged with fibrous tissue. The electrodes passing from the coil to the middle ear are bent to lie in position. If necessary they are sutured to the bone. No tissue glues are used. It is considered important to avoid diathermy once the package is in place and also if revision surgery is undertaken.

Post-operative care and complications

There have been no surgical complications of the procedure. Antibiotics are not used routinely. Possible complications of the implantation

https://doi.org/10.1017/S0022215100085005 Published online by Cambridge University Press

are infection, labyrinthine fistula and damage to the facial nerve, the latter hazard being very much related to surgical experience. Patients usually leave hospital on the fifth day.

In theory, vestibular symptoms from a labyrinthine fistula are a possibility. Two patients reported post-operative unsteadiness during stimulation. In one, surgical revision and alteration of the position of the ground wire helped. The Pittsburgh report (Bilger *et al.*, 1977) concluded that electrical stimulation of the cochlea can affect the vestibular apparatus. On the other hand, evaluation of vestibular effects in these patients is difficult since most of them had pre-operative evidence of abnormal vestibular function, many had vestibular symptoms and, in a few, the known pathology would indicate the likelihood of a continuing or progressive vestibular lesion.

Tinnitus was not a new post-implantation symptom; indeed, many of the patients with troublesome pre-implant tinnitus reported a diminution or abolition of the symptom during and following stimulation. In a few the tinnitus appeared to be cured.

Of the whole group only one patient had slight facial twitching with high levels of electrical stimulation.

The subcutaneous induction coil produces a small visible and palpable elevation above and behind the ear, partly in the hair-bearing area of the scalp. This does not appear to have caused any problems. This siting enables the external coil to be attached to spectacle frames.

Replacement of electrodes and revision surgery

Many of the implant patients have undergone surgery for replacement of connections or electrodes, and several have been re-implanted. The history of C.G., for example, (one of the patients examined by us) starts in 1968 with an acute experiment involving the insertion of electrodes into his right ear and their removal. This was followed by permanent implantation of a multichannel cochlear array and percutaneous connector on the right in 1970, then an induction coil and electrode system to the left ear in 1972 with revision of the induction coil and ground wire in 1973, and insertion of a completely new system in the left ear later that year. In 1974 the multiple channel percutaneous connector button was removed from the right ear, and replaced by a single electrode induction system. This was replaced in 1977.

Another subject, E.K., had a right fenestration in 1944, decompression of the right internal auditory canal in 1960, insertion of a gold wire into the right scala tympani in 1961, followed by its removal and insertion and removal of a 5-electrode implant later that year as an acute experiment. Still in 1961 a multiple channel induction coil system was implanted in the same ear and it was removed two weeks later. In 1973 a single channel induction coil system was implanted, again in the same ear.

https://doi.org/10.1017/S0022215100085005 Published online by Cambridge University Press

Patient S.S. had a right saccus operation in 1960 followed by a middle fossa vestibular neurectomy in 1961; at the same operation the cochlea was opened from above and a gold wire implanted. This was removed two months later. Also in 1961 a left saccus operation was performed, later revised and converted into a shunt operation. In 1962 the right saccus operation was converted into a shunt, and in 1973 a single electrode induction system was implanted into the right ear.

Subject M.N. had test electrodes inserted into the right scala tympani in 1961, a multiple electrode implanted into the same ear in 1970, removal of this assembly in 1972 and a single electrode induction coil system replaced in 1973.

With the passage of the years, though there have been fewer electrode replacements in subsequent patients, there have often been multiple otological operations, such as stapedectomies or decompressions of the internal auditory meatus. Fairly recently four patients were fitted with a newly designed radio frequency transcutaneous transmitter to a single channel system and all four have failed due to technical problems; these patients are awaiting re-implantation.

Dr. House reported no special surgical problems arising from re-implantation or replacement of the electrodes in the scale tympani apart from the changes which would be anticipated from any otological revision surgery. In particular there was no mention of new bone formation in the scala tympani or round window area. He considered that the function of the single electrode implants did not seem to be impaired by successive re-implantations.

Sterilization

The hardware for implantation is sterilized in the chemical solution 'CIDEX' and thoroughly washed prior to insertion.

2.1.9. Demonstration and Examination of Implanted Patients and Assessment of Responses

Five implanted subjects were demonstrated to an audience which, in addition to ourselves, included visitors from Germany and the United States. They came in one at a time and sat on a platform, where they were interviewed by Mrs. Norma Norton, a teacher of the deaf who is Director of Rehabilitation at the Center. She is expert in lip-speaking and sign language.

1. *Test Methods:*

Several types of test material were presented to each patient: first, a list of 5 typed sentences (i) was presented to the subject and they were read out in order as the patient studied the list. Mrs. Norton then spoke the

https://doi.org/10.1017/S0022215100085005 Published online by Cambridge University Press

sentences, in random order, with her face covered, and the patient was asked to repeat which of the five sentences he or she thought that she 'heard'. Each subject had a different sentence list; next, a list of 5 spondees (bisyllabic words) (ii)—airplane; duckpond; eardrum; headlight; white-wash—was presented, first in written and then in spoken form, at first without lip-reading but later (occasionally and randomly) with lip-reading; then, a second list of 5 spondees (iii)—hothouse; mousetrap; padlock; sidewalk; toothbrush—was presented in the same way. The same two lists of spondees were presented to each subject; unwritten random sentences (iv) were then presented, with lip-reading and in most instances with voiced sound, but occasionally and randomly with unvoiced speech followed by voiced speech; finally, tape-recorded environmental sounds (v) were presented and each subject was asked to identify and describe them. (These were the sounds of piano; harp; flute; drum roll; steam train; typewriter; traffic noise; orchestra; crooner with band accompaniment; motor car driving off; and telephone bell). The last subject to come in was also asked to identify, without lip-reading but with the implant activated, some cities and states in the U.S.A. (vi).

The subjects had been exposed to the same test material in April 1977. However, the room acoustics and test conditions on the present occasion were less than ideal.

2. *Subjects examined and assessment of responses:*

Five subjects were seen and examined:

(a) *B.F.* Otosclerosis was diagnosed at the age of 17. She had been profoundly deaf for 28 years, and had been implanted for $2\frac{1}{2}$ years (since 1974).

She scored 5 out of 6 with sentence list (i); 4 out of 7 with the first spondee list (ii); and 3 out of 6 with the second spondee list (iii). *When re-tested with this second spondee list, with lip-reading, all words were repeated correctly:* she scored 4 out of 5 with unwritten random sentences (iv), with lip-reading and voiced sounds. When four further random sentences were presented, with lip-reading but unvoiced, only one was repeated correctly, another imperfectly. *The two which were incorrect at the first attempt (unvoiced) were immediately corrected when they were repeated with voiced speech.* (*Comment:* This lady was a good lip-reader, and this skill appeared to be augmented by the activated implant. Although it may be argued that her correction of the (unvoiced) random sentences immediately after they were repeated with voiced speech may have been due simply to 'practice', the certainty of her responses (without any alteration in the structure of the sentences) would suggest that the speech sounds 'heard' through the implant were probably contributing significantly to her recognition of the voiced speech); of the 11 tape-recorded environmental sounds (v), only 4 (train, traffic noise, motor car and

https://doi.org/10.1017/S0022215100085005 Published online by Cambridge University Press

telephone bell) were identified correctly. The piano was called 'music', the drum roll 'some kind of music'.

(b) *M.N.* (Housewife). Had been profoundly deaf for 21 years, following treatment with ototoxic drugs at the age of 29; she had been implanted (in the right ear) for 4½ years (since March 1973).

She scored 4 out of 7 with sentence list (i); 0 out of 4 spondees from the first list (ii) when spoken rapidly, but 2 out of 4 when spoken (at her own request) more slowly; she scored only 2 out of 6 from the second spondee list (iii), spoken at moderate pace; with random sentences (iv), voiced and with lip-reading she scored only 1 out of 3, the third sentence being correctly 'heard' at a third repetition. Only 1 sentence out of 4 was repeated by lip-reading alone, although one was partially corrected when it was repeated with lip-reading *and* voiced speech; she identified only 3 of the 11 environmental sounds (v)—(piano, traffic noise, telephone bell)—but she described the motor car moving off as an 'engine warming up', and the crooner with band accompaniment as a "big, big full-bodied orchestra. There are two sounds on that one". (*Comment:* It is interesting that this lady, without any prompting, claimed that she was able to hear these environmental sounds better when she went to sit at the back of the room; and that each of the three sounds which she (and the first patient) did identify correctly (the piano, the 'throbbing' of traffic and the ringing of a telephone bell) possessed some 'rhythmic' quality, as also did the telephone bell, which was identified by the third and fifth subjects).

(c) *B.S.* (Accountant). Otosclerosis was diagnosed at the age of 16, and he had been profoundly deaf for 20 years; he had been implanted (in his left ear) for 4 years (since November, 1973). He lost his tinnitus 1½ months after surgery.

Without lip-reading, he scored 7 out of 9 with sentence list (i), 6 out of 6 with lip-reading; he scored 0 out of 4 with the first spondee list (ii), without lip-reading; 3 out of 6 with the second spondee list (iii), with lip-reading; out of 2 random sentences (iv), one was totally wrong, the other partially correct ('I worked till two last night' for 'I watched the late, late show last night'). Two further random sentences ('We are going to have company over the holidays' and 'I spilt coffee over the carpet') were both interpreted incorrectly when spoken *unvoiced*, but both were *immediately* identified correctly as soon as they were repeated with voiced speech (see comment on B.F.); only 2 of the 11 environmental sounds were identified correctly (steam train and telephone bell), but he also described the crooner with band as "a man talking, with some sort of background, possibly music". In response to direct questioning, he replied that the voice sounded softer than the 'background'.

(d) *D.L.* (Post Office worker), was born deaf (aetiology unknown) 46 years ago, and had been implanted (left ear) for 4½ years (since June, 1973).

https://doi.org/10.1017/S0022215100085005 Published online by Cambridge University Press

She scored only 1 out of 5 with sentence list (i). After the choice had been narrowed to only two sentences ('I'm sorry' and 'Don't tell me that'), she scored 2 correctly from 3 presentations; with two words only from the first spondee list (ii)—eardrum and headlight—the first word (eardrum) was interpreted incorrectly. When repeated more slowly, at her own request, she scored 3 out of 3 presentations. (*Comment:* As with M.N., it would appear that, as with lip-reading, so with 'listening' through an implanted electrode—or a hearing aid—slow speech is preferred to rapid speech); there was practically no identification of tape-recorded environmental sounds (v) (though 'orchestra' was described as 'music'). She claimed that she had 'heard' some music when she used to wear a hearing aid, and she thought this was why she was able to detect the music of the orchestra.

(e) *C.G.* (Librarian). Had ototoxic deafness, following the topical application of neomycin for infected burns. He had been profoundly deaf for 17 years. He had had five implants—in 1970, 1972, 1973, 1974 and the spring of 1977.

He scored 5 out of 8 with sentence list (i), but two of the incorrectly 'heard' sentences were very similar (twice he said 'That's not fair' for 'That's your share'); he scored 2 out of 6 in the first spondee list (ii), when still rather unsettled; 5 out of 9 in the second spondee list (iii), when more settled; he scored 6 out of 11 environmental sounds (v). Again these included the 'rhythmic' sounds of steam train, typewriter, traffic noise and telephone bell (see Comment on M.N.); and he identified the crooner with band as 'a vocalist with music'; he also identified correctly 6 out of 17 cities-and-states in the U.S.A., spoken randomly and without lip-reading. A further two were identified on the third presentation, and a further four when repeated with lip-reading.

3. *Discussions and interviews with patients:*

After each patient had been individually examined and demonstrated by Mrs. Norton, all five subjects returned to the platform together, for interview and discussion with Mrs. Norton and, through her, with the audience.

Q.1. *What do you like about your implant compared with your previously worn hearing aid(s)?*

M.N. felt that her hearing aid had been of no value to her, except that it had taken her "out of total silence". By contrast, the implant allowed discrimination of sounds; D.L. liked her implant better because she could hear more of her own voice; C.G. had worn an aid for 10 years, but all he had obtained from it was tactile information, "more like vibration", "like putting your fingers on your throat". What he heard now was "real sound"; B.F., who had worn an aid for 36 years, was always embarrassed

https://doi.org/10.1017/S0022215100085005 Published online by Cambridge University Press

by the feed-back, which was very noticeable when the volume was high—which it had to be. She had no such problem with her implant; B.S. could understand some conversation with a hearing aid but, "after 18 or 19 years of total deafness, I now get sound. This is a real boon to me".

Q.2. *How does your own voice sound with your implant?*

B.S. "can't hear much inflexion". To him it sounds "like a monotone", but otherwise it sounds natural; C.G. said that his own voice "sounds like a hum" but he had a feeling, he thought, for volume and inflexion; M.N., who had recently returned from a period in England, commented that most of her family and friends thought that her voice was "like a normal-speaking voice". Both Dr. House and Mrs. Norton, neither of whom had seen D.L. for about a year, were impressed by the great improvement in articulation since they last saw her, and much of her speech could be understood by the audience. (*Comment:* It was noticeable that at least three of these subjects had better modulation and articulation than one normally expects to hear in totally deaf subjects. In two they were excellent).

Q.3. *What do you like best about your implant?*

M.N.: "Everything! Just living! To hear every noise"; C.G.: "I just like sound. It makes all the difference of whether I'm completely out of society, or back in it"; B.F.: "It's the feeling of not being isolated. I can hear people laugh"; B.S.: "It's just the ability to hear sound".

Q.4. *What information do you get from speech?*

M.N. can hear 'k' and 'sh' better. This makes lip-reading less difficult and therefore allows her to relax in communication (45 minutes of conversation being about the limit of endurance for lip-reading in one session).

Q.5. *Is there any one sound which sounds exactly the same with your implant as it did before you lost your hearing?*

C.G. thought that sounds were now "rather like a short-wave radio" and were totally different from anything that he remembered hearing before he lost his hearing; however, he felt that the clues obtained from the implant could be very similar to those obtained from normal hearing. None of the patients could identify any sound which produced exactly the same sensations as those which they had heard before the onset of their deafness.

Q.6. *How do you cope with the implant in noisy surroundings?*

D.L. is "not bothered by noise"; M.N. could not control her voice level with a hearing aid. Now she knows when to lower it; C.G. finds noise

https://doi.org/10.1017/S0022215100085005 Published online by Cambridge University Press

"a big problem" and he needs to adjust his device in noisy situations, as when there is music in the background.

Q.7. *What noises bother you?*

Air and road traffic were troublesome to all, at least initially, but two of them (M.N. and B.S.) have become accustomed to it.

Q.8. *Is the aid comfortable?*

B.F. commented that the 'box' was uncomfortable, especially in hot weather, as it was worn "close to you". (It was noticeable that, in every case, the unit was worn inside the patients' clothing and they never adjusted the levels in our presence); C.G. found the glasses uncomfortable; both B.S. and M.N. found it a nuisance having to keep adjusting the alignment of the transmitter and subcutaneous receiver. It was noticeable that, when they had any difficulty with 'hearing', the subjects tended to press the transmitter on to the receiver, to improve the signal.

Q.9. *Since your implant, what has been the most important change in your relationship with the person closest to you?*

M.N. could now hear her husband's voice, so that she was able to recognize certain characteristics in it which enabled her to criticize him; D.L. can now tell when people are talking to her personally and she can turn towards the speaker; B.F. can hear other people's voices; and B.S. can now carry on a conversation with his wife. The implant, he says, permits one-to-one conversation, but not conversation in a group; C.G. finds it much less of a strain to communicate with people, "and people don't get worn out communicating with me at school". (He used to be a school teacher and is now the school librarian). He does not know sign language.

4. *Summary of functional results of implantation:*

Using a variety of tests, this Los Angeles group has compared the performance of profoundly deaf adults who have received cochlear implants (CI) with that of other profoundly deaf adults using hearing aids (HA). These are different subject groups, unmatched except in approximate numbers, and so far no direct comparison has been made between the performance of patients with hearing aids and that of the same patients following implantation.

The HRRC (Hearing Rehabilitation Research Center) Rhyme Test is a modification of tests of phonetically-balanced monosyllabic words devised by Earl Schubert (Stanford) and Elmer Owens (San Francisco). There are 50 items in each test list, with 4 choices, and eight implanted subjects have been compared with eight other patients using powerful hearing aids.

https://doi.org/10.1017/S0022215100085005 Published online by Cambridge University Press

In the HRRC Environmental Sound Test, the subjects are asked to identify a variety of environmental sounds, such as a whistle, a bass drum, or the slamming of a car door. This test has 30 items, with 5 choices. Nine implanted patients have been compared with 13 hearing aid users.

The S.S.I. (Simulated Sentence Index) Test has 10 items, and four implanted subjects have been compared with eight others wearing hearing aids.

All tests were given in 'multiple choice' form and the best scores of several re-test trials were chosen.

The results are summarized in the following table:

Cochlear Implant group v. Hearing Aid group	CI	HA	Difference
HRRC Rhyme Test	51·00%	36·00%	15·00%[1]
Spondee Discrimination Test	51·10%	22·75%	28·35%[1]
HRRC Environmental Sound Test	67·10%	47·40%	19·70%[2]
S.S.I. Test	75·00%	26·25%	43·75%[2]

[1] $p \leqq 0{\cdot}05$
[2] $p \leqq 0{\cdot}01$

5. *Psychological effects of implantation:*

The most evident benefit of implantation is the new-found sense of 'belonging' to a world of "real sound" (C.G.); "This is a real boon to me" (B.S.); "It's the feeling of not being isolated" (B.F.); "It makes all the difference whether I'm completely out of society, or back in it" (C.G.); "I can hear people laugh" (B.F.). To M.N. it is "Everything! Just living!". The implant is free from the embarrassment, inherent in all powerful hearing aids, of 'feed-back'.

There is an understandable tendency for nearly all implanted subjects to over-use the stimulator in the first few weeks, and no amount of warning seems to discourage them. Not infrequently they will return exhausted by endless experimentation, but usually after three or four weeks they learn to adjust the unit to its optimum level. In the next 2 or 3 months, they begin to discriminate different sounds; this they find an elating experience, and they are encouraged to record all the environmental sounds which they are learning to detect.

This initial improvement is often followed by a period of depression, usually between the third and six months after implantation, when they realize that there is no real speech discrimination as such; thereafter, most of them learn to accept the fact that the amount of information available to them (with a single-channel device) is indeed extremely limited, and they settle down to an established optimal daily use of the device. They begin to adapt to background noises and they learn to concentrate on foreground sounds; they begin to distinguish similar sounds (such as telephone bell and door bell), and the visual strain of speech-reading begins to fade.

https://doi.org/10.1017/S0022215100085005 Published online by Cambridge University Press

Difficult though it is to test psychological parameters objectively, no untoward personality disorders have been noted, and no changes in emotional problems have been known to occur. Not surprisingly, patients have reacted to failures of the implant system with feelings of disappointment, but there have been no protracted cases of depression. In most instances there seems to have been a definite improvement in the quality of life, and most of the recipients of single-channel implants have accepted them with enthusiasm.

Interestingly, the patients reported an apparent reduction, with time, in the effectiveness of their implants. This could well be 'adaptation' to the device in the manner of the well-known 'Hi-Fi effect' (where the vivid quality of one's equipment seems to disappear with continued exposure to it!).

6. *Implants and tinnitus:*

Although the symptom of tinnitus is not regarded as an indication for implantation, two of the Los Angeles patients have in fact lost their tinnitus, both of them about $1\frac{1}{2}$ months after the surgery. These are B.S. and M.N. The latter had previously been taking medication to enable her to sleep.

Disabling tinnitus could preclude some patients from such a taxing programme, and it is almost certain that one at least of Dr. House's implanted patients would have been excluded if psychological testing had been as stringent at the time of his selection as it is today.

7. *Comments on the Pittsburgh Study:*

The Bilger report (Bilger *et al.*, 1977) had been read by all the members of Dr. House's team, by all five patients seen by us in Los Angeles and by each of the three present authors. The contents and implications of this report were discussed by all present at the demonstration.

Dr. House considered that the Pittsburgh Study had been well done in the very limited time available (only 1 week's study of each patient); in particular it incorporated investigations (e.g. on psychophysical and speech discriminations) which had not been done in Los Angeles. However, the study had certain limitations, many of which were inevitable in the circumstances, and well recognized by the Pittsburgh team. The following additional criticisms were made by the House group: (a) The study did not have any pre-implant data for comparison; (b) The Pittsburgh group were not able to compare the performance of the 11 patients from Los Angeles with hearing aids, against their performance with cochlear implants; (c) Some of the positive data about these implanted patients had been rather 'buried' in this lengthy report, and were therefore not given sufficient emphasis; (d) The Pittsburgh study did not evaluate the results in accordance with the type of implant used; and (e) The Los

https://doi.org/10.1017/S0022215100085005 Published online by Cambridge University Press

Angeles group felt that other parameters could have been used to evaluate the effects of cochlear implantation. In support of this last suggestion, one of the patients (C.G.) felt that "they didn't test what I could really do". (It should be noted that none of the groups visited by us have obtained information on these points).

Objective evaluation is clearly difficult to carry out, but nonetheless necessary, for, as was pointed out, one of the factors that makes evaluation of these patients difficult is their 'evangelistic' enthusiasm for their implants.

Nevertheless, we felt that the performance of the five patients whom we saw in Los Angeles, all of them with single-channel prostheses, was consistent with the main conclusions of the Bilger report (see Appendix 7.3.), and appeared to justify the enthusiasm of the Los Angeles team for concentrating on the rehabilitation of patients implanted with single-channel devices.

2.1.10. Rehabilitation

In view of the recognized tendency for implanted subjects to over-use their devices in the early post-operative weeks, the patients are not issued with 'take home' stimulators in the first 4–6 weeks. This precaution not only prevents the patients from exhausting themselves, but also allows their wounds to heal. Thereafter, the programme of rehabilitation is geared to providing intensive instruction in auditory perception (especially critical listening ability), speech therapy and speech-reading (lip-reading).

The first tasks are to limit the use of the stimulator to two hours or so per day, and to establish individual tolerance levels to sound. With training and experience the subjects build up a gradual increase in tolerance, and they learn to reach and maintain a stable level.

The therapeutic sessions begin with training of the subjects' critical listening ability, starting with the simple differentiation of environmental sounds.

Auditory training concentrates on the differentiation of voices, phonetic features, and syllables and stresses in speech; and on matching the subjects' voices with others'. Attention is also directed to developing 'relaxed' phonation and improved articulation.

The first five patients in their programme of intensive rehabilitation, which began in 1973, were closely observed over a period of two years, and their progress provided a guide to further developments.

In the first few weeks after a new patient joins the rehabilitation programme, the aim is to see new patients daily, for two or three hours of testing per day. Thereafter they are seen monthly, and then reviewed yearly.

Patients are provided with a log book with detailed instructions,

https://doi.org/10.1017/S0022215100085005 Published online by Cambridge University Press

step-by-step, for developing the use of their devices, in which the patients are encouraged to note new percepts.

Individual therapy aims at training the subject to make maximal use of minimal cues, and in group meetings the patients are encouraged to share with other members of the programme their feelings, experiences, problems and criticisms. Family counselling and home practice are also essential, and a close relative or friend is used as an 'index relative', to corroborate progress as reported by the patient. The programme entails a total of about 60 hours of rehabilitation.

As part of the current H.R.R.C. research programme, extensive cognitive and emotional testing is carried out, in order to assess patients' progress.

So far, no direct comparisons have been made between the efficacy of electrode implants and that of hearing aids, vibro-tactile devices and related techniques of sensory substitution.

An outline of the current programme of rehabilitation is given in Appendix 7.4.

2.1.11. Current Status of Implant Programme

This programme started modestly with some acute surgical electrical stimulation experiments in the early 1960's and in its formative years was voluntarily supported and developed by Dr. William House and Mr. Jack Urban. It has now grown into a large active unit with all the necessary staffing and expertise, with the possible exception of a neurophysiologist/biophysicist. There is now considerable patient experience spread over many years. If the closely related Ear Research Institute and Otologic Medical Group are included, the clinical, surgical and diagnostic facilities are second to none. There has been no experimentation or testing of devices or techniques in animals.

Dr. House and the team consider that the limited information transfer from single channel unipolar implant stimulation has proved itself a useful clinical measure in the longterm rehabilitation of the profoundly deaf post-lingually deafened adult. The surgical technique is now established, though a search continues for better modifications for the implanted hardware and transcutaneous linkage. Stimulus-coding strategy is still under development.

Dr. House felt that his group had established that intra-cochlear implantation and stimulation were neither neurologically nor emotionally hazardous, at least over a seven-year period.

The Unit has developed a strong team. Patient selection is now rigorous. Comparative rehabilitation studies, using methods other than *artificial auditory stimulation (e.g. high-power hearing aids)*, are now under study, especially in pre-implant candidates.

https://doi.org/10.1017/S0022215100085005 Published online by Cambridge University Press

In order to meet earlier criticisms, that many of the post-implantation data were anecdotal, attempts are being made to evaluate objectively improvements at the communicative, cognitive and emotional levels. These have so far not proved conclusive, although the enormous difficulties involved in designing appropriate tests are well recognized.

There is no doubt about the devotion of the team to the motto of the Center: "That All May Hear".

2.1.12. Future Outlook of Implant Programme

It is hoped to develop animal experimentation in collaboration with the University of California, Los Angeles. A surface preparation laboratory is being established at the Walt Disney Hearing Rehabilitation Research Center. The Center is also developing its own audiological facilities to be independent, in this respect, of the Otologic Medical Group. In the future more psychophysical testing will be conducted. Electrical Response Audiometry (ERA) will be further developed and, in particular, it is hoped to study brain stem responses following artificial electrical stimulation. Studies will be conducted in the temporal bone histology laboratory where there resides a large collection of post-mortem material from patients whose clinical and audiological data were recorded before death.

On the rehabilitation side, an application has been made to the N.I.H. for a grant to cover some aspects of this work. Rehabilitation will be divided into five areas—evaluation prior to surgery, hearing aid training programme, post-surgical care and direction, a three-month training programme with the cochlear implant, and post-programme and follow-up evaluations. The outline of this programme is shown in Appendix 7.4.

Dr. House sees two main questions as requiring answers before the long term prospects for this work are clear:

1. How do we define the surviving neuronal population, the number of fibres surviving and their distribution; and what can be accomplished by their electrical stimulation in terms of both electrophysiology and psychophysical results?
2. What is the most effective way of carrying out multiple electrode stimulation; in the scala tympani, modiolus, cochlear nerve or brain stem?

The Los Angeles Group do not rule out multichannel implantation but consider that it may be 5 years before a practical system has been developed. Meantime they intend to continue evaluating the single channel electrode. On the question of the pre-lingual deaf child, Dr. House would like to undertake this work because of the potential advantages of implantation to these patients, but there are too many ethical, emotional and medicolegal problems at present.

https://doi.org/10.1017/S0022215100085005 Published online by Cambridge University Press

2.2. Coleman Memorial Laboratory, University of California, San Francisco School of Medicine (Wednesday and Thursday 19 and 20 October 1977)

2.2.1. Strategy

This group, led by Dr. Robin P. Michelson (otologist), had concentrated entirely on a study of bipolar electrode single channel (acute and chronic) scala tympani implants in 7 patients in conjunction with animal studies of the physiological adequacy and the anatomical consequences of implantation and use of the electrode systems.

A number of patients have been extensively tested psychophysically. Two of the patients had been equipped with body-worn control units, although only one had used his for long periods.

Careful attention has been given to the design of the electrodes in order to fit the scala tympani of the basal cochlear turn as closely as possible, in order to displace the perilymph and appose the electrodes to the cochlear partition, to minimize current spread. The electrode systems were developed after testing with similar systems in the scala tympani of cats.

Their present work is concentrated on the development of multi-channel electrode systems, speech encoding strategies, schemes of psycho-acoustic and electrophysiological (brain-stem evoked potential) evaluation, and rehabilitation, in addition to animal studies of the results of overstimulation.

No comparisons have so far been made of the effectiveness of the implants compared with that of high-power aids or vibro-tactile substitution devices.

2.2.2. Staffing and Facilities

The group have access to the facilities of the Coleman Laboratory, namely a physiological laboratory, audiological/clinical electrophysiological laboratory, histology and electron microscopy laboratory and preparation rooms. At present, inadequate space is available for patient interviewing and our interviews were conducted in a corridor and in one of the preparation rooms.

The group originally consisted of Dr. Robin P. Michelson (otologist) and an engineer. They were joined in 1972 by Dr. Michael Merzenich (physiologist). The current team consists of:

2 otologists concerned with surgery, electrode development and cochlear anatomy.

1 neurophysiologist concerned with physiological models of hearing, stimulus encoding, psychophysics and neuroanatomy (project director).

https://doi.org/10.1017/S0022215100085005 Published online by Cambridge University Press

1 engineer concerned with speech processing, engineering and device design.
1 associate engineer concerned with computer interface, hardware design and maintenance.
1 programmer concerned with implementation of speech processing, stimulation and testing systems.
1 predoctoral fellow in otolaryngology concerned with over-stimulation studies and psychoacoustics.
1 anatomist concerned with studies of cochlear anatomy, stimulation studies and animal surgery.
1 anatomy technician.
1 technical engineer (workshop director).
1 associate professor in audiology concerned with patient assessment, testing and rehabilitation.
3 assistant audiologists.
1 assistant professor in anatomy, concerned with changes in the Central Nervous System (CNS) due to electrical stimulation.
1 associate professor in microbiology concerned with cytochemical changes in the CNS.
3 graduate students assisting with electrophysiological studies, electrode development and photography.
1 research associate assisting with electrode development.
1 consultant engineer consulting on electrode and transmission devices for patients.
1 consultant psychiatrist responsible for psychiatric evaluations.

The involvement of the members of the team varies from 10–100 per cent.

2.2.3. Funding

Funding is obtained from the Federal and State Governments, and from a private foundation. They have recently received a large 5 year grant from N.I.H., providing support for 4 full-time and 2 part-time members of the team. In addition, they hold an N.I.H. Contract for anatomical and physiological evaluation of electrode systems in animals.

A related programme, funded by an N.I.H. Grant for 3 years, is on research into aural rehabilitation and evaluation of hearing aids in the profoundly deaf. This is in its second year, and is being run by Dr. Elmer Owens and his colleagues in the Audiology Department. Dr. Owens is involved in the cochlear implant programme in the selection of patients. It is intended that the first patients of the future implant series should be put through the aural rehabilitation programme developed for the hearing aid study.

The cost, per patient, of fitting an implant, was estimated at $8–$10,000, including surgical, rehabilitation, and electronic device costs. The patients are not charged.

https://doi.org/10.1017/S0022215100085005 Published online by Cambridge University Press

2.2.4. Patient Selection

Promontory stimulation is not used routinely by the San Francisco group, as they consider that a negative result is not necessarily indicative of absent or non-viable cochlear nerve fibres. However, this conclusion is based on a failure in some preliminary cases to respond to stimulation at 1 kHz, a result which would be expected since the lowest thresholds are obtained to stimulation at frequencies at about 100 Hz. This group places emphasis on the eliciting of auditory sensation by acute stimulation, under local anaesthesia, with an electrode in the scala tympani. Failure to elicit such responses has been used as a contra-indication to implantation in two subjects.

Dr. Michelson's patients therefore underwent a test procedure under local anaesthesia. In the first four of them this was an acute surgical experiment followed later in two cases by permanent implantation; subsequently in three patients the acute procedure was followed immediately by conversion to permanent implantation.

The first patient was a man of 59 with bilateral Menière's disease; he used a hearing aid in the right ear and was totally deaf in the left consequent upon a labyrinthectomy 10 years earlier; his left ear was implanted. The second patient was a woman of 50 who had been deaf from birth; she had small islands of hearing but little help from a hearing aid. These two patients were aware of 'noise' only with electrical stimulation, and were considered unsuitable for permanent implantation. The electrodes were removed and the middle ear closed, leaving the round window open. Both patients are lost from the series.

The third patient was a woman of 53 with hereditary adult sensorineural deafness; she had islands of hearing below 2 kHz on both sides; she was also on steroids for arthritis. The fourth patient (J.G.) was a man of 29, an engineer, deaf from birth, who used a hearing aid in the right ear where the hearing level was 60–100 dB; the left side (which was subsequently implanted) had a 95 dB flat loss up to 8 kHz. Both these patients expressed enthusiasm for the sensations they experienced on electrical stimulation and both responded to signals from 125 to 10,000 Hz. The test surgery was terminated and they were selected for future permanent implantation.

Because a number of complications followed this test surgery (see 2.2.7.), the fifth patient, a woman of 31, severely deaf from the age of three, was implanted in 1971, under local anaesthesia. She had a 75 dB loss in the right ear and total deafness in the left (implanted) ear. She responded well to the test procedure which had to be limited as the local anaesthesia wore off. The operation was completed by permanent implantation.

The sixth patient, M.H., a retired banker, was implanted in 1972, four years after the onset of topical neomycin-induced hearing loss.

https://doi.org/10.1017/S0022215100085005 Published online by Cambridge University Press

The aetiology of the deafness in the seventh patient (1977) is unknown to us and this patient has been lost to follow-up.

The ideal candidate for implantation is now considered to be a young ototoxically-deafened adult whose deafness was acquired post-lingually. For the time being at least, deaf mutes will be excluded because of the difficulty of evaluating, psychologically, patients with no established language patterns. Furthermore, whereas it is felt that deaf children might benefit considerably from implantation during their formative years, there might be problems in the long-term effects of skull growth on the leads, and of bone removal on subsequent bone growth, even though the dimensions of the cochlea itself remain approximately constant.

Since they regard cochlear implantation as an experimental (or 'experimental/therapeutic') procedure, protocols will therefore be reviewed by local ethical committees for human experimentation, following certain guidelines laid down by the Department of Health, Education and Welfare. These will include the following:

1. There must be sufficient disclosure of all material risks.
2. The patient must be allowed to make his own decision.
3. He should be given a written statement of risks, complications and expectations.
4. He should be warned *before* implantation that the sounds heard with existing prosthetic devices are but crude representations of normal sounds, and that they will not allow him to understand complicated sounds like speech.

These guidelines complement those accepted by the First International Conference on Electrical Stimulation of the Acoustic Nerve as a Treatment for Profound Sensori-neural Deafness in Man (see Appendix 7.5.). A detailed protocol has been drawn up for the review and selection of future patients, as follows:

Potential implant candidates will be referred to one of the Staff Otolaryngologists either directly or by other otolaryngologists, audiologists, clinics, hearing societies or other organizations serving the hearing-impaired population.

After otological and general medical examination, and the performance of appropriate audiological and vestibular tests, careful evaluation with hearing aid(s) will be undertaken. Any patient with a loss of more than 90 dB in his better hearing ear who fails to derive *any* benefit from the hearing aid rehabilitation programme (see 2.2.3.) will be referred to the project team for evaluation of acceptability to the implant programme; and if acceptable, he will be referred for psychiatric, psychological and psychophysical tests aimed at assessing the patient's emotional stability, linguistic skills, musical background and general perceptual capabilities.

The results of these tests will be considered by a selection committee, which will set aside a waiting period of at least one month during which members of the staff will be available to the patient and his family for

https://doi.org/10.1017/S0022215100085005 Published online by Cambridge University Press

consultation and counselling. If he still requests implantation, his name will then be put on the waiting list for surgery.

2.2.5. Electrodes

After early failure due to breakage of gold leads, their current electrodes are made of platinum-iridium 90:10 or platinum-rhodium. The latter is less springy than the former, although more difficult to alloy. The wires, 0·003″ in diameter, are insulated with Pyre ML. This is an excellent insulator in their experience, but has given some production difficulties.

For single channel electrode systems, they have used two arrangements of a bipolar electrode pair. In the first, termed the 'rail-road track' electrode, the two electrode wires run the length of the implant as two parallel 'railway lines'. At intervals, the insulation is absent from the wires, so that contact is made at numerous points along the underside of the cochlear partition. In the second type, a number of separate bipolar pairs of electrodes are embedded in the implant material and the 'right-hand' and 'left-hand' members of each pair are connected together outside the cochea. This leaves open the possibility of disconnection at a later date for use as a multichannel system.

For multichannel stimulation, they intend to use an 8 channel arrangement of 8 pairs of wires with about 0·5 mm spacing between each member of a pair, and 2 mm between each pair. These arrays (Merzenich and White, 1978) have been designed for implantation up to 20–23 mm into the scala tympani, and a central flat 'rib' of the electrode leads is employed, to confer mechanical stability in order to facilitate their insertion into the cochlea (see 2.2.8.).

In all cases, the insulated wires are embedded in a silicone rubber implant moulded to the shape of the first turn of the cochlea, with the clipped-off tips of the wires in the case of the bipolar wires, or the uninsulated segments in the case of the 'railroad track' electrodes, exposed on the upper surface of the implant, to contact the cochlear partition. Because the dimensions of the human cochlea are remarkably similar from individual to individual, the silicone rubber will fill the scala tympani. This displaces the perilymph and hopefully minimizes current shunting, and ensures close contact between electrodes and the cochlear partition.

The in-situ resistance, between the electrodes of the 'railroad track' single channel system was of the order of 2–4 k Ohms; whereas, as expected, for the multichannel bipolar pair electrodes, where the surface area of the clipped-off wires was very much smaller, it was 25–100 k Ohms: Surprisingly, the voltage threshold (in animal experiments) of the two systems was similar. This raises the question whether current density is the critical factor in cochlear stimulation. They intend to compare, in the future, the merits of constant current versus constant voltage stimulation.

https://doi.org/10.1017/S0022215100085005 Published online by Cambridge University Press

2.2.6. Transmission Link Systems

In the previously implanted designs the electrode wires were taken directly to the transmission link unit; in current designs, a subcutaneous connector will be interposed, to enable surgical modification without disturbance of the intracochlear electrodes. The interposed connector consists of a box holding the connecting pins, made of layers of epoxy and beeswax. The lid of the box is clamped on with screws, and the interior filled with beeswax. From this connector, a multiway cable leads to the transmission link unit.

The group regards the transcutaneous low-frequency inductive link as the best *presently* available transmission device. One of their existing long-term patients (M.H.) has such a receiver wound on a ferrite core screwed to the mastoid, and he attaches his transmitter coil over the subcutaneous receiver with adhesive tape in order to secure adequate alignment. Their other long-term patient (J.G.), who has had 2 implants, has a radio-frequency transcutaneous link. Alignment of the transmitter and receiver coils is much less critical than in the low frequency inductive system, and a latitude of the order of 1 cm was demonstrated to us. On the other hand, they have experienced some unreliability of the r.f. link systems.

In their future multichannel implants, the group intend to use, as a transmission link, a *percutaneous* connector embedded in vitreous (pyrolyzed) carbon. This material appears to allow a long-term (more than $2\frac{1}{2}$ years) stable cutaneous interface to form. This link will enable a flexible strategy of interelectrode connection and stimulation to be tried during the stages of optimization of the stimulus-coding to the multichannel device. In the long term, once coding was optimized, a transcutaneous link would be preferred.

In the first few weeks post-implantation, the thresholds for auditory percepts dropped by 5–6 dB, i.e. the sensitivity improved. This was ascribed to displacement of perilymph by a connective tissue envelope developing around the silicone rubber implant material. (However, it should be noted that similar findings were obtained by the Utah group who did not use silicone rubber in their implants).

The control unit in each case is contained in a metal box to be worn on a neckband under the clothes. It has a user-operated gain control. M.H.'s low-frequency inductive device receives input from a microphone in a hearing aid body situated behind one ear, and the drive to the transmitter is located in a similar body behind the other ear. This arrangement had the distinct advantage (noted by us in practice) that M.H. could localize speakers with some accuracy by small movements of the head. It would also eliminate acoustic interference from movements of clothing etc. which might be expected to be troublesome in the devices where the microphones were an integral part of the body-worn control units. J.G.'s

https://doi.org/10.1017/S0022215100085005 Published online by Cambridge University Press

r.f. control unit has an integral microphone and transmits directly to the transmitter coil, held over the subcutaneous receiving coil manually or by headband.

In both cases, the stimulating waveform is the analogue signal from the microphone input. The frequency response of the microphone amplifier is normalized for each patient to produce an approximately constant threshold across frequency. For the r.f. device, the stimulating wave-form is obtained by demodulation in the subcutaneously implanted receiver package. Interestingly, J.G. hears sounds as 'clicks', although the stimulating waveform is intended to be analogue. Automatic gain control is incorporated, to increase the effective dynamic range to 40–50 dB.

Both patients experienced problems with r.f. interference from sources such as automobile ignition systems. This was regarded as an advantage! One could detect the approach of vehicles 2 car lengths away by this means. Troublesome interference from television (raster) oscillators and electric shavers has been encountered.

The multichannel stimulation systems under development for future implants will be based on 8 channels. The form of encoding of the speech waveform for transmission to the different electrodes has yet to be decided. They intend to develop a flexible computer control of stimulation which will allow a number of encoding strategies to be employed on the patients to be implanted with the percutaneous vitreous 'carbon-button' connector. Among the strategies anticipated are the following:

1. Narrow band channel coding of the spectral density of voice formant frequencies on a channel vocoder principle (see Ainsworth (1976) for an introduction to these devices, and 1.1.2.). Information on the voice fundamental frequency (F_0) would be transmitted by a separate channel or by envelope modulation of the signals to all the channels.
2. Speech feature encoding. The notion here is to exploit some of the phonetic (i.e.: perceptual) cues for phoneme identification known to be extracted from speech signals, e.g. on the place, manner and voicing (see Liberman and Pisoni, 1977, for an introduction to these concepts). This strategy would require sophisticated encoding, and substantial training on the part of the patient.
3. An attempt at wholesale mimicking of the neural excitation patterns (in neural space and time) occurring normally in the peripheral auditory system.
4. Formant tracking techniques utilizing an analysis method analogous to that of a formant vocoder. The output would be distributed appropriately to the channels.

Once the most advantageous strategy had been determined, they would hope to be in a position to move away from the transcutaneous carbon-button connector link system to a fully implanted subcutaneous

https://doi.org/10.1017/S0022215100085005 Published online by Cambridge University Press

receiver-decoder integrated circuit package driven, for example, by an r.f. link. Analogue wave-form excitation would not be used; at present, a diphasic pulse of duration: 100 μsec per phase (i.e.: balanced phases leading to no nett charge transfer) is regarded as optimal from the point of view of minimizing the long-term toxic effects of electrical stimulation.

2.2.7. Systems Failures

All the first 4 *permanent* implants in this series failed within weeks of implantation as a result of breakage of the gold leads. These four patients were subsequently re-implanted, at least once, to replace the entire devices.

The implant in the most recent patient, an integrated circuit receiver, failed within a month because the engineer cut a groove in the package for surgical convenience but the groove penetrated the hermetic seal.

The two present long-term users (J.G. and M.H.) both have their second permanent implants, the former having previously had acute stimulation (see 2.2.8. for further details).

2.2.8. Surgical Considerations

Surgical Approach

A cine film of the recently used surgical approach and technique was demonstrated.

Dr. Michelson prefers to avoid opening the mastoid for fear of infection. Furthermore, the electrode system, being buried in a silastic mould of the basal coil of the human scala tympani, is much bulkier than a single or than multiple wires. The manoeuvre of uncoiling and inserting the electrode package could not be achieved solely through a relatively small facial recess opening into the middle ear from the mastoid.

The incision is post-auricular with elevation of the posterior meatal skin and tympanic annulus to gain entry to the middle ear. A gutter is drilled in the posterior meatal wall leading to the mastoid cortex below the attachment of the temporalis muscle. Posterior annular bone is removed to give a wider exposure of the round window. The round window membrane is exposed by drilling promontory bone above and anterior to the membrane which is then exised. The anterior margin of the round window is further drilled to allow entry of the silastic mould. The sickle-shaped silastic implant with contained electrodes and wires is passed up the scala tympani. Because it is made from a mould of the human cochlea, it has a small posteriorly placed 'shoulder' which, on insertion through the round window, prevents easy withdrawal or slippage. There is therefore no need for a tissue seal. The mould recoils to fit the cochlear curvature.

The early implants had single channel bipolar electrodes designed to

https://doi.org/10.1017/S0022215100085005 Published online by Cambridge University Press

go 9–11 mm into the basal coil with the two electrodes under the organ of Corti and the osseous spiral lamina (Michelson, 1971a; Michelson, 1971b; Merzenich *et al.*, 1973; Michelson *et al.*, 1973; Merzenich *et al.*, 1974). More recently, in 1977, a multichannel device was implanted using this surgical technique. The silastic mould went 22–24 mm into the scala tympani and the insertion proved quite difficult due to lateral twisting when the longer coil was unwound. It is hoped that a new technique of construction will solve this problem for the future multichannel implants. The wires leading from the 8 pairs of electrodes will be braided to form a flat 'backbone' for the silastic mould. Experiments on human cadaveric temporal bones suggest that insertion of this newly designed prosthesis will be straightforward.

Having inserted the electrode package, the leads are delivered along the gutter under the thin posterior meatal skin to the receiver on the mastoid cortex (future devices will have a connector interposed). Both low-frequency and radio-frequency coils have been used for transcutaneous linkage. The wire leads and receiver are 'glued' in position with methyl methacrylate cement, the "simplex cement" used by orthopaedic surgeons (Charnley, 1970). Until this form of cement fixation was used, the earlier devices all failed due to breakage of the leads. The wound is then closed. Surgery takes two to three hours.

Post-Operative Care and Surgical Complications

Compared with the Los Angeles group, patient experience is relatively limited and surveillance disappointing. Of the two patients who were only acutely stimulated, one had died (of unrelated causes) and the other is lost to follow-up. Of the five patients permanently implanted, two have died from unrelated causes and one has been lost to follow-up. No post-mortem material is available despite requests to patients and their agreement to donate their temporal bones to the Coleman Memorial Laboratory. Only two patients, both seen by us, have functioning implants. Partly for these reasons and partly due to the brevity of the visit, information on post-operative care and surgical complications is scanty.

A number of complications followed the acute *test* surgery in which electrodes were inserted into the scala tympani:

First, all patients who had residual cochlear function prior to the test lost it completely; secondly, one of these patients (J.G.) had post-operative tinnitus and vertigo for a few days after surgery. This may have been due to the fact that, after removal of the electrodes, no attempt was made to seal the round window; thirdly, in two patients who subsequently had permanent implants (including J.G.), the round window and scala tympani were found to be filled to a depth of almost 1 cm with newly-formed bone. In the case of J.G., this had to be drilled out, and again he had post-operative vertigo for about a week; fourthly, following removal of the

https://doi.org/10.1017/S0022215100085005 Published online by Cambridge University Press

bony 'plug' in these two patients, it was discovered that there had been trauma to the high-frequency areas of the cochlea.

In the case of the permanent implants we only have information that no immediate vertigo occurred in one of the patients, and that in another the wires became partially exposed in the external auditory canal, despite the use of methyl methacrylate cement, with resulting recurrent external otitis.

The difficulties presented by new bone formation in the scala tympani following the transcanal test procedure have been described. Dr. Michelson reported that there were no special surgical problems about removing and replacing the silastic electrode-supporting moulds in the other patients. He considers that removal and replacement can be effected without damage to the basilar membrane. The animal experiments from his own laboratory, however, give more variable and less optimistic results.

2.2.9. Demonstration and Examination of Implanted Patients and Assessment of Responses

Two patients were presented for examination in San Francisco, J.G. and M.H. These were the only two with working implants.

There was no *formal* demonstration of these patients; they were examined by interview in the less than satisfactory surroundings of a corridor or preparation room.

(1) *J.G.* (see p. 40, for aetiology and history) was wearing his implant (his second permanent one), but he had not renewed the batteries as he preferred to use his hearing aid alone (in his right ear). He is an excellent lip-reader. The electrode wires were exposed in the external auditory canal.

With the implant activated, he apparently 'hears' words in terms of their duration, sounds being heard as 'clicks'—consonants as clicks emitted at a high rate, vowels as clicks emitted at a low rate. He can discriminate frequency changes for frequencies up to 500 Hz but without lip-reading is unable to discriminate vowels, spondees or connected speech.

The input from his implant interferes with his excellent lip-reading skill, with which he scores 98–100 per cent when augmented by his hearing aid in the right ear; and with the device and his hearing aid both working, his performance is worse than with the hearing aid alone. He also has some radio-frequency pick-up problems, in that he can 'hear' a car from two car-lengths away by interference from the ignition system; and high-level stimulation of the device sometimes causes discomfort, though never pain.

Nevertheless, he prefers to retain his implant, partly to avoid further surgery and partly because he believes that, as the longest implantee, he can still be of help to the cochlear implant programme. He is also hopeful that, with potential improvements in future stimulating devices, the implant may provide him with some 'insurance' against the possibility of eventual total loss of hearing in his right ear.

https://doi.org/10.1017/S0022215100085005 Published online by Cambridge University Press

J.G. had some giddiness after each of the two earlier implants, lasting one day and one week respectively, but now he has none.

(2) *M.H.* (see p. 40, for aetiology and history) was wearing a device in which the microphone was housed in the body of a post-aural aid behind his left ear, and the transmitter was contained in a similar body behind the implanted (right) ear. The transmitter was stuck on with adhesive tape over the receiver.

He reported that, at first, he became easily exhausted by using the device. He had to learn to identify sounds anew and it was "like learning a foreign language". After practice, however, he was able to use it for 7 or 8 hours a day at work, although he uses it much less now that he is retired.

His present (second) implant was inserted in 1972 and his performance was evaluated in October 1974. At that time he was able to detect a tone of 2 kHz at 50 dB, speech at 40 dB, HL, I.S.O. His dynamic range was 40 dB (i.e. between 50 and 90 dB HL). With multiple-choice tests with vowels and consonants, he reached scores that were considered no more than chance; his PB max was 0 per cent.

M.H. is now able to distinguish between voices and it is claimed that his own speech has improved dramatically with the use of the implant. There is certainly excellent intonation in his voice.

He claims that with the implant there has been a considerable improvement in his lip-reading ability (which was very poor without the implant)—especially in his ability to distinguish b, t and p. Even with the implant activated he could lip-read slower speech much more readily than rapid speech; this was also observed in some patients in Los Angeles.

Typewriters sound like 'tick, tick, tick', telephone bells like a 'buzz'; music retains its rhythm but not its melody.

M.H. showed a remarkable (and surprising) ability to localize different speakers, probably by minor head movements, and there was apparently a great advantage in having the microphone installed in the body of a post-aural hearing aid.

The patient himself feels that the implant has given him "a new world" —he feels less isolated and ignored—and his wife said that he was much easier to live with; she does not have to repeat what she says so often. His improvement in lip-reading allowed him, before he retired, to return to his former occupation.

The most unpleasant stimulus is a steam-train or a truck (lorry), but there is a limiter in his device which eliminates any actual discomfort. He still has the tinnitus which was present before the implant, in his left (unimplanted) ear.

2.2.10. Rehabilitation

To date, there has been no formal programme of rehabilitation, but the team intend to embark on a detailed plan of rehabilitation, in which the aural rehabilitation programme of Dr. Elmer Owens will play a part.

https://doi.org/10.1017/S0022215100085005 Published online by Cambridge University Press

In future, limited testing of subjective responses to electrical stimulation will be carried out at the time of surgery, and within a few days of the implant, baseline psychophysical measurements will be made—of thresholds, subjective pitch discrimination, evaluation of electrode sites and other related parameters.

There will follow a period of rehabilitation and psychological evaluation, the outcome of which will be regular meetings of the team, to discuss progress and in particular to make decisions regarding the provision of wearable devices for selected individuals.

This will be succeeded by a period of aural rehabilitation which will include programmed learning, lip-reading and group work; and during this time an attempt will be made to work out optimum stimulus parameters.

Tests will include estimations of the dynamic response properties of the electrically stimulated systems, and tests of temporal resolution.

The programme is designed for multi-channel electrode implants, which it is planned to use in the future. If at any stage it becomes evident that the performance of the multi-channel device is equivalent to that of a single-channel stimulator, then the channels will be connected up in parallel, and an appropriate programme of rehabilitation will be followed.

At each stage of the rehabilitation programme, decisions will be made as to whether the patient will proceed to the next stage, return to an earlier one, or leave the programme.

It is intended to automate all these procedures by computer, and it is envisaged that testing and rehabilitation will occupy approximately one hour per day of each patient's time.

2.2.11. Animal Experiments

The Coleman Laboratory has carried out extensive physiological and anatomical studies designed to determine and optimize the effectiveness of various electrode systems, to determine the extent of damage to cochlear and neural structures from their implantation into the scalae tympani, and to determine the effects of long-term overstimulation.

The physiological studies have been the most longstanding (reported by Merzenich *et al.*, 1973). Carried out on anaesthetized cats, they have utilized a scaled-down version of their human 'railroad-track' bipolar electrode assembly and their prospective multi-channel bipolar system, embedded in a silicone rubber implant moulded to the scala tympani of the basal turn. Recordings were made of single neurones in the inferior colliculus. With these bilaterally innervated neurones it was possible to compare directly their responses to electrical stimulation by the implant with those to acoustic stimulation of the normal ear. With this implant they were able to demonstrate or infer the following:

1. The electrode assembly excited indiscriminately a large array of

https://doi.org/10.1017/S0022215100085005 Published online by Cambridge University Press

cochlear fibres arising from the basal half of the cochlea, i.e. neurones with characteristic frequencies* spanning the frequency range: about 3–50 kHz. (The normal acoustic range in the cat is about 0·1 kHz to 50 kHz).

2. Each neurone excited was driven over a large frequency range by analogue electrical excitation, compared with the normally very restricted frequency area obtained with acoustic stimulation.

3. Irrespective of the characteristic frequency of the neurone, the lowest thresholds were obtained with low frequency (20–200 Hz) stimulation: thresholds progressively rose with frequency, so that at 10 kHz they were 20–30 dB higher than those at 100 Hz. The most sensitive neural threshold frequency curves paralleled almost exactly the psychophysical thresholds of patients implanted with this type of electrode.

4. The period of low frequency electrical stimuli was represented in the temporal patterning of the neural discharges for frequencies up to some 500–600 Hz, as in the case of acoustic stimuli. This range corresponded approximately with the range of electrical stimulus frequencies where differences in frequency can be discriminated by the implanted patients.

5. The dynamic range for electrical stimulation between threshold and maximum rate of discharge of neurones was very restricted (5–30 dB) compared with the acoustic dynamic range.

6. No significant differences in response were observed with the passage of time up to 2·5 years of implantation (including those in neomycin-deafened cats) with the moulded scala tympani electrodes. Thus, sufficient numbers of cochlear neurones survive under their conditions of implantation for efficient stimulation of higher levels of the auditory nervous system.

7. Compared with monopolar stimulation, discrete bipolar pair electrodes, situated in contact with the cochlear partition, gave much more restricted patterns of the extent of stimulation (Merzenich *et al.*, 1974) equivalent in threshold terms to electrical attenuations of about 5 dB/mm of cochlear partition, or 15 dB/octave (see 1.1.2. above) for electrode separations of 1 mm. The discreteness of this excitation was degraded if this distance between the electrodes of a bipolar pair was less than 0·2 mm. Placement of the electrodes was critical: alignment with the basilar membrane was necessary; contact against the bony modiolus was relatively ineffective.

* The characteristic frequency (CF) of a neurone is its most sensitive frequency of tuning to acoustic stimulation; it reflects the locus in the cochlea of its origin or input.

https://doi.org/10.1017/S0022215100085005 Published online by Cambridge University Press

8. Electrode performance (reflected in reduction in thresholds to electrical stimulation) often improved over the course of up to about 6 weeks post-implantation.

9. The amplitude of the 'brain-stem' evoked potentials ('far-field potentials') was a simple function of the number of fibres excited electrically (inferred from studies mapping the number and extent of single units activated in the inferior colliculus).

Histological studies of these long-term implanted cochleas (with and without prior damage by neomycin) invariably reveal extensive or complete loss of hair cells in the organ of Corti directly in contact with the implant, within the first weeks post-implantation. This was accompanied by some loss of supporting cells. In the other turns of the cochlea, less extensive hair-cell loss was observed. In the region of the cochlea containing the implant, some loss of ganglion cells occurred, except in cases where the implant had penetrated the cochlear partition, where local neuronal degeneration was extensive in the region of penetration. (In longer term studies by Spoendlin (1975) of the effects of total hair-cell degeneration by acoustic overstimulation and ototoxic agents, extensive degeneration of the neuronal elements took at least five months to be manifested. Unfortunately, it is not clear how many of the animals in the published Coleman Laboratory series had been implanted for periods as long as this. The range of implantation periods was 3–34 weeks in cats where the cochlear partition had not been penetrated). In more recent long-term studies, however (Schindler *et al.*, 1978), they report survival of "the majority" of cochlear fibres and spiral ganglion cells for eight months, and survival of ganglion cells up to $2\frac{1}{2}$ years. Equally important, no evidence was found in these long-term studies of perilymphatic fistulae or of acute or chronic labyrinthitis. The complement of spiral ganglion cells appears to be relatively unaffected in the unimplanted regions of the cochlea.

In their current studies, the group is examining the histological changes accompanying long-term electrical stimulation of these implants (as distinct from the above changes arising simply from the presence of the electrode assemblies in the cochlea). With suprathreshold stimulation for a month, there was evidence of the accumulation of areolar connective tissue in regions of the scala tympani well away from the implant, e.g. extending into the second turn. The N.I.H. have expressed the desire to have studies of the effects of overstimulation completed before trials on patients are resumed. This series of experiments was not yet complete. So far, two animals had been stimulated for periods of 24–48 hours. The thresholds of brainstem evoked potentials and the impedances of the electrodes had not changed systematically during the period of stimulation and for at least two weeks thereafter.

https://doi.org/10.1017/S0022215100085005 Published online by Cambridge University Press

2.2.12. Current Status of Implant Programme

Not unlike the Walt Disney Hearing Rehabilitation Research Center, the Coleman Memorial Laboratory implantation programme had small beginnings, the team consisting of Dr. Robin Michelson, the otologist, supported by an engineer and being joined by Dr. Michael Merzenich, the neurophysiologist, about 5 years ago. Now with support from the N.I.H. from the State Government and from the private foundation a sizeable team has recently been developed and more staff will be added.

The human implantation work has been beset by surgical and/or engineering failures, including the one multichannel device implanted in 1977. Some of these problems arose following acute surgical experiments, under local anaesthesia, to assess the viability of the neuronal population.

The aim has been to develop a bipolar scala tympani electrode system delivered in a silastic mould of the scala. After the earlier single channel experiments, the policy changed to some extent. Human work was stopped in favour of animal experimentation, together with the engineering development of a multichannel bipolar electrode.

With the earlier human implant subjects, rehabilitation was given no emphasis. The objectives were more experimental, i.e. to make assessments of psychophysical responses to electrical stimulation over as long a period as possible. On the other hand, a patient-usable transcutaneous device was given to the patients from the earliest post-operative period and to this extent there was an element of rehabilitation. It is tempting to suggest that the poor follow-up from the series of implanted patients flowed from this lack of programmed rehabilitation, or the converse may apply.

In a discussion at Lake Tahoe (see 2.4.) on the current status of implantation, Dr. Michael Merzenich argued against widespread implantation on the grounds that cochlear damage from the first implantation would make subsequent implantation with a second generation (e.g. multiple electrode) device either difficult or impossible. Apart from surgical trauma to the cochlear structures, there was the possibility that electrical stimulation might encourage new bone formation, or give rise to electrolytic problems. He was prepared, however, to consider a single channel non-invasive technique.

2.2.13. Future Outlook of Implant Programme

The animal experimental studies will continue. They are now being supplemented, at the request of the N.I.H., by overstimulation experiments. Behavioural animal responses and brain-stem electrical responses will be examined. The histopathology, surface and electron microscope (EM) work will be further developed. Longer-term animal results will be studied before human implantation is recommenced, and Dr. Michelson indicated that they may be in a position to implant the next patient in about six months' time. Patients deafened by ototoxic drugs would be the

https://doi.org/10.1017/S0022215100085005 Published online by Cambridge University Press

best candidates. There is no plan to alter the surgical technique. Engineering development of the 8 channel bipolar scala tympani silastic mould device was nearing completion.

The initial objectives would be to use a subcutaneous connector and a percutaneous button, to have the patients visit the laboratory for psychoacoustic testing of many parameters and to make a start to the complex problem of coding for multichannel electrical stimulation. Dr. Michelson thought that a transcutaneous driving module, suitable for the 8 channel implant, might be developed within a year. It was more difficult to estimate the time required to solve the encoding; it could be 15 months or 15 years. Finally if the 8 channel implant was ineffective as a multichannel device in any or all of the subjects, there was always the simple option, without further surgery, of conversion to a single channel system.

With the multidisciplinary team now working at the Coleman Memorial Laboratory, post-implant rehabilitation will become a major area for development.

2.3. Department of Otolaryngology, Stanford Medical Center, Palo Alto, California (Friday 21 October 1977)

2.3.1. Strategy

While this group, led by Professor F. Blair Simmons, carried out their first permanent cochlear implant in 1964, they have not, since that case, implanted new patients until very recently (two patients in August and September 1977). Their emphasis has been on animal physiological experimentation and psychophysical evaluation of the patients implanted.

All 3 implants have been multichannel, made directly into the body of the cochlear nerve through the modiolus, in the belief that, with direct contact between electrodes and the nerve fibres, thresholds would be lower, excitation would be more discrete and there would be less chance in principle of electrodes encountering 'gaps' in the array of surviving fibres than in the cochlea. The 1964 subject was implanted with 6 electrodes, the current 2 subjects with 4 electrodes into the nerve. The reference (ground) electrode in the current cases is subcutaneous, whereas in the first case it was externally applied, or one of the six electrodes was utilized.

The current implants are regarded as experimental, the objective being to optimize stimulation strategies, although it is intended that the subjects will be provided with wearable control units in the future. The restriction of the number of channels to four is determined by two constraints: (a) the limited size of, and access to, the cochlear nerve. A larger electrode array might injure surviving fibres. (b) While the current subjects have a percutaneous transmission link, it is intended eventually to implant a subcutaneous integrated circuit 4 channel package which is at present under long-term test in animals. To add more channels to the package at

https://doi.org/10.1017/S0022215100085005 Published online by Cambridge University Press

this stage would cost an estimated $500,000 in terms of redesign, fabrication, and the overcoming of power supply limitations.

Although committed to a multi-channel strategy, Simmons considers it reasonable that experiments on patients, utilizing single *and* multiple channel systems be pursued. However, until definite evidence becomes available on whether or not practical multichannel systems could adequately convey unaided speech information, he feels that widespread prescription of single channel systems would be premature. At least 2 years of testing should elapse before this decision is made.

2.3.2. Staffing and Facilities

Electrode development, physiological studies and patient testing are carried out in the Departments of Otolaryngology, Electrical Engineering and Geophysics of Stanford University. (The latter contains the time-shared computer used for testing the patients). Custom-designed integrated circuits are fabricated in the Stanford Integrated Circuits Laboratory.

The team consists of:—

Otological surgeon and physiologist (Professor F. Blair Simmons, Department of Otolaryngology).
Electrical Engineering (Professor R. L. White, Department of Electrical Engineering), concerned with design and fabrication of the transcutaneous multichannel r.f./ultrasonic transmission link, currently under development.
2 graduate student electrical engineers concerned with the psychophysical testing of the patients and the subsequent specification of the implant coding strategy.
1 audiologist concerned with the audiological and psychological evaluation of the patients.
1 communication engineer.

2.3.3. Funding

The work is supported by a 3-year grant from the N.I.H. specifically for electrode development and animal testing. With renewal, this grant has been in operation for 4 years. It supports 3 graduate engineers, half the time of the senior electrical engineer, and a secretary.

2.3.4. Patient Selection

Two male patients have been recently implanted (in August and September, 1977) with 4 electrodes inserted directly into the cochlear nerve by the trans-modiolar route. Both patients have total deafness from topical neomycin intoxication (see Table 6.1.), and we saw one of them (J.McL.).

Patients who will be considered for future implants will be healthy English-speaking adults between 21 and 65 years of age, with total post-

https://doi.org/10.1017/S0022215100085005 Published online by Cambridge University Press

lingual deafness due to a variety of lesions in which there are likely to be surviving nerve fibres: it was indicated that these might include ototoxic damage; bilateral 'dead ears' following stapedectomy; skull trauma; retinitis pigmentosa; and some cases of sudden bilateral hearing loss of unknown aetiology. Post-meningitic hearing loss is not considered suitable, but consideration might be given to some cases of Cogan's disease, bilateral Menière's disease and certain pigmentary disturbances, such as the Waardenberg syndrome.

The patient must have a profound bilateral sensorineural hearing loss, with no measurable hearing to audiometric testing; and whatever lip-reading skills may exist, they should not be improved by any hearing aid.

Vision should be good and the subject should be able to make discriminative judgements as, for example, with the vibrotactile sensations produced by a head vibrator, in order to determine his ability to assess thresholds, loudness scaling, temporal discrimination and the like.

Patients would be selected even if the vestibular system were hypoactive, but ideally there should be some residual function.

The patient should be adequately motivated and he should still be functioning actively in society: he should live near enough to the hospital to attend regularly for rehabilitation, and his economic status should allow him to be self-supporting.

An independent 'patient's advocate' is recommended, to look at risk factors and to call a halt to the programme if he felt that the subject was unsuitable for implantation.

2.3.5. Electrodes

The electrodes are constructed from 0·003″ platinum-iridium (90:10) wires insulated with a 0·001″ coating of Teflon. Apparently, swelling of the teflon coating from contact with body fluids is not a problem. (In their experience, Pyre ML coatings did not survive more than 180 days in saline). The insulated wires are joined together in pairs by Formvar and cut to have a tip separation of about 1 mm or 0·5 mm, for the human or cat implants respectively. The teflon coating is stripped back to leave about 0·2 mm of the wire tip exposed. Two pairs thus prepared are affixed together to form a 4 electrode array with consistent spacing between electrode tips.

The ground electrode is a subcutaneous platinum:iridium wire.

Inter-electrode impedance is of the order of 2–4 kΩ (in terms of average voltage/current relation during a single pulse).

2.3.6. Transmission Link Systems

The electrode wires are first taken to a subcutaneous connector fabricated in epoxy and having cunningly sleeved connector pins to eliminate the need for an external coating of insulation medium. Adequate

https://doi.org/10.1017/S0022215100085005 Published online by Cambridge University Press

electrical insulation has been maintained in saline for a period of two years. Subcutaneous leads run from the connector, screwed behind the zygoma, to a percutaneous connector socket screwed to the mastoid. (The subcutaneous connector is designed to facilitate subsequent replacement of the percutaneous link system by a fully implanted integrated circuit package).

Biphasic pulse charge coupled stimulation is used, 250 μs in duration per phase. The thresholds of the successfully implanted electrodes in the two current patients are of the order of 3–20 nano Coulombs per phase.

As indicated in 2.3.1. above, the two presently implanted patients do not have 'take-home' control units. For testing sessions, they are connected to a charge-coupled stimulator unit controlled by a time-shared computer in the Geophysics Department. This arrangement, while allowing automatic patterning of stimuli and registration of (for example) thresholds, lacked flexibility—for instance that necessary for a demonstration of the percepts associated with different electrodes (without further programming).

A very impressive development is the future transcutaneous link system. This employs two separate transmission systems: an ultrasonic link transmitting pulse-coded information on when each of 4 channels is active, their pulse duration, phase and amplitude; and a radio frequency link providing the power for the implanted package. The implanted package measures about 3·5 cm square by 0·5 cm and consists of a central ultrasonic receiver surrounded by the r.f. receiving coil, the two mounted on the square hermetically-sealed ceramic integrated circuit package. The latter uses a hybrid thick film technique in which CMOS integrated circuits (decoder, charge redistribution digital-to-analogue demultiplexer) are embedded in a substrate in which the necessary connection patterns have been etched. The whole device is coated in epoxy, with a silicone rubber overcoat, including the leads to a subcutaneous connector of the type described above. The transmitter consists of a central ultrasonic crystal surrounded by a r.f. coil. The position of the transmitter relative to the receiver is not very critical: within ± 1 cm. The critical parameter is the angular alignment of the ultrasonic transmitter and receiver, where the tolerance is some ± 15°. The ultrasonic data link operates at 2 MHz, allowing 250 kilobits/sec information capacity, i.e.: an average stimulation rate of 1·5 kHz (biphasic pulses), with a dynamic range of about 40 dB, on each of 4 electrodes. The device utilizes a 'missing pulse' code, which confers simplicity of design of the decoder, high immunity to noise, and a 'fail-safe' property; for example, under conditions where the ultrasonic link is inadvertently interrupted or the internal regulation of the power link fails, producing an excess power supply voltage. Complete assemblies have been "on soak" for 2 years, with no failures in 30,000 hours of testing. Full details are given in Gheewala *et al.* (1975), and Gheewala (1976).

https://doi.org/10.1017/S0022215100085005 Published online by Cambridge University Press

The specification of a future 'take-home' control unit for the currently implanted subjects is under discussion. They wish to implement first a device yielding minimal information (to restrict learning) while the phase of evaluation of the potential effectiveness of the electrodes is in progress. It is intended that this would be replaced by a more sophisticated system, possibly coding the fundamental voice frequency (F_0).

2.3.7. Systems Failures

None of the implants have had to be replaced.

The first subject, implanted in 1964, was studied for 16 months, after which the implant was removed. The current two subjects had been implanted for only 2–3 months at the time of our visit. In one patient, one of the four electrodes is unuseable because it had a lower threshold for vestibular than for auditory stimulation. Also in one patient, there is a 200 mV d.c. potential present between electrodes, suggesting that there may have been leakage into the subcutaneous or percutaneous connectors.

2.3.8. Surgical Considerations

Pre-Operative Conditioning

Apart from the pre-operative selection of patients for implantation and excluding the psychological and other forms of preparation already described, Blair Simmons and his colleagues employ a vibrotactile device, developed in their Unit, to help train the patient before surgery to make the kind of discriminations to be expected of him with his implant.

This vibrotactile device, known affectionately as the 'head-thumper', is applied to the mastoid bone. It tests and practises the subject's ability to make judgements on threshold, loudness scaling, difference limens and temporal discrimination. Post-operatively he will better understand the fairly complex tasks to be performed in discriminating between various parameters of electrical stimulation. Sessions are undertaken with this head vibrator in the weeks preceding surgery and on the day before.

Employing this vibrotactile device with the stimulus above threshold it is found that the tactile detection of double pulses is not possible unless there is a separation of more than 15 msec between the pulses.

The poor temporal resolving power of the skin, of course, is likely to be one of the limiting factors for such devices in the rehabilitation of the severely deaf. Auditory detection of double electrical pulsed stimulation of the cochlear nerve is possible with a pulse separation of less than 3 msec.

Surgical Approach

The present clinical implant programme is designed to accommodate three patients, of whom one awaits surgery. Two had very recently had their surgery performed, in August and September 1977. Dr. Simmons

https://doi.org/10.1017/S0022215100085005 Published online by Cambridge University Press

does not use the promontory stimulation test but agrees that it may have a place in patient selection. Therefore, as in the Michelson-Merzenich Unit, the surgery was commenced under local anaesthesia with a test procedure designed to evaluate neuronal survival.

A modified endaural incision was made passing upwards and arching backwards to the posterior part of the mastoid. The upper end of this inverted 'U' incision extended over the lower end of the temporalis muscle. The soft tissues were retracted and a temporary 'set-screw' hole drilled 2 cm posterior to the canal; an electrode holder was fixed to the mastoid via a metal-tapping screw.

A posterior canal wall incision joined the endaural one and the middle ear was entered. Some annular bone was removed and the incus taken out. A 0·003″ teflon-coated steel wire was placed in the round window niche. The auditory perceptual threshold to 0·5 msec duration electrical pulses (50 per second) was measured. Threshold was obtained in both patients between 50–80 μA. If positive responses had not been obtained, the permanent implantation would have been abandoned.

The attic and aditus areas were next opened from the mastoid cortex. A slit was drilled in the outer attic wall and canal to connect the tympanotomy opening with the cortical hole. This would eventually accommodate the electrode leads.

The stapes arch was removed. A 1 mm burr was used to place a hole in the lateral wall of the first turn of the cochlea 0·5 mm anterior and inferior to the margin of the oval window. Through this opening the medial wall of the scala vestibuli was penetrated with a 0·6 mm burr and with picks to enter the internal auditory meatus. C.S.F. flowed through this hole at about 3 ml per minute.

The four-channel unipolar electrode array was passed through this hole to a depth of 5–6 mm, the lateral part of the electrode carrier being accommodated in the slit to the aditus where it was temporarily cemented with methyl methacrylate. It is necessary to have available a number of electrode arrays, since up to four have been damaged during this manoeuvre. The patients experienced loud noises during this electrode implantation into the cochlear fibres.

Each electrode was to be then tested separately for threshold, loudness range, difference limens of intensity and 'rate-pitch', temporal resolution of two pulses and adaptation. In the first patient (R.F.) only two electrodes seemed to be effective though the others functioned later—the connections were thought to be faulty during the acute experiment. The thresholds of the two effective electrodes were 10–20 μA. Increasing the current strength from 10–60 μA evoked a very loud percept, but no pain. The patient judged stimulation with 35 μA to be louder than 30 μA, but 30 μA and 32 μA were judged to be equal. In the second patient (J.McL.), because the local anaesthesia became inadequate, three electrodes only were tested for threshold.

https://doi.org/10.1017/S0022215100085005 Published online by Cambridge University Press

General anaesthesia was then commenced. The percutaneous 'button' link connector was screwed into the mastoid. A dummy electrode connector was screwed to the groove about the posterior root of the zygoma using a self-tapping screw over a stainless steel bracket. The male and female halves of the actual subcutaneous connector to be used—one from the electrodes, one from the link 'button'—were joined with a specially designed clamp. A tube of silastic was slipped over the joint from one end. If silastic is immersed in ether it expands and within 5–10 minutes contracts again to make a water-tight seal. The subcutaneous connector was then fixed in place of the dummy connector and the wires fixed with methyl methacrylate. Finally the ground electrode was buried subcutaneously near the mastoid tip, the wound closed in two layers, the meatal skin flaps replaced and the external canal packed with gelfoam and chloromycetin-soaked umbilical tape.

Electrocautery was used for haemostasis. Blood loss was estimated at less than 500 ml in each patient. Antibiotic cover was used. One operation took about 5 hours, the other approximately 7½ hours. The patients were discharged from hospital after about 5 days.

Post-operative Care and Surgical Complications

The first patient had C.S.F. leakage through the ear wound and C.S.F. rhinorrhoea for about three weeks. He developed a bacterial external otitis and partial facial paralysis. This latter palsy recovered completely. He had no spontaneous vertigo but stimulation of one electrode caused vertigo at a lower threshold than that of the auditory sensation, while stimulation of another electrode caused slight vertigo.

The second patient (J.McL.) lost C.S.F. through the dressing for one week. He had moderately severe spontaneous vertigo for two weeks. This has now settled and he has no vertigo on electrical stimulation. He does have tinnitus in the implanted ear; no information was readily available as to the presence or absence of this symptom before surgery. He continues to have external otitis, now fungal, with granulations along the incision lines in the external canal. At the time of examination by us he was only a few weeks post-implantation.

It was reported that electrical stimulation reduced the tinnitus experienced by one patient.

Replacement of Electrodes

All three implanted devices have functioned and there has been no need for replacement. Dr. Simmons would be loath to remove and replace the implanted trans-modiolar electrodes. The subcutaneous connector is designed to enable replacement of the link hardware, should a satisfactory permanent transcutaneous transmission device become available.

https://doi.org/10.1017/S0022215100085005 Published online by Cambridge University Press

Sterilization

The implanted hardware was sterilized by soaking in formaldehyde solution and washed repeatedly in normal saline prior to use.

2.3.9. Demonstration and Examination of Implanted Patient and Assessment of Responses

One of the two patients recently implanted (*R.F.*) was not available for examination and interview, but we were told that at first only two of the four electrodes were stimulable. The other two became effective about 2 weeks post-operatively, and it was thought that their initial failure might have been due to a poor contact in the percutaneous 'button'. The thresholds on the two electrodes were 10–20 μA with acute testing during surgery, 4–10 nC per phase post-operatively.

J.McL. We saw and examined this other patient, a retired real-estate executive, who still had some external otitis (due to an infection with Candida) in his left (implanted) ear.

He had a hearing aid for his right ear but stated that he heard only noise with that instrument. Everything sounded the same with it and it helped only very slightly with his not-more-than-modest lip-reading skills. On the contrary, the implant in his left ear sounded "entirely different".

We watched him being tested briefly under on-line computer control which produced pulses, at repetition rates of from 60 to 120 pulses per second; these represented the eight whole-tone intervals of a musical octave. At first the patient was allowed to track adaptively, with an amplitude control, his threshold for a stimulation of 50 pulses per second.

Only three of the four electrodes were stimulable (having thresholds of about 3–10 nC per phase). It was not possible at this stage to switch stimulation conveniently from one electrode to another, for comparison. A few simple 'tunes' were played ('Old Macdonald had a farm', 'Twinkle, twinkle, little star') at a supra-threshold level. Care was taken to ensure that each had a rhythm that would not enable one to be distinguished from the other (except by the length of the occasional silent intervals); hence recognition could only be attained by the discrimination of the frequency intervals. To a musically trained listener, it would have been possible to recognize these tunes by looking at the 'keyboard' (which J.McL. was doing) as the various 'notes' were played; yet he was unable to name any of the tunes by the information afforded by the implant.

Again with single-channel stimulation at supra-threshold level, J.McL. was asked to say when he could separate the 'pitch' of one tone from that of a succeeding tone. Whole-tone separations between succeeding stimulations were judged to be the same, but he could distinguish a musical 'fourth' with certainty, a musical 'third' tentatively; thus the discrimination limen was only about 30 per cent.

Double pulses were assessed as a single pulse until the two pulses

https://doi.org/10.1017/S0022215100085005 Published online by Cambridge University Press

were separated in time by at least 20 milliseconds; and comparing a single pulse on one electrode (after a change-over interval) with a different single pulse on another electrode, he said that the two "sound about the same". (Unfortunately, because it was not possible to switch stimulation to different electrodes, without a substantial interval, it was not possible at this session to elicit the patient's ability to detect perceptual differences between the electrodes).

The general psychophysical findings arising from the postoperative electrical stimulation performed so far in these two patients were as follows: the character of the percept evoked by a single pulse depended on the location of the electrode, in a manner consistent with 'place' theory; to repetitive pulse stimulation, the percepts were described as "hums" and "buzzes" at low frequencies, and "fast buzz or click, or a squealing sound" at high frequencies; differences in rate could be discriminated at rates up to 200 Hz. Thus far, the patients had not reported significant changes in perceived intensity of bursts of pulses (of constant burst duration) dependent upon the pulse repetition rate (from 50–800 Hz). However, differences in the duration of the bursts of pulses did appear to lead to differences in perceived intensity. Discrimination could be made between single and double pulse stimulation with inter-pulse intervals down to 0·75 ms in one patient and to 20 ms in the other.

2.3.10. Rehabilitation

So far there has been no formal rehabilitation programme in this centre.

2.3.11. Animal Experiments

For evidence of nerve fibre survival under conditions of modiolar implantation, reference was made to Simmons and Linehan (1968). In this experiment, long-term recordings were reported from one or more fibres by a 25 μ wire implanted in the cochlear nerve. While the thresholds of the fibres did not change substantially over a 6 week period, it is not clear that the conditions of this experiment are comparable to implantation with a number of wires each of three times the diameter. However, these experiments did demonstrate the damage caused to the basal turn of the cochlea (12 kHz region) resulting from the surgical approach.

In a series of experiments carried out on cats with Dr. T. J. Glattke (Simmons and Glattke, 1972), comparisons were made of the effectiveness of electrical stimulation of the cochlear nerve (in the otherwise normal ear), against acoustical stimulation of the same ear, on gross evoked potential responses in the contralateral inferior colliculus, in acute and chronic preparations. The 'frequency-following response' was very similar between the two conditions, apart from a shorter latency and less temporal jitter for the responses to electrical stimulation. The typical dynamic range of

https://doi.org/10.1017/S0022215100085005 Published online by Cambridge University Press

electrical stimulation was of the order of 20 dB, equivalent to 80 dB of acoustic stimulation.

2.3.12. Current Status of Implant Programme

Compared with the other two centres visited, the Stanford University team is much smaller. Also in contrast with the other centres, implantation is trans-modiolar, directly into the cochlear fibres in the internal auditory meatus. Cochlear implantation is considered entirely experimental, and consequently only a small number of selected volunteers have been implanted.

The programme is run on the 'master hearing aid' principle, for investigation only, and rehabilitation measures have not featured.

Prior to human experimentation, a certain amount of laboratory work in animals was carried out using trans-modiolar electrodes.

Dr. Simmons thought it reasonable that both single and multichannel electrode approaches be pursued. In his view, widespread prescription of single channel devices should not be made for at least two years, when there should be much more information on the results of multichannel stimulation. If, by then, the results of multichannel work was disappointing, while he personally would continue his work on multichannel paradigms, he would agree to the wide prescription by others of single channel devices.

2.3.13. Future Outlook of Implant Programme

The plan for the immediate future is to implant one further volunteer and to obtain as much psychophysical information as possible from the three subjects. On the basis of these results it is hoped eventually to develop a coding system which will establish transfer of information on, say, the amplitude envelope of the acoustic signals and on the speech fundamental (laryngeal) frequencies. There is still discussion within the team about the optimal strategy which should be employed both for the psychophysical testing and for the short- and long-term attempts at coding speech signals.

As indicated above (Section 2.3.6.), the Electrical Engineering Department is involved in the development of a new integrated circuit package device which, in the long term, could be implanted as a transcutaneous wearable device.

2.4. Weekend Symposium, Stanford University Campus, Lake Tahoe (22nd and 23rd October 1977)

2.4.1. Sponsorship by T.W.J. Foundation

The T.W.J. Foundation is a charitable Trust, set up by the descendants of the late Thomas Wickham Jones for the advancement of Otology and

https://doi.org/10.1017/S0022215100085005 Published online by Cambridge University Press

for furthering the relief of deafness. During the months preceding the October 1977 visit to U.S.A. centres, a weekend conference was arranged to bring together members from different groups working on cochlear implantation. It was felt that this would provide an opportunity to meet others who were unable to attend our meetings in Los Angeles, San Francisco or Palo Alto. An approach was therefore made to the TWJ Foundation whose trustees kindly and generously sponsored the meeting. The names of those who attended are listed in Appendix 7.6.

This weekend conference produced the first opportunity of discussion with the neurophysiologists, Dr. Ted Glattke and Dr. Michael Merzenich, and with the bioengineers, Dr. Mel Bartz and Dr. Mark White. For the sake of clarity much of the collected technical information on electrodes, insulation and other aspects of hardware have been included in the reports from the respective centres. Likewise discussions on coding strategy and the current status of the implant programmes (see 2.1.11., 2.2.12. and 2.3.12.), have been separated according to their centre of origin.

2.4.2. Information on Utah Project

The weekend symposium enabled us to meet Dr. Derald Brackmann, who provided us with first-hand information on the cochlear implantation programme being undertaken at Salt Lake City, Utah. Also, much additional information on the diagnostic value of promontory stimulation was obtained, and this is included in Appendix 7.2.

The Utah project is a joint effort between a number of centres. Patients are implanted by Dr. Derald Brackmann at the Ear Research Institute, Los Angeles, and the assessment of the patients and the development of electrode and stimulation systems takes place under the auspices of Drs. Dobelle and Eddington at Salt Lake City. Four patients have been implanted so far. Details on the first two have been submitted for publication (Eddington *et al.*, 1978).

Patient 1 J.B., a 61-year-old mechanical engineer, was deaf from birth (? due to hypoxia). He had small islands of hearing below 2 kHz at 100 dB ISO. He responded well to promontory testing. He was implanted in April, 1975. Electrodes 1 to 6 were passed up the scala tympani through the round window, exposed by a facial recess approach under general anaesthesia. The electrodes were passed individually and having 1 mm balls on the end, the first three shunted together. There have been no subsequent failures of this kind. Electrode 7 was inserted in the bone beneath the promontory and the ground electrode was placed under the temporalis muscle.

The electrodes consisted of 0·0025″ platinum covered with 0·0025″ extruded teflon and 1 mm flamed balls on the end. The electrodes were connected to a percutaneous pedestal ('button') made of pyrolized carbon with an 8-pin connector glued inside. The electrodes were crimped to the

https://doi.org/10.1017/S0022215100085005 Published online by Cambridge University Press

platinum contacts of this connector and the pedestal anchored to the mastoid bone with screws, a circular area of skin having been punched out to accommodate the percutaneous link. Because of the different coefficients of expansion of the components, sterilization was by gas, followed by extreme vacuum.

Pre-operatively, the patient had evidence of some vestibular dysfunction though he had no vestibular complaints. Post-operatively, he had mild dysequilibrium lasting several weeks.

Patient 2 P.H., a male janitor (sanitarian) of 61, had unilateral Menière's disease dating from 1960. In April 1975, a translabyrinthine vestibular neurectomy was performed on the affected side and the necessary bone work for a subsequent implant carried out. His other ear was normal. Six weeks later under local anaesthesia a test electrode was passed 25 mm into the scala tympani via the round window and acute pitch-matching experiments were carried out as the electrode was withdrawn. At 25 mm the 'pitch' elicited by electrical stimulation at 200 Hz matched acoustic tones of 1·5 kHz* in the normal ear; at 19 mm the percept matched at 2 kHz* tone. At 6 mm within the cochlea no response was elicited.

An attempt was made to pass an array of intra-cochlear electrodes into the scala tympani. However, it could only be inserted to a distance of 18 mm. Electrode 6 would not enter and it remained at the round window. A seventh electrode was inserted into the bone of the promontory, and the ground wire was placed under the temporalis muscle. The intra-cochlear array was in the form of a bundle with electrode tips spaced at 4 mm intervals. The longest wire had a 0·5 mm ball on its tip and subsequent electrodes consisted of three wraps of uninsulated wire encircling the connecting wires of the preceding electrodes. The bulkiness of the electrode assembly prevented electrode 6 from entering the scala tympani.

There have been no post-operative problems.

Patients 3 and 4 have recently been implanted. One suffers from progressive hereditary adult sensory deafness and the other had sudden bilateral idiopathic hearing loss 9 years earlier. These last two patients have not yet been stimulated but the technique of electrode fabrication and insertion has been modified. Six scala tympani electrodes of platinum insulated with extruded teflon—overall diameter 0·005″—with 0·5 mm balls on each tip are passed individually up the scala tympani, the most apical being at 24–26 mm, and the most basal at 3–4 mm, from the round window. They are held together by a Teflon sleeve. The seventh electrode is implanted in the bone of the promontory, the ground electrode under the temporalis muscle. The percutaneous link socket, in pyrolized carbon, has been used now for $2\frac{1}{2}$ years with no evidence of skin infection or reaction.

* From Békésy's (1960) map the frequencies would be expected to be approximately 0·5 kHz and 1·4 kHz respectively.

https://doi.org/10.1017/S0022215100085005 Published online by Cambridge University Press

Simple post-implant radiology gives an excellent picture of electrode positions.

To date, psychoacoustic data on frequency and intensity discrimination as well as the effects of differing types of stimulation on threshold and electrode position have been obtained. The results are said to be "extremely encouraging" from the point of view of developing an auditory prosthesis, and suggest that it *may* be possible to produce a continuum of both 'pitch' (by utilizing temporal and 'place' coding) and loudness. It is pointed out that, over the period of observation and stimulation, the subjective responses have remained stable. There have been no problems with tinnitus or vertigo, nor with undesirable facial nerve stimulation.

In one patient (2) who has a normal (unimplanted) ear, comparisons have usefully been made of the sensations from electrical stimulation in the implanted ear with acoustic sensation in the other ear. He obtained two different 'pitch' perceptions from the two most apical electrodes estimated at about 18 mm and 14 mm respectively from the round window. Electrode 1 evoked a percept which compared roughly with an acoustic signal of 1·2 to 1·3* kHz; that of electrode 2 matched with 1·6* kHz. However, the sound heard was not a pure tone and was in fact judged to be much less 'pure' than that experienced during the acute experiment at the time of implantation. To determine what this patient hears on electrical stimulation it will be necessary to compare the percept with complex acoustic stimuli—possibly selectively filtered white noise. From the most basal electrodes there was little or no difference in the 'pitch' evoked.

Data are being sought in these volunteer patients on many aspects of stimulation including loudness-matching between electrodes, adaptation, subjective differences resulting from stimulation with different wave forms, etc., energy requirements to reach threshold at different frequencies, difference limens of pitch and loudness, and dynamic ranges from threshhold to uncomfortable loudness. The results of single channel stimulation described by the other investigators in this field are confirmed. For example, the dynamic range from threshold to uncomfortable loudness was only 5–7 dB for pulse, and 12–15 dB for sinusoidal waveform stimulation.

The limitations of the promontory screening test were brought to our attention. For example, although there had been a good response to promontory stimulation in the unilaterally deaf volunteer; nevertheless, he appeared to lack excitable tissue under two of his permanently implanted electrodes, although it cannot be excluded that this resulted from damage from insertion of the electrodes.

The synthesis of complex percepts by multichannel stimulation based on the spectral characteristics of sounds, and of speech in particular, all lie in the future.

* These figures correlate more closely with the basilar membrane frequency map of Békésy (1960) than do those on p. 64.

https://doi.org/10.1017/S0022215100085005 Published online by Cambridge University Press

We were especially interested in obtaining information on the results of stimulating the implanted promontory electrode in these patients, and in Brackmann's wide experience of promontory stimulation. Current requirements to reach threshold were somewhat higher compared with the scala tympani electrode and, with current levels 2–3 times threshold, pain was evoked in the distribution of the glossopharyngeal nerve. This is not surprising considering the proximity of the promontory electrode to the tympanic branch of the IXth cranial nerve. Otherwise, there was no substantial difference between the percepts evoked by intracochlear stimulation and those evoked by promontory stimulation.

The philosophy of the Utah team is that multichannel stimulation is still very much at the developmental and experimental stage, hence the patients are regarded as experimental volunteers. They are not provided with 'take-home' control units, but visit the laboratory for testing. The percutaneous connector allows direct electrical connection to the electrodes in order to permit voltage and current to be measured and to permit complete flexibility of stimulation.

2.4.3. Implantation of Children

There was a discussion on the philosophy and ethics of implantation in young children. It was agreed in principle that, even with a single channel system, there could be a considerable potential benefit to the development of language through any 'critical period' of development that might exist and that in addition there might be a possible beneficial trophic effect of electrical stimulation on the nerve perhaps helping to counteract further degeneration. The evidence for the latter was inferred from Merzenich's animal studies on the effects of sectioning the VIIIth nerve. At 3–5 months morphological changes can be traced in cells extending from the cochlear nerve to the inferior colliculus. There was a decrease in the size of the neurones and decrease in the concentration of oxidative enzymes, but no loss in population. Merzenich speculated that electrical stimulation might offset these effects.

One contraindication to stimulating young children was the presently unsolved problem of implanting into growing tissue. It was also considered that possibly only 1 per cent of the congenitally deaf would have hearing losses which were so severe that implantation would be preferable to conventional lines of rehabilitation, and furthermore that, despite modern Electrical Response Audiometry (ERA), it might be difficult to identify such infants with certainty. The medico-legal difficulties, whereby children upon attaining adult status could bring claims for damage, excluded such 'experimental' lines of therapy, at least in the U.S.A.

2.4.4. Current Status of Implantation

Dr. Derald Brackmann felt that there was a place both for

https://doi.org/10.1017/S0022215100085005 Published online by Cambridge University Press

rehabilitation with single channel implants and for research into multi-channel schemes.

While some of those present argued against the widespread use of cochlear implants, on the grounds that damage might preclude subsequent implantation with better, second generation devices, others put forward different views. For example, considering that it might be many years before an adequate multichannel device was perfected, and that there was always the possibility of using the other ear, should better devices and techniques be developed, then many potential patients in the older age groups could justifiably be accepted for implantation and the measure of rehabilitation it offered.

All participants were agreed that, for multichannel work, at this stage, a *percutaneous* link should be used, to offer maximum flexibility and control of stimulation.

2.4.5. Acknowledgement to Dr. Mansfield Smith

Dr. Mansfield Smith acted as the local 'agent' for the T.W.J. Foundation and issued the weekend invitations. Acknowledgement is due to Dr. Smith for his excellent organization and for his kindness and generosity in putting his private residence at our disposal for the discussions.

2.5. Visit to National Institutes of Health, Bethesda, Maryland (Tuesday 25 October 1977)

2.5.1. Meeting with Dr. David G. Hanson, M.D. (Acting Director, Communicative Disorders Program)

Currently four *grants* have been awarded for research addressed specifically to the development and testing of auditory prostheses in animals, the recipients being Dr. F. Blair Simmons, M.D. (Stanford), for the development of a cochlear prosthesis; Dr. Michael Merzenich, Ph.D. (San Francisco), for differential intracochlear stimulation and prosthesis development; Dr. Josef Miller (Washington, Seattle), and Dr. Richard Walloch (Portland, Oregon), for behavioural and other studies (in animals) on the effects of implantation.

Additional *contracts* (i.e. initiated and advertised by the N.I.H.) have been awarded for the development of trans-dermal electronics for auditory prostheses (to Dr. Robert White); and for the evaluation of patients presently implanted with cochlear prostheses (to Dr. R. C. Bilger)—now concluded and published (Bilger *et al.*, 1977); a further contract is currently being advertised for studies on the development of multi-channel electrodes for auditory prostheses.

In addition to the above grants and contracts related directly to auditory prosthesis research, grants have been awarded which are partly

https://doi.org/10.1017/S0022215100085005 Published online by Cambridge University Press

or wholly designed to answer questions relating to auditory prostheses, in studies on the neurophysiology of the auditory system. Further grants have been made for research relevant to the prosthesis programme; for studies in the histopathology of the temporal bone; and for research into auditory perception and speech coding, including one project on tactile communication of speech to the deaf.

The N.I.H. are also supporting two groups which are carrying out work on vibro-tactile devices, and they are giving indirect support to the development of visual substitution methods, as by Upton-type eyeglasses (Upton, 1968).

Dr. Hanson's personal opinion was that cochlear implant work was still "extremely experimental". He felt that there was too little information about how the normal auditory system processed complex sounds like speech, and he believed that a great deal more needed to be accomplished in animals, particularly from behavioural studies.

He thought that the information gained (by the patient) from single electrode systems was limited and that, in principle, it could be transmitted equally well by high-powered hearing aids or vibro-tactile prostheses, the relative values of which had yet to be evaluated.

As far as he was concerned, the future probably lay in multi-channel systems, even though it might take five years or more before it became clear whether or not this was the case. However, one problem that worried him about the potential value of multi-channel electrodes was Dr. Schuknecht's finding that, if two-thirds of the cochlear nerve fibres were lost, then despite a normal audiogram, speech intelligibility became very poor.

He emphasized that for any implant programme to succeed, there would have to be unprecedented collaboration between otologists, cochlear physiologists, physicists, engineers and persons skilled in the rehabilitation of the deaf.

Exclusive of contracts, the Communicative Disorders Programme of the N.I.H. awards grants totalling about $1,000,000 per annum, for research relating directly or indirectly to cochlear implantation, including studies of nerve degeneration in relation to implantation.

(By way of comparison, about $1,000,000 per year is awarded for work on the vestibular system, and a further $1,000,000 per year for research on diseases of the ear, nose and throat, this latter sum including about $600,000 on diseases of the ear, such as Menière's disease and cholesteatoma).

The N.I.H. has no figures on the incidence of deafness in the population, and what figures there are, are thought to be inaccurate. According to a national census published by the National Association for the Deaf in 1974, there are 203 profoundly deaf persons per 100,000 population in the United States; and profoundly deaf children accounted for only

https://doi.org/10.1017/S0022215100085005 Published online by Cambridge University Press

0·075 per cent of hard-of-hearing children, and for 0·5 per cent of the total school population.

Dr. Hanson's feeling was that the total number of *ideal* candidates for multichannel cochlear implantation, out of a total of about 300,000 profoundly deaf adults in the U.S.A., would be very small, possibly as few as 2,000 or even 500.

2.5.2. Meeting with Dr. Karl Frank, Ph.D.

(Director of the Fundamental Neuro-Sciences Program in the National Institute of Neurological and Communicative Disorders and Stroke)

Dr. Frank commented on a number of interesting projects supported by the N.I.H., among which the following are relevant to the question of development of suitable materials for implantation.

Most of the materials studies in the U.S.A. have been conducted by a group in Gainsville, Florida. They have investigated not only metals and insulating media (suitable for insulating leads and packages), but also the damage done to the surfaces of the electrodes by different parameters of stimulation. Another group in Huntingdon, Pasadena, is investigating what damage is done to the nervous system by electrical stimulation. These latter studies have shown that monophasic pulses have severe effects on the blood-brain barrier (as demonstrated by an Evans' Blue technique), these effects having occurred with monophasic pulses at stimulus levels which are barely sufficient to evoke neural responses. Biphasic pulses appear to be much less damaging than monophasic pulses but, even with the former, there is still some damage to the blood-brain barrier, albeit at high current levels.

As far as the dissolution of electrode metals is concerned, one contractor in Boston has demonstrated that the addition of protein to a saline solution produces 100 times *less* corrosion of platinum during electrical stimulation than does saline alone.

Research is also being carried out on the effects of electrical stimulation on the local micro-circulation; it has been demonstrated already that the fine arterioles constrict, producing clumping of red blood cells, and that the capillaries tend to dilate. Further detailed experiments are required.

2.5.3. Meeting with Dr. Terry Hambrecht, M.D.
(Project Director of the Cochlear Implant Program)

Dr. Hambrecht was extremely concerned by the failure so far to solve the problems of selection of electrode, insulation and packaging materials.

The ideal insulator for electrode leads should allow flexibility and should be impervious to ions and water vapour. It is hoped to develop polymers possessing these properties.

He considered it not to be possible at present to make hermetically-sealed circuit packages which had adequate circuit complexity for multi-channel systems and yet were small enough for implantation near the ear.

https://doi.org/10.1017/S0022215100085005 Published online by Cambridge University Press

2.5.4. Visit by Dr. E. F. Evans to the Laboratory of Neural Control, National Institute of Neurological and Communicative Disorders and Stroke (Thursday, 27th October 1977) (Dr. G. E. Loeb)

Much of their intramural and contracted-out work has been directed at the choice of electrode materials and their insulation for long-term stimulation and recording in nervous tissue.

Electrode materials

The effects of trace quantities of platinum released into neural tissues as a result of long-term electrical stimulation were unknown. Paradoxically, platinum electrodes, although apparently inert, could have more serious effects than the more readily broken-down stainless steel electrodes, because ferrous ions were normal tissue trace elements.

Insulation and packaging materials

They agree with Donaldson (1973) and Brindley that silicone rubber is not an ideal insulator for electrode wires, because of its permeability to water and its unknown permeability to ions, and because it cannot be applied in thin uniform layers. While teflon had passed chronic tests (Donaldson, 1973) it was, in their experience, a very difficult material to work with to obtain a thin uniform coating free from pin holes. The common lacquers and varnishes were organic materials with limited long-term resistance to saline. Pyre ML was considered tough and it bonded well to materials. However, it would not survive autoclaving. Even epoxy absorbed water and eventually broke down in the very long-term (Loeb *et al.*, 1977). No plastic was a barrier to water in the absolute sense. The question was whether the water could get to the metal surface and dissolve impurities, thus producing a conducting medium sufficient to serve as a current shunt.

They had investigated parylene as an insulator of tungsten for very long term (1 year) *microelectrode recording* experiments (Loeb *et al*, 1977). This was an excellent test of long-term insulation properties, and in all but two respects the material was ideal. These were that it did not bond well to metals and it required a licence for production which was in itself difficult.

It was regrettable that there had been as yet no theoretical work on the nature of biocompatible insulation materials.

https://doi.org/10.1017/S0022215100085005 Published online by Cambridge University Press