RESULTS OF A PRELIMINARY CLINICAL TRIAL ON A MULTIPLE CHANNEL COCHLEAR PROSTHESIS

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Speech discrimination testing was carried out under clinical trial conditions for eight profoundly postlingually deaf adults to assess the efficacy of a newly developed 22-channel cochlear prosthesis and speech processor. Three months postoperatively, these patients showed significantly better results with the cochlear prosthesis than for preoperative testing with a conventional hearing aid or vibrotactile aid (following a 6-month trial with the aid) on each of a series of tests from the Minimal Auditory Capabilities battery. Assessment of lipreading enhancement using standard speech tests, consonant recognition studies, and speech tracking showed significant improvements for each patient when using the cochlear prosthesis. Six patients showed a significant amount of open set speech discrimination without lipreading at levels which have not been reported for single electrode cochlear prostheses. The two patients who performed poorly on these tests both had restricted multiple channel systems due to their disease, one patient being restricted to virtually a single channel system and the other to only ten of the 22 electrodes. These results indicate that this multiple channel cochlear prosthesis has potential as a treatment for profound postlingual deafness over a wide range of etiologies and ages.

KEY WORDS - cochlear prosthesis, speech recognition.

INTRODUCTION

Over the last two decades there have been a number of studies to evaluate cochlear implants for profoundly or totally deaf patients. These have involved devices which either provide processed or unprocessed speech as one channel of stimulation or, alternatively, implants where processed speech is conveyed as a multiple channel input.

In 1978, a prototype multiple channel cochlear implant was developed at the University of Melbourne to help restore useful hearing for profoundly deaf patients. Following extensive psychophysical investigations with two postlingually deafened patients, a speech-processing strategy was developed which, in simplified terms, mapped the position of the main middle frequency spectral peak (second formant) onto electrode position in the cochlea and the fundamental or voicing frequency onto pulse rate (frequency) of electrical stimulation. This speech-processing strategy was implemented in a laboratory system and later as a wearable device for home use. A series of speech discrimination tests was carried out to evaluate the performance of this speech-processing strategy. These included vowel, consonant, and word-recognition tasks as well as speech tracking. The results showed that the prosthesis could provide some open set recognition when used alone, and, when used in conjunction with lipreading, could give substantial improvements in communication ability.

Biological studies have also been undertaken to ensure that long-term stimulation with the electrode array would not lead to adverse effects on spiral ganglion cells. The results showed that there was no loss of cells for charge densities of 16 to 32 μC/cm² geom. phase for periods up to 2,000 hours of continuous stimulation.

In view of the encouraging results obtained with the prototype multiple channel cochlear prosthesis, it was redesigned and manufactured by a medical electronics firm (Nucleus Limited, Sydney, Australia).

The external speech processor (Fig 1A) has been designed for the implementation of the speech-processing strategy described above. The speech processor is a pocket-sized device connected to a microphone-headset. This headset incorporates a small directional microphone which supplies the acoustic input to the speech processor, and a coil unit for transmission of coded information and power from the speech processor to the implanted receiver-stimulator. The coil alignment is held firm by two light wire prongs which can be adjusted individually for each patient and worn under the hair. The speech processor is powered by three penlight cells. The implanted receiver-stimulator and electrode array are shown in Fig 1B. The electronics of the implanted device are contained on a single silicon chip enclosed in a hermetically sealed titanium capsule which has a diameter of 20 mm and a height of 5 mm. A single coil for receiving power and coded speech data from the speech processor encircles the titanium capsule and is sealed in medical grade...
Silastic. The 22-electrode array is attached to the receiver-stimulator via a special connector allowing replacement of the electronics package. This connector uses ceramic-to-metal seals, which have been adapted from cardiac pacemaker technology, to prevent fluid entry. The 22 Teflon-insulated lead wires to the electrode array are wound in a helical structure and encased in a 2-mm diameter Silastic carrier. The helical structure prevents the possibility of breakage due to flexing of the lead wire. The electrode array consists of 22 platinum foil bands 0.3 mm wide with a spacing of 0.45 mm along a Silastic carrier. The carrier tapers from 0.6 mm diameter at the apical end to 0.4 mm at the basal end.

The receiver-stimulator delivers biphasic charge-balanced current pulses to the electrode array. Any of the 22 electrode bands can be designated as the active electrode and any other band as the ground (bipolar stimulation). When operating with the current speech-processing strategy, the electrode designation changes at the glottal pulse rate of the speaker (100 to 300 times/s) and moves up and down the electrode array corresponding with the designation changes at the glottal pulse rate of the patient. A combination of these vowels as in “your” will produce a transition stimulus from the basal to apical end of the array. The current amplitude of stimulation pulses is variable from 50 μA to 1.5 mA in 239 discrete logarithmic steps, and the pulse width (per phase) is variable from 20 μs to 400 μs. Pulse rates to 1,400 pps can be used, and higher rates are possible depending on the pulse width.

This paper presents results for eight patients implanted with the 22-channel cochlear prosthesis in late 1982 and 1983.

PATIENTS

Rigorous criteria were used in selecting patients for this study. The most important of these were:

1. profound to total postlingual hearing loss with 0% open set speech discrimination
2. no significant benefit from a conventional hearing aid or hand-held vibrotactile aid after a 6-month trial and rehabilitation period
3. no radiological contraindication to surgery
4. positive result for electrical stimulation of the promontory
5. no general medical contraindications to surgery, and
6. patient’s willingness to participate in the clinical trial program.

The eight patients in this study are the first patients to have been implanted with this multiple channel cochlear prosthesis. A great deal of time was spent in preoperative counselling of the potential patients to ensure they had realistic expectations about the outcome of their implant surgery. In particular, patients were told that the cochlear prosthesis would allow increased awareness of environmental sounds and help with lipreading, and would provide some ability to discriminate speech without lipreading, but that the understanding of conversational speech without lipreading would not be possible. Informed consent was obtained after counselling using a special detailed form complying with the United States FDA guidelines.

Brief histories of the eight patients involved in this study are given below. All eight patients, during preoperative audiometric testing, showed no hearing thresholds under headphones in either ear at the maximum output of the audiometer. 90 dB HTL (ISO) at 250 Hz; 110 dB HTL at 500, 750, 1,000, 1,500, 2,000, 3,000, 4,000 and 6,000 Hz; and 90 dB HTL at 8,000 Hz; except for patient 6 who had hearing thresholds in the right ear at 90 dB HTL at 250 Hz and 105 dB HTL at 500 Hz but at no other frequencies for either ear.

Patient 1. A 37-year-old man suffered severe hearing loss after streptomycin treatment for burns at the age of 5 years. His hearing loss at this stage was total in the right ear, but he retained some useful residual hearing in the left ear, and was able to make use of a hearing aid until the age of 21. At this stage he suffered a sudden loss of hearing in his left ear leaving him totally deaf. He had thus been totally deaf for 16 years. He underwent a 6-month trial with a hearing aid prior to implant surgery but was unable to gain any benefit auditorily or with lipreading.

Patient 2. A 62-year-old woman gradually lost hearing in both ears after frequent attacks of otitis media in her teens. Her hearing deteriorated further during pregnancy until in her early 30s she was profoundly deaf in both ears. At this time she found she could get no benefit from a hearing aid, and since then had not tried a hearing aid until she came for evaluation for the implant procedure. She underwent approximately 2 years of rehabilitation with a powerful hearing aid before the implant surgery. She had been profoundly deaf for approximately 30 years.

Patient 3. A 22-year-old woman had no previous ear or hearing problems until she developed acute bacterial meningitis when she was 18 years old. This resulted in total hearing loss in both ears, severe tinnitus, and left-sided facial paralysis which lasted 3 weeks. She was unable to obtain hearing thresholds even with the most powerful of hearing aids, but received 12 months of inten-
sive training and rehabilitation with a vibratoactile aid prior to implant surgery. She had been totally deaf for 4 years.

**Patient 4.** A 23-year-old woman as a child had multiple ear infections associated with chronic perforations of the tympanic membrane in both ears. She had a number of operations on both ears including myringoplasty and tympanoplasty. At age 14 she had a profound bilateral hearing loss and could not gain benefit from hearing aids. She had thus been profoundly deaf for 9 years. She was unable to obtain any aided thresholds and thus underwent her 6-month hearing aid trial with a vibratoactile aid. Following surgery, patients 1 through 4 reported hearing sensation for stimulation at sites right across the 22-electrode array. Furthermore, they were able to discriminate the hearing percepts elicited at different sites across the entire array. These patients are all using 22 electrodes with their wearable speech processors.

**Patient 5.** A 74-year-old man had a sudden loss of hearing at the age of 35 years and became severely deaf. Since that time he had lost hearing in steps, and had become totally deaf 9 years prior to surgery, at which time he could no longer gain any benefit from a hearing aid. He underwent 12 months of rehabilitation with a vibratoactile aid prior to surgery. Polytome x-ray films showed resection of bone over the apical and middle turns of the cochlea and a narrow basal turn consistent with cochlear otosclerosis. At surgery, the round window niche was found replaced by bone, and the bone had to be drilled to a depth of approximately 3 mm before the scala tympani was entered. The electrode was then placed easily for a distance of 20 mm. At his first postoperative test session it was discovered that a facial twitch was produced by stimulating the more basal electrodes away from this area. The two most basal electrodes situated in the area drilled caused pain in the ear, presumably due to stimulation of the tympanic branch of the glossopharyngeal nerve. These unpleasant side effects have reduced the usable length of the electrode array from 16 to 2 mm for this patient. This effectively means that he is using a single channel rather than a multiple channel system.

**Patient 6.** A 65-year-old man had a progressive loss of hearing in both ears due to acoustic trauma and recurrent otitis media. He had been profoundly deaf in the left and totally deaf in the right ear since 1966. In 1970 he had a multiple channel cochlear implant operation in the left ear but the receiver-stimulator (and not the electrodes) had to be explanted in 1982 due to infection around the package. This occurred following the creation of a sinus by pressure from the arm of his glasses on a prominent edge of the receiver-stimulator. In view of the above discouraging speech perception results with the prototype device, this patient requested the improved cochlear prosthesis. In view of the infection in the left ear, it was considered desirable to operate on the right ear. This presented some difficulties as electrical stimulation of the promontory was negative, and he had a large exostosis in the auditory canal partly obscuring a scarred drum and central perforation. An operation was undertaken, the exostosis removed, the cochlea stimulated with a ball electrode placed on the round window, and the perforation grafted. The patient made a good recovery and a cochlear implant was subsequently performed. At surgery there was a lot of scar tissue in the middle ear and some had penetrated into the apical and middle turns of the cochlea through an area of resorbed bone. The electrode array was inserted for a distance of 20 mm. Following surgery it was found that electrodes in the apical half of the electrode array displayed high thresholds for auditory sensation and were not discriminated by the patient, whereas electrodes in the basal half of the array were well discriminated. This patient was able to effectively use 10 of the 22 electrodes in the array. He underwent a 6-month trial period with a hearing aid prior to implant surgery.

**Patient 7.** A 52-year-old man suffered sudden total hearing loss as a result of bacterial meningitis. He underwent multiple channel cochlear implant surgery in 1978 and was a research patient involved with the studies that led to the development of the present multiple channel prosthesis. After the first

Nucleus devices had been shown to be successful in 1982, this patient requested reimplantation with the new model with the advantages of the smaller speech processor, additional electrodes (22 compared with ten), and more sophisticated electronics. This patient could not obtain any aided thresholds in either ear with a conventional hearing aid and thus his preoperative testing was carried out with a hand-held vibratoactile aid.

**Patient 8.** A 38-year-old man was diagnosed as being severely deaf at 4 years of age. It is believed that the onset of hearing loss was at approximately 2 years, as language development was normal until this time. He was able to make use of hearing aids until age 16 after which he was found to have no aided thresholds in either ear, and his hearing aid trial and evaluation were carried out by means of a hand-held vibratoactile aid.

Patients 7 and 8 were both able to discriminate between all 22 electrodes of the implanted prosthesis and are using all of these with their wearable speech processors.

**SURGERY**

The cochlear implantation operations for these patients were carried out at The Royal Victorian Eye and Ear Hospital using horizontal laminar flow units, with a strict aseptic protocol to reduce the risk of postoperative infection to a minimum. This was considered important because there is a greater risk of infection occurring with an implanted foreign body.

Postauricular flaps of skin and fascia were created to expose a sufficient area of the temporal and occipital bone to allow the round window to be exposed through a posterior tympanotomy and a bed to be created for the receiver-stimulator package. After the mastoid air cells were exenterated and a good view of the round window obtained, the bed for the receiver-stimulator was created with both cutting and diamond paste burs. The bed was steel so that the anterior margin of the implant package lay at least 1 mm behind the posterior skin crease. If this is not done the wearing of glasses or placement of the transmitter coil could be difficult and lead to problems.

After ensuring hemostasis, the round window niche was drilled with a fine diamond paste bur to expose the round window membrane. If possible this was done anteroinferiorly around its circumference, care being taken to avoid damaging the osseous spiral lamina and basilar membrane posteriorly. The electrode array was then gently inserted as far as it would go without applying additional force. The insertion was facilitated by a specially designed microcatheter.

Finally, the receiver-stimulator was placed in its bed and the electrode array fixed in place by Teflon mesh stays inserted through holes drilled in the bone and passed around the electrode. It was considered important to leave the cortical bone of the mastoid tip so that the electrode array could be fixed in a groove beneath it and not be subjected to repeated movement from outside, e.g., from rubbing the overlying skin.

**METHOD**

**Preoperative Testing.** A series of speech discrimination and lipreading tests, which included tests from the Minimal Auditory Capabilities (MAC) battery, was administered preoperatively with patients using a hearing aid or vibratoactile aid. This was carried out following their trial-rehabilitation period with the aid. All tests were recorded on audio or video tape by a male actor with an Australian accent except for tests requiring different storytellers, e.g., male female, sentence discrimination tests, and presented in an audiometric test room via a headband receiver system at the patient's comfortable listening level.

The lipreading assessment consisted of the Central Institute for the Deaf (CID) everyday sentence test, the Consonant Nucleus Consonant (CNC) monosyllabic word test, and the Speech Perception in Noise (SPIN) sentence test under conditions of lipreading alone and lipreading with the aid. The patients showed no improvement on any of these tests when using the aid compared with lipreading alone.
Open set speech discrimination was administered in the aided condition using CID everyday sentences, monosyllabic words (Northwestern University [NU] auditory test 6 from MAC battery), AB monosyllabic words (scored on the basis of number of phonemes correct), and spondees (sponde test from the MAC battery). The eight patients obtained zero scores on these tests with a hearing or vibrotactile aid.

Postoperative Testing. Three weeks after surgery, postoperative testing commenced. This initially involved psychological tests required to program each patient's speech processor to their individual requirements (thresholds and dynamic ranges for each electrode). The patients then began a structured rehabilitation course which consisted of ten to two-hour sessions over approximately 2 months.

A number of speech discrimination studies were carried out on each patient during the initial rehabilitation sessions. These were undertaken with a familiar speaker (the rehabilitation audiologist) under five voice conditions. The speech-tracking method was used to assess patient communication speed and as a training procedure. Speech tracking requires the patient to repeat verbatim passages of text read by a tester. The tester does not continue reading until the patient has repeated each word correctly, and must use a hierarchy of strategies to help the patient if the response is incorrect. The more difficult a patient is having with communication the slower the task is performed, and hence the patient's performance is assessed by the number of words per minute correctly repeated.

Consonant recognition was also assessed during the rehabilitation program. The testing sessions involved the presentation of 12 consonants (p,b,m,l,j,v,d,t,n,s,z,g,k) in randomized lists containing four of each consonant. The lists were presented under conditions of visual recognition with the cochlear prosthesis, cochlear prosthesis alone, and visual recognition alone. This order of conditions loads any intrasession practice effects onto the visual recognition alone condition. The consonants were presented in an 'a consonant a context (e.g. ada, apa, ana). The patients had a list of the consonants in context from which to choose their response.

Postrehabilitation. At the completion of the rehabilitation sessions (approximately 3 months postoperatively), each patient's performance with the cochlear prosthesis was assessed using the same battery of speech discrimination and lipreading tests as presented preoperatively.

RESULTS

Figure 2 shows speech-tracking scores for the eight patients. Patient 5 found the procedure excessively difficult and testing was terminated after six sessions to avoid undue frustration. Patient 8 had only seven sessions of speech tracking due to time limitations. Each session consisted of ten minutes of lipreading alone and ten minutes of lipreading with the cochlear prosthesis. The order of conditions was alternated to control practice effects. Also shown are the mean tracking rates for the two conditions. All patients have significantly better results for the lipreading with cochlear prosthesis condition (p < 0.05) as shown by t tests. Significant improvements over time for the lipreading with cochlear prosthesis condition are evident for patients 2, 3, 4, 7, and 8.

In each case the tracking sessions represent 2 to 3 months of elapsed time.

The results presented in Table 1 show mean percent correct scores over two consonant test sessions for each patient. Each patient again shows significant improvement (p < 0.05) when using the cochlear prosthesis and visual recognition over visual recognition alone based on a binomial variable.

Table 1. Mean percent correct scores over two sessions of consonant recognition testing.

<table>
<thead>
<tr>
<th>Patient</th>
<th>Visual Recognition With Cochlear Prosthesis</th>
<th>Cochlear Prosthesis Alone</th>
<th>Visual Recognition Alone</th>
</tr>
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<tbody>
<tr>
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<td>2</td>
<td>71</td>
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</tr>
<tr>
<td>Mean</td>
<td>69</td>
<td>39</td>
<td>43</td>
</tr>
</tbody>
</table>

*Each testing session consisted of five voice presentations of randomized lists of 12 consonants (p,b,m,l,j,v,d,t,n,s,z,g,k) in a consonant in context, each list containing four occurrences of 12 consonants.
model analysis.19 All patients except patient 5 scored significantly above chance (p < 0.05) using the cochlear prosthesis alone.

The mean percent correct scores for the eight patients on tests from the MAC battery are shown in Table 2 both for the cochlear prosthesis and for the preoperative assessment with a conventional hearing aid or tactile device. Also shown are the scores expected for chance performance. The tests are divided into three categories: suprasegmental tests which apply to gross aspects of speech discrimination without involving actual understanding of words, closed set tests which involve discrimination of a certain response word from a fixed set of similar alternatives, and the open set environmental sound test. Based on modeling the scores for the various tests as a binomial variable, all mean test scores when using the cochlear prosthesis were significantly above the chance level (p < 0.05). This was the case for only five of the tests given with a conventional aid being used. Analysis using a simple t test indicated that the mean scores using a cochlear prosthesis for all tests were significantly better than the scores using a conventional hearing aid (p < 0.05). Open set test results are given in Table 3 for each patient separately. Preoperatively, scores on these open set tests using a hearing or vibrotactile aid for these patients were uniformly zero. It should be noted that the test materials had to be presented at levels of 90 dB and above progressively to enable patients to respond at all when using their hearing aids, but that normal conversational levels (70-75 dBA) were adequate for postoperative testing with the cochlear prosthesis.

The results for the three lipreading tests are given in Table 4 along with the mean scores for each condition. These show significant improvements (p < 0.05) for the lipreading with cochlear prosthesis condition over lipreading alone for each of the tests.

**DISCUSSION**

Results for the MAC battery tests have shown that, for these eight patients, performance on speech discrimination and recognition tasks with the multiple channel cochlear prosthesis was significantly better than that possible with a conventional hearing aid. Lipreading assessment has shown that these patients were able to use the auditory information they obtained from the cochlear prosthesis to improve their speech-recognition performance above the level possible with lipreading alone. This was the case not only at a purely analytic level as shown by the consonant-recognition studies, but also in a situation more closely related to normal communication such as speech tracking. It has also been demonstrated that this improvement is not restricted to tasks carried out with a familiar speaker, as the CID sentence, CNC word, and SPIN sentence tests used videotaped material of an unfamiliar speaker.

Good results for simple closed set speech discrimination tasks have been reported for single electrode cochlear prostheses; however, consistent open set speech results have not been possible. With the multiple channel prosthesis, using the speech-processing strategy developed at the University of Melbourne, consistent open set results are possible (Table 3). All patients obtain significant recognition of phonemes.
in monosyllables (Arthur Boothroyd test), and all patients except patients 5 and 6 recognize significant levels of spondees, monosyllables, and key words in everyday sentences. The results for patients 1, 3, 4, and 7 are to our knowledge the best reported for any set of cochlear prosthesis patients on these particular tests. Patients 5 and 6 who performed poorly on the open set tests both have limited multiple channel systems compared with the other patients due to their etiologies. Patient 5, whose overall results are considerably poorer, has a system that is virtually single channel. The patients who performed best on the open set testing (1, 3, 4, and 7) all show a greater than 100% improvement in communication speed on the speech-tracking task. Patients 4 and 7 have been able to perform speech tracking at rates of 20 and 16 words per minute, respectively, using the cochlear prosthesis without lipreading.

In assessing the benefit of the cochlear prosthesis it is necessary to consider not only the results of formal tests but to look at how the prosthesis affects the patients' everyday life. The most obvious question to consider is, how much do the patients use the wearable device? At this time six of the eight patients use the device during all waking hours each day (10-14 hours). The other patients use their prosthesis approximately four hours daily.

Although the present speech-processing strategy is designed specifically to help patients with speech understanding, a major part of the benefit to patients has been in the detection, discrimination, and recognition of environmental sounds. Patients have reported hearing and recognizing a wide variety of sounds including airplanes, clocks ticking, cars passing, kettles whistling, doors squeaking, and so on. The patients report that many of these sounds are similar to what they remember from their previous auditory experience although many sound strange.

Patient 4 is able to routinely carry out simple telephone conversations. Her ability to do this has been assessed in a number of rehabilitation sessions, and she was able to obtain a score of 58% on CID sentences over the telephone with one repeat of each sentence (unfamiliar speaker). Patients 1, 3, 6, and 7 have also used the telephone with some success, but cannot cope with an interactive conversation at this stage.

The results for these patients are comparable with results obtained with an acoustic simulation of the multiple channel cochlear prosthesis using the same speech-processing strategy with three normally hearing subjects. This suggests that the cochlear prosthesis patients are doing as well as might be expected with the information they are receiving. The present implanted device is sophisticated enough to provide more complex speech-processing strategies when more advanced external hardware is developed. Psychophysical and speech research is underway to assess new ways of providing more speech information to patients, and it is expected that improved speech recognition will be possible in the near future.

CONCLUSION

This study has indicated that the multiple channel cochlear prosthesis can give considerable benefit to profoundly postlingually deaf patients from a wide range of ages and etiologies, not only as a lipreading aid, but with the potential for significant open set speech discrimination without lipreading. Factors such as age, length of deafness, and pathology appear to contribute to overall performance along with motivational and social aspects. However, it would be premature at this stage to generalize about these factors until more patients have undergone the procedure. The Nucleus prosthesis has been shown to perform reliably. All of the devices implanted have operated without problem and are in daily use at the present time.

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