June 13, 2012

Josiah Morse, MPH
Program Director
Washington State Health Technology Assessment Program
Washington State Health Care Authority
P.O. Box 42682
Olympia, WA 98504-2682

Re: Washington State Health Technology Assessment for Unilateral/Bilateral Cochlear Implants

Dear Mr. Morse:

The American Academy of Otolaryngology – Head and Neck Surgery (AAO-HNS) is pleased to submit comments on the Washington State Health Technology Assessment on Unilateral and Bilateral Cochlear Implants. The AAO-HNS represents over 11,000 physicians in the United States who diagnose and treat disorders of the ears, nose, throat, and related structures of the head and neck. The medical ailments treated by this specialty are the most common that afflict all Americans, old and young, including hearing loss, balance disorders, chronic ear infection, rhinological disorders, snoring and sleep disorders, swallowing disorders, facial and cranial nerve disorders, and head and neck cancer.

The Academy’s Implantable Hearing Device Committee provided the attached expert input and the Physician Payment Policy (3P) workgroup reviewed and approved the response addressing the eight key points outlined in the instruction letter from the Health Technology Clinical Committee for the Washington State Health Care Authority (WSHCA). Each section addresses one of eight key points indicated on WSHCA’s letter and includes references for supporting literature at the end of each section.

We respectfully request that the WSHCA take the Academy’s comments into consideration. We welcome the opportunity to discuss this issue further with you. If you have any questions regarding our comments, please contact Harrison Peery, Health Policy Analyst (703) 535-3728 or via e-mail at hpeery@entnet.org.

Sincerely,

David R. Nielsen, MD, FACS
Executive Vice President and CEO

Enclosure
1. **Appropriate population for unilateral/bilateral implantation**

Cochlear implants are appropriate for children and adults with severe to profound bilateral sensorineural hearing loss. In general, this patient population gains little to no benefit with the use of conventional hearing aids. For children with prelingual severe to profound sensorineural hearing loss, speech development will generally not occur without the use of a cochlear implant, and the child will be required to learn communication through sign language only. On the other hand, children implanted with a cochlear implant at a young age will have an excellent chance of developing advanced auditory and speech skills.

The Food and Drug Administration (FDA) approves cochlear implantation for children 12 months or older, but may be considered earlier in children with certain conditions such as meningitis, which may result in labyrinthitis ossificans. Children with suspected severe to profound bilateral hearing loss are evaluated by an audiologist using both behavioral and physiologic measures to determine the child’s hearing status. This may include pure-tone audiometry and auditory brainstem response audiometry. A pure-tone average of 90 dB HL or greater in both ears is an indication for the consideration of cochlear implants. Children with less severe hearing loss may be deemed a candidate after appropriate evaluation. Once the child is identified with a severe to profound bilateral sensorineural hearing loss, a trial period using conventional hearing aids is initiated. If the child is not achieving benefit as measured by the acquisition of aural and speech skills, a cochlear implant is considered.

Adult patients with moderate to profound bilateral sensorineural hearing loss and poor speech understanding are evaluated by speech recognition testing that varies by center. Consonant Nucleus Consonant Test (CNC) Hearing in noise testing (HINT), AZ Bio Sentences Method (Azbio), monosyllabic words, and Bamford-Kowal-Bench Sentences in Noise Test (BKB-SIN) sentences are most commonly used to assess speech understanding in the best-aided condition. The FDA approves cochlear implantation with a HINT score of 60% or less. Medicare and some insurance carriers limit implantation to speech recognition scores of 40% or less.

Normal hearing individuals rely on binaural hearing for better speech understanding in both silent and noisy environments. Because of the advantages of binaural hearing, many children and adults who have shown no benefit with the use of a conventional hearing aid have undergone bilateral cochlear implantation. The advantages of bilateral implantation include insuring the better ear is implanted, allowing bilateral cortical stimulation and the development of auditory pathways, and restoration of binaural hearing (2). Bilateral cochlear implants have been shown to improve speech understanding in noise when compared to a unilateral cochlear implant (1).

The International Consensus on Bilateral Cochlear Implants and Bimodal Stimulation recommended the consideration for bilateral cochlear implants for the following patients:
Those in whom the benefits obtained with one CI is poor
• In meningitis, to prevent the possibility of incomplete electrode insertion in the case of ossification of the cochlea
• Those who want to restore binaural hearing or need it in order to remain in their chosen profession
• Children with permanent bilateral profound sensorineural hearing loss

The William House Cochlear Implant Study Group strongly endorses bilateral cochlear implants in clinically appropriate adults and children.

References


2. Effectiveness of cochlear implantation on indicated clinical conditions and quality of life

The efficacy of cochlear implantation on speech discrimination has been well documented and studied, particularly in postlingually deafened adults. More recent research has focused on prelingually deafened adults, the elderly and children. Klop et al showed that there was a significant improvement in word and phoneme scores in prelingually deafened adults after implantation. Multiple studies conducted on the elderly, typically defined as age > 70, have uniformly shown improved speech scores as well as high percentage of patients who are able to talk on the telephone. Studies conducted in multiple countries speaking multiple languages have shown benefit for children with an improvement in speech understanding scores and telephone usage. More recent studies in children focus on the speech intelligibility after cochlear implantation and have found improved speech intelligibility as well.

Quality of life after cochlear implantation has been shown to improve using multiple measures for postlingually deafened adults after cochlear implantation across multiple countries. Klop et al in a separate study of prelingually deafened adults also found a significant improvement in quality of life measures. Elderly cochlear implant recipients showed an increase in quality of life similar to younger adult recipients or even higher. Pediatric cochlear implant recipients also reported increased quality of life due to their cochlear implant with an increase in quality of life associated with an increased length of
cochlear implant usage \((22, 11)\). The majority were able to attend mainstream schools and achieve higher educational levels \((24)\).

References


3. How the indicated conditions diagnosed

Patient history, audiologic testing, and imaging studies are used to determine cochlear implant candidacy. The following factors are considered when determining implant candidacy:

1) Case history (duration of hearing loss, hearing aid use, family history of hearing loss, etiology, phone use, desired ear to be implanted i.e unilateral vs. bilateral, knowledge of a CI, surrounding support, patient motivation).

2) Unaided audiologic testing (ear specific air conduction, bone conduction, tympanometry).

3) Ear specific aided warble tone detection with hearing aids.

4) Real ear measurement to verify hearing aid settings are appropriate.

5) Aided (ear specific) Consonant Nucleus Consonant Test (CNC) Word Recognition Score (WRS) at 60dBA, and AZ Bio Sentences Method (AzBio) in quiet (ear specific). If the patient scores 50% or better then perform AzBio in noise.
6) Bamford-Kowal-Bench Sentences in Noise Test (BKB SIN) presented to determine the signal to noise ratio in which a patient with a CI can understand sentences. This should be measured pre and post operatively.

7) If a patient has any complaint of dizziness, a vestibular work up may be warranted. This may consist of VNG, Rotary Chair, Platform Posturography, Vestibular Evoked Magnetic Potential (VEMP), and/or Electrocochleography Testing (ECOG).

8) A CT of the temporal bones (with or without contrast) or MRI (with or without gadolinium) may be warranted prior to implantation to assess for signs of cochlear dysplasia/ossification and to rule out retrocochlear processes, such as an acoustic neuroma.

4. Value statement – what are the key benefits to patients (adult and pediatric) based on scientific/clinical evidence

The key benefits of pediatric and adult cochlear implants revolve around the restoration of sound perception (1, 2). Hearing is critical to environmental awareness and communication; the adverse impact of severe to profound hearing loss (deafness) is well documented in impaired language development, quality of life, safety, and employability (1, 3). Even with the heterogeneity of the scientific literature, the clinical and scientific findings of benefit are consistent.

Prelingually deaf children who receive cochlear implantation achieve positive clinically significant benefits in sensitivity to sound, and speech perception and production. Bilateral cochlear implantation in children have clinically significant benefits in improved sound localization, speech perception, and speech understanding in background noise when compared with children with unilateral cochlear implants and contralateral conventional amplification. Prelingually deaf pediatric cochlear recipients achieve educational and employment levels similar to those of their normal-hearing peers (4).

Postlingually deaf children and adults receiving cochlear implantation achieve improved speech perception, and improved quality of life (1, 2), prelingually deaf adults achieved improved speech perception, but less so than postlingually deaf adults (1, 2, 5); functional and quality of life assessments indicated perceived benefit. The benefits of cochlear implantation in geriatric recipients appear to closely mirror that of younger adults (6, 7). Employment status and job satisfaction has been found to improve following adult cochlear implantation (8). Bilateral cochlear implantation in adults has benefits in improved sound localization, reduced head shadow effect, and speech understanding in background noise when compared with adults with unilateral cochlear implants, though no clear distinction in quality of life has been identified (1).

References


5. What is the alternative treatment for these patients? How does this technology address a clinical need? What are the “off-sets” (additional surgeries, etc.) to implantation of cochlear implants?

Cochlear implants are typically used in cases of profound hearing loss. Hearing loss that is not profound, i.e., there is some ability of the ear to hear sounds, even if faintly, may respond to acoustic amplification. This is simply making sounds louder, intended to stimulate the inner hair cells of the cochlea in a more-or-less conventional way, albeit at a higher volume. These may include hearing aids, bone-conductors and semi-implantable electromechanical transducers. These all depend on the presence of at least some residual hearing. Effectiveness may be limited, however, by the numbers of remaining neurons available for processing sounds.

For a severely or profoundly deaf person, whose inner hair-cells or other key parts of the inner ear are not working, only a cochlear implant can provide true electro-neural stimulation, bypassing the normal inner hair cells and directly stimulating the acoustic nerve. This allows the perception of sound to be appreciated by the
person who otherwise has no hearing at all.

The perception of sound is critical to the development of a spoken language. The brain pathways that are required to be able to speak are developed almost exclusively in the first few years of life. The use of cochlear implants in these critical years is essential in the formation of these pathways in children who are otherwise deaf. Ample evidence now exists that shows bilateral implants in children provide superior results in speech performance (1).

The surgical procedure that results in the placement of the implant is only the beginning in a long process of programming and rehabilitation. The devices, though they can function “out-of-the-box”, are best utilized when customized to the individual. This can require several visits for programming, and in the case of a “pre-lingual” child, can involve years of speech training and audiologic support.

Additional surgical procedures that may be necessary in implant patients include the placement of pressure-equalization (PE) tubes for control of recurrent otitis media. Otitis is very common in the pediatric age group and the presence of bacteria in the middle ear and in proximity to the electrode entering the inner ear carries a slightly increased risk of suppurative labyrinthitis and possibly meningitis. Less common procedures might include the “overclosure” of the ear canal in the case of severe deformity or previous radical surgery. This is done to protect the slender electrode array from accidental exposure to the outside elements and subsequent contamination or even extrusion.

References


6. Measurable clinical outcomes based on clinical experience and peer-reviewed evidence

Measurable clinical outcomes are in two main categories: objective data and quality of life studies. The discussion that follows will be on available objective data. The data will be divided into that available for adult versus pediatric patients.

Unfortunately, there is an overlying theme of significant clinical heterogeneity within the studies available, and a minimum of randomized trials. However, it is unethical to randomly withhold cochlear implants from patients who qualify, given the overwhelming evidence for the efficacy of implantation. Due to the studies available, the data will be presented in mostly a narrative format.

PEDIATRIC PATIENTS

UNILATERAL CI VERSUS NO ACOUSTIC SUPPORT
There are 8 available studies discussing children with CI versus children without any technological aids (i.e. no hearing aids or tactile aids). A total of 848 patients were included, are range 15 months to 17 years 11months. Follow up ranged from 6 months to 12 years.

Manrique et al (n=182) found a significant improvement in pure-tone audiometry (PTA) scores at 12 months post-activation compared with pre-implantation (preimplantation = 115.8, SD 3.25; 12 months post-implantation = 34.3, SD 8.25; p<0.05). The study showed that implanted children were able to detect sound better (30).

Speech perception was measured in 666 children using several different objective instruments. Staller et al (n=78; age range 3-17) showed a 35% improvement with the word recognition to a 50% improvement in sentence recognition (5).

A Med-El report to the FDA (n=82) showed that younger children had a 50% improvement in two long syllables and 70% improvement in pattern perception testing. Older children had a 53% improvement in simple sentence perception and 79% difference in spondee identification. A weakness of the study was that not all children were entered for all the tests. Illig et al (n=167) reported on children ages 12 months to 15 years on several speech measures. Younger children (<7 years) had an improvement of 59% in pattern perception; older children (7-15 years) ranged from 15% improvement in minimal pair testing (words that differ by one feature) to 39% in pattern perception (6).

Illg et al, Staller et al, Med-El and Kessler et al all found a positive association between early implantation and improvements in speech understanding (1, 5, 6, 7). Harrison et al (n=82) in a study on children ages 2 to 13 found a positive trend in tests of auditory comprehension. (4). Similar results were found by Nikolopoulos et al (n=82), showing an association between earlier implantation and understanding of English grammar when compared to normal hearing peers, specifically, 2% preimplantation, and 67% postimplantation with a 5 year follow-up. Nikolopoulos et al also showed significantly greater improvements for younger implanted children than older-implanted children in Categories of Auditory Performance which is a measure of performance in quiet conditions. The group measures performance between 24 and 48 months of implant use and correlated with the age at implantation, with p=0.006 after 24 months of implantation (2, 3).

Nikolopoulos et al (n=82) used the Speech intelligibility rating to evaluate the effects of age at implantation on speech. They found a significant correlation between speech production and earlier implantation (p<0.01) (2, 3).

UNILATERAL CI VERSUS HEARING AIDS

There are six studies evaluating the effects of unilateral CI versus traditional optimized hearing aids. The total number of patients was 535 profound hearing impaired patients, and ages ranged from 9 months to 17 years. Outcome measures varied between studies.

The overall results indicated improved sensitivity to sound, speech perception and speech production outcomes. Van den Borne et al. studied 43 children pre and post implant, and found over 24 months both
groups improved in ability to detect everyday sounds, but the CI group improved by 3.5 points, and the hearing aid group by 1.9 points (8).

Across the reported studies, 209 children had their speech intelligibility measured. Midner et al. (n=49) did a cross-sectional study comparing CI and hearing aid children. A mean percentage gain in understanding visually and orally presented words in CI patients (p<0.01). Osberger et al (n=58) measured speech perception in 5 tests. Over an 18 month period, improvements were seen in all measures in favor of CI (p<0.0001) (11).

Svrinsky et al (n=297) compared the difference between PB-K word scores for CI patients with predicted PB-K scored for hearing aid patients. CI patients mean scores improved over 12 to 18 months, but they reported insufficient data to verify statistical significance (12). A smaller study by Osberger et al (n=30) measured speech perception using 3 instruments, using the patients as their own controls pre and post implantation. They found improvements in all measures for the CI group. Statistical significance was not reported (11).

Van den Borne et al (n=43) reported possible conflicting information on speech perception in CI patients (8). In a prospective cohort of patients, they showed relative small improvement in verbal reception for CI patients over hearing aid patients. However, the actual scores at 24 months were better for hearing aid patients (54) than CI patients (50). It was noted that the baseline scores were lower for the CI patients (CI 43, hearing aid 47.5).

Speech production was reported by Tomblin et al (n=58) in a prospective cohort study. They reported a mean difference 5-year scores of 19.6 in favor of CI patients. A regression analysis was done which showed that the length of CI use was the main factor in score improvement (10).

Overall, the evidence suggests that CI facilitate improvement to sound and speech outcomes for children with profound SNHL as compared with hearing aids.

UNILATERAL VERSUS BILATERAL COCHLEAR IMPLANTS

Three studies (n=61) have compared unilateral CI versus bilateral CI in children. All the studies are cross sectional studies. All the children in the studies had bilateral CI and were tested with either one or both components in place. All the studies were funded by the device manufacturers.

Peters et al (n=30) measured speech perception in quiet and noise. In quiet, speech perception was not statistically different between the groups but showed trends towards benefit for the bilateral CI group (13). They noted that children who received their second implant prior to age 8 did better than those who got the second CI after age 8. They tested sound directionality and showed a significant benefit to bilateral CI, especially in noise, when the noise was directed towards the 1st implanted ear (p<0.0001).

Kuhn-Inacker et al (n=18) measured speech perception in noise and quiet settings, and found trends in favor for bilateral CI. Unfortunately this study did not describe patient selection in any detail (14).

Litovsky et al (n=13) reported an advantage of bilateral implantation in improving the ability of indentifying sound directionality. In 9/13 participants, sound location was better with two CI than one (p<0.001) (15).
ADULT PATIENTS

UNILATERAL CI VERSUS NO ACOUSTIC SUPPORT

Four studies with 984 patients reviewed this question. The follow up period was 3 months to 24 months. Two studies had patients with profound hearing loss, and two studies had patients with severe to profound hearing loss. The studies measured speech perception or quality of life. All studies showed a significant benefit or trend towards benefit from unilateral CI. Between the 4 studies, 9 speech instruments were used, with some overlap between the studies.

The UK cochlear implant study group (n=316) measured speech perception and audiovisual gain preimplantation and 9 months postimplantation. Preimplantation, they divided the all patients into traditional candidate for CI patients (mean hearing level 117.1dB) and those who were marginal hearing aid users (mean hearing level 108.7dB). Both groups were profound hearing loss patients. The mean score for both groups on both measures improved postimplantation, with the traditional candidate CI patients having more improvement compared with the mariginal hearing aid users (17).

Mawman et al (n=124) did a retrospective study on patients at a UK CI center. Speech perception was measured preimplantation and 18 months post-CI. The group showed non-significant trends in favor of CI (19).

A 2002 study by Parkinson et al (n=216) evaluated speech perception pre and post implantation and showed significant positive benefits for CI 3 months postimplantation (p<0.001 on all measures) (20).

Another study by Kessler et al (n=238) found positive trends in speech outcomes, including telephone conversation, for CI by 12 months post-CI (7).

The UK cochlear implant study groups also showed a greater effectiveness of implantation being associated with implantation in the ear with the shorter duration of deafness. Speech and quality of life measures declined with the duration of deafness (p<0/01) (17).

UNILATERAL COCHLEAR IMPLANTS VERSUS HEARING AIDS

Four studies (n=248) have reviewed the evidence of cochlear implantation versus acoustic hearing aids. Three studies had patients with severe to profound hearing loss, and the fourth had patients with profound hearing loss. The outcomes measured by the studies included: sensitivity to sound, speech perception, speech production, functional performance, quality of life and adverse events.
Ching et al (n=21) used a cross-sectional design, and found a minimal benefit for CI as compared with hearing aids with regards to sound sensitivity. They did find a significant benefit in the measured speech perception in noise over hearing aids (p<0.001) (22).

The UK cochlear implant study group (n=84) used a prospective cohort study design to measure speech perception preimplantation and 9 months postimplantation. Speech outcomes improved at 9 months (17).

A MED-EL study (n=63) measured speech perception in quiet and noisy conditions preimplantation and 6 months postimplantation. They further sub-divided the groups and showed that prelingually deaf participants had a mean benefit of 20% in quiet conditions. Postlingually deaf participants who were impaired for less than 25 years did better than those with more than 25 years of hearing impairment in noisy conditions. CI recipients with postlingual hearing impairment less than 25 years also did better with the use of a telephone (6).

Hamzavi et al (n=37) used number and monosyllable tests preimplantation and 12 months postimplantation. Participants with CI had a mean score improvement of 90% as compared to 37% for acoustic hearing aids. Also, over 2 years, speech scores in quiet improved by 16% for CI users, whereas no improvement was seen in patients with acoustic hearing aids (25).

**UNILATERAL COCHLEAR IMPLANTS VERSUS BILATERAL COCHLEAR IMPLANTS**

Five studies (n=147) have compared unilateral CI with bilateral CI in adult patients. The follow-up period was 6-9 months, and all the studies used a nucleus 24 device. All studies were prospective studies. There is some overlap of patients between Summerfield et al, Ramsden et al, and Vershurr et al (25, 26, 27).

Summerfield et al (n=24) found a significant benefit for spatial hearing at 3 and 9 months postimplantation, compared with preimplantation, in favor of bilateral CI (p<0.01). They showed significant binaural gains for quality of hearing (p<0.05) and hearing for speech (p<0.01) (25).

Vershuur et al (n=20) found that bilateral CI participants made significantly fewer errors in sound direction, regardless of how the speakers were positioned (p<0.001) (26).

Litovsky et al (n=37) measured speech perception in quiet and in noise in simultaneously implanted adult patients. They showed significant binaural gains on all instruments (p<0.0001). Bilateral CI patients were able to use the head shadow effect in noise and had significant gain for bilateral CI versus either ear with unilateral CI (p<0.0001) (15).

Ramsden et al (n=29) measured speech perception in quiet and noise in sequentially implanted adults. A significant binaural benefit was noted over the first CI ear alone for speech and noise from the front (p<0.001). No binaural advantage was found in quiet (26).

Laszig et al (n=37) found improved speech perception through accessing the head shadow effect. They noted a significant binaural benefit in quiet conditions compared with the poorer unilateral ear alone (p=0.00009). In noisy conditions, they found a significant head shadow effect creating a bilateral advantage when the better ear was closest to the speech source than when the poorer ear was closest to the speech source (p<0.00001).
References


7. Cost-effectiveness/cost utility

The National Institute for Health and Clinical Excellence (NICE) issued their Guideline Summary NGC-7126 in 2009 on cochlear implants in children and adults with severe to profound sensorineural hearing loss. Included in that document is a section on cost analysis with reports issued by the cochlear implant manufacturers (Cochlear Europe, Advanced Bionics UK, MED-EL UK) and from the NICE Assessment Group. The studies examined reported outcomes based on one or more of the following measures: generic and/or disease specific quality of life (QOL), health utility, cost utility ratio, and incremental cost-effectiveness ratio. Although European studies typically use different metrics than those used in U.S. studies to measure changes in QOL, there is consistent agreement that unilateral cochlear implantation is a cost-effective treatment for children and adults with severe to profound deafness who do not derive adequate benefit from conventional hearing aids. In terms of bilateral cochlear implantation, the NICE Assessment Group concluded that if a cochlear implant could be acquired at the lowest price, including a discount of at least 40% for the second implant, then simultaneous bilateral cochlear implantation for appropriately assessed children with severe-profound deafness could be considered cost effective use of National Health System resources (1).

Several studies have demonstrated favorable cost utility (cost/quality adjusted life year (QALY)) of unilateral cochlear implants in children and post-lingually deafened adults. In addition, cost utility in older adult cochlear implant recipients has been found to be equally favorable (6, 12).

Nevertheless, previous studies have been criticized for study design (retrospective, limited number of patients) and failure to use both a validated generic and disease specific QOL measure in defining benefit in cochlear implant recipients. Recall bias is of particular concern in any retrospective study design. However, cochlear implant patients are not cured of their deafness and revisit their “deficit” whenever they remove their sound processor. Both retrospective and prospective studies have shown similar results in their assessment of cost utility in adult patients (4, 7).
Furthermore, in a study that evaluated cost utility in pediatric cochlear implant recipients, the Mark III Health Utility Index (HUI-III) responses obtained from parents were consistent whether recorded retrospectively or prospectively (5).

In terms of validated QOL instruments, health related QOL estimates and cost utility analysis demonstrated favorable results in a prospective study of 44 post-lingually deafened adult patients using both a generic and disease specific QOL measure. Studies in the U.S. that have evaluated cost utility in pediatric and adult cochlear implant recipients reported cost utility ratios of $5197-9029/QALY for children and $9530-16,061/QALY for adults (without respect to the use of discount rates or direct costs in computation). These figures are well under the accepted threshold of $20,000-25,000/QALY for procedures that are considered cost effective (favorable value or benefit for the money) (5, 4, 9).

A UK study explored the cost utility of pediatric cochlear implantation, incorporating potential savings associated with education into the analysis. While making some assumptions in terms of the functional hearing level of a child with a cochlear implant, the study reported a discounted difference in educational costs over 12 years to be 26,781 pound silver ($42,850). The cost per undiscounted QALY gain was estimated to be 1345 pound silver ($2,153) and per discounted QALY gain to be 10,341 pound silver ($16,545) (8).

A 2009 UK study used a systematic review and a model based probability utility gain measure in order to determine the effectiveness and cost effectiveness of cochlear implants in children and adults. Comparisons were made between, (1) unilateral cochlear implant and no implant, (2) simultaneous cochlear implants and unilateral cochlear implant, and (3) sequential cochlear implants and unilateral cochlear in the two patient cohorts. Disease specific QOL measures showed benefit for bilateral implantation and the majority of generic QOL measures showed a significant gain or positive trend in health utility gain. Incremental cost effective ratios analysis demonstrated favorable values for comparisons (1) and (2) in both children and adults (3).

A previous study (2002) that assessed cost utility based on similar group comparisons in adults while using an economic scenario analysis, concluded that there was a small gain in health related QOL (health utility) for bilateral cochlear implants as measured by the Mark II Health Utility Index (HUI-II) (10).

The same author later conducted a cost effectiveness analysis in a hypothetical group of pediatric patients receiving bilateral cochlear implants using an opportunity sample of 180 informants to perform an assessment of four separate patient profiles (vignettes). In as much as these “informants” may be unaware of the potential benefits of bilateral auditory cues to drive normal central auditory development, their perception of a sufficient additional quality of life from giving children two implants rather than one suggests a cost effective use of health care resources (11).

A prospective case control study was conducted in 23 bilateral cochlear implant patients using the Mark III HUI. The results demonstrated a 0.48 mean gain in health utility and a discounted (3% per annum) cost utility of $24,859/QALY in this group of patients. Comparison of patient scores for unilateral and bilateral use showed improvements in domains of hearing, speech, emotion, and cognition with a mean gain in health utility of 0.11. This study demonstrates both an incremental improvement in QOL and a favorable cost utility after bilateral cochlear implantation in patients with severe to profound deafness.
References


8. Safety

In 2010, the Food and Drug Administration (FDA) requested that the Association for the Advancement of Medical Instrumentation (AAMI) undertake the development of a new standard on cochlear implants that would establish performance, safety, and reliability requirements for the devices. It would also define a means for describing system performance and system output of cochlear implants. The AAMI standard would then be submitted to the ISO for consideration for incorporation, thereby achieving international recognition. All cochlear implant manufacturers are foreign owned entities that would have an inherent interest in adopting a standard that is developed through an international approach. The standard would describe a common set of performance criteria that all manufacturers would employ. It would also standardize the characterization and labeling of cochlear implant performance amongst manufacturers. AAMI is the US Tag for the review of ISO standards. Currently, the European Standard EN 45502-2-3 has been published and will be considered by the ISO. Therefore, the AAMI Cochlear Implant (CI) Committee is reviewing this document and may adopt elements of this standard. The AAMI Cochlear Implant Committee has representation from the FDA as well as from other organizations including: American Academy of Audiology (AAA), American Academy of Otolaryngology-Head and Neck Surgery, Inc. (AAO-HNS), American Speech-Language-Hearing Association (ASHA), American Auditory Society (AAS), Association for Research in Otolaryngology (ARO), International Hearing Society (HIS), and the National Institute of Standards and Technology (NIST). The first meeting of the AAMI CI Committee was convened in November 2011. A preliminary draft of the standard is due in December 2012.

Cochlear implants are classified by the FDA as Class III medical devices (i.e., those having the highest risk). In addition to the risks of surgery and anesthesia, there are risks associated with trauma to intra-cochlear structures, damage to neural tissue from DC current leakage, and potential overstimulation as a result of device malfunction. These devices contain many complex components including technologically advanced microprocessors and software and firmware algorithms.

Cochlear implantation is associated with a variety of potential medical and surgical complications, some of which may lead to a re-implantation procedure. Indications for revision cochlear implantation include: hard failure, soft failure, implantation site infection, soft tissue complications and/or device extrusion, improper electrode placement, and upgrade of cochlear implant technology. Hard failure is diagnosed when device malfunction can be determined by in vivo integrity testing. Although head trauma has been reported in up to 41% of hard failures (4), in most cases there is no identifiable precipitating event. Soft tissue failures occur when in vivo integrity testing fails to demonstrate a malfunction. Patients with a soft failure may experience a decline in performance in speech battery scores or experience adverse effects such as facial nerve stimulation, tinnitus, or intermittent functioning. Post explant analysis, however, identifies a defect in a large percentage of devices removed for suspected soft failure (1, 3). Revision cochlear implant surgery for hard or soft failures successfully restores auditory function in 75-100% of patients.

Other specific reported complications include: magnet displacement, cholesteatoma, cerebrospinal fluid (CSF) leak, persistent otitis media, persistent vertigo, facial palsy, and meningitis. Amongst those listed,
meningitis is, arguably, the complication of greatest concern. There have been 283 cases of meningitis after cochlear implantation reported since 2002 to the CDC Database Manufacturer and User Facility Device Experience, resulting in 30 deaths (9).

The incidence of meningitis caused by Streptococcus Pneumoniae (most common pathogen) in children had been estimated to be over thirty times that in similar aged children in the general population in a 2004 report (10).

It had been believed that an electrode positioner used in a particular type of cochlear implant device had been responsible for an increase in incidence of meningitis in cochlear implant recipients. Despite voluntary withdrawal of the positioner from the market by the manufacturer, cases of meningitis in subsequent cochlear implant recipients still occurred, although at a substantially lower and declining rate. The development of bacterial meningitis is also related to middle and inner ear infections and there may be greater risk in patients with inner ear malformations and CSF leaks.

Proper vaccination against the most prevalent causal organisms is an extremely important measure for reducing the risk of this potential complication in cochlear implant patients. On February 24, 2010, a 13-valent pneumococcal conjugate vaccine (PCV13 [Prevnar 13, Wyeth Pharmaceuticals Inc., a subsidiary of Pfizer, Inc.]) was licensed by the Food and Drug Administration (FDA) for prevention of invasive pneumococcal disease caused by the 13 pneumococcal serotypes covered by the vaccine and for prevention of otitis media caused by serotypes in the 7-valent pneumococcal conjugate vaccine formulation (PCV7 [Prevnar 7, Wyeth]). PCV13 is approved for use in children aged 6 weeks to 71 months and succeeds PCV7, which was licensed by the FDA in 2000. Recommendations for use in children were established by the Advisory Committee on Immunization Practices (ACIP) and reported by the CDC on March 12, 2010. Because children with cochlear implants are at increased risk for pneumococcal meningitis, the CDC recommends that they receive pneumococcal vaccination on the same schedule that is recommended for other groups at increased risk for invasive pneumococcal disease. Recommendations for the timing and type of pneumococcal vaccination vary with age and vaccination history. Specific recommendations can be viewed in detail on the CDC website (http://www.cdc.gov/mmwr/preview/mmwrhtml/mm5909a2.htm).

Recalls:

There have been four recalls to date for cochlear implants, three of which involved an Advanced Bionics device and one recently which involved the Cochlear Corporation Nucleus CI500 series device. The first was a voluntary recall in 2004 of unimplanted Clarion and HiResolution cochlear implants from Advanced Bionics because of a potential malfunction due to moisture within the receiver-stimulator. In 2006, a similar recall was undertaken for the unimplanted HiRes 90K devices, again because of a potential device failure due to moisture penetration. In both recalls patients and providers were advised to monitor already implanted patients for intermittent function, loss of sound, discomfort, pain, noise, or popping. In November 2010, Advanced Bionics voluntarily recalled the HiRes 90K in response to two instances where patients experienced early malfunction requiring explantation within 8-10 days of device activation. In September 2011, Cochlear Corporation issued a recall of unimplanted Nucleus CI500 series devices. In December 2011, the company reported the probable cause as loss of hermeticity due to variations in the brazing process that joins the feed-through to the titanium chassis (receiver-stimulator) during manufacturing. The failure rate of 2.4% for this device was believed to be
due to an increased susceptibility to microcracks in the braze joint during subsequent manufacturing steps leading to a loss of hermeticity and potential moisture penetration. The clinical symptoms experienced prior to failure included a period of intermittency followed by the implant shutting down. The company suggests that only devices manufactured during the first quarter of 2011 were affected by this aberration in the manufacturing process. The Nucleus CI24RE has served as a substitute device during the recall and is fully compatible with the manufacturer’s most recent audio processor upgrade.

References


