

Cochlear Implantation in Pediatric Cases of Unilateral Hearing Loss

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1) Introduction

Unilateral hearing loss (UHL) is a term used to describe a substantial hearing loss in one ear and normal hearing in the contralateral ear. Often patients with UHL have reduced speech perception in the affected ear, limiting the effectiveness of conventional amplification. Despite normal hearing in one ear, these patients experience reduced speech perception in noise (Welsh et al, 2004; Rothpletz, Wightman & Kistler, 2012), variable abilities on localization tasks (Slattery & Middlebrooks, 1994), increased reports of hearing handicap (Iwasaki et al, 2013), and reduced quality of life (Wie, Pripp & Tvette, 2010).

In the United States, the prevalence of UHL in children ranges from 0.03% to 3%, depending on the age of the child (Porter & Bess, 2011). Studies have indicated that of the children screened for hearing loss at birth, 0.03% have unilateral hearing loss, and of the children screened at school-age, the prevalence rises to 3% (Bess, et al, 1998). Although the premise that UHL creates educational, social and behavioral challenges for children has been acknowledged for several decades (Bess, 1986; Bess, et al, 1986; Lieu, 2004; Ruscetta et al, 2005; Tharpe, 2008; Borton, et al, 2010), our ability to treat and provide habilitation for such children has been limited to strategic interventions, such as preferential seating, or less effective technologies, such as hearing aids or bone-conduction devices. For children with moderate to profound hearing loss in one ear, a traditional hearing aid in the poorer ear typically provides inadequate amplification and poor sound quality due to the inability to provide sufficient audibility in the speech spectrum. CROS hearing aids and bone-conduction devices route the signal from the affected side to the better hearing ear. A CROS hearing aid uses a microphone/transmitter on the affected ear to send the acoustic signal to the receiver on the better hearing ear. Studies assessing the efficacy of CROS hearing aids in children have been performed. They indicate benefit for quality of life and speech recognition in quiet; however, these results were for children with thresholds in the mild to moderately-severe range (Kenworthy, et al, 1990; Updike, 1994; Briggs, et al, 2011). Bone-conduction devices use vibratory stimulation to transmit the signal to the cochlea on the side with better hearing. In a similar fashion to CROS aids, bone conduction aids route the signal to the better hearing ear, stimulating only one auditory pathway. Though listeners receive signals from both sides, they are unable to use binaural cues. This inability to stimulate both auditory pathway results in variable speech perception in noise (Kunst et al, 2007) and poor localization (Bosman et al, 2003; Hol et al, 2010). It is hypothesized that a cochlear implant, which would stimulate the auditory pathway on the affected side, may benefit this population by improving speech perception in the affected ear and offering binaural cues for improved localization and speech perception in noise.

A cochlear implant is a two-part system, including the internal receiver/electrode array and external speech processor. The internal receiver/electrode array is surgically implanted into the cochlea. The external speech processor detects sounds and codes and transmits this signal to the internal portion. The acoustic signal is presented through the implanted device within the cochlea via electrical pulses. Sound is then perceived and interpreted by the brain. Cochlear implantation performed for children with bilateral, severe to profound deafness has significant impacts on several aspects of child development. First, children who are deaf and are implanted early can acquire spoken language in a manner that follows the developmental trajectory experienced by children with normal hearing (Nicholas & Geers, 2007). These children have both better access to, and use of sound due to improved speech perception and better expressive and receptive language (Niparko, et al, 2010). Second, access to sound also stimulates social and emotional growth and development (Nicholas & Geers, 2003). Third, quality of life is perceived by parents and teachers as being improved for children with cochlear implants relative to their non-implanted peers (Stacy, et al, 2006). There is evidence that cochlear

implantation can stave off neurologically driven sensory deficits that impact neuro-cognitive development. Finally, children with unilateral hearing loss appear to require greater auditory effort to understand speech. In a classroom setting, this can result in greater fatigue in multiple domains including cognitive fatigue, thus leading to negative impacts on learning (Hornsby et al 2013). As audition is integrated into brain functions such as sequencing, sensory-motor control, and executive function, the lack of hearing from an early age may have cascading negative effects on higher level brain functions (Conway, Pisoni, Kronenberger, 2009; Sharma, Dorman, Spahr, 2002).

In Europe, cochlear implantation has become an accepted treatment for patients with UHL. The majority of literature regarding patients with UHL and cochlear implantation involves adults. It has been reported as a viable treatment option in cases of UHL, including sudden sensorineural hearing loss (Firszt et al, 2012), and severe tinnitus (Vermiere & Van de Heyning, 2009; Van de Heyning et al, 2008). Further, cochlear implantation has been shown to offer superior speech perception in noise, sound localization abilities, and subjective perception of hearing quality compared to CROS hearing aids and bone-conduction devices (Arndt et al, 2011).

The practice of providing cochlear implants to children who have significant hearing loss in one ear is of great interest and is occurring with greater frequency as reported in case studies and small set clinical reports (Gantz,, et al. 2000, Cadieux et al., 2013; Hassepass, et al., 2013; Plontke et al., 2013; Tzifa and Hanvey, 2013; Távora-Vieira and Rajan, 2015; Arndt, et al, 2015). Children with severe to profound UHL may have greater potential to benefit from cochlear implantation than adults with UHL from a developmental point of view due to their neural plasticity. They may be more amenable to gaining binaural listening skills after cochlear implantation.

The primary goal of this project is to determine whether children with UHL experience an improvement in speech perception, hearing in noise, localization, and quality of life with a cochlear implant as compared to an unaided listening condition.

2) Objective

The primary purpose of this feasibility study is to demonstrate the effectiveness of cochlear implantation in children with moderate to profound UHL. Postoperative results will be evaluated with:

- i) speech perception measures,
- ii) localization tasks,
- iii) hearing in noise tasks,
- iv) subjective reports.

3) Definitions

Adjusted Constant Error: the rms deviation of the mean responses from the diagonal, computed after compensating for bias. This procedure reduces the bias

when evaluating the relationship between the average response on the azimuth and signal source on the azimuth.

Bone-Conduction Device: A device on the poorer hearing ear that picks up the acoustic signal on the effected side and transmits to the better hearing ear via vibrations through the skull. This is accomplished by either securing the oscillator to the head with a headband or via an implanted titanium abutment in the skull bone.

CNC words: A standardized word list comprised of 50 words with consonant-vowel-consonant construction ie, Consonant-Nucleus-Consonant (CNC) words (Peterson & Lehiste, 1962). The CNC test assesses perception of monosyllabic words. The test includes 10 lists of 50 words each. Each word is preceded by a carrier word “ready.”

Cochlear Implant (CI): A two-part system, including the internal electrode array and external speech processor that stimulates the auditory pathway on the effected side. The internal electrode array is surgically implanted into the affected cochlea. The external speech processor receives sounds and transmits this signal to the internal portion. The electrode array presents the acoustic signal via electrical pulses within the cochlear space, which is interpreted by the brain as sound.

Constant Error: the rms deviation of the average responses from the source positions

Contralateral Routing of Signal (CROS) Hearing Aids: A two-part system consisting of a transmitter microphone on the deafened ear and a receiver on the normal hearing ear. The transmitter sends the signal from the deafened ear to the normal hearing ear. The auditory pathway on the normal hearing ear receives the sound.

Desired Sensation Level (DSL): The Desired Sensation Level (DSL) Method was originally developed to provide audiologists with a systematic, science-based approach to pediatric hearing instrument fitting that ensures audibility of amplified speech by accounting for factors that are uniquely associated with the provision of amplification to infants and young children who have hearing loss (Seewald, Ross and Spiro, 1985; Ross and Seewald, 1988; Seewald and Ross, 1988).

Pure Tone Average (PTA): The average threshold (dB HL) from 500, 1000, and 2000 Hz

Random Error: the standard deviation of responses at each signal source position, averaged across all potential signal sources

Root-Mean-Square (rms) Error: The difference between the location on the azimuth of the sound source and the participant’s response on each trial for the localization task

4) Investigational Device

Participants will be implanted with the commercially available MED-EL Synchrony cochlear implant with the FLEX28 or FLEX24 electrode array (MED-EL Corporation, Innsbruck, Austria). The devices consist of a stimulator, a coil with a magnet within its center, a reference electrode, an EAP reference electrode and an active electrode permanently attached to the stimulator.

The FLEX28 Electrode Array is 28 mm long. The contacts for the 12 channels are arranged as 5 single contacts at the apical array end and 7 contact pairs at the base, with a 2.1 mm spacing between each channel. The marker ring is located 28 mm from the electrode tip and indicates the deepest insertion.

The FLEX24 Electrode Array also features 12 electrode contacts, with five at the apical end and 7 at the base. This array is shorter than the FLEX28. The FLEX24 is 24 mm long and contacts are spaced 1.9 mm apart. The marker ring is 24 mm from the tip to indicate deepest insertion. This array is designed for a more shallow insertion depth.

Both arrays feature FLEX tip technology. The specially designed electrode tip offer increased mechanical flexibility for reduced insertion force. Near the marker ring, the electrode leads feature an additional marker on the same side of the array as the single apical contacts. The marker allows the surgeon to ensure appropriate alignment of the single contacts toward the modiolus.

The MED-EL audio processor is an external component of the MAESTRO Cochlear Implant System and is indicated for use on patients who have been implanted with a MED-EL cochlear implant. The audio processor analyzes the sound signal from the microphone according to the selected speech coding strategy and transforms it into a coded electrical signal that is sent to the externally worn coil. This coded signal contains information about how to stimulate the individual electrodes, so changes in pitch and loudness can be perceived. The coil, which is magnetically held in place over the implant, sends the coded signal across the skin to the implant package via an inductive link.

Programming of the device is completed using the MAX Programming Interface and MAESTRO System Software. The MAESTRO software is used for different intraoperative and postoperative purposes for the MED-EL Cochlear Implant System. It contains the implant Telemetry, Fitting and Configuration of all available audio processors, ART (Auditory nerve Response Telemetry), ESRT (Electrically Evoked Stapedius Reflex Threshold), EABR (Evoked Auditory Brainstem Response) and Audiogram functions. The MAESTRO software is an external component of the MED-EL Cochlear Implant System and is intended to be used in a clinical or office environment by persons adequately skilled and trained to perform all intended tasks and with patients who received one of the intended MED-EL Cochlear implants.

For the pediatric population, the MED-EL Synchrony cochlear implant is currently indicated for children 12 months to 17 years and 11 months of age, who have bilateral sensorineural hearing impairment and obtain limited benefit from appropriately fitted binaural hearing aids. In this study, the use of this system is considered investigational because it will be used for children who have unilateral moderate to profound sensorineural hearing loss rather than bilateral profound sensorineural hearing loss.

5) Study Duration

- a) Enrollment Period
4 years
- b) Study Timeline
Each participant's involvement will last approximately 2.5 years, including: candidacy evaluation, preoperative evaluation, surgical procedure, initial activation of the external speech processor, therapy schedule, and post-initial activation evaluations (3, 6, 9, 12, 18 and 24-months post-initial activation).
- c) Study Endpoint
The study endpoint for each participant is the 24-months post-initial activation interval.

6) Methods

- a) All procedures will be conducted by UNC investigators, including board-certified otologists, audiologists, and speech-language pathologists. Fully informed consent will be obtained from all participants and/or their parents.
- b) Participants must meet the following inclusion criteria and not exhibit any of the exclusion criteria.
 - i) Inclusion Criteria
 - (1) Unilateral moderate-to-profound sensorineural hearing loss.
 - (a) Unaided residual hearing thresholds that yield a PTA at frequencies 500Hz, 1K Hz and 2K Hz of ≥ 70 dB HL in the ear to be implanted. It is possible that subjects may have hearing at other frequencies not included in this average.
 - (b) Hearing thresholds in the contralateral ear of ≤ 25 dB HL
 - (2) Between 3 years, 6 mos and 6 years, 6 mos of age at implantation.
 - (3) Anatomically normal cochlear nerve
 - (4) Cochlear anatomy that is amenable to cochlear implantation as evaluated by imaging (modality at the physician's discretion) including:
 - (a) Normal cochlear anatomy or

- (b) Incomplete Partition Type II (IP2) with or without Enlarged Vestibular Aqueduct (EVA) or
- (c) EVA with normal partitioning
- (5) No evidence of progressive hearing loss.
- (6) Willing to undergo 4 week hearing aid trial as warranted based on achieving desired audibility when fitted via real ear DSL method. See Reference Appendix B.
- (7) Aided word recognition in the ear to be implanted of 30% or less as measured with CNC words (50-word list)
 - (a) When listening with an appropriately fit hearing aid and masking applied to the contralateral ear (Turner, 2004).
 - (b) Aided testing will be conducted in a sound-proof booth with the participant seated 1 meter from the sound source, facing 0° azimuth. Recorded materials will be presented at 60 dB SPL.
 - (c) The hearing aid output will be measured using DSL targets.
- (8) Realistic parental expectations: *a verbal acknowledgement of the potential benefits and risks, and postoperative variation in performance. For instance, cochlear implantation will not restore normal hearing.*
- (9) Willing to obtain recommended meningitis vaccinations per CDC recommendations.
- (9) Development and cognition within the normal range as measured by the Leiter-R test of nonverbal intelligence and cognitive abilities.
- (10) Parental commitment to study parameters including being able and willing to participate in evaluation schedule, involvement in prescribed therapy, and travel to investigational site and study-related activities.

ii) Exclusion Criteria

- (1) English is not primary language of the home
 - (a) Speech perception materials are presented in English
 - (b) Parental questionnaires are administered in English
- (2) Conductive hearing loss in either ear
- (3) Compromised auditory nerve
- (4) Ossification of the cochlea
- (5) Inability to participate in follow-up procedures (i.e., unwillingness, geographic location)
- (6) History of condition that contraindicates middle or inner ear surgery or anesthesia (i.e. otitis media refractory to treatment)
- (7) Case of sudden sensorineural hearing loss that has not been first evaluated by a physician

iii) Enrollment

- (2) This study seeks to enroll twenty (20) participants.

c) Timeline

Appendix A graphically depicts the timeline and associated measures

- i) **Candidacy Evaluation.** This interval may overlap with the Preoperative Evaluation interval.

(1) Audiologic Evaluation

- (a) Unaided air- and bone-conduction thresholds in both ears
 - (i) Air-conduction assessed with inserts
- (b) Unaided word recognition in both ears
 - (i) Measured with recorded CNC words (50-word list)
 - (ii) Masking provided when appropriate (Turner, 2004)
- (c) Tympanometry in both ears
- (d) Aided word recognition in the affected ear
 - (i) Measured with recorded CNC words (50-word list)
 - (ii) Masking applied to the contralateral ear
- (e) Completion of all questionnaires
- (f) Determine if potential participant meets candidacy criteria

(2) Speech-language and psycho-education evaluation

- (a) Oral Written Language Scale (OWLS-II)
- (b) Goldman Fristoe Test of Articulation
- (c) Leiter-R

(3) Medical Evaluation

- (a) Determine if potential participant is healthy enough to undergo cochlear implantation
- (b) Associated imaging studies
- (c) Discussion of alternative treatment options
- (d) Determine if potential participant meets candidacy criteria

(4) Informed Consent

- (a) Review and discussion of consent form
- (b) Provide time for participant and/or parents to review consent form and ask questions
- (c) Provide participant and/or parents with a signed copy of the completed consent form

- ii) **Preoperative Evaluation.** This interval may overlap with the Candidacy Evaluation interval.

The Preoperative Evaluation will be completed within 6 months of the surgery date.

(1) Audiologic Evaluation

- (a) Obtain a case history, including but not limited to:
 - (i) Onset of hearing loss
 - (ii) Stability or progression of sensorineural hearing loss
 - (iii) Suspected etiology of hearing loss

- (b) Unaided air- and bone-conduction thresholds in both ears assessed with insert phones
- (c) Unaided word recognition with CNC words in both ears
 - (i) Measured with recorded CNC words (50-word list)
 - (ii) Masking provided when appropriate (Turner, 2004)
- (d) Tympanometry in both ears
- (2) Speech-language and psycho-education evaluation
- (3) Parental Questionnaires – will serve as anchor point for future questionnaires
- (4) Counseling of parents on cochlear implant external technology, realistic expectations, study test battery, and postoperative timeline
- (5) Medical Evaluation
 - (a) Participants will undergo a medical assessment and review of medical history
 - (b) Associated imaging studies
 - (i) This is standard of care for these patient populations
 - (ii) May have been completed at Candidacy Evaluation
 - (c) Counseling on cochlear implantation surgical procedure and postoperative considerations, including MRI limitations due to internal magnet

iii) **Surgery: Cochlear Implantation**

Risk factors associated with cochlear implantation are listed in Section XI “Risk Analysis.”

All surgical procedures will take place at the UNC Memorial Hospital or UNC Ambulatory Care Center (ACC) operating rooms. All procedures will be completed by board-certified otologists.

iv) **Postoperative Evaluations and Follow up Visits**

- (1) Initial Follow-Up (approximately 1-3 weeks postoperatively)
 - (a) Medical Evaluation
 - (i) This is standard of care
 - (ii) Participant will be seen by the physician
 - (b) Audiologic Evaluation
 - (i) Unaided thresholds
 - 1. Air-conduction assessed with an insert phone in the contralateral ear
 - 2. Bone-conduction thresholds assessed in the surgical ear
- (2) Initial Activation of External Speech Processor (approximately 2-4 weeks postoperatively)
 - (a) Initial activation of external speech processor

- (i) Participants will be fit with the commercially available MED-EL audio processor (MED-EL Corporation, Innsbruck, Austria). Speech perception and localization measures at follow-up intervals will be conducted with the participant listening with the Sonnet external speech processor for the aided conditions
 - (ii) Mapping will be completed by board-certified audiologists.
- (b) Counseling on the external device and use
- (c) Aural habilitation session
- (3) Two-weeks Post-Initial Activation
 - (a) Mapping of the external speech processor
 - (b) Counseling on the external device and use as needed
 - (c) Aural habilitation session
- (4) Five-weeks Post-Initial Activation
 - (a) Mapping of the external speech processor
 - (b) Counseling on the external device and use as needed
 - (c) Aural habilitation session
- (5) Three-Months Post-Initial Activation
 - (a) Localization assessment
 - (b) Parental questionnaires – anchored to prior questionnaires
 - (c) Speech perception assessed with the cochlear implant via direct input to processor
 - (d) Mapping of the external speech processor
- (6) Six-Months Post-Initial Activation
 - (a) Hearing in noise assessment
 - (b) Parental questionnaires - anchored to prior questionnaires
 - (c) Speech perception assessed with the cochlear implant via direct input to processor
 - (d) Assessment of hearing in contralateral ear
 - (e) Mapping of the external speech processor
- (7) Nine-Months Post-Initial Activation
 - (a) Localization assessment
 - (b) Parental questionnaires - anchored to prior questionnaires
 - (c) Speech perception with the cochlear implant via direct input to processor
 - (d) Mapping of the external speech processor
- (8) Twelve-Months Post-Initial Activation
 - (a) Hearing in noise assessment
 - (b) Parental questionnaires - anchored to prior questionnaires
 - (c) Speech perception with the cochlear implant via direct input to processor

- (d) Mapping of the external speech processor
- (e) Assessment of hearing in contralateral ear
- (f) Speech-Language evaluation

(9) Eighteen Months Post-Initial Activation

- (a) Localization assessment
- (b) Parental questionnaires - anchored to prior questionnaires
- (c) Speech perception assessed with the cochlear implant via direct input to processor
- (d) Mapping of the external speech processor

(10) Twenty-four Months Post-Initial Activation

- (a) Localization assessment
- (b) Hearing in noise assessment
- (c) Parental questionnaires - anchored to prior questionnaires
- (d) Speech perception with the cochlear implant via direct input to processor
- (e) Mapping of the external speech processor
- (f) Assessment of hearing in contralateral ear
- (g) Speech-language evaluation

d) Test Battery

The following test battery will be completed at various assessment intervals (preoperative, and at 3, 6, 9, 12, 18, and 24 months postoperatively) as defined in 6.iv. All assessment and mapping will be conducted at the Children's Cochlear Implant Center at UNC or at the Carolina Crossing research lab by board-certified audiologists.

i) Hearing Assessment

- (1) Air-conduction thresholds in both ears
 - (a) Air-conduction assessed with insert phones
 - (b) Assess bone-conduction thresholds if there is a PTA shift of >15 dB as compared to the previous interval
- (2) Aided thresholds with the external speech processor on will be measured using warble tones
 - (a) Frequencies assessed: 250-8000 Hz
 - (b) Masking presented to the contralateral ear (Turner, 2004).

ii) Tympanometry for each ear

iii) Speech Perception Measures in Quiet in ear of implant

- (1) Recorded materials will be presented at a comfortable listening level via direct input
- (2) Speech perception materials will be presented in a hierarchy, with advancement to the next test contingent on performance on the previous test

- (3) Test materials to include:
 - (a) 3 subtests of Early Speech Perception Test (ESP), if > 70% then,
 - (b) CNC words
- iv) Speech Perception in Noise in binaural condition (6, 12, and 24 months post-initial activation)
 - (1) Speech processor on
 - (a) Listening conditions, noise orientation
 - (i) Speech and noise at 0° azimuth.
 - (ii) Speech 0° azimuth and noise to implanted side
 - (iii) Speech 0° azimuth and noise to contralateral ear
 - (b) Speech perception materials
 - (i) BKB-SIN
 - (2) Speech processor off
 - (a) Listening conditions, noise orientation
 - (i) Speech and noise at 0° azimuth.
 - (ii) Speech 0° azimuth and noise to implanted side
 - (iii) Speech 0° azimuth and noise to contralateral ear
 - (b) Speech perception materials
 - (i) BKB-SIN
- v) Sound Field Localization Measures (3, 9, 18, and 24 months post-initial activation)
 - (1) Postoperative aided sound field assessment will be measured in the free field with the Sonnet speech processor turned on and with the processor turned off.
 - (2) Testing will be completed in a double-walled soundproof booth. Eleven loudspeakers are arrayed in a 180-degree arc, with speakers evenly spaced at 18-degree intervals. Speakers are mounted at ear level, all spaced approximately 1-meter from the listener.
 - (3) The stimulus is a 200-ms speech-shaped noise, presented at 70-dB SPL. The speaker used to present the stimulus is randomly selected from the 11 alternatives on each trial, with the caveat that each speaker is used 3 times during a block of 33 trials. At least one block of 33 trials will be obtained in each condition (with and without the processor turned on).
 - (4) The listener faces the middle speaker prior to and during stimulus presentation. The task is to identify the source of the noise. Feedback is provided during instruction and training trials, but not during data collection.
 - (5) Listening Conditions
 - (a) Cochlear implant speech processor off at the 3, 9, 18 and 24 month intervals
 - (b) Cochlear implant speech processor on at the 3, 9, 18 and 24 month intervals

- (6) Performance is analyzed by computing the normalized RMS error, a metric that characterizes a listener's ability to discriminate between sound source locations.
- (7) These procedures have been used successfully to test children as young as 4 years of age.

vi) Parent questionnaires

- (1) Speech, Spatial and Qualities of Hearing Scale (SSQ), (Gatehouse & Noble, 2004). The SSQ questionnaire assesses performance in three domains, hearing speech in quiet and noise environments (9 items), spatial or directional hearing (5 items) and sound qualities (8 items), which address sound segregation and listening effort. Each item is rated on a 10-point scale. Domain scores represent an average of item ratings. A modified version of this test will be used.
- (2) Bern SSD Questionnaire, (Kompis, Pfiffner, Krebs & Caversaccio, 2011). This is a 10-item questionnaire used for rating the subjectively perceived benefit of a hearing technology designed to be used for persons with UHL. A modified version of this test that can be completed by a parent will be used.
- (3) PedsQL Multidimensional fatigue scale (Varni, Limbers & Burwinkle, 2007). This is a validated scale for determining fatigue in young children, including general fatigue, sleep/rest fatigue and cognitive fatigue. Scores from this test have been previously demonstrated to be substantially affected by hearing loss in children (Hornsby et al 2013).

e) Aural Rehabilitation

- i) Participants and their parents will participate in aural rehabilitation sessions with a board-certified speech-language pathologist
- ii) Sessions will occur either in person or via tele-therapy at the time of the initial stimulation, 2-week follow up, 5 week follow up, and twice a month following for the first 6 months after the initial stimulation. Sessions will continue once per month for the next 6 months until the first annual follow up.
- (a) The option to continue on a once per month basis for the second year following the initial stimulation will be offered but will not be required.

7) Proposed Claims

- a) Demonstrate the effectiveness of cochlear implantation in children with moderate to profound UHL
 - i) Demonstrate an improvement in speech perception abilities, localization, and/or subjective benefit in an aided (cochlear implant on) versus an unaided (cochlear implant off) condition

- ii) Demonstrate improvement in ability, or improved ease, to participate in natural environments based on parental perception of benefit.

8) Statistical Analysis

- a) Descriptive summaries will be provided for the following: participant demographics, and frequency of major and minor complications/adverse events.
- b) A single-subject design will be utilized, where each participant serves as his or her own control, for analysis of objective and subjective results. A single-subject design was chosen in order to accommodate the heterogeneity that is well known to characterize auditory prosthesis research. Repeated-measures ANOVA will be calculated with a p-value of ≤ 0.05 for statistical significance. Statistical analysis will be conducted with SPSS software.
 - i) Comparison of aided speech perception performance to the baseline condition (either unaided or aided with hearing aid, depending on the participants residual hearing) and in the post-initial activation intervals to evaluate trends over time
 - ii) Comparison of localization abilities to the baseline condition (either unaided or aided with hearing aid, depending on the participant's residual hearing) and in the post-initial activation intervals to evaluate trends over time
 - iii) Compute the overall rms error, random error, constant error, and adjusted constant error, as described by Grantham et al (2007)
 - iv) Comparison of subjective report scores in the post-initial activation intervals. Group means compared with Bonferroni's adjusted t tests or repeated-measure ANOVAs. Pearson's correlations will be used to analyze relationships between variables.
 - v) Subjective report scores will be compared to norms for this test. Group means compared with Bonferroni's adjusted t tests or repeated-measure ANOVAs. Pearson's correlations will be used to analyze relationships between variables.
- c) The incidence of interference between ears will be assessed at the 6,12 and 24 month post initial stimulation visit by comparing the speech perception performance in the 0° azimuth conditions for the contralateral ear only versus cochlear implant + contralateral ear conditions for each participant, as well as the individual's subjective report.

A sample size of 20 participants was selected due to known variability in conventional cochlear implant recipient outcomes and to allow for possible dropouts (approximately 20%). A comparable study, Hansen, Gantz & Dunn (2013) evaluated 29 adult cochlear implant participants with UHL, which included etiologies of sudden sensorineural hearing loss, Meniere's disease, and vestibular schwannoma. Authors reported a high degree of variability in their sample. This project will not enroll all of the etiologies included in the Hansen, Gantz & Dunn (2013) analysis (such as, Meniere's Disease with intractable vertigo or history of vestibular schwannoma), therefore a smaller sample size was selected. The inclusion/exclusion criteria associated with this study, as compared to the heterogeneity of the Hansen, Gantz, & Dunn (2013) subject sample, will allow for more generalized comments about subjective and objective outcomes of cochlear implantation in pediatric cases of UHL.

If needed, statistical consultation will be sought from the North Carolina Translational and Clinical Sciences Institute (TraCS) or UNC Odum Institute.

9) Endpoints

a) Safety endpoint

- i) The primary safety endpoint is the evaluation of Adverse Events. All Adverse Events will be reported to the UNC IRB. If the UNC IRB or study investigators deem an Adverse Event unacceptable, then this would result in termination of the study.

b) Primary effectiveness endpoint

- i) The primary effectiveness endpoint is the comparison of speech perception, localization abilities and/or subjective report when the cochlear implant is on versus the preoperative unaided condition as well as changes in quality of life as measured by the Speech, Spatial and Qualities of Hearing Scale (SSQ), (Gatehouse & Noble 2004), the modified Bern SSD Questionnaire, (Kompis, Pfiffner, Krebs & Caversaccio, 2011) and the PedsQL Multidimensional fatigue scale (Varni, Limbers & Burwinkle, 2007).

10) Risk Analysis

a) Potential risks to cochlear implantation

The following are risks associated with the MED-EL Synchrony implant, which is included in the device description:

1. Loss of residual hearing
2. Dizziness
3. Increased vertigo
4. Delay of healing of the scar
5. Impairment of the sense of taste

6. Potential for swallowing difficulties
7. Numbness
8. Increased tinnitus
9. Stimulation of the facial nerve
10. Temporary pain and uncomfortable sounds during stimulation

The following are potential risks the participant may experience related to the study procedure:

- b) Potential surgical risks
 - (1) Facial nerve injury
 - (a) Facial nerve monitoring is conducted during the surgical procedure
 - (2) Infection
 - (a) All participants and/or parents will be counseled regarding bacterial meningitis and recommended vaccinations
 - (3) Bleeding
 - (4) Cerebrospinal fluid (CSF) leak
 - (5) Pain
 - (6) Scarring
 - (7) Swelling around the incision and/or coil site
 - (8) Reduced or loss of pinna sensitivity on the surgical side
 - (a) Typically resolves 1-2 months postoperatively
 - (9) The cochlear implant may not provide any auditory stimulation
 - (10) The cochlear implant may provide auditory stimulation, but with a sound quality too poor to aid in the perception of speech
 - (11) The cochlear implant may provide auditory stimulation, but with a sound quality too poor to aid in localization
 - (12) Pain associated with the coil and/or placement of the external speech processor on the participant's ear
 - (13) Movement of the internal receiver
 - (14) Discomfort from electric stimulation
 - (15) Facial nerve stimulation
 - (16) Headache
 - (17) Dizziness
 - (18) Altered taste (i.e. reports of metallic tastes on the same side of the tongue as the surgical ear)
 - (19) Fatigue during follow-up assessment (completion of the test battery and/or mapping)
 - (20) The internal device may fail, requiring revision cochlear implantation
 - (21) The sound from the cochlear implant may interfere with the better hearing ear.
- c) Risk Mitigation
 - i) The audiometric and speech recognition criteria for inclusion in this study identify participants who have no or little functional use of residual hearing in the ear to be implanted. Potential subjects will

complete a hearing aid trial prior to enrollment to evaluate outcomes with conventional amplification. If a child has any residual hearing in the ear to be implanted, surgical placement of a cochlear implant will result in a loss of this hearing. The amount of functional gain a hearing aid can afford for a hearing loss with a pure tone average of >70dB HL will be very likely be insufficient to achieve comprehension of spoken language. Current research in performance outcomes for children with cochlear implants suggests that children with a 67dB PTA have a 80% chance of improved hearing with a cochlear implant and children with a 73dB PTA have a 85% chance of improvement with a cochlear implant (Leigh, Dettman & Dowell, 2016). If a child does not benefit from the cochlear implant, or does not elect to use it, this does not preclude him or her from use of a CROS hearing aid or Bone Conduction device in the future. This technology, which uses a contralateral microphone to route sound to the better hearing ear, either by way of short wave radio or bone conduction, can still be used.

- (1) The test battery includes a listening condition to assess the monaural performance of the contralateral ear. Interference of the cochlear implant on the performance of the contralateral ear can be evaluated by comparing the contralateral ear only condition to the cochlear implant + contralateral ear conditions when tested at 0° azimuth. This will be done at the 1 and 2 year test intervals only. Additionally, we will review the subjective benefit via the subjective questionnaires. If interference is found to impact speech perception and subjective benefit, the participant may elect to discontinue use of the cochlear implant and would still have access to currently approved technologies for UHL
 - ii) Magnet strength will be assessed at each interval to ensure comfort at the coil site.
 - iii) Reports of pain from the external speech processor placement will be addressed by different wearing options (i.e. moleskin between the external speech processor and the participant's ear, or different battery-wearing options to lighten weight on the pinna).
 - iv) Mapping will be conducted at each post-initial activation interval to improve audibility and comfort of the sound quality from electric stimulation.
 - v) The MED-EL cochlear implant has MRI limitations*. Participants may have CT scans or x-ray imaging postoperatively when warranted.
 - vi) *The MED-EL SYNCHRONY cochlear implant is approved for MRI of 1.5 or 3.0 Tesla when adhering to the conditions for safe scanning listed on MED-EL's website.
 - vii) An otologist will conduct medical follow-up evaluations at the 5 week, and 6 and 12-month intervals, which is standard of care for cochlear implant recipients.

- viii) Age appropriate vaccinations per the CDC recommendations will be completed by each participant prior to implantation. Participants will be counseled regarding meningitis vaccinations and directed where to obtain them by their implanting physician.

11) Potential Benefits

- a) Improvement in speech perception abilities in the ear of implant.
- b) Improvement in speech perception abilities in noise with the cochlear implant due to utilization of auditory cues from both ears.
- c) Improvement in localization abilities with the cochlear implant due to utilization of auditory cues from both ears.
- d) Improvements in subjective benefit with the cochlear implant as compared to preoperative performance or the processor on vs. processor off condition.

The potential benefits of cochlear implantation in cases of UHL are suspected to outweigh the risks listed in Section XI.A. The study sample will include participants with UHL who have completed a hearing aid trial if there is adequate hearing. This sample is similar to those in previously published reports who have benefited from cochlear implantation.

12) Adverse Events

- a) Anticipated versus Unanticipated Events
 - i) Anticipated Events: those events described as potential risks (section XI.A.) of the protocol
 - ii) Unanticipated Events: events not reported as potential risks (section XI.A.)
- (1) Unanticipated serious adverse events are defined as any serious adverse event related to the health or safety or any life-threatening problem or death caused by, or associated with, a device, if that event, problem, or death that was not previously defined in nature, severity, or degree of incidence in the literature or investigational plan. It can also include any other unanticipated serious problem associated with a device that relates to the rights, safety or welfare of participants.
- iii) Serious Adverse Event: Serious injury means an injury or illness that:
 - 1) is life-threatening, 2) results in permanent impairment of a body function or permanent damage to a body structure, or 2) necessitates medical or surgical intervention to preclude permanent impairment to a body function or permanent damage to a body structure.

- (1) Permanent means an irreversible impairment or damage to a body structure or function, excluding trivial impairment or damage.
 - (2) Revision cochlear implantation will be considered a serious anticipated adverse event.
- b) Reporting adverse events
- i) All adverse events will be reviewed by the PI during the preparation of the annual reports to the FDA and UNC IRB. Combined adverse events will be listed in an excel spreadsheet. Frequent adverse events will be discussed with co-investigators.
 - ii) Anticipated events will be reported to the FDA in the annual report
 - iii) Unanticipated events will be reported to the FDA and UNC IRB within 10 days of the investigator becoming aware of the event, as required by 21CFR 812.150.

13) Monitoring

- a) Participants will be monitored on a case-by-case basis for ongoing or unanticipated medical complications. Adverse events will be tracked on a case-by-case basis and recorded in study binders at the time of occurrence and followed up at resolution. Any adverse event will be reported to the UNC IRB. Should there be concern for the safety of participants because of their participation in the study by the investigators or the UNC IRB, the study would be halted at least temporarily and a detailed discussion with the investigators and UNC IRB would be undertaken to evaluate the viability of the study.
- b) Participants can withdraw from the study at any time and for any reason by notifying the Primary or Co-Investigators. If the investigator identifies the need to withdraw a participant from the study for any reason, this will be discussed in person during a scheduled evaluation. Participants may also be withdrawn if residual hearing changes in the contralateral (better hearing ear) to a moderate hearing loss or worse. In either scenario, the participant will continue to receive care irrespective of their participation in the study. Reasons for withdrawal from the study will be documented in the clinical visits and characterized based on the subjective reports from the child and family, performance on test measures, and the use of datalogging from the speech processor.
- c) Investigative Team
 - i) Co-investigators will review completed Consent Forms and Case Report Forms, including determining candidacy.
 - ii) The Principal Investigator will ensure that study site Standard Operating Procedures are followed by the study team.

- iii) Responsibilities for all study team members will be recorded in a Study Delegation Log. Not all team members will be responsible for all activities.
- iv) Source data will be maintained with completed Case Report Forms (such as, speech perception score sheets) when available.

14) Confidentiality

- a) Participants will be assigned a specific, anonymous subject number that will be associated with his or her data. Database entry will be by subject number only. All personal identifiers will be kept in a separate, secure data file that will be password protected and not associated with the study data. Only investigators will have access to the subject numbers.
- b) Subject specific binders will be maintained in a locked cabinet in the Children's Cochlear Implant Center and data will be saved to a password protected File Maker Data Base. Individual data collection sheets will be coded with the subject number and placed in the subject specific binder at each interval. For analysis, the data will not include identifiable information.
- c) Data will not be shared outside the investigative team except during reporting of anonymous results.
- d) After the closure of the study, subject data will be retained for seven years. At that time, paper data will be shredded and destroyed in a HIPAA compliant manner. Electronic data will be destroyed following UNC policy.
- e) A description of the clinical trial will be available on <http://ClinicalTrials.gov>. This web site will not include information that can identify research participants.

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Appendix A: Procedure Timeline

**Appendix B: The DSL Method for Pediatric and Adult Hearing Instrument Fitting:
Version 5**

The DSL Method for Pediatric and Adult Hearing Instrument Fitting: Version 5

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Abstract

The Desired Sensation Level (DSL) Method was originally developed to provide clinicians with a systematic, science-based approach to pediatric hearing instrument fitting that ensures audibility of amplified speech by accounting for factors that are uniquely associated with the provision of amplification to infants and young children who have hearing loss (Seewald, Ross and Spiro, 1985; Ross and Seewald, 1988; Seewald and Ross, 1988). This article summarizes a series of revisions that have been incorporated in the new Version 5 of the DSL Method including compatibility with auditory brainstem response (ABR) measurements; updates to Real-Ear-to-Coupler Difference (RECD) values and procedures; description of the multistage input/output algorithm for use with children and adults; and accommodating advances in hearing instrument technology and electro-acoustic verification procedures for use with DSL v5 target hearing instrument performance criteria.

Introduction

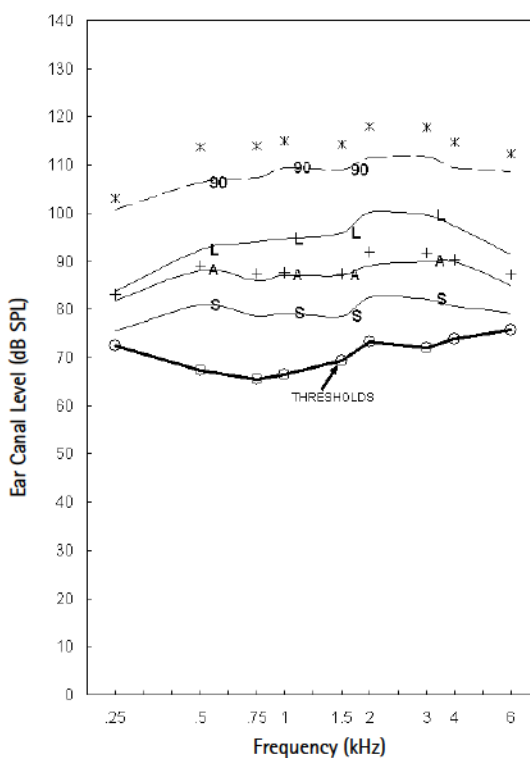
Initial publications on the development of the Desired Sensation Level (DSL) Method describe the electroacoustic fitting goal as the provision of frequency/gain characteristics that would deliver amplified speech to a child that was audible, comfortable and undistorted across the broadest relevant frequency range possible (Seewald, Ross and Spiro, 1985; Seewald, Stelmachowicz and Ross, 1987; Ross and Seewald, 1988; Seewald and Ross, 1988). The earliest versions of the DSL Method used tables of values that specified target sensation levels for amplified speech as a function of frequency and hearing level. These desired sensation levels, or DSLs, were based on data describing the speech sensation levels that were associated with comfortable listening levels across hearing levels (e.g., Kamm, Dirks and Mickey, 1978; Pascoe, 1978) and, more importantly, ceiling speech recognition performance in children with sensory hearing impairment (e.g., Gengel, Pascoe and Shore, 1971; Erber and Witt, 1977; Macrae, 1986; Smith and Boothroyd, 1989). The DSL Method also provided hearing instrument output limiting targets appropriate for use with young children that also varied as a function of frequency and hearing level (Seewald, 1991; Seewald, Ramji, Sinclair, Moodie and Jamieson, 1993). These look-up table of values and accompanying paper/pencil worksheets made clinical implementation of the DSL Method cumbersome. In 1991, the DSL Method (DSL v3.0) was made available as a software program making it the first published computer-assisted implementation for hearing instrument fitting for young children (Seewald, Zelisko, Ramji and Jamieson, 1991).

In 1995, Cornelisse, Seewald and Jamieson described an electroacoustic fitting algorithm

called the DSL input/output formula (DSL[i/o] v4.0) (Cornelisse, Seewald and Jamieson, 1995). This device-independent enhancement of the original DSL Method provided prescriptive targets for the fitting of wide-dynamic-range compression hearing aids which had become readily available by this time. The DSL[i/o] algorithm applied loudness data and a curvilinear fit to map a wide range of input levels to target hearing instrument output levels across frequencies. It has been used in DSL® software systems for v4.0 and v4.1 and in most hearing instrument, real-ear systems and manufacturers software implementations.

Figure 1

An SPLogram display showing hearing aid fitting results for a 6-month old child in dB SPL (re: TM) as a function of frequency (in kHz). The child's thresholds (circles) and upper limits of comfort (asterisk) outline the residual dynamic range to be fitted. The measured performance for aided average conversational speech (70 dB SPL) is shown (A) relative to the DSL targets (plus signs). Measured output for aided soft speech (S) and aided loud speech (L) are also shown, as is the measured hearing aid maximum output with a 90 dB input (90).



One of the primary traits of the DSL Method is the now well-recognized SPLogram display (Figure 1). The goal of packaging amplified speech within the residual auditory area can be best observed by plotting all thresholds using an ear canal dB SPL reference scale. A sample SPLogram is shown in Figure 1 for a child with a moderate hearing loss from .25 to 6 kHz. Unaided hearing thresholds and predicted thresholds of discomfort define the residual auditory area in a dB SPL reference level. Targets for amplified conversation-level speech are also plotted. Measured responses for amplified soft, average and loud conversational speech are shown, as is the hearing aid maximum output for a 90 dB narrowband input. Note that the extent of the child's residual auditory area and resulting location of aided speech and hearing aid maximum output are easily observable and compared with each other.

DSL Method for Children: Validation Studies

Many studies have shown that children with normal or impaired hearing require greater stimulus levels, greater signal-to-noise ratio levels and broader bandwidth than adults in order to achieve similar levels of performance (Elliott, Connors, Kille, Levin, Ball and Katz, 1979; Elliot and Katz, 1980; Nozza, 1987; Nabelek and Robinson, 1982; Neuman and Hochberg, 1982; Nittrouer and Boothroyd, 1990; Nozza, Rossman, Bond and Miller, 1990; Nozza, Miller, Rossman and Bond, 1991; Nozza, Rossman, and Bond, 1991; Kortekaas and Stelmachowicz, 2000; Serpanos and Gravel, 2000; Fallon, Trehub and Schneider, 2002). This may be related to several factors including maturation of the auditory and phonological systems (Nittrouer and Boothroyd, 1990; Hnath-Chisholm, Laipply and Boothroyd, 1998; Blamey et al., 2001; Nittrouer, 2002). Based on these facts, development of the DSL Method and its associated algorithm has focused on a

habilitative audibility approach to the provision of amplification (Scollie, 2005). The goal is to accurately fit infants and young children with the appropriate electroacoustic characteristics so that they will be provided with audibility of the full bandwidth and envelope of conversation-level speech for auditory learning (e.g., Seewald and Ross, 1985; Ling, 1989). Recently, several validation studies of the DSL Method v4.0 and v4.1 for children have been conducted in our laboratory (Jenstad, Seewald, Cornelisse and Shantz, 1999; Jenstad, Pumford, Seewald and Cornelisse, 2000; Scollie, Seewald, Moodie and Dekok, 2000). The findings of these studies will be briefly reviewed within the following sections.

Preferred listening levels of children who use hearing aids: Comparison to prescriptive targets

Scollie et al. (2000) measured the preferred listening levels (PLLs) of 18 children (mean age of ~10 years) with various degrees of sensorineural hearing loss using conversation-level speech heard through the children's own hearing aids. The purpose of the study was to determine if hearing aids fitted using DSL[i/o] v4.1 would amplify conversation-level speech to the children's PLLs. A second purpose was to compare the children's PLLs to prescriptive targets generated by the National Acoustics Laboratory (NAL) formulae (Byrne and Dillon 1986; Byrne, Parkinson and Newall, 1990; Dillon and Storey, 1998). Results of the study indicated that the DSL[i/o] algorithm appeared to more closely approximate pediatric user PLLs than did the NAL-RP/NL1 algorithm in children who were users of DSL-fitted hearing aids regardless of the level of hearing loss. The targets from DSL[i/o] v4.1 and NAL-RP/NL1 are plotted against the PLLs in Figure 2 (A) and 2 (B) respectively. Linear regressions of each fitting algorithm onto the PLL are shown. The 95 percent confidence intervals showed that the DSL targets

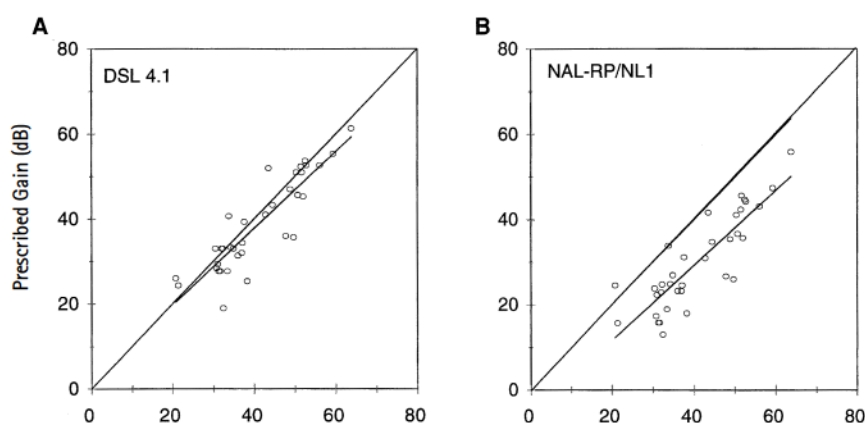
resulted in recommended listening levels that were, on average, 2 dB lower than the children's PLL, with approximately seventy percent of PLLs falling within 5 dB of the DSL target. In contrast, it was found that the NAL prescribed listening levels were, on average, 10 dB lower than the children's PLL, with approximately nine percent of PLLs falling within 5 dB of the NAL target. These data indicate that the amplified levels of conversational speech prescribed by the DSL[i/o] algorithm more closely approximated the pediatric users PLLs relative to those prescribed by the NAL-RP/NL1 algorithm in children who were prior users of DSL-fitted hearing aids regardless of the degree of the hearing loss.

Comparison of linear gain and wide dynamic range compression hearing aid circuits: Aided speech perception and aided loudness measures

In the late-1990s, two studies (Jenstad et al., 1999; 2000) were conducted to compare aided speech perception measures and aided loudness measures for linear gain and wide-dynamic-range compression (WDRC) hearing aids. In the first study which examined aided speech perception measures, 12 subjects (mean age of ~16 years) with moderate to severe sensorineural hearing loss were fitted with hearing aids set to DSL v4 targets for both linear gain and WDRC processing. Speech intelligibility was measured in (a) the unaided; (b) the linear gain; and (c) the WDRC conditions using two tasks in quiet: nonsense words and sentences. Results indicated that for both speech tests, more subjects received benefit in the WDRC condition than the linear condition. Results also showed that WDRC hearing aids fitted to the DSL[i/o] targets achieved comfort and intelligibility of speech across a range of speech input levels. In the companion study, which examined aided loudness measures, 10 subjects (mean age ~16 years) with moderate to severe sensorineural hearing loss were

Figure 2

DSL 4.1 and NAL-RP/NL1 recommended listening levels plotted against preferred listening levels, for individual ears, in the binaural listening condition. Linear regressions are also shown for each prescriptive formula (from Scollie, Seewald, Moodie and Dekok, 2000). Courtesy of the Journal of the American Academy of Audiology).



fitted with hearing aids set to DSL v4.0 targets for linear gain and WDRC processing (Jenstad et al., 2000). Threshold, upper limit of comfort and loudness growth were measured in the (a) unaided; (b) linear gain and (c) WDRC conditions for warble tones, environmental sounds and speech. Results of this study indicated that WDRC hearing aids fitted using the DSL[i/o] algorithm were able to normalize loudness perception for speech and other environmental sounds across a wide range of input levels.

In summary, for the fitting of amplification for children, the DSL Method and its associated prescriptive algorithm has been shown to: (1) significantly improve children's speech recognition scores over unaided performance; (2) improve low-level speech recognition and normalize loudness when a nonlinear version of the DSL prescription is used; and (3) more closely approximate pediatric users PLLs than does the NAL-RP/NL1 algorithm in children who were prior users of DSL-fitted hearing aids regardless of the degree of hearing loss.

Is it time for a new version of the DSL Method?

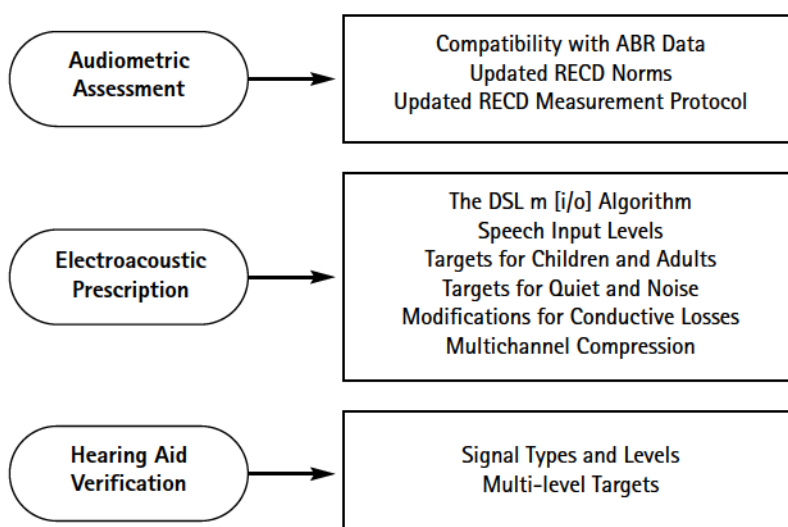
Recently several factors have made our laboratory consider a number of modifications and elaborations to both the DSL Method and the DSL[i/o] algorithm. First, children with hearing loss are being identified at birth and amplification is being provided to infants by 6 months of age (Joint Committee on Infant Hearing, 2000; American Academy of Audiology, 2003). These infants will wear their hearing instruments at settings determined by clinicians for at least the first few years of life increasing the importance of continued research and development on an objective, evidence-based procedure like the DSL Method for hearing instrument fitting. Secondly, improvements in auditory brainstem response (ABR) testing procedures, and significant advances in hearing instrument technology make continued development both desirable and necessary. In addition, since the release of the computer-assisted

implementation of DSL v4.1 in 1997 anecdotal reports from clinicians, research studies in our laboratory and published studies indicated some modifications could be applied to the algorithm for more appropriate adult application (e.g., Moore, Alcántara, and Marriage, 2001). Finally, clinicians still desire access to generic prescriptive algorithms relative to manufacturer-specific proprietary fitting algorithms, especially for their pediatric clients. This is understandable in light of recent published studies which have shown that adult clients with similar hearing losses might be fitted with substantially different amplification characteristics depending on the hearing instrument proprietary fitting method chosen (Smeds and Leijon, 2001; Keidser, Brew and Peck, 2003; Killion, 2004). Given all these considerations, work was initiated in the late 1990s on a new version of the DSL Method (DSL v5) which includes the DSL multi-stage input/output algorithm, referred to as DSL m[i/o].

The Role of Clinical Protocols

Although modifications to the DSL algorithm continue to be made into the 21st century, it is clear to us that electroacoustic selection cannot be isolated from the manner in which audiometric assessment data are collected or from the verification procedures that will be applied at the time of fitting. DSL is more than just an algorithm for electroacoustic selection, it is a method consisting of sequential stages in a well-integrated hearing instrument fitting process. As illustrated in Figure 3, the emphasis of our work has been on audiometric assessment, hearing instrument selection, and verification of aided auditory performance (Seewald, 1995; Seewald, Moodie, Sinclair and

Figure 3
The DSL Method recommended hearing aid fitting process. At each stage of the process the changes implemented in DSL v5 are shown.



Cornelisse, 1995). Our current research program includes the continued development of not only the DSL m[i/o] algorithm, but research and development of clinical procedures and protocols to assist with appropriate pediatric assessment, verification and validation procedures that can be implemented in routine clinical practice (Seewald et al., 1993; Moodie, Seewald and Sinclair, 1994; Seewald, 1995; Bagatto, 2001).

Information regarding the revisions and modifications made for DSL v5 are provided in Figure 3 for each stage of the hearing instrument fitting process. These revisions/modifications will be discussed in the subsequent sections.

DSL v5: Assessment Considerations

Compatibility with ABR assessment

Audiologists working with Early Hearing Detection and Intervention (EHDI) programs are assessing the hearing abilities of very young infants using electrophysiologic procedures (American Speech Language and Hearing Association, 2004; Joint Committee on Infant Hearing, 2000). The ABR measurement has been shown to be feasible for estimating hearing thresholds in young infants (Stapells, 2000a; 2000b; American Speech Language and Hearing Association, 2004; Joint Committee on Infant Hearing, 2000). While much research has focused on the development of frequency-specific (FS) ABR procedures for threshold estimation in infants, little work has been done to investigate how ABR data are to be applied in hearing aid prescriptive software. In DSL v5, clinicians may enter threshold data referenced to normalized HL (nHL) or estimated HL (eHL). The interested reader is

directed to Bagatto et al. (2005) for a detailed description of nHL and eHL-referenced electrophysiologic data. Many studies have shown that ABR threshold estimates are higher than behavioral thresholds. For this reason, a correction must be applied to the ABR threshold estimation to better predict the behavioral threshold that will be used for calculating the hearing aid prescription. It is important for the clinician to know if their ABR equipment has behavioral corrections imbedded in it or not. If the correction has not been imbedded in the system, a correction needs to be applied to the nHL value to provide a better estimate of behavioural thresholds. In this case, frequency-specific threshold estimates are entered in nHL, and corrections will be applied within the DSL software to convert the nHL data to eHL. These corrections can either be default values that are stored within the software, or the clinician can enter their own custom nHL to eHL correction values. The default values are appropriate for use with FS-ABR procedures that comply with the calibration and stimulus parameters outlined in Bagatto et al. (2005) and shown in Table 1. If the threshold estimates have already been corrected to an eHL reference by the clinician or if the ABR system has the corrections imbedded in it, no additional correction is required and is therefore not applied. Clinicians with these situations should choose ABR (eHL) and enter the data. Clinicians who assess the hearing of infants using ASSR procedures are cautioned to ensure that the ASSR system is applying an nHL to eHL correction that is valid for use with infants who have hearing loss (Stapells, Herdman, Small, Dimitrijevic and Hatton, 2005). In this case, data may be entered directly into DSL v5 by using the eHL reference.

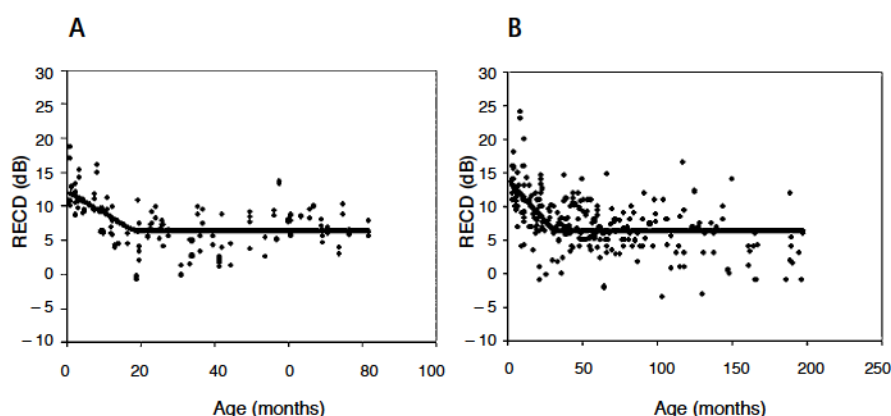
Table 1

Stimulus and recording parameters used to obtain frequency-specific ABR threshold estimations in a recent study comparing ABR thresholds to behavioural thresholds in RESPL.

Stimulus calibration (ER-3A)	500 Hz: 22 dB ppeSPL 1000 Hz: 25 dB ppeSPL 2000 Hz: 20 dB ppeSPL 4000 Hz: 26 dB ppeSPL
Filters	High pass: 30 Hz Low pass: 1500 Hz 6 or 12 dB/octave Analog
Stimuli	2-1-2 cycle, linearly gated tones
Window length	25 msec
Polarity	Alternating
Rate	37-41 sweeps/sec
Artifact reject	Trials exceeding 25 μ V or ± 2 SD of quietest EEG signal, whichever is smaller
Average	2000 sweeps per average At least 2 averages

Figure 4

Real-ear-to-coupler differences (RECD) (in dB) measured with (A) foam/immittance tips and (B) earmolds as a function of age at 3000 Hz. The sloping line indicates the linear regression represented by the prediction equation. The horizontal line represents the mean RECD values for a particular age group. (from Bagatto et al., 2005. *Reprinted with permission*).



Age-appropriate real-ear-to-coupler difference (RECD) values

The RECD is a clinically useful measurement, and may be feasibly and reliably obtained in the pediatric and adult populations in the majority of cases (Sinclair et al., 1996; Tharpe, Sladen, Huta and McKinley, 2001; Munro and Davis, 2003). The DSL method has always provided age-appropriate average RECD values in software implementations for cases where clinicians have not been able to directly obtain the measurement (Seewald et al., 1997; Seewald et al., 1993). For DSL v5 the age-appropriate average RECD values have been updated to include: (1) frequency-specific predictions by age for eartip coupling; and (2) frequency-specific predictions by age for earmold coupling (Bagatto et al., 2005; Bagatto, Scollie, Seewald, Moodie and Hoover, 2002). The 95% confidence intervals for predictions of RECDs for eartip coupling and earmold RECD predictions were examined to determine the accuracy of prediction (Bagatto et al., 2005). Depending on the frequency of interest, an eartip RECD can be predicted to fall within a range of ± 5.6 dB (at 500 Hz) at best and ± 10.9 dB (at 6000 Hz) at worst for children 24 months of age and younger. Predictions of earmold RECDs can span a range of accuracy from ± 6.7 dB (at 2000 Hz) to ± 12.4 dB (6000 Hz) for children 36 months of age and younger. Figure 4 illustrates the measured RECD values in dB as a function of age for one frequency for both coupling procedures. Although more desirable than using adult-based RECD average values when fitting amplification to infant and young children, these results indicate that age-appropriate predictions should not replace a more precise individualized RECD measurement.

Description of a modified RECD measurement procedure for use with infants

Procedures for measuring the RECD in the pediatric population have been published (Moodie et al, 1994). Other publications have provided recommended probe-tube insertion depth guidelines (Tharpe et al., 2001). The typical RECD measurement method described in most studies involves inserting the probe-tube and tip separately. This may not be practical in the infant population due to very small ear canals and the position of the infant during the measurement. Bagatto, Seewald, Scollie and Tharpe (2006) described details and study results for a new technique for obtaining accurate RECD measurements on an infant's ear. Briefly, the strategy involved simultaneous insertion of the probe-tube and the tip into the ear canal (see Figure 5). Study results indicated that extending the probe-tube approximately two to four millimeters (mm) beyond the tip resulted in appropriate insertion depth, as well as reliable and valid RECD values for infants between the ages of two to six months. A suitable insertion depth for the probe-tube was determined to be approximately 11mm from the entrance to the ear canal.

DSL v5: Selection and Fitting Considerations

The DSL multistage input/output algorithm: DSL $m[i/o]$

A detailed description of the development of the DSL $m[i/o]$ algorithm is provided in Scollie et al., 2005. A brief summary of some, but not all, important modifications, is provided here. Revisions to the DSL $[i/o]$ algorithm were determined to be necessary for at least two reasons: (1) to implement evidence-based revisions, additions, or corrections to the approach described as the DSL $[i/o]$ algorithm (Cornelisse et al., 1995; Seewald, Ramji, Sinclair, Moodie, and Jamieson, 1993a) and (2) to modify the scope of the algorithm to support specific hypothesis testing in pediatric hearing instrument research.

Figure 5

Probe tube coupled to ER-10 3.5 mm otoacoustic emission tip using plastic film (from Bagatto et al., 2006. *Reprinted with permission*).



Specific objectives for DSL version 5 include:

1. Avoidance of loudness discomfort during hearing instrument use;
2. Hearing instrument prescription that ensures audibility of important acoustic cues in conversational speech as much as possible;
3. Support for hearing instrument fitting in early hearing detection and intervention programs;
4. Prescription of hearing instrument compression that is appropriate for the degree and configuration of the hearing loss, but that attempt to make a wide range of speech inputs available to the listener;
5. Adaptation for the different listening needs of listeners with congenital versus acquired hearing loss;
6. Accommodation for the different listening requirements within quiet and noisy listening environments.

DSL $m[i/o]$ target generation

In DSL v5, we use the DSL $[i/o]$ algorithm (DSL v4.1) as a starting point, but modify it to apply WDRC to a smaller input range. The inputs selected for the WDRC range are intended to cover some or all of the conversational speech range. Low-level inputs are less likely to be included in the compression stage as hearing levels increase.

The DSL multistage input/output m[i/o] algorithm includes four stages of processing: (1) expansion; (2) linear gain; (3) compression; and (4) output limiting. These m[i/o] stages reflect conventional signal processing for amplitude control in current digital hearing instruments. The final result is a series of target input/output functions that prescribe how a multi-channel, multistage device should respond to speech inputs across vocal effort levels.

The output limiting stage

Version 5 of DSL provides three variables that facilitate definition of output limiting: (a) the user's upper limits of comfort (ULC) defined with narrowband inputs, which should not be exceeded by any aided narrowband signal; (b) targets for 90 dB SPL narrowband inputs – these targets may be slightly below the upper limits of comfort if the hearing instrument is not fully saturated by a 90 dB input; (c) the broadband output limiting thresholds (BOLT) per frequency, which defined the maximum one-third octave band levels for broadband sounds. These targets may be used for slightly different purposes, depending upon the test signals at hand, and/or the user's knowledge of the signal processing characteristics of the hearing instrument to be tested. Each of these target types will be discussed in more detail in the section below.

Narrowband output limiting targets

DSL v5 provides narrowband predictions of the listener's upper limit of comfort (ULC), which may be replaced by individually measured ULCs. In either case, the fitting goal is that aided levels of high-level pure tones, warbled pure tones or speech peaks should not exceed the ULC. The predicted ULCs are limited to a maximum of 140 dB SPL in the ear canal. Narrowband targets for 90 dB SPL inputs can be generated in DSL v5. These targets may be slightly below the upper

limits of comfort if the hearing instrument is not fully saturated by a 90 dB narrowband input. When verifying fit to targets using a narrowband signal, clinicians can choose to either match the 90 dB target, or to ensure that the maximum output does not exceed the ULC.

Broadband output limiting targets

DSL v5 incorporates a variable that prescribes a limiting stage for the one-third octave band levels of speech signals. This broadband output limiting threshold (BOLT) corresponds with a hearing instrument fitting that places the peaks of speech 13 dB below the upper limit of comfort. A detailed description of the rationale for BOLT is provided in Scollie et al., 2005. Clinical verification of fit to BOLT targets may not always be possible, depending upon the test signals and analyses that are currently available. This is not likely a problem if the narrowband limiting has been fitted appropriately (see above). However, the BOLT targets may be helpful in defining initial settings of programmable hearing instruments that include limiting controls for broadband stimuli – this type of setting may occur "behind the scenes" within hearing instrument programming software.

Compression

In DSL v5 we prescribe compression processing to meet the goals of providing audibility and comfortable loudness of important speech cues, given the gain limits of hearing instruments and the limited dynamic range of the individual hearing instrument user. This differs from the loudness normalization approach in previous versions of the DSL algorithm.

Prescription of the WDRC compression threshold (CT)

The DSL m[i/o] algorithm prescribes a variable CT based on hearing levels that attempts to

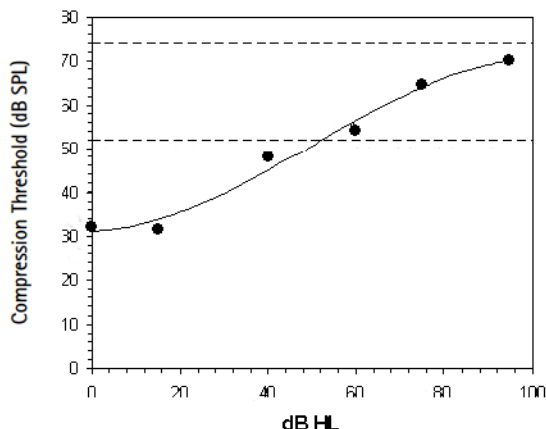
maintain the compression stage across as broad a speech input range as possible. The intention is to support low-level speech recognition whenever possible (Jenstad et al., 1999; 2000). For more severe-to-profound hearing losses this fitting goal is modified to use WDRC as a means for controlling loudness of high-level speech. Experimental validation of this hypothesis-driven aspect of DSL v5 is necessary. Therefore, in hearing instrument manufacturers software-based implementation of DSL v5, more ambitious goals for WDRC can be incorporated by using custom CTs if the higher gains can be achieved without feedback. Figure 6 illustrates the relationship between hearing threshold levels (dB HL), the proposed input levels (dB SPL in the sound field) and the prescribed WDRC threshold from the DSLm[i/o] algorithm.

Hearing instrument prescriptions for multi-channel compression

DSLm[i/o] target calculations can be tailored to correspond to the channel structure of multi-channel hearing instruments (Scollie et al., 2005). The one-third octave band frequencies are grouped into defined channel families using the crossover frequencies of the hearing instrument. The multistage input/output algorithm is then re-computed per channel, resulting in a single compression ratio target per channel. The gains within the compression region of the revised input/output target plots are also adjusted in an effort to preserve the frequency response for mid-level signals. A slight frequency re-shaping may occur to prevent hearing instruments with different channel structures from providing a different frequency response for mid-level speech signals. Targets at moderate input levels show very little effect of channelization, while targets for very high and very low inputs show a somewhat greater effect.

Figure 6

Relation between hearing threshold levels (dB HL) and proposed input levels (dB SPL in the sound field) for the wide-dynamic-range compression (WDRC) threshold. The solid line is a third-order polynomial fit to a set of hypothesized compression threshold values (•). Dashed lines indicate the range of speech inputs considered by DSL v5 (i.e., 52 and 74 dB SPL), for reference. (from Scollie et al., 2005. Reprinted with permission).

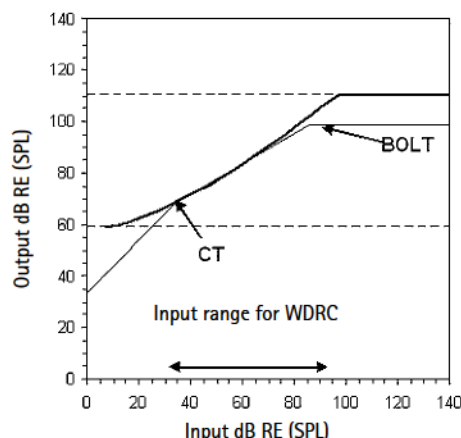


Gain prescription within the WDRC stage

To prescribe gain within the WDRC stage consideration must be given to the desired range of input levels considered appropriate for amplification; the individuals residual auditory area; and the technology to be fitted. Unlike the DSL[i/o] algorithm, the DSL m[i/o] algorithm restricts the input range over which the compressive algorithm is applied from approximately 30 dB SPL to 70 dB SPL (re: FF as a function of hearing loss). A target for 60 dB SPL speech input is calculated for all one-third octave band frequencies. The WDRC stage is then defined as the straight line with a slope that equals the compression ratio target that passes through this calculated DSL m[i/o] target. For hearing losses exceeding approximately 70 dB HL a higher CT is used by the DSL m[i/o] algorithm to derive the target for 60 dB SPL speech input. Some hearing instrument manufacturers or clinicians may choose to use a lower CT (i.e., more gain for low level

Figure 7

Comparison of DSL[i/o] and DSL m[i/o] target input/output functions, shown as thick and thin lines respectively. The dashed lines mark the detection thresholds and upper limits of comfort. The input range for WDRC is also indicated. BOLT = broadband output limiting threshold; CT = compression threshold; WDRC = wide-dynamic-range compression. (from Scollie et al., 2005. *Reprinted with permission*).



inputs) than recommended if the higher gains can be achieved without feedback. The WDRC stage begins at the calculated WDRC CT and ends where it meets the broadband output limiting stage. Figure 7 provides a target input/output function derived using the DSL m[i/o] algorithm compared to the target input/output function derived using the DSL[i/o] algorithm.

Gain prescription within the expansion stage and linear stage

The DSL m[i/o] algorithm calculates a default expansion threshold (ET) that is approximately 10 dB below the level of soft speech. It is assumed that input signals below this level are likely background noise and negative or no gain is desirable. The linear stage of the DSL m[i/o] algorithm spans the input range between the ET and the WDRC CT.

DSLm[i/o] algorithm effective compression ratio

The effective compression ratio calculated within the DSL m[i/o] algorithm is intended to functionally describe the amount of longterm

compression of soft to loud speech inputs encountered by the listener. It is not intended to be an electroacoustic descriptor for verification, nor is it intended to be interpreted in the way that traditional compression ratios are.

DSL m[i/o] Algorithm Considerations for Individual Fittings

Should the DSL algorithm generate different prescriptive targets for children and adults?

Published results of using DSL[i/o] with adults have been somewhat mixed, with some studies showing positive and acceptable results (Humes, 1999; Hornsby and Ricketts, 2003; Scollie et al., 2005), and others showing good speech recognition but higher ratings of loudness with higher level inputs and/or frequencies than those considered ideal (Lindley and Palmer, 1997; Alcántara, Moore and Marriage, 2004; Smeds, 2004).

Clinical trials that have compared DSL[i/o] with alternative fitting procedures have generally shown that less gain than prescribed by DSL is preferred by adults, either from a lower-gain prescription such as CAMFIT (Moore, Alcántara and Marriage, 2001) or from a patient-driven procedure that customizes gains to preference (Lindley and Palmer, 1997).

Currently there are differing opinions regarding the electroacoustic requirements for hearing aid performance for adults versus children. Some researchers believe that prescriptive procedures developed for adults can be used with young children (Ching, Dillon and Byrne, 2001). Others believe that infants and young children require different prescriptive procedures (e.g., Stelmachowicz, 1991; 2000; Seewald, 1995). Snik and Hombergen (1993) measured the preferred insertion gain for 40 adults and 60 children.

Figure 8 displays the preferred insertion gain as a function of the pure-tone average for the adults and children in this study. The results showed that overall the mean use insertion gain was 7 dB less for the adults relative to that used by the children.

Adult/child preferred listening levels

A recent study by Laurnagaray and Seewald (see Scollie et al., 2005) included 24 children who were full-time hearing aid wearers, 24 adults who were experienced hearing aid users, and 24 adults who were new hearing aid users. The hearing aids were fit to the DSL v4.1 prescription and new users were provided with a 15 to 20 day trial period. The objective of the study was to determine whether the preferred listening level (PLL) differed between adults and children who use hearing instruments, and whether adult PLLs differ between new and experienced adult users. A second purpose was to compare measured PLLs to the DSL v4.1 recommended listening level (RLL). As illustrated in Figure 9, analysis results indicated that all three of the groups differed from one another regarding their agreement between PLL and RLL. Children had a mean PLL that was approximately 2 dB below the DSL target (RLL). Experienced adults had a mean PLL 9 dB below the DSL target. New adult hearing instrument users had the lowest PLLs, which were 11 dB below target on average. In summary, there was an approximate difference of 8 dB in PLL between the adults and children in this study, and adults who were new hearing aid users preferred a slightly lower listening level than adult experienced hearing aid users. This finding is similar to the 7 dB adult/child difference measured by Snik and Hombergen (1993).

These study results indicate that the DSL[i/o] prescriptive algorithm likely overestimates preferred listening levels for adult hearing instrument users, with the greatest overestimation observed for inexperienced adults. These findings may not generalize to

Figure 8

The preferred insertion gain as a function of the pure-tone average for the adults (A) and children (B) in this study (from Snik and Hombergen, 1993).

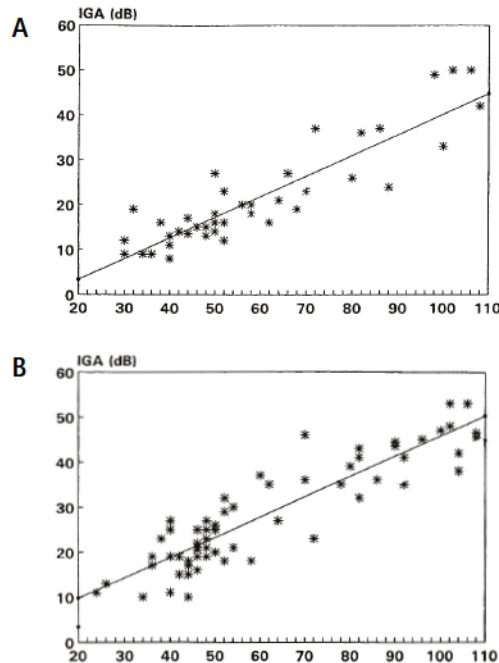
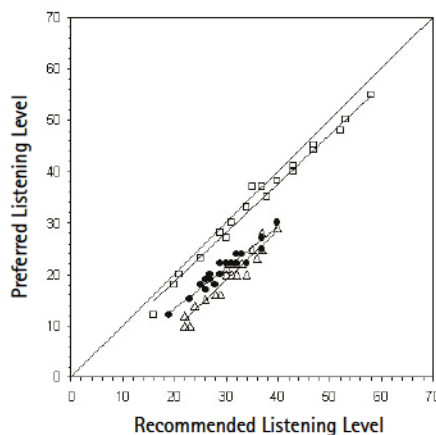


Figure 9

Recommended versus preferred listening levels (measured in 2cc coupler gain at 2000 Hz) for three groups of subjects: children (\square), new adult hearing aid users (\triangle), and experienced adult hearing aid users (\bullet). Regression lines are shown for each subject group, along with a diagonal line at target listening levels. (from Scollie et al., 2005. Reprinted with permission).



adults with severe-to-profound hearing loss as they have not been included in these studies. Nonetheless, the results make clear the concept that adults and children with hearing loss have distinctly different preferences for listening level. The results also agree with earlier studies of adult/child differences in listening level requirements for speech recognition performance (see above). In considering modifications to the DSL[i/o] algorithm it was decided that a comprehensive prescriptive approach would need to consider that adults and children not only require, but also prefer, different listening levels, perhaps by generating different prescriptions based on client age.

Determining an acceptable range for amplified speech for adult hearing aid wearers

A study was undertaken in an effort to better understand the acceptable range for amplified conversational speech for adults (Jenstad et al., under review). The purpose of the study was two-fold; first, to define the range of optimal hearing aid settings in both high and low frequencies using subjective ratings of loudness and quality and objective measures of speech intelligibility, and secondly, to determine if the DSL[i/o] 4.1 gain-by-frequency response falls within the optimal range for adult listeners. Measures of loudness, quality and speech intelligibility were obtained for 23 adult listeners with mild to moderately-severe sensorineural hearing loss, across a range of high and low-frequency responses. Consistent with the findings of other researchers (e.g., Dirks, Ahlstrom and Noffsinger, 1993), this study found that there was an approximately 10 dB range for these adult listeners that could be considered optimal hearing aid settings when both speech intelligibility and loudness criteria were considered together. Relative to the DSL[i/o] v4.1 prescription generated for each adult, results indicated that in the low frequencies the optimal range for hearing aid

settings spanned from 2 dB above the DSL[i/o] target to 7 dB below the DSL target. In the high frequencies the optimal range of settings spanned from 3.2 dB below the DSL[i/o] target to 13.2 dB below target.

Modifications made in the DSL v5 algorithm for adult hearing aid wearers

The DSL[i/o] algorithm described by Cornelisse et al., 1995, and used in the DSL Method: v4.1 attempted to define the ideal amplified output for a range of input levels. The DSL[i/o] algorithm used nonlinear scaling so that input levels corresponding to the acoustic dynamic range of the normal loudness function were mapped onto the auditory area of the loudness function associated with hearing impairment, while maintaining the normal loudness relationship per frequency (Cornelisse et al., 1995). The DSL[i/o] algorithm comprised a very broad compression phase beginning at 0 dB HL. We hypothesize that the resultant gain for low-to moderate speech input levels using this approach may contribute to higher loudness levels than preferred or necessary for adult hearing aid wearers.

The DSL multistage input/output algorithm (DSL m[i/o]) used in DSL v5, does not use a loudness normalization approach for several reasons. First, current loudness models do not account for the adult-child and developmental differences required for listening reported earlier in this article. Second, loudness normalization attempts to make all sounds audible and normally loud. It is not likely that this is an appropriate goal for low-level background noise, nor is it an attainable goal given the noise floor of most hearing instruments. In developing the DSL m[i/o] algorithm we use compression processing to meet the goals of providing audibility and comfortable loudness of important speech cues, considering the general limits of hearing instruments and the limited dynamic range of the individual

hearing instrument user. As discussed above, the compression stage spans as much of the range of conversational speech across vocal effort levels as possible. As a starting place, the DSL m[i/o] input range was limited to no lower than 20 dB HL for adult listeners with acquired hearing impairment. Compared to the 0 dB HL loudness normalization strategy in DSL[i/o] this provides adults with a lower level of prescribed gain and compression ratio for the entire input-output function. As shown in Figure 10, the differences in prescriptive targets are largest for mild-to-moderate losses. A smaller correction is applied as hearing loss increases which is a desired effect because it maintains audibility of speech for more severe-to-profound hearing losses for adults and children. Further experimental evaluation of this age-related correction is required, however, it appears to be in good agreement with the adult-child differences in preferred gain reported earlier in this chapter.

Hearing instrument prescriptions for conductive hearing loss

Listeners with conductive and/or mixed hearing losses have higher loudness discomfort levels and prefer a higher level of use gain than do listeners with entirely sensory hearing losses (Berger, 1980; Walker, 1997a; Walker, 1997b; Carlin and Browning, 1990; Liu and Chen, 2000). Several strategies for accounting for these effects in hearing instrument prescription have been proposed in the literature (Dillon and Storey, 1998; Walker, 1998; Walker 1997a; Carlin and Browning, 1990). The strategy applied in DSL v5 to correct for conductive hearing loss is to increase the predicted upper limits of comfort (ULC), causing the input/output function to steepen, hence becoming more linear and thereby employing more gain. We have applied several limits to this strategy. First, targets in DSL v5 will not exceed 140 dB SPL in the ear canal, regardless of circuit type or the presence of conductive hearing loss. Second, predictions of the upper

Figure 10

Average real-ear output target criteria for DSL v5 as a function of four-frequency pure-tone average threshold values (dB HL), for pediatric and adult target types in DSL v5. (from Scollie et al., 2005. Reprinted with permission).

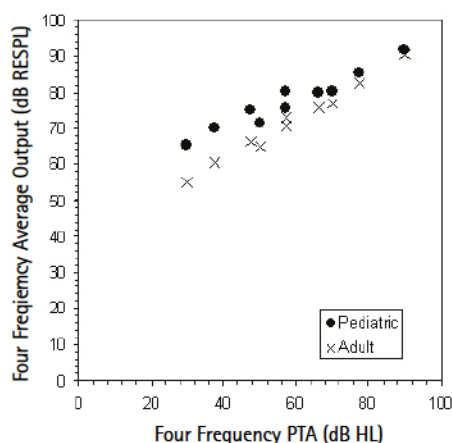
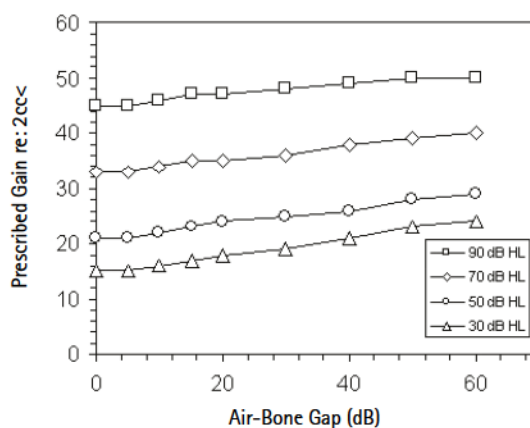


Figure 11

Effect of applying a conductive correction to the prescribed gains for conversational speech. Prescribed 2cc coupler gains (average gain for 500, 1000, 2000 Hz) for four flat hearing losses are shown, assuming either sensorineural loss or various degrees of conductive overlay within the stated hearing threshold level. (from Scollie et al., 2005. Reprinted with permission).



limit of comfort (ULC) are increased by 25% of the uncorrected air-bone gap, averaged across the frequencies of 500, 1000, 2000, and 4000 Hz, to a maximum of at 60 dB gap. The correction for conductive hearing loss is smaller as hearing level increases (often because the 140 dB limit to LDL is reached). Figure 11 illustrates the effect of applying a conductive correction to the prescribed gains for conversation-level speech inputs.

Hearing instrument venting corrections

Venting corrections are applied in DSL v5 using values reported by Dillon (2001) with some modification to account for the combined effects of sound lost through the vent, and sound coming in through the vent (Hoover, Stelmachowicz and Lewis, 2000). A lower limit of venting reduction is defined, in real ear SPL, as the input test level plus the age-appropriate real ear unaided gain. If the test frequency is below 1000 Hz, the venting reduction is limited to not fall below this unaided level. Venting corrections are only applied in the 2cc transform and will not affect the targets in real ear formats (REAR, REAG, REIG). Manufacturers can use their instrument-specific venting corrections in place of the DSL v5 venting corrections.

DSL v5: Verification Options

Targets from the DSL m[i/o] algorithm have best clinical utility when displayed on an SPLogram (see Figure 1) and compared with real-ear aided response (REAR) and output limiting targets for narrowband inputs and/or the upper limits of comfort, employing probe-microphone measures of real-ear performance. DSL m[i/o] targets can also be calculated for real-ear aided gain (REAG) and real-ear insertion gain (REIG) reference. If REIG targets are calculated using the DSL m[i/o] algorithm age-appropriate or measured real-ear unaided gain (REUG) values will be used (Bagatto et al., 2005). Targets for 2cc coupler gain can be calculated automatically using

the DSL m[i/o] REAR and RESR values using the following general equation:

$$\text{Real-Ear Targets (in dB SPL re: ear canal)} - \text{RECD} - \text{MLE} - \text{Input speech} = 2\text{cc target gain}$$

Target coupler gain values are advantageous when probe-microphone measurements may not be possible, such as when fitting hearing instruments for infants or young children. Coupler-assisted verification procedures can be clinically useful in predicting real-ear performance using the reverse of the equation above (Moodie et al., 1994). That is, $2\text{cc target gain} + \text{input speech} + \text{microphone location effect (MLE)} + \text{RECD} = \text{predicted real-ear aided response (in dB SPL re: ear canal)}$.

Targets from the DSL m[i/o] algorithm are appropriate for comparison with the aided long-term average speech spectrum, measured in one-third octave bands. This type of measurement can be made for soft (50 to 55 dB SPL), conversational (60 to 70 dB SPL), or loud (75-85 dB SPL) speech signals. Speech-based verification signals are strongly recommended for use with targets derived using DSL v5. Targets can be converted for use with speech-weighted noise and pure tone verification signals. The disadvantage of the corrections used in DSL v5 for signals other than speech is that it is less accurate and only useful for input levels between 50 and 70 dB SPL (Bagatto et al., 2005; Scollie and Seewald, 2002).

Summary

This article describes some of the research and development that has resulted in the most recent version of the DSL Method: DSL m[i/o] v5 for hearing instrument selection and fitting for children and adults. Although modifications to the DSL algorithm continue to be made into the 21st century, the goals and objectives expressed in the initial publications have not changed (Seewald et al., 1985; Seewald et al., 1987; Ross and Seewald, 1988; Seewald and Ross, 1988). Nor has the point of view that the hearing instrument fitting process is a series of well-integrated stages that include audiometric assessment, hearing instrument selection, verification and evaluation of aided auditory performance.

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