The clinical assessment of cochlear implant patients

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Introduction

THIS paper is a discussion of the clinical assessment routine adopted following experience gained over the last three years from evaluating 27 patients with severe sensori-neural deafness to determine whether they are suitable for the cochlear implantation of a multiple-electrode receiving and stimulating device developed jointly in the Departments of Otolaryngology and Electrical Engineering at the University of Melbourne.

It is considered that although there have been many advances with cochlear implant surgery, it has still not become fully established. Therefore, only a small number of patients should be operated on and thoroughly assessed before and after surgery, and we have selected 5 from the original 27 patients.

It is now generally accepted that hearing prostheses should be multiple-electrode systems, with data and power transmitted through intact skin to the receiver-stimulator device from the processor-transmitter unit. For this reason the implant surgery needs to be carried out in centres where the appropriate electrical engineering support is available.

Furthermore, as a variety of detailed pre-operative and post-operative tests are also needed, patients suitable for this procedure need to be assessed in centres where there is an inter-disciplinary team whose members have experience in acoustic phonetics, audiology, auditory physiology, electrical engineering, information science, otology, physics, psychology, psychoacoustics and speech rehabilitation.

Finally, the procedure should be carried out in accordance with the recommendations guiding doctors in clinical research laid down at the Declaration of Helsinki (1964). It is also our practice to abide by the Statement on Human Experimentation published by the National Health and Medical Research Council of Australia (1976).

In the sections that follow, it should be understood that the sex of the patient is immaterial, and that the personal pronoun 'he' is used in its general sense.

Medical assessment

Clinical history

In taking the clinical history, consideration is given to the patient's general suitability and medical condition, and the nature of the ear

pathology. In particular, it is necessary to determine his domestic situation in order to be sure he can attend test sessions regularly for a number of months before and after surgery. It is particularly important that patients should be available for testing and rehabilitation for a considerable period post-operatively, otherwise it is not desirable to embark on surgery. Other factors to consider are whether the patient is pre-lingually or post-lingually deaf, whether the deafness was of sudden or slow onset, and the length of time it has been present, previous languages spoken, the level of speech comprehension in each ear, the degree of success with lip reading, the nature of previous hearing aid fitting and counselling, the type of auditory experiences that are missed, his expectations from a cochlear implant, and his apparent psychological state.

A clinical history to help determine the nature of the ear pathology is very important as there are no really satisfactory tests to assess the presence of residual functioning auditory nerve fibres. As the nature of the pathology will affect the possibility of residual fibres being present, it is necessary to determine whether the deafness was due to inheritance, various noxious agents in pregnancy, meningitis, the childhood exanthemata, acute and chronic middle-ear infections, non-specific virus infections, Menière's disease, surgery, otosclerosis, trauma or vascular disease. It is also necessary to rule out psychogenic deafness and acoustic neuromas.

It is desirable to know the general state of the ear, nose and throat, and in particular the condition of the external and middle ears, and the function of the Eustachian tube. The general medical condition of the patient also needs assessment, and evidence of cerebral arteriosclerosis or other diseases affecting the central nervous system must be looked for, as patients with impaired cerebral function should not be normally considered for the procedure. If there is any doubt about the psychological state of the patient a psychiatric opinion needs to be obtained.

Clinical examination

The clinical examination of the ear, nose and throat should be carried out to help determine the hearing status, the nature of the underlying pathology, the condition of the external and middle ears, and the function of the Eustachian tube. It is also important to assess the width of the external auditory meatus, the condition of the tympanic membrane, the size of the mastoid process, the curvature of the mastoid portion of the temporal bone and the thickness of the skin and other soft tissues overlying the temporal bone, as these anatomical points are all important in relation to the implant operation.

Vestibular function should be evaluated, and a thorough examination made of the nervous system with special reference to the cranial nerves. It is desirable to measure the patients' visual acuity as this may have a bearing on their ability to lip read, and cope with post-operative re-

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habilitative measures. It is also necessary to make a complete medical examination to exclude intercurrent disease that may affect the patient's capacity to complete the course of treatment and evaluation.

Finally, it is important to carry out a laboratory examination for syphilis. For this purpose a test for lipiodophil antibody (Venereal Disease Research Laboratory test), the absorbed fluorescent Treponemal Antibody Test (FTA, ABS) and an indirect haemagglutination test (Cruickshank *et al.*, 1975) are carried out routinely.

Radiological assessment

The radiological assessment of the ear and temporal bone is also important as it enables a pre-operative assessment to be made of any surgical difficulties that might be experienced due to anatomical variations or underlying pathology. Anatomical variations that may cause difficulty in the correct placement of the implant receiver are: the size and extent of the mastoid air cells and in particular the posterior extension of the sigmoid sinus cells, the forward extent of the sigmoid sinus, the curvature of the mastoid portion of the temporal bone, the thickness of the overlying mastoid cortex, the lower limit of the middle fossa, the course of the descending portion of the facial nerve, and the orientation of the external auditory canal. These variations are best assessed in a routine Schuller view, and anteroposterior polytomes.

Polytomes are also of importance in assessing anatomical variations that are relevant to the cochlear electrode implantation. In particular, the width of the aditus to the round window and patency of the cochlear aqueduct can be seen in anteroposterior polytomes, the thickness of the bone overlying the apical and middle cochlear turns in axiopyramidal views, and the distance of the apical and middle turns from the oval window in lateral views.

Pathology in the middle ear, mastoid air cells and temporal bone can also be seen in the polytomes, and routine Schuller, Towne and basal X-rays. In particular, it is important to look for obliteration of the turns of the bony cochlea, poor aeration of the middle ear and mastoid air cells, destruction of the ossicles, evidence of chronic infection of the mastoid, signs of other disease of the temporal bone such as otosclerosis, and the presence of an acoustic neuroma.

Audiological assessment

The audiological assessment is carried out to help determine the nature and extent of the hearing loss, and the disability the patient has in communication. When the hearing loss is very severe, however, this will make it difficult to perform all the procedures discussed below. Furthermore, the patient's hearing aid and experience with aural rehabilitation methods

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are evaluated to make sure that nothing else can be done to improve his ability to hear and communicate with others.

Pure Tone Audiometry:

Pure tone air and bone conduction thresholds under headphones, together with free field pure tone thresholds with and without a hearing aid, are carried out in the early stages of the assessment so that patients with too much hearing can be screened out of the program. These thresholds are also measured at the completion of the pre-operative evaluation to determine whether there has been any alteration in hearing acuity. As patients suitable for cochlear implants have very high thresholds, it is important that the earphones and loud speakers have an adequate output response at high intensities.

Audiometry to Assess Cochlear vs. Retrocochlear Pathology:

The tests are necessary as cochlear is more likely than retrocochlear pathology to be associated with intact auditory nerve fibres suitable for electrical stimulation. Consequently, to help distinguish the two, stapedial reflexes, reflex decay, sweep frequency Békésy audiometry with interrupted and continuous tone presentation, short increment sensitivity index (S.I.S.I.), tone decay tests and loudness discomfort levels are attempted. A long off-time Békésy audiogram is also plotted to help exclude non-organic hearing loss.

Impedance Audiometry:

Impedance audiometry is performed primarily to evaluate the condition of the middle ear, and the function of the Eustachian tube. Adequate aeration of the middle ear is a necessary pre-requisite to surgery, otherwise there is a greater risk of infection or the accumulation of fluid in the middle ear and mastoid air cells, and this can produce an unfavourable environment for the receiver and electrodes, and also lead to the loss of residual auditory nerve fibres.

Hearing Aid Assessment:

The assessment of the patient's hearing aid performance is even more important than his lip reading ability, because satisfactory speech comprehension with a hearing aid is a definite contra-indication to a cochlear implant. It is considered desirable that a patient have a trial with an appropriate hearing aid for at least six months, and that he be given counselling during this time. In selecting an appropriate hearing aid, it is also important that the range include aids with a maximum output of 130-135 dB, a maximum gain of 70-75 dB, peak clipping and automatic gain controls, and extended low and high frequency responses.

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Lip Reading Assessment:

Lip reading ability is assessed by presenting a speech test developed in the Department of Otolaryngology, at the University of Melbourne. In this test phonetically balanced words spoken by an Australian with a standard accent are presented on a 16 mm film. The word intelligibility score with and without lip reading is measured at different intensities. In the assessment of lip reading ability, it is also important to determine the amount and quality of training the patient has experienced. If necessary, this should be supplemented so that the patient's handicap can be improved to an optimum level so that his pre-operative and post-operative speech comprehension can be compared more objectively.

Speech Audiometry:

The patient's ability to comprehend speech is a very important factor in the assessment of his suitability for a cochlear implant. For this reason, a battery of speech audiometric tests are carried out. Furthermore, it enables a more accurate assessment of post-operative results to be made.

The tests include the presentation of an AB word list (Boothroyd, 1968) through earphones to each ear separately. This word list has been chosen as it enables a speech audiogram to be plotted more rapidly over a range of intensities. These results are then useful in excluding a retrocochlear lesion, and also in assessing the patient's speech handicap at a range of intensities.

As the assessment of the patient's speech perception with a satisfactory hearing aid is of the greatest importance, these AB word lists are also presented to the patient in a free field situation with the hearing aid set at an optimal gain.

Further assessment of speech perception with a hearing aid is also carried out in a free field situation using phonetically balanced words (PBM), spondee word lists and Central Institute for the Deaf (C.I.D.) sentences, all adapted for Australian conditions by the National Acoustic Laboratories of Australia. An anechoic room is used for free field testing. If there are any discrepancies between the speech tests in the free field situation, the PBM, spondee and C.I.D. tests are presented through the earphones.

Finally, it is considered that a more realistic assessment of speech perception ability in an every day situation is achieved by presenting the AB word lists free field in white noise with a signal-to-noise ratio of 0 dB. If there is difficulty with speech comprehension it is repeated at a 10 dB signal-to-noise level. On the other hand, if there is no difficulty at a 0 dB signal-to-noise level it is given at -10 dB.

Electro-cochleography and Evoked Response Audiometry:

These tests are carried out to confirm that organic hearing loss is

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present. They are also useful in helping to determine whether the loss of hearing is retro-cochlear as it has been shown by Thornton (1976) that latency changes in recordings can indicate a brain stem or auditory nerve lesion.

Electrical Stimulation of the Cochlea and Auditory Nerve:

Electrical stimulation of the cochlea and auditory nerve is carried out to help determine whether there are functioning residual auditory nerve fibres. In adults the procedure is performed under aseptic conditions in an electrically shielded operating theatre, and the electrode tip placed on the promontory. Electrical stimulation is produced with a photo isolation unit, and the threshold currents for square wave pulses at rates of 50, 100, 200, 400 and 800 pulses per second determined, and the stimulus range between threshold and discomfort measured.

Psychological assessment

There are two main reasons for carrying out a psychological assessment of prospective implant patients. The first is to help determine whether the patient can adequately cope with all that is required by the procedure, and the second is to allow a complete evaluation of the results of surgery.

The assessment of the ability of the patient to cope is important as the pre-operative evaluation is extensive and sometimes tedious, requiring his full co-operation. Furthermore, an extensive post-operative evaluation and rehabilitation program will require the patient to work diligently and regularly for many months, and be capable of learning to utilize information in new and demanding ways. This assessment of the patient involves tests of personality, intelligence and the ability to abstract information or form new concepts.

A personality inventory needs to be administered to the patient at an early stage, and if the profile is unsatisfactory the patient should be screened from the program. The California Psychological Inventory (CPI) is used for this purpose, and when for example there are low scores on certain of the scales there should be strong doubts about the likelihood of the patient having the capacity or motivation to apply himself to the task required. On the other hand, a very high score on another scale would suggest that the patient had been attempting to falsify the test or had an inordinate desire to make a good impression. In either case these would be indications of undesirable traits in a prospective implant patient.

Unstructured interviewing and communication with the patient also play a part in his evaluation. Over a number of encounters, the psychologist is able to make a subjective assessment of the patient's motivational level, to appreciate him as a person and learn about his likes, dislikes, interests and hobbies. This latter aspect is important with regard to selecting material for use in a rehabilitation program. Furthermore, all

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members of the assessment team have opportunities to meet the patient and his close relations in a social setting.

The intellectual demands placed on an implant patient are quite considerable. Prior to surgery he needs to attend a regular educational program which includes instruction in how the hearing mechanism functions, the nature of the proposed surgery, the principles underlying the stimulating and receiving devices, and outlines of the evaluation and rehabilitation programs. Close family members are also invited to some of these sessions. The extensive post-operative testing, training and rehabilitation program will also place intellectual demands on the patient. It is, therefore, essential that these patients should perform at or above the average level on standardized intelligence tests. It should, however, be pointed out that in using intelligence tests, the emphasis is not so much on obtaining an I.Q. score, but rather in assessing the patient's ability to perform the necessary intellectually demanding tasks. Any test used must be administered and scored rigorously and objectively, but the subjective observations made in the clinical setting are also of great value in gaining an overall view of the patient's manner and level of functioning.

The Naylor Harwood Adult Intelligence Scale (NHAIS) is an Australian equivalent of the Wechsler Adult Intelligence Scale (WAIS), and thus considered more suitable for administration to our patients. Like the WAIS, the NHAIS consists of a set of verbal tests, and a set of performance tests. One worthwhile aspect of using this test is that inter-set comparison can give an indication of the effect of a hearing loss or its treatment with a cochlear implant on verbal ability. The very first patients considered for an implant should be post-lingually deaf, as they can compare the sensations induced by the stimulating electrodes with their memories of previously heard sounds. Therefore, they are likely to have a satisfactory verbal ability, and no substantial verbal-performance gap. On the other hand, it is with the pre-lingually deaf patients that a large verbal-performance gap can be expected, and the performance levels can have some prognostic significance, as the assumption is made that people who have developed normal performance ability would do equally well in verbal tasks if they had normal experience (Cronbach, 1960), and are therefore more likely to benefit from a cochlear implant.

An impression of certain other aspects of intellectual functioning may also be gained by looking at NHAIS sub-test scores. For example, the block design and object assembly sub-tests measure a factor termed 'perceptual organisation'. Arithmetic and digit span tests seem to strongly involve memory; both immediate memory and recall of previously learned material. The ability to concentrate is probably also involved in the memory factor (Anastasi, 1976).

The Raven's Progressive Matrices test is administered to all prospective implant patients. It can be given as a completely non-language test if

necessary, as it is quite simple to give instructions through miming and demonstration, and is therefore particularly suited for deaf patients. When administered within a set time limit, the Progressive Matrices test gives an indication of the capacity to think logically under stress. Mittler (1970) describes this test, when timed, as a measure of intellectual efficiency. It requires spatial aptitude, inductive reasoning and perceptual accuracy (Anastasi, 1976).

During the learning or rehabilitation stage, the implant patient will almost certainly hear new and complex sound patterns induced by the stimulating electrodes. From these patterns he must learn to abstract information and use only the relevant invariances relating to a particular paired visual stimulus presented to him, which may be a printed syllable, word, phrase or sentence, or a written description or pictorial representation of some other environmental sound. This task is expected to be a very difficult one indeed, certainly of far greater difficulty than that of learning a second language. We are in fact asking the patient to carry out voluntarily the sort of learning which is usually achieved only by young children quite involuntarily at a time when the human organism seems to have an inherent capacity to do so. Furthermore, it is claimed that the ability of deaf people to abstract information is poorer than those with normal hearing.

The ability to abstract information or form new concepts would thus seem of vital importance to the success of the rehabilitation program, and with the use of the Raven's progressive matrices test an assessment of the abstraction capacity can also be made. This test is most appropriate as it also requires the ability to abstract invariances and discard irrelevant dimensions.

In addition, we have chosen to use the Trist-Hargreaves test, which is one using wooden blocks (Semenoff and Trist, 1970). Patients are required to form groups of blocks based on the attributes of shape, shape integrity, top and edge colour and in this way they also abstract invariances with regard to a number of attributes.

Many studies have demonstrated the importance of rhythm in the perception of speech (Dooling, 1974; Martin, 1972; Neisser, 1967). For example, in Dooling's experiments, subjects perceived sentences more correctly if they were of an expected rhythmic rather than syntactic structure. Consequently, there is a need to study the rhythmic ability of the patient, and we have chosen to use the rhythm test of the Seashore Measure of Musical Talents. This test presents a series of two consecutive rhythmic patterns, and patients are asked to report if these are the same or different.

Indications for surgery

When considering the suitability of a patient for cochlear implant surgery, it is important to continually reassess them during the pre-

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operative test program. Adequate time should be made for general discussion so that the patient's expectations of a cochlear implant can be determined, and any misconceptions clarified.

Prospective patients vary a great deal in what they hope for and need from a cochlear implant operation, and great care must be taken to ensure that they are correctly informed about the possible results of the operation.

Providing the patients understand the limitations of the procedure, the indications and contra-indications can be considered under a number of headings. In some cases there are absolute contra-indications, and in others relative ones. If there are no absolute contra-indications to surgery their suitability is a matter of clinical judgement and should be made by a team with appropriate representatives from otology, audiology, psychology and speech rehabilitation. A medical ethics review committee set up for the purpose should also be consulted.

Age

Although congenital deafness is a significant cause of severe sensori-neural hearing loss, children should not have cochlear implant surgery until more is known about the long-term effects of the procedure, and the perceptual correlates of electric stimulation of the auditory nerve fibres.

Pure tone audiograms

At the present stage of development, patients should not be considered for the procedure unless they have a near total hearing handicap (Carhart, 1974). Total hearing loss has been defined by the American Academy of Ophthalmology and Otolaryngology (Davis, 1965) as an average hearing loss greater than 92 dB for the frequencies 500–2,000 Hz. On the other hand, it has been defined by the National Acoustic Laboratories of Australia as a hearing loss greater than 95 dB ISO in both ears at all frequencies from 500 to 4,000 Hz.

Social and domestic situation

As stated above, it is very important that the patient should be available for prolonged post-operative evaluation and rehabilitation before the procedure should be considered. The patient needs skilled rehabilitation by a team of personnel in an appropriate centre because he needs to learn to understand a new sensation. If this cannot be done then the operation should not be performed.

Otological findings

Active infective disease of the middle ear or mastoid cavity is a definite contra-indication to surgery, and any perforations of the tympanic membrane should be repaired before proceeding with the

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operation. Furthermore, if otitis externa is present it should be treated and have resolved.

The nature of the underlying pathology is also an important factor to consider in assessing the patient, as certain clinical conditions can result in the loss of auditory nerve fibres so that there are none suitable for electrical stimulation. For example, it has been shown that some types of inherited deafness and infections of the middle ear can lead to severe loss of auditory nerve fibres (Gacek, 1971, Paparella and Suguria, 1967). In the present state of knowledge, however, the nature of the ear pathology should not preclude the patient from surgery unless an infection has led to the obliteration of the cochlea by bone, which can be seen in appropriate X-rays.

Medical findings

In assessing whether the patient's general medical condition contra-indicates a cochlear implant, it is important to remember that a fairly prolonged and exacting post-operative test and rehabilitation program is normally required. Consequently, patients with medical conditions which require frequent treatment and hospitalization or cause debilitation, should not be considered. Furthermore, patients with diseases which affect the central nervous system and cause loss of concentration and other mental faculties are best not operated on. Otherwise, the assessment should probably be the same as for any routine ear surgery.

Radiological findings

As stated above, radiology is important in determining whether labyrinthitis ossificans is present. If this is the case, an electrode array cannot be passed around the cochlear turns, and drilling directly into the modiolus is also unlikely to be successful, as it is known that the condition is usually associated with a marked or total loss of auditory nerve fibres (Paparella and Suguria, 1967).

The X-rays also help to confirm the presence of acute and chronic middle-ear and mastoid disease, and are useful in finding a large cochlear aqueduct and other anatomical variations which could cause surgical difficulties. Anatomical variations such as an anteriorly placed sigmoid sinus are not absolute contra-indications to surgery as the implant package designed in the Departments of Otolaryngology and Electrical Engineering at the University of Melbourne can be accommodated to the situation. It is desirable, however, to know about the variations in advance as it takes a certain time to make a non-standard receiving device.

Audiological findings

As outlined above, the pure tone audiogram is useful in screening patients from the program who do not have total hearing loss. This is

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important in the present state of development as the beneficial effects of a cochlear implant are not clearly known, and cannot be weighed against those of a hearing aid.

In the final analysis, however, it will be the patient's ability to communicate and understand speech in his normal environment that is the best indication of whether he should have a cochlear implant. For this reason we carry out a number of speech audiograms in a free field situation, with varying signal-to-noise ratios, with and without hearing aids.

With recent developments in hearing aid design, and improvements in hearing aid fitting and counselling, many patients can be given satisfactory hearing, and consequently do not need to have a cochlear implant operation. Therefore, we consider the operation should not be carried out unless these conditions have been met.

Some patients with total hearing loss may appear to be socially adequate because they have an excellent lip reading ability. On further investigation, however, some will have domestic and work situations where their inability to hear is a severe handicap, and they should not be excluded from surgery.

Finally, it is considered that patients who have cochlear rather than retrocochlear audiological findings are more likely to benefit from an implant operation. Until more is known, however, about the factors which lead to a useful prognosis regarding the success of the procedure, patients should not necessarily be excluded on these grounds.

Psychological findings

The results of the psychological tests can be very helpful when taken in conjunction with impressions gained at a series of interviews, and a psychiatric opinion. Patients who have psychotic tendencies, have poor motivation, falsify results or have low intelligence, are best not considered for the procedure. Otherwise, the psychological tests are used to evaluate the patient before and after the procedure so that a better idea may be obtained of the type of patient most likely to benefit, and whether or not there has been an overall improvement in the patient's psychological functioning.

Summary

This study outlines the clinical assessment procedures adopted in the Department of Otolaryngology at the University of Melbourne for patients being considered for a cochlear implant. As the procedure is new and requires rigorous evaluation, it is considered preferable only to operate on a limited number of patients, and ensure that they have a thorough evaluation both before and after surgery. This should be carried out by a team whose members have experience in otology, audiology, aural rehabilitation, acoustics and psychology. The indications and contra-indications for surgery are also outlined.

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