Proceedings of the Annual Symposium of the American Cochlear Implant Alliance[†]

Introduction

Emerging Issues in Cochlear Implantation

The American Cochlear Implant Alliance (ACI Alliance) was incorporated in the late 2011 as a non-profit organization of cochlear implant clinicians from across the care continuum as well as scientists, parents, adult consumers and other advocates for access. Since that time, the organization has emerged as a unique entity with over 850 individual members and 64 organizational members, the latter representing universities, hospitals, clinics, and schools for children with hearing loss.

The mission of the ACI Alliance is to advance access to the gift of hearing provided by cochlear implantation through research, advocacy and awareness. Since its inception, the organization has advocated for improved insurance coverage for cochlear implant services including rehabilitation under public and private insurance programs. A position paper on the habilitation needs of children after cochlear implantation was published in 2015. A research study to expand candidacy criteria under Medicare was initiated with an aim of demonstrating that older adults benefit from having candidacy criteria comparable to that those currently in place for people under age 65. A network of State Champions throughout the United States advocates for appropriate Federal and state policies. The organization's website is designed to improve knowledge about cochlear implantation among primary care physicians, educators, and the general public. A continuing series of presentations and publications aim to improve awareness among general audiologists and hearing aid dispensers from outside of the CI field regarding candidacy criteria and outcomes. Additional details about programs and accomplishments are available at www.ACIAlliance.org.

The organization convenes an annual clinical research symposium bringing together individuals who address cochlear implants in a range of settings – universities, hospitals, private clinics, non-profit organizations, schools and governmental agencies. The CI 2015 'Emerging Issues in Cochlear Implantation' was the second conference that used this particular format. It was held in Washington, DC on 13–15 October 2015.

The principal goal of this conference was to facilitate timely sharing of information between scientists, clinicians, and educators. Cochlear implant candidacy and outcomes have advanced reflecting technology improvements, early identification, and better linkage between the surgical intervention and follow-up care. Children and adults with a range of hearing losses and other issues are now benefiting importantly from traditional cochlear implants as well as electric-acoustic stimulation and auditory brainstem implants. Cochlear implant candidacy guidelines have changed to include children and adults with more residual hearing as well as other anatomic, health, and learning issues that would have been considered 'absolute' or 'relative' contraindications in the past. Utilization of other technologies, in combination with the cochlear implant device, have provided further expansions in outcomes bringing recipients even closer to 'normal' hearing. With all of these changes have come a new recognition of the quality of life changes and cost utility made possible when the right device is matched to appropriate patients.

Six topics were explored by presenters who were drawn from a range of disciplines and also across the continuum of care for cochlear implantation. Speakers included basic scientists, ENT surgeons, audiologists, speech language pathologists, educators, insurance reimbursement experts, and parent/consumer advocates. We are grateful to the individuals who shared their knowledge and experience as presenters, panelists, and audience participants.

Donna L. Sorkin Colin Driscoll Craig Buchman
Executive Director Chair, Board of Directors
Immediate Past Chair
American Cochlear Implant Alliance

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AMERICAN COCHLEAR IMPLANT ALLIANCE

Research. Advocacy. Awareness.

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Auditory Brainstem Implants in Children

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In 2015, four US cochlear implant centers had FDA approved Investigational Device Exemptions (IDE) protocols for the implantation of children with deficient or absent cochleae or cochlear nerve deficiency. Approximately, 20 US children had been implanted as of October 2015 under IDEs. Among the key considerations for ABI use in children are the candidacy evaluation, audiological management, provision of a cochlear implant before ABI (to aide/confirm decision-making), surgical placement and complications, and expected speech and language development benefits. Objective measures and outcomes of ABI in children have been utilized to inform the decision-making in the provision of the ABI device.

Auditory Brainstem Implants in Children: New Challenges for Audiologists

Laurie S. Eisenberg

The auditory brainstem implant (ABI) is a sensory device for individuals with profound hearing loss who are not candidates for a cochlear implant (CI) or are unsuccessful CI users. At the present time, the U.S. Food and Drug Administration (FDA) has approved use of the Nucleus ABI in patients with neurofibromatosis type 2 (NF2), 12 years of age and older. During the past 3–4 years, the FDA has given permission for select teams in the U.S. to conduct Phase I safety trials in young non-NF2 children who meet strict inclusion criteria for an ABI. The pediatric ABI trial is indicated for children with cochlear nerve deficiency or cochlear ossification secondary to meningitis.

The Los Angeles Pediatric ABI program is one of the teams conducting a Phase I safety trial with the Nucleus ABI in 10 non-NF2 children as young as 2 years of age. The Los Angeles team is comprised of several centers around the greater Los Angeles area, including the University of Southern California (USC), Children's Hospital Los Angeles (CHLA), and the House Ear Clinic/Huntington Medical Research Institutes. The multidisciplinary team consists of members from such disciplines as neurotology, neurosurgery, pediatric neurosurgery, pediatrics, pediatric audiology, speech-language pathology, psychology, teacher of the deaf and hard of hearing, electrophysiology, radiology, anesthesiology, and regulatory/experimental methodology. In October 2015, five of eight enrolled pediatric subjects have met criteria to undergo surgery with the Nucleus ABI. The recipients all communicate using sign language. Results for the four children with 1-year follow-up indicate that conversational-level speech is audible and pattern perception is emerging.

In addition to the FDA Phase I trial, the team at USC clinically manages 10 pediatric ABI cases implanted outside of the U.S. who are implanted with either the Nucleus or Med-El device. Because the Med-El ABI is not approved for use in the U.S., a compassionate use exemption from the FDA is required to program the processor. Most of the children in this second group would not have met the inclusion criteria for the Phase I clinical trial due to additional disabilities, developmental delays, and/or other complicating anatomical and medical factors. Longitudinal data published by the team in Italy indicates that additional confounding factors can have detrimental effects on auditory skill development with the ABI (Colletti *et al.*, 2014). Several of the children in the USC clinical group are typically developing (i.e., no developmental delays or additional disabilities) and would have met inclusion criteria for the current Phase I trial, but were implanted before formal FDA trials were initiated. Results are highly variable with this group of children, ranging from intelligible speech to no evidence of a response.

With the availability of ABIs in children, new challenges are faced by pediatric audiologists who are experienced in managing children with CIs. Specific challenges with the ABI include all aspects of audiologic management: candidacy, initial activation and device programming, and follow-up assessment. Because the ABI electrode array is placed on the cochlear nucleus of the brainstem, it is not always evident what the child perceives with the ABI because he or she essentially receives a scrambled auditory signal through varying numbers of viable/discriminable electrodes. Moreover, many children undergo ABI surgery at an older age than is typical of children with CIs, experiencing longer durations of auditory deprivation by virtue of being born without a viable cochlea and/or VIII nerve.

When activating the ABI, there is the possibility of non-auditory side effects (e.g., dizziness, tingling sensation, facial twitching, coughing) during initial activation and programming of individual electrodes due to the proximity of the electrode array to other structures in or near the brainstem. For behavioral programming, Pediatric Advanced Life Support (PALS) and emergency equipment are on standby until all electrodes have been tested. Electrophysiological responses to individual ABI electrodes prior to behavioral activation may help the audiologist to identify non-auditory side effects for specific electrodes and provide guidance for initial programming.

As with other sensory device fittings, the goal in programming an ABI is to provide the child with an audible signal across a wide range of frequencies while not exceeding loudness discomfort. Progress with the ABI varies but is generally much slower than that observed for children with CIs. Auditory skill development with the ABI is somewhat reminiscent of that observed for children with the single-channel CI in the 1980s; those children also were older at the time of CI surgery and many communicated through sign language. Moreover, pattern perception and closed-set word identification were the norm with the single-channel CI, although a small group of children eventually developed open-set speech recognition. Based on published data and our own experiences, there are some children with the ABI who may eventually make sense of the scrambled auditory signal in a way that facilitates auditory development and spoken language. For most children, however, auditory benefit through the ABI will be enhanced by visual cues, fostering the need for multimodal processing of speech. It is critical that habilitation be tailored to the child's individual communication needs, which can be a delicate balancing act between supporting the child's most effective communication modality and maximizing auditory skill development.

In summary, audiologists encounter new and difficult challenges when managing a child with an ABI. Programming requires vigilance with the goal of providing an audible signal without stimulating non-auditory structures or exceeding loudness discomfort. Progress is slow, and an extended period of time is required to determine which children may or may not derive significant benefit in auditory skill development with the possibility of acquiring spoken language. [Supported in part by NIH/NIDCD grant U01DC013031.]

Surgical Placement and Complications of ABI in Children

J. Thomas Roland

Children without cochleae and/or without cochlea nerves are candidates for the Auditory Brainstem Implant. Additionally, children with cochlear nerve deficiency that do not benefit from cochlear implantation or children who initially had benefit from cochlear implant but no longer get benefit are candidates as well. The auditory brainstem implant has been used in institutions outside the United States since the late 1990s and mixed results have been reported (Sennaroglu *et al.*, 2013). Candidacy selection including determining variables that affect performance (such as cognitive impairment) is currently under investigation. Currently four centers in the United States have FDA approved Investigational Device Exemption studies underway (https://clinicaltrials.gov/ct2/results?term=ABI+Children&Search=Search). This section outlines the candidacy selection criteria, surgical process and outcomes, and reported complications reported by the participating centers.

While the protocols from the four centers differ slightly in content and number of approved implantations, the following candidacy selection criteria are consistent among the centers:

- Age 18 months to 18 years
- Younger the better – earliest age controversial
- Bilateral absent hearing documented on physiologic and behavioral assessment
- Imaging: both MRI and CT
- No cochlea or cochlear nerve aplasia/hypoplasia
- Inability to place a CI
- Lack of benefit from a CI
- Had benefit and lost benefit from CI
- No medical contraindications
- No diagnosed significant cognitive or developmental delays that could interfere
- Strong family support
- English language competency in guardians
- Reasonable expectations of family
- Parents understand that child may not develop oral language

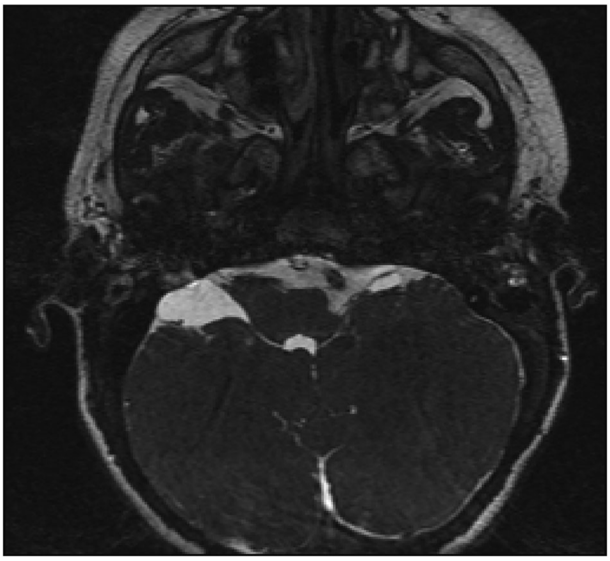

Figure 1 T2-CISS MRI axial image with absent cochleae and nerves bilaterally. Note an arachnoid cyst pointing to the foramen of Lushka.

The issue of cognitive or developmental delays is probably the most challenging criteria to interpret as many children without cochlear nerves have syndromes where cognitive and developmental concerns might arise after implantation and parents of children with these conditions are hopeful that the ABI might in some way improve quality of life and connectivity to the world of sound and oral language.

After documenting the hearing loss with standard physiologic and behavioral measures, imaging is obtained. An MRI with CISS sequences is essential to document the cochlear nerve status and to evaluate for other central nervous system anomalies that might affect the implantation process or the sound perception outcome after implantation.

A typical MRI image for an ABI candidate is presented below. Note the absence of cochleae bilaterally and the presence of only a facial nerve on both sides. Additionally, there is an arachnoid cyst on the right side dipping into the Foramen of Lushka where the ABI electrode paddle would be placed. In this instance, the team chose to implant the right side (Fig. 1).

As we cannot fully image the central auditory pathways, this project allows us to use advanced MRI techniques, such as diffusion tensor imaging, to gather a database of images that one can later compare to outcomes. It is hoped that we will thereby gain information about the central auditory pathways that could help predict outcomes. Diffusion tensor imaging and other advanced imaging techniques are under investigation at NYU. This image is an example of this technique (Fig. 2).

An example of another technique is shown here – Direction Encoded Color Track Density Imaging of the auditory pathway. We can see that some of the auditory pathway nuclei are visualized. This technique might allow images such as this and might give information about presence or absence of key structures (Fig. 3).

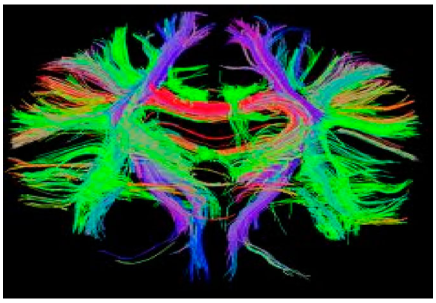

Figure 2 DTI image showing central brain tracts.

Consideration of anesthetic techniques is important and the following outline details current necessities:

- Pediatric Neurosurgery Anesthesia Team
- Non-paralytic technique with special considerations for monitoring
- Some agents suppress ability to monitor motor and sensory information
- Smooth emergence from anesthesia
- Communication imperative between surgeons and anesthesiologists

During surgery we monitor facial nerve, tenth nerve, somatosensory capacity in the extremities and electrical ABR capacity. Anesthetic agents that prevent such sensitive monitoring are not used.

A team consisting of a neurotologist, a neurosurgeon or two neurosurgeons (one skilled in ABI placement in adults and one pediatric neurosurgeon) performs the surgery.

After a retrosigmoid opening, the CSF is decompressed in the cerebello-pontine angle cistern and the target is found. By following the ninth cranial nerve to the foramen of Luschka and using the choroid

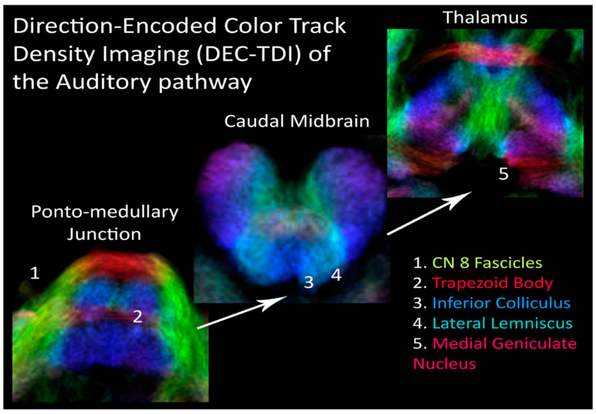

Figure 3 Direction-encoded color track density imaging of central auditory pathways.

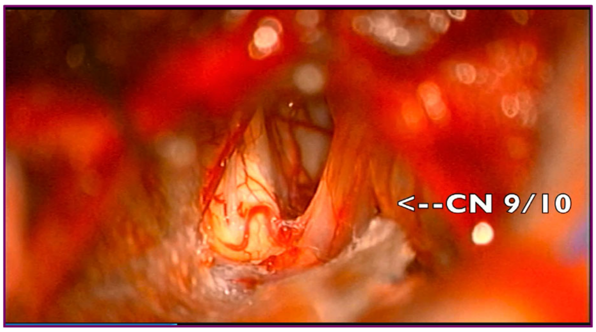

Figure 4 Intraoperative image of the very thin 8th nerve (cochlear nerve deficiency), small arrow and the lower cranial nerves on the right.

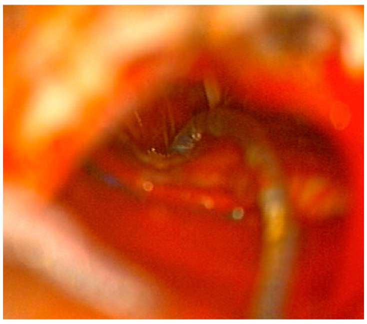

Figure 5 ABI paddle inserted into the foramen of Lushka proper location with ninth nerve just to right of paddle.

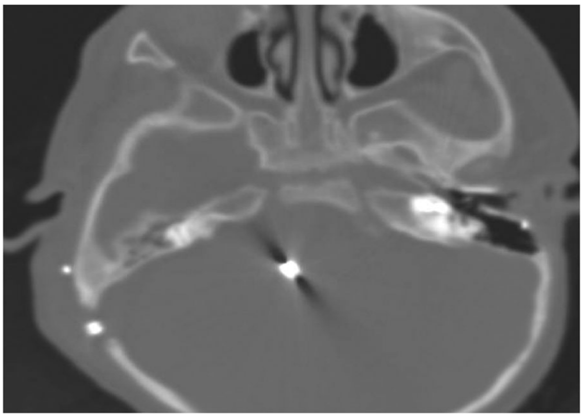

Figure 6 Post-operative CT scan, non contrast, showing ABI electrode paddle in good position just to R of midline.

plexus as a landmark, the implanting surgeon then gently dissects the lateral aspect of the foramen. Most often a cochlear nerve does not exist except in the case of a cochlear nerve deficiency where the nerve is small and almost wisp like. In the rare situation where the patient's cochleae have become unimplantable, there may be a normal cochlear nerve. The receiver stimulator is attached to the skull in a shallow well posterior and superior to the surgical field under the posterior flap and the free ground wire is placed medial to the temporalis muscle periosteum. The electrode paddle is then gently placed into the foramen to its' full depth with the electrode contacts aimed anteriorly against the cochlear nuclei. At this point electrically evoked auditory brainstem responses are elicited. The paddle may be adjusted in a superior to inferior direction or medial lateral direction until the maximum number of EABR responses are elicited. Untoward non-auditory responses are also recorded, such as facial nerve stimulation, vagal nerve stimulation or bradycardia. A paddleogram is designed detailing the auditory responses and the untoward responses so that the programming audiologist has a map for the initial activation. The operative image below shows a very thin cochlear nerve. Note the lower cranial nerves to the right. Normally, the cochlear nerve is similar in size to the ninth nerve.

The next set of images shows the region of the foramen after electrode paddle placement (Figs. 4 and 5).

Children are observed in an intensive care setting for one night and usually discharged from the hospital after 2 days. A CT scan of the head is obtained prior to discharge to verify paddle placement (Fig. 6).

Approximately 3 weeks after surgery, the ABI is activated while the child is under light anesthesia with monitoring. The audiology team again goes through EABR testing across the paddle looking for auditory and non-auditory stimulation. Of particular interest is the activation of the vagus nerve that might cause the child to have difficulties in the clinic. An electrode with non-auditory untoward stimulation would be left out of the map. The next day the child is activated live in the clinic.

The four centers previously mentioned shared their experience as 1 October 2015. Participating centers include Los Angeles Pediatric (LA), Mass Eye & Ear (MEE), New York University (NYU) and University of North Carolina (UNC) (Table 1).

The ABI in children cases documented here have been complicated by three CSF leaks, all via the wound. In each case this was resolved without sequelae. One center experienced two device failures soon

Table 1 Pediatric ABI performed at four US centers

	LA	MEE	NYU	UNC	Total
Number	4	4 (5)	9	5	22
Previous CI	3 (1 bilateral)	0	4	3	10
Age at ABI	27–58 months	11–16 months	21 months–17 years	26–66 months	39 ± 26
Gender	2M and 2F	1M and 3F	2M and 7F	2M and 3F	7M and 15F
Side	3R, 1L	3R, 1L	5R, 1L	3R, 2L	14R and 5L
Etiology	3 CND 1 Michel	3 CND 1 Michel	4 CND 2 Michel	5 CND 2 CHARGE 1 CC 2 CND alone	15 of 19 CND
eABR+	4 of 4	4 of 4	9 of 9	4 of 5	21 of 22
Other CN stim	0	0	0	0	0
Complications	1 CSF leak	2 Device failures	1 CSF leak	1 CSF leak Aseptic meningitis	3 CSF leaks 1 meningitis 2 device Failures
Sequelae	None	None	None	None	None
OR repeat stim	4	4	9	5	21–22
Aversive behavioral stimulation	1 of 4 Unsteady	0 of 4	4 of 9 Leg Leg, throat Chest Facial twitch	4 of 5 2 vestibular 1 cough 1 swallow	9 of 22 All de-mapped
Outcome	Resolved	Resolved	Resolved	Resolved	Resolved

after implantation. Successful re-implantation was performed.

In conclusion, ABI in children is a safe procedure when performed by a team with experience in ABI surgery and in CI and ABI programming. Untoward non-auditory stimulation effects can be programmed out of the ABI map. Long-term follow-up of these children is imperative to verify efficacy.

Abstract Speech and Language Development in ABI Candidates: Setting Expectations Lillian Henderson (with contributions from Holly F.B. Teagle, Shuman He, Craig A. Buchman, Matt Ewend)

Introduction: A clinical trial of the use of the Cochlear Nucleus 24 Auditory Brainstem Implant (ABI) to demonstrate safety and efficacy for children who are unable to use a cochlear implant due to cochlear anatomy disorders has been undertaken at the University of North Carolina. A team approach to management is essential; team members include a neuro-otologist, a neurosurgeon, audiologists, speech-language pathologists and auditory physiologists. Inclusion criteria included normal cognitive abilities and the potential to develop spoken language. Five children have undergone surgery, had devices activated, and have used the devices for up to 2 years. Of the five subjects, two have CHARGE association, one has an absent cochlea (Michele Aplasia), and two have known cochlear nerve deficiency. Three of the children underwent cochlear implantation prior to receiving the ABI and two children continue to use a cochlear implant on the contra-lateral ear.

Counseling parents on expectations for spoken language development through listening has been challenging given the limited long term experience with pediatric ABI as well as concomitant issues that negatively impact spoken language development in this population. Due to the uncertain prognosis for spoken language development through listening alone, it was advised that all recipients supplement with a visual communication system; one child uses Cued Speech, two use American Sign Language and two use Signed Exact English.

Objective/methods: A repeated measures, single subject design has been used to quantify outcomes of individual children to describe intervention and rate of progress with ABI recipients relative to children with cochlear implants. For the purpose of comparison, speech and language data from UNC's Childhood Development after Cochlear Implantation (CDaCI) population was used as a control group.

Results: Each child is a case study with unique outcomes. All ABI users have reliable detection audiograms in the soundfield. Subjects 1 and 3 can identify duration, pitch and intensity cues, and multi-syllable and mono-syllable words in a closed set listening activity. Although identification of familiar phrases has been addressed in therapy, identification of phrases through audition alone has been inconsistent. Subject 4 is 33% accurate with identification of word patterns and 16% accurate with identification of monosyllable words. Subjects 2 and 5 wear their device during all waking hours, but have not developed any discrimination or identification skills through listening at this time.

All of the ABI recipients are able to vocalize on demand and change the pitch and duration patterns of their vocalizations. After 2 years of device use, early developing consonants and vowels are shown in 60% of this population.

All of the ABI recipients are developing language skills through the use of listening paired with a visual system such as Cued Speech or sign language.

Conclusion: The ABI provides most children with sound awareness and increased potential to incorporate supra segmental cues for listening. Because the development of auditory skills is slow, language development must be supported by visual communication. Changes in vocal quality may indicate that spectral, intensity and temporal cues are being perceived through use of the ABI. Progress in auditory skills requires consistent, methodical and intensive therapy. Continued evaluation of this group of children is needed to understand the potential impact of ABI use on communication development.

Cortical Auditory Event-Related Potentials in Patients with Auditory Brainstem Implants

Shuman He

The auditory brainstem implant has recently been used as a treatment option for children with either absent or abnormally small auditory nerves (e.g. Choi *et al.*, 2011; Colletti *et al.*, 2005, 2009; Nevison *et al.*, 2002; Sennaroglu *et al.*, 2011). The programming process in pediatric ABI patients can be very complicated and extremely challenging due to the lack of reliable behavioral responses. The long-term goal of our research is to develop objective tools to assist the programming process in patients with ABIs. In this study, we evaluated the feasibility of using electrically evoked auditory event-related potentials (eERPs) to optimize programming parameters in ABI patients. Specifically, we investigated the association between morphological characteristics of the eERP and non-auditory sensations evoked by electrical stimulation of the ABI. In addition, we assessed the test–retest reliability of eERPs in ABI patients. We also explored the feasibility of using the eERP to estimate the lowest stimulation level that ABI patients can detect for individual electrodes (i.e. T level).

Study participants included five pediatric ABI users ranging in age between 2.8 and 10.2 years. These pediatric patients were implanted with ABIs due to cochlear nerve deficiency (CND). In addition, two adult ABI patients were included in this study. These two adult patients were diagnosed with neurofibromatosis II (NF2) and implanted with an ABI after a surgical removal of the tumors. The stimulus was a 100-ms biphasic charge-balanced pulse train. The speech processor was bypassed and the stimulus was directly delivered to individual electrodes. eERPs were recorded from multiple surface electrodes placed on the scalp using standard recording parameters.

Our results showed that eERPs were recorded in both NF2 and non-NF2 patients with ABIs. Consistent with our previous study (He *et al.*, 2015), two types of eERPs were recorded in these patients. The Type I response consisted of a single vertex-positive peak. In comparison, the Type II response showed complex waveforms and consisted of up to three groups of positive and negative peaks within a time window of 25–500 ms after stimulus onset. There was no consistent association between non-auditory sensations and the presence of Type I or Type II eERP responses in ABI patients tested in this study. However, the lack of association could be accounted by, at least partially, the lack of reliable behavioral responses and inability to discriminate auditory vs. non-auditory sensation in four pediatric ABI patients. Overall, eERPs in these ABI patients showed good test–retest reliability across test sessions. There was a robust correlation between T levels estimated using eERP measures and clinical behavioral testing procedure. Based on these results, we concluded that eERPs hold great promise to be used as a clinical tool to assist the programming process in ABI patients. However, further studies with more adult ABI patients are needed to evaluate the association between morphological characteristics of the eERP and non-auditory sensations in these patients. Details of this study and results will be reported in *Ear and Hearing* (He *et al.*, 2015).

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Expanded Indications for Cochlear Implantation

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Presenters: Camille Dunn[3], *Doug Sladen*[4], *Susan Arndt*[5], *Bradford May*[6], *Daniel Zeitler*[7]
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Traditional cochlear implant candidates have bilateral moderate to profound hearing loss and may receive a cochlear implant in one or both ears. In cases of unilateral implantation, the recipient may utilize a hearing aid on the non-implanted ear. The necessity of bilateral input for binaural processing is well documented. There is consideration of whether the current cochlear implant indications in adults and children should be expanded to those with less severe hearing loss in the non-implanted ear or even normal to near-normal hearing in the non-implanted ear. Among the issues to be considered are the specific candidacy, test measures, current results, and demographic variables that may affect performance, expectations, and patient report with expanded indications.

Cochlear Implantation as a Rehabilitative Option for Single-Sided Deafness

Camille C. Dunn (with contributions from Marlan Hansen, Bruce Gantz)

Every year, about 60 000 people in the United States acquire single-sided deafness (SSD) (Weaver, 2015), a condition in which they have nonfunctional hearing in one ear and do not clinically benefit from amplification in that ear, while the other ear functions normally or near normally. Regardless of having normal hearing in one ear, these individuals report significant difficulties in speech understanding in their everyday listening environments, along with significant communication handicaps that interfere with their quality of life (Wie *et al.*, 2010). Important aspects of hearing, such as sound localization and the ability to selectively listen to one conversation in a noisy room, become almost impossible. For many SSD sufferers, it is very difficult to follow conversations, making social interaction exhausting and frustrating, increasing irritability, stress, anxiety, and headaches. Even less obvious are the safety concerns for people coping with SSD. Without two working ears, the brain has difficulties distinguishing the origin of sounds, hampering a person's ability to determine the location and direction of a sound source.

Technologies, such as contralateral routing of signals hearing aids (CROS) and transcutaneous auditory osseointegrated implant systems (AOI), are available as treatment options for individuals with SSD. The major limitation with these technologies is that they do not restore binaural hearing. Cochlear implants (CI) are the only available technology that offers restoration of hearing to the deafened ear. In the small group of individuals with SSD who have received a CI, studies have demonstrated improved speech perception following cochlear implantation in the implanted ear (Arndt *et al.*, 2011; Buechner *et al.*, 2010; Firszt *et al.*, 2012a, b; Friedmann *et al.*, 2016; Hansen *et al.*, 2013; Kamal *et al.*, 2012; Vermeire and Van de Heyning, 2009; Zeitler *et al.*, 2015). Yet, in all of these studies, a great deal of variability in performance has also been demonstrated. Furthermore, a recent review examining published studies related to cochlear implantation in individuals with SSD found that while CI showed encouraging results as a rehabilitative option of SSD, it was recognized that all studies were negligent in presenting profound evidence of benefit (Cabral *et al.*, 2016).

At the University of Iowa, 50 patients have undergone CI for SSD. These subjects had a mean age at implantation of 53 years and an average duration of hearing loss of less than 4 years. Pre-operatively, these subjects' pure-tone-average at .5, 2, and 4 kHz in the ipsilateral impaired ear was 90 dB HL and that in the contralateral ear was 22 dB HL. The etiology of deafness was mixed with the majority being a result of Ménière's disease (42%) and Idiopathic Sensorineural Hearing Loss (36%, ISSNHL).

Speech perception, tested in quiet, completed using a direct connection to the CI speech processor, was assessed longitudinally on 39 subjects. Fig. 5 demonstrates the heterogeneity in this group of CI users on this test. Averaged CNC words (Peterson and Lehiste, 1962) (shown by the dark hashed line with X's) in this figure improved over time, but appeared to plateau by 3 months post-implantation. In an attempt to account for some of the variability in performance among this group, we assessed pre-implant hearing in the ipsilateral impaired ear and contralateral ear, duration of hearing loss, etiology and amount of CI use per day. Very little could be explained in this group of users. One caveat was the minimal variability in pre-implant hearing and duration of deafness. Etiology trended to show an effect with those with Ménière's disease showing better improvement over those with ISSNHL (Fig. 7).

An adaptive HINT (Nilsson *et al.*, 1994) test in noise was also used to assess the head shadow effect. Average results when comparing CI alone to CI and natural acoustic hearing (better ear) demonstrated a significant head shadow effect. Localization (Dunn *et al.*, 2005) also demonstrated an improvement in capabilities with both ears in comparison to using the normal hearing ear alone. When comparing

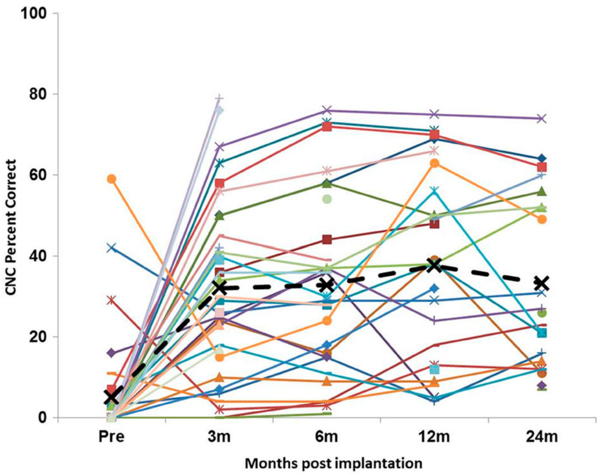

Figure 7 Speech perception of SSD patients.

localization abilities to other CI groups, the SSD listeners with a CI demonstrated abilities similar to hybrid cochlear implant users, which was significantly better than bimodal (CI + HA on opposite ears) users, but not as good as bilateral simultaneous CI users.

Overall, the results of this study show that many of the patients with SSD who receive a CI have improvements with sound localization and speech perception in quiet and in background noise. However, there is a lot of variability amongst individuals that cannot yet be explained. Further research is needed to investigate other variables which might contribute to outcomes.

Benefits of Cochlear Implantation Among Adults and Children with Unilateral Hearing Loss

Douglas P. Sladen (with contributions from Matthew L. Carlson, Brian A. Neff, Charles W. Beatty, Melissa D. DeJong, Brittany P. Dowling, Amy P. Olund, Ann Peterson, Katherine H. Teece, Colin L.W. Driscoll)

Background: Sudden sensorineural hearing loss occurs in approximately 5–20 per 100 000 persons per year (Fetterman *et al.*, 1996; Hughes *et al.*, 1996; Stachler *et al.*, 2012) and is nearly always, unilateral. Treatment options for permanent severe unilateral hearing loss (UHL), also called signal sided deafness (SSD), have been comprised of devices that route sound from the impaired ear to the normal hearing contralateral side and thus do not restore binaural function. In recent years, cochlear implantation (CI) has been suggested as a possible treatment option for patients with UHL. Current research has demonstrated that adults with UHL and a CI may achieve some binaural benefit, such as localization, though results vary (Hansen *et al.*, 2013; Mertens *et al.*, 2015; Tokita *et al.*, 2014). It is possible that benefits of a CI are present in other domains such as self-perceived benefit and possibly listening effort.

Objective: This study sought to determine if: (1) a CI will provide adequate hearing restoration for speech recognition to an ear with UHL, (2) patients with SSD are able to achieve binaural benefit as measured using speech-in-noise testing and self-perceived benefit, and (3) a CI will reduce listening effort when the device is on compared to off.

Methods: *Participants.* All participants had sudden onset unilateral sensorineural hearing loss (≤2 years and ≥6 months of hearing loss), ≤50% aided monosyllabic word recognition on affected side, and ≥70% word recognition on the contralateral side. To date, 15 adults and 2 adolescents have been implanted.

Materials. Test measures included: (1) speech recognition in quiet for the affected side using the Consonant-Nucleus-Consonant (CNC; Peterson and Lehiste, 1962) test and the AzBio sentence test (Spahr and Dorman, 2005), (2) speech recognition in noise in the bilateral condition using the Hearing in Noise Test (HINT; Nilsson *et al.*, 1994) sentences in an R-SPACE 8-speaker array, (3) self-perceived benefit using the Speech Spatial and Qualities of Hearing-Comparative (SSQ-C; Jensen *et al.*, 2009) and, (4) listening effort using a dual task paradigm. The dual task was comprised of a primary task, speech-in-noise recognition, and a secondary task, a button press in response to the appearance of a perfect square on a front centered computer screen. The square appeared randomly among tall and long rectangles.

Procedures. Speech recognition was tested preoperatively then at 6 and 12 months post-activation. The SSQ-C and listening effort task were tested at the 6-month post-activation interval.

Results: Results demonstrated significantly higher speech recognition performance for all test conditions. Results of the SSQ-C showed a preference for the device on versus off for each domain. Results of the listening effort task showed that reaction time was fastest in the baseline condition (button press only). Listening effort, as measured with reaction time, was not significantly different in the device on versus device off condition (Figs. 8 and 9).

Conclusions: The participants implanted thus far demonstrate significant improvement for speech understanding in quiet and noisy conditions in both the unilateral and bilateral listening conditions. Notably, the group average CNC word and AzBio sentence tests are lower than those reported for adults who are implanted following bilateral loss. Self-perceived benefit indicates that although the input from the implant is important for daily function, listening effort was not improved with the device on compared to the device off. Anecdotally, patients have reported that although they enjoy the implant and find it useful, they do have to exert energy to process

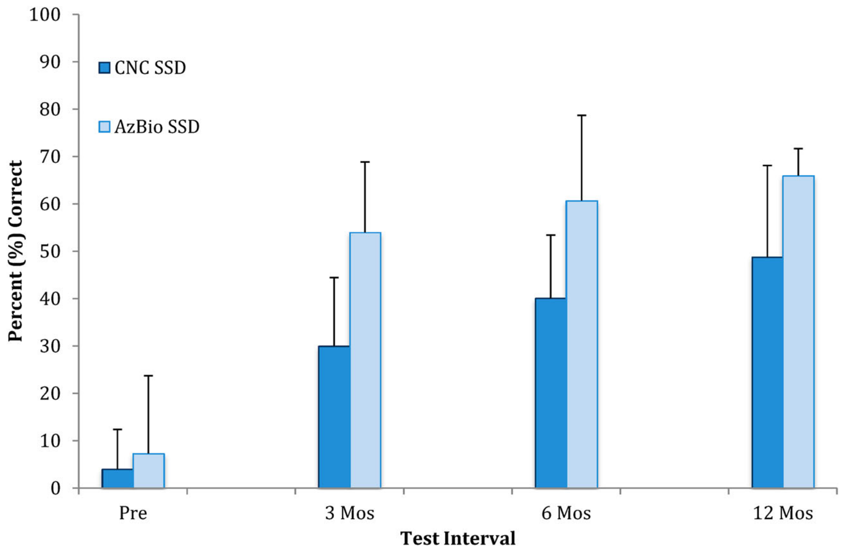

Figure 8 Average percent correct scores along with standard deviations for the ear implanted at each test interval.

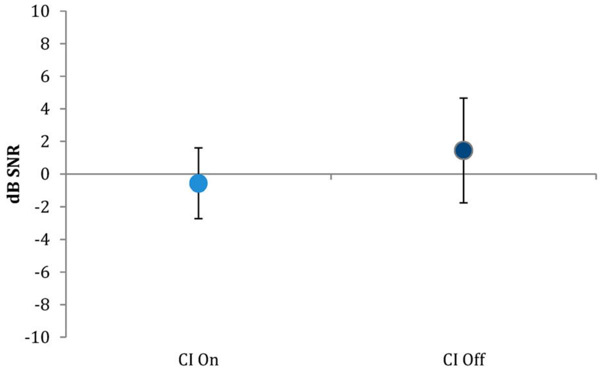

Figure 9 Average threshold signal-to-noise-ratio (SNR) for 50% correct along with standard deviations at 6-months post-activation for device-on versus device-off.

sounds from that ear. These outcomes are preliminary and should be interpreted with caution when generalizing to the broader population.

Measuring Listening Ability in Adults with Single-Sided Deafness

Bradford J. May

Conventional hearing tests are designed to measure speech comprehension under stable listening conditions. Typically, the most complex condition is speech in background noise. Such measures often fail to predict performance in the chaotic real world environments that represent a daily challenge for hearing impaired listeners. For example, when conversing in a room filled with other talkers, many hearing impaired listeners will have trouble understanding what is being said because they cannot separate the talkers into independent streams of information. This listening deficit is called ‘informational masking’.

To improve our methods for assessing how well a device supports speech comprehension in real world environments, we have developed a testing procedure that measures informational masking in hearing-impaired listeners. Here, we describe results obtained from adults with single-sided deafness (SSD; May *et al.*, 2014). These individuals have no hearing in one ear, usually the result of a surgical procedure, and normal hearing in the other ear.

We simulated a room filled with talkers by placing a speaker array inside an audiology booth. When different voices are presented from individual speakers in the array, listeners with normal hearing assign unique talker identities to the speaker locations by attending to binaural voice and direction cues. This ability to separate the talkers into individual auditory objects reduces informational masking when the talkers are speaking at the same time. We predicted SSD listeners would be more susceptible to informational masking than normal listeners because they cannot process the binaural cues that are necessary for talker separation.

The simulated talkers in our testing procedure repeat sentences from a library of color-number coordinates (CNCs). The coordinates are randomly selected from all possible combinations of four colors (blue, green, red, white) and eight numbers (1–8). CNCs provide a simple, quantifiable measure of speech comprehension because they can be reduced to three information elements: the color coordinate, the number coordinate, and an identifying call sign. The sample sentence ‘Ready EAGLE, go to BLUE-2, now’ requires the subject to report the color BLUE and the number 2 by pressing keys on a custom keyboard. Any other response is scored an error.

Subjects are assigned a target call sign prior to the test. They are instructed to listen to sentences that begin with that call sign and to ignore sentences with other call signs. EAGLE is the call sign in the

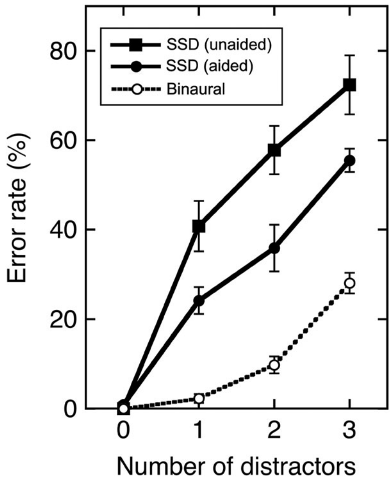

Figure 10 **Response errors of unaided SSD listeners.**

sample sentence above. To simulate a realistic conversational partner, every target sentence is spoken by the same male voice and is delivered from the same central location in the speaker array. Distracting sentences are spoken by other voices and are presented from other speaker locations. Each trial presents a target sentence with 0–3 distracting sentences.

Fig. 10 shows the response errors of unaided SSD listeners. For comparison, the responses of normal binaural listeners are also shown. Moving from left to right along the x-axis of the figure, the number of distracting sentences increases from 0 to 3. On trials where there is no distracting sentence, unaided SSD listeners match the perfect performance of binaural listeners. These results point out how exceptional performance under optimal listening conditions may fail to predict communication deficits under real world conditions.

Unaided SSD listeners produce many more errors than binaural listeners on trials with distracting sentences. Error rates exceed 40% with one distracting sentence, and climb steadily with additional distracting sentences. Listeners with binaural hearing produce error rates that are less than 30%, even when tested with three distracting sentences. These results support our prediction that SSD listeners are unusually susceptible to informational masking. The powerful detrimental effects of just one distracting sentence confirm that any social situation is a significant communication challenge for individuals with this type of hearing impairment.

SSD is often treated with an integrated bone conduction hearing aid, or IBC. The device is implanted behind the deaf ear and transmits sounds that originate on the deaf side of the head to the functioning ear through bone conduction. IBC-aided listeners still have just one functioning ear but they are more aware of talkers on both sides of the head. We predicted this increased awareness would improve talker separation cues and reduce informational masking.

The effects of an IBC on informational masking are also summarized in Fig. 10. As predicted, aided SSD listeners produce fewer errors than unaided listeners under all distracting conditions. In fact, aided listeners make fewer errors with two distracting sentences than unaided listeners make with one. This enhanced performance is critical for effective communication in real world listening conditions that often involve more than one talker. We believe these gains are behind the enthusiastic reviews of IBCs by individuals with SSD.

We are currently measuring how cochlear implants (CIs) influence informational masking. Our studies are focusing on CI users with residual hearing. These individuals have bilateral hearing loss that is treated with a CI in one ear and a conventional hearing aid in the other. Because bilateral aural awareness is critical for enhanced listening in IBC users, we predicted CI users would show lower error rates when tested with both CI and hearing aid.

Our preliminary results with CI users are shown in Fig. 11. The surprising observation is that error rates appear to be equivalent for monaural (CI alone) and binaural listening (CI + hearing aid). In other words, CI users do not take advantage of the additional binaural information that is provided by the hearing aid. This outcome may be explained by studies of individuals with normal binaural hearing that suggest talker separation cues reside in the low frequencies of complex sounds. Because conventional CIs are implanted in the high-frequency regions of the inner ear, these cues may not be adequately encoded.

Recent advances in CI electrodes now make it possible to restore or preserve low frequency hearing in the implanted ear. The extended frequency response of these implants should increase the availability of talker separation cues, making future CI users less susceptible to informational masking. The CNC paradigm offers an exciting new approach for objectively

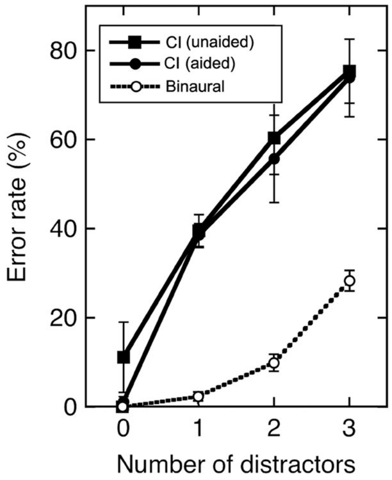

Figure 11 **Preliminary results with CI users.**

evaluating the real world performance of these innovative designs.

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Objective outcomes and cortical reorganization in children and adults following cochlear implantation for single-sided deafness

Daniel Zeitler

There is ample literature that patients with single-sided deafness (SSD) perform worse on complex listening tasks (i.e. localization, hearing in noise) and require increased listening effort in even the most routine environments (Dorman *et al.*, 2015; Douglas *et al.*, 2007). Traditionally, SSD has been treated with either an auditory osseointegrated implant (AOI) or CROS hearing aid with mixed results and in many cases poor user compliance. Over the last 7–8 years, cochlear implants (CIs) for SSD have been gaining popularity in Europe, and despite the lack of FDA approval in the United States, more centers are beginning to perform CI for SSD. Data in this population unequivocally show that patients undergoing CI for SSD gain significant improvements in speech in noise and sound source localization when compared to the SSD condition, and significantly outperform patients in both the AOI and CROS aid conditions (Arndt *et al.*, 2011).

Significant improvements in quality of life following CI for SSD have also been demonstrated (Harkonen *et al.*, 2015; Tavora-Vieria *et al.*, 2013). Performance in complex noise environments in SSD patients following CI has not been studied. Furthermore, cortical plasticity and higher order psychoacoustic changes in patients with SSD have been documented (Pross *et al.*, 2015) but it is unclear if these changes are reversible following cochlear implantation for SSD.

Nine subjects (eight adults, one child) with a mean age of 34.5 years and mean length of deafness of 2.7 years underwent CI for SSD. Mean length of CI use between implantation and complex speech in noise testing and sound source localization testing was approximately 7 months. In condition 1 (signal front, noise to normal hearing (NH) and CI ear), the subjects showed a mean Azbio percent correct improvement of 3.8%. In condition 2 (noise 360°, signal roving in front 180°) the subjects showed a mean Azbio percent correct improvement of 14.1%. In condition 3 (signal to CI, noise 360°), the subjects showed a mean Azbio percent correct improvement of 24.4%. Using root mean square (RMS) error to evaluate sound source localization, subjects performed no better than chance when using either their NH ear or CI ear alone (mean 64.7° and 76.8°, respectively). In the binaural condition using the CI, subjects improved significantly (RMS error mean 31.8°) with three subjects performing at the 95% confidence interval of NH listeners.

Cross-modal cortical neuroplasticity following CI for SSD was examined in two pediatric subjects. Using 128-lead high density EEG with current density source reconstruction using sLORETA, cortical auditory evoked potentials (CAEP), cortical visual evoked potentials (CVEPs), and cortical somatosensory evoked potentials (CSSEPs) were measured. Prior to CI, both subjects had a delayed P1 on CAEP with abnormal wave morphology and absence of N1 and P2 waves. By 14 months following CI, wave morphology and P1 latency normalized. Pre-CI, stimulation of the NH ear resulted in only contralateral activation of frontal and temporal regions while stimulation of the SSD ear resulted in only ipsilateral activation of frontal and temporal regions. At 6 months post-CI, stimulation of the implanted ear resulted in contralateral temporal activation with a reduction in frontal activation suggesting reduced listening effort and/or cognitive load. Using CVEP and CSSEP, cross-modal somatosensory and visual recruitment also appears to reverse following CI for SSD.

In conclusion, speech perception in complex noise is improved in patients with SSD following CI. Sound source localization is significantly better in SSD subjects following CI, and can approximate that of normal hearing listeners in some cases. These data have been published this year (Zeitler *et al.*, 2015). There is substantial cross-modal neuroplasticity that develops in pediatric patients with single-sided deafness, and this appears to be reversible following CI.

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Quality of Life and Cost-Effectiveness of Cochlear Implantation

Chair: John K. Niparko[1]
Presenters: Susan Emmett[2]*, Debara Tucci*[3]*, Joseph Chen*[4]*, Amy McConkey Robbins*[5]*, Ernest Schwefler*[6]
[1]*Keck School of Medicine of USC,* [2]*Johns Hopkins,* [3]*Duke Medicine,* [4]*University of Toronto,* [5]*Communication Consulting Services,* [6]*Contracting Officer USC Care*

Our present era of health care reform has brought increased scrutiny and pressure on the medical profession to provide both effective and cost-effective care. For the past 20 years, there has been a growing emphasis on evidence of effectiveness and cost-effectiveness in guiding policy decisions that direct reimbursement and the prioritization of health resources (Eddy, *JAMA*, 1996). As an estimated 30% of the recent increase in health care costs can be traced to advances in medical technology, we must continue to ask ourselves: 'Is the cochlear implant worth the price?' Further, in the US, cochlear implant candidates often endure a lengthy, challenging process in order to obtain third-party payment for their device, surgery and postoperative (re)habilitation. In many cases, reimbursement is significantly below the cost incurred by programs of support. Such challenges to patient access and sustained programmatic support require research data that evaluate the related medical economics, rating the effectiveness of interventions in an effort to optimize the use of health care dollars.

In examining the cost-effectiveness of cochlear implants, it is important not only to compare them with other medical interventions, but also to consider the implications and costs of untreated or undertreated sensorineural hearing loss. An assessment of research related to quality of life changes and cost effectiveness associated with cochlear implantation across various medical interventions as well as national settings around the world provides important insights regarding the quality of life changes and cost effectiveness associated with cochlear implantation.

Cost Effectiveness of Cochlear Implantation in Emerging Economies

Susan D. Emmett

Recent estimates suggest that 1.2 billion children and adults are affected by hearing loss worldwide (Global Burden of Disease Study 2013 Collaborators, 2015). This global burden is unequally distributed, with up to 80% of affected individuals residing in low- and middle-income countries (Olusanya, 2007). Cochlear implantation (CI) has become the standard of care for children with severe-to-profound congenital hearing loss, and cost effectiveness has been well established in high resource settings (Barton *et al.*, 2006; Bond *et al.*, 2009; Cheng *et al.*, 2000; Niparko *et al.*, 2010; Stacey *et al.*, 2006). Cochlear implant cost effectiveness is unknown in low resource settings, however, where access to the technology has traditionally been limited. With the incidence of congenital sensorineural hearing loss 5–6 times higher in low- and middle-income countries than the US and Europe, expanding cost effective management strategies to include these environments is essential.

We evaluated the cost effectiveness of managing prelingually deaf children in six Sub-Saharan African countries using a national cochlear implant program with mainstream education versus deaf education with sign language (Emmett *et al.*, 2015). This study is part of a larger series evaluating cochlear implant cost effectiveness in low resource settings around the world. Sub-Saharan Africa was selected for the first evaluation because of the range of economic development and existing CI infrastructure. Accessibility of services for prelingually deaf children continues to be lacking in this region of the world, highlighting the need for cooperation among higher resource countries, universities, and implant manufacturers to expand access to care.

Methods: A detailed description of the methods used in this study is available in the full-length manuscript (Emmett *et al.*, 2015). Briefly, cost effectiveness analyses were performed using disability adjusted life years (DALYs), the time-based measure of health recommended by the World Health Organization (WHO) for cost effectiveness analysis (WHO, 2003). DALYs consist of a combination of years of life lost and years lived with disability, with effectiveness measured by the number of DALYs averted as a result of a health intervention (Gold *et al.*, 2002). Existing capacity and costs were obtained from experts in Nigeria, South Africa, Kenya, Rwanda, Uganda and Malawi using known costs and published data, with estimation when necessary. Training costs were considered systems-level marginal costs due to the need to build capacity. The model assumed diagnosis and treatment would be initiated by 36 months of age and applied 3% discounting and 10-year length of analysis. A sensitivity analysis was performed to evaluate the effect of device cost, professional salaries, annual number of implants, and probability of device failure. Cost effectiveness ratios (CER) resulting from the model were divided by the gross domestic product (GDP) per capita of each country based on WHO guidelines, with CER/GDP less than 3 considered cost effective and less than 1 very cost effective (WHO, 2003).

Results: GDP per capita ranged from 12,258 in South Africa to 753 in Malawi. Three of the six countries had existing implant programs in place, including South Africa (230 implants per year), Nigeria (5 per year), and Kenya (6 per year). All countries except South Africa would require training of additional personnel to serve 30% of potential implant candidates. Four of six countries require training of additional surgeons, and increased audiology capacity is needed in Nigeria and Uganda. Speech therapists represented the largest personnel gap across countries, with all countries but South Africa requiring increased workforce in this area.

Cochlear implantation was cost effective in South Africa and Nigeria, with CER/GDP of 1.03 and 2.05, respectively (Table 2). Deaf education was cost effective in all countries investigated, with CER/GDP ranging from 0.55 to 1.56. The most influential factor in the sensitivity analysis was device cost, and thus the effect of discounted device cost on CER/GDP was further explored. Fig. 12 demonstrates that the WHO cost-effectiveness threshold of <3 can be reached in all countries employing discounted device costs that vary directly with GDP.

Maximum device cost that achieves WHO cost effectiveness criteria of CER/GDP less than 3 is $22,000 in Kenya, $10,000 in Rwanda, $8500 in Uganda, and $1100 in Malawi. Cochlear implantation is cost effective at all device costs in South Africa and Nigeria. GDP represents 2012 GDP per capita in international dollars.

Discussion: This is the first study to examine cost effectiveness of pediatric cochlear implantation and deaf education in the context of Sub-Saharan Africa, where economic and political stability, health infrastructure, and resources differ substantially from those of the United States and Europe. Both cochlear implantation and deaf education are cost effective in the upper-middle and lower-middle income economies

Table 2 Cochlear implant (CI) and deaf education cost effectiveness by country

	Cost effectiveness ratio per gross domestic project (CER/GDP)	
	CI (min–max)*	Deaf education
South Africa	1.03 (0.94–1.12)	1.56
Nigeria	2.05 (1.77–2.41)	0.69
Kenya	3.27 (2.83–3.80)	1.11
Rwanda	4.89 (4.23–5.66)	0.55
Uganda	5.43 (4.67–6.35)	1.30
Malawi	9.62 (8.37–11.07)	0.89

*Ratios from the CI sensitivity analysis are included. CER/GDP less than 3 is cost effective and less than 1 is very cost effective.

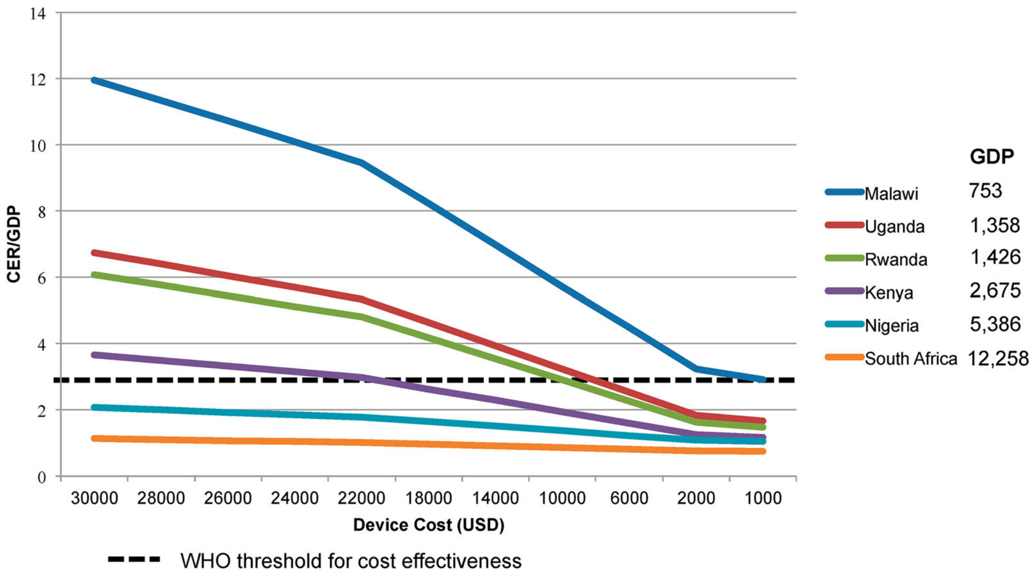

Figure 12 **Variation in CER/GDP with discounted device cost by country.**

of South Africa and Nigeria. With the most developed economy of the six participating countries and largest existing CI infrastructure, South Africa demonstrates that a highly cost effective cochlear implant program is an achievable and realistic goal in Sub-Saharan Africa. Recognizing that CI cost effectiveness is not geographically driven is essential in expanding global access to this technology. The current Nigerian implant program, consisting of a mere 5 implants per year, needs to grow by more than 500% to reach 30% of the estimated children in need. Our analyses indicate that cochlear implantation is cost effective in Nigeria even while accounting for the cost of this tremendous growth. The remaining countries in the study demonstrate the opportunity to expand CI programs to areas that traditionally have not had access to this technology. Kenya, Rwanda, Uganda, and Malawi highlight the role for philanthropic, university, and business collaborations in building capacity for robust national cochlear implant programs. Device cost and the associated maintenance are particularly influential in these emerging economies. Each country is able to reach the cost effective threshold with discounted device costs that vary directly with GDP. Partnerships with implant manufacturers that decrease the disproportionate impact of device and maintenance costs in these emerging economies will be essential for building cost-effective implant programs.

This study highlights the opportunity to expand cochlear implantation to areas of the world where access to the technology has traditionally been limited. Quantifying the cost effectiveness of a health intervention within the context of the local economic environment is essential to understanding where resources and support are needed. Our analyses demonstrate that a cost effective cochlear implant program is possible in the sub-Saharan Africa region and focuses attention on lower GDP countries where support is most needed to expand access to this technology. Partnerships between higher resource countries, universities, and implant manufacturers to build infrastructure and capacity in emerging economies will change the landscape of profound hearing loss management worldwide, shifting the focus from high resource environments to a truly global perspective.

Cost Effectiveness of Cochlear Implantation in the US and Europe

Debara L. Tucci

Cost-effectiveness, or cost-utility, analyses measure the improvement in health status (utility, or value) per cost of the intervention. Such assessments are commonly used by health economists and policy makers to prioritize health care expenditures (maximize value for cost) in the setting of fixed resources. Potential comparative analyses include direct comparison of two interventions in terms of cost and value, and analysis of incremental cost-utility of one intervention over another (such as comparison of bilateral to unilateral cochlear implantation, or unilateral CI to no intervention). Health care decision-making is generally based on a combination of cost-utility and the level of evidence of clinical effectiveness of the intervention.

Quality of life can be measured in one of two ways. The most commonly used measure in the *global* health arena is the Disability-Adjusted Life Year, or DALY. This measure was introduced by the World Health Organization (WHO) in the early 1990s and is the measure used to reflect disability in the global burden of disease (GBD) studies. Discussion related to cost effectiveness of CI in the global health context is covered above by Dr. Emmett. The most commonly used measure in the US, Canada and Europe and other developed countries is the Quality-Adjusted Life Year, or QALY. First described in 1968, the QALY provides utility values ranging from 1 (perfect health) to 0 (death), for a given state of health.

Cost-utility analyses are not simple, and require sophisticated decision-making about a large number of components that affect the final outcome. Cost components of the analysis generally include both fixed costs such as space, equipment, staff and training and variable patient-specific costs such as costs of the device (including maintenance and upgrades), surgery, surgical complications, rehabilitation and follow up. Costs and utility are generally discounted to account for the time value of money (the principal that a dollar in hand today is worth more than a dollar in hand in the future). As difficult as it can be to identify all the possible costs of an intervention, it can be even more challenging to assign a dollar value to benefits, and this is done to varying degrees in analyses.

Measures of utility and health related quality of life are also complex, and may be derived using validated or ad hoc measures that assess either generic or disease-specific quality of life. Outcomes can vary considerably depending on the measures used. Some of the more commonly used, validated, generic measures include: (1) Health Utilities Index Mark 3 (HUI3), which, although a generic measure does include assessment of hearing; (2) EuroQol descriptive system (EQ5D); (3) Visual Analogue Scale (VAS) which scores health state on a continuum; and (4) Time Trade Off (TTO), which asks the respondent to trade off the number of years in perfect health that they would be willing to trade to live the expected remaining years in their current state of health. In addition, a number of hearing-focused and even CI focused measures have been developed to capture disease-specific benefits. The choice of utility measure used can greatly affect the outcome of cost-utility analyses. The HUI3 has emerged from recent studies as a useful and conservative measure of CI cost-utility (Chen *et al.*, 2014; Kuthubutheen *et al.*, 2015).

Significant challenges have emerged. For one, utility measurements in children must be made by proxy (parental) responses. Second, utility of two vs. one (or no) CI has been difficult to assess based on current instruments. Benefits are subtle, dependent on the individual and environment and may change with time. Because utility is difficult to quantify, the cost-utility equation tends to be driven primarily by the cost side of the equation. For this reason, cost-utility is greatly affected by specific circumstances of the second implant, including any cost reduction for the second device and whether implants are placed simultaneously or at sequential surgeries. In order to account for the effects of many variables, sophisticated sensitivity analyses are performed to determine the effect of changes in each variable independently. In this way, parameters that greatly affect the overall analysis outcome can be identified. While cost-utility of one CI is clearly demonstrated to be cost effective in the vast majority of analyses, such is not always the case for the case of bilateral CI, which is highly dependent on the factors mentioned above. Analyses also vary as to country, and for this reason it is important to note the country of origin of the evaluation.

Whether or not an intervention is considered cost effective often depends upon whether cost of the intervention falls below a ‘willingness to pay’ (WTP) threshold for the episode of care. In the US this is established as roughly $50,000 per QALY. Using this criterion, unilateral CI is highly cost effective for adults and children. Cost utility is particularly high for children, given the longer time horizon of benefit and estimated lifelong cost savings due to educational benefits (Cheng *et al.*, 2000; Francis *et al.*, 1999). Cost utility of bilateral CI is less clear, but in studies performed in the US and Canada, reaches favorable cost utility ratios, as shown in Table 3 (Semenov *et al.*, 2012).

Table 3 Cost utility ratio of the cochlear implant in adults and children

				Cost-utility ratio ($)/QALY	
Study	Instrument	Country	Population	Unilateral vs. no CI	Bilateral vs. unilateral CI
Summerfield *et al.* (2010)	TTO	UK	Children	34 824	37 100
	VAS			23 026	30 973
Bond *et al.* (2009)	HUI	UK	Children	25 519	70 470
	HUI		Adults	33 132	86 425
Bichey and Miyamoto (2008)	HUI	US	Children	10 221	39 115
	HUI		Adults	11 092	38 189
Summerfield *et al.* (2002)	HUI	UK	Adults	45 215	118 387
Cheng *et al.* (2000)	TTO	US	Children	9029	–
	VAS			7500	
	HUI			5197	
Palmer *et al.* (1999)	HUI	US	Adults	14 670	–
Wyatt *et al.* (1996)	HUI	US	Adults	15 928	–

More recent studies of cost-utility of bilateral CI have demonstrated that simultaneous CI is cost effective (beneath WTP thresholds) for adults when compared with bilateral hearing aids for care delivered in Australia (Foteff *et al.*, 2016b) and the Netherlands (Smulders *et al.*, 2016). Bilateral (and unilateral) implantation is a cost effective treatment for children implanted in Australia, whether implants are placed simultaneously or sequentially (Foteff *et al.*, 2016a).

As analyses are further refined, information on cost-utility may be increasingly relied on to provide a more accurate reflection of total cost and benefit, both to society and to the individual. Where costs are high, such analyses along with evidence based practice guidelines may guide clinicians in appropriate cost savings measures that offer better value without compromising patient care and benefit (Foteff *et al.*, 2016a; McKinnon, 2013).

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Literacy and Cochlear Implantation: Outcomes and Intervention Strategies

Co-Chairs: Ann Geers[1], Amy Lederberg[2]

Presenters: Ann Geers[1], Amy Lederberg[2], Heather Hayes[3],

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The advent of cochlear implants (CI) as a treatment for prelingual profound deafness is associated with a dramatic reduction in the achievement gap relative to age-mates with normal hearing (Connor and Zwolan, 2004; Marschark *et al.*, 2007). Before CIs were available, about half of deaf students read below the fourth-grade reading level by the end of high school (Traxler, 2000) compared to a more recent study in which only 17% of teenagers with CIs scored this low (Geers and Hayes, 2011); however, significant delays remained. Over half of these teenagers failed to catch up with hearing peers after more than 10 years of CI use. The variability in reading levels achieved following cochlear implantation is quite large and we do not fully understand what enables successful outcomes. These summaries provide a brief overview of what we currently know about factors contributing to literacy development in children with CIs and poses three areas in which research must dive anew: (1) diverse populations of children with CIs, (2) effectiveness of classroom interventions, and (3) new methodological practices.

Emergence of Literacy throughout the School Years in Children with Cochlear Implants

Ann E. Geers

This presentation reviewed reading data collected in our laboratory from children with cochlear implants over the past 20 years. Reading scores were obtained from a nationwide sample that included many of the first children in the US to receive a cochlear implant between ages 2 and 5 years. The first wave of testing ($n = 181$) occurred in elementary grades (Geers, 2003). A battery of tests of speech, language, phonological processing, memory, word attack, word recognition, and sentence comprehension skills was administered. The group exhibited an average mid-second grade reading level (mean age = 8 years, 11 months) with 52% scoring within one standard deviation of hearing age-mates. Reading level was most highly correlated with language level (.80), but was also significantly associated with use of phonological coding strategies, working memory span, and speech intelligibility. A follow-up study of 121 of these students in high school (age 15–18 years) (Geers and Hayes 2011) documented reading scores ranging from second grade to post-high-school, with 47% of the sample scoring within a standard deviation of hearing age-mates. High school reading level was highly associated with language scores in elementary grades; those with age-appropriate vocabulary and syntax at ages 8–9 were most likely to develop reading skills at a normal rate throughout academic grades. Higher levels of auditory speech perception with a CI were associated with more efficient phonological processing which, in turn, predicted reading decoding and reading comprehension skills. Teenagers who continued using sign language in high school exhibited poorer phonological skills and lower reading outcome levels (Geers *et al.*, 2011). Ching and others (2013) further demonstrated that the relationship between phonological skill and reading in children with hearing loss is specific to reading and does not generalize to other academic abilities such as math reasoning.

Reading skills were next examined in a nationwide sample of 60 children who had received more recent implant technology at younger ages (12–38 months) and were educated within exclusively auditory-oral settings (Geers and Nicholas, 2013). More than 90% of these children achieved age-appropriate reading levels by mid-elementary grades. Reading scores at age 10.5 showed a moderate correlation with age at implant ($r = .30$) and a strong correlation with preschool language ($r = .58$). Reading skills of children with language delay that persisted from preschool through elementary grades were compared with those whose language delay resolved over this time period. The groups did not differ in reading decoding skills but were distinguished by lower reading comprehension scores as well as poorer speech perception with a CI (Geers *et al.*, 2016).

These results indicate that developmentally normal students who receive a CI along with listening and spoken language intervention by their third birthday can be expected to achieve age-appropriate reading levels in mid elementary grades if they score within a standard deviation of the normative average for hearing children on measures of spoken language. However, about one third of the sample did not reach age-appropriate language levels by mid-elementary grades and may be at risk for long-term delays. Implantation before 2 years of age, use of binaural or right-ear CI devices with the lowest possible aided thresholds and most recent speech processor technologies to optimize phonological perception and processing skills appear to increase the likelihood of age-appropriate development of language and literacy.

Effective Intervention Strategies for Teaching Early Literacy Skills to Deaf and Hard-of-Hearing Children

Amy R. Lederberg (Contributions from Susan Easterbrooks, Stacey Tucci, Victoria Burke, Hanah Goldberg)

Deaf and hard-of-hearing (DHH) children who are acquiring spoken language need the same foundational skills to learn to read as hearing children. Researchers have found that phonological awareness, alphabetic knowledge, and vocabulary predict reading abilities in young deaf children with CIs and hard-of-hearing children with hearing aids (Ambrose *et al.*, 2012; Cupples *et al.*, 2013; Easterbrooks *et al.*, 2008; Geers, 2003; Lederberg *et al.*, 2013; Nittrouer *et al.*, 2012; Webb & Lederberg, 2014). These studies showed that the majority of DHH children still have deficits in these skills compared to hearing children, with wide individual differences. Therefore, there is a strong need for early intervention with DHH children that focuses on these skills.

The current study evaluated the efficacy of a new early literacy intervention created specifically for DHH prekindergarten children, *Foundations for Literacy*. An interdisciplinary team of researchers in collaboration with teachers of DHH children developed this intervention over a period of five years. While adopting the literacy objectives of effective, integrated, code- and meaning-focused prekindergarten programs for hearing children, *Foundations for Literacy* is more systematic and its instruction is more explicit, multi-modal, and intensive than is typical in programs for hearing children. Each lesson also includes strategies for differentiating instruction based on children's speech perception and language abilities.

Foundations for Literacy was developed in two phases. During the first phase, research teachers implemented Foundations for Literacy with 25 DHH children in two schools. They taught children in small groups, 4 days per week, 1 hour per day, throughout the school year. A series of studies indicated that these children made educationally meaningful gains in phonological awareness, alphabetic knowledge, and vocabulary (Beal-Alvarez *et al.*, 2012; Bergeron *et al.*, 2009; Lederberg *et al.*, 2014; Miller *et al.*, 2013). During the second phase, 15 classroom teachers in 8 schools implemented *Foundations for Literacy* as part of their classroom instruction, 4 or 5 days a week, 1 hour per day, for the school year.

This presentation compared gains made by three groups of DHH children who were similar in their audiological and demographic characteristics: (a) 33 children taught by classroom teachers, (b) 25 children taught by research teachers, and (c) 32 comparison children who received their regular school-selected literacy curriculum. About 60% of children had cochlear implants; the rest were children with moderate-severe hearing loss who wore hearing aids (BEPTA, $M =$ 60 dB). All children were able to identify monosyllabic words on the Early Speech Perception Test (Moog and Geers, 1990.) A battery of language and literacy tests was administered in the fall and spring of the school year.

Children taught by classroom teachers increased their average standard scores on phonological awareness and vocabulary assessments such that they ended the year within a standard deviation of the normative average for hearing children. Statistical analyses showed that students taught with *Foundations for Literacy* made larger gains on tests of alphabetic knowledge, phonological awareness, and vocabulary than the comparison children. Children taught by classroom and research teachers made similar gains in phonological awareness and alphabetic knowledge. Children taught by classroom teachers made larger gains in receptive and expressive vocabulary than children taught by research teachers or children in the comparison group. There were no differences in the gains made by children with cochlear implants and those with moderate-severe hearing loss.

This quasi-experimental study suggests that interventions that are specifically designed for DHH children can result in improving early literacy skills of DHH children, ensuring they enter school with the foundational skills needed to learn to read. Furthermore, classroom teachers may be able to have even greater effects on student outcomes, especially language, than specially-trained research teachers. Future research that uses rigorous experimental designs (e.g., randomized controlled trial) will provide even stronger evidence of the efficacy of these types of intervention for DHH children.

Identifying Gaps in Our Knowledge of Literacy in Children with Cochlear Implants: What Do We Want to Know Next and Why?

Heather Hayes

The purpose of this presentation was to consider how gaps in research knowledge have substantial real-life effects on literacy instruction for children with cochlear implants (CIs). Researchers must include more diverse populations of children with CIs, must investigate interventions used in real classrooms, and be more open to different types of research designs in order to drive practical results in policy development, university-level preparation of teachers of the deaf, and ultimately classroom practice.

The first of the three gaps is a lack of knowledge about literacy development in diverse populations of children with CIs. We know that diversity in ethnicity is very important for research in all areas. However, it's also important, particularly for reading development, to consider economic and educational diversity. For example, the 2014 Census Bureau data states that 32% of the population ages 25 or older have earned a bachelor's degree or higher. In a sampling of literacy articles published in the last 5 years, the average level of parent education (of the child participants) was far above what would be expected in the general population (Geers and Hayes, 2011; Lederberg *et al.*, 2014; Nittrouer *et al.*, 2012; Webb *et al.*, 2015).

Given our limited resources, what aspects of diversity do we think will matter? Researchers should consider investigating more closely the effects of low socioeconomic status or low parental education, because low-income families are more likely to experience toxic stress. Toxic stress can have devastating effects on cognitive development in typically hearing children. Research could explore whether there are differential effects on children who are deaf or hard of hearing and who wear cochlear implants.

The second gap in knowledge is the effectiveness (or ineffectiveness) of literacy interventions in the classroom. To my knowledge, there are only a handful of recent studies that used experimental or quasi-experimental design to investigate the effects of a particular curriculum for children who are deaf – most of whom wore cochlear implants and most of whom used spoken language (Easterbrooks *et al.*, 2015; Lederberg *et al.*, 2014). Researchers much move out of the lab and into the schools, collaborating with teachers of the deaf to quantitatively determine which practices should be used in their classrooms.

Finally, because of the low-incidence nature of deafness, our field is severely limited in the number of gold-standard experimental design-type studies that have been conducted. Low population numbers mean poor statistical power and thus a limited ability to infer and generalize outcomes. One possibility is to use high-quality single-case design methodology that adheres to the rigorous Council for Exceptional Children standards (Kratochwill *et al.*, 2013). Perhaps a more powerful tool that can help us combat low participant numbers is simply making sure that schools, early intervention centers, and clinics use systematic ways to collect and disseminate data, and make those data accessible to researchers.

In summary, in order to drive decision-making at the federal, district, building, and teacher levels, we must fill these three gaps in the research literature, and do so in an unbiased, rigorous fashion.

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Trends in Objective Measures for Cochlear Implantation

Chair: Michelle Hughes[1]

Presenters: Michelle Hughes[1]*, Julie Bierer*[2]*, Shuman He*[3]

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Peripheral measures of auditory nerve function with a cochlear implant allow us objectively assess how the auditory system responds to stimulation from a cochlear implant. Such assessments include the effects of stimulus polarity on measurements of the electrically evoked compound action potential (ECAP), the relationship between evoked potentials and CT imaging, and findings on both ECAP and cortical auditory evoked potentials in children with cochlear implants and auditory neuropathy spectrum disorder. Recent research has expanded knowledge of how objective measures can be used to provide information about auditory pathway function in cochlear implant recipients that can contribute positively to clinician care practices.

What Can Stimulus Polarity and Interphase Gap Tell Us About Auditory Nerve Function?

Michelle L. Hughes (Contributions from Erin Glickman, Jenny L. Goehring)

Human auditory-nerve modeling studies suggest that both cathodic and anodic pulses effectively elicit action potentials when peripheral processes are intact (i.e., in the healthy ear) (Rattay *et al.*, 2001). However, evidence suggests that anodic pulses more effectively stimulate the deafened human auditory system (when compared to cathodic pulses) because the anodic phase directly activates the central axon (Macherey *et al.*, 2008; Undurraga *et al.*, 2010). Differences in electrically evoked compound action potential (ECAP) responses between polarities may therefore provide information about neural survival patterns on an individual basis. Specifically, we expect larger ECAP amplitudes and steeper slopes of the amplitude growth function for anodic than for cathodic stimuli in regions of poorer neural survival. To date, studies with CI recipients have used non-standard pulse shapes to study the effects of stimulus polarity (Macherey *et al.*, 2008; Undurraga *et al.*, 2010). Little is known about polarity effects in CI recipients using standard biphasic pulses. Another parameter that has been shown to relate to auditory nerve survival in animal studies is the duration of the interphase gap (IPG) (Prado-Guitierrez *et al.*, 2006; Ramekers *et al.*, 2014). Specifically, the ECAP input–output function shifts to lower current levels with increased IPG, and this shift is less apparent with greater neural loss. The goal of this study is to characterize the combined effects of stimulus polarity and IPG within and across subjects.

ECAP input–output functions were obtained with anodic-leading and cathodic-leading biphasic current pulses for short, medium, and long IPGs ranging from 7 to 58 s. Data for four electrodes were obtained from each subject. The following outcome measures were compared across conditions: ECAP threshold, maximum amplitude, and slope. Preliminary results show different patterns across individuals, likely reflecting differences in neural survival. In some cases, polarity effects were large and IPG effects were minimal, consistent with poorer neural survival. In other cases, polarity effects were minimal and IPG effects were large, consistent with good neural survival. Data so far suggest that polarity and IPG effects were generally consistent with expected trends for poorer or better neural survival, but further data collection is needed.

Objective Measures in Children with Auditory Neuropathy Spectrum Disorder (ANSD)

Shuman He

Children with auditory neuropathy spectrum disorder (ANSD) are known to have temporal processing deficits regardless of stimulus audibility, and the severity of the deficits strongly correlates with their speech perception abilities (Rance *et al.*, 2004; Starr *et al.*, 1991; Zeng *et al.*, 1999). It is generally believed that these temporal processing deficits are likely due to dyssynchroous neural discharge and/or abnormal neural conduction of the auditory nerve in children with ANSD (Zeng *et al.*, 1999, 2005). Cochlear implantation (CI) has been used a treatment option for children with ANSD who do not benefit from hearing aids. Compared with acoustic stimulation, electrical stimulation can result in more precise and repeatable neural synchronization at the level of the auditory nerve (Kiang and Moxon, 1972; Hartmann *et al.*, 1984). Even though the extent to which electrical stimulation improves neural synchrony and neural conduction at the level of the auditory nerve in implanted children with ANSD cannot be directly evaluated, useful information reflect these neural response properties can be derived by measuring the electrically evoked compound action potential (ECAP). The aims of this study were (1) to characterize temporal response properties of the auditory nerve in implanted children with ANSD; and (2) to compare results recorded in implanted children with ANSD with those measured in implanted children with sensorineural hearing loss (SNHL).

Study participants included 23 implanted children with ANSD and 26 children with SNHL. Both ears were tested in six implanted children with ANSD and in three children with SNHL. All subjects were Cochlear Nucleus device users. For each subject, three stimulating electrodes across the electrode array were tested. The stimulus was a biphasic charge-balanced pulse train consisting of 32 pulses. The pulse rates tested in this study were 500, 900, 1800 and 2400 pulses per second (pps). ECAPs evoked by each pulse (except for the second pulse) were measured using a modified forward masking paradigm (Hughes *et al.*, 2012, 2014; Miller *et al.*, 2000). Study groups, stimulating electrodes and pulse rates were independent variables. Dependent variables evaluated in this study included amplitude, N1 and P2 latencies, response width, alternating depth and adaptation index. All dependent variables were measured for the last six ECAP responses and the sequence of six consecutive ECAPs occurring within a fixed time window centered around 11 ms. The group difference of these dependent variables was assessed using a general linear mixed model.

Our results showed that implanted children with ANSD showed smaller ECAP amplitude, longer P2 latency, wider ECAP response, and more neural adaptation with long durations of stimulation than implanted children with SNHL. However, these differences were only observed in some but not all stimulating electrode locations. In addition, a new neural response pattern was observed in both subject groups. Details of this study have been reported in our most recent paper in *Ear and Hearing* (He *et al.*, 2015).

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Cochlear Implant Connectivity to Other Technologies

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Assistive technologies can improve outcomes of individuals with cochlear implants in their use of cell phones and in difficult listening environments. Federal legislation has helped push forward the development of such solutions that work with personal hearing technologies – hearing aids, cochlear implants, and osseointegrated devices. Evidence-based strategies for expanding outcomes of individuals with cochlear implants through the use of cell phone and remote-microphone assistive-technology applications provide important opportunities for recipients. Current Federal Communications Commission (FCC) regulations govern cell phone compatibility with hearing aids including a requirement that cell phone manufacturers test and 'rate' interference relative to cell phone linkage with hearing aids. It is believed (though research based assessments are lacking) that these same regulations and rating schemes are relevant to users of cochlear implants. Research supports the benefit of various cell phone-connectivity options such as direct audio input, Bluetooth, and telecoil. There is also evidence to support the efficacy and effectiveness of remote-microphone, hearing-assistance technologies including frequency modulation (FM) and digital transmission systems for both adults and children with cochlear implants. At the same, research demonstrates that there are benefits as well as pitfalls for technologies in terms of ease of use, benefit in various settings, sound clarity, speech recognition, reliability, and cost. Ease of use, benefit in various settings, sound clarity, speech recognition, and cost are all considerations that impact on user benefit.

Introduction: Why Federal Laws Requiring Communication Access Have Failed

Donna Sorkin

Children and adults with hearing loss live in a very different environment today relative to communication access than the one that existed in the past. Even as recently as 20 years ago, most products and facilities were not accessible to people using hearing technology. Legal change has come on the heels of dramatic improvements in cochlear implants and hearing aids as well as the fact that an increasing number of children born with hearing loss begin their hearing journey within the first 2 years of life due to newborn hearing screening. As a nation, we have moved from a perspective in which a deaf individual was expected to work in a 'deaf trade' that did not require much communication with co-workers to a society and a legal framework in which a person of any age who is qualified and motivated can pursue almost any educational opportunity or career that (s)he desires. The scope of our national laws has been broadly expanded to address discrimination based on disability and also the need for a facility or program to provide reasonable accommodations. In practical terms, this means those who need to access spoken language via technologies such as cell phones, landline phones, broadcast and cable television are *supposed* to be provided with appropriate linkage to their personal hearing technology. Theaters, museums, sport stadiums, transportation facilities and more are all public places that are *supposed* to provide communication access connectivity options to various hearing technology. The Americans with Disabilities Act, passed in 1990, set the stage for wide-ranging public laws and policies that were subsequently enacted and intended to welcome individuals with disabilities, including those with hearing loss, into every aspect of life (Table 4).

Table 4 US federal laws pertaining to connectivity in communication access (Source: Sorkin, 2014)

Education laws	Coverage
IDEA (Individuals with Disabilities Education Act)	Children must be provided with services to address their specific needs
Section 504 of Rehabilitation Act	If child does not qualify for IDEA, requires that related services such as FM or captions be provided
American with Disabilities Act (ADA)	May be applied like Sec 504. Relates to both public and private schools
Telecommunications laws	Coverage
Hearing Aid Compatibility (HAC) Rules for Wireless Telephones 2003	Expanded original HAC rules to wireless phones requiring manufacturers to produce usable handsets
Telecommunications Act of 1996	Requires companies make telephone products and services accessible *if readily achievable*
Section 504 of Rehabilitation Act	Requires Federal agencies to follow access requirements when purchasing electronic or information technology
General access	Coverage
ADA: Titles 1. (employment), 2. (state/local governments), 3. (Public Facilities), 4. (Telecommunications Relay Services)	Assistive technology and accessible telephones providing communication access required in public/private settings

Given the breadth of such laws and the thorough discussions that were part of the implementation process, one might expect that connectivity to cochlear implants and other hearing technologies has been appropriately addressed by public facilities, cell phone manufacturers, educational institutions and others. The reality is rather different for a variety of reasons. Underlying all of these laws and the accommodations that they are intended to deliver is the requirement for children (via their parents) and adults to make their needs known and to seek the services or technology they require to be able to hear. People must be advocates for themselves, a role that many find overly challenging or uncomfortable. Many public facilities report infrequent utilization of their assistive listening equipment and, as a consequence, repair and regular maintenance of equipment goes by the wayside and the quality of the sound signal provided may not provide clarity sufficient to warrant its use. Obsolescence with any equipment is an issue in our rapidly changing technology environment and this is true for personal hearing devices (i.e., CI sound processor) as well as for the devices people wish to connect to.

With cell phones particularly, technology changes every 12–18 months making it difficult for the cochlear implant user community to know what phones – out of the wide-ranging choices available – work best. A rating scheme on interference of cell phones with hearing technology covering both acoustic and telecoil modes is required as part of the HAC Act of 2003 (see Kosma-Spyteck below) though consumers (and even cell phone service provider employees) are often unknowledgeable about its existence much less how to use it to guide a phone purchase. Anecdotal reports indicate that there are now fewer cell phone options that offer the most interference free rating of 4/4. Hence although Federal laws require that connectivity solutions be provided, they are unreliable, consumers typically do not ask for them, and equipment maintenance is poor.

Cochlear implant recipients rely increasingly upon personal connectivity solutions that are part of CI system kits, options such as Bluetooth or direct connect, that put the individual in control of the connection and related devices. A consumer movement to utilize induction loops that connect directly to the telecoil in cochlear implants and hearing aids provides a solution that is often more reliable than the assistive devices provided in public places, which require use of an additional device. Sophisticated noise suppression programs in CI sound processors provide another important option of dealing with noisy environments.

In summary, despite having the most comprehensive set of disability access laws in the world encompassing every aspect of our lives, suitable CI connectivity with sound in public places and with telephones remains elusive in the US. CI manufacturers and the recipient community have responded by assembling a range of personal solutions that are often superior to those offered by public facilities and telephone companies.

Cell Phones and Cochlear Implants: How Telecommunications Accessibility Research Informs Clinical Practice

Linda Kozma-Spytek

Telecommunications accessibility research on cell phones is most often used to inform public policy work and standards development related to regulation of the wireless telephone (cell phone) industry for hearing aid compatibility (HAC). Even so, there is much from this work that can be garnered and applied to clinical practice. Two recent studies, one survey and the other experimental research, related to cell phones and cochlear implants (CI) are briefly discussed along with suggestions for how the results can inform clinical practice.

Cell phone use is ubiquitous among US adults. The Pew Research Center's Internet and American Life Project reported that 91% of US adults own cell phones (Raine, 2013), with voice calling being one of the most used smartphone features (Smith, 2015). A recent survey we conducted under the Telecommunications Access Rehabilitation Engineering Research Center found similar rates of cell phone ownership among adults with hearing loss who use voice communication. Of the 439 survey respondents, 85% owned a cell phone and most reported making several (3–5) voice telephone calls a day. One hundred six survey respondents were CI users, and three-quarters of those reported using their CI for voice communication on the phone. Among those respondents who use their CI for telephone communication, their rate of cell phone ownership was 89%. The most common way reported for listening over their cell phones was holding the phone to their ear and using their CI's microphone. For this type of telephone listening, when the phone is held at the ear, considerations related to hearing aid compatibility for wireless devices are important.

Wireless compatibility was addressed within the Hearing Aid Compatibility Act of 1988, a federal law enacted by Congress. In 2003, the Federal Communications Commission, the regulatory agency for establishing the rules and regulations for HAC, undertook a rulemaking on hearing aid compatibility for wireless phones. Compliance with the rulemaking is based on a standard, C63.19, which specifies both the measurement methodology and performance criteria for wireless devices and hearing aids (HA). There is no specification in the standard to evaluate CIs.

Wireless HAC is evaluated using a standard measurement procedure that assesses the interfering noise potential of the combined system, with the wireless device held at the ear next to the hearing aid for either acoustic coupling via the microphone or inductive coupling via a telecoil. The radio frequency (RF) emissions of wireless devices are assessed, and if they meet the performance criteria specified in the standard, they are given an M-rating (either M3 or M4). Telecoil coupling capability is assessed for those wireless devices receiving an M-rating. If they also meet these performance criteria, the devices are given a T-rating (T3 or 4) in addition to the M-rating. Unlike wireline phones, wireless phones currently have no acoustic volume control requirement. HAs are evaluated for their immunity to the RF emissions of a wireless device.

The performance criteria specified in the standard were developed based on testing with HA users. While there has been an assumption that the same criteria would hold for cochlear implant recipients, the question remained whether the performance criteria are adequate to provide similar levels of wireless phone usability for CI users. To determine whether the performance criteria are appropriate for CI users, we adapted the acceptable noise level procedure for use in our study (Julstrom and Kozma-Spytek, 2014). Twenty-one CI users listened to a travel passage and cell phone interfering noises using their preferred ear and coupling method via simulated wireless device use. Participants established their most comfortable level for telephone speech and then adjusted interfering noises according to several criteria including: their threshold for interfering noise in the presence of speech and levels of noise resulting in 'Excellent Performance', defined in the standard as little perception of interference resulting in M4; T4 ratings and 'Normal Use' performance, defined in the standard as interference acceptable for normal operation resulting in M3; T3 ratings.

The results indicate that CI and HA users have similar speech to noise level requirements for each of the criteria used. On average for the noise types, about a 21 dB S/N ratio was needed to provide half of the subjects with an 'acceptable for normal use' telephone experience, a rating that did allow for some audible interference noise. The subjective 'excellent performance' S/N choices for both CI and HA users closely tracked their objective noise threshold-in-speech S/N ratios, indicating that for this subjective category rating, neither wanted to hear any noise.

This study suggests that the performance criteria specified in the wireless HAC standard are adequate to provide similar levels of wireless phone usability for CI users as for HA users. Additionally, both CI and HA users had a preferred MCL for telephone speech of approximately 65 dB SPL acoustic input or −25 dB mA/m equivalent magnetic input.

With regard to clinical practice, it is important to include telecommunications use in both needs assessment and counseling. Given the high usage of cell phones for voice communication by CI users observed in the survey, clinicians should inquire specifically about cell phone usage and explore all possible connection options between an individual's CI and cell phone. For coupling at the ear, clinicians should observe the relative positioning of the cell phone and hearing device, what volume control setting is typically used on the cell phone and whether speech is on average comfortably loud. Clinicians can counsel CI users that the HAC ratings for wireless devices are applicable to not only HA users but CI users as well. Information on wireless HAC should also include an explanation of wireless device ratings and the consumer's right to try HAC-rated cell phones in service provider stores before making a purchase.

Remote-Microphone and Wireless Technologies for Cochlear Implants

Erin Schafer

Despite advances in cochlear implant (CI) technology, many adults and children continue to report difficulty hearing over the phone, hearing the television, and conversing in noisy environments. However, there are several evidence-based strategies for expanding outcomes of individuals with CIs through the use of various types of remote-microphone and wireless technologies.

First, there are multiple publications showing the significant benefits of electrically-coupled frequency modulation (FM) systems for individuals with CIs (Schafer and Thibodeau, 2003, 2004, 2006). These devices consist of a transmitter and microphone worn by the primary talker and a receiver that is coupled to the CI sound processor, often with an adaptor or special battery door. When compared to performance with the CI alone, improvements in speech recognition in noise with an FM system range from 30% to 47% (Schafer and Thibodeau, 2003, 2004; Wolfe *et al.*, 2009). Even greater benefit from the use of FM systems are achievable by individuals with CIs when the gain of the FM receiver is adaptively adjusted based on the background noise level as measured in the FM transmitter (Wolfe *et al.*, 2009). For example, speech recognition in noise (+7 signal-to-noise ratio) of individuals using Cochlear and Advanced Bionics sound processors improved by an average of 30–50% with adaptive FM relative to fixed-gain FM receivers with no adaptive adjustments.

More recently, the potential benefit of neckloop FM receivers, which require electromagnetic coupling to the sound processor (i.e., t-coil), was evaluated in adults and adolescents with CIs (Schafer *et al.*, 2012, 2013b). In one study, 14 adults and adolescents with Cochlear sound processors showed significantly better speech-in-noise thresholds at the 50% correct level with fixed-gain neckloop FM systems relative to their sound processor alone by an average of 12 dB (Schafer *et al.*, 2012). In the second study, speech-in-noise thresholds of nine participants with Advanced Bionics, Cochlear, or MED-EL sound processors were compared across three conditions: CI alone, neckloop FM receiver, and electrically coupled FM receiver (Schafer *et al.*, 2013b). Results of this investigation suggested that, on average, both types of FM system resulted in significantly better (lower) thresholds relative to the CI alone. However, on average and for most individuals, the neckloop FM receiver yielded superior performance over the electrically coupled FM receiver, which was unexpected given the equivalent volume settings on the two FM receivers (+8).

To further examine the performance discrepancy between the two FM receivers, a follow-up study was conducted to measure the electroacoustic output of the monitor earphones connected to CI sound processors coupled to FM systems (Schafer *et al.*, 2013a). In this laboratory study, hearing aid practice guidelines from the American Academy of Audiology (2008) were modified to allow for electroacoustic measurements with a hearing aid analyzer. The goal of the measurements was to achieve transparency, which is achieved when equivalent outputs from the CI and FM system are measured when equivalent inputs are presented to the CI and FM microphones. For each processor/FM combination, the FM gain or volume was adjusted to attempt to achieve transparency for outputs from the two input devices. Results of the electroacoustic measurements suggested that transparency was achieved for most processor/FM combinations. However, most systems required adjustments to FM gain or volume relative to the manufacturer default setting. For example, for the FM equipment used in the Schafer *et al.* study (2013b) described above, the performance discrepancy was due to a lack of transparency (approximately 10 dB difference) between the CI and FM system. According to the measurements completed by Schafer *et al.* (2013a), the neckloop FM had much higher output than the electrically coupled FM system. To confirm that transparent FM systems would result in similar performance, pilot data was collected from four participants to compare speech-in-noise thresholds with the neckloop and electrically coupled FM system, which were adjusted to achieve transparency. Use of the two transparent systems resulted in equivalent performance for all four participants. Results of this study were clinically significant because they highlight how (1) front-end processing and signal processing pathways of different CI sound processors may impact the output of electrically- and electromagnetically-coupled FM systems and (2) that volume/gain adjustments may be necessary to achieve optimal performance.

In 2013, Wolfe *et al.*, compared speech recognition performance in noise of 37 adults with Cochlear and Advanced Bionics sound processors when using fixed-gain FM systems, adaptive FM systems, and a newer system utilizing adaptive digital transmission. Results revealed superior speech recognition performance with the adaptive digital system over both FM systems at the higher-intensity noise levels (i.e., 70, 75, 80 dBA), with no differences across systems at the lower noise levels (i.e., 50, 55, 60, 65 dBA). Results of this study highlight the improved performance with digital transmission, which is less susceptible to interference from the environment.

Even more recently, CI manufacturers are beginning to release wireless, digital, audio-streaming accessories for the telephone and television as well as a fixed-gain, remote-microphone accessory. These accessories communicate with the CI sound processor by streaming a proprietary, digital, 2.4 GHz radio frequency. Three separate studies were conducted by Wolfe and colleagues to examine the potential benefit of these devices for adults with cochlear implants. In the first study, 16 adults with Cochlear sound processors participated in speech recognition conditions with the CI alone and with the CI coupled to the remote-microphone accessory (Wolfe *et al.*, 2015a). When compared to the CI alone conditions, use of the remote-microphone accessory resulted in significantly better speech recognition by an average of 10% in quiet and by 24–65% across the increasing-intensity noise conditions. Similarly, in a study on the potential benefit of the telephone accessory, 16 adults with Cochlear sound processors showed significant improvements in speech recognition by an average of 16% in the quiet condition and 28% in the noise condition when compared to the CI-alone conditions (Wolfe *et al.*, 2016b). The television accessory was also beneficial relative to the CI alone with average improvements of 7% in quiet and 23% in noise (Wolfe *et al.*, 2016a). Overall, the three wireless accessories for Cochlear users were highly beneficial. However, if users frequently encounter high-level noise environments at school or work, an adaptive digital transmission system is recommended because the adaptive feature will likely provide superior performance over the remote-microphone accessory (Wolfe *et al.*, 2015b).

In conclusion, there are multiple remote-microphone and streaming devices to improve the listening abilities of individuals with CIs when listening in quiet and noisy environments, over the telephone, and when watching television. Continued research efforts will focus on optimizing existing technologies and determining benefit of any new technologies designed for CIs.

Perspectives on Connectivity by an Educational Audiologist and User

Tina Childress

There are numerous approaches and technologies that can improve a CI listener's access to speech and environmental sounds or provide other types of alerts that can help. Hearing Assistive Technology (HAT) has evolved to bring people with hearing loss on a par with typically hearing people for access in a variety of settings. Accessories such as streamers or gateway devices and amplified neckloops are now part of patient kits offered by cochlear implant companies. CI technology linkages are expanding from frequency modulation (FM) to digital modulation (DM) protocols, which can improve the signal with less opportunity for interference. Telecoil technology is incorporated into cochlear implant processors, which provides another opportunity to connect to HAT. These technologies are required by law to be offered in many pubic settings including movie/live theaters, sports stadiums, workplaces, and educational institutions.

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