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# **Cochlear implants**

**Anthony R Lea**



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Anthony R Lea

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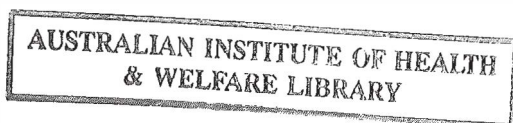
# Foreword

The cochlear implant has become established over the last few years as a novel technology for providing the sensation of sound to the profoundly deaf. Australia has played a major role in the development and application of the cochlear implant. This report has been prepared in view of the interest in the technology, describes its present status, and discusses directions for future research.



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# Summary

- A cochlear implant is a device used to provide the sensation of sound to the profoundly deaf. It includes an implantable receiver/stimulator module with an electrode array (placed either inside or outside the cochlea), a microphone and a speech processor.
- The Nucleus 22 channel cochlear implant is the current market leader. Development of the technology continues to be rapid.
- Profound deafness affects approximately 10,000 to 12,000 adults and 1,400 children in Australia. From this population there is a pool of approximately 2,000 adults and 570 children who are candidates for implantation.
- Over 300 implantation procedures have been conducted in Australia and between 5,000 and 6,000 worldwide.
- The selection criteria to assess the suitability of profoundly deaf adults wishing to receive a cochlear implant are settled, with the possible exception of the criterion for the threshold hearing level applied to severely deafened adults.
- Radiological examination excludes about 30 per cent of potential candidates for implantation. Further refinement of radiology techniques and further understanding of the disease process of both bacterial and viral meningitis would aid implantation teams in deciding when and if the surgery should be performed.
- Nearly all recipients of cochlear implants derive benefit through improved speech perception and by being able to hear environmental sounds. However, individuals derive varying degrees of benefit. Some recipients achieve open speech recognition on sound-only inputs, while others use the device as supplementation to lip-reading. Candidates must be extensively counselled as to the likely outcome of their surgery and rehabilitation.
- Benefits of the technology for pre-lingually deafened children are now emerging, with some achieving open-set speech perception.
- The use of cochlear implants in children continues to be controversial, with the Australian Association for the Deaf opposing both the implantation of pre- and post-lingually deafened children.
- The rehabilitation associated with the program makes a major contribution to the overall cost. However, offsetting savings are derived through the mainstreaming of children within the education system.
- Estimates of the cost of this treatment are approximately \$35,000 and \$25,915 for the first year for four-year-old children and adults respectively.
- Preliminary consideration of cost utility of the technology suggests that it is reasonable value for money.

- In Australia an overall complication rate following surgery of approximately five per cent has been observed. The most common surgical complication is infection/necrosis of the skin flap covering the receiver/stimulator module.
- While some trauma occurs on insertion of the electrode array, continued electrical stimulation does not deplete the numbers of ganglion cells.
- Hearing-impaired people also derive benefit from the use of tactile aids as supplementation to lip-reading and hearing aid inputs. However, the place of tactile devices may be limited by the competition from use of cochlear implants and the amount of rehabilitation required.
- As the numbers of cochlear implant recipients increase, further demands for audiology and other support services may need to be met. Attention may need to be given to the geographical distribution of these services.
- Further research is required in a number of areas, including the disease processes that cause deafness, assessment of the level of benefit from cochlear implants and the costs incurred by society resulting from profound deafness.

# Introduction

The cochlear implant is a device used to provide the sensation of sound to those who are profoundly deaf. It includes an implantable receiver/stimulator module with an electrode array which is placed either inside or outside the cochlea. (Relevant structures of the ear are shown in Figure 1.) The other components of the device consist of a directional microphone and a speech processor. The speech received by the microphone is treated in accordance with a speech processing strategy and a series of signals transmitted to the electrode array via the receiver/stimulator. The person fitted with the implant then perceives a representation of speech.

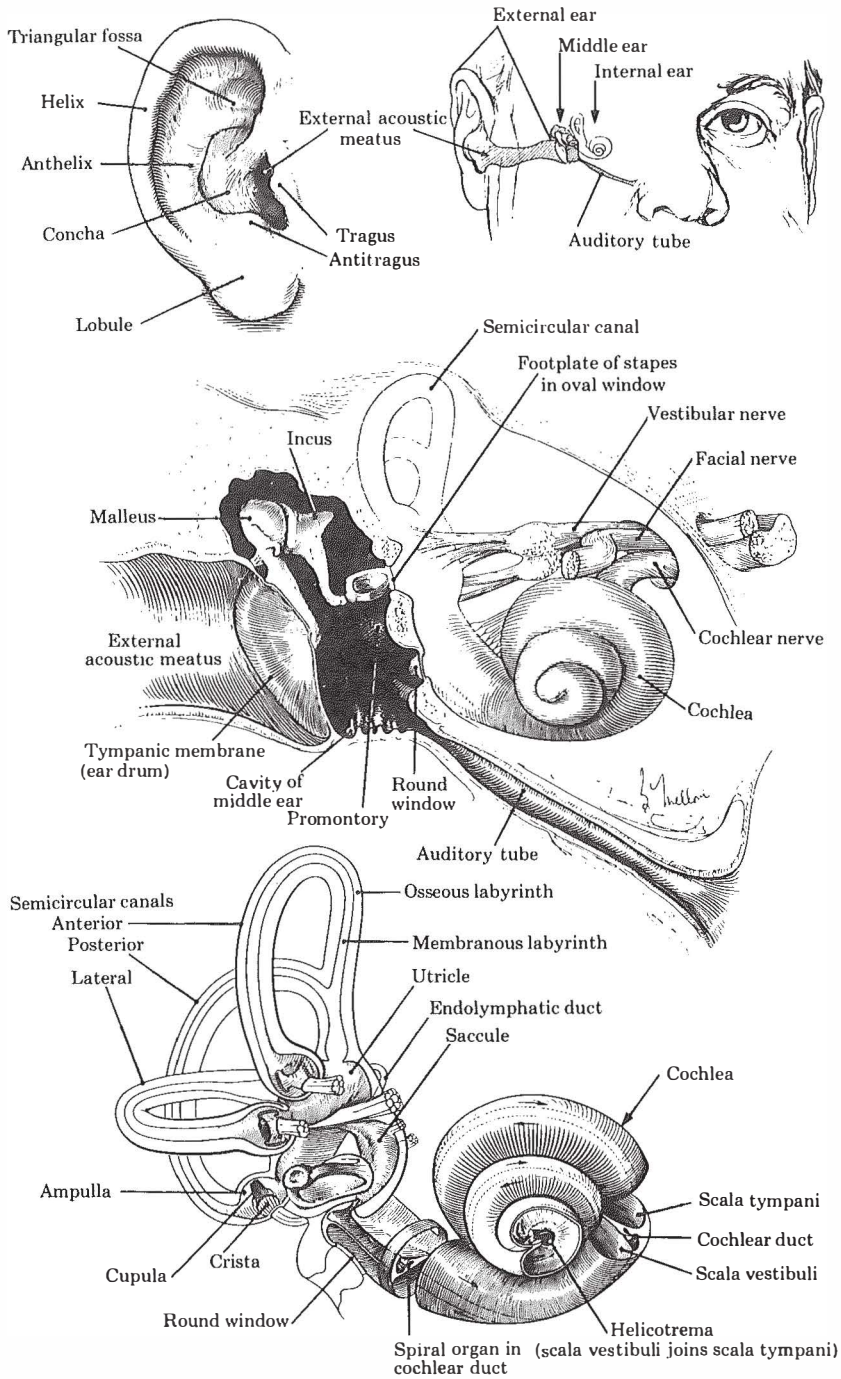
Electrical stimulation of the acoustic nerve has been a topic for research since the 1930s. Further progress was made in 1957 when a French group achieved successful electrical stimulation of the acoustic nerve.<sup>1,2</sup> The first successful implantation was performed by Simmons et al.<sup>3</sup> who directly stimulated the auditory nerve through multiple bipolar electrodes inserted into the cochlea and confirmed that pitch sensations were perceived upon stimulation. Several groups carried this research on through the 1960s. In 1973 the House group developed a diagnostic test battery to aid in the selection of patients and combined this approach with a postoperative rehabilitation program.<sup>4</sup>

Clark and coworkers<sup>2</sup> developed a multichannel electrode array and speech processor with the first three implants being carried out in 1978 and 1979. The subjects were postlingually deafened adults. Experience with the 1979 implant showed that the device could help patients to understand running speech with the aid of lip-reading and that some speech could be understood with electrical stimulation alone.

Since that time several different types of cochlear implant have been developed. Typically an implant includes a receiver placed in the mastoid bone behind the ear and approximately 5 mm below the skin, with the electrode array being placed adjacent to or inside the cochlea. A microphone and transmitter with the speech processor attached are fitted behind the ear.

The following features in design of cochlear implants have been developed and implemented in prototypes, but are not all currently available commercially:

- intracochlear electrodes
- extracochlear electrodes
- single channel operation
- multichannel operation
- speech feature extraction processing
- speech non-feature specific processing.



**Figure 1: External and internal structures of ear**

(Reproduced from *Dorland's Illustrated Medical Dictionary*, Twenty-sixth edition, 1985, with permission of the publisher, W.B. Saunders Company, Philadelphia, USA)

The actual position of the electrode array varies with the type of device, as does the depth to which the array is inserted. The electrode or electrode array for intracochlear implants is inserted into the cochlea. Single electrodes are inserted as far as the first bend of the cochlea. Multi-electrode arrays are inserted quite deeply towards the apex and may contain up to 22 electrodes which can be stimulated independently. Cowan (personal communication) advises that surgical policy at the Royal Victorian Eye and Ear Hospital is that insertion of the electrode array proceeds only until the first point of resistance, in order to avoid damage to cochlear structures. Extracochlear electrodes may be attached to the round window niche or, in some cases, to the promontory.

Cochlear implants may also be categorised according to the types of electrodes used (monopolar, bipolar), method of stimulation (pulsatile, continuous) or means of signal transmission through the skin (by wires or by radio frequency transmission).

In single channel devices, frequency of sound waves is transformed as a rate of stimulation by the speech processor. Multichannel devices may use the vocoder approach, with individual bands of energy of the waveform being supplied to different electrodes, or the speech extraction method, where important sections of the speech signal are tracked and submitted to the different electrodes.

### **Types of cochlear implant devices**

Loeb,<sup>5</sup> and De Foa and Loeb,<sup>6</sup> have provided overviews in tabular form of the devices that have been developed for implantation. Cowan (personal communication) has advised that approximately 12 implant systems are under development. Only three devices have been implanted in any significant numbers. The first of these were the 3M/House and 3M/Vienna (single channel) devices made by the 3M Corporation. Osberger<sup>7</sup> notes that these single channel implants are no longer being produced. The 3M Corporation has reached an agreement for the Cochlear Corporation to assume warranty and service obligations for external parts of the 3M/House and 3M/Vienna devices fitted by September 1989.

Another device being implanted in adults is the multichannel Ineraid, originally manufactured by Symbion Inc. and now being produced by the Richards Medical Company.<sup>7</sup> Loeb<sup>5</sup> states that this device has obtained IDE status from the US Food and Drug Administration (FDA). An IDE designation means this product is an investigational device to be inserted at approved centres only. Osberger<sup>7</sup> states that the ENT Advisory Panel to the FDA has recommended pre-marketing approval (PMA) for the Ineraid device contingent upon post market surveillance of pedestal infection rates.

The Ineraid device employs monopolar electrodes that are attached with wires to a percutaneous pedestal. Analog signals are transmitted to the electrodes after passing through banks of band pass filters. The device uses simultaneous stimulation of four ball electrodes with a remote reference electrode. These electrodes are activated with an analog full bandwidth representation of the speech wave form.

The Nucleus 22 channel cochlear implant system obtained PMA status for adults from the FDA in 1985 and for use in children in 1990.<sup>8</sup> The Nucleus device is the current

market leader. It operates on a formant extraction method in which an on-line microprocessor tracks the spectral location and relative amplitude of one or two speech formants (F0/F1/F2) and selects one or more electrodes for stimulation based on a previously stored map of pitch sensations at each available site.<sup>9</sup>

Despite the success of the WSPIII speech processor in the earlier version of the Nucleus device, a number of problems were identified. People who performed well with the device under quiet conditions could have significant difficulties under conditions of moderate background noise. Some had difficulties with the weight of the device and the external controls did not have the flexibility to cope with all acoustic environments. Many phonemes and environmental sounds have a high proportion of their energy above the range of frequency coded by the device.

The current Nucleus device employs two microprocessors and the Multipeak speech strategy. The speech processor extracts information from three high frequency bands in addition to estimating the first and second speech formants. Further information is conveyed to the electrodes by additional pulses to those provided under the F0/F1/F2 strategy. A new noise suppression method, which operates in a continuous manner, monitors the noise floor in each frequency band over a ten second period and subtracts the average value from the digitised signals. The additional high frequency information is intended to supply input on consonant voicing distinctions, and the higher formants of vowels. The ability to detect frication is extremely important for speech perception and is not generally available from either lip-reading or aided residual hearing.

Another multichannel device is the Clarion Multichannel Cochlear Implant, manufactured by Minimed Technologies. Ward (personal communication) advises that this device has now been implanted in three patients. It may offer considerable flexibility with options that can be altered to suit the individual patient.

Possible options are provided in speech coding and processing techniques and the signal is capable of being delivered in analog or pulsatile form.<sup>7</sup> Further options may also be available for the temporal distribution of the stimulation (either simultaneous or sequential). This flexibility is coupled with the ability to change the stimulation mode of the electrodes (either monopolar or bipolar).

# Selection of candidates for cochlear implants

## Selection of adults

Clark et al.<sup>2</sup> state that candidates for implantation must meet the following criteria:

- have a profound or total hearing loss;
- be postlingually deaf;
- have no psychiatric contraindications;
- have an intelligence quotient within the normal range;
- have no otological or X-ray finding to contraindicate implantation;
- have shown positive results for electrical stimulation of the promontory; and
- be medically fit for surgery.

Patients selected for cochlear implantation should have a severe to total hearing loss such that no benefit is achieved by the fitting of hearing aids. Profound total hearing loss has been defined as an average pure tone threshold of 90 dB HL in the better ear at 500, 1,000 and 2,000 Hz.<sup>2</sup> Kohut et al.<sup>10</sup> state that indications for an implant are a profound sensorineural hearing loss bilaterally, aided thresholds greater than 60 dB HL and zero per cent correct on open-set speech recognition. A lack of substantial improvement in lip-reading with an appropriately fitted hearing aid also forms part of their audiological criteria.

Clark et al.<sup>2</sup> state that the most important preoperative finding is whether the candidate for implant can achieve useful communication with a hearing aid or tactile device and, if so, whether it is better than the improvement expected from a cochlear device. Gantz<sup>11</sup> states that a comprehensive hearing aid trial is mandatory, and if necessary the person should be offered appropriate hearing aids. Gantz utilises the 65 db SPL level as the threshold of detection for further testing.

Current criteria in Australia applied to persons with severe or profound hearing impairment include open-set monosyllabic word tests for whole words, phonemes and sentences in the best aided binaural condition. Tyler, Tye-Murray and Gantz<sup>12</sup> administer speech perception tests to determine the amount of benefit derived from hearing aids and report that they would discourage adult candidates who have a score above 10 per cent (sound only).

## Postlingual deafness

Studies have shown that acquisition of language varies between individuals and may not be complete until six years of age. Clark et al.<sup>2</sup> state that they only include adult patients in the implant program if they lost their hearing after the age of four years.

## Psychiatric contraindications

Most psychiatric testing is done to exclude persons for whom cochlear implantation is likely to be unsuccessful, with either a severe psychosis or psycho-neurosis being a contraindication to surgery.<sup>2</sup> Potential candidates for implantation are also screened for mental retardation. Clark et al. state that patients are not selected on the basis of their IQ provided it is at or above the 95 per cent level.<sup>2</sup> They have found that the patient's IQ level does not correlate with results of auditory improvement following implantation.

Gantz<sup>11</sup> also states that verbal or performance IQ is not predictive of auditory performance and cites cases where persons with IQ scores as low as 85 have shown evidence of substantial open set word understanding. Cowan (personal communication) advises that psychological counselling is primarily aimed at ensuring that candidates have an accurate concept and reasonable expectations of the potential benefits of the device. De Foa and Loeb<sup>6</sup> note that appropriate counselling is regarded as an essential component in a cochlear implant program.

## Otological and radiological testing

It is necessary to exclude active infection in the external or middle ear, and to identify perforations of the tympanic membrane, or previous middle ear or mastoid surgery.<sup>2</sup> Infections must be treated before proceeding with an intracochlear or extracochlear implantation. Clark et al.<sup>2</sup> stress the need for treatment prior to intracochlear insertion of the electrodes, otherwise labyrinthitis may occur.

A CT scan is especially useful in showing whether the round window niche is present, and the extent of bony obliteration of the first part of the basal turn. Accurate appraisal of the cochlear coils is vital before the insertion of an intracochlear device.<sup>2,10</sup> Phelps, Annis and Robinson<sup>13</sup> detail cases where partial or complete obliteration of the cochlear coils was detected by CT.

Gray et al.<sup>14</sup> state that because its design requires a sufficiently intact scala tympani to allow insertion of the electrodes, implantation of the Ineraid device requires better preoperative radiology than the Nucleus device. These authors also report that only ultra high resolution CT gives sufficient detail to choose the side to implant and to provide confidence that not even a partial bony obstruction will be met. They say that a series of 12 x 1 mm contiguous slices, appropriately aligned, will give maximum information and result in a radiation dose of 70 mGy. A dose of 2000 mGy is associated with cataract formation.

Labyrinthitis ossificans would seem to be a contraindication to intracochlear implantation, although in at least one case<sup>14,15</sup> successful implantation appears to have been achieved by drilling out an artificial channel for 'the electrode to wrap around the modiolus'. Ward (personal communication) has advised that many surgeons now drill out ossified cochleas. In another case, a multi-electrode implantation was achieved by drilling 3 mm through an ossified scala tympani until an open scala tympani was reached.<sup>15</sup>

Steenerson, Gary and Wynens<sup>16</sup> reported two cases where, following episodes of meningitis, surgery was not possible by insertion through the scala tympani owing to



severe scala tympani cochlear ossification. The scala vestibuli was opened just anterior to the round window by drilling superior to the spiral ligament. In both cases a Nucleus implant was inserted to the fifth stiffening ring. Good healing was reported in both cases, with no postoperative vertigo. The audiological and functional results following implantation in these patients were as good as would have been expected with scala tympani implantation with full electrode insertion.

In cases of osteosclerosis, CT can show whether a bone plug in the round window is obscuring a fully patent basal turn of the cochlea. CT can also show cases of mixed osteosclerosis and osteospongiosis overloading on the cochlear lumen. Phelps, Annis and Robinson<sup>13</sup> state that both the position of the jugular bulb and the presence of a chain of retro- or intra-cochlear air cells are discernible by CT. These authors also believe that magnetic resonance imaging (MRI) may be a suitable adjunct to CT if increased spatial resolution for small areas can be developed.

Yune, Miyamoto and Yune<sup>17</sup> describe a case where an early CT examination was performed on a patient with pneumococcal meningitis and was negative. Two weeks later the patient developed severe bilateral sensorineural hearing loss. Four months later MRI examination showed focal areas of loss of endoperilymph signals in certain parts of the membranous labyrinth. This observation led this group to suggest that the early stages of evolution from meningitis to sclerosing labyrinthitis may be accurately demonstrated by MRI.

Wiet et al<sup>18</sup> found 10 abnormal CT scans in a series of 28 patients; of these abnormal scans four showed partial obliteration of the round window niche and two showed poor definition and partial obliteration of the cochlea. Two other scans showed partial obliteration from ossification secondary to meningitis. Mondini deformity and severe demineralisation of the cochlea were found in the other two cases. These authors also reported three false negative results.

Mueller, Dolan and Gantz<sup>19</sup> studied 24 ears and found problems of the temporal bones in 12 (eight subjects). The abnormalities detected included cochlear osteosclerosis, cochlear ossification, evidence of prior mastoidectomy and the Mondini deformity.

## **Electrical stimulation of the promontory**

Several techniques exist for the performance of the promontory electrical stimulation test. Gantz<sup>11</sup> states that attempts at correlating preoperative psychophysical measures obtained through electrical stimulation with audiological performance, such as threshold, dynamic range, gap detection, voicing frequency difference thresholds, and formant transition differences, have been of limited use to date. Gantz considers that although electrical stimulation is not predictive of auditory performance, it does indicate that there is sufficient neurological survival to proceed with the implantation and he continues to perform preoperative stimulation for that reason.

Preoperative promontory testing has now been taken a further stage in some centres where evoked response electroencephalography tracings have been recorded with electrical promontory testing (Canty, personal communication). Electrically evoked

potential measurements are also used to calibrate the settings during the mapping and programming phase of rehabilitation in young children.

In a study on postlingually deafened adults Blamey et al.<sup>20</sup> found that the thresholds for electrical stimulation were consistent across frequency. However, no correlation was observed between the results of the electrical stimulation and postoperative intracochlear thresholds or Central Institute for the Deaf (CID) sentence scores. They state that 'it is unlikely that promontory stimulation thresholds could be used as a predictor of cochlear implant outcome'.

A correlation was found between the stim-code measure of discrimination of temporal characteristics of waveforms above threshold levels and CID scores. Blamey et al. believe that on the basis of these findings there is some justification for using electrical stimulation of the promontory. They also report that, on anecdotal evidence, patients find it useful to experience the sounds produced by electrical stimulation in forming a realistic expectation of outcome. It is helpful to use a single channel speech processor during promontory stimulation to give the patient a preliminary experience of coded speech.

### **Additional issues**

The medical condition of the prospective patient should be sufficiently robust to tolerate general anesthesia and to allow the operation to be carried out safely. Gantz<sup>11</sup> gives details of the need for information to aid the overall selection process, such as onset of profound hearing loss, educational environment, etiology of deafness, previous ear disease and ear surgery.

Clark et al.<sup>2</sup> found a significant negative correlation between the benefit from a multi-channel prosthesis and the length of profound deafness. They found that the performance was worst if the duration of deafness exceeded 13 years. Clark et al. did not find any correlation between the age of the recipients and performance following implantation.

Gantz<sup>11</sup> believes that the prelingual and perilingual groups need counselling prior to any moves towards implantation because some of the prelingual adults have stopped using their devices following implantation. He also states that the etiology of acquired deafness does not show any significant correlation with performance of persons with cochlear implants.

Bacterial meningitis can result in total loss of auditory nerve ganglion cells; viral meningitis can also have this effect.<sup>10</sup> Gantz notes that ears with labyrinthitis and ossificans have a higher risk of ganglion cell depletion. Patients with a history of meningitis or labyrinthitis should be counselled as to the possibility of below-average performance because of limited ganglion cell survival.

Postoperative balance disturbance has been almost non-existent, even in the presence of abnormal labyrinthine function.<sup>21</sup> Electro-stimography is only recommended when the history suggests vestibular dysfunction.

Another unresolved issue is that of which ear to implant. Some physicians implant the worst ear while others have been implanting the most recently deafened and better

hearing side. Gantz selects the ear that responds to the greatest number of frequencies, subjectively sounds better and obtains the best response with electrical stimulation.<sup>10</sup> Osberger<sup>7</sup> selects the most appropriate ear by determining such psychophysical parameters as gap detection thresholds, dynamic range and electrical thresholds.

## **Selection of children for implantation**

Children whose onset of deafness occurs under three years of age, following normal hearing, have perception skills following cochlear implantation similar to those of implanted children who were born deaf.<sup>6</sup> Osberger contrasts the performance of this group with the superior perception skills of children who lost their hearing at five years of age.

Brookhouser, Worthington and Kelly<sup>22</sup> state that the auditory brainstem response evaluation (ABR) is an excellent source of reliable information regarding hearing sensitivity in infants under six months of age and other difficult-to-test children. However, they point out that a click-evoked ABR assesses hearing sensitivity primarily in the high frequency region (2000–4000 Hz), which may lead to erroneous conclusions regarding hearing at other frequencies. The absence of a response to a click-evoked ABR at a level of 90 to 100 db HL does not preclude normal low-frequency hearing.

The use of tone-burst ABRs using special stimulus parameters offers some resolution of the frequencies associated with the hearing loss. However, these tests cannot be carried out at most centres. The child's level of activity, interest in the task, state of wakefulness and rate of habituation to the test stimuli can affect the results. Evaluation of implants in toddlers with severe to profound bilateral post-meningitis hearing loss can be difficult.<sup>22</sup>

Brookhouser, Worthington and Kelly report that both aided and implanted children with identical aided thresholds can detect the presence of auditory stimuli across a broad range of frequencies, but that not all cochlear implants permit discrimination between frequencies above 500 Hz. They also state that children who derive significant benefit from conventional amplification for frequencies above 500 Hz can perceive many of these important frequency differences in speech.

These authors counsel caution to avoid placing an implant into the cochlea of a child who could have experienced greater benefit from conventional amplification. They recommend a closely supervised trial with conventional amplification for a minimum of one year, accompanied by an intensive aural rehabilitation program, before a final decision is made on cochlear implantation. Such an approach would need to be assessed on an individual basis in cases where evaluation over one year may be inappropriate.

Osberger<sup>7</sup> believes it is crucial that children be given adequate experience and training with appropriate hearing aids before a decision is made to conduct implantation. The audiological criterion that is used most to determine implant candidacy in children is based on pure tone thresholds. Osberger cautions that hearing sensitivity is an imperfect predictor of speech perception abilities. There are children with pro-

found hearing losses who possess residual hearing but who can only perceive supra-segmental features of speech with hearing aids. It is usual practice in Australia to test children for speech perception and speech production prior to implantation, and also to give them a hearing aid trial.

# Rehabilitation following surgery

## Surgery

Details of the procedure are well documented<sup>2,23,24</sup> and the preparation of the operating theatre for the implantation has been described by Hannon.<sup>25</sup> Details of complications and the methods used to circumvent these are also available.<sup>2,10,11</sup>

## Rehabilitation

Workers in the field of cochlear implantation agree that auditory rehabilitation should be a critical component of any implant program.<sup>6,10,26</sup> Banfai et al. state that the rehabilitation process is as important as the surgery.<sup>27</sup> Plant (personal communication) believes that the rehabilitation component of the cochlear implant program is a definite strength of the treatment. He also states that there are not sufficient rehabilitation services to allow persons fitted with hearing aids and commercial tactile aids to perform to the maximum.

Rehabilitation usually commences at approximately four to six weeks following surgery. Canty (personal communication) believes the rehabilitation sessions should commence before the surgery as it is important in adults for lip-reading classes to be undertaken for a long time preoperatively. He also believes that children can gain skills in the rehabilitation processes prior to the operation.

Initial sessions are used to set the thresholds for the electrodes and to acquaint the implanted person with the way in which loudness, pitch, rate of stimulation, the combined rate and place of stimulation, and time-varying rate and place of stimulation, are related to speech production. The subject is also acquainted with other variables such as multiple sites of stimulation, two-component pitch sensations and other aspects of speech processing strategies employed in the device. Cowan (personal communication) believes that rehabilitation needs to be individual in nature, with patients being encouraged to integrate the device into their everyday communication environments.

Alpiner, having reviewed the protocols available, states that the emphasis of aural rehabilitation that follows the initial sessions is analytic in nature.<sup>28</sup> He reports that one of the major activities used in rehabilitation is the speech tracking procedure in which the implanted persons are required to repeat verbatim a passage that has been read to them. When errors occur, the passage is repeated or an alternative cue is selected to help the person's performance. Performance is assessed by the number of words correctly repeated during ten-minute sessions. In this assessment the passage is read under the following conditions: lip-reading only, electrical stimulation only and lip-reading and electrical stimulation combined.

Many other rehabilitation activities are also used as measures to assess progress following implantation, and stress the development of abilities such as awareness, word

recognition and speech discrimination. Vowel discrimination, consonant discrimination, word identification (spondee tests) and open- and closed-set sentence identification are tasks used to develop perception abilities. The Minimal Auditory Capabilities (MAC) Battery also appears to be used frequently in cochlear implant protocols.<sup>28</sup>

Tucci, Lambert and Ruth<sup>26</sup> conducted a survey of rehabilitation programs by sending a questionnaire to over 200 otolaryngologists. Results were obtained on more than 1,400 implanted persons including adults, adolescents and children. Adults received  $21.5 \pm 13.7$  hours of rehabilitation while the children spent  $27.3 \pm 12.2$  hours working with rehabilitation personnel. Two-thirds of the programs spent up to 40 hours or more per child and worked with school personnel including teachers, speech pathologists, vocational counsellors, psychologists and administrators. Tucci, Lambert and Ruth show that significantly more professionals were involved in the auditory rehabilitation and speech pathology teams for children than in the teams developed for adults.

Alpiner<sup>28</sup> notes that the areas which encompass most communication situations are the home, work and social environments and that both those with cochlear implants and hearing aid users face the same general rehabilitative needs. Edgerton<sup>29</sup> lists early rehabilitation needs following implantation as:

- to obtain an optimal electrical setting of the device;
- to provide the implanted person and family with the necessary foundation for long-term care and maintenance of the cochlear implant stimulator;
- to introduce the implanted person to strategies that will yield the necessary critical listening and communication skills; and
- to assess the need for specific long-term rehabilitation programs.

Alpiner<sup>28</sup> believes a total approach to rehabilitative audiology should be implemented when dealing with a person who has been fitted with a cochlear implant. Alpiner's program is divided into a number of steps, the first of which is the assessment of the implanted person's communication needs, with the client providing significant input regarding communication ability.

The second step entails tailoring the rehabilitative procedures to the person's needs with combinations of lip-reading, communication training, auditory training, and counselling. The third stage is deciding which other professionals are needed for the implanted person, such as social workers, teachers, psychologists, vocational counsellors and family counsellors. Tucci, Lambert and Ruth<sup>26</sup> found that some people are required to travel long distances for rehabilitation sessions while many maintain frequent contact by telephone. Banfai et al.<sup>27</sup> describe patients who were unable to arrive at rehabilitation sessions owing to cost, family or distance factors. Because of these situations Alpiner<sup>28</sup> considers that it would be even more important to develop rehabilitation programs that are more communication-oriented than elemental.

Maddox, Stout and Jorgensen<sup>30</sup> believe it is essential to teach parents and educators of implanted children strategies for helping the children to use the device to its maximum potential. They state that children who receive implants will return to an educational environment with specific programs, including hierarchical auditory training

and speech and language plans, and teachers and therapists who are excited about utilising auditory training plans.

Maddox, Stout and Jorgensen emphasise the need for minimal disruption in the child's current educational environment with re-initiation of auditory skill development based on realistic expectations of implant use. Those caring for the child should gain familiarity with the implant, which would include the ability to put non-implanted components of the device on the child, a basic understanding of the device and the ability to perform basic troubleshooting techniques.

Teachers should also gain a similar level of familiarity with the implant.

At all times the language used by the parents, or modelled by the clinician, needs to provide a range of information, vocabulary, semantic relationships and language structures. Osberger et al. suggest that parents should be able to recognise signals such as those given when the child spontaneously imitates a parent's message.<sup>31</sup> At this stage the child may be ready to move on to an increasingly difficult selection of auditory tasks. The aim should be to facilitate the child's self-learning skills rather than to teach every sound or word.

The Developmental Approach to Successful Listening was developed for hearing-impaired children who could be helped by amplification. Maddox, Stout and Jorgensen<sup>30</sup> believe that this scheme is ideally suited to a child with a cochlear implant. The rehabilitation program is established about a hierarchical structure with built-in microincremental goals for each assessment parameter. These authors stress the need for simplicity to ensure that parents and teachers can administer the program. Allowance should also be made for the person who previously possessed no listening skills and had language deficits. The program should also be developed around the children's interests, with children being allowed to listen to their own voices. Maddox, Stout and Jorgensen consider that the program should include hierarchical steps in conversation rate.

Osberger<sup>7</sup> considers that the ideal rehabilitation program for adults should consist of counselling regarding realistic expectations of the benefits from the implant, sensory training in the form of audio-visual, and auditory-only speech perception training. The program should also assist the individual in developing appropriate communication strategies.

The ideal program for children should consist of assessment of the child's speech and language with appropriate rehabilitation strategies being developed in each area. The rehabilitation team in Osberger's program provide approximately 30 to 40 hours of individual attention during the first six to nine months of implant use. This time does not include that needed for the setting of thresholds. Osberger stresses that contact between the implant team and school professionals is essential because school staff often feel inadequately prepared to train children with implants.

# Measurement of outcome

## Pre- and postoperative assessment methods

Pre- and postoperative tests have been detailed by Clark et al.<sup>2</sup> and broadly include the following:

- threshold tests for signal detection level, maximum comfort level and loudness discomfort level
- a minimum auditory capabilities (MAC) battery which is performed preoperatively by auditory means and postoperatively by electrical stimulation alone
- assessment of the value of aid preoperatively or cochlear implant postoperatively for lip-reading. These tests include the Central Institute for the Deaf (CID) Everyday Sentences Test and the CNC Monosyllabic Words Test.

Additional measures used to assess performance preoperatively include:

- *CID everyday sentences*
- *Open-set word and sentence tests*—These consist of standardised word and sentence tests. The open-sets used in these tests are monosyllabic AB words.
- *Speech tracking*—This requires the subject to repeat sentences or phrases read by the tester and is seen as important in establishing the speech processing strategy to help the implant recipient's understanding of running speech. The score for this test is the number of words correctly repeated divided by the time taken.
- *Vowels and consonants*—These are tests to establish the subject's ability to recognise vowels and consonants under conditions of electrical stimulation alone. The results are averaged over a closed-set of six vowels and 10 consonants.

These abovementioned tests are performed under the conditions of lip-reading alone, electrical stimulation alone, and combined lip reading and electrical stimulation.

Doyle and Pijl<sup>32</sup> describe their postoperative evaluation procedure which includes a sound field warble tone and speech threshold measurements in addition to the House Ear Institute recordings. The House Ear Institute recordings consist of monosyllable, trochee, spondee and environmental sounds tests. Rosen et al.<sup>33</sup> also use additional tests from the MAC battery.

Dorman et al.,<sup>34</sup> following implantation of the Symbion device, utilised the MAC battery of tests, the Spondee Recognition Test, the CNC Monosyllabic Words Test and the CID Everyday Sentences Test.

## Tests for children

Tyler<sup>35</sup> describes a series of tests for children including a matrix test and an Australian version of the Word Intelligibility by Picture Identification (WIPI) tests. Vowel and



consonant tests were also employed, with audio-visual enhancement of the consonant recognition component.

### **Postoperative assessment of outcome**

Table 1 gives details of some of the results obtained from postoperative assessments of improvements in speech perception. Information in this table is by no means exhaustive and the measures used by some of the investigators may differ slightly. In some cases raw scores were included.

The range of improvements for some of the parameters measured lends support to the statement by Kohut et al.<sup>10</sup> 'Few medical interventions yield outcomes as varied as those for cochlear implantation. This statement does not detract from the real benefits that some patients derive from the implantation with a few recipients being able to conduct telephone conversations and communicate face to face without lip-reading'.

The most common outcome occurs as a result of a combination of electrical stimulation and lip-reading and is illustrated by the findings of Dorman et al.<sup>34</sup> They give results (percentage improvement) for CID Everyday Sentences Tests using electrical stimulation (45%), visual stimulation (64%) and combined visual and electrical stimulation (99%). These scores represent the averages obtained for the 50 persons studied.

Kohut et al.<sup>10</sup> report that some persons can barely distinguish between environmental sounds and that between 2 and 15 per cent may choose to discontinue the use of their prostheses.

The reasons for such individual variation in benefit obtained could arise from the length of time since loss of hearing, medical factors and differences in individual linguistic and cognitive skills. Shea, Domico and Orchik<sup>36</sup> add degree of education, length of hearing-aid use and etiology of deafness to the factors likely to influence recipient performance. They suggest that the duration of deafness should not be used as the sole predictor of speech recognition and quote the high variability in open set performance of their group of recipients who had fewer than 15 years deafness before implantation. Dorman et al.<sup>34</sup> found that once data from three meningitic subjects were removed from their series, there was no significant correlation between length of deafness and auditory comprehension.

### **Device characteristics and performance**

The characteristics of the different types of device may also be a variable. Doyle and Pijl,<sup>32</sup> reported improved scores with multichannel devices in persons who had previously had single channel devices implanted. These authors advise caution, however, as the state of the implanted or re-implanted cochleas in these persons represented a significant unknown.

Table 1: Performance of patients, following implantation

Source and type of implant	Number	Closed W.I.D.	Spondee	Vowels	Environmental Sound	Open- Set Speech	CID Everyday Sentences	F1/F2/F3	CID Everyday Sentences (Visual)
Doyle & Pijls <sup>2</sup> —multichannel (Cochlear)	12	>40%	>85%		55% (45–80%)	0–48%	5–90%		
—single channel (3M/House)	14	40%	55–67%			—			
Dorman et al. <sup>(a)</sup> Symbion	8	—	>70%				60% (49–79%)		
Dorman et al. <sup>34</sup>	50	14% (0–60%)	44% (0–100%)				45% (0–100%)		64% (0–100%)
Spivak & Waltzman <sup>(b)</sup> Nucleus 22 channel	15	4%	33%	41%			12%		
Mecklenburg & Brimacombe <sup>(c)</sup> Nucleus 22 channel	19	3.8% (open-set)	75.5% (closed-set)	43.6% ( <i>n</i> =17)	90.2% (noise/voice)		11.2%		
Shea, Domico & Orchik <sup>36</sup> Nucleus 22 channel	20	6.25 (±17.33)					48.4 (±59.1)		
Gantz, Tye–Murray & Tyler <sup>37</sup> 3M/Los Angeles Nucleus Symbion	10 13 15				Consonants 10–22% 12–47% 15–84%		0–3% 0–57% 0–92%		

The scores given for each parameter represent the percentage improvement. The ranges, when associated with means, are included in brackets.

Sources: (a) Dorman MF et al. *Ear and Hearing* 1989;10:40–43

(b) Spivak LG & Waltzman SB. *Journal of Speech and Hearing Research* 1990;33:511–519

(c) Mecklenburg DJ & Waltzman SB. *Seminars in Hearing* 1985;6:41–51

Gantz et al.<sup>37</sup> conducted research on the performance of recipients using the 3M/ House, Nucleus and Symbion devices and showed significant effect of implant type on the sentence scores, using a one way analysis of variance. Further statistical analysis showed that the results from the two multichannel devices were equivalent, and were superior to those obtained from persons implanted with the Los Angeles/3M device. Doyle and Pijl<sup>32</sup> believe that while the single-channel implant allows for the awareness of environmental sounds and aids the patient in lip reading, it does not by itself permit an understanding of speech. They state multichannel implants permit most recipients to understand varying degrees of speech with some being able to understand telephone conversations. Jerger and Watkins<sup>38</sup> see a place for the use of single channel extracochlear implants in cases where complete ossification of the cochlea has taken place.

Doyle and Pijl followed the progress of their group of implanted persons over a period of nine months following implantation with multichannel devices and noted improvements over that time. They contrasted these findings with those obtained for the long term follow-up of persons with single channel implants, where it was not possible to demonstrate significant improvements over time for most subtests.

Berliner et al.<sup>38</sup> conducted a longitudinal study with children for up to two years following implantation. They included an age-matched control group to take account of any contributions from motivation or continued training.

The first parameter tested, auditory detection, showed that 3 per cent of the 70 children could identify spondees in closed sets before implantation, 36 per cent after one year and 43 per cent after two years following implantation. When tested for auditory recognition (open-set) 26 out of 50 children had a mean correct score of 33 per cent for open-set word recognition. A 39 per cent response was obtained for open-set sentence comprehension by 17 out of 41 children. These authors also noted that some congenitally deaf children were able to obtain non-zero scores.

Eighty-five children were tested pre- and post-implant utilising the Ling Phonetic Level Speech Evaluation to measure any improvements in speech production. The results obtained by Berliner et al. for these assessments showed the younger age groups (2-5, 5-11 years) both made significant improvements on the nonsegmental aspects of speech following implantation. The same groups showed significant improvements from post-implantation to one year, and all age groups showed significant improvements over the period between the one- and two-year assessments.

Berliner et al. make the generalisation that the younger the recipient of the implant the greater the improvement in speech production. They cite a cross-sectional study<sup>39</sup> where the speech of 4- to 7-year-olds, who had received implants, was compared with that of age-matched controls. The scores for the children with the implants were significantly better than the speech scores for the control group.

The studies conducted to date show that speech perception is nearly always facilitated following implantation. This applies to both single channel and multichannel devices.

This improvement in speech perception is brought about in most cases by a combination of auditory perception and lip-reading. Individual cases where great improve-

ments have been made are reported in the literature.<sup>40,41</sup> The greatest improvements have been experienced by persons who have acquired language skills prior to losing their hearing. However, as Shea, Domico and Orchik point out, the duration of deafness cannot be used as an indicator of speech recognition following implantation.<sup>36</sup> The studies conducted to date also indicate that multichannel devices provide greater gains in speech recognition and speech production.

Comparative data on patient benefit using the Multipeak strategy included in a recent development of the Nucleus device are shown in Table 2.

**Table 2: Comparison of the benefits of the MSP and WSP coding strategies in Nucleus devices**

Study	Difference in scores (MSP minus WSP)			
	Vowels	Consonants	BKB sentences (quiet)	BKB sentences (+ noise)
Dowell et al. <sup>42</sup>	10.1%	5.7%	25.2%	23.5%
Skinner et al. <sup>43</sup>	17.5%	9.0%	19.0%	27.0%

Dowell et al.<sup>42</sup> state that the difference in performance with the consonant identification was not significant and suggest that the lack of difference between the two groups may be due to the innate ability of the WSP group at identifying consonants. Another possible reason canvassed was that the additional information provided by the MSP was in the high frequency range and that this information might be expected to aid the recognition of the voiced and unvoiced fricatives and affricates. These sounds were not well represented in the consonants chosen for the study.

Four Choices Spondee and open-set sentence tests were also applied under conditions of increased background noise. Subjects using the new system gave good performances on closed-set Four Choice Spondee testing (75% at zero dB Signal to Noise Ratio (SNR)) and scored well for open sentences at +10 dB SNR. The authors suggest from these results that the subjects could discern speech in moderately noisy environments. Dowell et al. believe that an additional advantage in the conditions used in their study would be the use of a directional ear level microphone (approximately 5 to 10 dB improvement in noisy backgrounds).

Skinner et al.<sup>43</sup> found that for the BKB sentence tests the difference in performance between subjects wearing the MSP and WSP devices was substantially larger for the noisy condition than for the quiet condition. The difference was found to be highly significant. In addition the mean scores showed significantly higher performance for the MSP over the WSP for the Four Choice Spondee test.

Skinner et al. reported that all subjects preferred using the MSP at home or work, for social occasions, on the telephone, for listening to music and overall, although one patient preferred the WSP for watching television.

Skinner et al. noted the similarity of their results with those of two other studies and commented that there was no significant difference in group mean scores on the medial consonant tests in the three studies.

Dawson et al.<sup>44</sup> conducted a study on a group of adolescents, children and prelinguistically deafened adults who had been using the cochlear prosthesis for between 12 and 65 months. Postoperative performance on the majority of closed-set speech perception tests was significantly better than the preoperative performance for all subjects. In a group of five children phoneme scores ranged from 30 per cent to 72 per cent and word scores in sentences ranged from 26 per cent to 74 per cent. Both tests were administered under open-set conditions using hearing without lip-reading. The remaining five subjects did not demonstrate open-set recognition and were found to have been implanted after a long period of profound deafness. Dowell et al.<sup>42</sup> have recorded scores ranging from 42 per cent to 86 per cent for open-set BKB sentences for a group of five postlingually deafened adults using the prosthesis,

Osberger et al.,<sup>45</sup> while recognising the difficulties in analysing of spontaneous speech samples in the young, found that children using the Nucleus device showed greater speech skills than Tactaid and 3M/House users. The children using the Nucleus implant achieved 67 per cent of their advances as recognisable phonemes of English 12 months after implantation.

### **Vocational benefits**

Dinner et al.<sup>46</sup> explored the vocational benefits of cochlear implants by posing 17 questions to 358 implant recipients. Of the 256 responses to the questionnaires, 202 were usable. Those who used the implant at work ( $n = 106$ ) formed the principal study group. In this group there was no significant change in employment, or any mobility from 'blue collar' to 'white collar' employment groups following implantation. However, a significant number increased the time spent in spoken communication at their workplace. Fifty-five per cent used spoken communication 4 to 8 hours a day while at work, and 17.9 per cent 2 to 3.9 hours per day. The vast majority (91.2 per cent) said their understanding of spoken communication on the job had increased since they received their implant. The majority of employed respondents (66.6 per cent) also thought that the cochlear implant had increased their job performance.

Lip-reading remained the most common mode of speech recognition. However, hearing was more frequently cited as a communication mode following implantation. Over half of the respondents (64 per cent) felt more confident of retaining their jobs following implantation and 56.4 per cent felt more confident about seeking other employment.

Five per cent of respondents considered that their implant had been responsible for their promotion, although a large majority (85 per cent) had no increase in income. A significant increase in job satisfaction was noted following implantation, although very few individuals considered that their hearing loss had interfered with the performance of their jobs. This study did not include data on the impressions of the supervisors of the persons using the implants.

### **Other benefits**

Other benefits of cochlear implantation include a positive impact on family and social relationships. An article by a mother of a teenage implantee points out the first change

noted was that her child was much less noisy and showed greater self-confidence.<sup>41</sup> The ability of recipients of cochlear devices to discern environmental sounds would add to their self-confidence and their ability to deal with certain situations. Social contact outside the deaf community would also be enhanced.

# Adverse effects associated with cochlear implants

Besides the risks associated with general anesthesia, the principal concern with implantation surgery is the risk of post-surgical infection of the skin flap behind the ear.<sup>10</sup> Cohen, Hoffman and Strochein<sup>21</sup> conducted a survey of surgeons performing cochlear implantations to ascertain the complication rate of the procedure. An overall return rate of 94 per cent was obtained, which represented 459 people implanted with Nucleus devices. Fifty-five complications (11.8 per cent) were reported, of which 4.8 per cent were major and 7 per cent were minor.

These findings result from practice in the USA and cover two models of the Nucleus device with differing shapes of incision. One life-threatening complication, but no deaths, were noted. The most common complication was with the skin flap behind the ear—22 cases were observed. Three of the 22 cases of flap breakdown involved seroma of the tissue, all of which were managed by aspiration and/or local drainage. Of the cases of flap necrosis, nine were considered serious enough to necessitate the removal of the cochlear implant. It was found that 80 per cent of the flap complications occurred within the first three operations performed by the surgeon.

Kohut et al.<sup>10</sup> mention that any facial nerve paralysis is usually a transient postoperative complication of implantation. Cohen, Hoffman and Stroschein<sup>21</sup> noted eight cases of delayed facial weakness—all were minor complications which resolved spontaneously. Four recipients experienced seventh nerve stimulation, with three of these cases being alleviated by programming out the offending electrodes. The other recipient had not benefited from program adjustment and the device had to be removed.

Vestibular problems are also considered as a possible complication, although Kohut et al.<sup>10</sup> consider that the level of current use is unlikely to produce vestibular symptoms. Cohen, Hoffman and Stroschein<sup>21</sup> state that five recipients reported postoperative dizziness, suggesting a perilymph fistula. In two of the cases the dizziness was resolved spontaneously while in three cases exploratory surgery was performed. One suspected fistula was repaired. Overall, eight patients required surgical exploration as a result of non-functioning implants. The need for these explorations resulted from either incorrect electrode position or electrode compression. A previous mastoidectomy necessitated the removal of another cochlear prosthesis.

Shelton et al.<sup>47</sup> investigated the cases of three children who were not receiving any benefit from their cochlear implants. They found that in all cases the internal auditory canal (IAC) diameter was much narrower than the average. Also X-rays showed the facial nerve exiting the IAC, but no apparent connection to the cochlear modiolus. Shelton et al. support their findings by the observation that the patients showed facial stimulation but no auditory stimulation from the cochlear implant. These researchers see a possible association between maternal diabetes and narrow IACs, and cite an association between diabetes and optic nerve hypoplasia.<sup>47,48</sup>

In Australia the rate of complications is less than five per cent (Cowan, personal communication). Gibson, Lam and Scrivener<sup>49</sup> describe the complications arising from 90 primary surgeries (67 adults and teenagers, 23 children), four changes of single-channel devices to the Nucleus device, five re-operations and one recipient who had an implant placed in her second ear. Overall, 19 serious surgical complications were reported, of which one was flap necrosis due primarily to a long-standing infection. There were five cases of infection at the implant site and three cases of facial palsy. In four cases misplacement or deformation of the electrode array had occurred. These authors also report three cases of probable deep vein thrombosis and one patient had a small primary embolism following chest radiology.

Gibson, Lam and Scrivener also reported on less serious surgical complications, such as hematomas under the skin flap. Numbness of the skin flap occurred in 28 recipients, although in the majority this loss of sensation had dissipated after four months. Vertigo or imbalance were the most common 'less serious' problems encountered by implanted persons and were mostly associated with congenitally deafened adults and teenagers. Most of these problems had settled down after two weeks. Facial muscle twitching was also a relatively common effect, but was resolved by switching off the offending electrodes.

Non-surgical difficulties were also observed, with device failure, discrepant electrodes, allergies to the cable and static shocks being noted. The static shocks were infrequent, with clear periods of several months; their cause is unknown. A theory offered by the authors is that a static charge builds up between the coil and implant and somehow causes all the electrodes to discharge simultaneously without warning.

Two post-meningitic patients suffered a deterioration in the dynamic range of their thresholds for electrical stimulation, but without flap necrosis. Gibson, Lam and Scrivener attribute this to the use of an anteriorly-based skin flap and to the breadth of the base being at least 1.5 times longer than the height of the skin flap. These authors conclude that the results from this series of 90 cases should reassure future patients that cochlear implant surgery is a safe procedure.

Webb et al.<sup>50</sup> compared the experience of Cohen et al.<sup>21</sup> in the USA with the complications in series in Hannover (153 persons implanted) and in Melbourne (97 persons implanted). In Hannover, one case of flap necrosis required the removal of the device and a further three cases of severe, but controlled wound infection were reported. There were nine cases of an electrode tie eroding through the external auditory canal skin; this complication was reduced by a change of position of the knot. Six persons reported an increase in tinnitus during electrical stimulation with the prosthesis. The tinnitus occurred in the implanted ear, although the problem was not so severe as to necessitate removal of the device. One case of facial nerve stimulation was controlled by programming out the electrodes concerned.

The Melbourne Cochlear Implant Clinic carried out 100 implantations, which resulted in one case of wound breakdown and subsequent device removal. This case arose from the need to avoid a ventriculo-peritoneal shunt, with a small inverted U-flap used. Another case of wound infection occurred which was treated conventionally. Webb et al. also report eight cases of thick skin flap, seven of which were transient cases. From the 100 implant operations, seven recipients suffered from in-



creased tinnitus, one of whom suffered from acute anxiety which was successfully controlled with intravenous diazepam. For three persons with tinnitus, the condition settled down after a few days, whereas the other three recipients had persistent problems which led to the device being removed in one instance. There were two cases of electrode slippage and one case of electrode tie erosion of the external auditory canal skin. Three persons had facial and/or tympanic nerve stimulation which was controlled by programming out the appropriate electrodes.

In both the Australian and Hannover series<sup>49,50</sup> there was a significantly lower incidence of skin flap necrosis and infection compared with the series described by Cohen et al.<sup>21</sup> All reports note that the incidence of complications decreased significantly with increasing experience of the surgical teams.

## Histopathology

Studies by Clark et al.<sup>51</sup> on the temporal bone for the effects of cochlear implantation showed that there appeared to be an adequate seal around the electrode at the round window entry point. These observations were considered to be encouraging for future intracochlear implantations, particularly those in children.

A sheath of mature fibrous tissue and the round window seal appeared to have been effective in limiting what might have been an earlier middle ear infection. Microscopic examination of the cochlea showed reduced numbers of spiral ganglion cells and dendrites in both the implanted and unoperated sides. These findings can be explained by reference to the histopathology and etiology associated with meningitis.

Clark et al. also report that in one case the electrode array had been inserted with minimal trauma to the cochlear structures; however, for human cochleas implanted with multi-electrode arrays containing a number of single platinum wires there was evidence of trauma.<sup>52</sup> New bone formation due to electrode insertion was much less than reported, and in one patient the new bone formation was not associated with any loss of ganglion cells. Clark et al. also found that the new bone in the basal region was woven in nature and the current was more likely to flow through the marrow spaces due to an appreciable difference in the resistances of the bone and marrow.

Clark et al. state that perhaps the most important finding for one recipient who had consistently used his device was that the electric stimuli from the device had not resulted in significant damage to the ganglion cells.

Linthicum et al.<sup>53</sup> examined 16 temporal bones from 13 persons who had been implanted from between 1 and 14 years prior to death. Bones from the non-implanted ears were available for comparison in eight cases. They found fibrosis of the scali vestibuli at the round window in all bones. Damage attributed to insertion of the electrodes was noted in all bones and was dependent on the design of the electrodes.

The short 3M/House device produced damage to the anterior position of the basal turn and injured the endosteum. The longer House electrodes were deflected through the spiral ligament and the electrode passed through the superior portion of the basal turn towards the modiolus and fractured the osseous spiral lamina, destroying the organ of Corti. There was degeneration of the organ of Corti and of dendrites. However, this degeneration had no effect upon the population of ganglion cells.

Examination of the temporal bones from a recipient of a Nucleus 22 electrode device showed damage to the organ of Corti and dendrites in the area. The Symbion device produced damage at the posterior middle turn, where there was fibrous tissue and ossification. Degeneration of the organ of Corti was almost total. However, only eight per cent less ganglion cells were observed compared with the non-implanted ear.

Linthicum et al. conclude that the degeneration of the cochlea is dependent on the amount of trauma at surgery, and that the damage that occurs in the cochlea has no effect on the ganglion population. Also, prolonged electrical stimulation does not affect the ganglion population or the auditory nerve.

The trauma caused on insertion of the electrode array depends on the design of the electrode system. The histological data that have been reported to date suggest that although some trauma is caused on insertion of the electrode arrays, the continued electrical stimulation does not decrease the population of ganglion cells.

# Attitudes to cochlear implants by the Deaf Community and educators

The hearing impaired population is heterogeneous, with variations in degree and etiology of hearing impairment, age at onset of deafness, knowledge of language, parental support, use of residual teachings and individual factors relating to family and situation.

Within this population, there exists a relatively small group (less than five per cent) which is predominantly comprised of the congenitally hearing impaired and is referred to as the 'Deaf Community' (Cowan, personal communication). This group 'do not see deafness as a deficiency, but just as another aspect of the "human condition", a way of life into which they fit comfortably and in which they construct happy, viable and satisfying lives' (Power, personal communication). Mohay<sup>54</sup> also states that many deaf adults place a high value on the language and culture and prefer to see themselves as a cultural minority group rather than disabled.

Use of cochlear implants as a technological medical intervention then tends to weaken the claim to being a cultural minority as well as being perceived as a threat to the long term existence of the Deaf Community. Mohay states that deaf adults also fear becoming second-class hearing citizens should they undergo implantation.

The current policy statement of the Australian Association of the Deaf (AAD) (see Appendix 1) calls for a moratorium on cochlear implants in children under eighteen until such time as the ethical issues have been addressed and more comprehensive information about deaf people's lives is available to caregivers and professionals. The AAD also believes that cochlear implants have received a disproportionate amount of favourable publicity and public funding. The AAD does, however, recognise the right of postlingually deafened adults to choose devices, such as cochlear implants, to regain some hearing.

Implementation of AAD's policy on the implantation of children would imply that the rapid learning period of early childhood would be lost to the patient and the rehabilitation team, and that the resultant young adults, who had been signing all their lives, would receive reduced benefit from the device when they were eventually implanted. Currently, congenitally deaf young adults who may be considering an implant are counselled very carefully that the most benefit they can expect from an implant is lip-reading enhancement and perception of environmental sounds. However, some recipients achieve more than these expectations.

Auslan (Australian Sign Language) is the language of the Deaf Community and is derived in most part from British Sign Language. A brief discussion of the manual languages used in the Australian community and schools is given in Appendix 2. In 1982, the Deaf Community called for recognition of Auslan as a community language under the National Language Policy.<sup>55</sup> The Deaf Community also made recommenda-

tions that educational institutions utilise its resources to provide teachers and teachers' aides for the deaf.

The question of which type of schooling best caters for children with cochlear implants is a matter of some debate. Power (personal communication) advises that: 'the auditory-verbal approach is only one of a number of approaches to developing listening and speaking skills in deaf children. Programs using it are in a tiny minority because the overwhelming preponderance of professional opinion among educators of the deaf favours multisensory approaches to the development of listening/speaking skills. The weight of theory and data strongly supports this position. It is clear that there are synergistic effects of the combined use of vision and audition which provides notable superiority for multisensory approaches as against the predominantly unisensory (auditory-only) "auditory-verbal approach". It cannot be stressed too strongly that this is a novel and largely data-unsupported approach which has no inherent virtue for children with implants'.

Somers<sup>56</sup> notes that comparison of implant users in aural and total communication programs with the control groups indicate that all children benefit from their cochlear implant, but orally educated children with the Nucleus device receive greater benefit than do those children in total communication programs. Parker (personal communication) has found the State deaf school system in Western Australia very supportive of children with cochlear implants, and private schools also take a keen interest in their implanted children.

The Parent Council for Deaf Education (PCDE) believes that there is already a shift away from an overall total communication philosophy within the New South Wales Department of School Education. The PCDE states all private centres use auditory/oral methods and lists the Shepherd Centre, the Catholic Centre for Deaf and Hearing Impaired at Strathfield, St Gabriel's School for Hearing Impaired Children and the Garfield Barwick School. The PCDE further advises that total communication is confined to the two NSW Department of Education schools, Farrar and North Rocks.

Cowan (personal communication) has provided details from a recent review of the eventual placement of hearing impaired children who attended the Taralye Kindergarten Centre of the Advisory Council for Children with Impaired Hearing. The review found that of the 113 children in the survey:

- 62 were totally integrated into regular classrooms (this total included 24 generally and 13 profoundly hearing-impaired children)
- 39 were studying in partial integration units attached to regular denominational schools (this total included 14 severely and 23 profoundly-hearing impaired children)
- 12 were in State schools, some in schools featuring oral education, some total communication and some which could cater for other disabilities as well as hearing impairment (this total included three severely and seven profoundly hearing-impaired children).

These results demonstrate the need for a flexible management philosophy for the rehabilitation program so that the use of the device can be integrated with the child's communication environment.

The public school system, if changed in line with the proposals of the Deaf Community, would tend to mitigate against the accommodation of children who were recipients of implants, as English would only be taught by 'English as a Second Language' (ESL) techniques. Kelly<sup>57</sup> notes that 95 per cent of all hearing impaired children are born to hearing parents and that those children have the right to the language of their family, which in most cases is spoken language. The PCDE states that the preferred option of most hearing parents is the language of the family.

# Utilisation and cost of cochlear implants

The 1988 ABS survey on Disability and Handicap<sup>58</sup> showed a total of 680,400 persons suffering from hearing loss in Australia. Of these persons 227,400 or 33.4 per cent used hearing aids. Of those persons surveyed, 345,500 reported that loss of hearing was their primary disability, and 24,300 were between 0 and 14 years of age.

The ABS report shows 64,100 hearing-impaired persons in the workforce with a further 5,000 suffering from hearing loss being unemployed. The ABS report also details the numbers and percentages of hearing-disabled children in different types of classrooms (Table 3).

**Table 3: Placement of hearing-impaired children within the education system**

Type of class	Per cent
Ordinary class	79.7
Special class	14.1
Special school	6.0
School at establishment	0.2

Source: Reference 58

Worldwide, between 5,000 and 6,000 implant operations have been performed, with about 3,500 Nucleus devices being implanted. It is estimated that 180 people have undergone further surgery to upgrade their single channel device to a multichannel implant.

In Australia, at the time of writing, approximately 309 implantations have been performed—102 on persons less than 21 years of age, the balance on postlingually deafened adults. Three Dortmann devices and at least 15 3M/House devices have been implanted (Canty, personal communication). Data from the National Acoustic Laboratories (NAL) (Birtles, personal communication) indicated that between 10,000 and 12,000 adults are profoundly deaf as are 1,419 children. The NAL estimates the patient pool in Australia to be between 2,000 and 2,400 adults, and 570 children.

Implant surgery is covered under Medicare Benefits Schedule Item number 5148 with a Schedule fee of \$1,260. Claimants against this item will be paid \$945. To the end of June 1991, 131 services had been charged against Medicare with a total of \$111,776 paid in benefits. The Nucleus device costs \$17,030 and is covered by private insurance. When the recipient is a public patient the cost of the device is met from the block grants given to the States under the Medicare agreement, or from other State sources.

Arrangements for public patients have led to a number of anomalies, particularly in Queensland where provision for the implantation of only five public patients per year

is permitted, provided that the cost of the implants does not increase the hospital's budget. Similar problems exist in the USA where the benefit set under the DRG system is insufficient to meet the cost of the device for patients covered under Medicare.<sup>59</sup> This has led to under-utilisation of the technology.

Table 4 details some of the costs associated with implantation in Australia.

**Table 4: Costs associated with cochlear implantation in Australia**

Service	Adults	Children
	\$	\$
CT Scan	400	490
Surgery	2,000	2,000
Device	17,030	17,030
3 day bed stay @ \$370/day	1,110	1,110
Rehabilitation @ \$75/h	2,250	2,250–15,000*
Total	22,790	22,880–36,630

\* The range of costs of rehabilitation corresponds to the different amounts required for post-lingually deafened children (\$2,250) and for congenitally and perilingually deafened children (\$15,000).

### Costs of rehabilitation

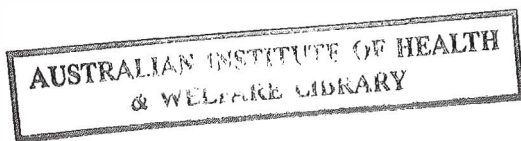
The distribution of persons who have received cochlear implants in Australia show clusters about the two major State capitals. This reflects the availability of rehabilitation services rather than ease of access to hospitals for surgery. Pickering, Szaday and Duerdoth<sup>60</sup> conducted a survey within Catholic schools in Victoria and identified the percentages of students suffering from hearing impairment in urban, regional and rural areas as 0.5 per cent, 0.3 per cent and 0.9 per cent respectively.

No form of compensation exists for costs of rehabilitation, so parents and adult recipients are requested to provide transport and meet the cost of the rehabilitation sessions. The total communication program currently operating in all States may not provide implanted children with the necessary rehabilitation. The unavailability of auditory-verbal classes in State schools mitigates against children from lower socio-economic groups who have cochlear implants. If an increased number of implantations were to be performed, particularly on recipients living outside the capital cities, strain would be placed on the availability of audiological services to conduct the rehabilitation and threshold checks.

Ward (personal communication) advises that a small number of private audiologists are practising in Australia. Approximately 50 per cent of Australian audiologists are employed by NAL to care for those who are helped by conventional amplification. Most of the remaining 50 per cent are employed in the major regional centres in public hospitals or private practice. An opportunity exists for the wider provision of

rehabilitation services although it may be difficult to encourage audiologists to country centres.

Canty (personal communication) feels that rehabilitation of implant recipients conducted by audiologists in centres outside the specialist clinics where implants occurred would probably misrepresent the difficulties associated with the rehabilitation program. He reports that rehabilitating implantees is a specialised area that requires training and experience which has been acquired over time and that the rehabilitation program is also tied to monitoring and manipulation of the speech processor. Overall, Canty believes that recipients might need to come to the major centre less frequently if appropriate rehabilitation were available in rural areas.





# Preliminary economic assessment

A preliminary economic assessment of the cochlear implant has been undertaken to give some further perspective on whether the technology represents value for money and its place in health care. The available data are limited and a number of assumptions have been made. The results are therefore indicative only and further work is required to obtain more reliable economic measures.

The key economic question is whether cochlear implants represent value for money compared to competing uses for health resources. This comparison should ideally have regard to what would happen in the 'base case' without the cochlear implant technology. The base case is necessary because costs and benefits of a new initiative are always incremental to what would have happened had the project not gone ahead.

An attempt was made to gather information on the costs and outcomes of profound deafness to the community, but little information was available. For this preliminary analysis, therefore, most costs were assumed to be additional to what is provided for the profoundly deaf at present. The estimates include the costs of service provision for selection of implant recipients, surgery/implantation and rehabilitation/implant maintenance over a 10-year period. Costs to recipients and their families of participating in a cochlear implant program have not been included.

The outcome measure chosen for the analysis is the likely improvement in the quality of life for recipients over a 10-year period. The Quality of Well-Being Scale described by Kaplan and Anderson<sup>61</sup> was used to obtain an indication of the impact of cochlear implantation on quality of life for the profoundly deaf. The Quality of Well-Being Scale includes weights both for symptoms and any functional consequences in terms of mobility, physical activity and social activity. The weights have been obtained from random sample surveys in the San Diego community during two consecutive years.

The weighting derived by Kaplan and Anderson for a group of symptoms and problems which included 'any trouble hearing—includes wearing a hearing aid' was  $-0.170$ , that is a 17 per cent decrease in quality of life as compared with a state of health with no specified symptoms or problems. This symptom measure does not include any additional weighting related to the functional consequence of profound deafness (for example on the social activity scale), which might well be relevant for profoundly deaf persons. Use of the cochlear implant should improve the quality of life but would not be expected to remove all of the deficit. In addition, the degree of response following cochlear implantation is known to be very variable. In the model used here, two levels of improvement in quality of life have been used, 15 per cent and 7.5 per cent.

The costs and incidence rates used in the construction of the project pathways shown in Figures 2 and 3 were obtained from the Melbourne University Clinic and the Royal Prince Alfred Hospital Clinic.

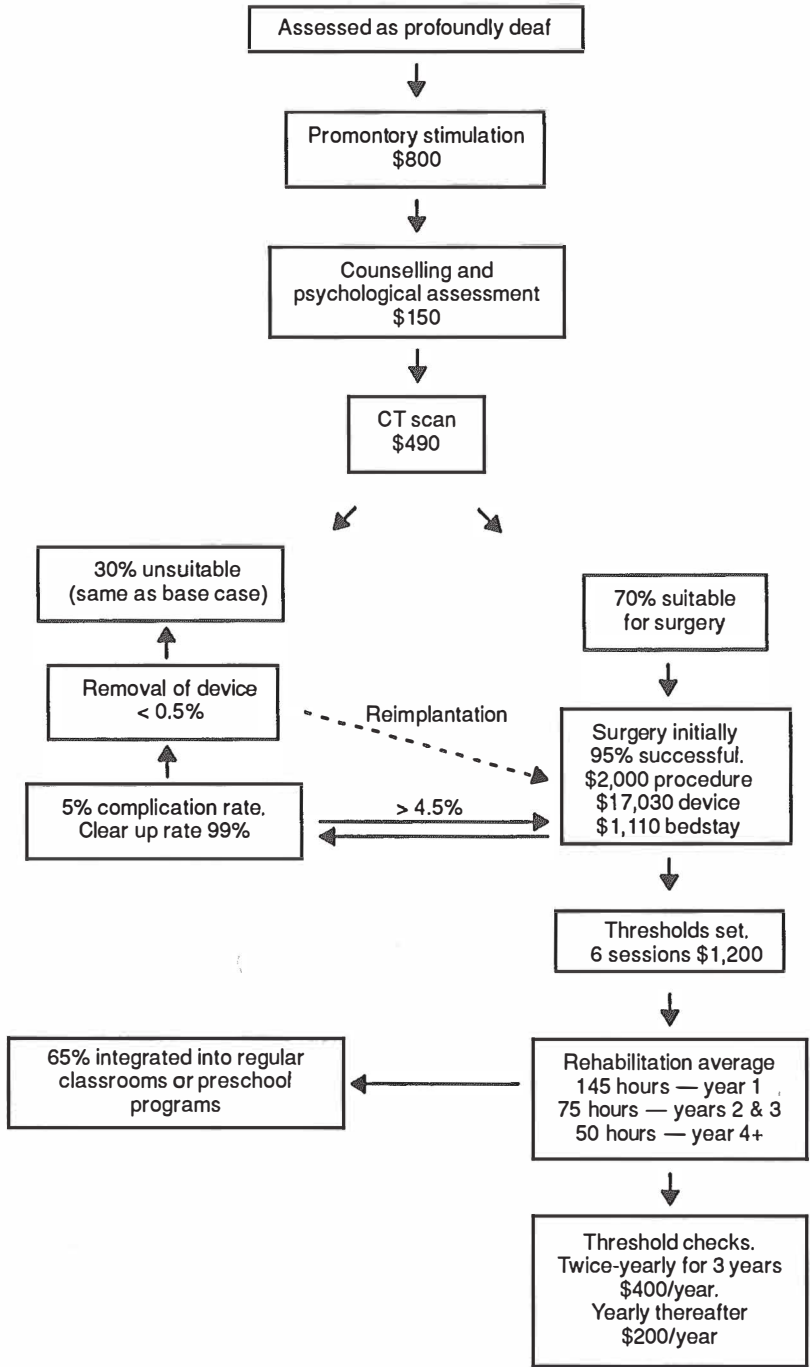


Figure 2: Project pathway—children

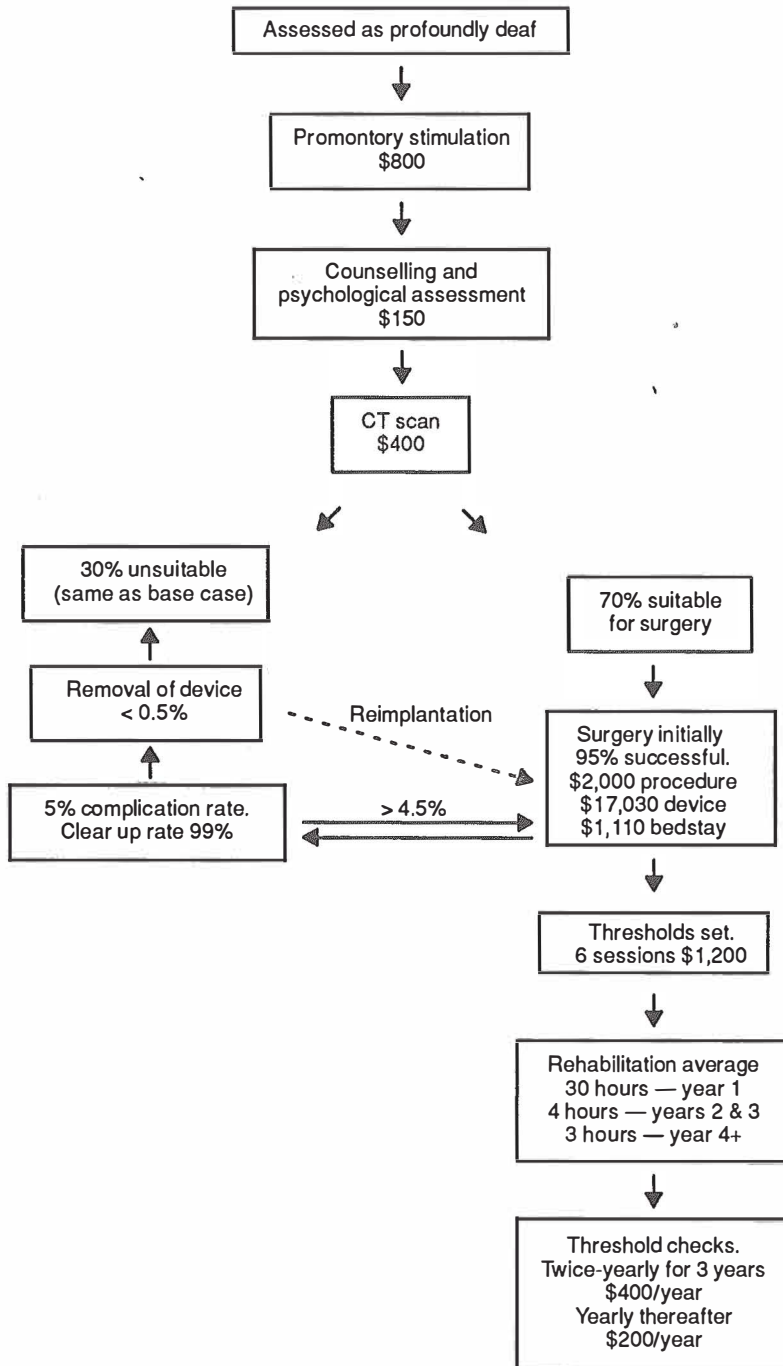


Figure 3: Project pathway—post-lingually deafened adults

Using the costs and probabilities shown in Figures 2 and 3, a preliminary assessment to calculate the cost per quality adjusted life year (QALY) was performed making the following assumptions:

- The lifetime of an implant effectively maintained is 10 years.
- On the basis of information received from Cochlear Pty Ltd, a supply constraint of 80 individuals implanted yearly (40 adults and 40 children) is included.
- Of the 40 children implanted there are 20 post-lingually deafened and 20 pre-lingually deafened children, all less than four years of age.
- The 40 adults are all post-lingually deafened.
- Within the two assessments (for children and adults) all amounts are in 1991 dollars, with a five per cent discount rate being applied for subsequent years to both costs and life years.
- There is a 30 per cent drop out rate through the selection process (based on the experience at Royal Prince Alfred Hospital).
- A three-day bed stay is associated with the surgery.
- A five per cent complication rate was incorporated within the costs for the first year of each cohort.
- For children, there are 145 hours of rehabilitation in the first year following implantation, followed by 75 hours for both years two and three. A further 50 hours per week is provided for the fourth and subsequent years.
- Threshold checks are conducted twice-yearly for the first three years and annually thereafter.
- The potential cost savings following implantation of children through mainstreaming their education does not commence until 18 months following implantation. The figure used for the saving per child per year was derived from the public school costs given by Pickering, Szaday and Duerdoth<sup>60</sup> and was applied for 65 per cent of the children in each cohort.
- Rehabilitation for post-lingually deafened adults consists of 30 hours for the first year, four hours for years two and three and two hours per year thereafter.
- No savings through education apply to post-lingually deafened adults.

The analysis was developed by considering 10 cohorts of 40 children and 40 adults, with each cohort starting on consecutive years, beginning with 1991, and running for 10 years. The ongoing costs for each cohort were discounted back to the starting year and sums of these discounted costs discounted back to 1991 dollars.

Rehabilitation for children represents a major cost in the implantation program. This cost does not take into account the training provided at schools which is considered to be common to both implanted children and children wearing hearing aids. Plant (personal communication) reports that dedicated programs of audiological rehabilitation are not available for children in Australia who use either hearing aids or commercial

tactile devices. This means that no comparative saving can be derived for the large amount of rehabilitation.

Using the assumptions listed above, the range of cost per QALY for children was found to be \$9,400 to \$18,800 for 15 per cent and 7.5 per cent improvement in quality of life respectively. The corresponding range for adults was \$15,067 to \$30,135 per QALY. Although the post-lingually deafened adults require substantially less rehabilitation than children, no direct savings could be attributed to the implant. Dinner et al.<sup>46</sup> found that employed implanted adults benefited in the workplace through their implants. However, no direct savings were found from productivity improvements and reduced absenteeism.

The question of whether cochlear implantation is value for money is a matter that cannot be answered in absolute terms. The figures given above are only indicative, and need to be confirmed by derivation of Australian quality of life weights, more detailed cost estimates, and further sensitivity analysis. To gain an indication of the dollar value of cochlear implantation, it would be necessary to examine whether this technology contributes more per dollar spent than competing uses of health resources. Some comparative estimates of economic cost per QALY gained or cost per life year are given in Table 5. Care should be exercised when making judgements based on inter-study comparisons. There are often important differences in methodology and assumptions made.

This preliminary economic assessment indicates that should the cochlear implantation process result in, say, a 10 per cent increase in quality of life, then costs per QALY might be of the order of \$14,000 for children and \$22,000 for adults. Costs per QALY of these magnitudes have often been regarded as representing good to reasonable value for money. The need to estimate the percentage of quality of life improvement demonstrates the requirement for research into the quality of life enhancement experienced by recipients of cochlear implants.

**Table 5: Australian cost utility/cost effectiveness results for selected medical procedures**

<b>Program</b>	<b>Adjusted cost per life year or per QALY at 1988–99 prices</b>
Hospital dialysis	\$47,789 per QALY
Cervical cancer screening using recommended approach	\$30,782 per life year
Breast cancer screening	\$6,600–\$11,000 per life year
Neonatal intensive care, babies <801 g	\$3,600–\$4,600 per life year
Kidney transplant	\$4,596 per life year
Neonatal intensive care, babies 1000–1500 g	\$1,200–\$3,000 per life year
Non-drug blood pressure reduction clinic	\$5,000 per life year

Source: *Cervical Cancer Screening in Australia: Options for Change*. Australian Institute of Health: Prevention Program Evaluation Series No. 2, AGPS, Canberra, 1991

Data on the societal costs of deafness could not be identified as part of this study. However, the societal impact of deafness, which could be reflected in the Social Activity Scale used by Kaplan and Anderson as a component of quality of life measurement, may include some of the social costs identified by Hartley<sup>62</sup> in her report on the social implications of inadequate literacy. These social costs include:

- decreased social skills and confidence
- reliance on others in the family
- restricted access to audible public and industrial health warnings
- a reduced ability to deal with the bureaucracy
- possible dependency on social welfare benefits
- labourforce implications, including diminished skills in the workplace, reduced flexibility and reduced personal advancement or portability.

However, caution should be exercised when equating a correlation with a causal relationship and thereby concluding that a particular cost arises from profound deafness.

# Tactile devices and cochlear implants

Tactile devices have been developed primarily as supplementary aids to be used in combination with lip-reading and aided hearing. The fundamental function of the tactile device is to stimulate the skin's sensory system in such a manner that the user can perceive a signal that represents speech. The modes of stimulus employed in these devices include mechanical vibration, piezo-electric ceramic transduction and electrocutaneous stimulation. Vibrotactile aids may be single or multiple channel devices that provide sensation to selected areas of the skin through a number of transducers.

Electrotactile devices operate by appropriate speech coding followed by provision of recognisable patterns of stimulation to the skin. Information from the stimulation supplements that available from lip-reading. Typically, such a device consists of an electrode handset and connecting cable, a stimulator unit, a speech processor and a microphone. Osberger<sup>7</sup> has described the various commercially available vibrotactile aids. The number of channels on available devices varies between one and thirty-two. Studies on volunteers with normal hearing<sup>63</sup> and hearing impaired persons<sup>64,65,66</sup> have shown that such aids may be effective as supplementary devices to assist persons with severe to profound hearing impairment. These studies indicate that there is improvement with closed- and open-set word recognition, with the greatest improvement in performance being when both tactile and visual cues are present.

The types of assessment procedures used to test the performance of wearers of these devices are essentially similar to those used for cochlear implant recipients.

Plant<sup>67</sup> has reported results for tactual-only encoding of time/intensity information, and presence/absence of high frequency information, using the Tactaid II device. However, comparative studies of Tactaid performance with that of a cochlear implant system showed that although the tactual device provided an awareness of sound, and enhanced the flow of conversation, benefits to lip-reading were small on videotaped words and sentences, and on speech tracking.<sup>68</sup> No significant tactile-alone response was observed in this study.

In a 1989 study Plant<sup>69</sup> compared five commercial tactile devices, testing a battery of speech feature contrasts. The results showed enormous variation between the five devices across 12 sub-tasks. The Minivib 3 performed best, but when the test conditions approached more realistic conditions, rather than very high levels of voicing contrast, its performance was much poorer.

In a study on 14 children, Cowan et al.<sup>70</sup> studied the difference between using hearing aids alone and hearing aids combined with the Tickle Talker, a device developed at the University of Melbourne. The speech detection thresholds showed that when the tactile aid was used the children were receiving sounds in normal conversation speech at everyday usage sensitivity levels.

Cowan et al. believe that optimum performance may only be achieved through utilisation of different encoding schemes to meet the requirements of children with differ-

ing degrees of impairment. These authors conclude that the greatest potential advantage of the device lies in its flexibility to employ various speech encoding schemes to meet the requirements of profoundly hearing-impaired children and adults with a range of residual hearing and communication needs.

Comparative studies<sup>66,71</sup> between the performance of electrotactile devices and cochlear implants indicated that the benefit to lip-reading was significantly greater with the cochlear implant than with the electrotactile aid. In particular Skinner et al.<sup>71</sup> report large differences between the two types of device for sound-only open-set speech tests. For the device-plus-vision tests the vibrotactile aid device provided some improvement. However, the improvements were substantially less than those obtained by cochlear implant recipients.

The data obtained for speech tracking clearly show the difference between communication with a vibrotactile aid and with the cochlear implant, with the multichannel cochlear implant showing the greater benefit to the patient. Skinner et al.<sup>71</sup> note that a number of post-lingually deafened adults do not meet the criteria for implantation or do not want surgery. Multichannel electrotactile speech processors may provide some enhancement of lip-reading and possibly reacquaint them with the world of sound.

Cowan et al.<sup>65</sup> conducted a study on four persons who did not qualify for or wish to undergo surgery and found that they derived substantial benefit from use of the multichannel speech processor (Tickle Talker). Benefits were observed for sound and speech detection, speech feature recognition, and for discrimination of open-set three words and sentences. Two of these persons showed improvements in speech tracking with a third showing benefits following 25 hours of training.

Cowan et al. report that substantial training was required for users of the tactile device to achieve improvements in open-set speech discrimination. They consider that their results clearly demonstrate that for hearing-impaired adults who do not meet the selection criteria for cochlear implantation, speech discrimination can be obtained through the use of electrotactile multichannel devices. These authors also see benefits in the use of tactile devices for severely to profoundly hearing-impaired persons who may perceive additional information to that provided by their hearing aids.

In her review on rehabilitation with cochlear implants and tactile aids,<sup>7</sup> Osberger states that all individuals who receive a tactile aid require extensive training in decoding the vibratory patterns into speech. She believes that as the amount of rehabilitation required for the complete use of vibrotactile aids is so great, the full potential of these devices in improving speech perception has not yet been demonstrated. She also points out that the training many individuals with electrotactile aids receive, especially children, is far from adequate. School personnel feel even more inadequate when dealing with a person wearing a tactile aid than they do when the child is wearing a hearing aid. Ward (personal communication) believes that very large efforts in rehabilitation would be necessary for the users of their aids to achieve reasonable open set scores.

Cowan et al.<sup>72</sup> state that substantial training was required with the tactile device before open-set discrimination improvements could be made. They express a concern that educators, audiologists and otologists may conceive of the cochlear implant as



obviating any necessity for further development or usage of tactual devices'. These authors and Skinner et al.<sup>71</sup> see a place for tactile devices in assisting those profoundly deaf persons who do not want to undergo surgical implantation or those who do not meet the selection criteria for implantation.

The studies conducted to date indicate that hearing-impaired persons do derive benefit from vibrotactile and electrotactile aids, particularly when associated with other devices. Lip-reading tactile aid users require a large investment in rehabilitation and this requirement is ongoing, as it is with cochlear implant users. However, it appears that users of tactile aids may require considerably more training. The place for this technology may be limited, given the comparative performance obtained with cochlear implants.

# Current status and future research needs

## Current status

Ward (personal communication) advises that of the more than 300 cochlear implantations that have taken place in Australia, in the vast majority of cases the implant is still being used as an aid to speech reading. This observation supports the findings of the various studies of the efficacy of these devices.

However, while this technology definitely provides benefits to the profoundly deaf, there is a large amount of individual variation in responses to an implant. Osberger,<sup>7</sup> when comparing the abilities of users of tactile aids and functioning implant users, points to the presence of 'star performers' within the implant population (this type of patient was not present among the tactile aid users). Not all recipients become star performers.

The ability of some implant recipients to converse on the telephone shows a strong sound-only response by some individuals. The ability of implant recipients to detect environmental sounds must also mean an enhancement of self confidence and possibly personal safety. Recent information indicates that all implantees from the Royal Victorian Eye and Ear Hospital achieve speech perception scores of almost 50 per cent in the implant-alone condition and that approximately 20 per cent can converse on the telephone.

Initially the implantation program was limited to post-lingually deafened adults, with a total of 230 individuals being implanted in Australia. Approximately 100 children have now been implanted in this country (both post-lingually deafened and pre-lingually deafened). Several points regarding the implantation of congenitally deafened children have raised considerable discussion. The first of these issues is the need to ensure that the child does not benefit from conventional amplification and the difficulty posed in assessing at a very early age whether the child is actually profoundly deaf.

De Foa and Loeb<sup>6</sup> have undertaken a survey on issues related to the technology. They report that issues seen as important for clinical acceptance include the performance of device components, cost reimbursement, diagnostic/prognostic screening and clinical fitting procedures. Insufficient third party coverage was seen as the major barrier to widespread application of cochlear prostheses. Educational barriers, resistance from the Deaf Community and professional prejudice by administrators and educators were also seen as factors.

## Concerns and uncertainties regarding cochlear implants

Another concern raised within the literature<sup>9</sup> is the long term implications of electrical stimulation of the cochlea for the survival of the nerve cells, and whether the possible damage done by an existing device would preclude the use of a more sophisticated

device in the future. The emerging histological information indicates that although some damage to the cochlea may occur on insertion of the electrode array, the continued electrical stimulation does not appear to decrease the numbers of ganglion cells available. These observations are given further credence by the performance of implantees who were only severely hearing impaired before the implantation and who retain some residual hearing following implantation.

The ability to gather information on the long term effects of electrical stimulation will be limited by the lack of knowledge of the condition of the cochlea and the auditory nerves prior to implantation. Any degradation associated with long-term use could also have resulted from the disease process that resulted in the recipient losing hearing in the first instance.

The age of implantation for young children may have a strong bearing on how readily the child responds to the implant and subsequent rehabilitation. Simmons<sup>73</sup> counsels that delays result in a child missing much of the prime period of language learning. Simmons states that the results of this may be negative, but not desperately so. This author reports that most of the scientific data on early learning come from studies on vision, and describes rapid early learning from hearing as a 'tacit belief'. Other workers believe it is generally established that delays in the provision of speech information to hearing-impaired children has significant effects on speech and language acquisition and academic achievement.

Osberger et al.<sup>74</sup> suggest that as more performance results are obtained from children and the benefits of implants become more clearly demonstrated, the question of 'whether' the child is a candidate for a cochlear implant has shifted to 'when' the child is a candidate. They raise the question of when to implant children with progressive hearing loss; that is whether to wait for the onset of total hearing loss or to conduct the operation when the child becomes profoundly hearing impaired. A condition of such early intervention would be a total loss of open-set speech recognition.

## **Selection criteria**

An emerging issue in the application of the selection criteria is that in the USA implant clinics are being approached by some adults with residual hearing who wish to have an implant in one ear while maintaining amplification in the other (Ward, personal communication). These requests contradict the FDA requirement for the prospective recipient to be profoundly deaf and it is understood that a lower threshold is being applied for these cases. The University of Melbourne Clinic/Royal Victorian Eye and Ear Hospital includes the severely hearing impaired in its selection criteria and has been evaluating these persons for cochlear implants.

Several persons who have single channel devices implanted have approached the Cochlear Corporation in the USA for implantation with the Nucleus device. Most of these persons were implanted in the other ear. However, a small number were re-implanted in the same cochlea without suffering any loss of speech perception.

Another concern in the selection of candidates for implantation is the length of delay in proceeding with patients who have lost hearing through meningitis. Those considerations represent a balance in options as the longer the waiting period the greater

the possibility of osteoneogenesis obliterating the cochlea. Spontaneous recovery can occur, so an appropriate period of observation should be undertaken.

Several authors<sup>4,9,10</sup> recommend caution in implanting cochlear devices in children before sufficient tests have been undertaken to fully establish the degree to which hearing is impaired. Kohut et al.<sup>10</sup> call for standardised tests for young children for the selection of implant candidates, based on tasks which are appropriate for pre-linguistically deafened children.

It may be necessary to relax the selection criteria to allow for the implantation of severely deafened adults who choose to receive auditory information by both hearing aid and cochlear implants. A further question as to when children with progressive hearing loss should be implanted also raises the need to have flexible criteria. Such early intervention would prevent the child losing his/her auditory memory; however, suitable criteria for such candidates need to be developed.

Implant teams may need to be aware when advising parents of the need for early implantation that the parents of the child may be involved in the grieving process, learning about how to cope with an impaired child, and may have difficulty in making an informed decision.

## Economic considerations

Cochlear implantation is not a cheap technology, but has provided important benefits for the profoundly deaf. The preliminary economic assessment in this report indicates that cochlear implantation represents reasonable value for money. Less quantifiable societal benefits would accrue from a decrease in underemployment and unemployment for post-lingually deafened adults. There would also be benefits through greater participation of deaf people within the general community and the ability to determine environmental sounds.

A report prepared by the Deaf Society of New South Wales<sup>75</sup> states that out of a sample of 302 deaf job seekers, 42 per cent had their highest qualification as the equivalent of School Certificate or less while only 1.6 per cent possessed the Higher School Certificate. Data from the Australian Bureau of Statistics (ABS)<sup>76</sup> show that 55.5 per cent of the Australian population attended the highest level at secondary school or have higher qualifications. This situation has the potential to create a structural problem, with deaf workers increasingly becoming less employable. Participation rates for persons with post-school qualifications are steadily increasing while the reverse trend is found for workers without post-school qualifications.<sup>76</sup> The Deaf Society of New South Wales report<sup>75</sup> shows that 78.8 per cent of these deaf persons registered with the Commonwealth Employment Service (CES) were unemployed for periods in excess of 12 months. The corresponding proportion for all unemployed persons in New South Wales was 30.4 per cent. The data in this publication also show that for deaf/hearing-impaired persons who are employed, the occupations obtained are predominantly in the basic manual, construction, materials handling and tertiary services industries. This suggests that hearing-impaired persons are economically disadvantaged. The cochlear implant provides an aid to overcoming such disadvantage for some individuals.

As a result of this relatively limited employment outlook for deafened persons, the Deaf Community has been active in trying to increase the self-esteem of deaf people and has lobbied for the acquisition of typewriter telephones and other assistance in the workplace. The Australian Association of the Deaf is also trying to improve the awareness of the community to deaf people's needs, their ability to cope with the law, and educational issues. Power<sup>79</sup> sees computer-based Telephone Typewriters for the Deaf (TTDs) as a means of providing access to communication for deaf people in years ahead. Likewise, office automation with electronic mail and 'computer-phone' facilities would also help deaf people communicate with hearing persons in the workplace.

## Research needs

Several authors<sup>78,79</sup> have suggested that further improvements in patient performance may result from the use of simultaneous pulsatile and analog signals being supplied to different electrodes. The benefits suggested include increased recognition of the second formant, a parameter which is not perceived well by existing devices.

Overall, Tyler<sup>79</sup> sees possible improvements through use of a periodic pulsatile stimulation coding frication on a high frequency channel, whereas analog stimulation could code the features of the other channels. Tyler sees the need for further developments in improving the perception of frication and the place of articulation.

Another area of research currently being undertaken by Cochlear Pty Ltd and St Vincent's Hospital, Sydney, is the use of single channel extra-cochlear electrical stimulation for the suppression of tinnitus (Ward, personal communication). The preliminary results are encouraging.

Further research is required in many areas involving this technology, including the following:

- Long term effects of electrical stimulation on the cochlea and related histopathological evaluation of the temporal bones and brain structures of implanted persons.
- Issues related to candidature for both adults and children.
- New imaging procedures and other test methods to assess suitability of candidates.
- Suitability of the technology for the moderately deaf. De Foa and Loeb<sup>6</sup> report opinion that the greatest hindrance to cochlear implants in severely or moderately deaf populations is the lack of a guarantee of sufficient efficacy in a given patient. They suggest it may be difficult to compete against improved (digital) hearing aids which present no surgical risk.
- The understanding of audition and the disease pathways that result in loss of hearing.
- Impact on the quality of life of implant patients (including educational benefits to children) and the collection of data to assess the cost benefit and cost utility of the implant procedure.

- The quality of life of deaf persons and the cost of deafness to the community.
- The development of speech processing hearing aids and combination cochlear implant and speech processing hearing.

Further knowledge of the audition process, including ways of perceiving speech, is required to better understand auditory mechanisms. Increased understanding of the steps involved in the loss of hearing as caused by disease should increase the ability of the implant clinics to predict the outcome of surgery. Additional understanding of the process by which some persons obtain spontaneous recovery of hearing following losses due to meningitis is also required.

Given the importance of training and rehabilitation to the success of the implant procedure, further research and development should be given to improve these services, particularly those services offered for pre-lingually deafened children. Also, considerable thought needs to be given to the provision of audiological rehabilitation in country areas, regional centres and urban areas removed from the implant clinics.

The lack of assessments of societal and quality of life implications indicates that further research is required in this area. Further work is also needed to provide a firm indication of the changes in quality of life associated with cochlear implantation.

# Conclusions

The place of cochlear implants is now established for post-lingually profoundly deafened adults, with this group obtaining proven benefits from speech perception and the awareness of environmental sounds.

A large variation exists in the degree of benefit an individual may receive from a cochlear implant. However, since the introduction of the Multipeak speech processing strategy a greater proportion of persons with implants are achieving open-set speech recognition on sound-only input.

The performance of persons with multichannel cochlear devices is superior to those using single channel devices.

The situation with the implantation of children remains reasonably controversial, although post-lingually deafened children show similar benefits to post-lingually deafened adults. An emerging issue with children with progressive hearing loss is whether to conduct the implantation prior to the child losing hearing totally. Such action would prevent a regression in speech perception skills and audiological memory.

The implantation of congenitally and perilingually deafened children is the most controversial area in the application of this technology. De Foa and Loeb<sup>6</sup> note that the degree of impairment must be assessed accurately, otherwise useful hearing may be lost iatrogenically. The speech perception benefits for such children are now emerging. The length of rehabilitation necessary to raise these children to acceptable levels of speech perception is up to 200 hours in the first year alone.

Emerging information indicates that although insertion of the electrode array may result in some trauma to the cochlea, the population of ganglion cells is not affected by continued electrical stimulation, and safety aspects of the technology are acceptable.

Tactile aids have also been shown to be useful in the treatment of the severely and profoundly deaf, but their application may be limited given the acceptance and superior performance of cochlear implantation.

On preliminary estimates of costs and benefits for children and adults, cochlear implantation linked to rehabilitation follow-up appears to provide reasonable value for money, particularly for children where benefits through avoidance of special education are obtained.

Consideration may need to be given to the provision of audiological services for the rehabilitation of implanted persons at a distance from the major clinics in the capital cities, so that potential benefits of the technology can be optimised. The variation between States in support provided for cochlear implantation also requires some consideration, as does the lack of rehabilitation and support services for deaf persons who use hearing aids.

While a number of issues require resolution, and research is continuing, cochlear implantation is now a successful, effective technology which benefits appropriately selected adults and children.

# Appendix 1

## Australian Association of the Deaf Policy on the cochlear implant

The Australian Association of the Deaf (AAD) represents the Deaf community of Australia. This community is largely composed of those who have been deaf from an early age, and who use Australian Sign Language (Auslan) as a primary means of communication. Such people usually feel whole, complete individuals, and most lead satisfying, productive lives. The language and culture of the Deaf community form a recognised part of our multicultural society (National Policy on Languages, 1987).

AAD's views on the cochlear implant should be seen in the context of this socio-cultural perspective on Deaf people's lives. Deaf people do not see deafness as something which needs to be 'cured'. Cochlear implant programs, however, tend to see deafness as a pathological condition which is open to medical and technological intervention. The disparity between these two views of deafness has led to much of the current debate about the cochlear implant.

AAD is aware that there are many adults who become deaf at a later age through illness or accident, or who for other reasons may not identify with the Deaf community and who wish to regain some hearing, however little. AAD fully recognises their right to choose devices such as cochlear implants, provided their choice is made freely and is based on full and accurate information.

AAD is conscious of Australia's leading role in the development and export of the cochlear implant device; however, it is also acutely aware of the feelings of most Deaf people about this issue. This policy has been prepared to reflect the attitudes of Deaf people about a procedure which is being portrayed as a major international success for Australian science and as providing much-needed relief for deaf people.

### Policy

AAD views the cochlear implant procedure with deep concern. Not only is it seen as invasive and unnecessary surgery, but it also raises many other issues which impact on Deaf people's lives. Some of these issues are addressed below.

#### 1. Publicity

Many Deaf people and their families have been disturbed by misleading publicity and information about the cochlear implant, either through the mass media or other sources, which imply that deaf people are ill or incomplete individuals, are lonely and unhappy, cannot communicate effectively with others, and are all desperately searching for a cure for their condition.

Such publicity demeans Deaf people, belittles their culture and language, and makes no acknowledgement of the diversity of lives Deaf people lead, or their many achieve-



ments. It is stressful for hearing parents of deaf children who are already struggling to come to terms with their child's deafness, and who are given a false impression that the implant will 'cure' their child.

**AAD believes that such misleading publicity should be challenged, not only by Deaf people themselves, but by spokespersons for cochlear implant programs.**

**AAD condemns in the strongest possible terms any cochlear implant program which uses such damaging publicity for its own ends.**

## **2. Cochlear implants in children**

AAD feels great concern about the fact that deaf children under the age of eighteen are undergoing cochlear implant surgery. The decision to implant such children is usually made by parents or guardians, and AAD has long felt that parents and guardians do not have access to full and complete information about the implications of deafness for their children's lives. Parents are usually led to see their children as pathologically deficient, and little information is available to them about the history, culture and language of Deaf people, or the possible lives of Deaf people in our society.

Until such time as more complete information is available to parents, and more productive associations develop between parents of deaf children and adult Deaf people, AAD feels that decisions to implant young deaf children are questionable. It should also be kept in mind that the implantation procedure effectively destroys the cochlea, and makes it unsuitable for future technological developments which may be less invasive.

**AAD believes that the medical ethics and social-emotional implications of such surgery on young children need to be discussed and researched in much greater depth.**

**In line with the policy of the World Federation of the Deaf, of which AAD is a member, AAD calls for a moratorium on cochlear implants in children under eighteen, until such time as the ethical issues have been addressed and more comprehensive information about Deaf people's lives is available to caregivers and professionals.**

## **3. Funding of cochlear implant programs**

The development of the cochlear implant device, the establishment of clinics for performing implant surgery, the surgery itself and pre- and post-operative care are all enormously expensive. Huge amounts of funding have been allocated to this over the years, from both private and government sources and through health insurance schemes.

The needs of Deaf people are many and diverse. Special education services, provisions for access such as interpreters and notetakers, and technological support such as TTYs and television decoders all enable Deaf people to lead comparatively 'normal' lives and to contribute to society. A cochlear implant does not necessarily remove the need for such services.

AAD believes that the cochlear implant receives a disproportionate amount of public funding, and that other services are more essential and serve a far greater number of deaf people (often including implantees themselves).

AAD suggests that greater consultation should take place with users of services to ensure a more equitable distribution of funds.

## **Conclusion**

AAD, in line with promoting greater community awareness of deafness and the diversity of Deaf people's lives in our society, calls for further discussion of and research into the cochlear implant and its impact on deaf people and their families.

## Appendix 2

### Auslan, Signed English and the education system

Australian Sign Language (Auslan) has been documented by Johnston.<sup>80</sup> Like British Sign Language, American Sign Language and Langue des Signe Francais, it is a language which cannot be dissected by a study of phonetics and the aural features of speech. Auslan does not use English syntax or word structure. The parameters that present the language are dynamic. Each sign can be described by the configuration, location, orientation (e.g. whether the palms are up or down), movement and the emphasis of the facial expression of the signer. An experienced signer will normally look at the face of another signer when Auslan is being used and take in the total picture of what is presented.

Johnston states that when Auslan is practised by experienced signers the apparent loss of tense markers, prepositions and pronoun forms is compensated for by use of location, direction, sign modulation, topicalisation and other mechanisms. Johnston suggests that Auslan may appear ungrammatical to less skilled observers but attributes this to the inexperience of the observers and to the fact that the grammar in 'spoken' languages is not studied. He states that grammar is studied only in written languages once they have been codified.

Treloar<sup>81</sup> conducted a survey of the attitudes of teachers of the deaf, school administrators and members of the Concerned Deaf Group as to the role of Auslan in the education of deaf children. The response rate of the different groups varied between 64 and 83 per cent, with the greatest response being obtained from the Deaf Community. Treloar reports a general feeling of inadequacy on behalf of many of the respondents. The exception to this finding was the forthright responses obtained from the deaf community. A general feeling of doubt about Auslan and its linguistic status was reported by the respondents and included a 40 per cent response by the Concerned Deaf Group indicating that Auslan was not as good as English.

Treloar also reported considerable differences in the responses between the administrators, teachers and the Concerned Deaf Group concerning the place of Auslan in the classroom. Both the teachers and administrators registered significant numbers of 'undecided' responses to many of the statements, including the development of the employment of deaf teachers and deaf teachers aides for the education of the hearing impaired. Treloar believes that this subject requires further research.

The education system for hearing impaired and deaf children in all States involves the Total Communication approach whereby the teacher speaks English and signs simultaneously to the class. As would be expected, these Total Communication classes include students with a gradation of disability so that some children will benefit from amplification while others would be following, using lip-reading and sign.

The signing system used in all States is Signed English as Auslan has not been available to deaf children for over 20 years. Ballge-Kimber and Giorcelli<sup>82</sup> state that no bilingual (Signed English and Auslan) education systems are available for deaf children in Australian schools, although Auslan is taught, usually by deaf people, in adult training colleges and institutes in some States. Power (personal communication) advises that bilingual programs are emerging in Australian school services for the deaf and that one has existed in Hobart for years.

Ballge-Kimber and Giorcelli surveyed the attitudes of 30 teachers of the deaf from three States on sign communication systems employed in the education of their students. All teachers surveyed were employed in Total Communication programs and covered all stages of primary and secondary education. The study was designed along the lines of previous overseas surveys and sought the teachers' reactions to the role of deaf adults in classrooms.

The teachers tended to support the use of Auslan, as 73 per cent believed that deaf children who received a bilingual education (Auslan and Signed English) would learn more English than with just learning Signed English. The teachers also perceived a need for the use of deaf people in classrooms as language and cultural role models for deaf children. Sixty-six per cent of teachers considered that Auslan should be taught in all Total Communication classes. A majority (60 per cent) also felt that parents should be encouraged to learn Signed English. Overall, the Australian teachers viewed Auslan as a valued sign language but were unsure of how it could be used in bilingual settings.

Mohay<sup>54</sup> states that artificial sign codes (Signed English for deaf people) were devised to replicate the syntax of spoken English, 'although the extent to which such codes are able to accurately reflect English syntax is questionable'. Mohay argues for the introduction of Auslan into the education system, with written English being taught as a second language. However, earlier in her article she states that 90 per cent of deaf children are born into hearing families. The parents of these children would probably wish their children to have a knowledge of English and would not themselves be sufficiently competent users of Auslan and would not provide a model for Auslan.

In response to Mohay, Parr<sup>83</sup> sees the question of Signed English versus Auslan as part of worldwide controversy as to the most appropriate manual methods. Mohay advocated the continued vigilance of both parents and medical practitioners to detect deafness in children.

Both Kelly and Parr stress the need for early detection and intervention so that the child may have the opportunity to develop language at an early stage. Kelly states that 90 per cent of deaf children can detect almost all the sounds of English speech with the application of appropriate amplification chosen from currently available devices. He also states that the nomination of Auslan as the target language for hearing-impaired children 'would continue the same poor language/reading levels evident over the last 100 years'.

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