SHOULD PATIENTS RECEIVE TWO COCHLEAR IMPLANTS?

INTRODUCTION

Normal hearing listeners use binaural hearing everyday to understand speech in noisy or reverberant environments, and to locate where a sound is coming from. With monaural listening, it is much more difficult to listen to a person talking with competing background noise, and to locate a sound in the environment. The "cocktail party effect" effectively shows how binaural hearing helps in understanding a person talking with the competing noise of other people talking. Research with hearing aid users clearly shows the advantages of bilateral aid fitting.[1] While there have been significant advances in speech processor technology which improve speech perception in noise, unilateral cochlear implant recipients do not have the advantages of binaural hearing which are available to normal hearing listeners.

Bilateral cochlear implants have the potential for improving speech understanding and the listening environment of cochlear implant recipients. While early studies with a small number of subjects only showed small benefits of bilateral cochlear implants,[2] more bilateral benefit might be achieved now that the outcomes for cochlear implant recipients have improved because of advances in implant technology. It is also more realistic to consider bilateral cochlear implants because the availability of behind the ear speech processors now makes wearing two processors considerably easier for the user.

Bilateral: *Both ears implanted (or fitted with hearing aids).*

Unilateral: *Only one ear implanted (or fitted with a hearing aid).*

Binaural: *Hearing with both ears.*

Monaural: *Hearing with one ear.*

Bilateral benefit: *Listening using the ear with the most favourable signal to noise ratio.*

Binaural advantage: *Combining the signal from both ears to improve on monaural listening.*

Now is an appropriate time to investigate bilateral cochlear implants in larger groups of subjects. These studies need to explore the incremental benefit of bilateral cochlear implants compared to unilateral implants for speech perception, sound localization, and in particular, quality of life and cost effectiveness. The medical and audiological indications for bilateral cochlear implants also need to be clearly identified.

WHAT ARE THE POSSIBLE BENEFITS OF BILATERAL COCHLEAR IMPLANTS FOR SPEECH PERCEPTION?

THE BILATERAL BENEFIT OF THE HEAD SHADOW EFFECT

The bilateral benefit is the ability to listen using the ear with the better signal-to-noise ratio. When speech and noise are from different locations, the signal-to-noise ratios of the two ears differ, primarily because of the head shadow effect. Normal hearers typically listen using the ear with the better signal-to-noise ratio. Bilateral cochlear implant recipients are also likely to obtain this bilateral benefit.

Preliminary results with the Nucleus® cochlear implant from the University of Iowa[3] and a conjoint study between the Cooperative Research Centre in Melbourne and the University of Manchester[4,5] have shown that almost all bilateral cochlear implant subjects were able to selectively use the ear with the most favourable signal-to-noise ratio and obtain a bilateral benefit (Figure 1).

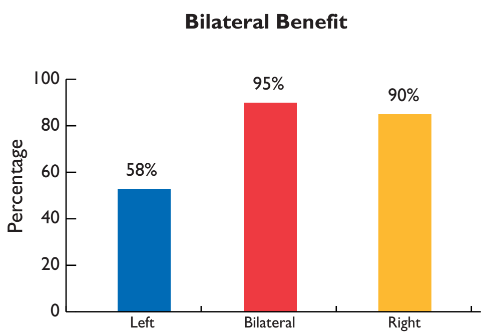

Figure 1. *Results from one subject at the University of Iowa for open set CUNY sentences presented at 10 dB signal-to-noise ratio[3]. Noise was from the left side and speech from the front. The subject wore two independent speech processors programmed with the SPEAK strategy. The right ear which had the better signal-to-noise ratio had the higher score in the (right) monaural condition. The left ear which had the worse signal-to-noise ratio had the lower score in the (left) monaural condition. The bilateral score was very similar to the better ear score on the right, indicating that the subject was using the ear with the most favourable signal-to-noise ratio.*

THE BINAURAL ADVANTAGE OF USING THE SIGNAL FROM BOTH EARS

The binaural advantage is the ability to combine the speech signals from both ears and improve on monaural listening. In normal hearing listeners there is only a small binaural advantage from the additive effect of having the same signal in both ears.

There is a greater advantage from binaural unmasking which arises when the noise delivered to each ear differs. However, only a small number of bilateral cochlear implant subjects have shown a binaural advantage (Figure 2). This could be because binaural unmasking predominantly depends on timing differences between the ears and bilateral implant subjects typically have poor perception of timing differences.

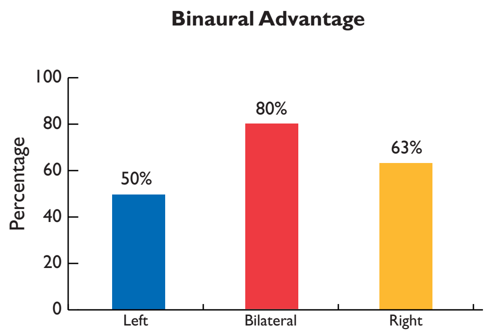

Figure 2. *Results for a subject tested at the University of Iowa for open set CUNY sentences presented at 10 dB signal-to-noise ratio[3]. The speech and noise were from a loudspeaker at the front of the subject. The subject wore two independent speech processors programmed with the SPEAK strategy. The bilateral score was 18% higher than the better monaural score for the right ear, thus the subject was able to reduce the impact of noise and combine speech information from both ears to understand speech in a noisy environment.*

CAPTURING THE BETTER EAR

Bilateral cochlear implantation will capture the ear with the best monaural performance. It is difficult pre-operatively to predict which ear will give the better speech perception result with the implant. Many unilateral cochlear implant recipients have been implanted in the ear with the longest duration of deafness and/or the poorest pre-operative hearing thresholds. The results of bilateral studies being conducted at the University of Iowa[3] and at other centres may help to better predict which ear should be selected for unilateral implantation. At this stage, however, it still is not possible to predict with certainty the ear which gives the best speech understanding post-operatively, and bilaterally implanted recipients can therefore take advantage of any differences between ears.

WHAT ARE THE POSSIBLE BENEFITS FOR SOUND LOCALIZATION?

Sound localization is the ability to locate and identify the person speaking, or the location of a sound in the environment. This is very difficult without binaural hearing, and noise and reverberation make the task even more difficult. Normal hearing listeners have excellent localization skills and are typically able to detect very small changes in sound location. Detection thresholds for horizontal localization can be as small as 1-2^0 from the front in normal hearing listeners. There have been very few comprehensive studies of sound localization with bilateral cochlear implant subjects in rigorous test environments (Figure 3).

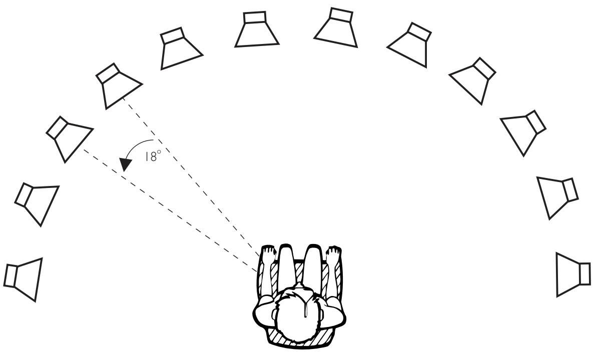

Figure 3. *Sound localization measurements used in the conjoint Melbourne-Manchester study.[5] An anechoic chamber was used. The angular distance between each loudspeaker was 18^0. The results from one subject showed an average absolute error in identifying the correct loudspeaker with the test signal in the order of 10^0.*

The two mechanisms for sound localization in the horizontal plane (as shown in Figure 3) are the interaural time delay, which is the time difference between the signal reaching the two ears, and the interaural level difference, which is the difference in the level of the signal at each ear. Thus to achieve optimal sound localization with bilateral cochlear implants, recipients need to have reasonable detection thresholds for interaural time delays or interaural level differences.

Preliminary studies with the Nucleus[2,5,6] and MED-EL[7] cochlear implants suggested that interaural level differences were the more important mechanism for sound localization in bilateral cochlear implant subjects. Research at a number of centers world-wide is investigating sound localization in bilateral cochlear subjects.

INTERAURAL TIME DELAYS

In normal hearing listeners the detection thresholds for interaural time delays can be as small as 10 μs[8]. Preliminary findings from bilateral cochlear implant subjects in Melbourne[2,5,6,9] and the Center for Auditory Research, Research Triangle Institute[10], showed that detection thresholds were quite variable across subjects as values were from 50 μs, the smallest delay assessed, to greater than 1 ms. These detection thresholds may also be sensitive to the stimulation pulse rate as thresholds for some subjects were poorer for the higher pulse rates at which pulse rate discrimination was also poorer. To achieve localization of 1-2^0 using only interaural time delays, detection thresholds in the order of 10 μs are required.

INTERAURAL INTENSITY DIFFERENCES

In normal hearing listeners the detection thresholds for interaural intensity differences can be as small as 0.5 dB to 1 dB.[8] The preliminary results from Melbourne[2,5,6,9] and the Center for Auditory Research, Research Triangle Institute,[10] showed that detection thresholds were as small as one current level step (0.2 dB for electric current) for some bilateral implant subjects, which was at the limits of the implant hardware. There was also less between-subject variability for the small number of subjects tested.

Given that some bilateral cochlear implant subjects with poor interaural time delay sensitivity were able to localize sound sources, the most important mechanism for sound localization was likely the interaural level differences. The subject in Figure 3 had detection thresholds for interaural time delays of about 400 μs, which would not be sufficient for the localization scores shown if using interaural time delays alone. The interaural level differences for this subject were less than four current levels (0.8 dB for electric current),[5] which would be sufficient for the localization scores shown. To achieve localization of 1–2^0 using only interaural intensity differences, detection thresholds of about 0.5 dB to 1 dB are needed in normal hearing listeners. The equivalent detection thresholds for bilateral implant recipients using electrical stimulation are not known.

COULD SIMILAR BENEFITS BE ACHIEVED USING BILATERAL INPUT TO ONE IMPLANT?

A bilateral input to one implant can be achieved by directing the outputs of two microphones to the unilateral implant. This could provide significant advantages above those obtained using a single microphone, and research is needed to determine how these advantages compare with those from true bilateral cochlear implants. It may be that the binaural advantage of combining the signals from both ears when using two independent speech processors could be similar to that from noise cancelling technology such as beam forming. Some of the benefit from the head shadow effect may be available from summing two microphones to a unilateral implant. Some sound localization ability may be achieved by the recipient actively moving his or her head to determine the direction where the signal is loudest. Current research is now comparing the benefits of bilateral cochlear implants with those from beam forming and dual microphone input to the better ear.

ARE BILATERAL IMPLANTS LIKELY TO BE COST-EFFECTIVE?

The improvement in the quality of life of cochlear implant recipients compares very favourably with other interventions and cochlear implants fall into the acceptable range on cost utility scales. However, the cost of a second implant some time after the first implant would be around 60% of the total cost, so the benefit would also need to add 60% to maintain parity in cost effectiveness. On the Health Utilities Index scale of 0 to 1, a unilateral implant on average moves recipients from about 0.6 to 0.8. The benefit of a second and subsequent implant would need to result in an improvement from about 0.8 to 0.92 on the same scale to justify the cost. The dilemma is that an index of 0.92 corresponds to about a moderate-severe hearing loss, and it is not known whether bilateral implants would give the same degree of function at this level.[11] The cost-effectiveness of sequential bilateral implants is being investigated in a multi-centre study in the UK in a minimum of 30 adults.

The surgical procedure for bilateral cochlear implants can also be carried out concurrently, or in two closely spaced procedures within the one hospital stay. The improvement in the quality of life of recipients will primarily be due to the acquisition of an implant and, at a minimum, will be the same as that for a unilateral implant. This change could be large enough such that the improvement in quality of life measures which are found for unilateral implantation may be adequate to offset the additional costs of bilateral implantation, even though the additional cost of the second implant will reduce the overall cost effectiveness. In addition, it is possible that concurrent bilateral implantation will be more cost effective than sequential implantation, due to the reduced surgical and programming costs.

WHAT ARE SOME OF THE ISSUES IN FITTING BILATERAL IMPLANTS?

A bilateral fitting requires more adjustment than just fitting each ear individually.

BINAURAL LOUDNESS SUMMATION

Bilateral implant subjects have judged the loudness of binaural input as being about twice as loud as that of monaural input.[2,9] This effect is known as binaural loudness summation. It is likely, therefore, that loudness will need to be reduced for bilateral fittings in most recipients.

It is preferable to adjust the volume control or comfortable listening (C) levels to compensate for binaural loudness summation rather than microphone sensitivity. If the microphone sensitivity was used to adjust loudness, the input gain would be reduced and this would potentially compromise speech understanding at low input levels. It is also important to maintain loudness balance across the two ears when adjusting the output levels for a bilateral fitting.

In addition, it would be useful to provide unilateral and bilateral MAPs for each speech processor. This would allow the recipient to select the unilateral MAP for monaural listening, for example when using the telephone.

PITCH MATCHING ACROSS EARS

Research is in progress to examine the possible effects on binaural listening of mismatches in pitch between corresponding electrodes on each side, and in particular the importance of matched pitch for speech perception. It is possible to MAP the processors so that sounds are perceived as being similar when the same input signal is presented to both ears, and the importance of this will be investigated in the ongoing research.

IS UPDATE RATE OR STIMULATION RATE IMPORTANT?

Update rate is unlikely to be of significant importance for sound localization in the majority of bilateral implant recipients. Studies at the Cooperative Research Centre in Melbourne with the Nucleus device[2,5,6] and at the University of Wuerzburg with the MED-EL device[7] have shown that the most likely mechanism for sound localization by bilateral implant subjects was the interaural level difference, especially for subjects with poor interaural time delay thresholds.

> ***Update rate:*** *Rate at which input signal is analyzed, which can be independent of simulation rate.*
>
> ***Stimulation rate:*** *Rate at which the intracochlear electrodes are stimulated.*

Interaural level differences are coded equally well using both high and low update rates. If interaural time delays are important for sound localization using bilateral implants, then the fine temporal structure of the input signal would need to be maintained. The preservation of temporal structures in the input signal is dependent on the update rate. Thus binaural cues which are wholly dependent on interaural timing delays between the two ears could be affected by update rate. It may also be important to present fine temporal input to both ears to gain binaural advantages in speech perception.

Recent findings from a subject in the Melbourne-Manchester study have shown that update rate and stimulation rate did not influence sound localization abilities (Figure 4). Further studies are underway to investigate the effects of update rate in bilateral and unilateral implant subjects.

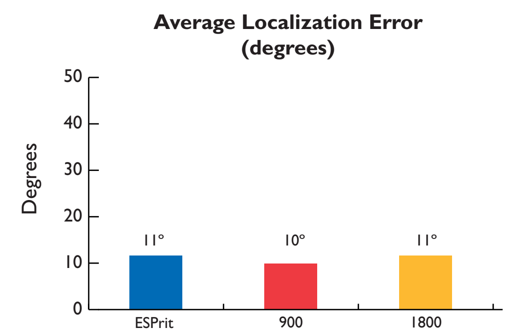

Figure 4. *Average absolute error identifying the correct loudspeaker with the test signal for one subject in the Melbourne-Manchester study using the ESPrit™ and body worn research processor[6]. The update rates in the research processor were 900 and 1800 samples/s, and the stimulation rate was 1800 pulses/s for both conditions. Channel filters were implemented using a DFT analysis (effective bandwidth 180 Hz) for the 900 samples/s condition and complex FIR filters, equivalent to a Hilbert transform, for the 1800 samples/s condition. The simulation rate of the ESPrit is 250 pulses/s. The test setup is shown in Figure 3 There were no significant differences between processors.*

HOW CAN THE BENEFITS OF BILATERAL IMPLANTS BE ASSESSED?

The key issues in the evaluation of bilateral cochlear implants are to demonstrate:

- **The bilateral benefit of using the ear with the better signal-to-noise ratio in speech perception.**
  Speech perception is measured with the speech signal and noise presented from separate loudspeakers, speech from the front and noise from the left and right side separately. A configuration representative of typical conversations is shown in Figure 5.[5,6]

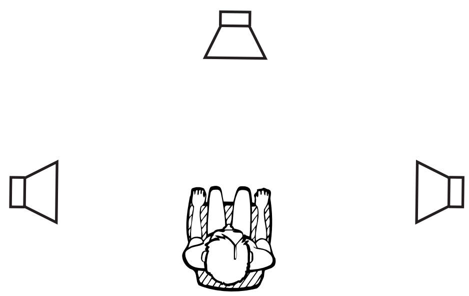

Figure 5. Test setup to measure bilateral benefit to speech perception. Noise is presented from either the right or the left side, and the speech signal is presented from the front.

It is important to ensure that the unilateral and bilateral conditions are loudness balanced. Loudness should be adjusted using the C–levels or loudness control to remove the influence of changes in the input gain and automatic gain control (AGC).

- **The binaural advantage of being able to combine the speech signals from both ears and improve on monaural listening.**
  Speech perception is measured with the signal and noise from the same loudspeaker in front of the subject, or where the speech signal is from the front loudspeaker and the noise is presented from both left and right loudspeakers (Figure 5). The unilateral and bilateral conditions should be loudness balanced.

- **The ability to localize sound.**
  Sound localization can be measured using an identification test where the subject identifies the location of the test signal presented from a single sound source (loudspeaker). An array of loudspeakers at equal distances from the subject and with equal angular spacings with respect to the subject position is used, an example is shown in Figure 3.[12]

- **The cost effectiveness of bilateral implantation.**
  Benefits can be quantified using formal scales of cost effectiveness and quality of life outcomes. Although concurrent implantation could be more cost effective than sequential implantation, the most effective method to determine the improvement in quality of life for bilateral implantation above that which is gained from unilateral implantation is to assess sequentially implanted recipients. This provides within-subject comparisons, and a smaller number of subjects is required to quantify the improvement in quality of life and the cost effectiveness of the additional implant.

- **Perception of interaural time delays and interaural level differences.**
  Direct control of the stimulation using specialist hardware and software is required to measure the perception of these parameters because accurate control of the electric stimulation is needed. Sound lateralization studies for interaural time delays and interaural level differences could also be used to determine the importance of time delays and level differences.[2]

SHOULD CHILDREN RECEIVE BILATERAL COCHLEAR IMPLANTS?

Historically, research on the benefits of advances in implant technology have been investigated in adults prior to children. If the benefits of bilateral implants are clearly shown in adults, then it is logical to extend these investigations to children in a series of clinical research studies.

Children may adapt to binaural input more effectively than adults because children are at an age where there is more neural plasticity. Children (and to a lesser extent adults) may also possibly benefit from the protective effects of electrical stimulation on the residual auditory nerves which could preserve neural integrity.[13]

The improvement in quality of life measures and the cost effectiveness of bilateral cochlear implants may be greater in children than in adults, similar to findings with monaural implants. There are cost savings on educational management for unilateral cochlear implants[14,15] and these would also be present with bilateral implants. There is also the total societal cost of deafness to consider, such as the potential loss of economic productivity, when calculating the cost effective indices. Thus the additional expenses associated with a second implant could have a less marked effect on cost effectiveness indices for children. However, where there is limited funding for implants it would be very important to determine whether the improvement in quality of life indices for a bilateral cochlear implant in one child is greater or less than that for unilateral implants in two children.

Another consideration is the amount of benefit that may be achieved by optimizing the hearing aid fitting in the non-implanted ear. Recent results at the National Acoustic Laboratories and the Children's Cochlear Implant Centre, Sydney, have shown that significant gains can be made by modifying the hearing aid fitting for better integration of the two signals.[16] This is being investigated further in a number of centres worldwide.

Finally, the potential advantages of bilateral implants in children may be compromised by difficulties in MAPping the two speech processors in very young children. It could be difficult to balance loudness and pitch across ears, although x-ray techniques may help determine electrode position in the cochlea. Studies in adults are required to show what are the important features of fitting bilateral speech processors, and these studies will also help in devising techniques that can be effectively used with children.

ARE THERE ANY POTENTIAL DISADVANTAGES OF BILATERAL COCHLEAR IMPLANTS?

One important issue is whether bilateral cochlear implantation precludes the implantation of future implants with improved technology. Reimplantation to replace faulty devices or to update implants is generally a successful procedure, and therefore, it is reasonable to expect that in most cases upgrades to future technology should be possible.

There may be some potential disadvantages of bilateral cochlear implants which could influence the successful use of two devices. Some recipients may not obtain significant advantages from bilateral implants or the benefit may be outweighed by the inconvenience of using two devices. However, these recipients would still have the advantages of being able to use the better monaural ear.

Finally, bilateral implantation may limit the number of patients who can have access to cochlear implants if there are limitations on the total number of implants provided by a clinic. This situation would arise where there is a finite budget allocation for cochlear implants. There may be other limitations imposed by the healthcare funding agencies which could lead to inequitable access to cochlear implants. There could also be additional costs of maintaining the two devices which may raise financial concerns for the recipients, the funding agencies, and the supporting clinics.

FURTHER RESEARCH IS NEEDED…

From this summary of current clinical research, it is clear there are many important questions which must be addressed before clinicians can recommend patients receive bilateral implants. There are opportunities for higher levels of benefit through improved performance in difficult listening environments and improved sound localization. However, it may be possible that some of these benefits can be delivered by a unilateral cochlear implant with more sophisticated processing and the use of dual microphone input.

Not surprisingly, there are many controversies in terms of cost effectiveness and how best to optimize device programming, as well as how well recipients will tolerate using two speech processors. Furthermore, many of these issues must be resolved before bilateral cochlear implants in children can be considered, despite the dilemma of keeping the non-implanted ear viable.

In collaboration with clinicians, Cochlear has participated in controlled clinical studies which have established the indications for cochlear implants in a continuing wider group of candidates, from the profound to the severe to profound hearing impaired adults, to children, and now infants. Cochlear is currently embarking on a series of clinical and research studies on bilateral cochlear implants in conjunction with a small number of cochlear implant centres worldwide. The main objectives of these studies are to determine the benefit of bilateral cochlear implantation, to determine the cost effectiveness of bilateral implants, to develop appropriate clinical methods for fitting bilateral implants, and to enhance our knowledge of binaural electrical stimulation to maximize the benefit to recipients.

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