Clinical trial of a multiple-channel cochlear prosthesis

An initial study in four patients with profound total hearing loss

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ABSTRACT: The clinical trial of a multiple-channel cochlear prosthesis was undertaken in four patients with postlingual deafness and profound total hearing loss. The results of open-set speech tests confirmed that, using electrical stimulation alone, one patient could have a meaningful conversation without resorting to lipreading (for example, this patient uses the prosthesis to converse with her husband on the telephone). The

results of closed-set speech tests also suggested that a multiple-channel stimulator is more effective than a single-channel one in conveying speech information. The cochlear prosthesis was especially effective in all four patients when it was used in conjunction with lipreading, and speech-tracking tests showed that the patients could combine the information obtained from both electrical stimulation and lipreading.

(Med J Aust 1983; 2; 430-433)

PATIENTS with profound total hearing loss cannot hear even with modern and powerful hearing aids. Researchers have been trying for years to develop sensory prostheses that would help such patients to understand speech, using electrical stimulation of residual auditory nerves, or mechanical and electrical stimulation of the skin, or by presenting speech as visual patterns. However, electrical stimulation of residual auditory nerves has advantages over the other methods, because the sensations are perceived as sound, and the auditory neural pathways are more appropriate for sending this information to the higher speech centres.

Over the last two decades, there have been increasing efforts to help patients hear speech by implanting one or more electrodes in the cochlea and stimulating the auditory nerves electrically. These cochlear prostheses are intended to present speech through one or more channels of electrical stimulation. With some systems, speech sounds are presented as a single-channel stimulus to the auditory nerve.^{1,3} As there are limitations to the speech information that can be conveyed through only one channel of stimulation, research

has also been carried out on the use of multiple-channel systems, which excite different groups of auditory nerve fibres. Multiple-channel stimulation is more likely to help patients to hear speech, because it can convey more information,⁴ and the response to it is more consistent with the findings of current psychological and speech research. For example, the higher frequencies of speech, in particular, excite different areas of the cochlea. Therefore, the hearing of consonants which contain high frequencies and convey a great deal of speech information requires multiple-channel stimulation.

Two multiple-channel systems have been evaluated. In the first system speech is filtered into different frequencies, and these excite appropriate electrodes along the cochlea.^{5,9} In the second system the important concentrations of frequency energy in speech, called formants, are analysed and presented to appropriate electrodes along the length of the basal and middle turns of the cochlea.^{10,11} These formants are very important for speech intelligibility and, when coded as an appropriate multiple-channel electrical stimulus, gave encouraging results in two patients with postlingual deafness who underwent operations in 1978 and 1979, respectively, at the Royal Victorian Eye and Ear Hospital, Melbourne.^{12,13}

We then undertook a series of biological studies to evaluate the long-term safety of the implantable electrode array and receiver-stimulator. These studies showed that there was no loss of auditory nerve fibres over the operating range of the cochlear prosthesis,^{14,15} and that tissue side effects were minimal, provided infection did not occur.¹⁶

As such research work had established that a multiple-channel cochlear prosthesis was safe and effective in

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providing significant help for patients with postlingual deafness and profound total hearing loss, there was then a need to miniaturize both the implantable receiver-stimulator and the wearable speech-processor, and manufacture them for the benefit of a greater number of patients. This was undertaken by the Australian biomedical firm, Nucleus Limited*, and the initial clinical trial of the device is reported in this study. It was carried out in accordance with the guidelines for human experimentation laid down by the National Health and Medical Research Council of Australia and the Helsinki Declaration of 1975.

Methods and patients

The receiver-stimulator and electrode array for implantation are shown in Figure 1. The silicon chip, which contains the equivalent of 2000 transistors for varying the stimuli to the 22 electrodes in the cochlea, is enclosed in a hermetically sealed titanium capsule. The sealing process is based on heart-pacemaker technology, and ensures that corrosive body fluids are unlikely to enter the container and cause electronic failure. Power and coded speech signals are transmitted to the receiver-stimulator through the intact skin by radio waves, and are picked up by the coil mounted around the titanium capsule. The signals are then relayed down the electrode array to appropriate combinations of the 22 electrodes in the cochlea for the stimulation of discrete groups of residual auditory nerve fibres. The electrode array is robust — mechanical vibrations produced by body movement should not cause electrode breakages. When tested by a procedure similar to that used for heart-pacemaker leads, the electrode array could withstand repeated flexing more than seven million times.

The speech-processing unit for the multiple-channel prosthesis is shown in Figure 2. When a person speaks to the patient, the sounds are picked up by a microphone and relayed to the speech-processor worn in a pocket or on a belt. This processor extracts the voicing frequency and the frequency of sound energy in the range from 750 Hz to 4000 Hz (sound formant), converts voicing frequency to rate of electrical stimulation, and refers the second formant to an appropriate electrode site. This information is then passed to the coil on the head band and transmitted through the intact skin to the underlying receiver coil on the implanted device (Figure 1) by inductive coupling at radio frequencies. This coded information, together with the power to energize the implant, is then decoded by the receiver-stimulator unit, and electrical currents activate appropriate combinations of electrodes along the scala tympani of the cochlea. This information is then conveyed to the higher auditory centres, and is interpreted as speech-like sounds.

FIGURE 1: The multiple-channel cochlear implant and electrode array.

FIGURE 2: The speech-processing unit of the multiple-channel cochlear prosthesis.

Preoperative clinical findings.

The four patients in this clinical trial had the following clinical histories:

Patient 1 was a 36-year-old man who had been profoundly deaf for 15 years after the administration of streptomycin for burns. He had received no benefit from a hearing aid.

Patient 2 was a 62-year-old woman who began to lose her hearing gradually in her teens, after recurrent frequent attacks of otitis media. Her hearing deteriorated further during pregnancy and, in her early thirties, she was profoundly deaf in both ears. At that time she had received no benefit from a hearing aid.

Patient 3 was a 22-year-old woman who suddenly lost her hearing and became totally deaf after bacterial meningitis four years before implantation surgery.

Patient 4 was a 23-year-old woman who gradually lost her hearing because of chronic otitis media which had required a number of reconstructive middle-ear operations. She had suffered from profound total hearing loss for nine years.

All patients were given a trial with an appropriate hearing aid, with a conventional earphone or a bone vibrator, for a period of six months. In addition, the residual auditory nerves were electrically stimulated with a needle inserted into the promontory of the cochlea through the tympanic membrane, to ensure that functioning nerves were present. Polytomographic X-ray films of the cochlea were also taken to establish that the cochlear turns were patent and had not been replaced with bone.

Surgery

The surgery was carried out at the Royal Victorian Eye and Ear Hospital, Melbourne, using a horizontal laminar flow unit and a strict aseptic routine to minimize the risk of postoperative infection, which is always increased when foreign material is implanted in a patient. The mastoid and occipital bones were exposed by raising skin and fascial flaps behind the ear. The mastoid air cells were removed, and a bed was drilled in the bone to accept the receiver-stimulator unit. The bundle of 22 electrodes, with an outside diameter of 0.6 mm, was then gently inserted along the scala tympani of the basal turn of the cochlea by means of a special microclaw.

After the operation, all patients made a good recovery. They did not experience any vertigo, were ambulatory on the day after surgery, and were discharged from hospital five to seven days after the operation.

Postoperative tests of speech perception

Two weeks after the operation, the patients returned for their first test session. This involved a series of psychophysical tests to determine the stimulation threshold, comfortable loudness level, and dynamic range for each electrode, as well as pitch ranking for all electrodes. This was carried out using a special diagnostic and

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FIGURE 3: A patient using the multiple-channel cochlear implant and speech processor to converse with an audiologist. The diagnostic and programming unit for establishing a patient's individual speech-processor requirements is shown in the background.

programming unit manufactured by Nucleus Limited. The individual parameters obtained were then programmed onto a silicon chip in the patient's speech-processor. This allowed optimal speech-processing management for any individual variations in patients' responses. By means of specially developed computer programmes, the whole procedure, which previously had required several months, could be completed in a few hours. The test set-up, showing a patient with an audiologist using the diagnostic and programming unit, is shown in Figure 3. After the patients' individual requirements had been programmed into their speech-processors, they began to attend sessions designed to help them learn to use new speech sounds.

After a few weeks of rehabilitation, the ability of each patient to hear speech and communicate was assessed by means of the Arthur Boothroyd (AB) word test,¹⁷ the Monosyllable-Trochee-Spondee (MTS) test,¹⁸ and speech tracking.¹⁹

In the AB test, three lists, each consisting of 10 consonant-vowel-consonant single-syllable words (30 phonemes), which contained phonemes in similar proportions, were given to each patient. As the test had not been presented to the patients previously, they had no prior knowledge of the words they would be hearing (an open-set test).

In the MTS test, there were four monosyllabic, four trochaic, and four spondaic words. Monosyllables consist of a single syllable (for example, "cat"); trochees are two-syllable words with the stress on the first syllable (for example, "doctor"); and spondees are two-syllable words with equal stress on both syllables (for example, "toothpaste"). In carrying out the closed-set tests, the patients had a list of the words in front of them, and heard each item once before the test began. Each of the 12 words on the list was presented twice in random order for a total of 24 presentations.

Finally, speech-tracking tests were undertaken to make a more direct measure of the patient's abilities in understanding speech. These tests were carried out by means of lipreading alone, as well as lipreading in conjunction with the multiple-channel cochlear prosthesis. This was done to determine whether the hearing improvement produced by electrical stimulation alone also occurred when combined with lipreading.

The tracking test was carried out by an audiologist reading from a book at a normal rate. After each passage, the patient repeated the words verbatim; if a mistake occurred, the audiologist adopted various strategies until the word was correctly identified. The patient's performance was measured by averaging the number of words repeated correctly per unit of time over a number of sessions.

Results

The results of the AB test (Table 1) were scored as the percentage of either words or phonemes correctly identified. (For example, if the word "bone" was presented, it could either be correctly identified as the word "bone", or, if only one or two phonemes are heard, it could be interpreted as "beam" or "phone".) The phoneme score, as well as the word score, is relevant, as it indicates the ability of the patient to understand speech.

In the MTS test, the responses were analysed as the percentage of words correctly recognized, or the stress categories (monosyllables, trochees, and spondees) correctly identified and measured as a percentage (Table 1).

The speech-tracking results in Table 2 show the improvement in speech perception when the multiple-channel cochlear prosthesis was used in combination with lipreading.

TABLE 1: Results of tests with multiple-channel electrical stimulation alone

Proportion of correctly identified items				
	Patient 1	Patient 2	Patient 3	Patient 4
AB open-set word test ¹⁷				
Words	10%	0	37%	33%
Phonemes	40%	30%	66%	63%
MTS closed-set word test ¹⁸				
Words	79%	96%	83%	100%
Stress	100%	100%	83%	100%

TABLE 2: Results of the speech-tracking test

Tracking (words per minute)			
Patient	LRA	LR + CP	Improvement
1	16.6	33.6	102%
2	19.6	31.6	60%
3	25.8	52.0	101%
4	21.8	48.1	126%

LRA = lipreading alone.
LR + CP = lipreading plus multiple-channel cochlear prosthesis.

Discussion

The open-set AB test word scores of 10%, 0, 37% and 33% with electrical stimulation alone are significant. It is known that there is a reasonable correlation between the word score and the ability to understand speech. For example, with a 50% score, a patient should readily understand speech, and, even with a 25% score, a patient should be able to comprehend simple speech which deals with familiar material.²⁰ Our results therefore indicate that, with the multiple-channel cochlear prosthesis, Patients 3 and 4 in particular should be able to have a meaningful conversation without any help from lipreading. This was consistent with the observation that Patient 4, for example, can converse with her husband over the telephone.

The results compare favourably with those obtained in

our first patients, who underwent operations in 1978 and 1979 respectively. In these patients, word scores with electrical stimulation alone were 10% and 0; both had phoneme scores of 20%.¹² Both patients, however, received considerable help from their prostheses when they were used in conjunction with lipreading, as did the patients reported here.

The results of the MTS test are further evidence of the value of the multiple-channel cochlear prosthesis in providing speech information. They are also useful in comparing the value of single versus multiple-channel stimulation. In our study, the average scores for the four patients were 90% for words and 96% for stress. In another study which was carried out in a similar manner to ours, 37 patients with single-channel electrical stimulation alone were assessed. The scores were 33.8% for words and 72.4% for stress.²¹ Although the numbers of patients in these two studies are very different, the findings suggest that more speech information is provided through multiple-channel stimulation than through single-channel stimulation. These results are consistent with our previous findings, which also showed that multiple-channel stimulation was superior to single-channel stimulation.^{22,23}

Finally, the speech-tracking tests show that patients were able to combine the information obtained with electrical stimulation with that obtained from lipreading in speech perception. The poorer speech-tracking results in Patient 2 may indicate the need for additional rehabilitation exercises.

Acknowledgements

We wish to acknowledge with gratitude the financial support provided by a public-interest grant from the Department of Science and Technology of the Commonwealth Government of Australia to Nucleus Limited, the National Health and Medical Research Council of Australia, and the Deafness Foundation of Victoria. We would like to thank Mr D. Money, Mr J. F. Patrick, Mr P. Crosby, Mr J. Kuzma and Dr M. Hirshorn from Nucleus Limited for their support; Mr J. Ridler for computer-programming assistance; members of the Royal Victorian Eye and Ear Hospital for their help and cooperation; Mr M. Harrison and Mr G. Cook for technical assistance; Dr B. Franz, Dr D. W. Marty, Dr S. Kleid, and Mrs A. Brock for their help in the management of patients; Mrs H. Hodgins for the assistance in preparation of the manuscript; and Mr G. Lier and Mrs G. Grant for the photography.

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Title:

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Date:

1983

Citation:

Clark, G. M., Dowell, R. C., Brown, A. M., Luscombe, S. M., Pyman, B. C., Webb, R. L., et al. (1983). Clinical trial of a multiple-channel cochlear prosthesis: an initial study in four patients with profound total hearing loss. Medical Journal of Australia, 2, 430-433.

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