

Rationale for Bilateral Cochlear Implantation in Children and Adults

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Provision of binaural hearing should be considered the standard of care for hearing impaired patients whenever it can be provided without significant risks. In the case of patients with severe to profound hearing loss effective binaural hearing may require bilateral cochlear implantation. The combined experience of many centers around the world has provided substantial insight into the benefits of bilateral cochlear implantation. At the Dallas Otolaryngology Cochlear Implant Program, over 40 children and 40 adults have been implanted bilaterally. Although there are some benefits that require further detailed study to quantify, there are many benefits that have become both objectively and subjectively apparent. Our experience, combined with published results of other centers, has allowed us to define guidelines for which the benefits of bilateral cochlear implantation significantly outweigh the risks. For these patients, bilateral implantation should be considered the standard of care, even as we continue to define the increasing benefits and expand the criteria to more patients over the long term.

This article will review the data available in the scientific literature as well as presentations at respected scientific meetings and will discuss our center's experience and rationale for providing binaural hearing to cochlear implant recipients of all age groups.

Despite proven objective and reported subjective benefits, a cochlear implant is unable to provide a recipient with "normal" hearing. An individual with a cochlear implant cannot hear with the same sensitivity or speech understanding in all acoustic environments as a normally hearing person. However, the details of what is not "normal" about hearing with a cochlear implant are complex, as is the physiology and physics behind how the normal human auditory system works. One area of limitation is the inability of current implant devices to represent all aspects of every acoustic signal to the cochlea

through direct electrical stimulation. Another limitation is the inability of the individual cochlea, and/or its central nerve connections, to receive all aspects of the electrically coded signal. One often overlooked aspect of normal hearing not experienced by the average implant recipient is that normal hearing is a "stereo", binaural (two ear) event and that the human brain is organized to receive and process sound from binaural sources. A significant amount of auditory system function, designed to enable us to "hear" in the real world of sound, depends on having two ears. The brain can sample and compare the spatial,

temporal, and amplitude characteristics of an acoustic signal and merge the incoming signals from the two ears together. In essence, "normally hearing" brains use rapid, real time analysis of signals from the two ears and use the combined data to hear.¹⁻²

According to the databases of the three major cochlear implant manufacturers, there are approximately 2803 bilaterally implanted individuals worldwide as of October 2005.³ Of these, 1638 (58%) are children. In light of this sizable experience, an international consensus report was written in favor

of bilateral cochlear implantation in appropriate candidates.⁴ This article will review research and presentations of import on the issue of bilateral cochlear implantation in children and adults.

BINAURAL HEARING: SUBJECTIVE IMPRESSIONS AND OBJECTIVE BENEFITS

The expected benefits of bilateral cochlear implantation are based on known deficits experienced by both unilateral cochlear implant users as well as individuals with unilateral profound hearing loss (single sided deafness-SSD). Subjectively, adult patients with normal hearing who suddenly lose all hearing in one ear are a good source of feedback concerning the benefits of binaural hearing. It is revealing that when adults who have had normal hearing in both ears their entire life suddenly lose all hearing in one ear, these individuals are often devastated by the loss. This is true even though they have better hearing in their remaining normal ear than is currently possible to achieve with a cochlear implant. They invariably report a dramatic decrease of speech understanding in the presence of even relatively mild background noise as well as marked impairment in the hearing of sounds originating on their deaf side. Many of these individuals withdraw from social and occupational arenas that present challenging acoustic environments. They state that "hearing" requires more conscious and intentional effort resulting in fatigue by the end of the day.⁵

Binaural hearing enables optimal performance of the auditory system. The binaural advantage results in improved speech understanding in quiet and in noise, as well as sound localization

ability.⁶⁻⁹ Binaural hearing is made possible by several sub-phenomena: the head shadow effect, binaural redundancy, and the binaural squelch effect.

The "head shadow effect" is a physical phenomenon that is the result of the head acting as an acoustic barrier to sounds and noise coming from different locations in space. The ear furthest from the noise source will have a more advantageous signal-to-noise ratio (SNR) than the ear closest to the noise source. This effect results in an average of 6.4dB of noise attenuation but can be as high as 20dB for high frequency speech sounds.^{10,11} This may not seem significant but increasing the SNR by that amount can result in substantial improvements in speech intelligibility, in some listening environments by as much as 50%.^{9,12} Interestingly, in patients with unilateral hearing loss, the head shadow effect still occurs but in their case can be a detriment if speech originates on the opposite side of the head from their only hearing ear.¹¹

Binaural redundancy and squelch are two central auditory processes which, when combined, improve on the distinct acoustic signals arriving at each ear. Binaural redundancy can be thought of as the advantage to be derived from listening with two ears, over one, even when the signal received at each ear is the same.¹³ For example, if speech and noise is presented from the same source in front of the listener binaural hearing affords a 1 to 2dB advantage in terms of SNR, compared with the monaural condition. If however the speech and noise signals are from spatially separated sources, the binaural squelch effect comes into play. When speech and noise are spatially separated each ear receives the signal at a different SNR. Binaural squelch is demonstrated by the addition

of a second ear receiving a poorer SNR. An improvement of 3dB on average is possible when compared to just listening to the ear receiving the better SNR.¹³ In effect, the SNR can be about 3dB worse for a binaural listener and still achieve the same speech understanding as a monaural listener via the squelch effect. Through these binaural mechanisms (head shadow, redundancy, and squelch) the binaural listener is able to understand speech with a more adverse SNR than a monaural listener.^{9,14}

Sound localization ability is made possible by the central auditory system's amazing ability to calculate minute differences in the characteristics of sound arriving at each ear. Differences in sound intensity, phase, frequency spectrum, and arrival time are calculated for each ear to determine the origin of sound.^{9,15-17} The normal human auditory system can distinguish as little as a 1dB difference in sound intensity between each ear and .1msec difference in arrival time.^{15,17} Frequency spectrum differences are caused by the variable attenuation of the head shadow effect and the shape of the pinna on different frequencies. The central auditory system, "knowing" these spectral effects, can calculate the origin of sound in both the horizontal and vertical planes. These mechanisms are so accurate that the normal hearing binaural listener has an accuracy down to 1 degree for identifying a sound source.¹⁷

These binaural mechanisms greatly enhance an individual's ability to understand speech in quiet as well as in the presence of background noise, in some instances by as much as 60% when compared to the monaural condition.⁹ It is through these mechanisms that the mature auditory system is able to process the time and intensity cues of

the auditory percept arriving at each ear for optimal hearing in adverse listening environments such as noisy restaurants, classrooms, and group meetings. Individuals with unilateral hearing are, for the most part, unable to utilize these binaural mechanisms that are important for effective hearing in the real world.^{9,18} Even with many years of experience with unilateral hearing loss central auditory mechanisms are unable to compensate for one-sided auditory deprivation.^{9,19}

ADULTS

Lessons from Bilateral Hearing Aids and Bimodal Stimulation

The importance of providing people who have hearing loss with binaural hearing has been recognized for many years with regard to hearing aid (HA) fitting practices.^{6,13,15} It is considered the “standard of care” to fit patients with bilateral symmetrical hearing loss with bilateral amplification in order to achieve binaural gains. Also, it is considered standard practice to fit patients with mild to severe unilateral hearing loss who have normal hearing in their other ear with a hearing aid in their poorer ear for the same purpose.^{11,13} The perceived limitations of sound quality through hearing aids is primarily related to the amount and quality of residual hearing available to the individual.

The benefit of a hearing aid used opposite a cochlear implant in patients with significant residual hearing in their non-implanted ear has also been studied.^{20,23} Cochlear implant recipients with preoperative contralateral HA word scores $\geq 20\%$ demonstrate the greatest bimodal (Contralateral hearing aid + cochlear implant) benefit in terms of improved binaural redundancy in quiet

and binaural squelch effects in noise.²⁰ These benefits are indicative of central auditory integration of the two different modes of stimulation, acoustic and electrical. However, such benefits have not been demonstrated for patients who use two microphones; one over each ear with one cochlear implant and processor processing both signals rather than using a hearing aid in the non-implanted ear.²⁴ A bilateral microphone arrangement of this type was found to have a potentially detrimental effect in certain listening conditions with regard to sound localization and could potentially worsen the SNR presented to the cochlear implant. This supports the premise that two distinct signals, processed by two cochlea are required to achieve binaural gains. It is apparent from the above referenced studies of bimodal benefit that the mature auditory system is capable of making use of whatever good quality auditory input it has available from either ear. It should now be considered standard practice to have all unilateral cochlear implant recipients utilize a hearing aid on their non-implanted ear if the residual hearing in that ear is capable of providing a binaural advantage. However, in our experience many cochlear implant recipients have poor residual hearing in their non-implanted ear and amplification either provides no benefit or even interferes with the hearing of the cochlear implant ear. In such cases the only way to provide effective binaural hearing is with bilateral cochlear implants.

Bilateral Cochlear Implantation in Adults

Improved speech discrimination in noise likely represents the most significant benefit of bilateral cochlear implantation, since competing background noise

represents the greatest challenge to communication in real world conditions. The fact that bilateral cochlear implants are able to provide a recipient with significant binaural benefit is now well documented by numerous adult studies.²⁵⁻³³ These studies have shown that all mechanisms of binaural auditory processing for improved speech understanding (head shadow, squelch, and redundancy) can occur in bilateral cochlear implant subjects.²⁶ The head shadow effect appears to be the most consistently beneficial mechanism for adult cochlear implant users. The binaural advantage of bilateral vs. unilateral cochlear implants for speech discrimination in noise increases with more adverse SNR.³² When tested in more favorable listening conditions (SNR of +10dB) speech scores for Cantonese lexical tones improve an average of 15-20% compared to the unilateral condition.³² However when tested in more adverse conditions (SNR -10 to -15dB) speech scores are immeasurable in the unilateral condition, but still average 80% in the bilateral condition in some patients.³²

Sound localization ability is greatly enhanced through bilateral cochlear implants when compared to one implant alone.^{17,27,28} This is achieved primarily through detection of interaural intensity differences.³¹ Most bilaterally implanted subjects cannot benefit from interaural timing differences with the current arrangement of separately programmed speech processors.

As is true with unilateral implantation, post-linguistically deafened adults receive the greatest binaural benefit for speech perception in quiet and in noise and sound localization ability versus their prelinguistically deafened

peers.^{27,28} This is to be expected to some extent since, in our center's experience, although prelinguistically deafened adults perceive great benefit for environmental sound awareness and lip-reading cues with their first cochlear implant they have more limited open-set speech discrimination than their postlingually deafened peers. Bilaterally implanted adults with prelingual onset of severe to profound hearing loss appear to have limited ability to benefit from binaural mechanisms except the head shadow effect.^{27,28} This limitation of central auditory processes in prelinguistically deafened patients supports the concept of a "critical period" of neural plasticity in early childhood which will be detailed further in the discussion on pediatric bilateral implantation.

The favorable results of bilateral implantation in adults are consistent with the subjective experiences of these patients. Patient satisfaction and benefit questionnaires overwhelmingly favor bilateral implantation in both prelingually and postlingually deafened adults.^{27,33}

In studies for which experienced bilateral implant users were required to go without the use of one implant for a period of time, their great frustration with monaural hearing was similar to that described by normal hearing individuals who experience sudden sensorineural hearing loss in one ear.²⁷ Once they had experienced binaural hearing through two cochlear implants, they found the impairments of monaural hearing to be unsatisfactory. It is likely that our current measures of binaural benefit are still somewhat inadequate in their ability to clearly quantify what bilaterally implanted patients describe as the "three dimensional" aspects of sound they enjoy when wearing bilateral

sound processors.³³ The subjective benefit perceived by the select few prelingual and perilingually deafened adults implanted at our center is self-rated as "high" despite their more modest measurable binaural gains. These individuals still overwhelmingly prefer the bilateral to the unilateral condition.

CHILDREN

Effects of Unilateral Hearing Loss

Studies that analyze the speech-language, educational, and psychosocial impact of unilateral profound sensorineural hearing loss in children can be useful in predicting the potential benefits of bilateral cochlear implantation in this age group. Bess, Tharpe, and Gibler (1986) demonstrated that the more adverse the listening situation (greater amounts of background noise), the greater the difference in speech recognition ability between children with normal hearing in both ears and children with unilateral hearing loss.³⁴ These children experience far greater difficulty in school and are 10 times more likely to fail a grade or to require educational resource assistance. They are twice as likely to exhibit behavioral difficulties in the classroom as their binaurally hearing peers. More recent reviews of the conflicting literature on this topic have drawn similar conclusions.³⁵ This information lends support for an approach to provide binaural hearing to children whenever possible.

Hearing Aids and Bimodal Stimulation in Children

As in adults, bilateral hearing aid fitting has been the standard of care for children with bilateral hearing loss for many years.^{36,37} It is also recommended for children with moderate to severe

unilateral hearing loss if the residual hearing can allow for good quality aided benefit that will not interfere with the normal hearing of the other ear.^{38,39} In both of these instances binaural gains are seen that are superior to the monaural hearing condition, and optimize the child's academic and social functioning.

Bimodal (Cochlear implant + contralateral hearing aid) stimulation has also been studied in unilaterally implanted children who have residual hearing in their non-implanted ear.^{40,41} Children are able to merge the different inputs and obtain significant binaural gains with this arrangement. The degree of benefit the hearing aid provides is related to the amount of residual hearing in the non-implanted ear and the child's experience with the bimodal condition. The use of a hearing aid on the non-implanted ear may be very important in children during the "critical period" of auditory integration if future use of that ear is ever desired. In cases of profound hearing loss in the non-implanted ear, early bilateral cochlear implantation may be the only way to achieve binaural hearing and to develop viable bilateral auditory pathways.

Bilateral Cochlear Implantation in Children

As mentioned in the introduction, there are currently at least 1600 bilaterally implanted children globally. Numerous scientific presentations have been given at internationally significant scientific meetings over the past four years that describe the benefits bilaterally implanted children receive and the active long term evaluations that are in process.⁴²⁻⁵⁸ Of greatest importance is the absence of any pattern of adverse outcomes or complications from the various centers involved with

bilateral implantation in children in the references cited here. The more than seven year history of children who have had bilateral cochlear implants is encouraging.⁴⁴ Children tolerate bilateral simultaneous surgery well and no long-term vestibular complications have been reported to date.⁴⁴

The greatest difficulty when studying bilaterally implanted young children is the complexity of measuring the various aspects of binaural benefit in this age group and comparing their outcomes to unilaterally implanted children.^{49,50} The young age and developing language of these children make speech discrimination in noise and sound localization testing very challenging. Comparing language outcomes between unilaterally and bilaterally implanted children requires several years of detailed monitoring. Testing protocols have been developed for evaluating sound localization ability and speech understanding in noise.^{57,58} A pattern of clearly positive benefit has emerged from these various studies with regard to objective test measures as well as parent questionnaires.^{48,54}

Since most children with cochlear implants receive intensive auditory-verbal therapy (especially those participating in controlled studies) the comparison of language outcomes between unilaterally and bilaterally implanted children may underestimate the real world benefit of bilateral implantation for children. It is possible, if not likely, that bilaterally implanted children may be able to acquire speech and language more passively as an unconscious part of every day life than unilaterally implanted children. This could result in a cost savings by reducing the frequency and duration of post implant therapy

that may be underestimated in such a controlled study. What is needed, as will be discussed below, are measures of central auditory development that can be reliably correlated with outcomes.

The central auditory system requires sound input in the first few years of life if effective central auditory development is to take place, lest irreversible changes in the brain occur. This window of opportunity is known as the “critical” or “sensitive” period and appears to be maximal in the first 3.5 years of life, remains open in some (but not all) until approximately age 7 years and completely closes by 12 years of age.^{59,60} Because every year of opportunity in the critical period that is lost is very difficult if not impossible to recover, children are now implanted with their first device as young as 12

months of age with the expectation of an excellent speech and language outcome. Just as with unilateral implantation, the age a child receives their second implant has a significant effect on the amount of benefit received and even a child's willingness to use the second device.⁵⁷ This is a consistent pattern in the 40 children we have bilaterally implanted, all of whom are high performing unilateral users and who ranged in age from 12 months to 15 years at the time of their second implant. This is in keeping with the concept of a “critical” or “sensitive” period of neural plasticity and central auditory integration.^{59,61} It is now well known that the younger a child receives their first cochlear implant, the better

their hearing and speech outcome.⁶¹⁻⁶³ Children who do not receive their first cochlear implant prior to 6 years of age have significantly poorer communication abilities than their peers who do.⁶²⁻⁶⁴

A measurable correlate of the critical period is now available in the form of cortical auditory evoked potentials (CAEP). These potentials reflect EEG activity in response to sound stimulation. The most commonly measured PI wave of the CAEP is thought to reflect synaptic propagation through the thalamo-cortical portions of the central auditory pathways. The PI latency is considered an index of maturation in these areas. Children who receive their first cochlear implant prior to 3.5

years of age have their PI latencies come into the range for normal hearing peers within 6 months of implant

Children who receive their first implant after age 7 years never achieve normal PI latencies, correlating with the observed poorer speech and language outcomes for this age group.

use.^{60,61} However, children who receive their first implant after age 7 years never achieve normal PI latencies, correlating with the observed poorer speech and language outcomes for this age group.

The same sensitive period and time course for normalization of the CAEP is now known to exist for the second implanted ear in bilaterally implanted children. Even early implantation and long term CI use in one ear is inadequate in preserving the plasticity of the auditory pathways that serve the opposite ear.⁶⁵ In the children sequentially implanted at our center who have been tested to date, the trajectory of PI latency change of the second implanted ear was similar

to the trajectories of children who received their first cochlear implant at the same age at which the test subject received their second implant. In other words, there was limited benefit to the central auditory system serving the second ear of the early implantation of the first ear. This is strong evidence that a sensitive period or “window” of opportunity exists for children to acquire effective binaural integration from their second ear. Based on preliminary CAEP data, reported outcomes for sequentially implanted children, and what is known about outcomes with unilateral implantation the window of opportunity for children to maximally develop central binaural mechanisms from second ear implantation would seem to be highest under 3.5 years of age, intermediate potential up to 7 years of age, and minimal potential over age 12 years, despite being high performers with their first implant.^{57,59,65}

It is reasonable to assume, and consistent with observations at our center, that the use of a hearing aid in a child's non-implanted second ear will enable some maturation of the auditory pathways for that ear, enabling easier transition to a cochlear implant later on. This will occur, however, only to a degree related to the amount of residual hearing. Until implantation of the second ear takes place, hearing aid use in that ear should be strongly encouraged if any auditory benefit can be obtained from doing so. This will likely maintain some degree of central auditory preparedness for later implantation of that ear. The effectiveness of a hearing aid for such purposes can be monitored with CAEP.⁶⁶ In children with profound hearing loss in

their second ear whose aided CAEP fails to show a time course of development, cochlear implantation of that ear is the only way to achieve optimal central binaural development.

These findings call into question the wisdom of "saving" one ear for future technological developments.

These findings call into question the wisdom of “saving” one ear of a pediatric cochlear implant recipient for future technological developments. If a unilaterally implanted child's second ear does not receive auditory input during the critical period of cortical development, later technology, no matter how advanced, will only provide input to a cortex incapable of receiving it. The benefit of such technology is likely to be arrested at that stage in an individual's life. If there are no effective connections within cortical layers and to the higher-order auditory and language cortex, even hair cell regeneration will be of limited benefit after the critical-sensitive period has elapsed, whether or not the individual is an effective unilateral cochlear implant user.

COMPLICATIONS OF BILATERAL COCHLEAR IMPLANTATION

Unilateral cochlear implantation is now a common procedure with few complications. With regard to bilateral cochlear implantation, the effect on the vestibular system has been the complication of greatest concern. The effect of unilateral and bilateral cochlear implantation on the vestibular system has been studied in detail.⁶⁷⁻⁷⁰ Vestibular symptoms are often present for a few days but quickly abate in the majority

of patients. Long-term vestibular complaints are rare in both adult and pediatric populations. Anecdotal experience at our center suggests that vestibular complaints are no greater in bilaterally implanted patients than in those after unilateral implantation. Nonetheless, consideration of the vestibular function and balance history of patients is prudent prior to both unilateral and bilateral implantation.

GUIDELINES FOR BILATERAL COCHLEAR IMPLANTATION

Based on published data and our center's experience, reasonable guidelines can be described for bilateral implantation in both children and adults. It is notable that factors supporting a good outcome parallel the candidacy for unilateral implantation. In these patients, the available data supports the theory that the benefits of bilateral cochlear implantation significantly outweigh the risks and can be considered an appropriate treatment. It should not be automatically assumed that patients who fail to meet these guidelines are ineligible or that they will not benefit from bilateral implantation. Further research is needed to define other categories of candidacy and benefit in patients with more complex histories. Such patients must have all factors carefully considered on an individual basis.

Simultaneous Implantation: It has been our experience that this should be reserved for only the most ideal candidates and we have attempted to develop guidelines to assist in the decision between simultaneous and sequential implantation for our patients. Simultaneous surgery allows a more seamless adjustment to the

two devices, particularly in young children. If a child or adult has factors that raise concern, a sequential approach should be considered.

In our center's guidelines, adults should have a history of adult onset hearing loss (beginning in late teenage years or after) to assure full binaural cortical development. They should have the most favorable hearing loss history; that is, a short duration of profound hearing loss of less than 15 years or the continued consistent use of amplification in both ears up to the time of implantation. There should be no prior history of vestibular disorders or recurrent vestibular symptoms such as Meniere's disease. Aided CNC word scores should be $\leq 30\%$ in each ear with normal cochlear anatomy in both ears. If one ear has word scores $\geq 30\%$ unilateral implantation should be considered first to allow testing in the bimodal condition. Sequential bilateral implantation can always be considered.

Children should be 12 to 36 months of age with profound hearing loss in both ears and no notable aided benefit. Preferably aided CAEP can be performed prior to implantation to ascertain if any signs of cortical development are present with either ear that would prompt unilateral

implantation and the continued use of a hearing aid on the ear with the most favorable responses. There should be normal cochlear anatomy, no other neurological or medical comorbid factors, and strong, conscientious parental involvement.

Sequential Implantation: The sequential approach allows the patient to continue hearing aid use in the non-implanted ear for later determination of bimodal benefit before committing the second ear to implantation. It also allows the center to ascertain the response to the first implant and the conscientiousness of the patient and/or parents in follow-up.

Adults are considered for sequential bilateral implantation based on the successful use of the first implant and the degree of bimodal benefit derived from an optimally fitted hearing aid in the second ear. The second ear should have a favorable hearing loss history (useful hearing either with or without a hearing aid into the teenage years). Implantation of that ear is likely to be advantageous if testing in the bimodal condition fails to increase word scores by 10% or sentence scores by 20% in both quiet and in noise (SNR +10dB) when compared to the implant only condition. A history of prior vestibular disorders or the absence of vestibular function

in the first implanted ear should raise significant concern, which must be addressed on an individual basis.

Children should be good-to-excellent unilateral implant users and their families have shown themselves conscientious in therapy. The age at which a second implant is contemplated matters a great deal unless consistent hearing aid use has continued in that ear. In the absence of consistent contralateral hearing aid use, we consider children less than eight years of age to be the most ideal candidates. We are reluctant to implant the second ear of children over 12 years of age who did not use a hearing aid in the second ear at least until six years of age. With continued hearing aid use, children of any age can be considered good candidates. For this reason, we strongly encourage continued hearing aid use in our unilaterally implanted children. Audiometric assessment of bimodal benefit is used in older children but can be difficult in younger children because of language limitations. CAEP on the aided ear can be used to determine if the hearing aid input is sufficient for central auditory system development. If so, hearing aid use is continued in lieu of implantation.

Conclusion: Provision of binaural hearing should be considered the standard of care for hearing-impaired patients whenever it can be provided without significant risks. In severe to profoundly hearing impaired individuals, this can only be provided with bilateral cochlear implantation when hearing aids are inadequate. In carefully selected candidates, the benefits derived are significant, the surgical procedures well tolerated, and negative effects infrequent in both children and adults. Future research will hopefully help define the roll of bilateral cochlear implantation in patients with less favorable historical factors and challenging co-morbid conditions as well as improving binaural gains with newer processing strategies and more advanced devices.

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