The Clinical Trial of a Multi-Channel Cochlear Prosthesis

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The results of a multiple-electrode cochlear implant carried out on 1st August, 1978 on a totally deaf patient (post-lingual hearing loss) showed that he could perceive sounds of different pitches depending on the electrode stimulated, and this finding was consistent with the place theory of frequency coding. Furthermore, stimulating individual electrodes produced percepts which the patient described as vowel-like in quality. The patient could also perceive different pitches which varied with the rate of stimulation up to 200 pulses/second, but at higher rates he had difficulties perceiving pitch changes (Clark et al. 1978; Tong et al., 1979).

As a result of the psychophysical studies a speech processor was developed. The speech processor extracted: firstly, the voicing frequency to help the patient hear the rhythm of speech and know whether a speech sound was voiced or unvoiced (e.g., /b/ versus /p/); and, secondly, the second formant to enable the patient to recognize vowels and consonants and so hear words. In order to maximize speech intelligibility, the second formant stimulated an appropriate electrode, and the rate of stimulation on that electrode was related to the voicing frequency.

The speech processor was evaluated on the above patient, and also on a second post-lingually deaf patient with a profound hearing loss, implanted on 17 July, 1979. A number of closed and open-set audiological tests were carried out on both patients to adequately evaluate their abilities in perceiving speech. The results, which have been summarized (Clark and Tong, 1982), showed that the multi-channel cochlear prosthesis produced very significant improvements in communication when used in conjunction with lipreading, compared to lipreading alone. The first patient in particular could also have a limited conversation on familiar subjects when using the prosthesis alone without lipreading. In addition, the tests also showed significantly better results for multi-channel compared to single-channel stimulation (Clark et al., 1981; Clark et al., in press — a).

In view of the encouraging results obtained with the initial device, a multi-channel cochlear prosthesis was manufactured by the Australian biomedical firm, Nucleus Limited. This prosthesis is smaller and more reliable than the original prototype, and has recently been evaluated in a clinical trial on four post-lingually deaf patients with a profound-total hearing loss who had the prosthesis implanted over a period of three months from September to November, 1982. Two additional patients are also being evaluated.

The new multi-channel cochlear prosthesis and its clinical trial are described in this paper.

THE MULTI-CHANNEL COCHLEAR PROSTHESIS

The multi-channel cochlear prosthesis receiver stimulator unit, manufactured by Nucleus Limited, is shown in Figure 1. The electronics, which contain the equivalent of 2,000 transistors on a single chip, are enclosed in a hermetically-sealed titanium capsule having a diameter of 20mm and thickness of 5mm.

Electrical power and coded speech signals are transmitted through the intact skin at radio frequencies to the antenna which encircles the capsule. It enters the titanium capsule through

![Fig. 1: The multi-channel cochlear prosthesis receiver stimulator unit with connector and 22 electrode array manufactured by Nucleus Limited (14 Mars Road, Lane Cove, 2066).](image-url)
a special ceramic seal that has been modified from heart pacemaker technology to prevent body fluids entering the electronics package. There are also 22 stimulating electrodes which exit through special ceramic seals, and these make contact with the 22 electrode array by means of a connector screwed into the titanium capsule. The proximal electrode array has been specially strengthened to make it robust and reduce the chance of fractured electrodes occurring many months later due to small repeated head movements. The whole unit is enclosed in a medical grade silastic to make it biocompatible.

Fig. 2: The wearable speech processor: microphone and transmitter coil.

The external unit for the prosthesis is shown in Figure 2. Speech is picked up by a microphone worn behind the ear or on a head band, and the electrical signals sent to the speech processor unit. The unit is powered by three AA cells and is worn in a pocket or on a belt. It has dimensions of 13.0cm, 7.5cm, 1.8cm, and a weight of 210g including batteries. It has two external controls. The first control has a silent mode where there is a switch which comes on automatically at a predetermined level of background noise, while in the normal mode all sounds detected are processed. The second control provides five sensitivity levels, and a test position for use when aligning the transmitter coil over the implanted receiver coil. There is also a socket to enable the patient to plug in a hand-held microphone to maximize the speech perceived in small group conversations. This socket is also used to connect to a television set or other external device. Power and the coded speech signals are then transmitted from an external coil worn on a head band to the underlying antenna of the implanted receiver stimulator unit.

PATIENT SELECTION AND EVALUATION

All four patients were post-lingually deaf with a profound-total hearing loss, and had 0% open-set speech discrimination scores. They had received no significant benefit from a powerful hearing aid or vibrotactile device after a six-month trial period. There were no medical or radiological contraindications to surgery, and electrical stimulation of the promontory produced positive results. The patients were all independently reviewed by an ethics committee to ensure that they had received adequate counselling, and that their expectations were realistic. A series of speech discrimination tests, including a modified version of the Minimal Auditory Capabilities (MAC) test battery (Owens et al, 1981), were carried out after the six-month trial with the powerful hearing aid or vibrotactile device so that these pre-operative results could be compared with those obtained post-operatively with the cochlear prosthesis.

Patient 1 was a 37-year old male who developed a severe hearing loss at the age of five following the administration of streptomycin for burns. At the time he had complete loss of hearing in the right ear, but some useful hearing in the left. When he was 21 he suddenly lost hearing in the left ear, and was then totally deaf.

Patient 2 was a 62-year old female who lost hearing gradually following recurrent otitis media as a teenager. When she was pregnant in her early thirties there was a further deterioration in her hearing, and she was then no longer able to receive any benefit from a hearing aid.

Patient 3 was a 22-year old female who became totally deaf following an attack of meningitis at the age of 18.

Patient 4 was a 23-year old female who gradually lost hearing following recurrent bouts of otitis media as a child and later required a number of tympanoplasty operations to repair perforations of the tympanic membrane and restore the ossicular chain. She had been profoundly deaf for nine years and obtained no benefit from a hearing aid during that period.

COCHLEAR IMPLANT SURGERY

The surgery was undertaken in a horizontal laminar flow of filtered air, and with a strict aseptic routine. This is desirable as the implantation of foreign material carries a higher risk of post-operative infection. The success of the operation. The temporal and occipital bones were exposed by elevating an inferiorly based flap of skin and subcutaneous tissue, and an anteriorly based flap of deep fascia, muscle attachments and periosteum. The mastoid cells were exenterated, the vertical segment of the facial nerve skeletonized, the posterior tympanotomy completed and the round window niche inspected. The cortex over the mastoid tip was preserved to later protect the electrode array.

A bed for the receiver stimulator capsule was then created in the mastoid and occipital bones. It was sited so that the anterior edge of the package would be at least 1cm behind the incision in the postaural sulcus. A diamond paste milling burr was found useful in making a circular bed with straight sides to stabilize the package. After creating fascial flaps to cover

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the capsule and ensuring haemostasis, holes were drilled in the mastoid cortex to place Dacron mesh stay sutures that were used to fix the electrode array in a groove beneath the cortical bone. The bony overhang of the round window was then drilled away. The round window membrane was incised antero-inferiorly and a good view along the basal turn of the cochlea was obtained.

The package was held in one hand and the electrode array gently inserted along the scala tympani of the basal turn. The insertion was facilitated with a specially designed microclaw. The stay sutures were tightened to hold the electrode array in place, and fascia placed around the electrodes in the round window. The wound was irrigated with a dilute solution of Ampicillin and Cloxacillin, and the wound closed in layers. The pre-operative antibiotics which were commenced at the start of the operation were continued for three to four days.

All the patients in the clinical trial made a good post-operative recovery, had no wound infection, were free of vertigo, and went home five to seven days after surgery (Clark et al., in press - b).

CLINICAL RESULTS

The patients returned for their first post-operative test session two to three weeks after discharge from hospital. At the first test session all electrodes were tested and the thresholds, comfortable loudness levels and dynamic ranges for each electrode determined. In addition, the patient was asked to rank the pitches perceived at each electrode. All this information, which can vary for individual patients, was then put onto a programmable read only memory (PROM) silicon chip in the patient's speech processor. This was done using a diagnostic and programming unit. In this way, multiple-channel stimulation could be optimised for individual patients and make allowance for variations in the electrode placement and individual nerve fibre populations.

The patients then had a course of rehabilitation in the use of the prosthesis which lasted for two to three months. Following the course they were assessed with a number of speech perception tests to see how well they could communicate. A series of tests were used as no one test is adequate in evaluating how the patient can be helped in their everyday life.

Finally the MAC battery was repeated using the cochlear prosthesis alone so the results would be compared with those obtained pre-operatively when using a hearing aid or bone vibrator. The results when analyzed statistically showed the cochlear prosthesis was significantly better than the hearing aid or bone vibrator on 13 of the 16 tests. The exceptions being the male/female speaker, question/statement, and environmental sound test, where both devices performed equally well.

The audiological tests included open-sets of Arthur Boothroyd (AB) phonetically balanced words, the closed-set Monosyllable-Trochee-Spondee (MTS) test, open-sets of spondees, open-sets of CNC phonetically balanced monosyllabic words, open-sets of Central Institute for the Deaf (CID) everyday sentences, open-sets of speech perception in noise (SPIN) sentences, and speech tracking tests (Clark et al., submitted; Dowell et al., submitted). In most cases they were presented under the three conditions: cochlear prosthesis alone, lipreading alone, and cochlear prosthesis combined with lipreading. They were also administered for most tests with prerecorded material using an unfamiliar speaker.

The results of most interest are those obtained for open-set phonetically balanced (PB) words, open-set CID sentences, and open-set spondees (Clark et al., submitted). These were difficult tests, especially as prerecorded material and unfamiliar speakers were used. Furthermore, they were open-sets, and the patients were not previously tested with the words. The results are shown in Table I. From this, it can be seen that, when using the cochlear prosthesis alone, the PB word scores varied

<table>
<thead>
<tr>
<th>TABLE I</th>
</tr>
</thead>
<tbody>
<tr>
<td>OPEN-SET SPEECH TESTS</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>TEST</th>
<th>CONDITION</th>
<th>1</th>
<th>2</th>
<th>3</th>
<th>4</th>
</tr>
</thead>
<tbody>
<tr>
<td>PB monosyllabic word test</td>
<td>CPA</td>
<td>8%</td>
<td>2%</td>
<td>6%</td>
<td>14%</td>
</tr>
<tr>
<td></td>
<td>LA</td>
<td>32%</td>
<td>16%</td>
<td>42%</td>
<td>26%</td>
</tr>
<tr>
<td></td>
<td>L+CP</td>
<td>60%</td>
<td>38%</td>
<td>62%</td>
<td>68%</td>
</tr>
<tr>
<td>CID everyday sentence test</td>
<td>CPA</td>
<td>2%</td>
<td>4%</td>
<td>4%</td>
<td>38%</td>
</tr>
<tr>
<td></td>
<td>LA</td>
<td>82%</td>
<td>70%</td>
<td>72%</td>
<td>74%</td>
</tr>
<tr>
<td></td>
<td>L+CP</td>
<td>98%</td>
<td>90%</td>
<td>90%</td>
<td>100%</td>
</tr>
<tr>
<td>Spondee</td>
<td>CPA</td>
<td>26%</td>
<td>4%</td>
<td>22%</td>
<td>32%</td>
</tr>
</tbody>
</table>

(CPA - Cochlear prosthesis alone; LA - Lipreading alone; L+CP - Lipreading plus cochlear prosthesis.)
from 2%-14% and for the CID sentence test from 2%-38%. In all cases there were significant improvements when using the cochlear prosthesis combined with lipreading compared to lipreading alone. The spondee test which was administered as an open-set, also gave good results for the cochlear prosthesis alone. The results are interesting as open-set word recognition has not been obtained with single-channel stimulation, and although they show that communication with electrical stimulation alone is difficult this should improve as the full potential of multi-channel stimulation has not been explored. Furthermore, the results in patient 4 in particular were most encouraging, and suggest that she should be able to converse on familiar topics using the cochlear prosthesis alone without any help from lipreading. This, in fact, is the case, as she is able to use the prosthesis to have a meaningful conversation on the phone, not only with her husband but other people. She can do this by hearing speech and not by the detection of pre-arranged signals. Finally, the value of the device can also be assessed by the number of hours a day the patients find it useful. In the present trial all four patients are using the prosthesis all the time while they are at work or at home.

CONCLUSION

This clinical trial has shown that a multi-channel cochlear prosthesis can provide significant help for post-lingually deaf patients with a profound-total hearing loss, and as its potential has not been fully explored it can be expected that further improvements should be possible in the future.

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